Committee for Risk Assessment

RAC

Annex 2

Response to comments document (RCOM)

to the Opinion proposing harmonised classification and labelling at EU level of

Silver

EC Number: 231-131-3
CAS Number: 7440-22-4

CLH-O-0000007152-82-01/F

Adopted

2 June 2022

COMMENTS AND RESPONSE TO COMMENTS ON CLH: PROPOSAL AND JUSTIFICATION

Comments provided during consultation are made available in the table below as submitted through the web form. Any attachments received are referred to in this table and listed underneath, or have been copied directly into the table.

All comments and attachments including confidential information received during the consultation have been provided in full to the dossier submitter (Member State Competent Authority), the Committees and to the European Commission. Non-confidential attachments that have not been copied into the table directly are published after the consultation and are also published together with the opinion (after adoption) on ECHA's website. Dossier submitters who are manufacturers, importers or downstream users, will only receive the comments and non-confidential attachments, and not the confidential information received from other parties. Journal articles are not confidential; however they are not published on the website due to Intellectual Property Rights.

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Substance name: Silver massive: [particle diameter ≥ 1 mm]; Silver powder: [particle diameter > 100 nm < 1 mm]; Silver nano: [particle diameter > 1 nm ≤ 100 nm]
EC number: 231-131-3
CAS number: 7440-22-4
Dossier submitter: Sweden

GENERAL COMMENTS

Date	Country	Organisation	Type of Organisation	Comment number
16.12.2020	Germany	Carl Weishaupt	Company-Manufacturer	1
Comment received				
Ladies and Gentlemen, My family has been appointed by the court to manuacture silverware since 1692 in Munich and are following up to now. All countries worldwide ever respected the high cultural value of works in silver. Silver did proove to be the most human friendly material within several thousand years of experiment, we cannot accept to ignore the fact silver being a most helpful material to mankind in history. Your concern with Ag+ ions in suspension, if it could have an effect used in different products, is a totally different issue, and cannot be presented in conjunction with solid silver. It would be dangerous to create a wrong public perception without any reason. The manufacuring process of silverware eleminates automatically Ag+ ions together with copper in the suface. Their dissolution in a medium would anyhow be impossible in normal use. The presence of these ions has no effect to health anyhow, if not used in a very high dosis. If under this condition any recommendation from your side would be appropriate, is beyond our knowledge. However it has to be separated from the term silver, but in case clearly related to the relative product only, which you might have in mind. Life is toxic, silver ranges among the less toxic materials ever, and is the most wonderful one. ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Silver Metal letter.pdf				

Dossier Submitter's Response
This classification proposal is not limited to silverware but intended to include all forms or physical states in which elemental silver is placed on the market. We understand that classification and labelling may hay have consequences for companies however this is outside the scope of the CLP process. Classification and labelling is based on the intrinsic properties of the active substance and consequences thereof are handled by downstream regulations. With respect to dose levels, classification is based on the intrinsic properties of a substance to cause (an) adverse effect(s) and for the human hazard classes skin/eye irritation, respiratory sensitisation, carcinogenicity, mutagenicity and reproductive toxicity the dose level at which the property is expressed is not taken into account.
RAC's response
Noted. A distinction between the bulk / nano forms of silver and other soluble types is considered based on toxicokinetic data and the different properties of different forms of silver coumpounds.

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Germany	<confidential>	Company-Manufacturer	2
Comment received				
Dear Sir/Madam, We have attached our comment, on the Proposal for Harmonised Classification and Labelling of Silver, in a Word document. Best regards <confidential> ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment <confidential>.pdf				
Dossier Submitter's Response				
This classification proposal is intended to include all forms or physical states in which elemental silver is placed on the market. We understand that classification and labelling may hay have consequences for companies however this is outside the scope of the CLP process. Classification and labelling is based on the intrinsic properties of the active substance and consequences thereof are handled by downstream regulations. We note the support for the comments submitted by the European Precious Metals Federation (EPMF). Please note our response to comment 23.				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Belgium	Test and Measurement Coalition	Industry or trade association	3
Comment received				
Test & Measurement Coalition members use silver solder is used as an electrical conductor on printed circuit boards. Silver is also used in finishes, plating (for connectors or conductive epoxy), as conductive ink, or as filling in epoxy or in components. The				

choice to use Tin-silver-copper (SnAgCu, also known as SAC) solders was made after extensive reliability evaluations over the past decade. No alternatives are currently available that are RoHS-compliant and meet these reliability needs. Substitution of silver in these applications is not currently possible without introducing reliability concerns or having performance implications. Any restriction on the use of silver in electronics would necessitate changes to virtually every component in the global supply chain in addition to product redesign and re-qualification that would involve Billions of Euros globally and take more than a decade to achieve. ECHA note – An attachment was submitted with the comment above. Refer to public attachment Input silver CLH - TMC - 18.12.2020.pdf
Dossier Submitter's Response
We note the support for the comments submitted by the European Precious Metals Federation (EPMF). Please note our response to comment 95. The classification proposal include all forms or physical states in which elemental silver is placed on the market. We understand that classification and labelling may have consequences for companies however this is not within the scope of the CLP process. Classification and labelling is based on the intrinsic properties of the active substance and consequences thereof are handled by downstream regulations.
RAC's response
Noted.

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	France	RECHARGE	Industry or trade association	4
Comment received				
see attachement ECHA note – An attachment was submitted with the comment above. Refer to public attachment RECHARGE Silver classificationPublic Consultation.pdf				
Dossier Submitter's Response				
We note the support for the comments submitted by the European Precious Metals Federation (EPMF). Please note our response to comment 23.				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Germany	AURUBIS AG	Company-Manufacturer	5
Comment received				
We support the scientific comments submitted by the European Precious Metals Federation (EPMF). More information is provided in the attached document. ECHA note – An attachment was submitted with the comment above. Refer to public attachment Aurubis comments to Silver CLH proposal 2020-12-18.pdf				
Dossier Submitter's Response				
We note the support for the comments submitted by the European Precious Metals Federation (EPMF). Please note our response to comment 23.				

RAC's response
Noted.

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Germany	AZUR SPACE Solar Power GmbH	Company-Downstream user	6
Comment received				
We would like to comment on the proposal for silver harmonized classification: We manufacture solar cells for space satellite applications. Our uses of silver are a) to coat product surfaces with a massive silver layer for electrical contacts and b) massiv silver alloy stripes to form electrical contact bars from them as part of the products. All residual silver is recycled. No silver is released to environment. These uses can not be substituted by other metals without loosing the functionality.				
Dossier Submitter's Response				
OK, thank you for this information.				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Poland	<confidential>	Company-Manufacturer	7
Comment received				
On behalf of the <confidential> I would like to inform that in our 254 years history we never found nor observed hazardous influence of silver on life and health of our employees and environment. We deal with silver everyday on a mass scale when produce numismatic coins, tokens, bars, national distinctions and other products. Every year we produce few millions of these products and use few tones of silver. ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Silver - <confidential> statement.docx				
Dossier Submitter's Response				
Thank you for the information. We note the support for the comments submitted by the European Precious Metals Federation (EPMF). Please note our response to comment 23.				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Austria	Wirtschaftskammer Österreich		8
Comment received				
see attachment ECHA note – An attachment was submitted with the comment above. Refer to public attachment su_309_StN öK Silber CLH.pdf				
Dossier Submitter's Response				
Thank you.				

RAC's response
Noted.

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Germany	WirtschaftsVereinigung Metalle	Industry or trade association	9

Comment received
• Silver is as an indispensable material for many branches downstream the WVMetalle members. Silver is used in a very wide range of essential uses like in electrical applications and electronic parts, in energy generation and transmission, in solar panels and wind turbines, in solders and brazing sticks, in medical equipment and healthcare products etc. A lot of further examples and detailed technical aspects for the non-substitutable nature of silver will be delivered during this consultation by a brought range of European and national federations as well as by individual companies. There-fore, we have serious concerns about the potentially far-reaching consequences of the proposed classification. • WVMetalle support the scientific comments submitted by the European Precious Metals Federation (EPMF). We especially agree with EPMF that a read-across from silver salts to metallic silver is not scientifically justified as bioavailability is an intrinsic property which needs to be considered when assessing the hazards of metals. ECHA note – An attachment was submitted with the comment above. Refer to public attachment 2020-12-18_WVMetalle Comment on CLH Proposal for Silver.pdf
Dossier Submitter's Response
We note the support for the comments submitted by the European Precious Metals Federation (EPMF). Please note our response to comment 23. The data available for this assessment has been compared to the CLP criteria and the considerations in the Guidance on the Application of CLP criteria. To our knowledge, there is no adequate data demonstrating that metallic silver is not bioavailable.
RAC's response
Noted.

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Germany	Netzwerk NanoSilber	Industry or trade association	10

Comment received
The following comments on the Proposal for Harmonized Classification and Labelling for Silver (CAS 7440-22-4) are submitted on behalf of the Network NanoSilber. The network consists of various partners from industry and academia. For us, the unbiased investigation of the opportunities and risks of nanosilver and elemental silver over the entire product life cycle is very important. We are particularly committed to the responsible planning of R&D projects and our goal is to develop products that offer an additional benefit for the customer while ensuring high product safety. We appreciate the opportunity to comment on this publication at this stage of the CLH process and we recognize the efforts of the authors to investigate the toxicological assessment of silver using the cited data. However, we have detected several serious deficiencies:

The CLH proposal covers only a brief list of important uses of silver (p. 18). In fact, silver has many more uses critical to everyday life. The high technical potential of silver stems from its excellent antimicrobial properties, its thermal and electrical conductivity as well as its special optical properties. This opens up important application fields, ranging from flexible displays to antimicrobial equipment for hospital textiles, wound dressings, wall panels and water preservation. Silver is also an important substance to achieve the goals of the EU regarding climate protection and controlling the growing danger of multi-resistant germs.

The network NanoSilber and its partner use silver and nanosilver for medical applications, functional coatings (including antimicrobial, antiviral, dissipative, and antistatic coatings), as well as for water treatment. Silver is also used to replace human toxic compounds like isothiazolinones. Restricting the use of silver will force users to apply hazard chemicals. The network further cooperates with various authorities and several medical facilities to develop safe silver containing coatings to fight germ transmission as well as antimicrobial resistance. Almost all industry projects in the network are based on the use of silver.

- GBneuhaus GmbH uses silver and nanosilver not only as antimicrobial additive but also for electrical conductive, antistatic and dissipative coatings based on sol-gel technology. The patented technology is applied in various industries, including automotive, building, and electronics.

- The economic importance of silver, nanosilver and, above all, the technologies associated with them in all fields of application is essential for the Fraunhofer Institute for Chemical Technology (ICT) and for the associated industrial partners.

- RAS AG has been developing technologies based on silver and nanosilver for more than 20 years. Silver is used because of its high electrical conductivity as well as its unique antimicrobial properties, enabling applications, which are used among other reasons to meet the goals of the EU with regard to climate protection and growing danger of multi-resistant germs.

- The start-up Silvertex aqua GmbH is active in the drinking and industrial water segment, preserving high amounts of water with a globally patented 3D spacer fabric consisting of silver yarns and polyester. In Germany alone, over 80.000 mobile drinking water canister in caravans and boats are suited with this technology, protecting against legionella, e coli- and pseudomonas. Silver is also used in air humidifiers as well as in cooling towers and in warm water circulation systems in hospitals. Due to its unique character silver is the only metal applicable for this kind of use that requires neither additional energy nor the use of additional chemicals.

Silver is also of high value to other sectors and networks:

- printed electronics as key topic of the network nanoInk, a cooperation network for industrial inkjet printing including various partner from industry and academia. Silver and nanosilver is highly relevant for the development of printed electronics (e.g. photovoltaics, integrated sensors). Silver is used because of its high conductivity and stability against oxidation and corrosion. Currently, the network coordinates more than eight industry projects based on the technical use of nanosilver.

- electromobility as key topic of the network Nano4eMob, a cooperation network for electro mobility including various partner from industry and academia. Silver and

nanosilver is used for the development of batteries, renewable energy technologies, fuel cells, and electronics because of its high electrical and thermal conductivity.

Our main comments on the proposal for harmonised classification and labelling (CLH) for silver are as follows (see also public attachment):

ECHA note – An attachment was submitted with the comment above. Refer to public attachment CLH public consultation silver - Comments by Netzwerk NanoSilber.pdf

Dossier Submitter's Response

Thank you. We agree that there is a vast range of uses of silver and the classification proposal is intended to include all forms or physical states in which elemental silver is placed on the market. We understand that classification and labelling may have consequences for companies however this is outside the scope of the CLP process. Classification and labelling is based on the intrinsic properties of the active substance and consequences thereof are handled by downstream regulations.
Certainly the CLH report does not include all information on silver available. Only in Pub Med (biomedical literature from MEDLINE, life science journals, and online booksilver), the search terms silver and nanosilver generates 111,942 and 4000 results, respectively. As stated in section 4, submitting a proposal for classification and labelling was justified by the requirements for the review of silver under the BPR. Reviewing all information of possible relevance is not manageable but the information discussed in this CLH report is mainly published or industry-sponsored information submitted by the applicant under the BPR, information from the REACH registration dossier or additional published information identified by the dossier submitter. The information has thus not been picked exclusively by the dossier submitter and we expect the information to reflect, as far as possible, the true properties of silver.

RAC's response

Noted.

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	United Kingdom	<confidential>	Company-Manufacturer	11

Comment received

The following comments are submitted in response to the Proposal for Harmonized Classification and Labelling for Silver (CAS 7440-22-4).
Our company is a manufacturer of silver and silver products which go into numerous sectors and applications. The figure attached provides a very high level summary of these markets/applications.
There is no single substance that is an ideal alternative to the silver compounds in these applications, and in fact, for the more specialised uses such as in certain electronic circuitry applications, currently no technically equivalents alternatives are available to replace silver. Higher-end applications (e.g. in automotive applications) where there is a need for high levels of reliability and longer lifespans of products, potential silver alternatives such as copper are not viable.

We support, and actively contributed to the preparation of, the scientific comments submitted by the European Precious Metals Federation (EPMF). Rather than reiterating all of these comments we would like to draw particular attention to / supplement the following key messages and arguments which are addressed in more detail in the EPMF's

comments: ECHA note – An attachment was submitted with the comment above. Refer to public attachment Silver products.pdf
Dossier Submitter's Response
We note the support for the comments submitted by the European Precious Metals Federation (EPMF). Please note our response to comment 23.
RAC's response
Noted.

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Portugal	<confidential>	Company-Manufacturer	12
Comment received				
As the <confidential>, we have been using Silver in our operations with no evidence of any hazardous situation. Silver is a fundamental material for a substancial number of our operations.				
Dossier Submitter's Response				
Thank you. In the absence of any information regarding exposure levels, exposure route, type or form of silver etc we cannot assess this information.				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	United Kingdom	Ames Goldsmith UK Ltd	Company-Manufacturer	13
Comment received				
Ames Goldsmith is a global producer of chemically produced silver products. We use silver to produce silver chemicals (silver nitrate and silver oxide) and to produce high performance silver powders. Metallic silver is all round us in our everyday lives and is essential to communication technologies and in renewable energy supply. Our plant in the UK reflects the largest historic use of silver for photography since it is a former Kodak plant. As Ames Goldsmith this site has worked with customers and our chemicals are now used to form silver in many applications – electrical contacts, Mirrors (including solar mirrors), catalysts, and batteries. Globally our plants produce silver powders which are used in electronics, touch screens and solar (PV) panels. We will always work to safety and environmental best practise, but believe that the science supporting those regulation should be done thoroughly and correctly.				
Dossier Submitter's Response				
OK, thank you.				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Italy	<confidential>	Company-Manufacturer	14
Comment received				
The attachment describes our process regarding the production of silver coins and the protective measures adopted. ECHA note – An attachment was submitted with the comment above. Refer to public attachment 2020 12 17 Public attachment in the questionnarie <confidential> (003).docx				
Dossier Submitter's Response				
OK, thank you.				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Germany	Bio-Gate AG	Company-Manufacturer	15
Comment received				
Dear Sir/Madam, These comments are submitted on behalf of Bio-Gate AG, Germany. We would like to comment on the Proposal for Harmonized Classification and Labelling for Silver (CAS 7440-22-4). Bio-Gate uses metallic/elemental silver in a lot of applications and due to its special properties it is indispensable and cannot be replaced by other substances. Metallic silver has a lot of unique properties which are combined in one single substance like: • skin conditioner • antimicrobial • antiviral • anti-inflammatory (limited) • skin and microbiome friendly • is not able to penetrate the skin and mucosa tissue There is no other known natural ingredients that offers this range of positive effects. Bio-Gate manufactures its silver MicroSilver BG from pure metallic/elemental silver with medical grade. There are three different grades available: - MicroSilver BG for cosmetic applications o This grade is also certified for natural cosmetics because metallic silver is a natural ingredient - MicroSilver BG Med for medical devices - MicroSilver BG Tec for industrial/consumer and biocidal applications Bio-Gate's use metallic/elemental silver includes the following applications: • wound care products				

• derma cosmetic products • coating of implants • surface treatments • other medical devices like catheters and bone cement We have more than 200 customers who have more than 500 different cosmetic products on the market. A lot of these products are used for therapy-accompanying care of e.g. atopic dermatitis. Regarding the Proposed Classification of silver: Bio-Gate disagrees with the proposed classification for silver metal according to the Harmonised Classification and Labelling (CLH) as the scientific methodology used for all endpoints (listed below) in the proposed Harmonised Classification and Labelling (CLH) classification for silver metal is not fully based on evidence. In particular the endpoint for the proposed classification of silver metal as a Category 1B Reproductive Toxicant (Repr. 1B) under the Biocidal Products Regulation (BPR). This data and conclusion is not based on metallic/elemental silver. Bio-Gate would prefer for the OECD Test Guideline (TG443)-compliant Extended One-Generation Reproductive Toxicity Study (EOGRTS) to be first concluded or even the same is performed with metallic/elemental silver before any classification decision is made. Until there is evidence Bio-Gate believes it is both prudent and pragmatic not to prematurely classify silver metal until all the scientific data is available. Bio-Gate agrees with the comments on the silver metal endpoint classification of the EPMF and extends them by further points: ECHA note – An attachment was submitted with the comment above. Refer to public attachment Bio-Gate Safety Studies.zip ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Bio-Gate Microsilver BG Confidential Safety Studies.zip
Dossier Submitter's Response
Thank you for the information about all different uses of silver. We note the support the comments submitted by the European Precious Metals Federation (EPMF). The Extended One-Generation Reproductive Toxicity Study (EOGRTS) is indeed expected to provide useful information however decisions under CLP must be taken without awaiting information that may become available in the future. Other processes e.g. decisions on approval under the BPR depend on the classification and labelling of a substance thus the CLP process cannot be delayed.
RAC's response
Noted.

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Germany	I&P Europe - Imaging and Printing Association e.V.	Industry or trade association	16
Comment received				
see attached document				

ECHA note – An attachment was submitted with the comment above. Refer to public attachment Comments to the silver metal CLH public consultation.pdf
Dossier Submitter's Response
Thank you for the information about all different uses of silver. We note the support the comments submitted by the European Precious Metals Federation (EPMF).
RAC's response
Noted.

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Belgium	T&D Europe	Industry or trade association	17
Comment received				
The CLH report refers to a very limited list of uses of silver in industry (section 5, p.18). The report should have given a comprehensive overview of the diversity of use in order to reflect the importance of silver in a wide range of manufacturing processes. We would like to highlight the essential need of silver in the electrical equipment domain, in particular for the manufacturing of electricity transmission and distribution grid equipment. The use of silver in electricity transmission and distribution equipment shows specific and outstanding characteristics like its electrical conductivity, hardness, melting point, corrosion and friction properties. Such advantageous property combination is not found anywhere else on the periodic table of elements. Silver allows the electricity grid network to be energy efficient, safe and reliable. For a detailed overview of the use of silver in electricity transmission and distribution, please refer to the additional public document provided in this consultation. ECHA note – An attachment was submitted with the comment above. Refer to public attachment TD Europe CLH Consultation Silver_Dec2020_final.pdf				
Dossier Submitter's Response				
Thank you for the information about different uses of silver. Information on the different uses and forms of silver on the market is important to assure that the data used for the proposal relate to the forms or physical states in which the substance is placed on the market and in which it can reasonably be expected to be used. We understand that classification and labelling may have consequences for companies however this is not within the scope of the CLP process since classification and labelling is based on the intrinsic properties of the active substance. Consequences thereof may be handled by downstream regulations.				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Belgium	Eurometaux	Industry or trade association	18
Comment received				
It is exceptional that Eurometaux submits direct comments on the CLP public consultations for RAC examination of single substances, whereby Eurometaux' s main attention and interest focusses on the correct and full application of the REACH and CLP				

guidance. As such the present case on the environmental classification of Silver metal warrants an intervention for the Public Consultation, given the upcoming review touches upon several important aspects of the CLP guidance for data rich substances and metals in particular. ECHA note – An attachment was submitted with the comment above. Refer to public attachment Enclosure 2 - Overview of metal environmental classification entries including some history.zip
Dossier Submitter's Response
Thank you for your comment. Please see the DS' response in comment number 311.
RAC's response
Noted.

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	France		MemberState	19
Comment received				
Please RMS specify if the particle size distribution of each compound tested (Silver powder, Nanosilver) is number based or volume based? The purity of the test items used to perform all physicochemical properties tests should be reported.				
Dossier Submitter's Response				
With regards to the purity of the test materials for physicochemical properties studies, please note that most of the reported endpoints are from sources (i.e. handbooks and databases) where information on purity is not available. The purity of the test material used in the various T/D-studies referred to under section 7 were as follows: CIMM, 2009: nominally 99% ECTX, 2010: typically 99-100% ECTX, 2013: 99.99% VITO NV, 2017: purity not stated (applied as a suspension of nanosilver) The purity is not reported for the studies provided in the Reach-dossier for granulometry. The particle size distribution data provided in the physicochemical section was volume based except for the data on the coated nanosilver used in the T/D study which was number based. In general, the size distribution data provided in the CLH-dossier for the nanomaterial is mostly volume based but in some studies the data is number based. However, since the material characterised as nanosilver clearly falls within the definition as a nanomaterial, it is deemed that the basis for the particle distribution is of less relevance.				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Germany	ZVEI - German Electrical and Electronic Manufacturers' Association	Industry or trade association	20

Comment received

We would like to comment on the Proposal for Harmonized Classification and Labelling for Silver (CAS 7440-22-4).
Particularly, we want to emphasize the importance of silver as a material for our industry and express our serious concerns about the potentially far-reaching indirect consequences of the current classification proposal for our industry.

Comment 1:
Chapter 5, p. 18: Identified Uses of the CLH report :
The current description is insufficient and does not reflect properly the different uses of silver metals.
Silver is technically essential for numerous applications throughout the whole electrical and electronics industry (see table in the attachement with the most important, basic applications). It is also of utmost relevance to fulfil the goals of the Green Deal by the European Commission. Metallic silver is applied for example in wires, pins, contacts, solders, brazing, sintering, adhesives, fuses, lead frames, printed circuit boards, semiconductors and LEDs (non-exhaustive list). These components are utilized in switchgear and apparatus for electric energy generation by conservative power plants and e.g. solar panels and wind farms, electric energy transmission on high voltage level and distribution on medium and low voltage level, consumer/industrial electric equipment (phones, computers, white goods, domestic installation, low voltage switchgear, etc), electric equipment for transportation (trains, aircrafts and cars/e-mobility) and electric medical equipment.
The wide use of silver is caused by its outranging technical functionalities, such as electrical conductivity, power dissipation, hardness, melting point, corrosion and friction properties, contact wear, reflectivity, whisker protection and thermal conductivity.
The overall functionality of silver cannot generally be replaced by other materials without a negative impact on the appliances it is used in.
Neither copper nor gold are suitable substitutes for the wide range of silver applications from a technical point of view. Moreover, gold is also a conflict raw material. There are ongoing huge efforts to reduce the quantity of silver used in electrical and electronic applications for cost reasons for decades. This has led in most cases already to a minimum use of silver and silver compounds in the EEE applications.
Due to the high volumes of silver (roughly one third of the global demand of silver can be assigned to the EEE industry) used in the EEE sector we fear the possible indirect consequences of silver being classified as a CMR substance (Reprotox 1B) under the CLP regulation. This could lead to further regulatory measures under the REACH Regulation (EC No 1907/2006), such as inclusion in the REACH candidate list with significant information duties under art. 33 (1) REACH and according to the requirements of the SCIP database, authorisation (Annex XIV) and possible restrictions (Annex XVII).
In addition, the listing in Annex II of the RoHS Directive 2011/65/EU (Restriction of Hazardous Substances in Electrical and Electronic Equipment) could be a consequence of the planned reclassification of silver. It should be mentioned here, that silver was already the alternative for lead that had to be laboriously substituted as a result of the

introduction of the ELV and RoHS directives at the beginning of the millennium, and that those efforts so far have not reached completion. While achieving this substitution, all soldering processes had to be converted to higher bath temperatures, extended heating phases and application/qualification of new electronic components that were able to withstand these conditions. Silver and/or copper served to increase the melting temperature, mechanical strength and structural stability.
The handling of silver containing materials within the EEE sector requires special know-how, the workers are trained for. Workers are obliged to wear gloves and/or other protection in order to prevent damaging the parts during manufacturing of the respective electronic products/parts (their functionality), e.g. through fingerprints. General public is not exposed to silver by EEE products. The silver components used in EEE products are in general not accessible to public and evaporation or release of silver powder or silver salts does not occur. Exposure to operator and maintenance personnel of EEE products is negligible. As another example silver plating on contact surfaces during manufacturing is mostly done by galvanization. Health of employees is taken care of by using the appropriate protective equipment. Low voltage contacts may e.g. be manufactured by sintering silver and metal oxide powder within automated processes. Exposure to workers is prevented by closed production lines additionally to health and safety measures. Where there are water condensation or strong environmental influences, the device is usually protected against these, so no leakage into the environment or contact with silver or silver salts is to be expected (protection goal of the Low Voltage Directive).

Comment 2:
We support the scientific comments submitted by the European Precious Metals Federation (EPMF).

Comment 3:
In June 2019, the European Chemicals Agency (ECHA) accepted the EPMF's proposal for an EOGRTS. As far as we are informed, this assessment is currently underway alongside an assessment of toxicokinetics, to allow robust read-across from silver acetate to different silver substances. Unfortunately, from the current perspective, the obtained results will be available too late to be fed into the adopted RAC opinion for the CLH proposal for silver metal. In view of the possible consequences for our industry, we find this very regrettable and do not perceive why the consultation and decision making has not been postponed until these for this matter very relevant studies are completed. In addition, we doubt that a read-across from silver salts to metallic silver can be justified at all from a scientific point of view. We support the statement made by EPMF in its statement to this consultation that bioavailability is an intrinsic property of substances.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment 20201218 ZVEI Silver Applications in EEE and Comments Ag CLH Consultation.pdf

Dossier Submitter's Response

1. Thank you for the information about different uses of silver. Information on the different uses and forms of silver is important to assure that the data used for the proposal relate to the forms or physical states in which the substance is placed on the market and in which it can reasonably be expected to be used. We understand that classification and labelling may have consequences for companies however this is not within the scope of the CLP process since classification and labelling is based on the intrinsic properties of the active substance. Consequences thereof may be handled by downstream regulations.

2. We note the support for the comments submitted by the European Precious Metals Federation (EPMF).
3. The Extended One-Generation Reproductive Toxicity Study (EOGRTS) is indeed expected to provide useful information however decisions under CLP must be taken without awaiting information that may become available in the future. Other processes e.g. decisions on approval under the BPR depend on the classification and labelling of a substance thus the CLP process cannot be delayed. The possibility to submit new classification proposals based on new information remains.

RAC's response

Noted. RAC has received the full audited report for the Extended One-Generation Reproductive Toxicity Study (EOGRTS) and this is incorporated into the final opinion for Silver.

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Germany	C.HAFNER GmbH + Co. KG	Company-Manufacturer	21

Comment received

Comments of the Company C. HAFNER GmbH + Co. KG on the Public Consultation of the Silver CLH Proposal

C.HAFNER is one of Europe's leading companies in the field of precious metal technology. We recover precious metals especially gold and silver from secondary material, which we process into different materials for a wide sector of use.
We use massive silver to produce silver containing alloys for semi-finished products for the use in jewelry, for dental and industrial applications.
We produce µ-sized silver powder as well in completely separated manufacturing process. It is used to produce semi-finished products and brazing pastes for the jewelry industry as well as conduct parts for industrial applications.
When looking for alternatives for silver it becomes evident that these have not the unique properties of silver (e.g. ductility, conductivity) at the same available quantities and with comparable costs. Silver was replaced by other metals wherever it was technically and economically feasible.
The proposed classification will have severe influence on the future use of silver.
Therefore, we require environmental classification according ECHA Guidelines – different classification of Ag massive and powder – and that other proposed classifications are based on hard and comprehensible scientific facts. Silver in a massive form should not be classified. C.HAFNER is a member of the European Precious Metals Federation (EPMF) and a joined registrant of silver under the REACh legislation. Hence C.HAFNER supports the scientific comments submitted by the EPMF.

We would be pleased if you could consider our comments in the further process.

Please do not hesitate to contact us if you have any further questions.

Dossier Submitter's Response

Thank you for the information about different uses of silver. Information on the different uses and forms of silver on the market is important to assure that the data used for the proposal relate to the forms or physical states in which the substance is placed on the market and in which it can reasonably be expected to be used. We understand that the

proposal may have consequences for companies however this is not within the scope of the CLP process since classification and labelling is based on the intrinsic properties of the active substance. Consequences thereof may be handled by downstream regulations. We note the support for the comments submitted by the European Precious Metals Federation (EPMF).
RAC's response
Noted.

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Germany	<confidential>	Company-Manufacturer	22
Comment received				
I would like to refer to the document under "Public Attachment" ECHA note – An attachment was submitted with the comment above. Refer to public attachment <confidential>_Public Cons. Ag CLH Proposal.pdf				
Dossier Submitter's Response				
We note the support for the comments submitted by the European Precious Metals Federation (EPMF). We understand that the proposal may have consequences for companies however this is not within the scope of the CLP process since classification and labelling is based on the intrinsic properties of the active substance. Consequences thereof may be handled by downstream regulations.				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Belgium	European Precious Metals Federation (EPMF)	Industry or trade association	23
Comment received				
Comments on uses (CLH report section 'identified uses' - p.18): The section on identified uses of silver in the CLH report is very short and mainly focuses on the biocidal use of silver. We would like to highlight that silver has many more uses critical to everyday life: silver is used in electronics and electrical equipment used in consumer applications, industrial applications, automotive uses, green energy (including solar and wind) and brazing and soldering applications and is also used in medical devices and in vitro diagnostic (IVD) medical devices. Furthermore, silver is used in jewellery and in tableware/silverware. Other uses include use of silver in aeroplanes, satellites and defence applications, in personal care products, in photographic films, papers and emulsions and in a variety of industrial applications not accounted for in the list above, in diamond tools, as investments, or in the manufacture of other chemical substances, mirrors and surface treatment. In this respect, we also refer to the individual comments submitted by several silver downstream users, further describing the uses and criticality of silver. Summary of comments on read-across (CLH report section 'data sources' - p.18-22): • In the absence of substance specific data, it is not justified to perform read-across from any silver containing substance with silver content ranging from 2.5 to 75%, for which conclusive silver ion release data are not available, for which the overall composition is in				

many cases unknown and for which other constituents contribute (or even be responsible) for observed effects.
• In vitro bioelution data cannot be used on their own to reliably predict silver bioavailability, as silver behaviour and speciation in in vitro assays is driven by bioelution media composition (like presence of chlorides) rather than test item characteristics. Also, behaviour and speciation in vivo are complex and are influenced by a variety of chemical and biochemical processes, which influence the absorption characteristics of silver forms.
• To address this further, EPMF is currently conducting comparative in vivo toxicokinetic (TK) studies, covering ionic Ag forms, AgNP and massive/powdered forms of elemental Ag as test articles. Results of these studies have to be awaited since no alternative in vivo data on bioavailability of metallic Ag are available to investigate and potentially justify the read-across possibilities. The test data will be available H1 2021.
• The CLH report incorrectly states that bioavailability is not an intrinsic property.
For further details / justification, please refer to the attached document pages 7-10.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment CLH Ag Comments FINAL_201217.pdf

Dossier Submitter's Response

IDENTIFIED USES (CLH REPORT P. 18):
Thank you for the information about different uses of silver. Information on the different uses and forms of silver is important to assure that the data used for the proposal relate to the forms or physical states in which the substance is placed on the market and in which it can reasonably be expected to be used. Otherwise, the intended uses have no impact on the assessment if the intrinsic properties of the substance fulfil criteria for classification and labelling.

DATA SOURCES (CLH REPORT P. 18-22)
General: certainly the CLH report does not include all information on silver available. Only in Pub Med (biomedical literature from MEDLINE, life science journals, and online booksilver), the search terms silver and nanosilver generates 111,942 and 4000 results, respectively. As stated in section 4, submitting a proposal for classification and labelling was justified by the requirements for the review of silver under the BPR. Reviewing all information of possible relevance is not manageable but the information discussed in this CLH report is mainly published or industry-sponsored information submitted by the applicant under the BPR, information from the REACH registration dossier or additional published information identified by the dossier submitter. The information has thus not been picked exclusively by the dossier submitter and we expect the information to reflect, as far as possible, the true properties of silver.

p. 18-19: The possible influence on toxicity of different constituents is indeed recognised in the CLH report. Therefore, as far as possible, robust and reliable data obtained with chemically less complex silver salts and with nanosilver is used for the hazard assessment. However, for some endpoints such information is missing or insufficient as stand-alone thus data for more complex substances are used in a weight of evidence approach. In these cases the similarity of effects noted in studies with different substances and thus the likelihood that effects are due to the silver ion rather than other constituents, are taken into consideration. Also expected differences in silver ion exposure due to differences in silver content and expected release are taken into consideration when discussing the relevance of results to assess the intrinsic properties of 100% silver (ions).
We note that when results indicate lack of adverse effects, use of data for other SCAS is yet supported by the EPMF. E.g. for genotoxicity, the EPMF states *"It is acknowledged*

that such SCAS also contain constituents other than introduces silver which some interpretative complexity. However, the achieved Ag-equivalent treatment levels were moderately high, and this group of studies is therefore considered to provide useful confirmatory information regarding an absence of mutagenic or DNA damaging effects in the case of these read-across reference substances."

p. 18: We certainly agree that information on the bioavailability of silver from in vivo data and physiological conditions is preferred over data for in vitro conditions intended to simulate the gastrointestinal tract of the rat. However, the classification proposal is based on existing information available and it is not possible to await further information that may become available in the future since this would delay other processes, e.g. approval under the BPR, that depend on harmonised classification and labelling.

p. 19: reference to lead: the separate entries for lead massive and particles was decided upon after the discussion in RAC separate entries were not considered supported by the scientific data. The human health assessments of massive and particles are both based primarily on studies performed with salts of lead (ions), i.e. in similarity with silver. The RAC opinion states (page 5) *"The RAC noted that the Guidance on the Application of the CLP Criteria, section 1.3.2.1, refers to a few specific cases in which bioavailability may have an influence on hazard classification, e.g. some metals* when*, where the nature of the physical form (metals in solid form) may limit absorption. In order to conclude that there is a lack of or reduced bioavailability there needs to be a high burden of proof, supported by robust data and expert evaluation. Information on bioavailability is usually obtained from adequate, reliable, and conclusive toxicokinetic studies for all relevant routes of exposure and all relevant forms or physical states where the substance and/or metabolite(s) of the substance have been quantified in body fluids and/or target organs. Since such data have not been presented by the DS or during the public consultation (PC), the RAC agreed with the DS that the classification should apply to all physical forms of lead, regardless of particle size."*
p. 20: in the absence of information on the bioavailability of elemental silver in massive form, it is assumed to release silver ions in contact with moist and with biological fluids.

p. 20-21: the purpose of including the read-across matrices for nanomaterials included in the ECHA's Guidance on QSARs and Grouping is to illustrate the actual situation for published literature which generally only includes limited information on the majority of parameters requested in the guidance to describe nanomaterials. Neverthelss, as stated in the CLH report, the lack of information on these parameters is not considered to justify disregarding the information available for nanosilver.

RAC's response
Noted.

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Netherlands		MemberState	24

Comment received
Specific comments The dossier submitter justifies the use of data from silver nanoparticles and silver containing active substances (SCAS) to use in a read-across approach as there is no data available for massive silver. We agree with this approach but remark that this is only applicable to systemic endpoints. For local effects, it is important to justify if the effects observed are also expected after contact with massive silver or to propose a separate

classification for different forms.
Effects with nanosilver are considered to represent an intrinsic property of the silver ion. This seems to be based on a single study only (van der Zande M, IIIB, page 20). The reliability of the van der Zande article is not stated in the summary table and text. Please reflect on the reliability as it seems to provide key information about silver forms toxicokinetics and bioavailability.
Taken together, data used for classification should preferably incorporate studies with silver salts with components that are not expected to influence toxicity as well as data on silver nanoparticles. The NL-CA agrees studies with these compounds provide adequate data for classification of silver.

The DS proposes to set the dermal uptake at an upper level of 5%. This may be a valid approach for setting a limit value when performing a risk assessment. However the relevance for this dossier is unclear and this approach is normally not appropriate for hazard based classification purposes.

Dossier Submitter's Response

We agree that it is not possible to exclude that different forms of silver may differ in local toxicity. However, in the absence of data for massive silver such entry would still need to be based on data obtained with other forms of elemental silver.

The study by Van der Zande et al was given reliability score 2-3 (see study summaries included at the end of the CLH report) since the information available in the published study is not as detailed as would be in a GLP study report e.g. with respect to individual animal data and detailed pathological findings, if any. Although the study is not performed according to a recognised guideline or to the principles of GLP, the results are presented in a peer-reviewed scientific journal and thus considered reliable.
While there is a huge amount of toxicological studies on nanosilver and a number of studies on silver salts available in the open literature, the study by Van der Zande et al seems to be one of few that actually investigates nanosilver and a silver salt in the same study and thus allows for a comparative assessment.
We agree that data obtained with silver salts with constituents that are not expected to influence toxicity is preferred however this type of information, especially when taking into account robustness and reliability, is very limited. Therefore, data obtained with SCAS and showing similar effects is taken into account.
The information on dermal absorption is indeed of most relevance for risk assessment. It is included since the report is structured according to the joint format for the CLH report and the CA report for biocides.

RAC's response

Noted.

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Netherlands	<confidential>	Company-Manufacturer	25

Comment received

Dear Madam/Sir,
These comments are submitted on behalf of <confidential>

We manufacture and sell circulation and commemorative coins to 70 central banks worldwide. The use of silver is critical for our commemorative coins, our most important activity. Silver is unique in its appearance and value. Silver coins are a unique way to

celebrate and give meaning to historical events or people of national importance. Silver coins can be sold in a price range different from gold and makes commemorative coins more accessible to the greater public.

In addition, we use silver for our royal decorations and jewellery for the royal chancellory and other public institutions. Silver has unique properties in terms of appearance, enamel and coating. Making these products in other materials is not possible.

Moreover, having 100.000s of customers, buying silver coins from us for centuries, we never received comments that there were hazardous risks of silver. People have been using silver cutlery, jewellery and other silver products for centuries. We do not believe that there are material hazards related to silver, never having received any indications of this kind. The hazards described in the Proposal for Harmonized Classification and Labelling for Silver (CAS 7440-22-4) are often not sufficiently substantiated.

In short, silver is a crucial commodity for our business operation and our customers. The business will not disappear with European regulation. The result will be that non-European mints take over our activities.

Dossier Submitter's Response

We understand that the proposal may have consequences for companies however this is not within the scope of the CLP process since classification and labelling is based on the intrinsic properties of the active substance. Consequences thereof may be handled by downstream regulations.

RAC's response

Noted.

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	France	FRANCECLAT, BOCI and UFBJOP	Industry or trade association	26

Comment received

Please find our general comments in the attached document.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment Comments on CLH proposal for silver.pdf

Dossier Submitter's Response

Thank you for the information about different uses of silver. Information on the different uses and forms of silver on the market is important to assure that the data used for the proposal relate to the forms or physical states in which the substance is placed on the market and in which it can reasonably be expected to be used.
As stated in section 4, the justification for the classification proposal is the need for harmonised classification and labelling resulting from the review under the BPR. However, the CLH report also informs that there are more uses than the intended biocidal uses triggering an action *"Apart from biocidal use, silver has 92 active registrations under REACH in June 2019. It has wide uses by industry, professionals and consumers."*
We understand that classification and labelling may have consequences for companies however this is not within the scope of the CLP process since classification and labelling is based on the intrinsic properties of the active substance. Consequences thereof may be handled by downstream regulations.
The Extended One-Generation Reproductive Toxicity Study (EOGRTS) is indeed expected to provide useful information however decisions under CLP must be taken without

awaiting information that may become available in the future. Other processes e.g. decisions on approval under the BPR depend on the classification and labelling of a substance thus the CLP process cannot be delayed. The possibility to submit new classification proposals based on new information remains.
RAC's response
Noted and refer back to comment 20.

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Germany	Fachvereinigung Edelmetalle e. V.	Industry or trade association	27
Comment received				
The precious metal silver has been used in various ways since ancient times. It has the lowest contact resistance and the highest electrical and thermal conductivity of all metals which makes it essential in many components of Green Technologies. Solar panels, rapid charging-stations, in-road applications and certain types of electrodes all require silver. It is used in switches, circuit boards and in some types of batteries when the required speed of conduction exceeds that of what copper can deliver. Silver is used in X-rays, other medical applications and equipment because of its natural antimicrobial properties. With the rapid rise of antibiotic-resistant strains of microbes researchers are focusing on silver as one of the keys to future defences to protect human health. It is used for water purification also. The use of silver is sustainable, as unlimited recycling is possible and due to elemental characteristics, silver and silver alloys will be essential for future European Green Deal. When looking on alternatives, it becomes evident that these have inferior properties (non-precious metals) or are much more costly, not thinking about required quantities (other pre-cious metals). The proposed classification will have severe influence on the future use of silver. Therefore, we require environmental classification according ECHA Guidelines – different classification of Ag massive and powder – and that other proposed classifications are based on hard and comprehensible scientific facts. Silver in a massive form should not be classified. Reduction or more precisely the minimization of Silver used in applications was major R&D focus over the last decade. A replacement of Silver was executed wherever technically pos-sible mainly due to cost reasons. However, a vast amount of Silver is technically irreplace-able in electric industry sector due to the combination of high conductivity and low corrosion. Silver has various areas of application • Massive silver is used to produce investment bars and alloys containing silver for semi-finished products for the use in jewelry, for industrial and dental applications. The silver compounds potassium silver cyanide, silver cyanide and silver nitrate are used in electroplating baths. • Pure silver powder and silver containing powder is mainly used in industrial applica-tions to produce semi-finished products like electrical contact industry and brazing pastes for the jewelry industry. • In the electronics industry silver is an essential part for the production of contact ma-terials, contact parts and functional surfaces, as they are used in e.g. electric contac-tors, relays, circuit breakers, inverters, electric connectors, EV batteries by our down-stream users. These semi-finished materials are manufactured via powder- and melt-ing-metallurgical methods. Also due to its catalytic effect, silver cannot be replaced in its industrial application:				

o Formaldehyde is one of the most important chemical raw materials (approx. 5-10 million tons p.a. worldwide). It is needed for the production of various resins (phenolic resins, melamine, etc.) and polymers. The synthesis is done indus-trially almost exclusively from methanol, either by dehydrogenation or partial oxidation. The most important manufacturing process, according to which ap-prox. 80% of the industrial plants operate, is the so-called silver contact pro-cess. In this process, fine silver is used as a catalyst to increase the yield with less energy consumption (temperature/pressure). In the course of the process the silver catalyst ages and after 4-7 months of operation an increased production of formic acid occurs. This corrodes the plant and starts an unwanted polymerization of the product. The catalyst must therefore be replaced at regular intervals. Silver is therefore indispensable for this important process in the basic industry.
Furthermore, silver is not substitutable for the production of ethylene oxide. The large-scale production of ethylene oxide is carried out exclusively by the catalytic oxidation of ethene with oxygen.
Finely dispersed silver powder, which is applied to an inorganic, oxide-con-taining carrier (preferably aluminium oxide), is used as a catalyst.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment FVEM comments CLH silver.pdf

Dossier Submitter's Response

Thank you for the information about different uses of silver. Information on the different uses and forms of silver on the market is important to assure that the data used for the proposal relate to the forms or physical states in which the substance is placed on the market and in which it can reasonably be expected to be used.

RAC's response

Noted.

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Germany	Federal Associations of the German Jewellery and Silverware Industry	Industry or trade association	28

Comment received

The Federal Associations of the German Jewellery and Silverware Industry as a group was founded in 1952 with the aim of uniting all German organizations in the jewellery and silverware sector, from industry to crafts and trade. It represents a necessary platform on which all German representatives of the industry can exchange views on the issues that affect the entire industry, find common posi-tions on these issues and represent their interests on a national and international level. The main focus of the association is the representation of German interests in the World Jewellery Confeder-ation CIBJO for the benefit of the industry, the craft and the trade.
The following associations are members of the association:
- German Association of Jewelry, Watches, Silverware and Related Industries e.V.
- German Association of the Gemstone and Diamond Industry e. V.
- German Association of Jewelers, Jewelry and Watch Specialists e.V.
- German Association of Importers and Exporters of Gemstones and Pearls e.V.
- Association of the Gablonz Industry e.V.
- Precious Metals Association, Schwäbisch Gmünd

• Society for the Art of Goldsmithing, Hanau

Silver and silver compounds are used in the jewellery, watch and silverware sector in various com-ponents and products, where applications include the use of massive silver, silver plating and the use as a component in silver, gold and copper alloys. These are used within in a broad range of end products that are designed for everyday use, mid-tier products and luxury products. The key prop-erties of silver and silver compounds include its function as a reflective/ornamental and store of value, but also its natural antimicrobial properties.
As the combined group of representations of the German jewellery, watch and silverware industry sector we would like to indicate that it would not be possible to find an alternative to metallic silver for most of its uses in mid-tier and luxury products, since it is not possible to provide the same aes-thetic, economic and technical functionality. For products in everyday use, these can and have al-ready be substituted with other cheaper alternatives (e.g. stainless steel).
In response to the proposed Reprotox Cat. 1B classification of silver and silver compounds, the com-panies of our industry sector as downstream users of these compounds in the jewellery, watch and silverware sector will suffer greatly, not only because of the restrictions to silver products, but espe-cially because of the use of silver in almost any other precious metal alloy. Most companies will most likely at least try to continue operations. However, the future of our industry sector will be subject to both the affordability of future products, and how consumer demand changes after silver is clas-sified Repr. 1B, as it is possible consumers will demand jewellery, watch and silverware without the use of silver, which is near to impossible.
We would also like to point out that the costs of the proposed classification are unforeseeable for the mostly small and medium-sized enterprises in our industry sector. They range from costs of com-pliance (additional risk management measures, monitoring and data requirements, etc.) to the loss in value added due to stigma effects.
In contrast to costs, the benefit of the proposed classification from the reduced exposure of the af-fected population is unknown due to insufficient scientific evidence on the potential reproductive toxicity of the silver and silver compounds (including whether there are any risks). Therefore, the Federal Associations of the German Jewellery and Silverware Industry strongly support the scientific comments submitted by the European Precious Metals Federation (EPMF).

ECHA note – An attachment was submitted with the comment above. Refer to public attachment 20201216-comments-vbv-clh-silver.pdf

Dossier Submitter's Response

Thank you for the information about different uses of silver. Information on the different uses and forms of silver on the market is important to assure that the data used for the proposal relate to the forms or physical states in which the substance is placed on the market and in which it can reasonably be expected to be used. We understand that the proposal may have consequences for companies however this is not within the scope of the CLP process since classification and labelling is based on the intrinsic properties of the active substance. Consequences thereof may be handled by downstream regulations. The Extended One-Generation Reproductive Toxicity Study (EOGRTS) is indeed expected to provide useful information however decisions under CLP must be taken without awaiting information that may become available in the future. Other processes e.g. decisions on approval under the BPR depend on the classification and labelling of a substance thus the CLP process cannot be delayed. The possibility to submit new classification proposals based on new information remains. We note the support for the comments by EPMF.

RAC's response
Noted.

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Austria	<confidential>	Company-Manufacturer	29
Comment received				
It has been known since ancient times that silver has an antibiotic effect. It has been known for over 3,000 years that water in silver vessels stays fresh longer. In the past, you put a silver coin in milk to keep it fresh longer. In the 19th and early 20th centuries, silver was of great medical importance. At the end of the 19th century, silver nitrate was dripped into the eyes of newborn babies to prevent the then widespread eye tripper. Then in 1928 penicillin was discovered and the antibiotic effect of silver was forgotten. The Rennaissance experienced silver in the form of colloidal silver in the late 1990s, as the increasingly antibiotic-resistant strains of bacteria develop. In many relectrotechnical products silver is used for plating contacts, as well as in fuse-links (melting strip) and electronics. It has perfect features for these applications. Without silver it is not possible to reach such a low power loss (e.g. melting strip of a fuse-link) and constant electrical conductivity of contact systems. We use silver in the switchgear we are producing. Without silver it would not be possible to produce sustainable and environmentally friendly devices with less power loss!				
Dossier Submitter's Response				
Thank you for the information about different uses of silver. Information on the different uses and forms of silver on the market is important to assure that the data used for the proposal relate to the forms or physical states in which the substance is placed on the market and in which it can reasonably be expected to be used. We understand that the proposal may have consequences for companies however this is not within the scope of the CLP process since classification and labelling is based on the intrinsic properties of the active substance.				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Germany	European Committee for Surface Treatment aisbl	Industry or trade association	30
Comment received				
CETS is gratefully taking the opportunity to comment the proposal. Please consider our comments summarized in the attached file. ECHA note – An attachment was submitted with the comment above. Refer to public attachment CETS-comments Silver labelling CAS 7440-22-4 201217.pdf				
Dossier Submitter's Response				
Thank you for the information about different uses of silver. Information on the different uses and forms of silver on the market is important to assure that the data used for the proposal relate to the forms or physical states in which the substance is placed on the				

market and in which it can reasonably be expected to be used. We understand that the proposal may have consequences for companies however this is not within the scope of the CLP process since classification and labelling is based on the intrinsic properties of the active substance. Consequences thereof may be handled by downstream regulations. The Extended One-Generation Reproductive Toxicity Study (EOGRTS) is indeed expected to provide useful information however decisions under CLP must be taken without awaiting information that may become available in the future. Other processes e.g. decisions on approval under the BPR depend on the classification and labelling of a substance thus the CLP process cannot be delayed. The possibility to submit new classification proposals based on new information remains. We note the support for the comments by EPMF.
RAC's response
Noted.

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Germany		Individual	31
Comment received				
As a citizen of Europe I have to express that the approach of classifying Silver metal as harmful seems to be weird. Silver metal has been used for jewelry for thousands of years, in long-term skin contact. If there were any significant adverse effects it would have been major concerns in the public - which are not! Therefore a classification of Silver metal in general appears to be irrational. If there should be any concerns about specific appearance of Silver like dust or nano form, Eu-Commission should first implement clear definition of the specific forms. The the classification has to be restricted to the form of concern. If CLP does not give this opportunity, the classification of Silver in the proposed way has to be rejected necessarily. Please consider my deep concern about the usage of tax money by EU Commission and Agencies. Personally I do not agree spending it to such questionable topics.				
Dossier Submitter's Response				
Thank you.				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Germany	Zentralverband Oberflächentechnik e.V.	Industry or trade association	32
Comment received				
Zentralverband Oberflächentechnik e.V. is grateful for the opportunity to comment on the proposed new classification and labelling of Silver metal. Please consider the comments summarized in the document attached. ECHA note – An attachment was submitted with the comment above. Refer to public attachment 2020-12-11 comment public consultation Ag ZVO.pdf				
Dossier Submitter's Response				
Thank you for the information about different uses of silver. Information on the different uses and forms of silver on the market is important to assure that the data used for the proposal relate to the forms or physical states in which the substance is placed on the				

market and in which it can reasonably be expected to be used. We understand that the proposal may have consequences for companies however this is not within the scope of the CLP process since classification and labelling is based on the intrinsic properties of the active substance. Consequences thereof may be handled by downstream regulations. The Extended One-Generation Reproductive Toxicity Study (EOGRTS) is indeed expected to provide useful information however decisions under CLP must be taken without awaiting information that may become available in the future. Other processes e.g. decisions on approval under the BPR depend on the classification and labelling of a substance thus the CLP process cannot be delayed. The possibility to submit new classification proposals based on new information remains. We note the support for the comments by EPMF.
RAC's response
Noted.

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Austria	<confidential>	Industry or trade association	33
Comment received				
Silberlegierungen werden zur Erzeugung von Schmuck und Hartloten verwendet. Darüberhinaus wird die Rückseite von Kristallen mit einer Silberschicht chemisch verspiegelt (nasschemisches Sprühverfahren auf Silbernitratbasis). Ebenso wird Silber bei der nasschemischen Verspiegelung von Flachglas (Automotive, Sicherheit, Möbel, Bad, etc) benötigt. Im Bereich TableWare kommt Silber bei Tafelgeschirr und Besteck zum Einsatz. Neben den technischen Eigenschaften von Silber spielt vor allem das hohe Reflexionsvermögen und der Weiß-Grad eine wesentliche Rolle. Silber hat eine antiseptische Wirkung. Es sind uns keine gesundheitsbedenklichen Fälle in der Anwendung und/oder Verarbeitung bekannt. Es liegen uns auch keine Indizien für Hautirritationen vor. Aus diesem Grund können wir zu den nachstehenden "Comments on the open Hazard classes" nichts beitragen, da die dort angeführten Eigenschaften/Klassifizierungen nach unserem Wissensstand nicht gegeben sind. Bei der Herstellung von Schmuck und Tafelgeschirr wird Silber üblicherweise in kompakter Form verarbeitet. Dabei kann es zu Abrieben kommen. Allfällige Schädigungen der Gesundheit und der Umwelt sind uns dabei nicht bekannt bzw. werden diese durch Einhaltung der bereits bestehenden gesetzlichen Vorschriften (Arbeitnehmerschutz) auf ein Minimum reduziert. Uns ist vor allem bei der Schmuckerzeugung und Verspiegelung kein alternatives Produkt zu Silber bekannt, welches dieselben Eigenschaften und Qualitätsanforderungen hätte.				
Dossier Submitter's Response				
Thank you.				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Czech Republic	SAFINA, a.s.	Company-Manufacturer	34
Comment received				
Please see the attached file.				

ECHA note – An attachment was submitted with the comment above. Refer to public attachment SAFINA_CLH public consultation_silver metal - completed.pdf
Dossier Submitter's Response
Thank you for the information about different uses of silver. We note the support for the comments by EPMF.
RAC's response
Noted.

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Norway	<confidential>	Company-Manufacturer	35
Comment received				
Precious metals are not at the heart of our process and represent small volumes. Nevertheless, and as described further in the attached document, their production, including silver production, is critical for ourproduction process. Indeed, one of the conditions to continue in a sustainable way our main productions of nickel, copper and cobalt, is to be able to recover as much as possible of the other elements contained in the raw material. Please see the attached document. Beyond the criticality of the silver production within our production process as a whole, we support the scientific comments submitted by the European Precious Metals Federation (EPMF) that are specified below in the comments on the open hazard classes. ECHA note – An attachment was submitted with the comment above. Refer to public attachment Comments CLH Ag -17.12.20.pdf ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Comments CLH Ag - <confidential> - 17.12.20 - confidential info.pdf				
Dossier Submitter's Response				
Thank you for the information about your use of silver. We understand that the proposal may have consequences for companies however this is not within the scope of the CLP process since classification and labelling is based on the intrinsic properties of the active substance. Consequences thereof may be handled by downstream regulations. We note the support for the comments by EPMF.				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Spain	CAPIEL	Industry or trade association	36
Comment received				
Dear colleagues, Please find enclosed the comments prepared by CAPIEL on the dossier proposing harmonised classification and labelling for Silver ECHA note – An attachment was submitted with the comment above. Refer to public attachment CAPIEL Comments.pdf				

Dossier Submitter's Response
Thank you for the information about your use of silver. Please note that classification and labelling is based on the intrinsic properties of the active substance and does not take exposure into account.
RAC's response
Noted.

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Germany	Heimerle + Meule GmbH	Company-Manufacturer	37
Comment received				
The precious metal silver has been used in various ways since ancient times. It has the lowest contact resistance and the highest electrical and thermal conductivity of all metals which makes it essential in many components of Green Technologies. Solar panels, rapid charging-stations, in-road applications and certain types of electrodes all require silver. It is used in switches, circuit boards and in some types of batteries when the required speed of conduction exceeds that of what copper can deliver. Silver is used in X-rays, other medical applications and equipment because of its natural antimicrobial properties. With the rapid rise of antibiotic-resistant strains of microbes researchers are focusing on silver as one of the keys to future defences to protect human health. It is used for water purification also. The use of silver is sustainable, as unlimited recycling is possible and due to elemental characteristics, silver and silver alloys will be essential for future European Green Deal. When looking on alternatives, it becomes evident that these have inferior properties (non-precious metals) or are much more costly, not thinking about required quantities (other precious metals). The proposed classification will have severe influence on the future use of silver. Therefore, we require environmental classification according ECHA Guidelines – different classification of Ag massive and powder – and that other proposed classifications are based on hard and comprehensible scientific facts. Silver in a massive form should not be classified. Reduction or more precisely the minimization of silver used in applications was a major R&D focus over the last decade. A replacement of silver was executed wherever technically possible mainly due to cost reasons. However, a vast amount of silver is technically irreplaceable in electric industry sector due to the combination of high conductivity and low corrosion. Silver has various areas of application in which Heimerle+Meule products are used: • Massive silver is used to produce investment bars and alloys containing silver for semi-finished products for the use in jewellery, for industrial and dental applications. Silver compounds such as potassium silver cyanide, silver cyanide and silver nitrate are used in electroplating baths. • In the electronics industry silver is an essential part for the production of contact materials, contact parts and functional surfaces, since those are used in e.g. electric contactors, relays, circuit breakers, inverters, electric connectors, EV batteries by our down-stream users. These semi-finished materials are manufactured via powder- and melting-metallurgical methods. There are also a lot of other applications in which silver is used: • Pure silver powder and silver containing powder is mainly used in industrial applications to produce semi-finished products like electrical contact industry and brazing pastes for				

the jewellery industry.
• Due to its catalytic effect, silver cannot be replaced in different industrial applications.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment H+M comments CLH silver.pdf

Dossier Submitter's Response

Thank you for the information about different uses of silver. Information on the different uses and forms of silver on the market is important to assure that the data used for the proposal relate to the forms or physical states in which the substance is placed on the market and in which it can reasonably be expected to be used. We understand that the proposal may have consequences for companies however this is not within the scope of the CLP process since classification and labelling is based on the intrinsic properties of the active substance. Consequences thereof may be handled by downstream regulations. The Extended One-Generation Reproductive Toxicity Study (EOGRTS) is indeed expected to provide useful information however decisions under CLP must be taken without awaiting information that may become available in the future. Other processes e.g. decisions on approval under the BPR depend on the classification and labelling of a substance thus the CLP process cannot be delayed. The possibility to submit new classification proposals based on new information remains. We note the support for the comments by EPMF.

RAC's response

Noted.

Date	Country	Organisation	Type of Organisation	Comment number
16.12.2020	Belgium	ACEA	Company-Manufacturer	38

Comment received

The automotive industry is following the new proposal for the classification of silver and its salts with concern. A classification of silver and its salts as reprotoxic 1B and Skin Sens. 1 can endanger current and future developments in the automotive industry.
Silver is used in particular in many areas of the automotive industry due to its diverse physical and chemical properties. Because of its properties resulting in the highest electrical and thermal conductivity of all metals, a good corrosion resistance, a low melting point, a temperature resistance and pressure tightness, silver is used in products such as solders, adhesives, paints, polymeric materials, semiconductors, ceramics and many more. Without the use of silver, the resulting components such as pins, cables, screws, electrical circuits, light emitting diodes (LEDs), printed circuit boards (PCBs), housings, electrical tubes, heating units, security systems, airbag systems, displays, multimedia interface systems, instrument panels, lamps, etc would no longer be able to fulfill the high quality standards of the automotive industries on durability, safety and environment. The excellent light reflection properties of silver can also be found in components such as mirrors as well as in lighting applications in the automotive industry. Finally also the development of alternative drive technologies would be endangered in case of stricter classifications.
In general terms, especially because of the high market price of silver, it is only used in very limited cases where it is technically required and were a substitution by less expensive substances is technically impossible. Since silver has such a wide range of uses, a general substitution either is not possible at all or would at least have a high economic impact on our sector because the production of automobiles in their current form would simply no longer be possible any longer.
We therefore call for a distinction between the classification of solid silver and silver in

powder form.
Dossier Submitter's Response
Thank you for the information about uses of silver. Information on the different uses and forms of silver on the market is important to assure that the data used for the proposal relate to the forms or physical states in which the substance is placed on the market and in which it can reasonably be expected to be used. We understand that the proposal may have consequences for companies however this is not within the scope of the CLP process since classification and labelling is based on the intrinsic properties of the active substance. Consequences thereof may be handled by downstream regulations.
RAC's response
Noted.

Date	Country	Organisation	Type of Organisation	Comment number
16.12.2020	Austria	FEEI - Fachverband der Elektro- und Elektronikindustrie	Industry or trade association	39
Comment received				
Sehr geehrte Damen und Herren, der Fachverband der Elektro- und Elektronikindustrie vertritt in Österreich rund 300 Unternehmen und möchte zum vorliegenden Vorschlag für eine harmonisierte Klassifizierung und Kennzeichnung von Silber (CAS 7440-22-4) wie folgt Stellung nehmen: Im Bereich der Sicherungen und Schaltgeräte verwenden die Hersteller Silber in einem Großteil ihrer Produkte als Kontaktmaterial. Nahezu in allen Komponenten – außer in Verteiler-Schränken – ist Silber enthalten: Fehlerstromschutzschalter, Leitungsschutzschalter, Leistungsschalter, offene Air Circuit Breaker, Hilfskontakte, Zubehörgeräte, Trennschalter, elektrische Steckverbinder, etc. Durch langwierige und kostenintensive Forschungsarbeit hat sich Silber als das am besten geeignetste Schmelzleitermaterial für den Kurzschlussschutz im Niederspannungsbereich für Halbleiter sowie im Mittelspannungsbereich für Transformatoren, Kondensatoren und Motoren herausgestellt. Auch bei elektronischen Schutz- u. Leittechnikgeräten für das Steuern und Schützen von Umspannwerken, Übertragungsnetzen und Großtransformatoren für Energieversorgungsunternehmen oder bei der Herstellung von elektronischen passiven Bauelementen (Widerstände), die in leistungselektronischen/-elektrischen Systemen eingesetzt werden, wird Silber in Loten verwendet. Bei letzterem auch in Kontaktierungen, galvanischen Beschichtungen und im Silbersinterprozess. Silber wird außerdem in kritischen elektrischen Kontaktelementen verwendet, welche thermisch bedingten Relativbewegungen ausgesetzt sind. Alternative Beschichtungen führen in derartigen Anwendungen zu Ausfällen. Aufgrund der erhöhten elektrischen, chemischen und mechanischen Eigenschaften (u.a. hohe elektrische Leitfähigkeit, konstant niedrig bleibende Übergangswiderstände im Betrieb, gute Verbindung mit Kupfer, Viskosität, Korrosionsschutz, etc.) oder auch als Ersatz für Blei, gibt es keine Alternative zu Silber. Insbesondere hitzeempfindliche Bauteile benötigen ein Lot mit höherem Silberanteil. Um in elektrischen Anlagen einen optimalen Schutz bieten zu können, ist Silber ebenfalls ein unerlässliches Material. Ohne Silber wird eine Strom-Verteilung, wie wir sie heute kennen, nicht mehr möglich sein, da Zuleitungen für Geschoße (auch schon in				

Einfamilien-Häusern) und jede Industrie-Anwendung ohne Silber nicht mehr geschaltet werden kann.
Eine einwandfreie Lötqualität ist auch für elektronische Produkte, welche in der kritischen Infrastruktur eingesetzt werden, unumgänglich. Mit einem Verbot von Silber würde daher der sichere Schutz der elektrischen Netze (kritische Infrastruktur) in Gefahr gebracht. Daneben verursachen Alternativen zu Silber überwiegend auch mehr Verlustleistung und würden daher Bemühungen zu Energie-Einsparungen entgegenwirken.
Abschließend möchte ich darauf hinweisen, dass Silber während des Be- und Verarbeitungsprozesses schon jetzt sehr streng kontrolliert und sowohl bei der Be- als auch Verarbeitung sowie Nutzung des Endprodukts kein Silber in Pulverform freigesetzt wird. Normalerweise sind die silber-hältigen Anwendungen verkapselt und kommen nicht mit der Umwelt in Berührung (Ausnahme Galvanische Oberflächenbeschichtungen). Darüber hinaus gibt es gerade für Elektro-Altgeräte wohl definierte Prozesse zum Recycling von Rohstoffen. Nachdem Silber einen teuren Rohstoff darstellt, wird ein besonderes Augenmerk darauf gelegt, dass dieser umfassend wiederverwendet wird und nicht in die Umwelt gelangt.

Auf Grund der von uns vorgebrachten Argumente sind wir der Ansicht, dass eine harmonisierte Einstufung von Silber als Skin.Sens. 1, Muta. 2 und Repr. 1B nicht gerechtfertigt ist. Selbiges gilt auch für die harmonisierten Einstufung von Silber in massiver Form hinsichtlich von Umweltgefahr.

Ich ersuche um Berücksichtigung unserer Argumente und stehe bei Fragen gerne unter <confidential>bzw.<confidential> Verfügung.
Freundliche Grüße,

<confidential>
Senior Consultant

ECHA note – An attachment was submitted with the comment above. Refer to public attachment 201214_Stellungnahme_FEEI_CAS_7440-22-4_Upload.pdf

Dossier Submitter's Response

Thank you for the information about uses of silver. Information on the different uses and forms of silver on the market is important to assure that the data used for the proposal relate to the forms or physical states in which the substance is placed on the market and in which it can reasonably be expected to be used. We understand that the proposal may have consequences for companies however this is not within the scope of the CLP process since classification and labelling is based on the intrinsic properties of the active substance. Consequences thereof may be handled by downstream regulations.

RAC's response

Noted.

Date	Country	Organisation	Type of Organisation	Comment number
16.12.2020	Germany	Siemens AG	Company-Manufacturer	40

Comment received

Chapter 5, p. 18: Identified Uses of the CLH report: The current description is insufficient and does not reflect properly the different uses of silver metals. On the other hand, the European Chemicals Agency (ECHA) did accept in June 2019 a proposal by the European Precious Metals Foundation (EPMF) for an Extended One-Generation Reproductive Toxicity

Study (EOGRTS). This TG443 compliant EOGRTS (under EU REACH; including DIT and DNT cohorts) study is designed to fill the identified data gaps for this endpoint and will allow a conclusive judgement for this endpoint. In view of the possible consequences for our company, we find this very regrettable and urge to postpone the decision making until these for this matter very relevant studies are completed. Silver is technically essential for numerous applications throughout our electrical and electronics products and solutions, which are furthermore of very high importance to fulfil the requirements of the EcoDesign Directive supporting the goals of the Green Deal set by the European Commission. Metallic silver is applied for example in wires, pins, contacts, solders, brazing, sintering, adhesives, fuses, lead frames, printed circuit boards, semiconductors and LEDs (non-exhaustive list). These components are utilized in switchgear and apparatus for energy-efficient automatization and drive technologies, as well as electricity distribution and transmission on high voltage level and distribution on medium and low voltage level and electric equipment for transportation (trains, commercial vehicles). The wide use of silver is due to its physical properties leading to the necessary technical functionalities for efficient operations, such as high electrical conductivity, power dissipation, hardness, melting point, corrosion and friction properties, contact wear, reflectivity, whisker protection and thermal conductivity. The overall functionality of silver hinders a general replacement by other materials without a negative impact on the appliances where it is used in, possibly even leading to the shut-down of such applications. Neither copper nor gold are suitable substitutes for the wide range of silver applications from a technical point of view, rendering the whole system of electricity distribution and protection dependent on silver. Moreover, gold is also a critical raw material with high environmental impacts associated during e.g. mining, as well as a known conflict raw material.
Dossier Submitter's Response
Thank you for the information about different uses of silver. Information on the different uses and forms of silver on the market is important to assure that the data used for the proposal relate to the forms or physical states in which the substance is placed on the market and in which it can reasonably be expected to be used. As stated in section 4, the justification for the classification proposal is the need for harmonised classification and labelling resulting from the review under the BPR. However, the CLH report also informs that there are more uses than the intended biocidal uses triggering an action "Apart from biocidal use, silver has 92 active registrations under REACH in June 2019. It has wide uses by industry, professionals and consumers." We understand that classification and labelling may have consequences for companies however this is not within the scope of the CLP process since classification and labelling is based on the intrinsic properties of the active substance. Consequences thereof may be handled by downstream regulations. The Extended One-Generation Reproductive Toxicity Study (EOGRTS) is indeed expected to provide useful information however decisions under CLP must be taken without awaiting information that may become available in the future. Other processes e.g. decisions on approval under the BPR depend on the classification and labelling of a substance thus the CLP process cannot be delayed. The possibility to submit new classification proposals based on new information remains.
RAC's response
Noted and refer to comment 20.

Date	Country	Organisation	Type of Organisation	Comment number
16.12.2020	Germany	<confidential>	Industry or trade association	41
Comment received				
<confidential> was founded in Pforzheim in 1947. As a lobby group for over 170 predominantly medium-sized member companies, <confidential> represents the interests of its members at a national, European and inter-national level. <confidential> is a member of the Federation of German Industries (BDI). It is responsible for coordinating the federal associations of the German jewellery and silverware industry. In this capaci-ty it is also integrated in global efforts of the World Jewellery Confederation, CIBJO. <confidential> represents the interests of the German watch and clock industry at a European level as a member of the Europe-an watchmaking associations EUROTempus and CPHE. <confidential> is also a member of the Responsible Jewellery Council (RJC). Silver and silver compounds are used in the jewellery, watch and silverware sector in various compo-nents and products, where applications include the use of massive silver, silver plating and the use as a component in silver, gold and copper alloys. These are used within in a broad range of end prod-ucts that are designed for everyday use, mid-tier products and luxury products. The key properties of silver and silver compounds include its function as a reflective/ornamental and store of value, but also its natural antimicrobial properties. As a representation of the jewellery, watch and silverware industry sector we would like to indicate that it would not be possible to find an alternative to metallic silver for most of its uses in mid-tier and luxury products, since it is not possible to provide the same aesthetic, economic and technical functionality. For products in everyday use, these can and have already be substituted with other cheaper alternatives (e.g. stainless steel). - Page 2 of 3 - In response to the proposed Reprotox Cat. 1B classification of silver and silver compounds, the com-panies of our industry sector as downstream users of these compounds in the jewellery, watch and silverware sector will suffer greatly, not only because of the restrictions to silver products, but espe-cially because of the use of silver in almost any other precious metal alloy. Most companies will most likely at least try to continue operations. However, the future of our industry sector will be subject to both the affordability of future products, and how consumer demand changes after silver is classified Repr. 1B, as it is possible consumers will demand jewellery, watch and silverware without the use of silver, which is near to impossible. We would also like to point out that the costs of the proposed classification are unforeseeable for the mostly small and medium-sized enterprises in our industry sector. They range from costs of compli-ance (additional risk management measures, monitoring and data requirements, etc.) to the loss in value added due to stigma effects. In contrast to costs, the benefit of the proposed classification from the reduced exposure of the af-fected population is unknown due to insufficient scientific evidence on the potential reproductive toxicity of the silver and silver compounds (including whether there are any risks). Therefore, the <confidential> strongly supports the scientific comments submitted by the European Precious Metals Federation (EPMF).				

ECHA note – An attachment was submitted with the comment above. Refer to public attachment 20201214-<confidential>-clh-silver-comments.pdf
Dossier Submitter's Response
Thank you for the information about different uses of silver. Information on the different uses and forms of silver on the market is important to assure that the data used for the proposal relate to the forms or physical states in which the substance is placed on the market and in which it can reasonably be expected to be used. We understand that classification and labelling may have consequences for companies however this is not within the scope of the CLP process since classification and labelling is based on the intrinsic properties of the active substance. Consequences thereof may be handled by downstream regulations. We note the support for the comments by EPMF.
RAC's response
Noted.

Date	Country	Organisation	Type of Organisation	Comment number
16.12.2020	Finland	<confidential>	Company-Manufacturer	42
Comment received				
Type of organization - Only representative on non-EU manufacturer				
Dossier Submitter's Response				
-				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
16.12.2020	Germany		MemberState	43
Comment received				
The DE CA agrees that read-across from uncoated nanosilver to massive silver is generally acceptable for the purpose of classification for health hazards, since it will not underestimate the hazard. To our knowledge, nanosilver is usually coated and nanosilver without modifications is rather uncommon. Coating may influence physicochemical, toxicokinetic and toxicological properties of the nanomaterial. This should be reflected in the classification decision. Regarding the testing of silver in nano size we would like to stress that it is not clear to us if the entry in Annex VI of the CLP Regulation as proposed in table 7 of the report is for coated or uncoated particles or for both. This needs to be clarified and, if necessary, the read-across concept should be presented. Next to this, the given EC number in table 7 seems to be not correct. As far as we understand, a coated form of nanosilver was used in T/D studies. As mentioned in the report (section 11.3.1) it is not unambiguously shown that the coated nano silver was dissolved to Ag+ ions. It is stated that there are indications "that a major part of the conventional dissolved silver was in particulate/colloidal form." It is not clear to us how this was taken into account when assessing nano-silver particles. Therefore, it is not clear whether Ag+ or other forms of silver induce the measured effects. Are only				

Ag-ions in the solution due to the ultrafiltration?

Also the report states: "With regards to the test material it is not known to what extent the type of surface coating present influenced the dissolution of silver. It is stated in the report that much of the coating was removed in the cleaning steps."
Does this mean that more or less uncoated silver was used in the tests? Indeed, we are wondering what influence the coating on the solubility of the particles has. Is one coating sufficient to draw a conclusion for all silver nanoparticles coated or uncoated?

Moreover, we generally question the appropriateness of the CLH proposal to split the CLP Annex VI entry in „Silver - with the exception of other forms of silver metal specified elsewhere in this Annex" and „Silver, nano [1-100 nm] as defined by (2011/696/EU)". If a split entry should indeed be considered, reference to the solubility and not to the form of silver would be more appropriate in our opinion.

Finally, we do not support the read-across from silver-zinc-zeolite to nanosilver and massive silver because of the possible confounding effects of the zinc ion.
In the conclusions on classification, clear differentiation should be made between "classification not possible" resulting from inconclusive or lacking data and "no classification" based on evidence for inactivity (e.g. page 59, 120, and 237).

Dossier Submitter's Response

Thank you. We agree that the type of coating (as well as size and shape) may influence physicochemical, toxicokinetic and toxicological properties of the nanomaterial. This is discussed in the CLH report, e.g. in section 6:
"It is well known that surface coatings stabilises the nanoparticles and thereby impact on the release of silver ions (e.g. Reidy. B. et al (2013)). However in the majority of articles it is not clear if particles are coated and the type of coating used hence it is not possible to analyse the possible impact on the results. As shown in the read-across matrices attached to this report (annex 3), information available regarding the nanoparticles in published studies is very limited compared to the information requested in the template for read-across presented in the guidance document (Appendix 2 of Appendix R. 6-1 for nanomaterials applicable to the Guidance on QSARs and Grouping of Chemicals). Nevertheless, it would not be scientifically justified to exclude the studies and ignore the effects noted on that basis. Although factors such as the surface coating could impact on the silver ion release and explain differences in effects observed between studies, classification is based on the intrinsic properties thus effects with nanosilver referred to in this report are considered to represent an intrinsic property of the silver ion."

In the absence of details regarding types of surface coatings and their properties we do not understand how to reflect this in the decision on classification and labelling for the human health classes.
Furthermore, the CLH report refers to CLP guidance stating in section 1.2.3.2 (regarding the significance of the terms 'form or physical state' and 'reasonably expected use' with respect to classification according to clp*):*
"Also for human health, different forms (e.g. particle sizes, coating) or physical states may result in different hazardous properties of a substance or mixture in use. However, due to test complexity, not every form or physical state can be tested for each health hazard. In general, testing should be performed on the smallest available particle size and the default approach is to test for different routes of exposure (oral, dermal, inhalation). Again, due to test complexity, mostly the data for only one exposure route are available.

In general, the assumption is made that the testing conditions of valid animal assays reflect the hazards to man and these data must be used for classification. Moreover, it is assumed that classification for human health hazards takes into account all the potential hazards which are likely to be faced for all forms or physical states in which the substance is placed on the market and can reasonably be expected to be used."
It is noted though that in the study by Van der Zande, M., et al, the author concluded no significant differences in distribution profiles between the two types of AgNPs; the coating had no effect on the tissue distribution behaviour.

RAC's response

Noted. Agree with DE not to support the read-across from silver-zinc-zeolite to nanosilver and massive silver. Indeed read-across is treated with caution in this case because it is recognised that differences in basic properties such as solubility, ion release, bioavailability, etc., exist between the different silver compounds. Treating a soluble silver salt as if it was representative of the elemental metal in regard to the release of Ag+ ions demands a high level of caution. Bioavailability and toxicokinetic properties are different for different silver compounds and this poses a problem for read-across. In some cases read across may be very loosely used in support of a worst case scenario but at all times we must take care to also consider representative exposure cases and the potential or not for toxicity. All types of nanosilver are grouped together in this assessment, sufficient data to distinguish between the forms is lacking and the nanoform is simply regarded as the smallest particle size of metallic silver. We do not have the information or data to separate out different classes of nanoparticles according to properties such as ion release and size and their impact on any potential adversity in animal studies.

Date	Country	Organisation	Type of Organisation	Comment number
16.12.2020	Switzerland	Federation of the Swiss Watch Industry FH	Industry or trade association	44

Comment received

To conclude, the FH therefore wishes to emphasize the following points:
- For the CLP classification of metallic silver it is essential to consider nano-, powder and massive forms separately.
- Despite a huge experience accumulated by regular exposure of a large majority of the population during very long periods, the prevalence of allergies to massive silver or silver containing alloys is extremely low. The classification of massive silver as a skin sensitizer is therefore not justified.
- It is essential to wait for the publication of the results of the EPMF study before taking a decision on the elemental silver reprotoxic classification.
More generally, we fully support the scientific comments submitted by the EPMF in their position letter.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment 4388_001.pdf

Dossier Submitter's Response

We note the support for the comments by EPMF. The Extended One-Generation Reproductive Toxicity Study (EOGRTS) is indeed expected to provide useful information however decisions under CLP must be taken without awaiting information that may become available in the future. Other processes e.g. decisions on approval under the BPR

depend on the classification and labelling of a substance thus the CLP process cannot be delayed. The possibility to submit new classification proposals based on new information remains.
RAC's response
Noted.

Date	Country	Organisation	Type of Organisation	Comment number
16.12.2020	France	FEC Federation of European manufacturers of Cookware and cutlery	Industry or trade association	45
Comment received				
FEC comments on the proposed harmonized classification and labeling of silver are in the attached document. ECHA note – An attachment was submitted with the comment above. Refer to public attachment FEC response to Public consultation_Silver classification proposal.pdf				
Dossier Submitter's Response				
Art. 12 of CLP states *"bioavailability shall only be considered for classification purposes when conclusive scientific experimental data show that the substance is not biologically available and those data have been ascertained to be adequate and reliable".* The study results referred to are claimed to investigate silver release from cutlery and serving dishes at a stable 70◦C temperature over a 2 h-period of time. Without access to this information it is not possible to assess the reliability of the study or if results are representative of all different uses of silver in massive form e.g. use as electrodes in water purification systems when an electrical current is applied.				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
16.12.2020	Germany	Heraeus Deutschland GmbH & Co. KG	Company-Manufacturer	46
Comment received				
Heraeus Deutschland GmbH & Co KG, GBU Heraeus Medical Components is a Global Business Unit of the Heraeus Group – a market leading device outsourcing partner to medical device OEMs. Silver in form of metal or in alloys is used in several components, e.g. wires, sensors, implantable pulse generators, X-ray tubes, which are used in production of medical devices. o Medical devices – refer to "products, services or solutions that prevent, diagnose, monitor, treat and care for human beings by physical means". o In-vitro diagnostic (IVD) medical devices – refer to "non-invasive tests used on biological samples (for example blood, urine or tissues) to determine the status of one's health". Technical function of silver-based components might be: o electrical conductor in cardiac rhythm management (CRM) or neuro modulation leads o mechanical joint for brazing of vacuum-tight connections in implantable pulse				

generators (IPGs) and X-ray tubes o X-ray radiation filter for mammography to detect breast cancer o electrochemical sensor for continuous glucose monitoring (CGM), electrocardiography (ECG), electroencephalography (EEG), transcutaneous electrical nerve stimulation (TENS) o antimicrobial function in wound healing. For CGM applications, about 100 Mio. sensors were produced in 2020 and with the estimated trend in diabetes patients worldwide, there is an annual growth of more than 25% in application of these sensors to monitor and treat this disease. We support the scientific comments submitted by the European Precious Metals Federation (EPMF). The use of silver in medical devices provides huge advantages within medical investigations and medical treatments. Substitution of substances for medical devices have several restrictions in terms of biocompatibility or risks connected with failed devices when substitute substances have negative effects on lifetime or other critical quality features. For applications like CGM sensors there is no known substitute to silver based electrodes. As world leading supplier of components for medical devices, we fear that proposed classification Skin Sens. Cat 1 H317, Muta 2 H 341 and Reprotox. H360FD will imply legal barriers for use of silver in medical devices and additionally, it may generate psychological barriers at physicians and patients. In any case, if the decision for the mentioned classification is made, the decision should be made on clear and founded scientific studies.
Dossier Submitter's Response
A proposal for harmonised classification and labelling is justified as it is required for the use of silver as a biocidal active substance. The proposal is based on the data available for the review under BPR and to a manageable extent additional information identified and considered relevant for the silver ion released from the forms of silver considered in this assessment. We understand that classification and labelling may have consequences for companies however this is not within the scope of the CLP process since classification and labelling is based on the intrinsic properties of the active substance. Consequences thereof may be handled by downstream regulations. We note the support for comments submitted by the European Precious Metals Federation (EPMF).
RAC's response
Noted.

Date	Country	Organisation	Type of Organisation	Comment number
15.12.2020	France	SCHNEIDER ELECTRIC INDUSTRIES SAS	Company-Manufacturer	47
Comment received				
The purpose of our answer to this consultation is not to debate around silver toxicity as it's not under our competencies, but to give some key elements on the usages, the controlled exposure risks and the technico-economic impacts, in order to help ECHA to evaluate the most appropriate regulatory option if needed in a second step, according to the conclusions of the toxicity studies. More detailed information are given in the confidential attachement section.				

ECHA note – An attachment was submitted with the comment above. Refer to public attachment Silver_consultation_2020_non_confidential.pdf ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Silver_consultation_2020_Schneider_Electric.pdf
Dossier Submitter's Response
Thank you for information about the use of silver. We understand that classification and labelling may have consequences for companies however this is not within the scope of the CLP process since classification and labelling is based on the intrinsic properties of the active substance and it does not take exposure into account. Consequences of the C & L may be handled by downstream regulations.
RAC's response
Noted.

Date	Country	Organisation	Type of Organisation	Comment number
15.12.2020	Germany	RAS AG	Company-Manufacturer	48
Comment received				
see comment_CLH_silver_RAS_AG.pdf attached ECHA note – An attachment was submitted with the comment above. Refer to public attachment comment_CLH_silver_RAS_AG_public.pdf ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment comment_CLH_Silver_RAS_AG.zip				
Dossier Submitter's Response				
Thank you for information about the use of silver. We understand that classification and labelling may have consequences for companies however this is not within the scope of the CLP process since classification and labelling is based on the intrinsic properties of the active substance and it does not take exposure into account. Consequences of the C & L may be handled by downstream regulations. The test results referred to, which was not available to the DS, seems to be based on a study with a substance containing an amount of silver that do not allow for an adequate investigation of the intrinsic properties of silver.				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
15.12.2020	Switzerland	Argor-Heraeus SA	Company-Manufacturer	49
Comment received				
Argor-Heraeus S.A. is the largest global provider of services in the precious metal industry. The business includes: o refining gold, silver, platinum, palladium o Ingots for banks, traders and products for the electronic and chemical industry o Semi-finished products and solutions for watchmaking and luxury jewelry o Services for the physical trading of precious metals Silver, on its own or as component of alloys is one of our key materials. We support the scientific comments submitted by the European Precious Metals Federation (EPMF).				

The proposed classification of silver as Reprotox. Cat 1 and Aquatic Acute 1 and Aquatic Chronic 1 for silver massive, might trigger restrictions/substitution for silver in future. The proposed classification will have severe influence on the future use of silver. Therefore, we require environmental classification according ECHA Guidelines – different classification of Ag massive and powder – and that other proposed classifications are based on hard and comprehensible scientific facts. Silver massive should not be classified.
Dossier Submitter's Response
Thank you for information about your use of silver. We understand that classification and labelling may have consequences for companies however this is not within the scope of the CLP process since classification and labelling is based on the intrinsic properties of the active substance and it does not take exposure into account. Consequences of the C & L may be handled by downstream regulations. We note the support for the comments submitted by EPMF.
RAC's response
Noted.

Date	Country	Organisation	Type of Organisation	Comment number
15.12.2020	Belgium	Umicore	Company-Manufacturer	50
Comment received				
Dear Sir or Madame, We as the Umicore group for several legal entities in different Member States would like to comment on the Proposal for Harmonized Classification and Labelling for Silver (CAS 7440-22-4). Please find the description of our uses, the impact and the scientific comments in attached pfd. thank you for taking these into consideration best regards <confidential> ECHA note – An attachment was submitted with the comment above. Refer to public attachment Umicore public consultation_final 20201215.pdf				
Dossier Submitter's Response				
We understand that classification and labelling may have consequences for companies however this is not within the scope of the CLP process since classification and labelling is based on the intrinsic properties of the active substance and it does not take exposure into account. Consequences of the C & L may be handled by downstream regulations. We note the support for the comments by EPMF. The Extended One-Generation Reproductive Toxicity Study (EOGRTS) is indeed expected to provide useful information however decisions under CLP must be taken without awaiting information that may become available in the future. Other processes e.g. decisions on approval under the BPR depend on the classification and labelling of a substance thus the CLP process cannot be delayed. The possibility to submit new classification proposals based on new information remains.				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
15.12.2020	United Kingdom	AeroSpace and Defence (ASD) Industries Association of Europe	Industry or trade association	51

Comment received

These comments are submitted on behalf of the AeroSpace and Defence (ASD) Industries Association of Europe. We would like to comment on the Proposal for Harmonized Classification and Labelling for Silver (CAS 7440-22-4) since it is a relatively ubiquitous substance within our sector with few or no known alternatives affording similar and reliable (i.e. suitably tested and verified for aerospace & defence (A&D) applications) physiochemical properties.

To summarise, the use of silver in the A&D and space sector include:-

o Ag in A&D conductive coatings, pastes, resins, glues, epoxies & inks. Ag may also be added as silver flake. Thermal pastes are used to conduct heat away from integrated circuits (ICs) in A&D electronics
o Silver loaded conductive electromagnetic compatibility (EMC) gaskets are used in A&D applications to get an electrical connection and provide a complete screen
o Silver coatings on glass for A&D mirrors and optics
o Ag metal in A&D piezoceramic manufacture & other sector applications
o Certain A&D batteries
o Ingredient in Pb solder wire & paste (including braze paste) for A&D applications
o Ingredient in Pb-free solder wire & paste (including braze paste) for A&D applications
o In A&D electronic assemblies within metalisation of parts/components, e.g. fasteners, diodes, resistors, sensors, bushes, connectors, RF connectors, pins etc

Concerning the criticality of Ag metal in the our sector, ASD would like to highlight that there are no universal alternatives to Ag metal affording the same suitability for a wide variety of critical properties associated with silver such as corrosion resistance, electrical conductivity, high oxidisation potential, temperature resistance, self-lubrication and anti-galling properties.
A&D end products affected include aeroplanes, rotorcraft vehicles (including drones and helicopters), satellites and specific defence applications.
Non-exhaustive examples of silver use and criticality are provided below:-

o Silver is used in sintering pastes as an alloying addition to join components at temperatures typically between 217 - 221°C. The sector primarily use tin-silver-copper, or 'SAC', alloys (SnAgCu) with different concentrations of silver (Ag) and copper (Cu). These Ag-based alloys are used so as to provide better wetting, improved joint reliability and afford a wider processing window and due to lead (Pb) being restricted for certain electronic applications under the RoHS Directive. This has led the sector to favour using SAC alloys in the short-medium term. Solder pastes are also used outside our sector in generic electronic applications. ASD politely requests that when the CLH process is finalised once the correct scientific methodologies for all endpoints have been fully agreed, any restriction/prohibition of silver resulting from a reclassification should take the criticality of Ag metal for our sector into account due to the safety-critical

requirements of articles operating in extreme environments.

o Silver is used in brazing pastes to join components at temperatures above 600°C. The primary use of brazing in our sector is for use with electronic applications. This includes silver as an alloying addition in solder wire and paste (including brazing paste) since silver provides improved strength and conductivity.
Silver pastes are used to create conductive tracks on ceramic substrates such as alumina. These are used in current high temperature and high powered electronic applications and will become more important in the future due to the higher voltage and current requirements due to increased demand for electric vehicle technologies.

o Busbars are copper bars that carry the high current around the aircraft, which are coated with silver to ensure good electrical conductivity with the flight computer systems. Similarly satellites also contain significant amount of electronics, in the form of electronic circuitry, computers, LEDs, solar cells etc.

o Silver is used for its light sensitivity and used to help test the aeroplanes/rotorcrafts (and their components).

o Silver-zinc batteries and silver chloride-magnesium batteries are used in the aerospace and defence sector. The benefits of silver zinc-batteries are: (i) they have the highest output of any battery chemistries, which is important for certain applications; and (ii) silver batteries can also be left for longer periods of time without the need for maintenance (i.e. they are also more reliable than alternative battery technologies). Where alterative battery chemistries exist, i.e, with lithium-ion batteries, such chemistries afford shorter lifespans of battery products. Compared to silver-zinc batteries, lithium-ion batteries need to be recharged and undergo maintenance within shorter timeframes than their silver-based counterparts.

o Waveguides are used to send and receive electromagnetic waves (e.g. mobile calls and internet traffic) – the primary role of communications satellites and are made from aluminium which is coated in silver. Satellites use silver-plating as it has the longest working lifespan of the metals being used. This is especially important as satellites aren't accessible after launch and the technology needs to be reliable and resistant to degradation (e.g. from extreme fluctuation of temperatures in space). This is also why multiple waveguides are installed on satellites, so that if one part of the satellite stops working (for example it is hit by debris), then the rest of the satellite can still function. Replacing silver would require a redesign of the waveguides which may not be effective in the transmission of specific wavelength transmission.

o Silver plating of fasteners (e.g. springs, screws and screw inserts) or mechanical parts (e.g. bearings) for anti-galling or anti-voltaic corrosion purposes to allow the components to survive elevated temperatures without welding together. Ag users within our sector have indicated that this is a very important use, where silver-plated fasteners are the only known type to be able to withstand extreme temperatures and can be removed after flight for servicing of the parts (e.g. engines). Other components that are plated include aeroplane wheel and brake applications, as well as electroplating of aircraft ground products and facilities (e.g. test rigs, simulators & test equipment), related oil pumps and electronic components (e.g. sensors). Finally, as a very good conductor of electricity, silver plated components are also used in areas of the aeroplane/rotorcraft to help dissipate electrical lightning strikes.

o For combat torpedoes no alternative to silver has been identified given the long-term requirements for storage without maintenance and need for reliability.

Other metal alternatives do not possess the same thermal (or electrical) conductivity as silver since many are softer than silver or have lower melting temperatures than silver. Where silver metal alternatives do exist for certain applications, the alternative in question may include gold, platinum, nickel and tin, each of which have their downsides, such as higher cost (for the precious metals) or a reduction in functionality.

Proposed Classification of silver:-

ASD understand there is currently disagreement in relation to the scientific methodology used for all endpoints in the proposed Harmonised Classification and Labelling (CLH) classification for silver metal.
In relation one particular endpoint, i.e. the proposed intention to classify silver metal as a Category 1B Reproductive Toxicant (Repr. 1B) under the Biocidal Products Regulation (BPR), ASD would prefer for the OECD Test Guideline (TG443)-compliant Extended One-Generation Reproductive Toxicity Study (EOGRTS) to be first concluded before any classification decision is made.
Until there is a consensus on the scientific methodologies used to classify silver metal concerning the comments put forward by the European Precious Metals Federation (EPMF) regarding all endpoint classification criteria, ASD believe it is both prudent and pragmatic not to prematurely classify silver metal until all the scientific data is available.

Dossier Submitter's Response

Thank you for the information on your uses of silver. We understand that classification and labelling may have consequences for companies however this is not within the scope of the CLP process since classification and labelling is based on the intrinsic properties of the active substance and it does not take exposure into account.
Consequences of the C & L may be handled by downstream regulations.

The Extended One-Generation Reproductive Toxicity Study (EOGRTS) is indeed expected to provide useful information however decisions under CLP must be taken without awaiting information that may become available in the future. Other processes e.g. decisions on approval under the BPR depend on the classification and labelling of a substance thus the CLP process cannot be delayed. The possibility to submit new classification proposals based on new information remains. We note the support for the comments by EPMF.

RAC's response

Noted.

Date	Country	Organisation	Type of Organisation	Comment number
14.12.2020	Germany	Heraeus Metals Germany GmbH & Co. KG	Company-Importer	52

Comment received

I would like to refer to the document under "Public Attachment''

ECHA note – An attachment was submitted with the comment above. Refer to public attachment AG_HMG_FM.pdf
Dossier Submitter's Response
We note your support for the comments by EPMF.
RAC's response
Noted.

Date	Country	Organisation	Type of Organisation	Comment number
14.12.2020	France	<confidential>	Company-Manufacturer	53
Comment received				
<confidential> uses silver as a constituent of impregnated activated carbon. The silver is strongly attached to the surface of the activated carbon. Activated carbon is used as a versatile sorbent and the silver changes the properties by enhancing the removal efficiency for contaminants in air or water which otherwise cannot be removed. The use of silver in our products ensures the proper functionality and for some products is required by international standards. This especially is the case for same activated carbon grades manufactured for the protection of humans against toxic industrial chemicals and warfare gases. In other cases, the presence of silver is necessary to maintain the safety of the treatment device, such that it does not age or itself become deleterious to human health.				
Dossier Submitter's Response				
Thank you for the information.				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
12.12.2020	Netherlands	Vereniging ION	Industry or trade association	54
Comment received				
See our letter in the appendix. ECHA note – An attachment was submitted with the comment above. Refer to public attachment ECHA Silver 20201212.pdf				
Dossier Submitter's Response				
Thank you for your comment.				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
11.12.2020	Romania	Heraeus Romania SRL	Company-Manufacturer	55
Comment received				
I would like to refer to the document under "Public Attachment" ECHA note – An attachment was submitted with the comment above. Refer to public attachment Heraeus Romania SRL_Public Cons. Ag CLH Proposal_11.12.2020_signed.pdf				

Dossier Submitter's Response
Thank you for the information on your uses of silver. We understand that classification and labelling may have consequences for companies however this is not within the scope of the CLP process since classification and labelling is based on the intrinsic properties of the active substance and it does not take exposure into account. Consequences of the C & L may be handled by downstream regulations. We note your support for the comments by EPMF.
RAC's response
Noted.

Date	Country	Organisation	Type of Organisation	Comment number
11.12.2020	Germany	<confidential>	Company-Manufacturer	56
Comment received				
"<confidential> is a world leading company, providing, materials solutions for the packaging and component industry. These types of materials are used in electronics for consumer applications, industrial applications, automotive, aerospace, solar and wind energy. Due to high conductivity, stability and comparable low price, silver and silver alloys are base materials within the industry. We support the scientific comments submitted by the European Precious Metals Federation (EPMF). The proposed classification of silver as Reprotox. Cat 1 and Aquatic Acute 1 and Aquatic Chronic 1 for silver massive, might trigger restrictions/substitution for silver in future. Silver is a base material in electric and electronic equipment. It provides high conductivity, a good corrosion resistance. Therefore, silver guarantees low energy consumption and a longer life cycle of devices. When looking on alternatives, it becomes evident that these have inferior properties (non-precious metals) or are much more costly, not thinking about required quantities (other precious metals). The proposed classification will have severe influence on the future use of silver. Therefore, we require environmental classification according ECHA Guidelines – different classification of Ag massive and powder – and that other proposed classifications are based on hard and comprehensible scientific facts."				
Dossier Submitter's Response				
Thank you for the information on your uses of silver. We understand that classification and labelling may have consequences for companies however this is not within the scope of the CLP process since classification and labelling is based on the intrinsic properties of the active substance and it does not take exposure into account. Consequences of the C & L may be handled by downstream regulations. We note your support for the comments submitted by the EPMF.				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
10.12.2020	France	ERCUIS	Company-Manufacturer	57
Comment received				
Dear Madam/Sir, We would like to comment on the Proposal for Harmonized Classification and Labelling for Silver (CAS 7440-22-4).				

We are FCM manufacturer and, alongside our products, we have several silverplated items, such as cutlery and holloware. Including silver and its compound in the REACH candidate list would heavily affect our business, since it is impossible to substitute silver with any other precious metal: sterling silver and silverplated items are used in cutlery and tableware since the beginning of time. Due to this impossible substitution, keeping the silverplated objects in our offer will result in a drastic increase of production costs to insure the food contact and safety compliance for both product and process. Costs increase are due to: - Labelling requirements - Migration tests - Risk assessment for health and safety - Worker's extra training - Worker relocation But the worst consequence will be the stigma effects, resulting from silver association with health hazards. We support the scientific comments submitted by the European Precious Metals Federation (EPMF). Key messages and arguments addressed in EPMF's comments: ECHA note – An attachment was submitted with the comment above. Refer to public attachment Consultation européenne sur l'argent ERCUIS_12-2020.pdf
Dossier Submitter's Response
We understand that classification and labelling may have consequences for companies however this is not within the scope of the CLP process since classification and labelling is based on the intrinsic properties of the active substance. Consequences of the C & L may be handled by downstream regulations. We note your support for the comments submitted by the EPMF.
RAC's response
Noted.

Date	Country	Organisation	Type of Organisation	Comment number
10.12.2020	Germany	SAXONIA Technical Materials GmbH	Company-Manufacturer	58
Comment received				
SAXONIA Technical Materials GmbH operating in Hanau (Germany) is a manufacturer of silver-based semi-finished materials with approx. 250 employees. These semi-finished materials are silver-based contact materials and brazing alloys, as they are used in e.g. electric contactors, relays, circuit breakers, automotive inverters (HEV, EV), electric motors and generators (wind power), vacuum interrupters, x-ray tubes by our downstream users. These semi-finished materials are manufactured via powder- and melting-metallurgical methods. Reduction or more precisely the minimization of silver used in above applications was major R&D focus over the last decade. A replacement of silver was executed wherever technically possible mainly due to cost reasons. However, a vast amount of silver is technically irreplaceable in electric industry sector due to the combination of high conductivity and low corrosion.				
Dossier Submitter's Response				
Thank you for the information.				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
10.12.2020	Germany	Heraeus Deutschland GmbH & Co. KG	Company-Manufacturer	59
Comment received				
I would like to refer to the document under "Public Attachment" ECHA note – An attachment was submitted with the comment above. Refer to public attachment HPM_RC_Public Cons. Ag CLH Proposal.docx				
Dossier Submitter's Response				
Thank you. We note your support for the comments submitted by EPMF.				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
10.12.2020	Netherlands	Holland Water B.V.	Company-Downstream user	60
Comment received				
reference is made to attached le ECHA note – An attachment was submitted with the comment above. Refer to public attachment 201208_Public_Consultation_HW_comments_final.pdf				
Dossier Submitter's Response				
Thank you for the information about your use of silver. We note the support for the comments submitted by EPMF.				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
10.12.2020	Germany	Doduco	Company-Manufacturer	61
Comment received				
DODUCO is operating following production sites with approx. 600 employees in Europe: Pforzheim (GER), Sinsheim (GER), Madrid (ESP), and Sibiu (ROU) DODUCO focuses on refining of precious metals (majority Silver) and – using refined materials as basis – the production of new value added semi-finished materials for use in electrical industry sector. These are Silver-based contact materials, contact parts and functional surfaces, as they are used in e.g. electric contactors, relays, circuit breakers, inverters, electric connectors, EV batteries by our downstream users. These semi-finished materials are manufactured via powder- and melting-metallurgical methods. Reduction or more precisely the minimization of Silver used in above applications was major R&D focus over the last decade. A replacement of Silver was executed wherever technically possible mainly due to cost reasons. However, a vast amount of Silver is technically irreplaceable in electric industry sector due to the combination of high conductivity and low corrosion.				
Dossier Submitter's Response				
Thank you for the information.				

RAC's response
Noted.

Date	Country	Organisation	Type of Organisation	Comment number
09.12.2020	France	Comité Colbert	Industry or trade association	62

Comment received
Founded in 1954, the Comité Colbert is the French luxury association which gathers 85 French luxury houses, 16 cultural institutions and 6 European members. Registered in the EU Transparency Register (62379572263-63), we are keen to participate in the EU decision making process and therefore provide input on EU consultations. We represent 14 different sectors of activities, many of which use silver in their products (i.e. jewelry, silverware, cosmetics, etc.), and we are therefore happy to contribute to the public consultation on the silver metal CLH proposal. In this context, the Comité Colbert wishes to state its full support to the comments of the European Precious Metals Federation (EPMF). We also wish to stress our concern that the classification proposals are often based on a low number of reliable information and are therefore lacking conclusive criteria. ECHA note – An attachment was submitted with the comment above. Refer to public attachment LT_Comité_Colbert_ECHA.pdf
Dossier Submitter's Response
We note the support for the comments by EPMF.
RAC's response
Noted.

Date	Country	Organisation	Type of Organisation	Comment number
08.12.2020	Germany	Heraeus Deutschland GmbH & Co. KG	Company-Manufacturer	63

Comment received
Heraeus Photovoltaic is the global market leader in the metallization paste business to metallize front and back sides of solar cells. Metallization with silver is the key process of todays and future green energy harvesting of solar cells. As silver being the metal with highest conductivity, it guarantees highest yield of energy. We support the scientific comments submitted by the European Precious Metals Federation (EPMF). Generally, we would like to mention, that a classification according the CLH proposal, will provide a negative touch to all uses of silver, even if capsuled. People becoming aware, may refuse to buy or use articles containing silver. In case of photovoltaic industry there is a huge risk that this will lead to a drawback of the European Green Dial. ECHA note – An attachment was submitted with the comment above. Refer to public attachment HPT_Public Cons. Ag CLH Proposal_AH.pdf

Dossier Submitter's Response
We understand that classification and labelling may have consequences for companies however this is not within the scope of the CLP process since classification and labelling is based on the intrinsic properties of the active substance. We note the support for the comments by EPMF.
RAC's response
Noted.

Date	Country	Organisation	Type of Organisation	Comment number
03.12.2020	France		Individual	64
Comment received				
Good Afternoon, I do not hunderstand very well the differnts signification of the analyse for silver. We do not know the level maxi of the classes. It"s about 50 years I work the silver, I had never any problem with silver. I am 74 years and I have the best health. Tank you to answere. <confidential>				
Dossier Submitter's Response				
Thank you for your comment.				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
02.12.2020	France	Metalor Technologies	Company-Manufacturer	65
Comment received				
Dear Madam/Sir, These comments are submitted on behalf of company Metalor Technologies Electrotechnics (France) S.A.S. We would like to comment on the Proposal for Harmonized Classification and Labelling for Silver (CAS 7440-22-4). We use silver for the following activities: • Refining of silver scrap which meets EU circular economy objectives • Manufacturing of silver products: o Silver bars for investment purposes o Silver electrical contacts for several uses: automotive, medical, energy (silver panels),… o Silver powders for technical applications o Silver for jewelry o Manufacturing of silver salts as silver nitrate, silver chloride,… Regarding all our uses of silver and the quantities at more than 100 tonnes / year, silver is critical for our business and the different businesses of our customers.				

Best regards, <confidential> Regulatory Affairs Cousel <confidential> Phone: <confidential>
Dossier Submitter's Response
We understand that classification and labelling may have consequences for companies however this is not within the scope of the CLP process since classification and labelling is based on the intrinsic properties of the active substance.
RAC's response
Noted.

CARCINOGENICITY

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Netherlands		MemberState	66
Comment received				
The NL-CA agrees classification for carcinogenicity is not warranted because of inconclusive data. There are no studies with decent quality that assess the carcinogenic potency of silver compounds.				
Dossier Submitter's Response				
Thank you.				
RAC's response				
Agreed, no classification for Carc.				

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Italy	IPZS S.p.A.	Company-Manufacturer	67
Comment received				
no evidence ECHA note – An attachment was submitted with the comment above. Refer to public attachment Public attachment in the questionnarie.docx				
Dossier Submitter's Response				
Thank you. Classification and labelling is based on the intrinsic properties of the substance and does not take exposure (with or without personal protective equipment) into account.				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	France	MONNAIE DE PARIS	Company-Downstream user	68
Comment received				
Solid (massive) silver presents no carcinogenicity risks, as far as we know, and there is no scientific evidence showing the contrary. ECHA note – An attachment was submitted with the comment above. Refer to public attachment 2020 12 18 ECHA MdP 2020 survey CLH for Silver_VDEF.pdf				
Dossier Submitter's Response				
Thank you for the information on your use of silver. We note the support for the EPMF.				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
09.12.2020	France	Comité Colbert	Industry or trade association	69
Comment received				
We support the conclusions on page 120. ECHA note – An attachment was submitted with the comment above. Refer to public attachment LT_Comité_Colbert_ECHA.pdf				
Dossier Submitter's Response				
We note the support for the comments by EPMF.				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Poland	<confidential>	Company-Manufacturer	70
Comment received				
Carcinogenicity - never found nor observed in the <confidential>. ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Silver - <confidential> statement.docx				
Dossier Submitter's Response				
Thank you for the information. We note the support for the comments submitted by the European Precious Metals Federation (EPMF). Please note our response to comment 23.				
RAC's response				
Noted. No classification is supported.				

Date	Country	Organisation	Type of Organisation	Comment number
02.12.2020	France	Metalor Technologies	Company-Manufacturer	71
Comment received				
-				
Dossier Submitter's Response				
-				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Germany	Netzwerk NanoSilber	Industry or trade association	72
Comment received				
none ECHA note – An attachment was submitted with the comment above. Refer to public attachment CLH public consultation silver - Comments by Netzwerk NanoSilber.pdf				
Dossier Submitter's Response				
Thank you for the information about different uses of silver. Information on the different uses and forms of silver is important to assure that the data used for the proposal relate to the forms or physical states in which the substance is placed on the market and in which it can reasonably be expected to be used. However, classification and labelling is based on the intrinsic properties of the substance and does not take different uses and exposure situations into account.				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Portugal	<confidential>	Company-Manufacturer	73
Comment received				
We are not aware of any hazard originated my metalic silver and we have been using silver for a very long time.				
Dossier Submitter's Response				
Thank you.				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Italy	<confidential>	Company-Manufacturer	74
Comment received				
no evidence				

ECHA note – An attachment was submitted with the comment above. Refer to public attachment 2020 12 17 Public attachment in the questionnarie <confidential> (003).docx
Dossier Submitter's Response
Thank you for the information. We note the support for the comments by EPMF.
RAC's response
Noted.

Date	Country	Organisation	Type of Organisation	Comment number
16.12.2020	Germany		MemberState	75
Comment received				
pages 111-120 We agree that data on silver and nanosilver are insufficient for classification, because of the low reliability of the respective animal studies. Read-across from silver-zinc-zeolite is not applicable. Therefore, classification is not possible.				
Dossier Submitter's Response				
Thank you.				
RAC's response				
Noted. No classification is supported.				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Belgium	T&D Europe	Industry or trade association	76
Comment received				
no comment ECHA note – An attachment was submitted with the comment above. Refer to public attachment TD Europe CLH Consultation Silver_Dec2020_final.pdf				
Dossier Submitter's Response				
Thank you for the information. We understand that classification and labelling may have consequences for companies however this is not within the scope of the CLP process. Moreover, exposure and the use of personal protective equipment during certain uses of silver is not taken into account for classification and labelling since it is based on the intrinsic properties of the active substance.				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
16.12.2020	Germany	Heraeus Deutschland GmbH & Co. KG	Company-Manufacturer	77
Comment received				
N/A				
Dossier Submitter's Response				
-				

RAC's response
Noted.

Date	Country	Organisation	Type of Organisation	Comment number
15.12.2020	France	SCHNEIDER ELECTRIC INDUSTRIES SAS	Company-Manufacturer	78
Comment received				
No comment ECHA note – An attachment was submitted with the comment above. Refer to public attachment Silver_consultation_2020_non_confidential.pdf ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Silver_consultation_2020_Schneider_Electric.pdf				
Dossier Submitter's Response				
We understand that classification and labelling may have consequences for companies however this is not within the scope of the CLP process. Moreover, exposure and the use of personal protective equipment during certain uses of silver is not taken into account for classification and labelling since it is based on the intrinsic properties of the active substance.				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
15.12.2020	Germany	RAS AG	Company-Manufacturer	79
Comment received				
see comment_CLH_silver_RAS_AG.pdf attached ECHA note – An attachment was submitted with the comment above. Refer to public attachment comment_CLH_silver_RAS_AG_public.pdf ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment comment_CLH_Silver_RAS_AG.zip				
Dossier Submitter's Response				
Thank you for information about the use of silver. We understand that classification and labelling may have consequences for companies however this is not within the scope of the CLP process since classification and labelling is based on the intrinsic properties of the active substance and it does not take exposure into account. Consequences of the C & L may be handled by downstream regulations. The test referred to, which was not available to the DS, seems to be performed with a substance containing very small amount of silver and it can thus be questioned if the intrinsic properties of the silver ion has been adequately investigated. We note the support for the comments by EPMF.				
RAC's response				
Noted.				

MUTAGENICITY

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Germany	WirtschaftsVereinigung Metalle	Industry or trade association	80
Comment received				
We think that the criteria for classifying silver as a germ cell mutagen have not been conclusively met as there is no direct human evidence that elemental silver (or ionic silver) is able to induce heritable genetic mutations and the weight of evidence from a series of reliable studies – including in vivo models which cover multiple mutagenicity endpoints – support a non-classification for this endpoint. The proposed classification is based on low-reliability studies which are inadequate for classification purposes. ECHA note – An attachment was submitted with the comment above. Refer to public attachment 2020-12-18_WVMetalle Comment on CLH Proposal for Silver.pdf				
Dossier Submitter's Response				
As stated in section 4, the classification proposal is justified by the need for harmonised classification and labelling in the review under the BPR. Direct evidence that silver induces heritable genetic mutations in humans is not required to fulfil criteria for classification in Category 2 as proposed in the CLH report. Classification in Category 2 includes "Substances which cause concern for humans owing to the possibility that they may induce heritable mutations in the germ cells of humans." – Positive evidence obtained from experiments in mammals and/or in some cases from in vitro experiments, obtained from: – Somatic cell mutagenicity tests in vivo, in mammals; or – Other in vivo somatic cell genotoxicity tests which are supported by positive results from in vitro mutagenicity assays. Note: Substances which are positive in in vitro mammalian mutagenicity assays, and which also show chemical structure activity relationship to known germ cell mutagens, shall be considered for classification as Category 2 mutagens. In the absence of further information, it is not clear to the dossier submitter what reliable studies referred to should take precedence over the data presented.				
RAC's response				
Noted. RAC proposes no classification.				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Germany	Netzwerk NanoSilber	Industry or trade association	81
Comment received				
The criteria for classifying silver as a germ cell mutagen have not been conclusively met. Silver and nanosilver has been used for centuries and there is no direct evidence that silver induces heritable genetic mutations in humans. The CLH report refers to a number of low-reliability studies that did not conform to recognised test guideline. A number of studies with higher reliability do not support a classification of silver as a germ cell mutagen (see public attachment).				

ECHA note – An attachment was submitted with the comment above. Refer to public attachment CLH public consultation silver - Comments by Netzwerk NanoSilber.pdf
Dossier Submitter's Response
Direct evidence that silver induces heritable genetic mutations in humans is not required to fulfil criteria for classification in Category 2 as proposed in the CLH report. Classification in Category 2 includes "Substances which cause concern for humans owing to the possibility that they may induce heritable mutations in the germ cells of humans." *– Positive evidence obtained from experiments in mammals and/or in some cases from in vitro experiments, obtained from:* *– Somatic cell mutagenicity tests in vivo, in mammals; or* *– Other in vivo somatic cell genotoxicity tests which are supported by positive results from in vitro mutagenicity assays.* *Note: Substances which are positive in in vitro mammalian mutagenicity assays, and which also show chemical structure activity relationship to known germ cell mutagens, shall be considered for classification as Category 2 mutagens.* Thank you for the information about different uses of silver. Information on the different uses and forms of silver on the market is important to assure that the data used for the proposal relate to the forms or physical states in which the substance is placed on the market and in which it can reasonably be expected to be used. However, classification and labelling is based on the intrinsic properties of the substance and does not take different uses and exposure situations into account. In the absence of further information, it is not clear to the dossier submitter what reliable studies referred to should take precedence over the data presented.
RAC's response
Noted.

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	United Kingdom	<confidential>	Company-Manufacturer	82
Comment received				
The criteria for classifying silver as a mutagen have not been conclusively met: • There appears to be rather a selective choice of data included in the CLH report that does not reflect the full dataset. ECHA note – An attachment was submitted with the comment above. Refer to public attachment Silver products.pdf				
Dossier Submitter's Response				
Thank you for the information about different uses of silver. There is an abundance of data on silver available in the open literature. It is not possible to include every study or publication but to an extent considered manageable, the dossier submitter has tried to include data that considered relevant for the assessment. This includes data submitted by industry in the REACH registration dossier, data submitted by the applicant for the review under the BPR and additional information identified by the dossier submitter.				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Portugal	<confidential>	Company-Manufacturer	83
Comment received				
To the best of our knwoledge the criteria for classifying silver as a germ cell mutagen have not been conclusively met: o there is no direct human evidence that elemental silver, or ionic silver substances, are able to induce heritable genetic mutations (nor is there useful data on somatic cell mutagenicity), and o the weight of evidence from a series of reliable studies – including in vivo models which cover multiple mutagenicity endpoints – support a non-classification for this endpoint (in contrast to the proposed classification based on a number of low-reliability studies)				
Dossier Submitter's Response				
Direct evidence that silver induces heritable genetic mutations in humans is not required to fulfil criteria for classification in Category 2 as proposed in the CLH report. Classification in Category 2 includes "Substances which cause concern for humans owing to the possibility that they may induce heritable mutations in the germ cells of humans." In the absence of further information, it is not clear to the dossier submitter what reliable studies referred to should take precedence over the data presented.				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Germany	aap Implantate AG	Company-Manufacturer	84
Comment received				
The criteria for classification as cell mutagen cannot be confirmed. ECHA note – An attachment was submitted with the comment above. Refer to public attachment aap Implantate AG_CLH_public_consultation_non-confidential_CAS 7440-22-4.pdf ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment aap Implantate AG_CLH_public_consultation_confidential_CAS 7440-22-4.pdf				
Dossier Submitter's Response				
Thank you for the information. In the absence of further information on the data referred to it is not possible to assess if the information is relevant to assess the intrinsic properties of 100% of the substance and/or if data is robust and reliable.				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	United Kingdom	Ames Goldsmith UK Ltd	Company-Manufacturer	85
Comment received				
• Germ cell mutagenicity - the criteria for classifying silver as a germ cell mutagen have not been conclusively met: o there is no direct human evidence that elemental silver, or ionic silver substances, are able to induce heritable genetic mutations (nor is there useful data on somatic cell mutagenicity), and o the weight of evidence from a series of reliable studies – including in vivo models which cover multiple mutagenicity endpoints – support a non-classification for this endpoint (in contrast to the proposed classification based on a number of low-reliability studies)				
Dossier Submitter's Response				
Direct evidence that silver induces heritable genetic mutations in humans is not required to fulfil criteria for classification in Category 2 as proposed in the CLH report. Classification in Category 2 includes "Substances which cause concern for humans owing to the possibility that they may induce heritable mutations in the germ cells of humans." In the absence of further information, it is not clear to the dossier submitter what reliable studies referred to should take precedence over the data presented.				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Italy	<confidential>	Company-Manufacturer	86
Comment received				
no evidence ECHA note – An attachment was submitted with the comment above. Refer to public attachment 2020 12 17 Public attachment in the questionnarie <confidential> (003).docx				
Dossier Submitter's Response				
Thank you. Classification and labelling is based on the intrinsic properties of the substance and does not take exposure (with or without personal protective equipment) into account.				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Poland		Individual	87
Comment received				

• Germ cell mutagenicity - the criteria for classifying silver as a germ cell mutagen have not been conclusively met: ☐ there is no direct human evidence that elemental silver, or ionic silver substances, are able to induce heritable genetic mutations (nor is there useful data on somatic cell mutagenicity), and ☐ the weight of evidence from a series of reliable studies – including in vivo models which cover multiple mutagenicity endpoints – support a non-classification for this endpoint (in contrast to the proposed classification based on a number of low-reliability studies) ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment comment.pdf
Dossier Submitter's Response
Direct evidence that silver induces heritable genetic mutations in humans is not required to fulfil criteria for classification in Category 2 as proposed in the CLH report. Classification in Category 2 includes "Substances which cause concern for humans owing to the possibility that they may induce heritable mutations in the germ cells of humans." In the absence of further information, it is not clear to the dossier submitter what reliable studies referred to should take precedence over the data presented.
RAC's response
Noted.

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Germany	Bio-Gate AG	Company-Manufacturer	88
Comment received				
- the criteria for classifying silver as a germ cell mutagen have not been conclusively met: - there is no direct human evidence that elemental silver is able to induce heritable genetic mutations (nor is there useful data on somatic cell mutagenicity), and - the weight of evidence from a series of reliable studies – including in vivo models which cover multiple mutagenicity endpoints – support a non-classification for this endpoint (in contrast to the proposed classification based on a number of low-reliability studies) - to use silver nitrate as a surrogate for metallic/elemental silver cannot be justified as silver nitrate and other silver types have a very different silver ion release profile than elemental silver, which as a precious metal releases a low amount silver ions. Please see attached a human study on bone cement with metallic/elemental silver where silver ions only have an effect in the viscinity of the bone cement. The elution profile and bioavailability of the generated silver ions is so low that it is not possible for the amount of silver ions to induce heritable genetic mutations. ECHA note – An attachment was submitted with the comment above. Refer to public attachment Bio-Gate Safety Studies.zip ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Bio-Gate Microsilver BG Confidential Safety Studies.zip				
Dossier Submitter's Response				
Thank you for the information about all different uses of silver. Direct evidence that silver induces heritable genetic mutations in humans is not required to fulfil criteria for classification in Category 2 as proposed in the CLH report. Classification in Category 2 includes "Substances which cause concern for humans owing to the possibility that they				

may induce heritable mutations in the germ cells of humans." In the absence of further information, it is not clear to the dossier submitter what reliable studies referred to should take precedence over the data presented. The toxicological data used for the human health assessment must cover all forms or physical states in which elemental silver is placed on the market. We doubt that the results from the non-guideline, non-GLP studies performed with a particular formulation with a certain silver content represent 100% of the active substances in all relevant forms. We note the support the comments submitted by the European Precious Metals Federation (EPMF).
RAC's response
Noted.

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Germany	I&P Europe - Imaging and Printing Association e.V.	Industry or trade association	89
Comment received				
see attached document ECHA note – An attachment was submitted with the comment above. Refer to public attachment Comments to the silver metal CLH public consultation.pdf				
Dossier Submitter's Response				
Thank you for the information about your uses of silver. We note the support the comments submitted by the European Precious Metals Federation (EPMF).				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Belgium	T&D Europe	Industry or trade association	90
Comment received				
no comment ECHA note – An attachment was submitted with the comment above. Refer to public attachment TD Europe CLH Consultation Silver_Dec2020_final.pdf				
Dossier Submitter's Response				
We understand that classification and labelling may have consequences for companies however this is not within the scope of the CLP process. Moreover, exposure and the use of personal protective equipment during certain uses of silver is not taken into account for classification and labelling since it is based on the intrinsic properties of the active substance.				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Germany	<confidential>	Company-Manufacturer	91
Comment received				
o there is no direct human evidence that elemental silver, or ionic silver substances, are able to induce heritable genetic mutations (nor is there useful data on somatic cell mutagenicity), and o the weight of evidence from a series of reliable studies – including in vivo models which cover multiple mutagenicity endpoints – support a non-classification for this endpoint (in contrast to the proposed classification based on a number of low-reliability studies)				
Dossier Submitter's Response				
Direct evidence that silver induces heritable genetic mutations in humans is not required to fulfil criteria for classification in Category 2 as proposed in the CLH report. Classification in Category 2 includes "Substances which cause concern for humans owing to the possibility that they may induce heritable mutations in the germ cells of humans." In the absence of further information, it is not clear to the dossier submitter what reliable studies referred to should take precedence over the data presented.				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	France		MemberState	92
Comment received				
In agreement with the proposal of classification: Muta. 2, H341				
Dossier Submitter's Response				
Thank you.				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Germany	ZVEI - German Electrical and Electronic Manufacturers' Association	Industry or trade association	93
Comment received				
Germ cell mutagenicity - the criteria for classifying silver as a germ cell mutagen have not been conclusively met: o there is no direct human evidence that elemental silver, or ionic silver substances, are able to induce heritable genetic mutations (nor is there useful data on somatic cell				

mutagenicity), and
o the weight of evidence from a series of reliable studies – including in vivo models which cover multiple mutagenicity endpoints – support a non-classification for this endpoint (in contrast to the proposed classification based on several low-reliability studies)

ECHA note – An attachment was submitted with the comment above. Refer to public attachment 20201218 ZVEI Silver Applications in EEE and Comments Ag CLH Consultation.pdf

Dossier Submitter's Response

Direct evidence that silver induces heritable genetic mutations in humans is not required to fulfil criteria for classification in Category 2, as proposed in the CLH report.
Classification in Category 2 includes "Substances which cause concern for humans owing to the possibility that they may induce heritable mutations in the germ cells of humans."
In the absence of further information, it is not clear to the dossier submitter what reliable studies referred to should take precedence over the data presented.
Response to comments in attachment:

1. Thank you for the information about different uses of silver. Information on the different uses and forms of silver on the market is important to assure that the data used for the proposal relate to the forms or physical states in which the substance is placed on the market and in which it can reasonably be expected to be used. We understand that classification and labelling may have consequences for companies however this is not within the scope of the CLP process since classification and labelling is based on the intrinsic properties of the active substance. Consequences thereof may be handled by downstream regulations.
2. We note the support for the comments submitted by the European Precious Metals Federation (EPMF).
3. The Extended One-Generation Reproductive Toxicity Study (EOGRTS) is indeed expected to provide useful information however decisions under CLP must be taken without awaiting information that may become available in the future. Other processes e.g. decisions on approval under the BPR depend on the classification and labelling of a substance thus the CLP process cannot be delayed. The possibility to submit new classification proposals based on new information remains.

RAC's response

Noted.

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Germany	C.HAFNER GmbH + Co. KG	Company-Manufacturer	94

Comment received

The criteria for classifying silver as a germ cell mutagen have not been conclusively met:
o there is no direct human evidence that elemental silver, or ionic silver substances, are able to induce heritable genetic mutations (nor is there useful data on somatic cell mutagenicity), and
o the weight of evidence from a series of reliable studies – including in vivo models which cover multiple mutagenicity endpoints – support a non-classification for this endpoint (in contrast to the proposed classification based on a number of low-reliability studies)
Please refer to the scientific comments submitted by the European Precious Metals

Federation (EPMF).
Dossier Submitter's Response
Direct evidence that silver induces heritable genetic mutations in humans is not required to fulfil criteria for classification in Category 2 as proposed in the CLH report. Classification in Category 2 includes "Substances which cause concern for humans owing to the possibility that they may induce heritable mutations in the germ cells of humans." In the absence of further information, it is not clear to the dossier submitter what reliable studies referred to should take precedence over the data presented. We note the support the comments submitted by the European Precious Metals Federation (EPMF).
RAC's response
Noted.

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Belgium	European Precious Metals Federation (EPMF)	Industry or trade association	95
Comment received				
Summary of comments on germ cell mutagenicity (CLH report p.72-111): The criteria for classifying silver as a germ cell mutagen have not been conclusively met: o there is no direct human evidence that elemental silver, or ionic silver substances, are able to induce heritable genetic mutations (nor is there useful data on somatic cell mutagenicity), and o the weight of evidence from a series of reliable studies - including in vivo models which cover multiple mutagenicity endpoints - support a non-classification for this endpoint (in contrast to the proposed classification based on a selective number of low-reliability studies). For further details / justification, please refer to the attached document pages 20-33. ECHA note – An attachment was submitted with the comment above. Refer to public attachment CLH Ag Comments FINAL_201217.pdf				
Dossier Submitter's Response				
The comment on genotoxicity is in the form of a 14 pages debate, please find below a response to some comments or statements made in the attachment. Certainly the CLH report does not include all information on any silver substance available. Only in Pub Med (biomedical literature from MEDLINE, life science journals, and online booksilver), the search terms silver and nanosilver generates 111,942 and 4000 results, respectively. As stated in section 4, submitting a proposal for classification and labelling was justified by the requirements for the review of silver under the BPR. Reviewing all information of possible relevance is not manageable but the information discussed in this CLH report is a compilation of published or industry-sponsored information submitted by the applicant to fulfil the data requirements under the BPR, information from the REACH registration dossier or additional published information identified by the dossier submitter. The information has thus not been selected exclusively by the dossier submitter and we expect the information to reflect, as far as possible, the true properties of silver. It is regrettable that no robust and relevant genotoxicity data for silver in massive or ionic form is available.				

The published studies do have deficiencies compared to GLP and guideline studies and this is discussed in the CLH report. Also the view of the registrant regarding the reliability of REACH data has been given much space on page 98 in the CLH report.
Of course the reliability of studies could be more thoroughly discussed or be illustrated and categorised in different ways such as proposed by EMPF. However, data is yet the same and we think it is quite clear in the report that the assessment of the genotoxic potential is assessed based on data obtained in studies that, in isolation, may be of low reliability but in a WoE approach can provide sufficient information on the substance. The difference between a reliability score of 2 and 3 for a published study is difficult to assess and inevitably subjected to some subjectiveness regardless of how presented or categorised. Our assessment of reliability is primarily based on robustness estimated through the information available regarding study conduct and results in comparison with OECD guidelines. However, when giving weight to certain studies, not only reliability but relevance of data for certain silver substances is taken into account. Tests performed with silver substances with low amount of silver and/or limited solubility may not accurately reflect the intrinsic genotoxic of silver and thus be given less weight.
Despite the criticism by EPMF put forward for the other hazard classes regarding the use of results obtained in studies with more complex silver salts, the negative data obtained with different SCAS is yet considered relevant for this hazard class: *"It is acknowledged that such SCAS also contain constituents other than introduces silver which some interpretative complexity. However, the achieved Ag-equivalent treatment levels were moderately high, and this group of studies is therefore considered to provide useful confirmatory information regarding an absence of mutagenic or DNA damaging effects in the case of these read-across reference substances."*
It should be noted that he highest dose tested with the SCAS in vivo is estimated to be 68 mg/kg bw/d which is in our opinion not moderately high in comparison with the recommendations in guidelines. Therefore, the DS concluded in the section on in vitro genotoxicity listing positive results for several SCAS *"However, while giving some support for the assessment of the silver ion, these SCAS contain additional ions and less amount of silver ion equivalents thus the results are of limited use for the assessment of elemental silver and are therefore not discussed further."*

In similarity with the majority of published studies, the study by Kovvuru (investigating micronucleus induction, DNA damage and repair assessments) was non-GLP and not performed according to any guideline. Therefore, the study was given reliability score 2-3 since the results for what was aimed to investigate was yet considered reliable.
The characterisation of nanoparticles in the study seems comparable to or even more detailed than in other published studies with nanosilver.
EPMF considers the frequency of micronuclei in controls unusually low but presents no reference to data considered "normal". Moreover, besides the increased frequency of micronuclei in the bone marrow, the study also showed large DNA deletions in developing embryos of mice.
As also recognised by the EPMF, most of the published studies, irrespective of being positive or negative, suffer from deficiencies compared to guidelines. The EMPF refers to several studies not included in the CLH report considered to be more reliable.
The study by Boudreau (2016) referred to seems overall well-conducted however the information on the genotoxicity investigations is limited to the following *"The genotoxic effects of AgNP exposure or AgOAc exposure in male and female rats were examined with a micronucleus assay, using flow cytometric analysis of peripheral blood (Witt et al., 2008). Blood samples obtained from rats at weeks 1, 4, and 12 of the study were fixed in ultracold methanol and stored at -80°C until analyzed for the frequency of micronucleated cells in 20 000 reticulocytes per sample."*

Regarding results, the authors state: *"The results of the micronuclei assay of peripheral blood are reported in Supplementary Table S4 and show that the data were negative for each time point in the peripheral blood of rats treated with AgNP. Male and female rats administered AgOAc at 400 mg/kg bw had a small but significant increase in the frequency of micronucleated reticulocytes at week-4, but not at subsequent time points (Supplementary Table S4). These animals had severe gastrointestinal distress and only 1 female and no male rats survived to week 12."* The authors also state that nanoparticles aggregate in the lumen matrix reducing uptake. Therefore, the actual silverexposure of target tissue can be questioned (according to the autors *"the silver content in blood and bone marrow averaged 3–4 times lower than the silver content of the heart (Supplementary Table S3), which had the lowest content of silver among the major organs analyzed and indicated that the contribution of silver accumulation in the blood and bone marrow was minimal."* While the study provides useful information on distribution, it is unclear to the DS why the genotoxcity part of this study is considered more reliable than other published data on nanosilver. Another negative study referred to by the EPMF and not included in the CLH report, investigated genotoxicity using the Comet or Micronucleus assays (Narciso et al). The author states *"TEM analysis showed the presence of AgNPs into the cells of liver and duodenum, in agreement with several previous works (Boudreau et al., 2016; Loeschner et al., 2011; Garcia et al., 2016). In fact, AgNPs were never located into the nucleus and this could explain the absence of genotoxic damages."* Interestingly, the article also states *"Indeed, in aqueous solutions, AgNPs can dissolute in Ag ions (Ag+) which are mainly responsible of the toxicity induced by AgNPs (McShan and Ray, 2014) and massive amount of Ag+ improves ROS production (Beer et al., 2012). In this work, although a direct measure of potential Ag+ formation has not been performed, the AgNP dispersions had pH 7 and in this condition the formation of Ag+ ions was certified to be minimal (De Matteis et al.,2015). Since a direct contact of AgNPs with the nucleus has been excluded, and no genotoxicity has been recorded, this can be considered n indirect evidence of no Ag+ ion formation in the present conditions. Moreover, validation test performed before the biodistribution analysis suggested that AgNPs or the Ag+ ion recovery were similar in different tissues and the potential dissolution of AgNPs in Ag+ ions may be excluded."* Based on this information it can be questioned if the results from this study can be used to accurately represent the intrinsic properties of silver (ions) since formation of Ag ions was considered minimal. The authors suggested that smaller particles are more likely than larger particles to release silver ions from the surface (Patlolla et al., 2015b) and states *"As for other nanosized particles of the same elemental composition (EFSA Scientific Committee et al., 2018), the physicochemical characteristics, including size, can lead to different biological activities, thus affecting the outcome of hazard identification."* Since data on nanosilver is primarily used in this assessment to represent the effescts of the silver ion when released from different forms of silver, the adequacy of this data is questioned.
RAC's response
Noted.

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Netherlands		MemberState	96
Comment received				
The NL-CA supports classification for silver as mutagenic because there are numerous in vitro and in vivo mutagenicity studies that indicate genotoxicity after exposure to silver nanoparticles. Based on the studies and summaries in the section about germ cell mutagenicity, category 2 seems appropriate. However, it is noted that silver is able to reach the testis and cause adverse effects based on studies described in the sections about toxicokinetics and sexual function and fertility. In the latter section, there was also a study describing mutagenic effects in germ cells although this was after IV administration only. Please reflect if these studies together provide sufficient evidence for germ cell mutagenicity (category 1B).				
Dossier Submitter's Response				
According to CLP, classification in category 1 applies to substances **known** to induce heritable mutations whereas category 2 applies to substances which **cause concern** for humans owing to the possibility that they **may** induce heritable mutations in the germ cells of humans. The toxicokinetic information on silver is limited. According to the results by van der Zande et al, silver was distributed to testis in rats both following administration as AgNO3 and in the form of two types of AgNPs. Also in the study by Boudreau (2016), discussed in comment 95, pigmentation in ovaries was observed following administration of silver in both nano and ionic form. However, taking into account the deficiencies in the published studies and the lack of robust in vivo genotoxicity data for a silver salt (for which particle size would not bring uncertainty regarding if the genotoxic potential is adequately investigated), we doubt it is possible to conclude that the substance is **known** to induce heritable mutations.				
RAC's response				
Noted. RAC proposes no classification.				

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Netherlands	<confidential>	Company-Manufacturer	97
Comment received				
Germ cell mutagenicity - the criteria for classifying silver as a germ cell mutagen have not been conclusively met: * there is no direct human evidence that elemental silver, or ionic silver substances, are able to induce heritable genetic mutations. The same is true about useful data on somatic cell mutagenicity * the weight of evidence from a series of reliable studies support a non-classification for this endpoint				
Dossier Submitter's Response				
Direct evidence that silver induces heritable genetic mutations in humans is not required to fulfil criteria for classification in Category 2 as proposed in the CLH report. Classification in Category 2 includes "Substances which cause concern for humans owing to the possibility that they may induce heritable mutations in the germ cells of humans."				

In the absence of further information, it is not clear to the dossier submitter what reliable studies referred to should take precedence over the data presented.
RAC's response
Noted.

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	France	FRANCECLAT, BOCI and UFBJOP	Industry or trade association	98
Comment received				
Please find our comments on this specific hazard in the attached document. ECHA note – An attachment was submitted with the comment above. Refer to public attachment Comments on CLH proposal for silver.pdf				
Dossier Submitter's Response				
Thank you for the information about your uses of silver. We understand that classification and labelling may have consequences for companies however this is not within the scope of the CLP process. Moreover, exposure and the use of personal protective equipment during certain uses of silver is not taken into account for classification and labelling since it is based on the intrinsic properties of the active substance. Consequences of C & L may be handled by downstream regulations. The justification for submitting a proposal is indeed based on the requirement for an opinion on harmonised classification and labelling in the review under the BPR. However, the CLH report also informs that there are more uses than the intended biocidal uses triggering an action "Apart from biocidal use, silver has 92 active registrations under REACH in June 2019. It has wide uses by industry, professionals and consumers." Information on the different uses and forms of silver on the market is important to assure that the data used for the proposal relate to the forms or physical states in which the substance is placed on the market and in which it can reasonably be expected to be used, otherwise uses are not taken into account for the assessment if criteria for classification are fulfilled. The number of robust and reliable studies available for the forms or physical states in which the substance is placed on the market is limited. However, similar effects are seen among different studies with various silver substances and this is the basis why studies with different silver substances releasing silver ions are considered for the assessment. Regarding the question what led us to this proposal; the basis for our proposal is the comparison of effects noted in studies considered relevant against the criteria for classification and the considerations in CLP guidance. We note the support the comments submitted by the European Precious Metals Federation (EPMF).				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Germany	Fachvereinigung Edelmetalle e. V.	Industry or trade association	99
Comment received				
The criteria for classifying silver as a germ cell mutagen have not been conclusively met: o there is no direct human evidence that elemental silver, or ionic silver sub-stances, are able to induce heritable genetic mutations (nor is there useful data on somatic cell mutagenicity), and o the weight of evidence from a series of reliable studies – including in vivo mod-els which cover multiple mutagenicity endpoints – support a non-classification for this endpoint (in contrast to the proposed classification based on a number of low-reliability studies) ECHA note – An attachment was submitted with the comment above. Refer to public attachment FVEM comments CLH silver.pdf				
Dossier Submitter's Response				
Direct evidence that silver induces heritable genetic mutations in humans is not required to fulfil criteria for classification in Category 2 as proposed in the CLH report. Classification in Category 2 includes "Substances which cause concern for humans owing to the possibility that they may induce heritable mutations in the germ cells of humans." In the absence of further information, it is not clear to the dossier submitter what reliable studies referred to should take precedence over the data presented.				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Germany	Federal Associations of the German Jewellery and Silverware Industry	Industry or trade association	100
Comment received				
The criteria for classifying silver as a germ cell mutagen have not been conclusively met: - there is no direct human evidence that elemental silver, or ionic silver substances, are able to induce heritable genetic mutations (nor is there useful data on somatic cell mutagenicity), and - the weight of evidence from a series of reliable studies – including in vivo models which cover multiple mutagenicity endpoints – support a non-classification for this endpoint (in contrast to the proposed classification based on a number of low-reliability studies) ECHA note – An attachment was submitted with the comment above. Refer to public attachment 20201216-comments-vbv-clh-silver.pdf				
Dossier Submitter's Response				
Direct evidence that silver induces heritable genetic mutations in humans is not required to fulfil criteria for classification in Category 2 as proposed in the CLH report. Classification in Category 2 includes "Substances which cause concern for humans owing to the possibility that they may induce heritable mutations in the germ cells of humans."				

In the absence of further information, it is not clear to the dossier submitter what reliable studies referred to should take precedence over the data presented. We note the support the comments submitted by the European Precious Metals Federation (EPMF).
RAC's response
Noted.

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Italy	IPZS S.p.A.	Company-Manufacturer	101
Comment received				
no evidence ECHA note – An attachment was submitted with the comment above. Refer to public attachment Public attachment in the questionnarie.docx				
Dossier Submitter's Response				
Thank you for the information. We note the support the comments submitted by the European Precious Metals Federation (EPMF).				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Germany	HAGER GROUP	Company-Downstream user	102
Comment received				
Germ cell mutagenicity - the criteria for classifying silver as a germ cell mutagen have not been conclusively met: o there is no direct human evidence that elemental silver, or ionic silver substances, are able to induce heritable genetic mutations (nor is there useful data on somatic cell mutagenicity), and o the weight of evidence from a series of reliable studies – including in vivo models which cover multiple mutagenicity endpoints – support a non-classification for this endpoint (in contrast to the proposed classification based on a number of low-reliability studies) ECHA note – An attachment was submitted with the comment above. Refer to public attachment CHL Ag- DU contribution- Hager group.docx				
Dossier Submitter's Response				
Thank you for the information about your uses of silver. We understand that classification and labelling may have consequences for companies however this is not within the scope of the CLP process. Moreover, exposure and the use of personal protective equipment during certain uses of silver is not taken into account for classification and labelling since it is based on the intrinsic properties of the active substance. Consequences of C & L may be handled by downstream regulations. Direct evidence that silver induces heritable genetic mutations in humans is not required to fulfil criteria for classification in Category 2 as proposed in the CLH report. Classification in Category 2 includes "Substances which cause concern for humans owing to the possibility that they may induce heritable mutations in the germ cells of humans."				

In the absence of further information, it is not clear to the dossier submitter what reliable studies referred to should take precedence over the data presented. We note the support the comments submitted by the European Precious Metals Federation (EPMF).
RAC's response
Noted.

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Czech Republic	SAFINA, a.s.	Company-Manufacturer	103
Comment received				
Please see the attached file. ECHA note – An attachment was submitted with the comment above. Refer to public attachment SAFINA_CLH public consultation_silver metal - completed.pdf				
Dossier Submitter's Response				
Thank you for the information about your uses of silver. We note the support for the comments submitted by the EPMF.				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Norway	<confidential>	Company-Manufacturer	104
Comment received				
The criteria for classifying silver as a germ cell mutagen have not been conclusively met: - there is no direct human evidence that elemental silver, or ionic silver substances, are able to induce heritable genetic mutations (nor is there useful data on somatic cell mutagenicity) - the weight of evidence from a series of reliable studies – including in vivo models which cover multiple mutagenicity endpoints – support a non-classification for this endpoint (in contrast to the proposed classification based on a number of low-reliability studies) ECHA note – An attachment was submitted with the comment above. Refer to public attachment Comments CLH Ag -17.12.20.pdf ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Comments CLH Ag - <confidential> - 17.12.20 - confidential info.pdf				
Dossier Submitter's Response				
Direct evidence that silver induces heritable genetic mutations in humans is not required to fulfil criteria for classification in Category 2 as proposed in the CLH report. Classification in Category 2 includes "Substances which cause concern for humans owing to the possibility that they may induce heritable mutations in the germ cells of humans." In the absence of further information, it is not clear to the dossier submitter what reliable studies referred to should take precedence over the data presented. We note the support the comments submitted by the European Precious Metals Federation (EPMF).				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Germany	Heimerle + Meule GmbH	Company-Manufacturer	105
Comment received				
The criteria for classifying silver as a germ cell mutagen have not been conclusively met: o there is no direct human evidence that elemental silver, or ionic silver substances, are able to induce heritable genetic mutations (nor is there useful data on somatic cell mutagenicity), and o the weight of evidence from a series of reliable studies – including in vivo models which cover multiple mutagenicity endpoints – support a non-classification for this endpoint (in contrast to the proposed classification based on a number of low-reliability studies) ECHA note – An attachment was submitted with the comment above. Refer to public attachment H+M comments CLH silver.pdf				
Dossier Submitter's Response				
Thank you for the information on uses of silver. Direct evidence that silver induces heritable genetic mutations in humans is not required to fulfil criteria for classification in Category 2 as proposed in the CLH report. Classification in Category 2 includes "Substances which cause concern for humans owing to the possibility that they may induce heritable mutations in the germ cells of humans." In the absence of further information, it is not clear to the dossier submitter what reliable studies referred to should take precedence over the data presented. We note the support the comments submitted by the European Precious Metals Federation (EPMF).				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
16.12.2020	Germany	Siemens AG	Company-Manufacturer	106
Comment received				
Based on our assessment of the report and the discussion with industry experts, we think that the criteria for classifying silver as a germ cell mutagen have not been conclusively met, since there is no direct human evidence that elemental silver, or ionic silver substances, are able to induce heritable genetic mutations (nor is there useful data on somatic cell mutagenicity). Furthermore the weight of evidence from a series of reliable studies – including in vivo models which cover multiple mutagenicity endpoints – support a non-classification for this endpoint (in contrast to the proposed classification based on several low-reliability studies).				
Dossier Submitter's Response				
Direct evidence that silver induces heritable genetic mutations in humans is not required to fulfil criteria for classification in Category 2 as proposed in the CLH report. Classification in Category 2 includes "Substances which cause concern for humans owing to the possibility that they may induce heritable mutations in the germ cells of humans." In the absence of further information, it is not clear to the dossier submitter what reliable studies referred to should take precedence over the data presented.				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
16.12.2020	Germany	<confidential>	Industry or trade association	107
Comment received				
The criteria for classifying silver as a germ cell mutagen have not been conclusively met: - there is no direct human evidence that elemental silver, or ionic silver substances, are able to induce heritable genetic mutations (nor is there useful data on somatic cell mutagenicity), and - the weight of evidence from a series of reliable studies – including in vivo models which cover multiple mutagenicity endpoints – support a non-classification for this endpoint (in contrast to the proposed classification based on a number of low-reliability studies) ECHA note – An attachment was submitted with the comment above. Refer to public attachment 20201214-<confidential>-clh-silver-comments.pdf				
Dossier Submitter's Response				
Direct evidence that silver induces heritable genetic mutations in humans is not required to fulfil criteria for classification in Category 2 as proposed in the CLH report. Classification in Category 2 includes "Substances which cause concern for humans owing to the possibility that they may induce heritable mutations in the germ cells of humans." In the absence of further information, it is not clear to the dossier submitter what reliable studies referred to should take precedence over the data presented. We note the support the comments submitted by the European Precious Metals Federation (EPMF).				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
16.12.2020	Finland	<confidential>	Company-Manufacturer	108
Comment received				
the criteria for classifying silver as a germ cell mutagen have not been conclusively met: there is no direct human evidence that elemental silver, or ionic silver substances, are able to induce heritable genetic mutations, and the weight of evidence from a series of reliable studies – including in vivo models which cover multiple mutagenicity endpoints – support a non-classification for this endpoint (in contrast to the proposed classification based on a number of low-reliability studies)				
Dossier Submitter's Response				
Direct evidence that silver induces heritable genetic mutations in humans is not required to fulfil criteria for classification in Category 2 as proposed in the CLH report. Classification in Category 2 includes "Substances which cause concern for humans owing to the possibility that they may induce heritable mutations in the germ cells of humans." In the absence of further information, it is not clear to the dossier submitter what reliable studies referred to should take precedence over the data presented.				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
16.12.2020	Germany		MemberState	109

Comment received

pages 72-111
There is a complex data situation with positive and negative results of in vitro and in vivo studies on nanosilver, silver salts, silver zinc (or copper) zeolite and Alphasan (silver sodium hydrogen zirconium phosphate). Assessing the data jointly results in an equivocal outcome. Thus, we agree that a WoE approach should be applied as the CLP guidance (2017) states: "In the case where there are also negative or equivocal data, a weight of evidence approach using expert judgement has to be applied."
The CLP guidance further states: "A complex data situation with positive and negative results might still lead to classification. This is because all tests detecting a certain type of mutation (e.g. point mutations) have been positive and all tests detecting chromosome mutations have been negative. Such circumstances clearly warrant classification although several tests have been negative which is plausible in this case. "
We suggests to apply a differentiated consideration of the individual silver species, nano particulate silver, ionic silver and silver in mixed materials (e.g. zeolites), as the toxicological results differ accordingly. In addition, we think that the read-across to the silver-containing biocidal active ingredients is not suitable, as they also contain other elements such as zinc or copper that may contribute to toxicity.

The individual consideration of silver species shows positive effects for in vitro MN, CA and comet assay, while reported negative outcomes were observed for surface modified silver nanoparticles. Silver in ionic form was reported predominantly with negative outcome.
In vivo studies show equivocal results with positive and negative reports.
In vivo CA tests were positive but some in vivo MN tests were negative. Moreover, some of the studies show deviations from OECD test guidelines.

Consequently, we conclude that the WoE justification in section 10.8.2. (Comparison with the CLP criteria) would justify the classification on Mutagenicity Cat. 2. However, it may be discussed whether some nanosilver species, e.g. those that are stably coated, and massive silver can be exempted.

Note: including the CLP guidance section on intraperitoneal application may be misleading, since there are oral studies, which were also considered for classification

Dossier Submitter's Response

The use of toxicological data on nanosilver as well as data on different silver salts for the hazard assessment of silver in different forms is based on the release of silver ions. Since all forms of elemental silver considered here, in the absence of robust data demonstrating non-bioavailability also including massive silver, are expected to release silver ions in contact with moist and biological fluids all data investigating the toxicity of silver ions is considered potentially relevant. It is not fully clear to the DS why nanosilver species, e.g. those that are stably coated, and massive silver should be exempted for this particular hazard class. We agree that data with SCAS containing additional constituents of possible toxicological impact and with a maximum silver release that do not represent 100% silver is less relevant. This is statedin the CLH report.

RAC's response
RAC notes the concern over silver massive and considered a split classification proposal. The data to support silver nanoform classification was quite mixed, not always clear and the bulk of the silver data was generated from silver nanoforms rather than from non nanoforms. Based on a weight of evidence approach, RAC proposed no classification.

Date	Country	Organisation	Type of Organisation	Comment number
16.12.2020	Germany	Heraeus Deutschland GmbH & Co. KG	Company-Manufacturer	110
Comment received				
Germ cell mutagenicity - the criteria for classifying silver as a germ cell mutagen have not been conclusively met o there is no direct human evidence that elemental silver, or ionic silver substances, are able to induce heritable genetic mutations (nor is there useful data on somatic cell mutagenicity), and o the weight of evidence from a series of reliable studies – including in vivo models which cover multiple mutagenicity endpoints – support a non-classification for this endpoint (in contrast to the proposed classification based on a number of low-reliability studies)				
Dossier Submitter's Response				
Direct evidence that silver induces heritable genetic mutations in humans is not required to fulfil criteria for classification in Category 2 as proposed in the CLH report. Classification in Category 2 includes "Substances which cause concern for humans owing to the possibility that they may induce heritable mutations in the germ cells of humans." In the absence of further information, it is not clear to the dossier submitter what reliable studies referred to should take precedence over the data presented. We note the support the comments submitted by the European Precious Metals Federation (EPMF).				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
15.12.2020	France	SCHNEIDER ELECTRIC INDUSTRIES SAS	Company-Manufacturer	111
Comment received				
No comment ECHA note – An attachment was submitted with the comment above. Refer to public attachment Silver_consultation_2020_non_confidential.pdf ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Silver_consultation_2020_Schneider_Electric.pdf				
Dossier Submitter's Response				
Thank you for the information about your uses of silver. We understand that classification and labelling may have consequences for companies however this is not within the scope of the CLP process. Moreover, exposure and the use of personal protective equipment during certain uses of silver is not taken into account for classification and labelling since				

it is based on the intrinsic properties of the active substance. Consequences of C & L may be handled by downstream regulations.
RAC's response
Noted.

Date	Country	Organisation	Type of Organisation	Comment number
15.12.2020	Germany	RAS AG	Company-Manufacturer	112
Comment received				
see comment_CLH_silver_RAS_AG.pdf attached ECHA note – An attachment was submitted with the comment above. Refer to public attachment comment_CLH_silver_RAS_AG_public.pdf ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment comment_CLH_Silver_RAS_AG.zip				
Dossier Submitter's Response				
Thank you for the information about your uses of silver. We understand that classification and labelling may have consequences for companies however this is not within the scope of the CLP process. We note the support the comments submitted by the European Precious Metals Federation (EPMF).				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
15.12.2020	Switzerland	Argor-Heraeus SA	Company-Manufacturer	113
Comment received				
Germ cell mutagenicity - the criteria for classifying silver as a germ cell mutagen have not been conclusively met o there is no direct human evidence that elemental silver, or ionic silver substances, are able to induce heritable genetic mutations (nor is there useful data on somatic cell mutagenicity), and o the weight of evidence from a series of reliable studies – including in vivo models which cover multiple mutagenicity endpoints – support a non-classification for this endpoint (in contrast to the proposed classification based on a number of low-reliability studies)				
Dossier Submitter's Response				
Direct evidence that silver induces heritable genetic mutations in humans is not required to fulfil criteria for classification in Category 2 as proposed in the CLH report. Classification in Category 2 includes "Substances which cause concern for humans owing to the possibility that they may induce heritable mutations in the germ cells of humans." In the absence of further information, it is not clear to the dossier submitter what reliable studies referred to should take precedence over the data presented.				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
15.12.2020	Belgium	Umicore	Company-Manufacturer	114
Comment received				
Germ cell mutagenicity - the criteria for classifying silver as a germ cell mutagen have not been conclusively met: • there is no direct human evidence that elemental silver, or ionic silver substances, are able to induce heritable genetic mutations (nor is there useful data on somatic cell mutagenicity), and • the CLH proposal does not cite all relevant studies (in vivo / in vitro) • the majority of the genotoxicity studies are performed on AgNP (nanoparticles) and these studies often performed non-standardized testing. We are faced with the risk that non-reliable studies on AgNP will drive the full Ag mutagenicity profile. Moreover, there are certain read-across uncertainties between AgNP and more massive Ag forms, • the weight of evidence from a series of reliable studies – including in vivo models which cover multiple mutagenicity endpoints – support a non-classification for this endpoint (in contrast to the proposed classification based on a number of low-reliability studies). ECHA note – An attachment was submitted with the comment above. Refer to public attachment Umicore public consultation_final 20201215.pdf				
Dossier Submitter's Response				
The use of toxicological data on nanosilver as well as data on different silver salts for the hazard assessment of silver is based on the different forms releasing silver ions. Since all forms of elemental silver considered here, including massive silver in the absence of robust data demonstrating non-bioavailablbility, are expected to release silver ions in contact with moist and biological fluids, data investigating the toxicity of silver ions is considered relevant.				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
15.12.2020	United Kingdom	AeroSpace and Defence (ASD) Industries Association of Europe	Industry or trade association	115
Comment received				
The criteria for classifying silver as a germ cell mutagen have not been conclusively met: • there is no direct human evidence that elemental silver, or ionic silver substances, are able to induce heritable genetic mutations (nor is there useful data on somatic cell mutagenicity), • and the weight of evidence from a series of reliable studies – including in vivo models which cover multiple mutagenicity endpoints – support a non-classification for this endpoint (in contrast to the proposed classification based on a number of low-reliability studies)				

Dossier Submitter's Response
Direct evidence that silver induces heritable genetic mutations in humans is not required to fulfil criteria for classification in Category 2 as proposed in the CLH report. Classification in Category 2 includes "Substances which cause concern for humans owing to the possibility that they may induce heritable mutations in the germ cells of humans." In the absence of further information, it is not clear to the dossier submitter what reliable studies referred to should take precedence over the data presented.
RAC's response
Noted.

Date	Country	Organisation	Type of Organisation	Comment number
14.12.2020	France	<confidential>	Company-Manufacturer	116
Comment received				
The criteria for classifying silver as a germ cell mutagen have not been conclusively met: - there is no direct human evidence that ionic silver substances, or elemental silver, are able to induce heritable genetic mutations (nor is there useful data on somatic cell mutagenicity), and - a non-classification for this endpoint is supported by the weight of evidence from a series of reliable studies – including in vivo models which cover multiple mutagenicity endpoint.				
Dossier Submitter's Response				
Direct evidence that silver induces heritable genetic mutations in humans is not required to fulfil criteria for classification in Category 2 as proposed in the CLH report. Classification in Category 2 includes "Substances which cause concern for humans owing to the possibility that they may induce heritable mutations in the germ cells of humans." In the absence of further information, it is not clear to the dossier submitter what reliable studies referred to should take precedence over the data presented.				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
11.12.2020	Germany	<confidential>	Company-Manufacturer	117
Comment received				
"Germ cell mutagenicity - the criteria for classifying silver as a germ cell mutagen have not been conclusively met o there is no direct human evidence that elemental silver, or ionic silver substances, are able to induce heritable genetic mutations (nor is there useful data on somatic cell mutagenicity), and o the weight of evidence from a series of reliable studies – including in vivo models which cover multiple mutagenicity endpoints – support a non-classification for this endpoint (in contrast to the proposed classification based on a number of low-reliability studies)				
Dossier Submitter's Response				
Direct evidence that silver induces heritable genetic mutations in humans is not required to fulfil criteria for classification in Category 2 as proposed in the CLH report. Classification in Category 2 includes "Substances which cause concern for humans owing to the possibility that they may induce heritable mutations in the germ cells of humans."				

In the absence of further information, it is not clear to the dossier submitter what reliable studies referred to should take precedence over the data presented.
RAC's response
Noted.

Date	Country	Organisation	Type of Organisation	Comment number
10.12.2020	Germany	SAXONIA Technical Materials GmbH	Company-Manufacturer	118
Comment received				
elemental silver inducing heritable genetic mutations is not familiar to us, and the weight of evidence from a series of reliable studies – including in vivo models which cover multiple mutagenicity endpoints – support a non-classification for this endpoint (in contrast to the proposed classification based on a number of low-reliability studies)				
Dossier Submitter's Response				
In the absence of further information, it is not clear to the dossier submitter what reliable studies referred to should take precedence over the data presented.				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
10.12.2020	Germany	Doduco	Company-Manufacturer	119
Comment received				
no data showing direct human evidence that elemental silver is able to induce heritable genetic mutations is available				
Dossier Submitter's Response				
Thank you.				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
09.12.2020	France	Comité Colbert	Industry or trade association	120
Comment received				
The criteria for classifying silver as a germ cell mutagen have not been conclusively met. There is currently no direct human evidence that elemental silver, or ionic silver substances, are able to induce heritable genetic mutations. On the contrary, the weight of evidence from a series of reliable studies – including in vivo models which cover multiple mutagenicity endpoints – support a non-classification for this endpoint. Please refer to the EPMF full report for detailed analysis. ECHA note – An attachment was submitted with the comment above. Refer to public attachment LT_Comité_Colbert_ECHA.pdf				

Dossier Submitter's Response
Direct evidence that silver induces heritable genetic mutations in humans is not required to fulfil criteria for classification in Category 2 as proposed in the CLH report. Classification in Category 2 includes "Substances which cause concern for humans owing to the possibility that they may induce heritable mutations in the germ cells of humans." In the absence of further information, it is not clear to the dossier submitter what reliable studies referred to should take precedence over the data presented. We note the support for the comments submitted by the EPMF.
RAC's response
Noted.

Date	Country	Organisation	Type of Organisation	Comment number
08.12.2020	Germany	Heraeus Deutschland GmbH & Co. KG	Company-Manufacturer	121
Comment received				
Germ cell mutagenicity - the criteria for classifying silver as a germ cell mutagen have not been conclusively met o there is no direct human evidence that elemental silver, or ionic silver substances, are able to induce heritable genetic mutations (nor is there useful data on somatic cell mutagenicity), and o the weight of evidence from a series of reliable studies – including in vivo models which cover multiple mutagenicity endpoints – support a non-classification for this endpoint (in contrast to the proposed classification based on a number of low-reliability studies) ECHA note – An attachment was submitted with the comment above. Refer to public attachment HPT_Public Cons. Ag CLH Proposal_AH.pdf				
Dossier Submitter's Response				
Direct evidence that silver induces heritable genetic mutations in humans is not required to fulfil criteria for classification in Category 2 as proposed in the CLH report. Classification in Category 2 includes "Substances which cause concern for humans owing to the possibility that they may induce heritable mutations in the germ cells of humans." In the absence of further information, it is not clear to the dossier submitter what reliable studies referred to should take precedence over the data presented. We note the support for the comments submitted by the EPMF.				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
02.12.2020	France	Metalor Technologies	Company-Manufacturer	122
Comment received				
The criteria for classifying silver as a germ cell mutagen have not been conclusively met: o there is no direct human evidence that elemental silver, or ionic silver substances, are able to induce heritable genetic mutations (nor is there useful data on somatic cell mutagenicity), and				

o the weight of evidence from a series of reliable studies – including in vivo models which cover multiple mutagenicity endpoints – support a non-classification for this endpoint (in contrast to the proposed classification based on a number of low-reliability studies)
Dossier Submitter's Response
Direct evidence that silver induces heritable genetic mutations in humans is not required to fulfil criteria for classification in Category 2 as proposed in the CLH report. Classification in Category 2 includes "Substances which cause concern for humans owing to the possibility that they may induce heritable mutations in the germ cells of humans." In the absence of further information, it is not clear to the dossier submitter what reliable studies referred to should take precedence over the data presented. We note the support for the comments submitted by the EPMF.
RAC's response
Noted.

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Germany	AURUBIS AG	Company-Manufacturer	123
Comment received				
» Germ cell mutagenicity - the criteria for classifying silver as a germ cell mutagen have not been conclusively met: - there is no direct human evidence that elemental silver, or ionic silver substances, are able to induce heritable genetic mutations (nor is there useful data on somatic cell mutagenicity), and - the weight of evidence from a series of reliable studies – including in vivo models which cover multiple mutagenicity endpoints – support a non-classification for this endpoint (in contrast to the proposed classification based on a number of low-reliability studies) ECHA note – An attachment was submitted with the comment above. Refer to public attachment Aurubis comments to Silver CLH proposal 2020-12-18.pdf				
Dossier Submitter's Response				
Direct evidence that silver induces heritable genetic mutations in humans is not required to fulfil criteria for classification in Category 2 as proposed in the CLH report. Classification in Category 2 includes "Substances which cause concern for humans owing to the possibility that they may induce heritable mutations in the germ cells of humans." In the absence of further information, it is not clear to the dossier submitter what reliable studies referred to should take precedence over the data presented.				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	France	MONNAIE DE PARIS	Company-Downstream user	124
Comment received				
No evidence exists of direct human heritable genetic transformation or mutation. Studies even show no incidence. The classification under this risk would not be relevant to date.				

ECHA note – An attachment was submitted with the comment above. Refer to public attachment 2020 12 18 ECHA MdP 2020 survey CLH for Silver_VDEF.pdf
Dossier Submitter's Response
Thank you for the information.
RAC's response
Noted.

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	United Kingdom	EU BPR Silver Task Force	Company-Downstream user	125
Comment received				
10.8 GERM CELL MUTAGENICITY (Sections 10.8.1 – 10.8.10 – CLH Report p.72-111 The proposed basis for the classification of silver as Muta. 2; H341 is dependent on conclusions from a number of low-reliability investigations of mammalian mutagenicity/genotoxicity for elemental and ionic silver forms. In addition, it does not properly take account of the weight of evidence from a series of reliable studies – including in vivo models that cover multiple mutagenicity endpoints – that have provided clear negative results. The classification proposal places undue emphasis on published studies on silver nano-materials. These investigations are of widely varying quality and they present contradictory results as to the genotoxicity potential of silver nano particles. Our view is that classification for mutagenicity cannot be assigned to metallic silver based on these nano silver data. For further information please refer to the attached document: Silver - STF comment on Muta 2 H341 - December 2020. ECHA note – An attachment was submitted with the comment above. Refer to public attachment Silver - STF comment on Muta 2 H341 - December 2020.pdf				
Dossier Submitter's Response				
The use of toxicological data on nanosilver as well as data on different silver salts for the hazard assessment of silver is based on the different forms releasing silver ions. Since all forms of elemental silver considered here, including massive silver in the absence of robust data demonstrating non-bioavailablbility, are expected to release silver ions in contact with moist and biological fluids, data investigating the toxicity of silver ions is considered relevant. As discussed in comment 95, the article by Narciso et al suggests that smaller particles are more likely than larger particles to release silver ions from the surface. Consequently, the silver ion exposure levels may differ for different nanoparticles in similarity with the different exposures from different silver substances and thus explain differencies between results.				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Germany	AZUR SPACE Solar Power GmbH	Company-Downstream user	126
Comment received				
The criteria for classifying silver as a mutagen have not been conclusively met: o there is no direct human evidence that elemental silver, or ionic silver substances, are				

able to induce heritable genetic mutations (nor is there useful data on somatic cell mutagenicity), and o the weight of evidence from a series of reliable studies – including in vivo models which cover multiple mutagenicity endpoints – support a non-classification for this endpoint (in contrast to the proposed classification based on a number of low-reliability studies)
Dossier Submitter's Response
Direct evidence that silver induces heritable genetic mutations in humans is not required to fulfil criteria for classification in Category 2 as proposed in the CLH report. Classification in Category 2 includes "Substances which cause concern for humans owing to the possibility that they may induce heritable mutations in the germ cells of humans." In the absence of further information, it is not clear to the dossier submitter what reliable studies referred to should take precedence over the data presented.
RAC's response
Noted.

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Poland	<confidential>	Company-Manufacturer	127
Comment received				
Mutagenicity - never found nor observed in the <confidential>. ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Silver - <confidential> statement.docx				
Dossier Submitter's Response				
Thank you for the information. We note the support for the comments submitted by the European Precious Metals Federation (EPMF).				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Austria	Wirtschaftskammer Österreich		128
Comment received				
see attachment ECHA note – An attachment was submitted with the comment above. Refer to public attachment su_309_StN öK Silber CLH.pdf				
Dossier Submitter's Response				
Thank you for the information about your uses of silver. We note the support for the comments submitted by the EPMF.				
RAC's response				
Noted.				

TOXICITY TO REPRODUCTION

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Germany	WirtschaftsVereinigung Metalle	Industry or trade association	129
Comment received				
We think that the criteria for classifying silver as a reproductive toxicant have not been conclusively met due to the very limited available human information that do not sup-port a classification. The key studies used in the read-across approach show several defi-ciencies, uncertainties and inconsistencies as outlined in EPMF's detailed comments. As-signment of a developmental toxicity classification for elemental silver is therefore premature. In agreement with the REACH regulation procedures and following the deci-sion at ECHA level in June 2019 EPMF is currently performing a TG443 compliant EOGRT study (including DIT and DNT cohorts) which is designed to fill the identified data gaps for this endpoint. The results of this study will allow a conclusive judgement for this end-point and should be waited for instead of starting a CLH discussion on silver now. ECHA note – An attachment was submitted with the comment above. Refer to public attachment 2020-12-18_WVMetalle Comment on CLH Proposal for Silver.pdf				
Dossier Submitter's Response				
The Extended One-Generation Reproductive Toxicity Study (EOGRTS) is indeed expected to provide useful information however decisions under CLP must be taken without awaiting information that may become available in the future otherwise approval under the BPR and possibly other processes will be delayed. The possibility to submit new classification proposals based on new information remains. We note the support for the comments by EPMF.				
RAC's response				
Noted. Many effects from the silver nanoparticle studies may be due to a combination of particulate AND substance specific effects and frequently describe an impact on sperm motility and numbers with some evidence for changes in morphology of the germ cells. RAC is of the opinion that the published studies with silver nanoparticles support classification with category 2; H361f.				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Germany	Netzwerk NanoSilber	Industry or trade association	130
Comment received				
The criteria for classifying silver as a reproductive toxicant have not been conclusively met. The CLH report covers a very limited amount of data on reproductive toxicity in humans and does not support its classification for Cat. 1A. Additional reproductive toxicity investigations are needed to provide higher quality and information that is more robust. ECHA note – An attachment was submitted with the comment above. Refer to public attachment CLH public consultation silver - Comments by Netzwerk NanoSilber.pdf				
Dossier Submitter's Response				
Please note that the classification proposed is Cat. 1B.				

RAC's response
Noted. See response to comment 129.

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	United Kingdom	<confidential>	Company-Manufacturer	131
Comment received				
The criteria for classifying silver as a reproductive toxicant have not been conclusively met: • During ECHA's Testing Proposal Evaluation for reproductive toxicity endpoints (of the silver compounds REACH registrations) – which included consultation with MSCAs – it was decided that the Extended One Generation Reproductive Toxicity study (EOGRTs) was required to fill this datagap. This should be seen as a clear indication that this robust evaluation process determined insufficient reliable and relevant data were available to confirm classification or not. • Registrants have initiated work to meet the ECHA decision on the EOGRTs, which is a complex and expensive study to perform, with results to be provided by January 2022. • The evaluation of the proposed reproductive toxicity classification should preferably only be initiated once the data from this potentially definitive study, which to reiterate has been required following a regulatory decision under REACH, are available for consideration. ECHA note – An attachment was submitted with the comment above. Refer to public attachment Silver products.pdf				
Dossier Submitter's Response				
The Extended One-Generation Reproductive Toxicity Study (EOGRTS) is indeed expected to provide useful information however decisions under CLP must be taken without awaiting information that may become available in the future otherwise approval under the BPR and possibly other processes will be delayed. The possibility to submit new classification proposals based on new information remains. We note the support for the comments by EPMF.				
RAC's response				
Noted. See response to comment 129.				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Portugal	<confidential>	Company-Manufacturer	132
Comment received				
To the best of our knwledge, the criteria for classifying silver as a reproductive toxicant have not been conclusively met: o the very limited available human data do not support a classification as reproductive toxicant, o the strength of the evidence from animal studies do currently not provide clear evidence of an adverse effect on sexual function/fertility, and o the key studies used in a read-across approach show several deficiencies, uncertainties and inconsistencies as outlined in EPMF's detailed comments. Assignment of a developmental toxicity classification for elemental silver at this time is premature. The				

Europea Precious Metals Federation (EPMF) is currently performing a TG443 compliant EOGRTS (under EU REACH; including DIT and DNT cohorts). The study is designed to fill the identified datagaps for this endpoint and will allow a conclusive judgement for this endpoint.
Dossier Submitter's Response
The Extended One-Generation Reproductive Toxicity Study (EOGRTS) is indeed expected to provide useful information however decisions under CLP must be taken without awaiting information that may become available in the future otherwise approval under the BPR and possibly other processes will be delayed. The possibility to submit new classification proposals based on new information remains. We note the support for the comments by EPMF.
RAC's response
Noted. See response to comment 129.

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Germany	aap Implantate AG	Company-Manufacturer	133
Comment received				
The criteria for classification as toxic for reproduction cannot be confirmed. ECHA note – An attachment was submitted with the comment above. Refer to public attachment aap Implantate AG_CLH_public_consultation_non-confidential_CAS 7440-22-4.pdf ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment aap Implantate AG_CLH_public_consultation_confidential_CAS 7440-22-4.pdf				
Dossier Submitter's Response				
Thank you for the information. In the absence of further information, it is unclear if results from the toxicological studies referred to were performed with a silver substance and concentration representing 100% of silver. We note the support for the comments submitted by the EPMF.				
RAC's response				
Noted. See response to comment 129.				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	United Kingdom	Ames Goldsmith UK Ltd	Company-Manufacturer	134
Comment received				
• Reproductive toxicity - the criteria for classifying silver as a reproductive toxicant have not been conclusively met: o the very limited available human data do not support a classification as reproductive toxicant, o the strength of the evidence from animal studies do currently not provide clear evidence of an adverse effect on sexual function/fertility, and o the key studies used in a read-across approach show several deficiencies, uncertainties and inconsistencies as outlined in EPMF's detailed comments. Assignment of a developmental toxicity classification for elemental silver at this time is premature. The EPMF is currently				

performing a TG443 compliant EOGRTS (under EU REACH; including DIT and DNT cohorts). The study is designed to fill the identified datagaps for this endpoint and will allow a conclusive judgement for this endpoint.
Dossier Submitter's Response
The Extended One-Generation Reproductive Toxicity Study (EOGRTS) is indeed expected to provide useful information however decisions under CLP must be taken without awaiting information that may become available in the future otherwise approval under the BPR and possibly other processes will be delayed. The possibility to submit new classification proposals based on new information remains. We note the support for the comments by EPMF.
RAC's response
Noted. See response to comment 129.

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Italy	<confidential>	Company-Manufacturer	135
Comment received				
no evidence ECHA note – An attachment was submitted with the comment above. Refer to public attachment 2020 12 17 Public attachment in the questionnarie <confidential> (003).docx				
Dossier Submitter's Response				
Thank you. We note the support for the comments by EPMF.				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Poland		Individual	136
Comment received				
• Reproductive toxicity - the criteria for classifying silver as a reproductive toxicant have not been conclusively met: ☐ the very limited available human data do not support a classification as reproductive toxicant, ☐ the strength of the evidence from animal studies do currently not provide clear evidence of an adverse effect on sexual function/fertility, and ☐ the key studies used in a read-across approach show several deficiencies, uncertainties and inconsistencies as outlined in EPMF's detailed comments. Assignment of a developmental toxicity classification for elemental silver at this time is premature. The EPMF is currently performing a TG443 compliant EOGRTS (under EU REACH; including DIT and DNT cohorts). The study is designed to fill the identified datagaps for this endpoint and will allow a conclusive judgement for this endpoint. ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment comment.pdf				
Dossier Submitter's Response				
The Extended One-Generation Reproductive Toxicity Study (EOGRTS) is indeed expected to provide useful information however decisions under CLP must be taken without				

awaiting information that may become available in the future otherwise approval under the BPR and possibly other processes will be delayed. The possibility to submit new classification proposals based on new information remains. We note the support for the comments by EPMF.
RAC's response
Noted. See response to comment 129.

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Germany	Bio-Gate AG	Company-Manufacturer	137
Comment received				
- the criteria for classifying silver as a reproductive toxicant have not been conclusively met: - the very limited available human data do not support a classification as reproductive toxicant, - the strength of the evidence from animal studies do currently not provide clear evidence of an adverse effect on sexual function/fertility, and - the key studies used in a read-across approach show several deficiencies, uncertainties and inconsistencies as outlined in EPMF's detailed comments. Assignment of a developmental toxicity classification for elemental silver at this time is premature. The EPMF is currently performing a TG443 compliant EOGRTS (under EU REACH; including DIT and DNT cohorts). The study is designed to fill the identified datagaps for this endpoint and will allow a conclusive judgement for this endpoint. - when used in cosmetic applications metallic/elemental silver like MicroSilver BG it not able to penetrate the skin or mucosa tissue (please see attached studies on skin penetration), therefore an effect like reproductive toxicity is not possible - to use silver nitrate as a surrogate for metallic/elemental silver cannot be justified as silver nitrate and other silver types have a very different silver ion release profile than elemental silver, which as a precious metal releases a low amount silver ions. Please see attached a human study on bone cement with metallic/elemental silver where silver ions only have an effect in the viscinity of the bone cement. The elution profile and bioavailability of the generated silver ions is so low that it is not possible for the amount of silver ions to induce reproductive toxicity. ECHA note – An attachment was submitted with the comment above. Refer to public attachment Bio-Gate Safety Studies.zip ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Bio-Gate Microsilver BG Confidential Safety Studies.zip				
Dossier Submitter's Response				
The Extended One-Generation Reproductive Toxicity Study (EOGRTS) is indeed expected to provide useful information however decisions under CLP must be taken without awaiting information that may become available in the future otherwise approval under the BPR and possibly other processes will be delayed. The possibility to submit new classification proposals based on new information remains. We doubt that the data submitted is relevant to assess the intrinsic reproductive toxicity potential of silver (ions). We note the support for the comments by EPMF.				
RAC's response				
Noted. See response to comment 129.				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Germany	I&P Europe - Imaging and Printing Association e.V.	Industry or trade association	138
Comment received				
see attached document ECHA note – An attachment was submitted with the comment above. Refer to public attachment Comments to the silver metal CLH public consultation.pdf				
Dossier Submitter's Response				
Thank you. We note the support for the comments by EPMF.				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Belgium	T&D Europe	Industry or trade association	139
Comment received				
no comment ECHA note – An attachment was submitted with the comment above. Refer to public attachment TD Europe CLH Consultation Silver_Dec2020_final.pdf				
Dossier Submitter's Response				
We understand that classification and labelling may have consequences for companies however this is not within the scope of the CLP process. Moreover, exposure and the use of personal protective equipment during certain uses of silver is not taken into account for classification and labelling since it is based on the intrinsic properties of the active substance.				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Finland		MemberState	140
Comment received				
The dossier submitter proposes to classify silver Repr. 1B; H360F. We do not consider the data sufficient for Repr. 1B; H360F. Instead, it should be considered whether classification for Repr. 2; H361f is warranted for the substance. The proposal for Repr. 1B; 360F is primarily based on a few findings (reduced female fertility index, reduced number of implantations) in high dose animals of one one generation study with silver acetate (open literature publication). This study has major deficiencies. The two OECD guideline compliant two-generation studies with different silver containing active substances do not provide support for the findings of the one generation study. In our opinion, the justification for giving more weight on a few positive findings of the one-generation study and dismissing the negative findings of the two two-				

generation studies is insufficient.

In the CLH-report the reproductive toxicity of the silver is assessed based on indirect information from studies performed with different silver containing active substances (SCAS) that release silver ions and studies on nanosilver. These include one-generation reproductive toxicity study with silver acetate (open literature publication, non GLP, according to FDA CFSAN Redbook, 2000), the two OECD TG 416 compliant two-generation studies performed with silver zinc zeolite and silver sodium zirconium hydrogenphosphate and open literature publications with nanosilver. In the CLH-report there is no reference for the publication of one generation study, but it appears to be Sprando RL et al. Silver acetate exposure: Effects on reproduction and post natal development. Food Chem Toxicol Aug; 106(PtA):547-557, 2017. We note that apparently before its publication the same data/study has been provided to EFSA for the Re-evaluation of silver (E 174) as food additive (EFSA Journal 2016;14(1):4364). Perhaps more detailed data than presented in the publication, could be available.

The dossier submitter proposes to classify silver for Repr. 1B ;H360F on the basis of following findings:
- The reduction of female fertility index (10%, not statistically analysed) and the statistically significant reduction of the number of implantations (22%, 11.3 compared to 14.4 in control) in high dose dams observed in the one generation study with silver acetate (IIIA 6.8.2-06).
- Effects on spermatogenesis and number of spermatogenic cells and delay in onset of puberty in open literature studies with nanosilver.

Female fertility index and the reduced number of implantations
According to dossier submitter no statistical analyses has been performed on the female fertility index data and no individual animal data is available for the one-generation study with silver acetate. Moreover, several important parameters e.g. oestrus cyclicity, sperm parameters, histopathology of the reproductive organs (other than testes) have not been analysed in this study. It is therefore difficult to assess the toxicological significance of this result. The 10 % decrease in female fertility index is due to two dams which did not become pregnant i.e did not have implantation sites (two dams had total resorptions and did not produce litters). The difference in ability of males to produce litters between the control and the high dose group is small (16 high dose males produced litter vs. 17 control males). The data does not reveal the ability of high dose males to produce sperm that can fertilize egg (male fertility index) since implantations are not reported with respect to male data. According to publication testes weights were measured from all treatment groups and histopathology was analysed from 10 control and high dose individuals but there were no remarkable findings (it remains unclear whether testes were analysed histopathologically also from the pups). We note that this negative finding is not stated in the CLH-report.

No effects on fertily index or implantations are reported in the two-generation studies with silver sodium zirconium hydrogenphosphate and silver zinc zeolite. Only some findings of unknown significance are reported in these studies (e.g. changes in semen parameters, pre-coital interval of females, gestation length, the primordial follicle counts). The results of the two two generation studies therefore do not support the findings of the one generation study and classification for Repr. 1B; H360F.

The dossier submitter considers the two-generation studies most robust, but the classification proposal gives more weight for the one-generation study and the open

literature studies with nanosilver. On pages 147- 148 of the CLH-report this is justified as follows: ”The data on silver zinc zeolite and silver sodium zirconium hydrogen phosphate are considered most robust but the substances also contain additional elements of possible toxicological significance and the amount of silver ions tested are limited by silver content and release. Therefore, data for a particular SCAS is not given precedence over another in this assessment, rather are positive findings noted for several SCAS given preference over negative results taking also into consideration silver content and release.”… “Although the estimated dose of silver ions tested actually was higher in the study with silver sodium hydrogen zirconium phosphate compared to the one-generation study with silver acetate, the latter was administered in drinking water and thus in ionic form compared to silver sodium hydrogen zirconium phosphate which was administered mixed in diet. Silver ions easily bind to thiol groups of proteins and the formation of different silver complexes with biomolecules may at least theoretically limit the availability of silver ions for absorption in the gastrointestinal tract.” We doubt whether this justification for dismissing the negative findings of two guideline compliant two-generation studies is appropriate. The justification seems to only be based on theoretical considerations, not on data on poorer bioavailability of silver ions in these studies. Therefore, the CLH-report seems to give preference for positive findings over negative findings without proper justification (e.g. reliability or relevance of the studies).

Effects on spermatogenesis and number of spermatogenic cells and delay in onset of puberty in open literature studies with nanosilver.
In the CLH report the results from several studies performed with nanosilver are considered to support an effect of silver ions on germ cells as they show a reduced number of sperm and alterations in sperm morphology (IIIB, 6.8.2-14, Miresmaeili et al., 2013; IIIB, 6.8.2-15, Baki, et al., 2014; IIIB, 6.8.2-17, Mathias et al., 2015; IIIB, 6.8.2-18, Thakur et al., 2014; IIIB, 6.8.2-19, Lafuente, et al., 2016; and Gromadzka-Ostrowska et al., 2012). The studies are not performed according to guidelines or the principles of GLP hence fewer animals and dose levels than required in guidelines were used in most of the studies. Therefore, as stated in the CLH-report it is difficult to assess the reliability and relevance of the results.

In conclusion, we dot not consider the data presented as clear evidence of an adverse effect on sexual function and fertility and thus sufficient to classification for Repr. 1B; 360F Instead, it should be considered whether classification for Repr. 2; 360f is warranted.

Dossier Submitter’s Response
Please see our response to comment 145.
RAC’s response
Noted. Finland’s concern is echoed by RAC and we agree that the data does not support Cat1B classification. It would seem that the strongest argument for Cat. 2 is from public literature regarding sperm parameters. RAC acknowledges that this with concern and a case for Cat2 was proposed. See response to comment 129.

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Germany	<confidential>	Company-Manufacturer	141
Comment received				
o the very limited available human data do not support a classification as reproductive toxicant, o the strength of the evidence from animal studies do currently not provide clear evidence of an adverse effect on sexual function/fertility, and o the key studies used in a read-across approach show several deficiencies, uncertainties and inconsistencies as outlined in EPMF's detailed comments. Assignment of a developmental toxicity classification for elemental silver at this time is premature. The EPMF is currently performing a TG443 compliant EOGRTS (under EU REACH; including DIT and DNT cohorts). The study is designed to fill the identified datagaps for this endpoint and will allow a conclusive judgement for this endpoint.				
Dossier Submitter's Response				
The Extended One-Generation Reproductive Toxicity Study (EOGRTS) is indeed expected to provide useful information however decisions under CLP must be taken without awaiting information that may become available in the future otherwise approval under the BPR and possibly other processes will be delayed. The possibility to submit new classification proposals based on new information remains. We note the support for the comments by EPMF.				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	France		MemberState	142
Comment received				
In agreement with the proposal of classification: Repr. 1B, H360FD				
Dossier Submitter's Response				
Thank you.				
RAC's response				
Noted. RAC does not support Cat1 for either fertility or development but does consider classification for Repr. 2; 361f is warranted. See response to comment 129.				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Germany	ZVEI - German Electrical and Electronic Manufacturers' Association	Industry or trade association	143
Comment received				
The criteria for classifying silver as a reproductive toxicant have not been conclusively met:				

o the very limited available data on human toxicological investigations do not support a classification as reproductive toxicant, o the strength of the evidence from animal studies do currently not provide clear evidence of an adverse effect on sexual function/fertility, and o the key studies used in a read-across approach show several deficiencies, uncertainties and inconsistencies as outlined in EPMF's detailed comments. Assignment of a developmental toxicity classification for elemental silver at this time is premature. The EPMF is currently performing a TG443 compliant Extended One-Generation Reproductive Toxicity Study (EOGRTS) (under EU REACH; including DIT and DNT cohorts). The study is designed to fill the identified data gaps for this endpoint and will allow a conclusive judgement for this endpoint. ECHA note – An attachment was submitted with the comment above. Refer to public attachment 20201218 ZVEI Silver Applications in EEE and Comments Ag CLH Consultation.pdf
Dossier Submitter's Response
The Extended One-Generation Reproductive Toxicity Study (EOGRTS) is indeed expected to provide useful information however decisions under CLP must be taken without awaiting information that may become available in the future otherwise approval under the BPR and possibly other processes will be delayed. The possibility to submit new classification proposals based on new information remains. We note the support for the comments by EPMF.
RAC's response
Noted. See response to comment 129.

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Germany	C.HAFNER GmbH + Co. KG	Company-Manufacturer	144
Comment received				
The criteria for classifying silver as a reproductive toxicant have not been conclusively met: o the very limited available human data do not support a classification as reproductive toxicant, o the strength of the evidence from animal studies do currently not provide clear evidence of an adverse effect on sexual function/fertility, and o the key studies used in a read-across approach show several deficiencies, uncertainties and inconsistencies as outlined in EPMF's detailed comments. Assignment of a developmental toxicity classification for elemental silver at this time is premature. The EPMF is currently performing a TG443 compliant EOGRTS (under EU REACH; including DIT and DNT cohorts). The study is designed to fill the identified datagaps for this endpoint and will allow a conclusive judgement for this endpoint. Please refer to the scientific comments submitted by the European Precious Metals Federation (EPMF).				
Dossier Submitter's Response				
The Extended One-Generation Reproductive Toxicity Study (EOGRTS) is indeed expected to provide useful information however decisions under CLP must be taken without awaiting information that may become available in the future otherwise approval under the BPR and possibly other processes will be delayed. The possibility to submit new				

classification proposals based on new information remains. We note the support for the comments by EPMF.
RAC's response
Noted. See response to comment 129.

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Belgium	European Precious Metals Federation (EPMF)	Industry or trade association	145

Comment received

Summary of comments on reproductive toxicity (CLH report p.121-194):
The criteria for classifying silver as a reproductive toxicant have not been conclusively met:
o the very limited available human data do not support a classification as reproductive toxicant,
o the strength of the evidence from animal studies do currently not provide clear evidence of an adverse effect on sexual function/fertility, and
o the key studies used in a read-across approach show several deficiencies, uncertainties and inconsistencies as outlined in EPMF's detailed comments. Assignment of a reprotoxicity classification for elemental silver at this time is premature. The EPMF is currently performing a TG443 compliant EOGRTS with silver acetate (under EU REACH; including DIT and DNT cohorts). The study is designed to fill the identified data gaps for this endpoint and will allow a conclusive judgement for this endpoint for ionic silver (with read-across to silver depending on ongoing TK studies). During ECHA's Testing Proposal Evaluation for reproductive toxicity endpoints – which included consultation with MSCAs – it was decided that the EOGRTS was required. This is a clear indication that this evaluation process determined insufficient reliable and relevant data were available to confirm classification or not.
For further details / justification, please refer to the attached document pages 34-47.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment CLH Ag Comments FINAL_201217.pdf

Dossier Submitter's Response

The comments on reproductive toxicity is submitted in the form of a debate comprising 14 pages. Please find below comments from the DS on some specific statements made.

Certainly the CLH report does not include all information on any silver substance available. Only in Pub Med (biomedical literature from MEDLINE, life science journals, and online booksilver), the search terms silver and nanosilver generates 111,942 and 4000 results, respectively. As stated in section 4, submitting a proposal for classification and labelling was justified by the requirements for the review of silver under the BPR. Reviewing all information of possible relevance is not manageable but the information discussed in this CLH report is a compilation of published or industry-sponsored information submitted by the applicant to fulfil the data requirements under the BPR, information from the REACH registration dossier or additional published information identified by the dossier submitter. The information has thus not been selected exclusively by the dossier submitter and we expect the information to reflect, as far as possible, the true properties of silver.
The reliability of studies could be more thoroughly discussed or be illustrated and categorised in different ways. However, data is yet the same and we think it is quite clear

in the report that the assessment is based on data obtained in studies that, in isolation, may be of low reliability but in a WoE approach can provide sufficient information on the substance. The difference between a reliability score of 2 and 3 for a published study is difficult to assess and inevitably subjected to some subjectiveness, in the REACH registration dossier as well. Moreover, when giving weight to certain studies, not only reliability but relevance of data for certain silver substances is taken into account. Tests performed with silver substances with low amount of silver and/or limited solubility may not accurately reflect the intrinsic genotoxic of silver and thus be given less weight.

The 422 study by Hong 2014 referred to by EPMF as well-conducted and reliable is yet a screening study. As recognised in the OECD 422 guideline *"This Guideline is designed to generate limited information concerning the effects of a test chemical on male and female reproductive performance such as gonadal function, mating behaviour, conception, development of the conceptus and parturition. It is not an alternative to, nor does it replace the existing Test Guidelines 414, 415, 416 or 443."*
The classification proposal for fertility is primarily based on the data on silver acetate and various publications on nanosilver indicating effects on germ cells. Data obtained with different SCAS are considered more robust but only to provide information on a certain level of silver exposure and the possible influence of other elements in the SCAS is also recognised. However, in response to comments made by the EPMF it should be noted that the kidney effects observed with SZZ were more severe in males based on higher incidences/severity of chronic interstitial nephritis and the mortality among parental animals was observed in males.
The plausible mechanism for the devolpmental toxicity observed, i.e. silver competing with copper for binding to ceruloplasmin, is likely exacerbated by the presence of zinc in SZZ. This may explain differences in developmental toxicity between SZZ and SSHZP when tested at similar levels and both administered in diet.
Both negative and positive findings are taken into account but it is not considered safe to overrule severe findings in several studies by negative results taking also into account that results may depend on the amount of silver ions released from different types of nanoparticles.
"As for other nanosized particles of the same elemental composition (EFSA Scientific Committee et al., 2018), the physicochemical characteristics, including size, can lead to different biological activities, thus affecting the outcome of hazard identification."
Regarding the statement that the increased number of runts in the study by Sprando was only seen in the mid but not the top dose, the CLH report suggests that this could be due to the foetal/pup mortality in the high group masking such effects.
Finally, we agree that there are many deficiencies in study design in the published studies. However, it should be noted that several of the deficiencies pointed out by the EPMF, e.g. low number of animals, one dose level would actually reduce the ability to detect adverse effects.

RAC's response

Noted. See response to comment 129.

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Netherlands		MemberState	146

Comment received

1. Sexual function and fertility

The dossier submitter proposes to classify silver for adverse effects on for sexual function

and fertily in category 1B, with heavy weight to the data from the study with silver acetate. It is noted only the highest dose level caused some fertility parameters to be affected in the presence of other toxicity (significant organ weight changes). The adverse effects were limited to 10% lower fertility index and 22% fewer implantations. This study was not GLP compliant. The NL-CA considers there are some uncertainties related to the outcome of this study and therefore a classification in category 2 may be more appropriate based on this study alone. However, numerous other studies indicate silver (nanoparticles) cause changes in several sexual function related parameters (e.g. sperm). There is no confirmation if these findings lead to actual adverse effects on fertility apart from the study with silver acetate. Overall the NL-CA considers the body of evidence to indicate silver is likely to be able to cause adverse effects on sexual function and fertility with minor uncertainty. Classification for effects on sexual function and fertility in category 1B can therefore be supported. 2. Developmental toxicity We agree that there is sufficient evidence to fulfil the classification criteria for adverse effects on development category 1B. There is evidence of developmental toxicity as a result of exposure to a variety of silver containing substances, such as silver chloride, silver acetate, silver zinc zeolite, silver sodium zirconium hydrogenphospate and nanosilver. Some confounding effects such as differences in administration routes, duration of exposure and the presence of zinc or zirconium may have altered the study outcomes. Nevertheless, developmental toxicity, i.e. increased mortality rates of pups, chryptorchidism, and lower pup weights occurred in the majority of the described studies without relevant maternal toxicity. The proposed mechanism for toxicity is copper deficiency due to competitive binding of silver and copper for ceruloplasmin which seems plausible and increases the certainty silver is able to cause developmental toxicity. As this mechanism is considered to be relevant to humans, classification in category 1B is appropriate.
Dossier Submitter's Response
Thank you. Our interpretation of available data is that the developmental toxicity of different silver compounds depends on the amount of silver ions exposed to which in turn depends on e.g. silver content and release. The plausible mechanism for the devolpmental toxicity observed, i.e. silver competing with copper for binding to ceruloplasmin, is likely exacerbated by the presence of zinc in SZZ. This may explain differences in developmental toxicity between SZZ and SSHZP when tested at similar levels and both administered in diet.
RAC's response
Noted. RAC does not support 1B classification. Read across is not supported, there are important differences between the tested compounds that give rise to different Ag+ ion exposures. Some of the tested substances are unlikely to be representative of elemental silver metal. The main cause for concern are effects on sperm parameters from published papers investigating silver nanoforms. Classification for Repr. 2; 361f is considered warranted by RAC. See also response to comment 129.

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Netherlands	<confidential>	Company-Manufacturer	147
Comment received				
Reproductive toxicity - the criteria for classifying silver as a reproductive toxicant have not been conclusively met: * the very limited available human data do not support a classification as reproductive toxicant * the strength of the evidence from animal studies do currently not provide clear evidence of an adverse effect on sexual function/fertility * the key studies used in a read-across approach show several deficiencies, uncertainties and inconsistencies as outlined in EPMF's detailed comments. Assignment of a developmental toxicity classification for elemental silver at this time is premature. The EPMF is currently performing a TG443 compliant EOGRTS. The study is designed to fill the identified datagaps for this endpoint and will allow a conclusive judgement for this endpoint.				
Dossier Submitter's Response				
The Extended One-Generation Reproductive Toxicity Study (EOGRTS) is indeed expected to provide useful information however decisions under CLP must be taken without awaiting information that may become available in the future otherwise approval under the BPR and possibly other processes will be delayed. The possibility to submit new classification proposals based on new information remains.				
RAC's response				
Noted. See also response to comments 129, 140 and 146.				

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	France	FRANCECLAT, BOCI and UFBJOP	Industry or trade association	148
Comment received				
Please find our comments on this specific hazard in the attached document. ECHA note – An attachment was submitted with the comment above. Refer to public attachment Comments on CLH proposal for silver.pdf				
Dossier Submitter's Response				
Thank you for the information about your uses of silver. We understand that classification and labelling may have consequences for companies however this is not within the scope of the CLP process. Moreover, exposure and the use of personal protective equipment during certain uses of silver is not taken into account for classification and labelling since it is based on the intrinsic properties of the active substance. Consequences of C & L may be handled by downstream regulations. The justification for submitting a proposal is indeed based on the requirement for an opinion on harmonised classification and labelling in the review under the BPR. However, the CLH report also informs that there are more uses than the intended biocidal uses triggering an action "Apart from biocidal use, silver has 92 active registrations under REACH in June 2019. It has wide uses by industry, professionals and consumers." Information on the different uses and forms of silver on the market is important to assure that the data used for the proposal relate to the forms or physical states in which the substance is placed on the market and in which it can reasonably be expected to be used,				

otherwise uses are not taken into account for the assessment if criteria for classification are fulfilled. The number of robust and reliable studies available for the forms or physical states in which the substance is placed on the market is limited. However, similar effects are seen among different studies with various silver substances and this is the basis why studies with different silver substances releasing silver ions are considered for the assessment. The Extended One-Generation Reproductive Toxicity Study (EOGRTS) is indeed expected to provide useful information however decisions under CLP must be taken without awaiting information that may become available in the future otherwise approval under the BPR and possibly other processes will be delayed. The possibility to submit new classification proposals based on new information remains. We note the support for the comments by EPMF.
RAC's response
Noted.

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Germany	Fachvereinigung Edelmetalle e. V.	Industry or trade association	149
Comment received				
The criteria of classifying silver as a reproductive toxicant have not been consistenty met: o the very limited available human data do not support a classification as repro-ductive toxicant, o the strength of the evidence from animal studies do currently not provide clear evidence of an adverse effect on sexual function/fertility, and o the key studies used in a read-across approach show several deficiencies, uncertainties and inconsistencies as outlined in EPMF's detailed comments. Assignment of a developmental toxicity classification for elemental silver at this time is premature. The EPMF is currently performing a TG443 compliant EOGRTS (under EU REACH; including DIT and DNT cohorts). The study is designed to fill the identified datagaps for this endpoint and will allow a conclu-sive judgement for this endpoint. ECHA note – An attachment was submitted with the comment above. Refer to public attachment FVEM comments CLH silver.pdf				
Dossier Submitter's Response				
The Extended One-Generation Reproductive Toxicity Study (EOGRTS) is indeed expected to provide useful information however decisions under CLP must be taken without awaiting information that may become available in the future otherwise approval under the BPR and possibly other processes will be delayed. The possibility to submit new classification proposals based on new information remains. We note the support for the comments by EPMF.				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Germany	Federal Associations of the German Jewellery and Silverware Industry	Industry or trade association	150

Comment received

The criteria for classifying silver as a reproductive toxicant have not been conclusively met:
- the very limited available human data do not support a classification as reproductive toxicant,
- the strength of the evidence from animal studies do currently not provide clear evidence of an adverse effect on sexual function/fertility, and
- the key studies used in a read-across approach show several deficiencies, uncertainties and inconsistencies as outlined in EPMF's detailed comments. Assignment of a develop-mental toxicity classification for elemental silver at this time is premature. The EPMF is currently performing a TG443 compliant EOGRTS (under EU REACH; including DIT and DNT cohorts). The study is designed to fill the identified datagaps for this endpoint and will allow a conclusive judgement for this endpoint.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment 20201216-comments-vbv-clh-silver.pdf

Dossier Submitter's Response

The Extended One-Generation Reproductive Toxicity Study (EOGRTS) is indeed expected to provide useful information however decisions under CLP must be taken without awaiting information that may become available in the future otherwise approval under the BPR and possibly other processes will be delayed. The possibility to submit new classification proposals based on new information remains. We note the support for the comments by EPMF.

RAC's response

Noted. See also response to comments 129, 140 and 146.

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Italy	IPZS S.p.A.	Company-Manufacturer	151

Comment received

no evidence

ECHA note – An attachment was submitted with the comment above. Refer to public attachment Public attachment in the questionnarie.docx

Dossier Submitter's Response

Thank you for the information.
We note the support the comments submitted by the European Precious Metals Federation (EPMF).

RAC's response

Noted.

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Germany	HAGER GROUP	Company-Downstream user	152
Comment received				
Reproductive toxicity - the criteria for classifying silver as a reproductive toxicant have not been conclusively met: o the very limited available human data do not support a classification as reproductive toxicant, o the strength of the evidence from animal studies do currently not provide clear evidence of an adverse effect on sexual function/fertility, and o the key studies used in a read-across approach show several deficiencies, uncertainties and inconsistencies as outlined in EPMF's detailed comments. Assignment of a developmental toxicity classification for elemental silver at this time is premature. The EPMF is currently performing a TG443 compliant EOGRTS (under EU REACH; including DIT and DNT cohorts). The study is designed to fill the identified data gaps for this endpoint and will allow a conclusive judgement for this endpoint. ECHA note – An attachment was submitted with the comment above. Refer to public attachment CHL Ag- DU contribution- Hager group.docx				
Dossier Submitter's Response				
Thank you for the information on your uses of silver. The Extended One-Generation Reproductive Toxicity Study (EOGRTS) is indeed expected to provide useful information however decisions under CLP must be taken without awaiting information that may become available in the future otherwise approval under the BPR and possibly other processes will be delayed. The possibility to submit new classification proposals based on new information remains. We note the support for the comments by EPMF.				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Czech Republic	SAFINA, a.s.	Company-Manufacturer	153
Comment received				
Please see the attached file. ECHA note – An attachment was submitted with the comment above. Refer to public attachment SAFINA_CLH public consultation_silver metal - completed.pdf				
Dossier Submitter's Response				
Thank you for the information about your uses of silver. We note the support for the comments submitted by the EPMF.				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Norway	<confidential>	Company-Manufacturer	154
Comment received				
The criteria for classifying silver as a reproductive toxicant have not been conclusively met:				

- the very limited available human data do not support a classification as reproductive toxicant, - the strength of the evidence from animal studies do currently not provide clear evidence of an adverse effect on sexual function/fertility - the key studies used in a read-across approach show several deficiencies, uncertainties and inconsistencies as outlined in EPMF's detailed comments. Assignment of a developmental toxicity classification for elemental silver at this time is premature. The EPMF is currently performing a TG443 compliant EOGRTS (under EU REACH; including DIT and DNT cohorts). The study is designed to fill the identified datagaps for this endpoint and will allow a conclusive judgement for this endpoint. ECHA note – An attachment was submitted with the comment above. Refer to public attachment Comments CLH Ag -17.12.20.pdf ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Comments CLH Ag - <confidential> - 17.12.20 - confidential info.pdf
Dossier Submitter's Response
Thank you for the information on your uses of silver. The Extended One-Generation Reproductive Toxicity Study (EOGRTS) is indeed expected to provide useful information however decisions under CLP must be taken without awaiting information that may become available in the future otherwise approval under the BPR and possibly other processes will be delayed. The possibility to submit new classification proposals based on new information remains. We note the support for the comments by EPMF.
RAC's response
Noted.

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Germany	Heimerle + Meule GmbH	Company-Manufacturer	155
Comment received				
The criteria of classifying silver as a reproductive toxicant have not been consistently met: o the very limited available human data do not support a classification as reproductive toxicant, o the strength of the evidence from animal studies do currently not provide clear evidence of an adverse effect on sexual function/fertility, and o the key studies used in a read-across approach show several deficiencies, uncertainties and inconsistencies as outlined in EPMF's detailed comments. Assignment of a developmental toxicity classification for elemental silver at this time is premature. The EPMF is currently performing a TG443 compliant EOGRTS (under EU REACH; including DIT and DNT cohorts). The study is designed to fill the identified data gaps for this endpoint and will allow a conclusive judgement for this endpoint. ECHA note – An attachment was submitted with the comment above. Refer to public attachment H+M comments CLH silver.pdf				
Dossier Submitter's Response				
Thank you for the information regarding your uses of silver. The Extended One-Generation Reproductive Toxicity Study (EOGRTS) is indeed expected to provide useful information however decisions under CLP must be taken without awaiting information that may become available in the future otherwise approval under the BPR and possibly other				

processes will be delayed. The possibility to submit new classification proposals based on new information remains. We note the support for the comments by EPMF.
RAC's response
Noted.

Date	Country	Organisation	Type of Organisation	Comment number
16.12.2020	Germany	Siemens AG	Company-Manufacturer	156
Comment received				
Based on our assessment of the report and the discussion with industry experts, we think that the criteria for classifying silver as reproduction toxic have not been conclusively met. We would like to point out that the very limited available data on human toxicological investigations do not support a classification as reproductive toxicant. Further does the strength of the evidence from animal studies currently not provide clear evidence of an adverse effect on sexual function/fertility, and the key studies used in a read-across approach show several deficiencies, uncertainties and inconsistencies. Hence we see the assignment of a developmental toxicity classification for elemental silver at this time as being premature.				
Dossier Submitter's Response				
Thank you.				
RAC's response				
Noted. See also response to comments 129, 140 and 146.				

Date	Country	Organisation	Type of Organisation	Comment number
16.12.2020	Germany	<confidential>	Industry or trade association	157
Comment received				
The criteria for classifying silver as a reproductive toxicant have not been conclusively met: - the very limited available human data do not support a classification as reproductive tox-icant, - the strength of the evidence from animal studies do currently not provide clear evidence of an adverse effect on sexual function/fertility, and - the key studies used in a read-across approach show several deficiencies, uncertainties and inconsistencies as outlined in EPMF's detailed comments. Assignment of a develop-mental toxicity classification for elemental silver at this time is premature. The EPMF is currently performing a TG443 compliant EOGRTS (under EU REACH; including DIT and DNT cohorts). The study is designed to fill the identified datagaps for this endpoint and will allow a conclusive judgement for this endpoint. ECHA note – An attachment was submitted with the comment above. Refer to public attachment 20201214-<confidential>-clh-silver-comments.pdf				
Dossier Submitter's Response				
Thank you for the information regarding your uses of silver. The Extended One-Generation Reproductive Toxicity Study (EOGRTS) is indeed expected to provide useful information however decisions under CLP must be taken without awaiting information that may become available in the future otherwise approval under the BPR and possibly other processes will be delayed. The possibility to submit new classification proposals based on new information remains. We note the support for the comments by EPMF.				

RAC's response
Noted.

Date	Country	Organisation	Type of Organisation	Comment number
16.12.2020	Finland	<confidential>	Company-Manufacturer	158
Comment received				
the criteria for classifying silver as a reproductive toxicant have not been conclusively met: the very limited available human data do not support a classification as reproductive toxicant, the strength of the evidence from animal studies do currently not provide clear evidence of an adverse effect on sexual function/fertility, and the key studies used in a read-across approach show several deficiencies, uncertainties and inconsistencies as outlined in EPMF's detailed comments. Assignment of a developmental toxicity classification for elemental silver at this time is premature. The EPMF is currently performing a TG443 compliant EOGRTS (under EU REACH; including DIT and DNT cohorts). The study is designed to fill the identified datagaps for this endpoint and will allow a conclusive judgement for this endpoint.				
Dossier Submitter's Response				
Thank you for the information regarding your uses of silver. The Extended One-Generation Reproductive Toxicity Study (EOGRTS) is indeed expected to provide useful information however decisions under CLP must be taken without awaiting information that may become available in the future otherwise approval under the BPR and possibly other processes will be delayed. The possibility to submit new classification proposals based on new information remains. We note the support for the comments by EPMF.				
RAC's response				
Noted. See also response to comments 129, 140 and 146.				

Date	Country	Organisation	Type of Organisation	Comment number
16.12.2020	Germany		MemberState	159
Comment received				
pages 121-194 The argumentation for the proposed classification for reproductive toxicity in Category 1B (H360FD) for silver and nanosilver [1-100nm] is not convincing. No studies, in which the toxicity of elemental silver in massive or powder form was investigated, are available. The proposal is based on studies with silver containing active substances, silver salts and silver nanoparticles. For classification, it has to be differentiated between the different forms releasing silver ions. From our point of view, the read across to silver containing active substances is not justified because the substances contain additional elements of possible toxicological significance. For example, zinc may contribute to the developmental toxicity of silver zinc zeolite, which is classified for reproductive toxicity in Category 2 (H361d). Read across to silver salts may be accepted as worst-case approach where the human health effects are caused by free silver ions. Release rates of silver ions can be expected to differ significantly between elemental, silver in massive or powder form and silver nanoparticles. The solubility of the silver nanoparticles is orders of magnitude higher. Therefore, a read across to silver nanoparticles would also be a worst-case approach.				

Due to the large database, only studies discussed by the dossier submitter as relevant for classification were checked in detail. The following issues should be considered when deciding on classification:

a) effects on fertility
The proposed classification for effects on fertility (Repr. 1B, H360F) is based on the reduction of the fertility index (10%) and reduced number of implants (22%) observed in a published study after oral application of 40 mg/kg bw/d silver acetatecitrate (equivalent to 25 mg silver ion/kg bw/d) via drinking water in rats (Sprando et al., 2017). According to the dossier submitter, these findings are supported by various published studies regarding effects of silver nanoparticles on the male reproductive system in rats after oral exposure (gavage).

From our point of view, the small reduction of the fertility index (10%) could be an incidental finding. Are you aware of any historical control data that might be helpful for the assessment of the reduced fertility index and the reduced implantation numbers?

Furthermore, we ask, how the reduced number of implants was interpreted by the dossier submitter. Should this be an indication of pre-implantation loss? If yes, the number of corpora lutea is necessary to calculate the pre-implantation loss. Please note that the observed increased pre-implantation loss in the published study with silver nanoparticles by Yu et al. (2013) should not be regarded as treatment-related because the test material was administered after implantation.

Due to the large database for silver nanoparticles, a detailed examination could not be carried out. However, it is evident that the presented studies with silver nanoparticles are not performed in accordance with test guidelines and GLP principles. Moreover, detailed information on the nanomaterial is lacking in the publications (e.g. regarding the degree of purity). In some publications, only one dose was tested (e.g. Castellini et al. 2014), or clear dose-response relationships were missing (e.g. Gromadzka-Ostrowska et al. 2012), or animal observations were not reported (e.g. Miresmaeili et al. 2013). Additionally, different types of silver nanoparticles have been used in these studies. It has to be mentioned that the amount of silver ions released from the nanoparticles depends among other things on the surface coating. The silver ion exposure in the studies with silver nanoparticles is unclear. Other factors of possible toxicity should also be considered, e.g. translocation of silver nanoparticles and subsequent release of free silver ions or the formation of reactive oxygen species caused by nanoparticles in general compared to elemental silver in massive or powder form.
Altogether, this raises some questions to the relevance of the published studies with silver nanoparticles for classification of silver regarding effects on fertility.
Please note that the observed increased pre-implantation loss in the published study with silver nanoparticles by Yu et al. (2013) should not be regarded as treatment-related because the test material was administered after implantation. Finally, the dossier submitter argues that classification in category 1A based on evidence from humans is not possible since such data is not available (see report on p. 150). However, argyria is a known disease which occurred in humans after prolonged exposure to silver. Does this mean that even in persons sick from argyria no impairment of fertility has been reported? If this is the case, one could possibly argue that this lack of evidence should give rise to doubts to propose for (nano)silver classification in category 1B based on animal data.

Dossier Submitter's Response
We are not aware of any historical control data that would be relevant for the lab and conditions used in the published study. The number of corpora lutea is not analysed thus it is not possible to assess if statistically significant reduction of number of implants is due to pre-implantation loss. We agree regarding the comment on the pre-implanation loss in the study by Yu et al. (2013). Argyria is to our understanding not a common condition and we are not aware of any relevant and reliable information that would be considered appropriate to assess the intrinsic potential of silver for reproductive toxicicity. Please note our response to comment 145.
RAC's response
Noted. Agree that classification with 1B is not warranted. See also response to comments 129, 140 and 146.

Date	Country	Organisation	Type of Organisation	Comment number
16.12.2020	Germany	Heraeus Deutschland GmbH & Co. KG	Company-Manufacturer	160
Comment received				
Reproductive toxicity - the criteria for classifying silver as a reproductive toxicant have not been conclusively met: o the very limited available human data do not support a classification as reproductive toxicant, o the strength of the evidence from animal studies do currently not provide clear evidence of an adverse effect on sexual function/fertility, and o the key studies used in a read-across approach show several deficiencies, uncertainties and inconsistencies as outlined in EPMF's detailed comments. Assignment of developmental toxicity classification for elemental silver at this time is premature. The EPMF is currently performing a TG443 compliant EOGRTS (under EU REACH; including DIT and DNT cohorts). The study is designed to fill the identified data gaps for this endpoint and will allow a conclusive judgement for this endpoint.				
Dossier Submitter's Response				
Thank you for the information regarding your uses of silver. The Extended One-Generation Reproductive Toxicity Study (EOGRTS) is indeed expected to provide useful information however decisions under CLP must be taken without awaiting information that may become available in the future otherwise approval under the BPR and possibly other processes will be delayed. The possibility to submit new classification proposals based on new information remains. We note the support for the comments by EPMF.				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
15.12.2020	France	SCHNEIDER ELECTRIC INDUSTRIES SAS	Company-Manufacturer	161
Comment received				
No comment ECHA note – An attachment was submitted with the comment above. Refer to public attachment Silver_consultation_2020_non_confidential.pdf ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Silver_consultation_2020_Schneider_Electric.pdf				
Dossier Submitter's Response				
Thank you for the information about your uses of silver. We understand that classification and labelling may have consequences for companies however this is not within the scope of the CLP process. Moreover, exposure and the use of personal protective equipment during certain uses of silver is not taken into account for classification and labelling since it is based on the intrinsic properties of the active substance. Consequences of C & L may be handled by downstream regulations.				
RAC's response				
Noted. See also response to comments 129, 140 and 146.				

Date	Country	Organisation	Type of Organisation	Comment number
15.12.2020	Germany	RAS AG	Company-Manufacturer	162
Comment received				
see comment_CLH_silver_RAS_AG.pdf attached ECHA note – An attachment was submitted with the comment above. Refer to public attachment comment_CLH_silver_RAS_AG_public.pdf ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment comment_CLH_Silver_RAS_AG.zip				
Dossier Submitter's Response				
Thank you for the information about your uses of silver. We understand that classification and labelling may have consequences for companies however this is not within the scope of the CLP process. The Extended One-Generation Reproductive Toxicity Study (EOGRTS) is indeed expected to provide useful information however decisions under CLP must be taken without awaiting information that may become available in the future otherwise approval under the BPR and possibly other processes will be delayed. The possibility to submit new classification proposals based on new information remains. We note the support for the comments by EPMF.				
RAC's response				
Noted. See also response to comments 129, 140 and 146.				

Date	Country	Organisation	Type of Organisation	Comment number
15.12.2020	Switzerland	Argor-Heraeus SA	Company-Manufacturer	163
Comment received				
Reproductive toxicity - the criteria for classifying silver as a reproductive toxicant have not been conclusively met: o the very limited available human data do not support a classification as reproductive toxicant, o the strength of the evidence from animal studies do currently not provide clear evidence of an adverse effect on sexual function/fertility, and o the key studies used in a read-across approach show several deficiencies, uncertainties and inconsistencies as outlined in EPMF's detailed comments. Assignment of developmental toxicity classification for elemental silver at this time is premature. The EPMF is currently performing a TG443 compliant EOGRTS (under EU REACH; including DIT and DNT cohorts). The study is designed to fill the identified data gaps for this endpoint and will allow a conclusive judgement for this endpoint.				
Dossier Submitter's Response				
The Extended One-Generation Reproductive Toxicity Study (EOGRTS) is indeed expected to provide useful information however decisions under CLP must be taken without awaiting information that may become available in the future otherwise approval under the BPR and possibly other processes will be delayed. The possibility to submit new classification proposals based on new information remains. We note the support for the comments by EPMF.				
RAC's response				
Noted. See also response to comments 129, 140 and 146.				

Date	Country	Organisation	Type of Organisation	Comment number
15.12.2020	Belgium	Umicore	Company-Manufacturer	164
Comment received				
Reproductive toxicity - the criteria for classifying silver as a reproductive toxicant have not been conclusively met: • human evidence is limited available but does not support a classification as reproductive toxicant, • the strength of the evidence from animal studies does currently not provide clear evidence of an adverse effect on sexual function/fertility, and • the key studies used in the read-across approach are not reliable, as outlined in EPMF's detailed comments. • EPMF is currently performing a TG443 compliant EOGRTS under EU REACH (including DIT and DNT cohorts). The study is designed to fill the identified data gaps for this endpoint and will allow a conclusive judgement for this endpoint. • Moreover, the bio-availability of silver metal is not taken into account in the CLH proposal. EPMF is performing a toxicokinetic study with the anticipated outcome that silver metal could be differentiated from the other silver substances ECHA note – An attachment was submitted with the comment above. Refer to public attachment Umicore public consultation_final 20201215.pdf				

Dossier Submitter's Response
We understand that classification and labelling may have consequences for companies however this is not within the scope of the CLP process since classification and labelling is based on the intrinsic properties of the active substance and it does not take exposure into account. Consequences of the C & L may be handled by downstream regulations. The Extended One-Generation Reproductive Toxicity Study (EOGRTS) is indeed expected to provide useful information however decisions under CLP must be taken without awaiting information that may become available in the future. Other processes e.g. decisions on approval under the BPR depend on the classification and labelling of a substance thus the CLP process cannot be delayed. The possibility to submit new classification proposals based on new information remains. We note the support for the comments by EPMF.
RAC's response
Noted. See also response to comments 129, 140 and 146.

Date	Country	Organisation	Type of Organisation	Comment number
15.12.2020	United Kingdom	AeroSpace and Defence (ASD) Industries Association of Europe	Industry or trade association	165
Comment received				
The criteria for classifying silver as a reproductive toxicant have not been conclusively met since the very limited available human data does not support a classification as reproductive toxicant, the strength of the evidence from animal studies do currently not provide clear evidence of an adverse effect on sexual function/fertility and the key studies used in a read-across approach show several deficiencies, uncertainties and inconsistencies as outlined by the European Precious Metals Federation (EPMF). Assignment of a developmental toxicity classification for elemental silver at this time is premature. The EPMF is currently performing a TG443 compliant EOGRTS under EU REACH including developmental immunotoxicity & developmental neurotoxicity (DIT and DNT) cohorts. The study is designed to fill the identified datagaps for this endpoint and will allow a conclusive judgement for this endpoint.				
Dossier Submitter's Response				
We note the support for the comments by EPMF. The Extended One-Generation Reproductive Toxicity Study (EOGRTS) is indeed expected to provide useful information however decisions under CLP must be taken without awaiting information that may become available in the future. Other processes e.g. decisions on approval under the BPR depend on the classification and labelling of a substance thus the CLP process cannot be delayed. The possibility to submit new classification proposals based on new information remains.				
RAC's response				
Noted. See also response to comments 129, 140 and 146.				

Date	Country	Organisation	Type of Organisation	Comment number
14.12.2020	France	<confidential>	Company-Manufacturer	166
Comment received				
The criteria for classifying silver as a reproductive toxicant have not been conclusively met: - the classification as reproductive toxicant is not supported by the very limited available human data, - currently no strong proof for a negative impact on sexual function and fertility can be deducted from animal studies, and, - as discussed in EPMF's detailed comments the key studies used in a read-across approach show several deficiencies, uncertainties and inconsistencies. From the actually existing data for elemental silver an assignment of a developmental toxicity classification for elemental silver is premature and we strongly recommend to wait for the results of the TG443 compliant EOGRTS (under EU REACH; including DIT and DNT cohorts), performed by the EPMF. The study has been designed to fill the identified datagaps for this endpoint and the results will lead to a secured judgement for this endpoint.				
Dossier Submitter's Response				
We note the support for the comments by EPMF. The Extended One-Generation Reproductive Toxicity Study (EOGRTS) is indeed expected to provide useful information however decisions under CLP must be taken without awaiting information that may become available in the future. Other processes e.g. decisions on approval under the BPR depend on the classification and labelling of a substance thus the CLP process cannot be delayed. The possibility to submit new classification proposals based on new information remains.				
RAC's response				
Noted. See also response to comments 129, 140 and 146.				

Date	Country	Organisation	Type of Organisation	Comment number
11.12.2020	Germany	<confidential>	Company-Manufacturer	167
Comment received				
"Reproductive toxicity - the criteria for classifying silver as a reproductive toxicant have not been conclusively met: o the very limited available human data do not support a classification as reproductive toxicant, o the strength of the evidence from animal studies do currently not provide clear evidence of an adverse effect on sexual function/fertility, and o the key studies used in a read-across approach show several deficiencies, uncertainties and inconsistencies as outlined in EPMF's detailed comments. Assignment of developmental toxicity classification for elemental silver at this time is premature. The EPMF is currently performing a TG443 compliant EOGRTS (under EU REACH; including DIT and DNT cohorts). The study is designed to fill the identified data gaps for this endpoint and will allow a conclusive judgement for this endpoint."				
Dossier Submitter's Response				
We note the support for the comments by EPMF. The Extended One-Generation Reproductive Toxicity Study (EOGRTS) is indeed expected to provide useful information however decisions under CLP must be taken without awaiting information that may become available in the future. Other processes e.g.				

decisions on approval under the BPR depend on the classification and labelling of a substance thus the CLP process cannot be delayed. The possibility to submit new classification proposals based on new information remains.
RAC's response
Noted. See also response to comments 129, 140 and 146.

Date	Country	Organisation	Type of Organisation	Comment number
10.12.2020	France	ERCUIS	Company-Manufacturer	168
Comment received				
Reproductive toxicity - the criteria for classifying silver as a reproductive toxicant have not been conclusively met: • the very limited available human data do not support a classification as reproductive toxicant, • the strength of the evidence from animal studies do currently not provide clear evidence of an adverse effect on sexual function/fertility, and • the key studies used in a read-across approach show several deficiencies, uncertainties and inconsistencies as outlined in EPMF's detailed comments. Assignment of a developmental toxicity classification for elemental silver at this time is premature. The EPMF is currently performing a TG443 compliant EOGRTS (under EU REACH; including DIT and DNT cohorts). The study is designed to fill the identified datagaps for this endpoint and will allow a conclusive judgement for this endpoint. ECHA note – An attachment was submitted with the comment above. Refer to public attachment Consultation européenne sur l'argent ERCUIS_12-2020.pdf				
Dossier Submitter's Response				
We understand that classification and labelling may have consequences for companies however this is not within the scope of the CLP process since classification and labelling is based on the intrinsic properties of the active substance and it does not take exposure into account. Consequences of the C & L may be handled by downstream regulations. We note the support for the comments by EPMF. The Extended One-Generation Reproductive Toxicity Study (EOGRTS) is indeed expected to provide useful information however decisions under CLP must be taken without awaiting information that may become available in the future. Other processes e.g. decisions on approval under the BPR depend on the classification and labelling of a substance thus the CLP process cannot be delayed. The possibility to submit new classification proposals based on new information remains.				
RAC's response				
Noted. See also response to comments 129, 140 and 146.				

Date	Country	Organisation	Type of Organisation	Comment number
10.12.2020	Germany	SAXONIA Technical Materials GmbH	Company-Manufacturer	169
Comment received				
SAXONIA supports EPMF's currently performed TG443 compliant EOGRTS (under EU REACH; including DIT and DNT cohorts). The study is designed to fill the identified datagaps for this endpoint and will allow a conclusive judgement for this endpoint				

Dossier Submitter's Response
The Extended One-Generation Reproductive Toxicity Study (EOGRTS) is indeed expected to provide useful information however decisions under CLP must be taken without awaiting information that may become available in the future. Other processes e.g. decisions on approval under the BPR depend on the classification and labelling of a substance thus the CLP process cannot be delayed. The possibility to submit new classification proposals based on new information remains.
RAC's response
Noted. See also response to comments 129, 140 and 146.

Date	Country	Organisation	Type of Organisation	Comment number
10.12.2020	Germany	Doduco	Company-Manufacturer	170
Comment received				
very limited available human data do not support a classification as reproductive toxicant also strength of the evidence from animal studies do currently not provide clear evidence of an adverse effect on sexual function/fertility therefore Doduco is supporting the actual EPMF TG443 compliant EOGRTS (under EU REACH; including DIT and DNT cohorts)				
Dossier Submitter's Response				
The Extended One-Generation Reproductive Toxicity Study (EOGRTS) is indeed expected to provide useful information however decisions under CLP must be taken without awaiting information that may become available in the future. Other processes e.g. decisions on approval under the BPR depend on the classification and labelling of a substance thus the CLP process cannot be delayed. The possibility to submit new classification proposals based on new information remains.				
RAC's response				
Noted. See also response to comments 129, 140 and 146.				

Date	Country	Organisation	Type of Organisation	Comment number
09.12.2020	France	Comité Colbert	Industry or trade association	171
Comment received				
The very limited human data available do not support a classification as reproductive toxicant. The results from animal studies neither provide clear evidence of an adverse effect on sexual function/fertility. Furthermore, the key studies used in a read-across approach show several deficiencies, uncertainties and inconsistencies as outlined in EPMF's detailed comments. Therefore the assignment of a developmental toxicity classification for elemental silver is not relevant at this stage. ECHA note – An attachment was submitted with the comment above. Refer to public attachment LT_Comité_Colbert_ECHA.pdf				
Dossier Submitter's Response				
The Extended One-Generation Reproductive Toxicity Study (EOGRTS) is indeed expected to provide useful information however decisions under CLP must be taken without				

awaiting information that may become available in the future. Other processes e.g. decisions on approval under the BPR depend on the classification and labelling of a substance thus the CLP process cannot be delayed. The possibility to submit new classification proposals based on new information remains.
RAC's response
Noted. See also response to comments 129, 140 and 146.

Date	Country	Organisation	Type of Organisation	Comment number
08.12.2020	Germany	Heraeus Deutschland GmbH & Co. KG	Company-Manufacturer	172
Comment received				
Reproductive toxicity - the criteria for classifying silver as a reproductive toxicant have not been conclusively met: o the very limited available human data do not support a classification as reproductive toxicant, o the strength of the evidence from animal studies do currently not provide clear evidence of an adverse effect on sexual function/fertility, and o the key studies used in a read-across approach show several deficiencies, uncertainties and inconsistencies as outlined in EPMF's detailed comments. Assignment of developmental toxicity classification for elemental silver at this time is premature. The EPMF is currently performing a TG443 compliant EOGRTS (under EU REACH; including DIT and DNT cohorts). The study is designed to fill the identified data gaps for this endpoint and will allow a conclusive judgement for this endpoint. ECHA note – An attachment was submitted with the comment above. Refer to public attachment HPT_Public Cons. Ag CLH Proposal_AH.pdf				
Dossier Submitter's Response				
The Extended One-Generation Reproductive Toxicity Study (EOGRTS) is indeed expected to provide useful information however decisions under CLP must be taken without awaiting information that may become available in the future. Other processes e.g. decisions on approval under the BPR depend on the classification and labelling of a substance thus the CLP process cannot be delayed. The possibility to submit new classification proposals based on new information remains.				
RAC's response				
Noted. See also response to comments 129, 140 and 146.				

Date	Country	Organisation	Type of Organisation	Comment number
02.12.2020	France	Metalor Technologies	Company-Manufacturer	173
Comment received				
The criteria for classifying silver as a reproductive toxicant have not been conclusively met: o the very limited available human data do not support a classification as reproductive toxicant, o the strength of the evidence from animal studies do currently not provide clear evidence of an adverse effect on sexual function/fertility,				

Dossier Submitter's Response
Thank you.
RAC's response
Noted. See also response to comments 129, 140 and 146.

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Germany	AURUBIS AG	Company-Manufacturer	174
Comment received				
» Reproductive toxicity - the criteria for classifying silver as a reproductive toxicant have not been conclusively met: - the very limited available human data do not support a classification as reproductive toxicant, - the strength of the evidence from animal studies do currently not provide clear evidence of an adverse effect on sexual function/fertility, and - the key studies used in a read-across approach show several deficiencies, uncertainties and inconsistencies as outlined in EPMF's detailed comments. Assignment of a developmental toxicity classification for elemental silver at this time is premature. The EPMF is currently performing a TG443 compliant EOGRTS (under EU REACH; including DIT and DNT cohorts). The study is designed to fill the identified data gaps for this endpoint and will allow a conclusive judgement for this endpoint ECHA note – An attachment was submitted with the comment above. Refer to public attachment Aurubis comments to Silver CLH proposal 2020-12-18.pdf				
Dossier Submitter's Response				
The Extended One-Generation Reproductive Toxicity Study (EOGRTS) including the TK investigatiois indeed expected to provide useful information however decisions under CLP must be taken without awaiting information that may become available in the future. Other processes e.g. decisions on approval under the BPR depend on the classification and labelling of a substance thus the CLP process cannot be delayed. The possibility to submit new classification proposals based on new information remains.				
RAC's response				
Noted. See also response to comments 129, 140 and 146.				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	France	MONNAIE DE PARIS	Company-Downstream user	175
Comment received				
Not enough data available. Studies still ongoing according to EPMF european precious metals federation.The classification under this risk would not be relevant to date. ECHA note – An attachment was submitted with the comment above. Refer to public attachment 2020 12 18 ECHA MdP 2020 survey CLH for Silver_VDEF.pdf				
Dossier Submitter's Response				
The Extended One-Generation Reproductive Toxicity Study (EOGRTS) including the TK investigations is indeed expected to provide useful information however decisions under CLP must be taken without awaiting information that may become available in the future. Other processes e.g. decisions on approval under the BPR depend on the classification				

and labelling of a substance thus the CLP process cannot be delayed. The possibility to submit new classification proposals based on new information remains.
RAC's response
Noted. See also response to comments 129, 140 and 146.

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	United Kingdom	EU BPR Silver Task Force	Company-Downstream user	176
Comment received				
10.10 REPRODUCTIVE TOXICITY (Sections 10.10.1 – 10.10.10, p. 121-194 The proposed basis for the classification of silver as Repr. 1B; H360 FD is not supported by an adequate weight of evidence when considered in the context of the CLP criteria for this endpoint. The classification proposal places undue emphasis on published studies on silver nano-materials. These investigations are of widely varying quality and they present contradictory results as to the reproductive toxicity potential of silver nano particles. Our view is that classification for reproductive effects cannot be assigned to metallic silver based on these nano silver data. For further information please refer to the attached document: Silver - STF comment on Repr 1B H360 - December 2020. ECHA note – An attachment was submitted with the comment above. Refer to public attachment Silver - STF comment on Repr 1B H360 - December 2020.pdf				
Dossier Submitter's Response				
Please see our response to comment 145.				
RAC's response				
Noted. See also response to comments 129, 140 and 146.				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Germany	AZUR SPACE Solar Power GmbH	Company-Downstream user	177
Comment received				
The criteria for classifying silver as a reproductive toxicant have not been conclusively met: o the very limited available human data do not support a classification as reproductive toxicant, o the strength of the evidence from animal studies do currently not provide clear evidence of an adverse effect on sexual function/fertility, and o the key studies used in a read-across approach show several deficiencies, uncertainties and inconsistencies as outlined in EPMF's detailed comments. Assignment of a developmental toxicity classification for elemental silver at this time is premature. The EPMF is currently performing a TG443 compliant EOGRTS (under EU REACH; including DIT and DNT cohorts). The study is designed to fill the identified datagaps for this endpoint and will allow a conclusive judgement for this endpoint. We promote to wait for its results and continue the clascification process then.				
Dossier Submitter's Response				
The Extended One-Generation Reproductive Toxicity Study (EOGRTS) is indeed expected to provide useful information however decisions under CLP must be taken without awaiting information that may become available in the future. Other processes e.g. decisions on approval under the BPR depend on the classification and labelling of a				

substance thus the CLP process cannot be delayed. The possibility to submit new classification proposals based on new information remains.
RAC's response
Noted. See also response to comments 129, 140 and 146.

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Poland	<confidential>	Company-Manufacturer	178
Comment received				
Reproductive toxicity - never found nor observed in the <confidential>. ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Silver - <confidential> statement.docx				
Dossier Submitter's Response				
The attachment could not be found.				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Austria	Wirtschaftskammer Österreich		179
Comment received				
see attachment ECHA note – An attachment was submitted with the comment above. Refer to public attachment su_309_StN öK Silber CLH.pdf				
Dossier Submitter's Response				
Thank you for the information regarding your uses of silver.				
RAC's response				
Noted.				

RESPIRATORY SENSITISATION

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Italy	<confidential>	Company-Manufacturer	180
Comment received				
no evidence ECHA note – An attachment was submitted with the comment above. Refer to public attachment 2020 12 17 Public attachment in the questionnarie <confidential> (003).docx				
Dossier Submitter's Response				
Thank you.				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
09.12.2020	France	Comité Colbert	Industry or trade association	181
Comment received				
We support the conclusions on page 61. ECHA note – An attachment was submitted with the comment above. Refer to public attachment LT_Comité_Colbert_ECHA.pdf				
Dossier Submitter's Response				
Thank you				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Italy	IPZS S.p.A.	Company-Manufacturer	182
Comment received				
no evidence ECHA note – An attachment was submitted with the comment above. Refer to public attachment Public attachment in the questionnarie.docx				
Dossier Submitter's Response				
Thank you.				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Belgium	T&D Europe	Industry or trade association	183
Comment received				
no comment ECHA note – An attachment was submitted with the comment above. Refer to public attachment TD Europe CLH Consultation Silver_Dec2020_final.pdf				
Dossier Submitter's Response				
Thank you for the information.				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
16.12.2020	Germany		MemberState	184
Comment received				
pages 59-61 We agree with the dossier submitter that no conclusion on classification is possible due to inconclusive data. The comparison with the CLP criteria makes clear that the provided				

human data from the two reported cases using colloidal silver nasal drops/spray is too weak evidence for respiratory sensitisation caused by silver, taking into account that the protein vehicle is also likely to induce an immune response.
Dossier Submitter's Response
Thank you.
RAC's response
Noted. See also response to comments 129, 140 and 146.

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Poland	<confidential>	Company-Manufacturer	185
Comment received				
Respiratory Sensitisation - never found nor observed in the <confidential>. ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Silver - <confidential> statement.docx				
Dossier Submitter's Response				
Thank you.				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
16.12.2020	Germany	Heraeus Deutschland GmbH & Co. KG	Company-Manufacturer	186
Comment received				
N/A				
Dossier Submitter's Response				
OK				
RAC's response				
Note lack of comment.				

Date	Country	Organisation	Type of Organisation	Comment number
15.12.2020	France	SCHNEIDER ELECTRIC INDUSTRIES SAS	Company-Manufacturer	187
Comment received				
No comment ECHA note – An attachment was submitted with the comment above. Refer to public attachment Silver_consultation_2020_non_confidential.pdf ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Silver_consultation_2020_Schneider_Electric.pdf				
Dossier Submitter's Response				
OK				

RAC's response
Noted.

Date	Country	Organisation	Type of Organisation	Comment number
15.12.2020	Germany	RAS AG	Company-Manufacturer	188
Comment received				
see comment_CLH_silver_RAS_AG.pdf attached ECHA note – An attachment was submitted with the comment above. Refer to public attachment comment_CLH_silver_RAS_AG_public.pdf ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment comment_CLH_Silver_RAS_AG.zip				
Dossier Submitter's Response				
Thank you.				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
02.12.2020	France	Metalor Technologies	Company-Manufacturer	189
Comment received				
-				
Dossier Submitter's Response				
-				
RAC's response				
Note lack of comment.				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Germany	Netzwerk NanoSilber	Industry or trade association	190
Comment received				
none ECHA note – An attachment was submitted with the comment above. Refer to public attachment CLH public consultation silver - Comments by Netzwerk NanoSilber.pdf				
Dossier Submitter's Response				
OK				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Portugal	<confidential>	Company-Manufacturer	191
Comment received				
We are not aware of any hazard originated my metalic silver and we have been using silver for a very long time.				
Dossier Submitter's Response				
Thank you				
RAC's response				
Noted.				

OTHER HAZARDS AND ENDPOINTS – Acute Toxicity

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Italy	IPZS S.p.A.	Company-Manufacturer	192
Comment received				
no evidence ECHA note – An attachment was submitted with the comment above. Refer to public attachment Public attachment in the questionnarie.docx				
Dossier Submitter's Response				
Thank you				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
09.12.2020	France	Comité Colbert	Industry or trade association	193
Comment received				
We support the conclusions on page 61. ECHA note – An attachment was submitted with the comment above. Refer to public attachment LT_Comité_Colbert_ECHA.pdf				
Dossier Submitter's Response				
Thank you				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Germany	AZUR SPACE Solar Power GmbH	Company-Downstream user	194
Comment received				
The criteria for classification of silver metal (massive) as toxic to the aquatic environment are not fulfilled: o the available scientific and industrial evidence confirm that a split classification for silver				

massive versus silver powder is justified, and o silver massive should not be classified.
Dossier Submitter's Response
Thank you for your comment. Regarding your proposal for a separate consideration for silver in the massive form, please see the DS response to comment number 316.352
RAC's response
Noted.

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Poland	<confidential>	Company-Manufacturer	195
Comment received				
Acute toxicity - never found nor observed in the <confidential>. ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Silver - <confidential> statement.docx				
Dossier Submitter's Response				
Thank you.				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
02.12.2020	France	Metalor Technologies	Company-Manufacturer	196
Comment received				
-				
Dossier Submitter's Response				
-				
RAC's response				
Note lack of comment.				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Germany	Netzwerk NanoSilber	Industry or trade association	197
Comment received				
none ECHA note – An attachment was submitted with the comment above. Refer to public attachment CLH public consultation silver - Comments by Netzwerk NanoSilber.pdf				
Dossier Submitter's Response				
OK				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Portugal	<confidential>	Company-Manufacturer	198
Comment received				
We are not aware of any hazard originated my metalic silver and we have been using silver for a very long time.				
Dossier Submitter's Response				
Thank you.				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Germany	aap Implantate AG	Company-Manufacturer	199
Comment received				
The criteria for classification as acute toxic cannot be confirmed. ECHA note – An attachment was submitted with the comment above. Refer to public attachment aap Implantate AG_CLH_public_consultation_non-confidential_CAS 7440-22-4.pdf ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment aap Implantate AG_CLH_public_consultation_confidential_CAS 7440-22-4.pdf				
Dossier Submitter's Response				
Classification for acute toxicity is not proposed.				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Italy	<confidential>	Company-Manufacturer	200
Comment received				
no evidence ECHA note – An attachment was submitted with the comment above. Refer to public attachment 2020 12 17 Public attachment in the questionnarie <confidential> (003).docx				
Dossier Submitter's Response				
Thank you.				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
16.12.2020	Germany		MemberState	201
Comment received				
pages 46-56 Oral: The study/studies relevant for (no) classification were not made clear when comparing with the CLP criteria. However, based on the rat study IIIA 6.1.1-14 (OECD TG 423) with LD50 >2000 mg/kg bw using nanosilver, we agree with the decision no classification for acute oral toxicity.				

Dermal: Based on the study with nanosilver IIIA 6.1.2-09 (OECD TG 402) with LD50 >2000 mg/kg bw in rats, we agree with the decision of no classification for acute dermal toxicity. Inhalation: The dossier submitter stated: "The information in this table is based on information available from the lead registration dossier submitted under REACH. The original study reports are not available to the dossier submitter thus the information cannot be verified." Based on the rat study summary with silver powder from the REACH dossier (OECD TG 436) with LD50 >5.16 mg/L air, we agree with the decision of no classification for acute inhalation toxicity. However, this decision should be based on the original study report.
Dossier Submitter's Response
Agree however the information is not available to the dossier submitter.
RAC's response
Agree, no classification but rat study IIIA 6.1.1-14 (OECD TG 423), acute oral LD50 > 2000 mg/kg is based on nanoparticulate silver colloid not the actual content of silver. The silver dose (assuming 20.5% of the colloidal solution is silver and 2000mg = 1.7ml) in the highest dose group was approximately 340 mg Ag/kg bw.

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Belgium	T&D Europe	Industry or trade association	202
Comment received				
no comment ECHA note – An attachment was submitted with the comment above. Refer to public attachment TD Europe CLH Consultation Silver_Dec2020_final.pdf				
Dossier Submitter's Response				
OK				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
16.12.2020	Germany	Heraeus Deutschland GmbH & Co. KG	Company-Manufacturer	203
Comment received				
N/A				
Dossier Submitter's Response				
OK				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
15.12.2020	France	SCHNEIDER ELECTRIC INDUSTRIES SAS	Company-Manufacturer	204
Comment received				
No comment ECHA note – An attachment was submitted with the comment above. Refer to public attachment Silver_consultation_2020_non_confidential.pdf ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Silver_consultation_2020_Schneider_Electric.pdf				
Dossier Submitter's Response				
OK				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
15.12.2020	Germany	RAS AG	Company-Manufacturer	205
Comment received				
see comment_CLH_silver_RAS_AG.pdf attached ECHA note – An attachment was submitted with the comment above. Refer to public attachment comment_CLH_silver_RAS_AG_public.pdf ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment comment_CLH_Silver_RAS_AG.zip				
Dossier Submitter's Response				
Thank you for the information however no classification is proposed for this hazard class.				
RAC's response				
Noted.				

OTHER HAZARDS AND ENDPOINTS – Skin Hazard

Date	Country	Organisation	Type of Organisation	Comment number
10.12.2020	Germany	SAXONIA Technical Materials GmbH	Company-Manufacturer	206
Comment received				
silver causing skin sensitisation is not known to us based on decades of manufacturing silver based products incl. regular medical check-up of our employees				
Dossier Submitter's Response				
Thank you.				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Italy	IPZS S.p.A.	Company-Manufacturer	207
Comment received				
no evidence ECHA note – An attachment was submitted with the comment above. Refer to public attachment Public attachment in the questionnarie.docx				
Dossier Submitter's Response				
Thank you.				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
10.12.2020	Germany	Doduco	Company-Manufacturer	208
Comment received				
we are working with silver over 100 years, and even intensive medical check-ups on our workers over the last decades didn't reveal any evidence that silver causes skin sensitisation				
Dossier Submitter's Response				
Thank you.				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	France	MONNAIE DE PARIS	Company-Downstream user	209
Comment received				
Skin corrosion for end user also is not showed and even less proved. There are no clinical cases known. The classification under this risk would not be relevant to date. ECHA note – An attachment was submitted with the comment above. Refer to public attachment 2020 12 18 ECHA MdP 2020 survey CLH for Silver_VDEF.pdf				
Dossier Submitter's Response				
Classification is not proposed.				
RAC's response				
Noted. No classification is proposed for skin corrosion/irritation.				

Date	Country	Organisation	Type of Organisation	Comment number
09.12.2020	France	Comité Colbert	Industry or trade association	210
Comment received				
We support the conclusions on page 57.				

ECHA note – An attachment was submitted with the comment above. Refer to public attachment LT_Comité_Colbert_ECHA.pdf
Dossier Submitter's Response
Thank you.
RAC's response
Noted.

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Poland	<confidential>	Company-Manufacturer	211
Comment received				
Skin corrosion/irritation - never found nor observed in the <confidential>. ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Silver - <confidential> statement.docx				
Dossier Submitter's Response				
Thank you.				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Austria	Wirtschaftskammer Österreich	Please select organisation type..	212
Comment received				
see attachment ECHA note – An attachment was submitted with the comment above. Refer to public attachment su_309_StN öK Silber CLH.pdf				
Dossier Submitter's Response				
Thank you for the information however classification is not proposed.				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
02.12.2020	France	Metalor Technologies	Company-Manufacturer	213
Comment received				
-				
Dossier Submitter's Response				
-				
RAC's response				
Nothing to comment on.				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Germany	Netzwerk NanoSilber	Industry or trade association	214
Comment received				
none ECHA note – An attachment was submitted with the comment above. Refer to public attachment CLH public consultation silver - Comments by Netzwerk NanoSilber.pdf				
Dossier Submitter's Response				
OK				
RAC's response				
Noted, single comment on low potential for skin irritation but document mainly concentrated on skin sensitisation as well as other endpoints.				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Portugal	<confidential>	Company-Manufacturer	215
Comment received				
We are not aware of any hazard originated my metalic silver and we have been using silver for a very long time.				
Dossier Submitter's Response				
Thank you				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
16.12.2020	Germany	Siemens AG	Company-Manufacturer	216
Comment received				
Based on our assessment of the report and discussions with industry experts we like to point out that, we see the criteria for classification as a skin sensitizer as not fulfilled. There's no reliable human evidence showing that silver causes skin sensitization and a high number of animal studies with a variety of chemical forms of ionic silver show non-sensitizing potential of silver (note that the animal dataset in the CLH report is incomplete).				
Dossier Submitter's Response				
Thank you.				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Italy	<confidential>	Company-Manufacturer	217
Comment received				
no evidence				

ECHA note – An attachment was submitted with the comment above. Refer to public attachment 2020 12 17 Public attachment in the questionnarie <confidential> (003).docx
Dossier Submitter's Response
Thank you. Classification is not proposed for this hazard class.
RAC's response
Noted, but there was no discussion regarding classification for skin irritancy in the document.

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Poland		Individual	218
Comment received				
We support the scientific comments submitted by the European Precious Metals Federation (EPMF). Key messages and arguments addressed in EPMF's comments: • Skin sensitisation - the criteria for classification as a skin sensitiser are not fulfilled: ☐ reliable human evidence showing that silver causes skin sensitisation in a substantial number of persons is lacking, and ☐ a high number of animal studies with a variety of chemical forms of ionic silver show nonsensitising potential of silver (note that the animal dataset in the CLH report is incomplete). ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment comment.pdf				
Dossier Submitter's Response				
We note the support for the comments by EPMF.				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Germany	I&P Europe - Imaging and Printing Association e.V.	Industry or trade association	219
Comment received				
see attached document ECHA note – An attachment was submitted with the comment above. Refer to public attachment Comments to the silver metal CLH public consultation.pdf				
Dossier Submitter's Response				
Thank you. Please note that no classification is proposed for this hazard class.				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Belgium	T&D Europe	Industry or trade association	220
Comment received				
no comment ECHA note – An attachment was submitted with the comment above. Refer to public attachment TD Europe CLH Consultation Silver_Dec2020_final.pdf				
Dossier Submitter's Response				
OK				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
16.12.2020	Germany	Heraeus Deutschland GmbH & Co. KG	Company-Manufacturer	221
Comment received				
N/A				
Dossier Submitter's Response				
OK				
RAC's response				
Note lack of comment.				

Date	Country	Organisation	Type of Organisation	Comment number
15.12.2020	France	SCHNEIDER ELECTRIC INDUSTRIES SAS	Company-Manufacturer	222
Comment received				
No comment ECHA note – An attachment was submitted with the comment above. Refer to public attachment Silver_consultation_2020_non_confidential.pdf ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Silver_consultation_2020_Schneider_Electric.pdf				
Dossier Submitter's Response				
OK				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
15.12.2020	Germany	RAS AG	Company-Manufacturer	223
Comment received				
see comment_CLH_silver_RAS_AG.pdf attached				

ECHA note – An attachment was submitted with the comment above. Refer to public attachment comment_CLH_silver_RAS_AG_public.pdf ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment comment_CLH_Silver_RAS_AG.zip
Dossier Submitter's Response
Thank you. Please note that no classification is proposed for this hazard class.
RAC's response
Noted.

OTHER HAZARDS AND ENDPOINTS – Eye Hazard

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Italy	<confidential>	Company-Manufacturer	224
Comment received				
no evidence ECHA note – An attachment was submitted with the comment above. Refer to public attachment 2020 12 17 Public attachment in the questionnarie <confidential> (003).docx				
Dossier Submitter's Response				
Thank you.				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
09.12.2020	France	Comité Colbert	Industry or trade association	225
Comment received				
We support the conclusions on page 59. ECHA note – An attachment was submitted with the comment above. Refer to public attachment LT_Comité_Colbert_ECHA.pdf				
Dossier Submitter's Response				
Thank you				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Italy	IPZS S.p.A.	Company-Manufacturer	226
Comment received				
no evidence ECHA note – An attachment was submitted with the comment above. Refer to public attachment Public attachment in the questionnarie.docx				
Dossier Submitter's Response				
Thank you				

RAC's response
Noted.

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Belgium	T&D Europe	Industry or trade association	227
Comment received				
no comment ECHA note – An attachment was submitted with the comment above. Refer to public attachment TD Europe CLH Consultation Silver_Dec2020_final.pdf				
Dossier Submitter's Response				
OK				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
16.12.2020	Germany		MemberState	228
Comment received				
pages 58-59 The dossier submitter concluded that based on the results from eye irritation studies performed with nanosilver, silver does not fulfil criteria for classification. However, it was stated that in the respective rabbit study IIIA 6.1.4-20, the applied dose was only 0.1 mg, which is much lower than 100 mg as recommended in the OECD TG 405. In contrast, the detailed study report states that 100 mg of the test material was applied, which, however, contained only 20.48 % silver. Therefore, it is unclear if eye irritation could be induced by applying the dose recommended in the OECD TG. Reliability of the two supportive studies from the REACH dossier is not given. Furthermore, dosing was not according to OECD TG for one supportive study and was not given for the other. Therefore, based on the information provided in the CLH report classification is not possible instead of "no classification"				
Dossier Submitter's Response				
We apologize for the mistake in the overview table of eye irritation studies. The dose applied in study IIIA 6.1.4-20 was 100 mg. The registrant considered the reliability score of the two key studies in the Reach registration 2 (reliable with restrictions). The rationale for the reliability score in the guniea pig study was *"In principle well documented GLP-study, but no information on test item purity was provided."* whereas the justification for the rabbit study was "*Publication, not full study report, GLP. However, the study has apparently been conducted in accordance with OECD 405 and relevant experimental details and results are reported."* In the study with guinea pigs, 0.1 mL of colloidal AgNPs suspension with the respective Ag concentration of 50 and 2000 ppm was placed in the conjunctival sac of one eye of each animal. In the rabbit study 100 mg volume of silver powder was dropped into the conjunctival sac of the left eye of male rabbits. We agree that the exposure in study IIIA 6.1.4-20 is below the recommendations but the negative result with silver powder is considered to supported the result.				

RAC's response
RAC supports the DS conclusion for no classification.

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Poland	<confidential>	Company-Manufacturer	229
Comment received				
Serious eye damage/eye irritation - never found nor observed in the <confidential>. ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Silver - <confidential> statement.docx				
Dossier Submitter's Response				
Thank you				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
16.12.2020	Germany	Heraeus Deutschland GmbH & Co. KG	Company-Manufacturer	230
Comment received				
N/A				
Dossier Submitter's Response				
OK				
RAC's response				
Note lack of comment.				

Date	Country	Organisation	Type of Organisation	Comment number
15.12.2020	France	SCHNEIDER ELECTRIC INDUSTRIES SAS	Company-Manufacturer	231
Comment received				
No comment ECHA note – An attachment was submitted with the comment above. Refer to public attachment Silver_consultation_2020_non_confidential.pdf ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Silver_consultation_2020_Schneider_Electric.pdf				
Dossier Submitter's Response				
OK				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
15.12.2020	Germany	RAS AG	Company-Manufacturer	232
Comment received				
see comment_CLH_silver_RAS_AG.pdf attached ECHA note – An attachment was submitted with the comment above. Refer to public attachment comment_CLH_silver_RAS_AG_public.pdf ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment comment_CLH_Silver_RAS_AG.zip				
Dossier Submitter's Response				
Thank you. Please note that no classification is proposed for this hazard class.				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
02.12.2020	France	Metalor Technologies	Company-Manufacturer	233
Comment received				
-				
Dossier Submitter's Response				
-				
RAC's response				
Note lack of comment.				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Germany	Netzwerk NanoSilber	Industry or trade association	234
Comment received				
none ECHA note – An attachment was submitted with the comment above. Refer to public attachment CLH public consultation silver - Comments by Netzwerk NanoSilber.pdf				
Dossier Submitter's Response				
OK				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Portugal	<confidential>	Company-Manufacturer	235
Comment received				
We are not aware of any hazard originated my metalic silver and we have been using silver for a very long time.				
Dossier Submitter's Response				
Thank you				

RAC's response
Noted.

OTHER HAZARDS AND ENDPOINTS – Skin Sensitisation Hazard

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Germany	WirtschaftsVereinigung Metalle	Industry or trade association	236
Comment received				
We think that the criteria for classification as a skin sensitiser are not fulfilled as reliable human evidence showing that silver causes skin sensitisation in a substantial number of persons is lacking. In addition, a high number of animal studies with a variety of chemical forms of ionic silver show non-sensitising potential of silver. ECHA note – An attachment was submitted with the comment above. Refer to public attachment 2020-12-18_WVMetalle Comment on CLH Proposal for Silver.pdf				
Dossier Submitter's Response				
Please see the justification in the CLH report why it is not considered safe to disregard information indicating that criteria are fulfilled. Please also note that the silver content among different silver compunds differ and the results of these tests may thus not accurately represent the intrinsic sensitising potential of silver (ions) since it is not maximised in the test.				
RAC's response				
RAC does not support a proposal of Category 1 for skin sensitisation. See response to comment 250.				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Germany	Netzwerk NanoSilber	Industry or trade association	237
Comment received				
The criteria for classifying silver as a skin sensitizer are not fulfilled. Silver and nanosilver has been used for centuries without observing a sensitising effect in a significant number of people. Also, the CLH report is incomplete, excluding a high number of studies about silver and nanosilver, showing a non-sensitising effect. Respective research performed by our network partners and others can be found in the public attachment. ECHA note – An attachment was submitted with the comment above. Refer to public attachment CLH public consultation silver - Comments by Netzwerk NanoSilber.pdf				
Dossier Submitter's Response				
Thank you. Please see the justification in the CLH report why it is not considered safe to disregard information indicating that criteria are fulfilled. Please also note that the silver content among different silver compunds differ and the results of these tests may thus not accurately represent the intrinsic sensitising potential of silver (ions) since it is not maximised in the test.				
RAC's response				
RAC does not support a proposal of Category 1 for skin sensitisation. See response to comment 250.				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	United Kingdom	<confidential>	Company-Manufacturer	238
Comment received				
The criteria for classification as a skin sensitiser are not fulfilled: • Reliable human evidence showing that silver causes skin sensitisation in a substantial number of persons is lacking and in fact, across three of our European sites that have handled silver powder (and its compounds) for between 25 and 40 years, although only directly involving 5-10 employees at any one time, we have not had any reports of sensitisation or other adverse health effects associated with silver powder handling in our workforce. • A high number of animal studies with a variety of chemical forms of ionic silver show non-sensitising potential of silver (note that the animal dataset in the CLH report is incomplete). ECHA note – An attachment was submitted with the comment above. Refer to public attachment Silver products.pdf				
Dossier Submitter's Response				
Thank you. Please see the justification in the CLH report why it is not considered safe to disregard information indicating that criteria are fulfilled.				
RAC's response				
RAC does not support a proposal of Category 1 for skin sensitisation. See response to comment 250.				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Portugal	<confidential>	Company-Manufacturer	239
Comment received				
As far as we know, the criteria for classification of silver as a skin sensitiser are not fulfilled: o reliable human evidence showing that silver causes skin sensitisation in a substantial number of persons is lacking, and o a high number of animal studies with a variety of chemical forms of ionic silver show nonsensitising potential of silver (note that the animal dataset in the CLH report is incomplete).				
Dossier Submitter's Response				
Thank you. Please see the justification in the CLH report why it is not considered safe to disregard information indicating that criteria are fulfilled.				
RAC's response				
RAC does not support a proposal of Category 1 for skin sensitisation. See response to comment 250.				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Germany	aap Implantate AG	Company-Manufacturer	240
Comment received				
The criteria for the classification as skin sensitizing cannot be confirmed.				

ECHA note – An attachment was submitted with the comment above. Refer to public attachment aap Implantate AG_CLH_public_consultation_non-confidential_CAS 7440-22-4.pdf ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment aap Implantate AG_CLH_public_consultation_confidential_CAS 7440-22-4.pdf
Dossier Submitter's Response
Thank you. Please see the justification in the CLH report why it is not considered safe to disregard information indicating that criteria are fulfilled.
RAC's response
RAC does not support a proposal of Category 1 for skin sensitisation. See response to comment 250.

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	United Kingdom	Ames Goldsmith UK Ltd	Company-Manufacturer	241
Comment received				
• Skin sensitisation - the criteria for classification as a skin sensitiser are not fulfilled: o reliable human evidence showing that silver causes skin sensitisation in a substantial number of persons is lacking, and o a high number of animal studies with a variety of chemical forms of ionic silver show nonsensitising potential of silver (note that the animal dataset in the CLH report is incomplete).				
Dossier Submitter's Response				
Thank you. Please see the justification in the CLH report why it is not considered safe to disregard information indicating that criteria are fulfilled.				
RAC's response				
RAC does not support a proposal of Category 1 for skin sensitisation. See response to comment 250.				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Italy	<confidential>	Company-Manufacturer	242
Comment received				
no evidence ECHA note – An attachment was submitted with the comment above. Refer to public attachment 2020 12 17 Public attachment in the questionnarie <confidential> (003).docx				
Dossier Submitter's Response				
Thank you. We note the support for the comments by EPMF.				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Germany	Bio-Gate AG	Company-Manufacturer	243
Comment received				
- reliable human evidence showing that silver causes skin sensitisation in a substantial number of persons is lacking, and - a high number of animal studies with a variety of chemical forms of ionic silver show nonsensitising potential of silver (note that the animal dataset in the CLH report is incomplete). - Several studies with metallic silver containing cosmetics show that silver in cosmetics improves the appearance of the skin and does lead to side effects. Please see attached study: Müller-Steinmann et al., Prospective dermatologically controlled study of the efficacy of a silver containing nurturing cream (MicroSilver BG™ 0.1%) in atopic dermatitis, Kosmetische Medizin – Cosmetic Medicine 28., Issue 4, 2008, ISSN 1430-4031. - there are almost no publications available regarding skin issues with metallic silver. Please see attached publication "Group A., Lea A., Contact Dermatitis With a Highlight on Silver: A Review, WOUNDS 2010;22(12): 311–315" that shows that there are only a handful of reported skin irritations which where mostly caused by silver nitrate and not pure metallic silver. In comparison there is huge amount of publications on pubmed that mention skin issues with copper, and there is also a whole book available: Copper and the Skin by Jurij Hostynek and Howard Maibach (2006, CRC Press, ISBN: 978-1-4200-0943-9) ECHA note – An attachment was submitted with the comment above. Refer to public attachment Bio-Gate Safety Studies.zip ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Bio-Gate Microsilver BG Confidential Safety Studies.zip				
Dossier Submitter's Response				
Thank you. Please see the justification in the CLH report why it is not considered safe to disregard information indicating that criteria are fulfilled. Please also note that the silver content among different silver compunds differ and the results of these tests may thus not accurately represent the intrinsic sensitising potential of silver (ions) since it is not maximised in the test.				
RAC's response				
RAC does not support a proposal of Category 1 for skin sensitisation. See response to comment 250.				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Belgium	T&D Europe	Industry or trade association	244
Comment received				
no comment ECHA note – An attachment was submitted with the comment above. Refer to public attachment TD Europe CLH Consultation Silver_Dec2020_final.pdf				
Dossier Submitter's Response				
OK				

RAC's response
Noted.

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Germany	<confidential>	Company-Manufacturer	245
Comment received				
o reliable human evidence showing that silver causes skin sensitisation in a substantial number of persons is lacking, and o a high number of animal studies with a variety of chemical forms of ionic silver show nonsensitising potential of silver (note that the animal dataset in the CLH report is incomplete).				
Dossier Submitter's Response				
Thank you. Please see the justification in the CLH report why it is not considered safe to disregard information indicating that criteria are fulfilled. Please also note that the silver content among different silver compunds differ and the results of these tests may thus not accurately represent the intrinsic sensitising potential of silver (ions) since it is not maximised in the test.				
RAC's response				
RAC does not support a proposal of Category 1 for skin sensitisation. See response to comment 250.				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	France		MemberState	246
Comment received				
In agreement with the proposal of classification: Skin Sens. 1, H317				
Dossier Submitter's Response				
Thank you.				
RAC's response				
RAC does not support a proposal of Category 1 for skin sensitisation. See response to comment 250.				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Germany	ZVEI - German Electrical and Electronic Manufacturers' Association	Industry or trade association	247
Comment received				
The criteria for classification as a skin sensitiser are not fulfilled: o reliable human evidence showing that silver causes skin sensitisation in a substantial number of persons is lacking, and o a high number of animal studies with a variety of chemical forms of ionic silver show				

non-sensitising potential of silver (note that the animal dataset in the CLH report is incomplete). ECHA note – An attachment was submitted with the comment above. Refer to public attachment 20201218 ZVEI Silver Applications in EEE and Comments Ag CLH Consultation.pdf
Dossier Submitter's Response
Thank you. Please see the justification in the CLH report why it is not considered safe to disregard information indicating that criteria are fulfilled. Please also note that the silver content among different silver compunds differ and the results of these tests may thus not accurately represent the intrinsic sensitising potential of silver (ions) since it is not maximised in the test.
RAC's response
RAC does not support a proposal of Category 1 for skin sensitisation. See response to comment 250.

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Germany	C.HAFNER GmbH + Co. KG	Company-Manufacturer	248
Comment received				
The criteria for classification as a skin sensitiser are not fulfilled: o reliable human evidence showing that silver causes skin sensitisation in a substantial number of persons is lacking, and o a high number of animal studies with a variety of chemical forms of ionic silver show nonsensitising potential of silver (note that the animal dataset in the CLH report is incomplete). Please refer to the scientific comments submitted by the European Precious Metals Federation (EPMF). Recycling, processing and uses of silver containing materials are well known for many centuries. Over the whole period of time there was no evidence of skin sensitization caused by silver at the exposed worker or consumers.				
Dossier Submitter's Response				
Thank you. Please see the justification in the CLH report why it is not considered safe to disregard information indicating that criteria are fulfilled. Please also note that the silver content among different silver compunds differ and the results of these tests may thus not accurately represent the intrinsic sensitising potential of silver (ions) since it is not maximised in the test.				
RAC's response				
RAC does not support a proposal of Category 1 for skin sensitisation. See response to comment 250.				

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Belgium	European Precious Metals Federation (EPMF)	Industry or trade association	249

Comment received

Summary of comments on skin sensitisation (CLH report p.62-71):
The criteria for classification of silver as a skin sensitiser are not fulfilled:
o reliable human evidence showing that silver causes skin sensitisation in a substantial number of persons is lacking, and
o a high number of animal studies with a variety of chemical forms of ionic silver show non-sensitising potential of silver (note that the animal dataset in the CLH report is incomplete).
For further details / justification, please refer to the attached document pages 12-19.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment CLH Ag Comments FINAL_201217.pdf

Dossier Submitter's Response

Animal data on skin sensitisation performed with different silver substances is challenging to assess since the different substances give rise to different levels of silver exposure and thus do not fully represent the intrinsic properties of silver (ion).
The silver content in the substances listed in the summary table by the EMPF to support the conclusion that silver lacks sensitising properties is low; silver tiosulphate contains only 10 g/kg (1%) silver, citric acid / silver(I) citrate mixture contains 3.2% silver dihydrogen citrate monohydrate and the silver content of the different silver zeolites and silver sodium hydrogen zirconium phosphate varies between 3 and 10%. The silver content in silver zeolite Type AD is higher.
With respect to the interpretation of reactions of grade 0,5 in two Buehler tests, it is already discussed in the report that if reactions were incidental or due to wrapping materials used in the study, similar results would be expected in treated animals and controls and/or the irritation to material would have been noted in the study protocol.
Studies with nanosilver can be difficult to interpret since the silver ion release in this type of study and the actual dose tested is sometimes difficult to compare with recommendations in guideline.

Reviews of silver often state that silver is not associated with sensitisation. It is difficult to assess the robustness of such general statements since it is unclear if this reflects the lack of investigations of silver or if it is based on data and in that case the silver substances, tests and/or exposure situations this refers to. The low number of cases reported and the shortcomings of the data base is already discussed in the CLP report. Although the potency of silver (ions) may be low we do not find it safe to ignore the cases observed. Also the recent review by Hadrup et al. (2018) mentioned by EPMF refers to a limited number of additional cases.
Taking into account the considerations in CLP guidance, we do not find it possible to disregard that criterion (a) isolated episodes of allergic contact dermatitis and criterion (e) positive results from close structural analogues could be considered fulfilled.

RAC's response

RAC does not support a proposal of Category 1 for skin sensitisation. See response to comment 250.

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Netherlands		MemberState	250

Comment received

The dossier submitter proposes a classification for skin sens.1 based on a weight of evidence approach where the individual data have clear limitations. We can agree the skin reactions graded 0.5 in the animal study are likely similar as grade 1 in the OECD test guideline. However, there is some uncertainty. The level of positive response compared to the controls are very limited and considering the limitations of the study due to the scoring and irritating concentrations used and the high background level, it can hardly be taken into account.
A limited number of human case reports indicate the ionic form of silver may be sensitizing. However, the number of case reports and limited detailed information are hardly sufficient evidence for classification as a skin sensitizer for silver.

More importantly, skin sensitisation is a local effect, therefore it seems inappropriate to classify the natural solid form of silver for skin sensitization based on data with the ionic form of silver. The limited data suggests the ionic form may have some skin sensitization potential. Therefore it is necessary to assess whether skin contact to silver will lead to sufficient local exposure of the ionic form, which is not justified in the dossier. Sufficient exposure to the ionic form does not seem very likely after dermal contact to the solid form of silver. In addition, solid silver is frequently used in jewelry and there does not seem to be any data or case reports that indicate (solid) silver causes dermal sensitization reactions.
Overall, the NL-CA does not agree to propose classification for silver as a sensitiser (category 1).

Dossier Submitter's Response

Thank you.
In the absence of information on the contrary, the solid form of silver is expected to release silver ions in contact with moist. Although the potency of silver (ions) may be low we do not find it safe to ignore the cases observed.

RAC's response

Agree with the assessment by NL. Reliable evidence that silver has caused skin sensitisation in a substantial number of humans is lacking. RAC takes a weight of evidence approach in this case and disagrees with the DS on the interpretation of the results from the two Buehler studies. The data does not support a proposal of Category 1 for skin sensitisation. RAC proposes no classification on the basis of conclusive data.

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Netherlands	<confidential>	Company-Manufacturer	251

Comment received

For the coin industry, silver coins are stored in a plastic capsule. People do not touch them with their hands. Also, proof quality coins are only touched with gloves.

Skin sensitisation - the criteria for classification as a skin sensitiser are not fulfilled:
* reliable human evidence showing that silver causes skin sensitisation in a substantial number of persons is lacking
* a high number of animal studies with a variety of chemical forms of ionic silver show

nonsensitising potential of silver
Dossier Submitter's Response
Thank you. Please note that the silver content among different silver compunds differ and that classification is based on intrinsic properties and does not take exposure into account.
RAC's response
RAC does not support a proposal of Category 1 for skin sensitisation. See response to comment 250.

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	France	FRANCECLAT, BOCI and UFBJOP	Industry or trade association	252
Comment received				
Please find our comments on this specific hazard in the attached document. ECHA note – An attachment was submitted with the comment above. Refer to public attachment Comments on CLH proposal for silver.pdf				
Dossier Submitter's Response				
Thank you. Please see the justification in the CLH report why it is not considered safe to disregard information indicating that criteria are fulfilled. Please also note that the silver content among different silver compunds differ and the results of these tests may thus not accurately represent the intrinsic sensitising potential of silver (ions) since it is not maximised in the test. The classification and labelling must include all forms or physical states in which elemental silver is placed on the market. In our view, we cannot disregard information indicating that silver ions released have a sensitising potential since silver ions are released from silver, e.g. in contact with moist or when an electrical current is applied such as in electrodes used for water purification.				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Germany	Fachvereinigung Edelmetalle e. V.	Industry or trade association	253
Comment received				
The criteria for classification of silver as a skin sensitiser are not fulfilled: o reliable human evidence showing that silver causes skin sensitisation in a sub-stantial number of persons is lacking, and o a high number of animal studies with a variety of chemical forms of ionic silver show nonsensitising potential of silver (note that the animal dataset in the CLH report is incomplete). o The recycling and processing of material flows containing silver (including met-allurgical enrichment, chemical processing, melting of Ag or Ag alloys, machin-ing of Ag or Ag alloys) shows no conspicuousness in the hazard analysis after approx. 250 years of production experience with regard to skin irritation or al-lergic reactions. Occupational medical check-ups are inconspicuous and have not led to any occupational group-specific impairment.				

ECHA note – An attachment was submitted with the comment above. Refer to public attachment FVEM comments CLH silver.pdf
Dossier Submitter's Response
Thank you. Please see the justification in the CLH report why it is not considered safe to disregard information indicating that criteria are fulfilled. Please also note that the silver content among different silver compunds differ and the results of these tests may thus not accurately represent the intrinsic sensitising potential of silver (ions) since it is not maximised in the test.
RAC's response
RAC does not support a proposal of Category 1 for skin sensitisation. See response to comment 250.

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Germany	Federal Associations of the German Jewellery and Silverware Industry	Industry or trade association	254
Comment received				
The criteria for classification as a skin sensitiser are not fulfilled: - reliable human evidence showing that silver causes skin sensitisation in a substantial number of persons is lacking, and - a high number of animal studies with a variety of chemical forms of ionic silver show non-sensitising potential of silver (note that the animal dataset in the CLH report is in-complete). ECHA note – An attachment was submitted with the comment above. Refer to public attachment 20201216-comments-vbv-clh-silver.pdf				
Dossier Submitter's Response				
Thank you. Please see the justification in the CLH report why it is not considered safe to disregard information indicating that criteria are fulfilled. Please also note that the silver content among different silver compunds differ and the results of these tests may thus not accurately represent the intrinsic sensitising potential of silver (ions) since it is not maximised in the test.				
RAC's response				
RAC does not support a proposal of Category 1 for skin sensitisation. See response to comment 250.				

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Italy	IPZS S.p.A.	Company-Manufacturer	255
Comment received				
no evidence ECHA note – An attachment was submitted with the comment above. Refer to public attachment Public attachment in the questionnarie.docx				
Dossier Submitter's Response				
Thank you.				

RAC's response
Noted.

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Germany	HAGER GROUP	Company-Downstream user	256
Comment received				
Skin sensitisation - the criteria for classification as a skin sensitiser are not fulfilled: o reliable human evidence showing that silver causes skin sensitisation in a substantial number of persons is lacking, and o a high number of animal studies with a variety of chemical forms of ionic silver show nonsensitising potential of silver (note that the animal dataset in the CLH report is incomplete). ECHA note – An attachment was submitted with the comment above. Refer to public attachment CHL Ag- DU contribution- Hager group.docx				
Dossier Submitter's Response				
Thank you. Please see the justification in the CLH report why it is not considered safe to disregard information indicating that criteria are fulfilled. Please also note that the silver content among different silver compunds differ and the results of these tests may thus not accurately represent the intrinsic sensitising potential of silver (ions) since it is not maximised in the test.				
RAC's response				
RAC does not support a proposal of Category 1 for skin sensitisation. See response to comment 250.				

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Czech Republic	SAFINA, a.s.	Company-Manufacturer	257
Comment received				
Please see the attached file. ECHA note – An attachment was submitted with the comment above. Refer to public attachment SAFINA_CLH public consultation_silver metal - completed.pdf				
Dossier Submitter's Response				
Thank you. Please see the justification in the CLH report why it is not considered safe to disregard information indicating that criteria are fulfilled. Please also note that the silver content among different silver compunds differ and the results of these tests may thus not accurately represent the intrinsic sensitising potential of silver (ions) since it is not maximised in the test.				
Thank you for the information about your uses of silver. We note the support for the comments submitted by the EPMF.				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Norway	<confidential>	Company-Manufacturer	258
Comment received				
The criteria for classification as a skin sensitiser are not fulfilled: - reliable human evidence showing that silver causes skin sensitisation in a substantial number of persons is lacking - a high number of animal studies with a variety of chemical forms of ionic silver show non sensitising potential of silver ECHA note – An attachment was submitted with the comment above. Refer to public attachment Comments CLH Ag -17.12.20.pdf ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Comments CLH Ag - <confidential> - 17.12.20 - confidential info.pdf				
Dossier Submitter's Response				
Thank you. Please see the justification in the CLH report why it is not considered safe to disregard information indicating that criteria are fulfilled. Please also note that the silver content among different silver compunds differ and the results of these tests may thus not accurately represent the intrinsic sensitising potential of silver (ions) since it is not maximised in the test. The confidential attachment was not found.				
RAC's response				
RAC does not support a proposal of Category 1 for skin sensitisation. See response to comment 250.				

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Germany	Heimerle + Meule GmbH	Company-Manufacturer	259
Comment received				
The criteria for classification of silver as a skin sensitizer are not fulfilled: o reliable human evidence showing that silver causes skin sensitisation in a substantial number of persons is lacking, and o a high number of animal studies with a variety of chemical forms of ionic silver show non-sensitising potential of silver (note that the animal dataset in the CLH report is incomplete). o The recycling and processing of material flows containing silver (including metallurgical enrichment, chemical processing, melting of Ag or Ag alloys, machining of Ag or Ag alloys) shows no conspicuousness in the hazard analysis after approx. 250 years of production experience with regard to skin irritation or allergic reactions. Occupational medical check-ups are inconspicuous and have not led to any occupational group-specific impairment. ECHA note – An attachment was submitted with the comment above. Refer to public attachment H+M comments CLH silver.pdf				
Dossier Submitter's Response				
Thank you. Please see the justification in the CLH report why it is not considered safe to disregard information indicating that criteria are fulfilled. Please also note that the silver content among different silver compunds differ and the results of these tests may thus				

not accurately represent the intrinsic sensitising potential of silver (ions) since it is not maximised in the test.
RAC's response
RAC does not support a proposal of Category 1 for skin sensitisation. See response to comment 250.

Date	Country	Organisation	Type of Organisation	Comment number
16.12.2020	Germany	<confidential>	Industry or trade association	260
Comment received				
The criteria for classification as a skin sensitiser are not fulfilled: - reliable human evidence showing that silver causes skin sensitisation in a substantial number of persons is lacking, and - a high number of animal studies with a variety of chemical forms of ionic silver show non-sensitising potential of silver (note that the animal dataset in the CLH report is incom-plete). ECHA note – An attachment was submitted with the comment above. Refer to public attachment 20201214-<confidential>-clh-silver-comments.pdf				
Dossier Submitter's Response				
Thank you. Please see the justification in the CLH report why it is not considered safe to disregard information indicating that criteria are fulfilled. Please also note that the silver content among different silver compunds differ and the results of these tests may thus not accurately represent the intrinsic sensitising potential of silver (ions) since it is not maximised in the test. The attachment was not found.				
RAC's response				
RAC does not support a proposal of Category 1 for skin sensitisation. See response to comment 250.				

Date	Country	Organisation	Type of Organisation	Comment number
16.12.2020	Finland	<confidential>	Company-Manufacturer	261
Comment received				
the criteria for classification as a skin sensitiser are not fulfilled: reliable human evidence showing that silver causes skin sensitisation in a substantial number of persons is lacking, and a high number of animal studies with a variety of chemical forms of ionic silver show non-sensitising potential of silver and the animal dataset in the CLH report is incomplete				
Dossier Submitter's Response				
Thank you. Please see the justification in the CLH report why it is not considered safe to disregard information indicating that criteria are fulfilled. Please also note that the silver content among different silver compunds differ and the results of these tests may thus not accurately represent the intrinsic sensitising potential of silver (ions) since it is not maximised in the test.				
RAC's response				
RAC does not support a proposal of Category 1 for skin sensitisation. See response to comment 250.				

Date	Country	Organisation	Type of Organisation	Comment number
16.12.2020	Germany		MemberState	262

Comment received

pages 62-71
The dossier submitter concluded classification of silver as Skin Sens. Cat. 1 based on a WoE approach, taking into account human data (case reports primarily for silver nitrate) and two positive Buehler assays (OECD 406 or US-EPA guideline) using silver citrate/laurate solution or silver zeolite. The positives rates from the Buehler tests would allow classification, however, the relatively high rates in the negative controls, the low score of the graded reactions and the presence of citrate/laureate or zeolite limit the significance of the positive results. Effects were seen predominantly with formulations containing silver ions, which appear to permit a more reliable skin exposure, rather than studies with nanosilver. Therefore, the negative result in the GPMT using nanosilver was given lower priority. These issues were discussed comprehensively by the dossier submitter and consequently the WoE approach including the human data was applied. The human data are derived from a book chapter summarising eight case reports, six on silver nitrate and two on colloidal silver. The wording in the summary table indicates a true allergic response in only three of the reports on silver nitrate (Gaul and Underwood, 1948; Agarwal and Gawkrodger, 2002; Fisher, 1987).

We agree with the decision of choosing the WoE approach. However, the applied criteria for the final decision for classification are not completely clear. It is not clear, whether criteria of Annex I/3.4.2.2.4.1 were dismissed in place of the criteria of Annex I/3.4.2.2.4.3. We would conclude, that criteria of Annex I/3.4.2.2.4.1 are not met, since the animal data (c) alone are not sufficient for the WoE as they were not considered for classification in the first place and the few episodes of allergic contact dermatitis (e) are not well documented. As for Annex I/3.4.2.2.4.3., we agree that basically the criteria (a) and (e) are fulfilled. However, the data basis of a single book chapter is unsatisfactory. Original study reports of the book chapter were not evaluated. Regarding the frequent exposure by wound dressings and the use of colloidal silver in large area burn injuries in relation to few cases of silver allergy, classification should be considered only on a more comprehensive data basis.

In case categorisation for skin sensitisation is taken into consideration, we agree that data on frequency and exposure would be insufficient for sub-categorisation. However, the human evidence based on a book chapter with a low number of case reports does not warrant classification for skin sensitisation.

Dossier Submitter's Response

Please see our response to comment 249.

RAC's response

Agree with the concerns expressed by the Member State. RAC does not support a proposal of Category 1 for skin sensitisation. See response to comment 250.

Date	Country	Organisation	Type of Organisation	Comment number
16.12.2020	Germany	Heraeus Deutschland GmbH & Co. KG	Company-Manufacturer	263
Comment received				
Skin sensitization - the criteria for classification as a skin sensitizer are not fulfilled: o reliable human evidence showing that silver causes skin sensitization in a substantial number of persons is lacking, and o a high number of animal studies with a variety of chemical forms of ionic silver show non-sensitizing potential of silver (note that the animal dataset in the CLH report is incomplete).				
Dossier Submitter's Response				
Thank you. Please see the justification in the CLH report why it is not considered safe to disregard information indicating that criteria are fulfilled. Please also note that the silver content among different silver compunds differ and the results of these tests may thus not accurately represent the intrinsic sensitising potential of silver (ions) since it is not maximised in the test.				
RAC's response				
RAC does not support a proposal of Category 1 for skin sensitisation. See response to comment 250.				

Date	Country	Organisation	Type of Organisation	Comment number
15.12.2020	France	SCHNEIDER ELECTRIC INDUSTRIES SAS	Company-Manufacturer	264
Comment received				
No comment ECHA note – An attachment was submitted with the comment above. Refer to public attachment Silver_consultation_2020_non_confidential.pdf ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Silver_consultation_2020_Schneider_Electric.pdf				
Dossier Submitter's Response				
Thank you.				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
15.12.2020	Germany	RAS AG	Company-Manufacturer	265
Comment received				
see comment_CLH_silver_RAS_AG.pdf attached ECHA note – An attachment was submitted with the comment above. Refer to public attachment comment_CLH_silver_RAS_AG_public.pdf ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment comment_CLH_Silver_RAS_AG.zip				

Dossier Submitter's Response
Thank you. Based on the data submitted, the results discussed seem to relate to a certain product that do not represent 100% of the active substance. Therefore, the intrinsic sensitising potential of silver (ions) is not considered adequately investigated in this study. Regarding safe use of silver it is clear from various reviews that robust data for several toxicological endpoints is limited. Therefore, the safe use may only reflect that effects of silver has not been carefully investigated.
RAC's response
Noted.

Date	Country	Organisation	Type of Organisation	Comment number
15.12.2020	Switzerland	Argor-Heraeus SA	Company-Manufacturer	266
Comment received				
Skin sensitization - the criteria for classification as a skin sensitizer are not fulfilled: o reliable human evidence showing that silver causes skin sensitization in a substantial number of persons is lacking, and o a high number of animal studies with a variety of chemical forms of ionic silver show non-sensitizing potential of silver (note that the animal dataset in the CLH report is incomplete).				
Dossier Submitter's Response				
Thank you. Please see the justification in the CLH report why it is not considered safe to disregard information indicating that criteria are fulfilled. Please also note that the silver content among different silver compunds differ and the results of these tests may thus not accurately represent the intrinsic sensitising potential of silver (ions) since it is not maximised in the test.				
RAC's response				
RAC does not support a proposal of Category 1 for skin sensitisation. See response to comment 250.				

Date	Country	Organisation	Type of Organisation	Comment number
15.12.2020	Belgium	Umicore	Company-Manufacturer	267
Comment received				
Skin sensitisation - the criteria for classification as a skin sensitizer are not fulfilled: • There is very low incidence of human dermal sensitization despite extensive silver exposure (medical, dental, jewelry applications etc.). • a high number of animal studies with a variety of chemical forms of ionic silver show non sensitizing potential of silver (note that the animal dataset in the CLH report is incomplete). • Silver metal should not be classified as a skin sensitizer. ECHA note – An attachment was submitted with the comment above. Refer to public attachment Umicore public consultation_final 20201215.pdf				
Dossier Submitter's Response				
Thank you. Please see the justification in the CLH report why it is not considered safe to disregard information indicating that criteria are fulfilled. Please also note that the silver content among different silver compunds differ and the results of these tests may thus				

not accurately represent the intrinsic sensitising potential of silver (ions) since it is not maximised in the test.
RAC's response
RAC does not support a proposal of Category 1 for skin sensitisation. See response to comment 250.

Date	Country	Organisation	Type of Organisation	Comment number
15.12.2020	United Kingdom	AeroSpace and Defence (ASD) Industries Association of Europe	Industry or trade association	268
Comment received				
The criteria for classification as a skin sensitiser are not fulfilled since reliable human evidence showing that silver causes skin sensitisation in a substantial number of persons is lacking and a high number of animal studies with a variety of chemical forms of ionic silver show non-sensitising potential of silver (note that the animal dataset in the CLH report is incomplete).				
Dossier Submitter's Response				
Thank you. Please see the justification in the CLH report why it is not considered safe to disregard information indicating that criteria are fulfilled. Please also note that the silver content among different silver compunds differ and the results of these tests may thus not accurately represent the intrinsic sensitising potential of silver (ions) since it is not maximised in the test.				
RAC's response				
RAC does not support a proposal of Category 1 for skin sensitisation. See response to comment 250.				

Date	Country	Organisation	Type of Organisation	Comment number
14.12.2020	France	<confidential>	Company-Manufacturer	269
Comment received				
The criteria for classification as a skin sensitiser are not fulfilled: - there is a lack of reliable human evidence showing that silver causes skin sensitisation in a substantial number of persons, and - different ionic silver compounds have been used in a high number of animal studies not leading to the conclusion that there is a sensitising potential of silver, Nevertheless, the animal dataset in the CLH report is still incomplete.				
Dossier Submitter's Response				
Thank you. Please see the justification in the CLH report why it is not considered safe to disregard information indicating that criteria are fulfilled. Please also note that the silver content among different silver compunds differ and the results of these tests may thus not accurately represent the intrinsic sensitising potential of silver (ions) since it is not maximised in the test.				
RAC's response				
RAC does not support a proposal of Category 1 for skin sensitisation. See response to comment 250.				

Date	Country	Organisation	Type of Organisation	Comment number
11.12.2020	Germany	<confidential>	Company-Manufacturer	270
Comment received				
"Skin sensitization - the criteria for classification as a skin sensitizer are not fulfilled: o reliable human evidence showing that silver causes skin sensitization in a substantial number of persons is lacking, and o a high number of animal studies with a variety of chemical forms of ionic silver show non-sensitizing potential of silver (note that the animal dataset in the CLH report is incomplete)."				
Dossier Submitter's Response				
Thank you. Please see the justification in the CLH report why it is not considered safe to disregard information indicating that criteria are fulfilled. Please also note that the silver content among different silver compunds differ and the results of these tests may thus not accurately represent the intrinsic sensitising potential of silver (ions) since it is not maximised in the test.				
RAC's response				
RAC does not support a proposal of Category 1 for skin sensitisation. See response to comment 250.				

Date	Country	Organisation	Type of Organisation	Comment number
10.12.2020	France	ERCUIS	Company-Manufacturer	271
Comment received				
Skin sensitisation - the criteria for classification as a skin sensitiser are not fulfilled: • reliable human evidence showing that silver causes skin sensitisation in a substantial number of persons is lacking, and • a high number of animal studies with a variety of chemical forms of ionic silver show nonsensitising potential of silver (note that the animal dataset in the CLH report is incomplete). ECHA note – An attachment was submitted with the comment above. Refer to public attachment Consultation européenne sur l'argent ERCUIS_12-2020.pdf				
Dossier Submitter's Response				
Thank you. Please see the justification in the CLH report why it is not considered safe to disregard information indicating that criteria are fulfilled. Please also note that the silver content among different silver compunds differ and the results of these tests may thus not accurately represent the intrinsic sensitising potential of silver (ions) since it is not maximised in the test.				
RAC's response				
RAC does not support a proposal of Category 1 for skin sensitisation. See response to comment 250.				

Date	Country	Organisation	Type of Organisation	Comment number
09.12.2020	France	Comité Colbert	Industry or trade association	272
Comment received				
There is no reliable evidence that silver causes skin sensitisation in a substantial number of humans. We also wish to stress that there is a high number of animal studies with a variety of chemical forms of ionic silver which show silver's nonsensitising potential. Please also note in this context that the animal dataset in the CLH report is incomplete. We also wish to state that the classification is based on the textbook "Silver in healthcare" by A. B. G. Lansdown (2010). But this report specifically mentions that « according to the author, many people tolerate metals in their solid state ». Massive silver should therefore not be classified. Please refer to the EPMF full report for detailed analysis. ECHA note – An attachment was submitted with the comment above. Refer to public attachment LT_Comité_Colbert_ECHA.pdf				
Dossier Submitter's Response				
Thank you. Please see the justification in the CLH report why it is not considered safe to disregard information indicating that criteria are fulfilled. Please also note that the silver content among different silver compunds differ and the results of these tests may thus not accurately represent the intrinsic sensitising potential of silver (ions) since it is not maximised in the test.				
RAC's response				
RAC does not support a proposal of Category 1 for skin sensitisation. See response to comment 250.				

Date	Country	Organisation	Type of Organisation	Comment number
08.12.2020	Germany	Heraeus Deutschland GmbH & Co. KG	Company-Manufacturer	273
Comment received				
Skin sensitization - the criteria for classification as a skin sensitizer are not fulfilled: o reliable human evidence showing that silver causes skin sensitization in a substantial number of persons is lacking, and o a high number of animal studies with a variety of chemical forms of ionic silver show non-sensitizing potential of silver (note that the animal dataset in the CLH report is incomplete). ECHA note – An attachment was submitted with the comment above. Refer to public attachment HPT_Public Cons. Ag CLH Proposal_AH.pdf				
Dossier Submitter's Response				
Thank you. Please see the justification in the CLH report why it is not considered safe to disregard information indicating that criteria are fulfilled. Please also note that the silver content among different silver compunds differ and the results of these tests may thus				

not accurately represent the intrinsic sensitising potential of silver (ions) since it is not maximised in the test.
RAC's response
RAC does not support a proposal of Category 1 for skin sensitisation. See response to comment 250.

Date	Country	Organisation	Type of Organisation	Comment number
02.12.2020	France	Metalor Technologies	Company-Manufacturer	274
Comment received				
The criteria for classification as a skin sensitiser are not fulfilled: o reliable human evidence showing that silver causes skin sensitisation in a substantial number of persons is lacking, and o a high number of animal studies with a variety of chemical forms of ionic silver show nonsensitising potential of silver (note that the animal dataset in the CLH report is incomplete).				
Dossier Submitter's Response				
Thank you. Please see the justification in the CLH report why it is not considered safe to disregard information indicating that criteria are fulfilled. Please also note that the silver content among different silver compunds differ and the results of these tests may thus not accurately represent the intrinsic sensitising potential of silver (ions) since it is not maximised in the test.				
RAC's response				
RAC does not support a proposal of Category 1 for skin sensitisation. See response to comment 250.				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Germany	AURUBIS AG	Company-Manufacturer	275
Comment received				
» Skin sensitisation - the criteria for classification as a skin sensitiser are not fulfilled: - reliable human evidence showing that silver causes skin sensitisation in a substantial number of persons is lacking, and - a high number of animal studies with a variety of chemical forms of ionic silver show nonsensitising potential of silver (note that the animal dataset in the CLH report is incomplete). ECHA note – An attachment was submitted with the comment above. Refer to public attachment Aurubis comments to Silver CLH proposal 2020-12-18.pdf				
Dossier Submitter's Response				
Thank you. Please see the justification in the CLH report why it is not considered safe to disregard information indicating that criteria are fulfilled. Please also note that the silver content among different silver compunds differ and the results of these tests may thus not accurately represent the intrinsic sensitising potential of silver (ions) since it is not maximised in the test.				

RAC's response
RAC does not support a proposal of Category 1 for skin sensitisation. See response to comment 250.

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	France	MONNAIE DE PARIS	Company-Downstream user	276
Comment received				
Skin sensitisation for end user also is not showed and even less proved. There are no clinical cases. The classification under this risk would not be relevant to date. ECHA note – An attachment was submitted with the comment above. Refer to public attachment 2020 12 18 ECHA MdP 2020 survey CLH for Silver_VDEF.pdf				
Dossier Submitter's Response				
Thank you.				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Germany	AZUR SPACE Solar Power GmbH	Company-Downstream user	277
Comment received				
The criteria for classification as a skin sensitiser are not fulfilled for us: o reliable human evidence showing that silver causes skin sensitisation in a substantial number of persons is lacking and o a high number of animal studies with a variety of chemical forms of ionic silver show nonsensitising potential of silver (note that the animal dataset in the CLH report is incomplete).				
Dossier Submitter's Response				
Thank you. Please see the justification in the CLH report why it is not considered safe to disregard information indicating that criteria are fulfilled. Please also note that the silver content among different silver compunds differ and the results of these tests may thus not accurately represent the intrinsic sensitising potential of silver (ions) since it is not maximised in the test.				
RAC's response				
RAC does not support a proposal of Category 1 for skin sensitisation. See response to comment 250.				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Poland	<confidential>	Company-Manufacturer	278
Comment received				
Skin sensitization - never found nor observed in the <confidential>. ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Silver - <confidential> statement.docx				
Dossier Submitter's Response				
Thank you. The statement could not be found.				

RAC's response
Noted.

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Austria	Wirtschaftskammer Österreich		279
Comment received				
see attachment ECHA note – An attachment was submitted with the comment above. Refer to public attachment su_309_StN öK Silber CLH.pdf				
Dossier Submitter's Response				
Thank you. We note the support for the comments submitted by the EPMF.				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Finland	Boliden Harjavalta	Company-Manufacturer	280
Comment received				
Skin sensitisation - the criteria for classification as a skin sensitiser are not fulfilled: o reliable human evidence showing that silver causes skin sensitisation in a substantial number of persons is lacking, and o a high number of animal studies with a variety of chemical forms of ionic silver show nonsensitising potential of silver (note that the animal dataset in the CLH report is incomplete).				
Dossier Submitter's Response				
Thank you.				
RAC's response				
RAC does not support a proposal of Category 1 for skin sensitisation. See response to comment 250.				

OTHER HAZARDS AND ENDPOINTS – Specific Target Organ Toxicity Single Exposure

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Italy	<confidential>	Company-Manufacturer	281
Comment received				
no evidence ECHA note – An attachment was submitted with the comment above. Refer to public attachment 2020 12 17 Public attachment in the questionnarie <confidential> (003).docx				
Dossier Submitter's Response				
Thank you.				
RAC's response				
There is no clear evidence of toxicity to a specific organ after a single exposure event.				

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Italy	IPZS S.p.A.	Company-Manufacturer	282
Comment received				
no evidence ECHA note – An attachment was submitted with the comment above. Refer to public attachment Public attachment in the questionnarie.docx				
Dossier Submitter's Response				
Thank you.				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Belgium	T&D Europe	Industry or trade association	283
Comment received				
no comment ECHA note – An attachment was submitted with the comment above. Refer to public attachment TD Europe CLH Consultation Silver_Dec2020_final.pdf				
Dossier Submitter's Response				
OK				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Poland	<confidential>	Company-Manufacturer	284
Comment received				
Specific target organ toxicity – single exposure - never found nor observed in the <confidential>. ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Silver - <confidential> statement.docx				
Dossier Submitter's Response				
OK				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
16.12.2020	Germany	Heraeus Deutschland GmbH & Co. KG	Company-Manufacturer	285
Comment received				
N/A				
Dossier Submitter's Response				
OK				

RAC's response
Note lack of comment.

Date	Country	Organisation	Type of Organisation	Comment number
15.12.2020	France	SCHNEIDER ELECTRIC INDUSTRIES SAS	Company-Manufacturer	286
Comment received				
No comment ECHA note – An attachment was submitted with the comment above. Refer to public attachment Silver_consultation_2020_non_confidential.pdf ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Silver_consultation_2020_Schneider_Electric.pdf				
Dossier Submitter's Response				
OK				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
15.12.2020	Germany	RAS AG	Company-Manufacturer	287
Comment received				
see comment_CLH_silver_RAS_AG.pdf attached ECHA note – An attachment was submitted with the comment above. Refer to public attachment comment_CLH_silver_RAS_AG_public.pdf ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment comment_CLH_Silver_RAS_AG.zip				
Dossier Submitter's Response				
Thank you.				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
02.12.2020	France	Metalor Technologies	Company-Manufacturer	288
Comment received				
-				
Dossier Submitter's Response				
-				
RAC's response				
Note lack of comment.				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Germany	Netzwerk NanoSilber	Industry or trade association	289
Comment received				
none ECHA note – An attachment was submitted with the comment above. Refer to public attachment CLH public consultation silver - Comments by Netzwerk NanoSilber.pdf				
Dossier Submitter's Response				
OK				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Portugal	<confidential>	Company-Manufacturer	290
Comment received				
We are not aware of any hazard originated my metalic silver and we have been using silver for a very long time.				
Dossier Submitter's Response				
Thank you.				
RAC's response				
Noted.				

OTHER HAZARDS AND ENDPOINTS – Specific Target Organ Toxicity Repeated Exposure

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Italy	<confidential>	Company-Manufacturer	291
Comment received				
no evidence ECHA note – An attachment was submitted with the comment above. Refer to public attachment 2020 12 17 Public attachment in the questionnarie <confidential> (003).docx				
Dossier Submitter's Response				
Thank you.				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Italy	IPZS S.p.A.	Company-Manufacturer	292
Comment received				
no evidence ECHA note – An attachment was submitted with the comment above. Refer to public attachment Public attachment in the questionnarie.docx				

Dossier Submitter's Response
Thank you
RAC's response
Noted.

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Belgium	T&D Europe	Industry or trade association	293
Comment received				
no comment ECHA note – An attachment was submitted with the comment above. Refer to public attachment TD Europe CLH Consultation Silver_Dec2020_final.pdf				
Dossier Submitter's Response				
OK				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
16.12.2020	Germany		MemberState	294
Comment received				
pages 195-237 We agree with the dossier submitter on the neurotoxicity concern raised by the oral study on pregnant rats using silver nanoparticles (IIIA, 6.8.2-10). We would like to emphasise the importance of bioaccumulation of silver in this context. However, we agree that based on the overall data, criteria for classification are not fulfilled.				
Dossier Submitter's Response				
Thank you				
RAC's response				
The most concerning effect noted by the DS and RAC is the potential for neurotoxicity. There is evidence to classify on this basis. Taking a weight of evidence approach from a selection of different studies it is concluded that classification for STOT RE is warranted. In the case of STOT RE there are several sources of supporting information from different forms of silver. RAC supports classification with STOT RE 2 (nervous system).				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Poland	<confidential>	Company-Manufacturer	295
Comment received				
Specific target organ toxicity – repeated exposure - never found nor observed in the <confidential>. ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Silver - <confidential> statement.docx				
Dossier Submitter's Response				
Thank you.				

RAC's response
Noted.

Date	Country	Organisation	Type of Organisation	Comment number
16.12.2020	Germany	Heraeus Deutschland GmbH & Co. KG	Company-Manufacturer	296
Comment received				
N/A				
Dossier Submitter's Response				
OK				
RAC's response				
Note lack of comment.				

Date	Country	Organisation	Type of Organisation	Comment number
15.12.2020	France	SCHNEIDER ELECTRIC INDUSTRIES SAS	Company-Manufacturer	297
Comment received				
No comment ECHA note – An attachment was submitted with the comment above. Refer to public attachment Silver_consultation_2020_non_confidential.pdf ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Silver_consultation_2020_Schneider_Electric.pdf				
Dossier Submitter's Response				
OK				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
15.12.2020	Germany	RAS AG	Company-Manufacturer	298
Comment received				
see comment_CLH_silver_RAS_AG.pdf attached ECHA note – An attachment was submitted with the comment above. Refer to public attachment comment_CLH_silver_RAS_AG_public.pdf ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment comment_CLH_Silver_RAS_AG.zip				
Dossier Submitter's Response				
Thank you.				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
02.12.2020	France	Metalor Technologies	Company-Manufacturer	299
Comment received				
-				
Dossier Submitter's Response				
-				
RAC's response				
Note lack of comment.				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Germany	Netzwerk NanoSilber	Industry or trade association	300
Comment received				
none ECHA note – An attachment was submitted with the comment above. Refer to public attachment CLH public consultation silver - Comments by Netzwerk NanoSilber.pdf				
Dossier Submitter's Response				
OK				
RAC's response				
Note lack of comment.				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Portugal	<confidential>	Company-Manufacturer	301
Comment received				
We are not aware of any hazard originated my metalic silver and we have been using silver for a very long time.				
Dossier Submitter's Response				
Thank you				
RAC's response				
Noted. Please see response to comment 294.				

OTHER HAZARDS AND ENDPOINTS – Hazardous to the Aquatic Environment

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Germany	WirtschaftsVereinigung Metalle	Industry or trade association	302
Comment received				
We think that the criteria for classification of massive silver as toxic to the aquatic environment are not fulfilled either. The available scientific information as well as evidence from internal industry data confirm that a split classification for silver massive versus silver powder is justified. Following the specific guidance developed for the hazard assessment of metals would result in a non-classification of massive silver.				

ECHA note – An attachment was submitted with the comment above. Refer to public attachment 2020-12-18_WVMetalle Comment on CLH Proposal for Silver.pdf
Dossier Submitter's Response
The commenting party claims that available scientific information as well as evidence from internal industry data confirm that a split classification for silver massive versus silver powder is justified. However, no reference to supporting data for this statement is provided by the commenting party. Thank you for your comment. The CLP regulation, (EC) No 1272/2008, needs to be followed and associated guidelines considered. For a split classification there need to be evidence available for why this is warranted. Please also note that the general principle for classification is one classification per substance not per form of the substance. Please also see the DS' response to comment number 316.
RAC's response
EPMF sent additional information for reasonable hadling and uses of massive silver. Information in the IA document from October 2021 indicates that particles < 1 mm might be released from the manufacturing/finishing of jewellery and tableware after polishing of (semi-) finished articles - processes of polishing (dry or wet), sanding or brushing might generate particles <1 mm. As declared by IA - losses via these processes are intentionally kept minimal, and material loss from these surface treatments are <0.01 wt% of the article. The collected material (either from the dry or wet processes) is never pure silver metal but always of unspecified and variable composition including e.g. sand, alloying elements, carrier material or polishing cloth next to silver metal. This implies that all these released and collected fractions are registered as UVCBs and not pure silver metal. These UVCBs subsequently undergo a stepwise treatment and refinement to recover the silver again. From this pont of view massive silver should be classified separately. Taking into account data from T/D test no classification is justified for massive silver.

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Germany	Netzwerk NanoSilber	Industry or trade association	303
Comment received				
none ECHA note – An attachment was submitted with the comment above. Refer to public attachment CLH public consultation silver - Comments by Netzwerk NanoSilber.pdf				
Dossier Submitter's Response				
The DS could not find any comments regarding the hazards in the aquatic environment, in the attachment.				
RAC's response				
RAC could not find any comments regarding the hazards in the aquatic environment, in the attachment.				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Portugal	<confidential>	Company-Manufacturer	304
Comment received				
To the best of our knoweledge, the criteria for classification of silver metal (massive) as toxic to the aquatic environment are not fulfilled:				

o the available scientific and industrial evidence confirm that a split classification for silver massive versus silver powder is justified, and o silver massive should not be classified.
Dossier Submitter's Response
Thank you for your comment. Regarding your proposal for a separate consideration for silver in the massive form, please see the DS response to comment number 316.
RAC's response
Please, see response to comment number 302.

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	United Kingdom	Ames Goldsmith UK Ltd	Company-Manufacturer	305
Comment received				
• Hazardous to the aquatic environment - the criteria for classification of silver metal (massive) as toxic to the aquatic environment are not fulfilled: o the available scientific and industrial evidence confirm that a split classification for silver massive versus silver powder is justified, and o silver massive should not be classified.				
Dossier Submitter's Response				
Thank you for your comment. Regarding your proposal for separate consideration for silver in the massive form, please see the DS response to comment number 316 in the present RCOM.				
RAC's response				
Please, see response to comment number 302.				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Italy	<confidential>	Company-Manufacturer	306
Comment received				
no evidence ECHA note – An attachment was submitted with the comment above. Refer to public attachment 2020 12 17 Public attachment in the questionnarie <confidential> (003).docx				
Dossier Submitter's Response				
Thank you for your comment and referral to the EPMF's comments. Please see the DS response to comment number 316 in the present RCOM.				
RAC's response				
Thank you for your comment. Please, see response to comment number 302 and comment number 316.				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Poland		Individual	307
Comment received				
• Hazardous to the aquatic environment - the criteria for classification of silver metal (massive) as toxic to the aquatic environment are not fulfilled:				

☐ the available scientific and industrial evidence confirm that a split classification for silver massive versus silver powder is justified, and ☐ silver massive should not be classified. ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment comment.pdf
Dossier Submitter's Response
Thank you for your comment. Regarding your proposal for separate consideration for silver in the massive form, please see the DS response to comment number 316 in the present RCOM.
RAC's response
Please, see response to comment number 302.

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Germany	Bio-Gate AG	Company-Manufacturer	308
Comment received				
- the available scientific and industrial evidence confirm that a split classification for silver massive versus silver powder is justified, and silver massive should not be classified. - due to the special particles of MicroSilver BG Bio-Gate disagrees with the hazardous to the aquatic environment classification for metallic silver powder with special properties like MicroSilver BG. To prove this Bio-Gate started an OECD study according to OECD 202, OECD 210 and OECD 211. Results will be available in Q3/20201. - regarding persistence - Metallic silver is a chemical element. Thus it cannot be degraded. Just like gold also silver exists stable in elementary form. MicroSilver BG like any other metallic silver is a precious metal, behaving mostly inert. The metallic silver itself is not bioactive, so there is no toxicity related to the elementary metal. The kind of persistence which is relevant for toxicological considerations (e.g. when chlororganic compounds are discussed, that are poorly degraded and maintain their toxicity), cannot be applied for silver or for gold. Both just show stability, but - from a toxcological point of view - that alone should not considered to be persistence. - regarding bioaccumulation: The fear is that a compound that is persistent and toxic can bioaccumulate over time in biota and even more important is enriching in the food chain. Metallic silver is not bioaccumulative. There are only reports for bioaccumulation of silver compounds that is ionic silver. However, these reports are limited to selected biota and it is known that such bound material is only very difficult to mobilize. So that the required toxic action cannot unfold and passage via the food chain is interrupted. Also given the natural input of silver into the environment or its longtime use in industry there is no evidence for extended associated risks. ECHA note – An attachment was submitted with the comment above. Refer to public attachment Bio-Gate Safety Studies.zip ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Bio-Gate Microsilver BG Confidential Safety Studies.zip				
Dossier Submitter's Response				
Thank you for your comments. Regarding your proposal for a separate consideration for silver in the massive form, please see the DS response to comment number 316 in the present RCOM. Regarding your comment concerning persistence (P), bioaccumulation (B) and toxicity (T) properties. It is not clear if you really refer to the present CLH-dossier or if you refer to				

something else. The environmental classification proposal under the CLP-regulation should cover hazards in the aquatic environment. It was not possible to draw a general conclusion based on the available information regarding bioaccumulation of silver (see CLH dossier page 249). Generally, persistence is not a relevant property for elements.
RAC's response
Regarding your proposal for a separate consideration for silver in the massive form, please see response to comment number 302. As a chemical element silver exists in the aquatic environment as different chemical species with different bioavailability – silver ion and silver monochloride complex are bioavailable. According to silver chemical properties transformation of silver chemical species to non bioavailable form is not expected at environmentali relevant silver concentrations. Taking into account data for silver biouptake in fish and invertebrates it might be concluded that silver has low potential for bioaccumulation. RAC notes that the studies referred to above have not been provided. However, as the approach using the lowest ERV value has been used to classify all forms of silver, it is highly unlikely that results from the studies named above would serve to reduce the determined classification for aquatic hazards.

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Germany	I&P Europe - Imaging and Printing Association e.V.	Industry or trade association	309
Comment received				
see attached document ECHA note – An attachment was submitted with the comment above. Refer to public attachment Comments to the silver metal CLH public consultation.pdf				
Dossier Submitter's Response				
Thank you for your comment. Regarding your proposal for separate consideration for silver in the massive form, please see the DS' response to comment number 316 in the present RCOM.				
RAC's response				
Thank you for your comment. Please, see response to comment number 302.				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Belgium	T&D Europe	Industry or trade association	310
Comment received				
no comment ECHA note – An attachment was submitted with the comment above. Refer to public attachment TD Europe CLH Consultation Silver_Dec2020_final.pdf				
Dossier Submitter's Response				
Thank you for your comment and your brief description of your production of silver powder. Please also see the DS' response to comment number 316, in the present RCOM.				

RAC's response
Thank you for your comment. Please, see response to comment number 302.

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Belgium	Eurometaux	Industry or trade association	311

Comment received

In general, Eurometaux would make a strong plea for 1) using all evidence of good quality provided in the registration dossiers or during the Public Consultation, 2) following the (metal specific) CLP guidance without further interpreting it and 3) ensuring consistency with other metal dossiers previously assessed for their environmental hazard and classification.
All these aspects are relevant to the assessment of the environmental aquatic classification review of Silver metal given:
- Only a selective choice of ecotoxicity data has been included in the Dossier Submitters report. As a consequence, not all data available in the registration dossier or in publicly available literature were used. This comment goes beyond the identification of ecotoxicity data and relates also to models like the acute BLM to some extend demonstrating the pH effect at acute level, or the Ticket-Unit World model demonstrating the removal of the soluble ion on a theoretical base

- Several derivations from the published CLP guidance on metals or extended interpretations (e.g. statistical treatment of large ecotoxicity data sets and criteria for a separate classification entry for metals in massive form), further discussed here below under the specific comments.

- There is some lack in consistency with how previous comparable data sets on metals were handled (e.g. in respect to separate entries for the massive and powder form while introducing an entry for the nano form).

- In line with the two previous comments all relevant evidence is available to make a clear and distinguished hazard assessment and classification for the massive and the powder form.

- We noted the intention of Sweden to submit a hazard assessment and classification file for a soluble form (AgNO3). It would have been far more logic to assess first the ecotoxicity and environmental hazard classification of the soluble ion, before assessing the metal form. Indeed, the ecotoxicity of the soluble form is the common base for all Ag compounds including the metal. The metal file could subsequently have been limited to the assessment of the relevancy and robustness of the TDp (OECD 29) results to derive the environmental classification for the metal. It is unclear to us while the Dossier Submitter opted to submit the two files in the opposite way of expectations.

Most positively, we noted that the proposal from the Dossier Submitter recognises the outcome of the Substance Evaluation on Silver in nanoform in respect to the M-factor setting. Furthermore we noted recognition for the importance of the pH dependency of the TDp and ecotoxicity data, the latter at least for the chronic environmental hazard endpoint.

We noted in particular that recent RAC assessments of metal environmental classification

cases (Cu flakes and granules, Lead metal and this one on Silver metal) all use somewhat different methods and interpretations of the CLP guidance section on metals (especially in respect to section IV 5.5). In our view this challenges the predictability and transparency of the harmonised classification process.
Eurometaux would therefore call RAC to use all evidence available by screening it for quality and relevance and ensuring the CLP guidance for metals is applied in full and consistently with previous dossiers.
Complementary to the generic comments, Eurometaux would like to raise some specific comments and input on:
1. The restricted application of the metal's classification scheme
The proposed acute and chronic ERVs for classification are incomplete given:
- Derived on a selective data sets with unknown selection criteria which impacts (limits) the statistical derivation of the ERVs
- No pH dependency has been defined for the acute ecotoxicity data set while a validated acute BLM is available in the registration file which would allow normalisation for pH before the acute ERV and acute environmental hazard class is defined

2. Including ecotoxicity data developed under non-standard conditions for other purposes then hazard assessment for classification
The test conducted by Schlich et al. 2017 for the purpose of the Ag nano Substance Evaluation should not be used for the acute and chronic ERV derivation given tested under circumstances that are non-standard and not relevant to natural conditions (no chloride content). This would require reassessing the Chronic ERV, not the acute ERV, given this chronic reference is the most sensitive value, while for the acute assessment there are several more sensitive values.

3. The splitting of the metal classification entry for the environmental endpoint for the different forms
The 3 Silver metal forms (massive, powder and nano) provide very different dissolution rates and equilibria warranting different classification entries. This difference in transformation dissolution rate covers more than 3 orders of magnitude between the powder and massive form. Not recognising this robust evidence would highly overestimate the hazard for the massive form. While so far, for metals, only an entry for the massive form and for the powder form was applied, it seems that this case warrants a separate entry for the nano form unless the hazard classification entry would be equal to the one that RAC would decide for the upcoming soluble salt case on AgNO3.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment Enclosure 2 - Overview of metal environmental classification entries including some history.zip

Dossier Submitter's Response

Thank you for your comments. Regarding your first four comments, please see the DS response to comment number 316 in the present RCOM.

The CLH dossiers for silver nitrate and silver have been prepared in parallel. Due to circumstances related to the evaluation under the Biocides Regulation, the dossier for silver was submitted first.

Regarding your comment numbered 1.
Regarding your comment that not all available acute and chronic data has been referred to, please note that all reliable and relevant ecotoxicity data based on dissolved silver available to DS at the time of CLH-dossier submission are listed in annex I together with

reliability assessment. The presentation and selection of data based on reliability and relevance is further explained in the section 11.5 and 11.6 in the CLH-report for acute and chronic data, respectively. Please also see the DS response to comment number 316 in the present RCOM.

Regarding pH please see the DS response below.
Section 11.7 in the CLH-dossier, where pH T/D-test results are compared with pH ecotoxicity tests, concerns both acute and chronic data and states: "The key ecotoxicity tests in the data set for silver were performed at approximately pH = 8 and this is also the pH that showed the highest T/D-test result for silver powder."
As the T/D-data and ecotoxicity data preferably should be compared at the same pH in a conservative manner a normalisation to other pH is not considered necessary in this case.
For acute toxicity data the SSD method is not considered applicable, please see further the JRC draft report attached to the present RCOM. (pH in the individual aquatic toxicity tests are listed in annex I to the CLH-dossier for both acute and chronic data. The pH in the ecotoxicity test is generally between 7 and 8.)

Regarding your comment numbered 2 and 3,
Please see the DS' response to comment number 316 in the present RCOM.

RAC's response

Regarding general coment that only a selective choice of ecotoxicity data has been included in the Dossier Submitters report.
RAC noted that all available data from recent JRC report for silver EQS derivation as well as data from published study of Katrien Arijs et al. (2021) have been taken into account for ERV derivation.
Regarding the study of Schlich et al. 2017
This study is included in dataset for SSD calculation in Katrien Arijs et al. (2021) with acceptable reliability.
Regarding BLM application
Acute BLM is validated only for fish, chronic BLM is not available for silver, normalization tools for silver are not developed.
Regarding the pH effect at acute level
RAC demonstrates that concentration of DOC and the presence of thiol containg groups are most important parameters modifying Ag toxicity. For classification pH of T/D test coinside with pH of key ecotoxicity tests, no need of data normalization.
Regarding Ticket-Unit World model: RAC takes into account all additional information presented by EPMF (study of Nijs 2021, application Visual Minteq 3.1; meso- and microcosm studies **(**Jiang et al (2017), Colman et al (2014)) and concluded that silver transformation to nonbioavailable forms is not expected under environmentally relevant conditions (please, see also response to comment number 316).
For silver metal classification, please, see response to comment number 302.

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Germany	<confidential>	Company-Manufacturer	312
Comment received				
o the available scientific and industrial evidence confirm that a split classification for silver massive versus silver powder is justified, and o silver massive should not be classified.				
Dossier Submitter's Response				
Thank you for your comment. Regarding your proposal for a separate consideration for silver in the massive form, please see the DS' response to comment number 316 in the present RCOM.				
RAC's response				
Thank you for comment. Please see response to comment number 302.				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	France		MemberState	313
Comment received				
In agreement with the proposed classification for environment. M-factors estimation: In agreement with a separate environmental classification for nanosilver based on the approach for soluble silver compounds. A recent study (Pang et al. 2020) confirms that the dissolution of AgNPs was dependent on the coating of AgNP with highest dissolution according to the type of coating. The study shows that the coated silver nanoparticles seem to behave more like a soluble silver salt than a poorly soluble metal.				
Dossier Submitter's Response				
Thank you for your comment and support.				
RAC's response				
Thank you for your comment and support.				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Germany	ZVEI - German Electrical and Electronic Manufacturers' Association	Industry or trade association	314
Comment received				
The criteria for classification of silver metal (massive) as toxic to the aquatic environment are not fulfilled: o the available scientific and industrial evidence confirm that a split classification for silver massive versus silver powder is justified, and o silver massive should not be classified. ECHA note – An attachment was submitted with the comment above. Refer to public attachment 20201218 ZVEI Silver Applications in EEE and Comments Ag CLH Consultation.pdf				

Dossier Submitter's Response
The commenting party supports the arguments provided by EPMF. Thank you for your comment. Please see the DS' response to comment number 316 in the present RCOM.
RAC's response
Please see response to comment number 302.

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Germany	C.HAFNER GmbH + Co. KG	Company-Manufacturer	315
Comment received				
The criteria for classification of silver metal (massive) as toxic to the aquatic environment are not fulfilled: o the available scientific and industrial evidence confirm that a split classification for silver massive versus silver powder is justified, and o silver massive should not be classified. Please refer to the scientific comments submitted by the European Precious Metals Federation (EPMF).				
Dossier Submitter's Response				
Thank you for your comment. Regarding your proposal for a separate consideration for silver in the massive form, please see the DS' response to comment number 316 in the present RCOM.				
RAC's response				
Thank you for your comment. Please, see response to comment number 302.				

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Belgium	European Precious Metals Federation (EPMF)	Industry or trade association	316
Comment received				
Summary of comments on the environmental hazard assessment (CLH report p.239-272): • Evidence is available showing rapid removal of silver from the water column. • T/Dp studies should be recognised and taken into account for classification purposes, and a separate classification entry for nanosilver and silver powder is warranted. In addition, a separate entry for the massive form (not classified for environmental hazards) is justified based on T/Dp data and based on the fact that silver powder is produced by a special process and is not generally generated from the massive metal, and the massive does not produce powders under foreseeable use. • Not all available data for acute and long-term aquatic hazard have been referred to in the CLH proposal / used for classification. For further details / justification, please refer to the attached document pages 48-56. ECHA note – An attachment was submitted with the comment above. Refer to public attachment CLH Ag Comments FINAL_201217.pdf				
Dossier Submitter's Response				
Thank you for your comments, please see the DS' response below.				

Regarding rapid removal from the water column (Environmental transformation of metals or inorganic metals compounds, 11.2):

Thank you for your information regarding your work on tests performed with silver in accordance with the extension of the transformation-dissolution protocol (T/DP-E) and the upcoming inclusion of this data in the REACH registration dossiers.

In the CLP-guidance on application of the CLP criteria, Annex IV, introduction, it is stated: "However, partitioning of the metal ion from the water column to other environmental media does not necessarily mean that it is no longer bioavailable, nor does it necessarily mean that the metal has been made permanently unavailable."
In the same guidance there is also a note from ECHA in the chapter regarding environmental transformation in the annex concerning metals and poorly soluble metal compounds (annex IV chapter 3) that there is lack of scientific consensus and continuing discussions on the interpretation of rapid removal from the water column. It is also mentioned that there is currently no agreement on the validity of use of the concept of rapid removal for classification purposes.

The TD/P-E has been previously discussed in a "Rapid Removal Workshop" that was organised by ECHA in Helsinki. The new extended T/D protocol was then (11 June 2019) presented by the industry. However, the workshop concluded that the protocol was not suitable for hazard assessment and use under CLP. The main reason for this was that TD/P-E cannot be applied to a wide range of different environmental conditions and that the irreversibility of the removal of metals is a fundamental issue and is not yet demonstrated by the method so far. Furthermore, for organic substances the rapid removal through binding to particles that settle and bind in the sediment has already been dismissed as it is considered more relevant for risk assessment and not suitable for hazard assessment. Therefore, the proposed concept of rapid removal for metals would be inconsistent with the existing approach for organic substances.
To conclude, there is still no harmonized approach or guidance available on the concept "rapid removal" for inorganic substances. Consequently, silver is not considered to be rapidly removed from the water column for the purpose of classification and labelling in this CLH report.

The conclusion in the present CLH-report is as follows:
"In summary, it is not possible to conclude that silver is transformed in a way that would rapidly and permanently remove it from the water column."

Regarding chapter 11.3 and your proposal for separate consideration for massive silver and silver powder.

Thank you for your support regarding our proposal for environmental classification of nanosilver.

Regarding your proposal that silver massive metal and silver powder should be considered separately:
As mentioned in the CLH-report, chapter 11, the DS had not at the time of submission of the CLH-dossier been presented with evidence to your statement that silver powder cannot be representative for silver. Generated particles during reasonably expected use need to be taken into account when assessing the intrinsic hazard of the massive form of

a metal. No evidence that particles < 1 mm is not generated in sufficient quantities from the massive metal during reasonably expected use had been presented in the Reach registration dossier or otherwise come to the knowledge of the DS. (The ECHA guidance on the application of the CLP criteria defines in section 1.2 the term 'reasonably expected use' as all physical forms and states of a substance or mixture that may occur during intended use or reasonably foreseeable conditions of misuse. It includes production, handling, disposal, any technical operations (e.g. sawing, drilling, grinding, etc), any professional and non-professional uses as well as reasonably foreseeable accidental exposure but not abuse such as criminal or suicidal uses.)
In your attachment to the present RCOM you have now provided arguments for silver massive metal to be considered separately from silver powder such as a description of silver as a malleable and ductile material and a description of the production process for silver powder. The DS is however uncertain whether these descriptions are sufficient as evidence or if actual data is needed and would like to hear the RAC opinion on this matter.

You also mention that the CLP-guidance indicate that different classifications can be applied to massive and powder if there is a significant difference in dissolution rate between the massive form and the powder form. Please note that different dissolution rate between massive and powder form is expected. But again, a crucial question is if particles < 1 mm is generated in sufficient quantities from the massive metal during reasonably expected use.

Please note that the classification does not take account of the specific form of the metal. However, the form of the metal may be taken into account in deciding on the labelling of the massive metal. Please see the excerpt from the CLP-guidance below.

Section 1.2.3.3 states the following in relation to environmental hazards:

> *The system of classification is designed to ensure that a single classification applies to a substance. In general it takes no account of the specific form since this can vary and is not intrinsic to the substance. The form in which the substance is placed on the market is taken into account when deciding what label to apply and various derogations from labelling exist, e.g. for metals in the massive form. In the massive form the hazard may not be present and the substance need not be labelled. The SDS will, however, indicate the classification and intrinsic hazardous properties to warn the user that subsequent transformation of the substance may produce the hazardous form. (CLP guidance, 1.2.3.3)*

Regarding aquatic hazards, chapter 11.5 and 6:

Comparison of aquatic toxicity data and solubility data based on pH: Regarding your comment on this topic, please see the CLH-report section 11.7. The worst-case approach has been followed as recommended in the CLP-guidance on application of the CLP-criteria.

Regarding your comment that not all available acute data has been referred to, please note that all reliable ecotoxicity data based on dissolved silver available to DS are listed in annex I together with reliability assessment. The presentation and selection of data based on reliability and relevance is further explained in the section 11.5 and 11.6 in the CLH-report for acute and chronic data respectively. It is not clarified what data you refer to as missing and therefore it is difficult to further specify this answer.

Regarding the inclusion of a probabilistic method (species sensitivity distribution analysis):
The DS agree that for chronic data an SSD analysis could be relevant as there is now data available for a sufficient number of taxonomic groups of species that allow an SSD analysis for chronic aquatic toxicity. Currently, the JRC is preparing a dossier with Environmental Quality Standards (EQS) for silver. A few more recently available studies that have been considered as sufficiently reliable have been added to the dataset that was presented in the CLH dossier. The preliminary analysis based on dissolved silver and freshwater species showed a median HC5 of 0.06 µg/L or 0.08 µg/l depending on considerations regarding reliability for certain data. Please also see the draft JRC report as an attachment to this RCOM. This draft will be discussed and possibly revised by the Scientific Committee on Health, Environmental and Emerging Risks (SCHEER). The dossier submitter recommends RAC to use the SSD prepared by JRC for the purpose of classification for chronic aquatic hazard and to use the most updated version. The preliminary values from the SSD analysis for the aquatic chronic toxicity endpoint is slightly lower than obtained from the deterministic approach used for the current CLH-dossier (aquatic chronic ecotoxicity value of 0.1 µg/l) but will not affect the classification nor M-factors.

For the acute dataset the probabilistic SSD approach was not considered appropriate for the following reasons:
(i) the lack of major taxonomic groups (e.g. Mollusca, amphibian and insect) according to the requirements in European Communities (2018),
(ii) it was not possible to compile consistent datasets because of different experimental set-ups affecting the bioavailability of silver, thus the datasets would not reflect the distribution of sensitivity among the species.

Regarding the EPMF comment that the study by Schlich, et al. (2017) should not be used for classification due to that the EDTA concentration was reduced:
The test medium (AAP normally containing 0.3 mg/L EDTA) was modified in order to reduce the presence of silver complexing agents: EDTA was reduced by 50% and compounds including chloride was replaced by nitrate compounds.
As the results for the aquatic toxicity data are based on measured dissolved silver the amount of EDTA and chloride does not have an effect on the conservativeness of the results with regards to bioavailability. Neither does it affect the study's relevancy for classification compared to other studies, included in the CLH-dossier, with results also based on measured dissolved silver.
Furthermore, the validity criteria including e.g. requirements for biomass increase in the control cultures were fulfilled and therefore there is no reason to suspect that the reduction in EDTA has had significant effect on growth.

The studies presented in the EPMF table over chronic data (included in the attachment "CLH Ag Comments FINAL_201217") are mostly covered already in the CLH-report, please also see the annex I to the CLH-report. The DS notes though that the values in EPMF's table are not always easy to track as there are some geometric means presented without reporting the individual values the means are based on. Some values seem e.g. to be based on total silver (e.g. the value 0.38 µg/l for hatching, P. promelas by Dethloff, G., Naddy, R., Gorsuch, J.; 2007b) as opposed to values for dissolved silver as reported in the CLH-report. Anyhow, a compilation of the available studies (including studies mentioned by EPMF that were not presented int the actual CLH dossier) is available in the dossier recently prepared by the JRC with the purpose to derive environmental water

quality standards under the Water Framework Directive. We attached the most updated draft.

24022021_Silver_EQS Dossier_Final Draft

RAC's response

Regarding evidence, available showing rapid removal of silver from the water column: EPMF sent a study of Nijs 2021, (October 2021) for Ag speciation using speciation code Visual Minteq 3.1. This study shows possibilities for silver transformation to nonbioavailable species, namely precipitation to Ag2S, however in the presence of relatively high concentration of chromium reducible sulfide. Additional meso- and microcosm studies of **(**Jiang et al (2017), Colman et al (2014)) presented were performed at very high Ag concentration. Overal results from these studies does not support the conclusion for silver transformation to non bioavailable form under environmentally relevant conditions.

Regarding a separate entry for the massive form (not classified for environmental hazards) and silver powder. EPMF sent additional information for reasonable hadling and uses of massive silver. Information in the IA document from October 2021 indicates that particles < 1 mm might be released from the manufacturing/finishing of jewellery and tableware after polishing of (semi-) finished articles - processes of polishing (dry or wet), sanding or brushing might generate particles <1 mm. As declared by IA - losses via these processes are intentionally kept minimal, and material loss from these surface treatments are <0.01 wt% of the article. The collected material (either from the dry or wet processes) is never pure silver metal but always of unspecified and variable composition including e.g. sand, alloying elements, carrier material or polishing cloth next to silver metal. This implies that all these released and collected fractions are registered as UVCBs and not pure silver metal. These UVCBs subsequently undergo a stepwise treatment and refinement to recover the silver again. From this pont of view massive silver should be classified separately. Taking into account data from T/D test no classification is justified for massive silver

Regarding critics that not all available data for acute and long-term aquatic hazard have been referred to in the CLH proposal/used for classification.
RAC supports deterministic approach used by DS with data from JRC report on EQS derivation for silver. It is worth mentioned that the most sensitive endpoints, identified by the DS coincide with these used in JRC reported and also supported by RAC. Result for HC5 from SSD calculations for chronic toxicity of 0.084 µg/L in JRC report is in the same range with value of 0.1 µg/L obtained by deterministic approach. In addition study published by Katrien Arijs et al. (2021) was presented by IA. Overal results for HC5 calculated in JRC report (0.084 µg/L) and in the study of Katrien Arijs et al. (0.088 µg/L) coincide if normal distribution is used for SSD calculations. RAC concludes that derived ERV values are relible and based on most relevant information for acute and chronic Ag toxicity.

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Netherlands		MemberState	317

Comment received

Thank you for the proposal for the aquatic toxicity classification of bulk/powdered silver and nano-silver. We agree with the separate classification for nano-silver as its rate of

dissolution is much higher than that of bulk silver and powdered silver. As was concluded after the REACH substance evaluation for silver and nanoforms of silver (EC no. 231-131-3), results from tests with nano-silver on daphnids, algae and soil microorganisms indicate that silver nitrate (ionic silver) is equally or more toxic as compared to the silver nanoparticles tested. Consequently, it was concluded that the PNEC values derived from silver nitrate can also serve as PNEC values for the nanoforms of silver that are covered by the REACH registration dossier(s) submitted for Silver. As the proposed classification for nano-silver, obtained through the application of ERVs, is equal to that proposed for silver nitrate, the SEv conclusion is covered by this proposal. However, we are uncertain if the M-factor for chronic aquatic toxicity should be 100 or 1000. The dossier submitter derives an M-factor of 100 on the basis of the ERV applying the M-factors as given in table 4.1.3 of Annex I of the CLP regulation. For comparison, an M-factor of 1000 is derived on the basis of the ratio between T/D and ERV. It is unclear why the M-factor of 100 is finally selected. Furthermore, the upper limit for the selection of M-factors in table 4.1.3 is given as a "smaller than or equal to" symbol (≤). This is in contrast with table IV.1 in the guidance where only "smaller than" symbols are used, but it can be presumed that the table in the regulation is leading A NOEC of 0.1 µg/L would then result in an M-factor of 1000 as also indicated by the T/D-ERV method. On the basis of this it seems that the M-factor should be 1000, also from a precautionary point of view. The dossier submitter is requested to explain their choice for the M-factor of 100.
Dossier Submitter's Response
Thank you for your comment. Yes, we believe that you are right. The M-factor should indeed be 1000 for chronic toxicity as the table in the 4.1.3 in Annex I in the CLP regulation is leading.
RAC's response
Thank you for your comment. The M-factor should indeed be 1000 for chronic toxicity as the Table in the 4.1.3 in Annex I in the CLP regulation is leading.

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Netherlands	<confidential>	Company-Manufacturer	318
Comment received				
Hazardous to the aquatic environment - the criteria for classification of silver metal (massive) as toxic to the aquatic environment are not fulfilled: * the available scientific and industrial evidence confirm that a split classification for silver massive versus silver powder is justified * silver massive should not be classified				
Dossier Submitter's Response				
Thank you for your comment. Regarding your proposal for a separate consideration for silver in the massive form, please see the DS' response to comment number 316 in the present RCOM.				
RAC's response				
Thank you for your comment. Please, see response to comment number 302.				

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Germany	Fachvereinigung Edelmetalle e. V.	Industry or trade association	319
Comment received				
The criteria for classification of silver metal (massive) as toxic to the aquatic environment are not fulfilled: o the available scientific and industrial evidence confirm that a split classification for silvermassive versus silver powder is justified, and o silver massive should not be classified. ECHA note – An attachment was submitted with the comment above. Refer to public attachment FVEM comments CLH silver.pdf				
Dossier Submitter's Response				
The commenting party supports the arguments provided by EPMF. Thank you for your comment. Please see the DS' response to comment number 316 in the present RCOM.				
RAC's response				
Please, see response to comment number 302.				

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Germany	Federal Associations of the German Jewellery and Silverware Industry	Industry or trade association	320
Comment received				
The criteria for classification of silver metal (massive) as toxic to the aquatic environment are not fulfilled: - the available scientific and industrial evidence confirm that a split classification for silver massive versus silver powder is justified, and - massive silver should not be classified. ECHA note – An attachment was submitted with the comment above. Refer to public attachment 20201216-comments-vbv-clh-silver.pdf				
Dossier Submitter's Response				
The commenting party supports the arguments provided by EPMF. Thank you for your comment. Please see the DS' response to comment number 316 in the present RCOM.				
RAC's response				
Please, see response to comment number 302.				

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Italy	IPZS S.p.A.	Company-Manufacturer	321
Comment received				
no evidence				

ECHA note – An attachment was submitted with the comment above. Refer to public attachment Public attachment in the questionnarie.docx
Dossier Submitter's Response
The commenting party supports the arguments provided by EPMF. Thank you for your comment. Please see the DS' response to comment number 316 in the present RCOM.
RAC's response
Please, see response to comment number 302.

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Germany	HAGER GROUP	Company-Downstream user	322
Comment received				
Hazardous to the aquatic environment - the criteria for classification of silver metal (massive) as toxic to the aquatic environment are not fulfilled: - the available scientific and industrial evidence confirm that a split classification for silver massive versus silver powder is justified, and - silver massive should not be classified ECHA note – An attachment was submitted with the comment above. Refer to public attachment CHL Ag- DU contribution- Hager group.docx				
Dossier Submitter's Response				
The commenting party supports the arguments provided by EPMF. Thank you for your comment. Please see the DS' response to comment number 316 in the present RCOM.				
RAC's response				
Please, see response to comment number 302.				

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Czech Republic	SAFINA, a.s.	Company-Manufacturer	323
Comment received				
Please see the attached file. ECHA note – An attachment was submitted with the comment above. Refer to public attachment SAFINA_CLH public consultation_silver metal - completed.pdf				
Dossier Submitter's Response				
The commenting party supports the arguments provided by EPMF. Thank you for your comment. Please see the DS' response to comment number 316 in the present RCOM.				
RAC's response				
Please, see response to comment number 302.				

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Norway	<confidential>	Company-Manufacturer	324
Comment received				
The criteria for classification of silver metal (massive) as toxic to the aquatic environment are not fulfilled: - the available scientific and industrial evidence confirm that a split classification for silver massive versus silver powder is justified - silver massive should not be classified. ECHA note – An attachment was submitted with the comment above. Refer to public attachment Comments CLH Ag -17.12.20.pdf ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Comments CLH Ag - <confidential> - 17.12.20 - confidential info.pdf				
Dossier Submitter's Response				
The commenting party supports the arguments provided by EPMF. Thank you for your comment. Please see the DS' response to comment number 316 in the present RCOM.				
RAC's response				
Please, see response to comment number 302.				

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Germany	Heimerle + Meule GmbH	Company-Manufacturer	325
Comment received				
The criteria for classification of silver metal (massive) as toxic to the aquatic environment are not fulfilled: o the available scientific and industrial evidence confirm that a split classification for massive silver versus silver powder is justified, and o massive silver should not be classified. ECHA note – An attachment was submitted with the comment above. Refer to public attachment H+M comments CLH silver.pdf				
Dossier Submitter's Response				
Thank you for your comment. Please see the DS' response to comment number 316 in the present RCOM.				
RAC's response				
Please, see response to comment number 302.				

Date	Country	Organisation	Type of Organisation	Comment number
16.12.2020	Germany	Siemens AG	Company-Manufacturer	326
Comment received				
Based on our assessment of the report and discussio with industry experts, we think that the criteria for classification of silver metal (massive) as toxic to the aquatic environment are not fulfilled. Available scientific and industrial evidence confirm that a split				

classification for silver massive versus silver powder is justified, and silver massive should not be classified.
Dossier Submitter's Response
Thank you for your comment. Please see the DS' response to comment number 316 in the present RCOM.
RAC's response
Please, see response to comment number 302.

Date	Country	Organisation	Type of Organisation	Comment number
16.12.2020	Germany	<confidential>	Industry or trade association	327
Comment received				
The criteria for classification of silver metal (massive) as toxic to the aquatic environment are not fulfilled: - the available scientific and industrial evidence confirm that a split classification for silver massive versus silver powder is justified, and - massive silver should not be classified. ECHA note – An attachment was submitted with the comment above. Refer to public attachment 20201214-<confidential>-clh-silver-comments.pdf				
Dossier Submitter's Response				
Thank you for your comment. Please see the DS' response to comment number 316 in the present RCOM. The DS was not able to find the attachment mentioned in the comment.				
RAC's response				
Thank you for your comment. Please, see response to comment number 302.				

Date	Country	Organisation	Type of Organisation	Comment number
16.12.2020	Finland	<confidential>	Company-Manufacturer	328
Comment received				
the criteria for classification of silver metal (massive) as toxic to the aquatic environment are not fulfilled: the available scientific and industrial evidence confirm that a split classification for silver massive versus silver powder is justified, and silver massive should not be classified.				
Dossier Submitter's Response				
Thank you for your comment. Please see the DS' response to comment number 316 in the present RCOM.				
RAC's response				
Please, see response to comment number 302.				

Date	Country	Organisation	Type of Organisation	Comment number
16.12.2020	Germany		MemberState	329
Comment received				
For environmental classification, contrary to the classification of health hazards, a separate entry for nanosilver seems justified based on the available data.				

Dossier Submitter's Response
The commenting party supports the proposal made by the DS. Thank you for your comment and support.
RAC's response
Thank you for your comment and support.

Date	Country	Organisation	Type of Organisation	Comment number
16.12.2020	Germany	Heraeus Deutschland GmbH & Co. KG	Company-Manufacturer	330
Comment received				
Hazardous to the aquatic environment - the criteria for classification of silver metal (massive) as toxic to the aquatic environment are not fulfilled: o the available scientific and industrial evidence confirm that a split classification for silver massive versus silver powder is justified, and o silver massive should not be classified.				
Dossier Submitter's Response				
Thank you for your comment. Please see the DS' response to comment number 316 in the present RCOM.				
RAC's response				
Please, see response to comment number 302.				

Date	Country	Organisation	Type of Organisation	Comment number
15.12.2020	France	SCHNEIDER ELECTRIC INDUSTRIES SAS	Company-Manufacturer	331
Comment received				
No comment ECHA note – An attachment was submitted with the comment above. Refer to public attachment Silver_consultation_2020_non_confidential.pdf ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Silver_consultation_2020_Schneider_Electric.pdf				
Dossier Submitter's Response				
Thank you for your comment and the brief overview of the manufacturing of silver powder and your silver products. The DS would like to comment that while the production process is one piece in the puzzle in the CLH process a crucial question is if particles < 1 mm is generated (in sufficient quantities) from the massive metal during reasonably expected use. Please also see DS' response to comment number 316.				
RAC's response				
Thank you for information on the production of silver powder and your silver products. For silver classification, please see response to comment number 302.				

Date	Country	Organisation	Type of Organisation	Comment number
15.12.2020	Germany	RAS AG	Company-Manufacturer	332
Comment received				
see comment_CLH_silver_RAS_AG.pdf attached ECHA note – An attachment was submitted with the comment above. Refer to public attachment comment_CLH_silver_RAS_AG_public.pdf ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment comment_CLH_Silver_RAS_AG.zip				
Dossier Submitter's Response				
The commenting party supports the arguments provided by EPMF. Thank you for your comment. Please see the DS' response to comment number 316 in the present RCOM.				
RAC's response				
Please, see response to comment number 302.				

Date	Country	Organisation	Type of Organisation	Comment number
15.12.2020	Switzerland	Argor-Heraeus SA	Company-Manufacturer	333
Comment received				
Hazardous to the aquatic environment - the criteria for classification of silver metal (massive) as toxic to the aquatic environment are not fulfilled: o the available scientific and industrial evidence confirm that a split classification for silver massive versus silver powder is justified, and o silver massive should not be classified.				
Dossier Submitter's Response				
Thank you for your comment. Please see the DS' response to comment number 316 in the present RCOM.				
RAC's response				
Please, see response to comment number 302.				

Date	Country	Organisation	Type of Organisation	Comment number
15.12.2020	Belgium	Umicore	Company-Manufacturer	334
Comment received				
Hazardous to the aquatic environment - the criteria for classification of silver metal (massive) as toxic to the aquatic environment are not fulfilled: • the full dataset of environmental toxicity studies is not taken into account. • the available scientific and industrial evidence confirm that a split classification for silver massive versus silver powder is justified, and • silver massive should not be classified. ECHA note – An attachment was submitted with the comment above. Refer to public attachment Umicore public consultation_final 20201215.pdf				
Dossier Submitter's Response				
The commenting party supports the arguments provided by EPMF.				

Thank you for your comment. Please see the DS' response to comment number 316 in the present RCOM.
RAC's response
Please, see response to comment number 302 and comment number 316.

Date	Country	Organisation	Type of Organisation	Comment number
15.12.2020	United Kingdom	AeroSpace and Defence (ASD) Industries Association of Europe	Industry or trade association	335
Comment received				
The criteria for classification of silver metal (massive) as toxic to the aquatic environment is not fulfilled since available scientific and industrial evidence confirm that a split classification for silver massive versus silver powder is justified and silver massive should not be classified the same as silver powder form.				
Dossier Submitter's Response				
Thank you for your comment. Please see the DS' response to comment number 316 in the present RCOM.				
RAC's response				
Please, see response to comment number 302.				

Date	Country	Organisation	Type of Organisation	Comment number
14.12.2020	France	<confidential>	Company-Manufacturer	336
Comment received				
The criteria for classification of silver metal (massive) as toxic to the aquatic environment are not fulfilled: - different behavior can be expected for massive and powdered silver, which is confirmed by scientific and industrial evidence. This leads to the conclusion, that a split classification for these two forms is justified, and - there at least is no justification for the classification of massive silver, however it is understood form Eurometaux that all forms of a metal must be considered concurrently. As Kemi has omitted silver massive from its submission, should the submission itself not be rejected?				
Dossier Submitter's Response				
Thank you for your comment. The CLP regulation, (EC) No 1272/2008, needs to be followed and associated guidelines considered. For a split classification there need to be evidence available for why this is warranted. Please also note that the general principle for classification is one classification per substance not per form of the substance. Please also see the DS' response to comment number 316.				
RAC's response				
Thank you for your comment. As noted by DS CLP regulation, (EC) No 1272/2008, needs to be followed and associated guidelines considered. Please, see response to comment number 302.				

Date	Country	Organisation	Type of Organisation	Comment number
11.12.2020	Germany	<confidential>	Company-Manufacturer	337
Comment received				
"Hazardous to the aquatic environment - the criteria for classification of silver metal (massive) as toxic to the aquatic environment are not fulfilled: o the available scientific and industrial evidence confirm that a split classification for silver massive versus silver powder is justified, and o silver massive should not be classified."				
Dossier Submitter's Response				
Thank you for your comment. Please see the DS' response to comment number 316 in the present RCOM.				
RAC's response				
Please, see response to comment number 302.				

Date	Country	Organisation	Type of Organisation	Comment number
10.12.2020	France	ERCUIS	Company-Manufacturer	338
Comment received				
the criteria for classification of silver metal (massive) as toxic to the aquatic environment are not fulfilled: • the available scientific and industrial evidence confirm that a split classification for silver massive versus silver powder is justified, and • silver massive should not be classified. ECHA note – An attachment was submitted with the comment above. Refer to public attachment Consultation européenne sur l'argent ERCUIS_12-2020.pdf				
Dossier Submitter's Response				
Thank you for your comment. Please see the DS' response to comment number 316 in the present RCOM.				
RAC's response				
Please, see response to comment number 302.				

Date	Country	Organisation	Type of Organisation	Comment number
10.12.2020	Germany	SAXONIA Technical Materials GmbH	Company-Manufacturer	339
Comment received				
Massive silver, as used by our downstream users, should not be classified and strictly split from silver powder classification				
Dossier Submitter's Response				
The commenting party does not provide arguments for their statement. Thank you for your comment. Please see the DS' response to comment number 316 in the present RCOM.				
RAC's response				
Please, see response to comment number 302.				

Date	Country	Organisation	Type of Organisation	Comment number
10.12.2020	Germany	Doduco	Company-Manufacturer	340
Comment received				
it should be distinguished between massive and particle silver; massive silver, as used by our DU, should not be classified available scientific and industrial evidence confirm that a split classification for silver massive versus silver powder is justified				
Dossier Submitter's Response				
Thank you for your comment. Please see the DS' response to comment number 316 in the present RCOM.				
RAC's response				
Please, see response to comment number 302.				

Date	Country	Organisation	Type of Organisation	Comment number
09.12.2020	France	Comité Colbert	Industry or trade association	341
Comment received				
The criteria for the classification of silver metal (massive) as toxic to the aquatic environment are not fulfilled. The available scientific and industrial evidence confirm that a split classification for silver massive versus silver powder is justified and that massive silver should not be classified. Please refer to the EPMF full report for detailed analysis. ECHA note – An attachment was submitted with the comment above. Refer to public attachment LT_Comité_Colbert_ECHA.pdf				
Dossier Submitter's Response				
The commenting party supports the arguments provided by EPMF. Thank you for your comment. Please see the DS' response to comment number 316 in the present RCOM.				
RAC's response				
Please, see response to comment number 302.				

Date	Country	Organisation	Type of Organisation	Comment number
08.12.2020	France	UITS	Industry or trade association	342
Comment received				
we support the scientific comments sent to you by the European Precious Metals Federation (EPMF) both regarding to human health and the environment. ECHA note – An attachment was submitted with the comment above. Refer to public attachment ARGENT.pdf				
Dossier Submitter's Response				
The commenting party supports the arguments provided by EPMF. Thank you for your comment. Please see the DS' response to comment number 316 in the present RCOM.				

RAC's response
EPMF comments are carefully considered. Please, see response to comment number 302.

Date	Country	Organisation	Type of Organisation	Comment number
08.12.2020	Germany	Heraeus Deutschland GmbH & Co. KG	Company-Manufacturer	343
Comment received				
Hazardous to the aquatic environment - the criteria for classification of silver metal (massive) as toxic to the aquatic environment are not fulfilled: o the available scientific and industrial evidence confirm that a split classification for silver massive versus silver powder is justified, and o silver massive should not be classified. ECHA note – An attachment was submitted with the comment above. Refer to public attachment HPT_Public Cons. Ag CLH Proposal_AH.pdf				
Dossier Submitter's Response				
The commenting party supports the arguments provided by EPMF. Thank you for your comment. Please see the DS' response to comment number 316 in the present RCOM.				
RAC's response				
Please, see response to comment number 302.				

Date	Country	Organisation	Type of Organisation	Comment number
02.12.2020	France	Metalor Technologies	Company-Manufacturer	344
Comment received				
The criteria for classification of silver metal (massive) as toxic to the aquatic environment are not fulfilled: o the available scientific and industrial evidence confirm that a split classification for silver massive versus silver powder is justified, and o silver massive should not be classified.				
Dossier Submitter's Response				
Thank you for your comment. Please see the DS' response to comment number 316 in the present RCOM.				
RAC's response				
Please, see response to comment number 302.				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Germany	AURUBIS AG	Company-Manufacturer	345
Comment received				
» Hazardous to the aquatic environment - the criteria for classification of silver metal (massive) as toxic to the aquatic environment are not fulfilled: - the available scientific and industrial evidence confirm that a split classification for silver massive versus silver powder is justified, and - silver massive should not be classified				

Furthermore we would like to emphasise that no powder is generated during production and use of massive silver.
High ductility, malleability, conductivity are important physical properties of silver. Pure silver has the highest electrical and thermal conductivity of all the metals.
Silver is very malleable and ductile material. These properties allow silver to be formed and stretched into various complex and intricate shapes and surfaces without breaking. This can be seen in many silver articles encountered in everyday life. In addition, silver is resistant to fracture, and it is a relatively soft metal, meaning that it can be easily scratched by other materials. Silver has one of highest physical ductility (0.73) . Silver is a also relatively soft metal (Hardness Mons scale 2.5 – 3).
As a consequence of its malleability, ductility and softness silver does not break. Consequently, silver powder is not produced or generated during the production of silver massive or during the industrial and professional uses of silver massive.
There is clear and reported evidence that the criteria for a different classification of silver in massive form are fulfilled:
- special process is used to produce silver metal powder
- massive does not produce powder under reasonably expected use, and
- there is a significant difference in dissolution rate of the silver ion into solution from massive silver compared with silver metal powder silver when tested in the OECD Test Guideline 29 (Transformation Dissolution protocol).

In line with the CLP guidance and experimental data provided in the REACH registration dossier, Silver massive (> 1 mm) shall not be classified for environmental hazards.
More information is provided in the attached document.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment Aurubis comments to Silver CLH proposal 2020-12-18.pdf

Dossier Submitter's Response

The commenting party claims that silver powder is not produced or generated during the production of silver massive or during the industrial and professional uses of silver massive. However, no reference to supporting data for this statement is provided. Regarding the statement that the available scientific and industrial evidence confirm that a split classification for silver massive versus silver powder is justified please see response to comment number 316.

RAC's response

RAC consider information for silver metal properties and in addition information presented by EPMF for the generation of particles below 1 mm from massive silver. Please, see response to comment number 302.

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	France	MONNAIE DE PARIS	Company-Downstream user	346

Comment received

Silver solid (massive) compounds are not hazardous to aquatic environment. Their classification under this risk would not be relevant to date.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment 2020 12 18 ECHA MdP 2020 survey CLH for Silver_VDEF.pdf
Dossier Submitter's Response
The commenting party supports the arguments provided by EPMF. Thank you for your comment. Please see the DS' response to comment number 316 in the present RCOM.
RAC's response
Please, see response to comment number 302.

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Poland	<confidential>	Company-Manufacturer	347
Comment received				
Hazardous to the aquatic environment - never found nor observed in the <confidential>. ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Silver - <confidential> statement.docx				
Dossier Submitter's Response				
The DS was not able to find the attachment and the sentence in the comment box seems incomplete. Therefore, the comment is difficult to understand, and the DS is unable to answer.				
RAC's response				
Thank you for your comment. Classification divides chemical substances and mixtures into different categories, based on their physical properties and health and environmental hazards. Chemicals are then labelled according to category requirements. This is valid for silver metal which exists on the market under different physical forms depending on size of silver particles. RAC ensures that all information on physical hazards and toxicity for silver available is taken into account in order to enhance the protection of human health and the environment during the handling, transport and use of different silver forms on the market. RAC considers carefully all comments submitted by the European Precious Metals Federation (EPMF). RAC thanks for the usefull information, which has been taken into account for final classification of different silver forms.				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Austria	Wirtschaftskammer Österreich		348
Comment received				
see attachment ECHA note – An attachment was submitted with the comment above. Refer to public attachment su_309_StN öK Silber CLH.pdf				
Dossier Submitter's Response				
The commenting party supports the arguments provided by EPMF. Thank you for your comment. Please see the DS' response to comment number 316 in the present RCOM.				
RAC's response				
Please, see response to comment number 302.				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Finland	Boliden Harjavalta	Company-Manufacturer	349
Comment received				
Hazardous to the aquatic environment - the criteria for classification of silver metal (massive) as toxic to the aquatic environment are not fulfilled: o the available scientific and industrial evidence confirm that a split classification for silver massive versus silver powder is justified, and o silver massive should not be classified.				
Dossier Submitter's Response				
Thank you for your comment. Please see the DS' response to comment number 316 in the present RCOM.				
RAC's response				
Please, see response to comment number 302.				

OTHER HAZARDS AND ENDPOINTS – Physical Hazards

OTHER HAZARDS AND ENDPOINTS – Physical Hazards

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Italy	<confidential>	Company-Manufacturer	350
Comment received				
no evidence ECHA note – An attachment was submitted with the comment above. Refer to public attachment 2020 12 17 Public attachment in the questionnarie <confidential> (003).docx				
Dossier Submitter's Response				
We interpret the comment as an agreement to the proposed no classification for physical hazard.				
RAC's response				
Noted				

Date	Country	Organisation	Type of Organisation	Comment number
17.12.2020	Italy	IPZS S.p.A.	Company-Manufacturer	351
Comment received				
no evidence ECHA note – An attachment was submitted with the comment above. Refer to public attachment Public attachment in the questionnarie.docx				
Dossier Submitter's Response				
We interpret the comment as an agreement to the proposed no classification for physical hazard.				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	France	MONNAIE DE PARIS	Company-Downstream user	352
Comment received				
The classification under this risk would not be relevant to date. ECHA note – An attachment was submitted with the comment above. Refer to public attachment 2020 12 18 ECHA MdP 2020 survey CLH for Silver_VDEF.pdf				
Dossier Submitter's Response				
We interpret the comment as an agreement to the proposed no classification for physical hazard.				
RAC's response				
Noted				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Belgium	T&D Europe	Industry or trade association	353
Comment received				
no comment ECHA note – An attachment was submitted with the comment above. Refer to public attachment TD Europe CLH Consultation Silver_Dec2020_final.pdf				
Dossier Submitter's Response				
We interpret the comment as an agreement to the proposed no classification for physical hazard.				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
16.12.2020	Germany		MemberState	354
Comment received				
The physical hazards were evaluated for silver in powder form (macroscale silver) only, for which no classification is proposed. Since the particle size and the specific surface area affects the outcome of the test results, studies should be submitted for silver in nanoform without any surface treatment, otherwise no conclusion on classification is possible. The evaluation on the basis of new studies for nanosilver results from the requirements under Article 8(6) and Article 9(5) of Regulation (EC) No 1272/2008. Thus, the CLH report on nanosilver appears questionable and not robust in terms of classification for physical hazards.				
Dossier Submitter's Response				
We generally agree that particle size and specific surface area may have a great impact on the classification for physicochemical properties of a substance. However, please note that the proposal for no classification of silver and nanosilver is mostly based on waivers due to the intrinsic properties of silver as a precious metal. We cannot generally see that any of the physical hazards could be affected by the significantly smaller particle size and				

higher specific surface area of nanomaterials so that it would warrant any classification. Please also note that, technically, it may be difficult to test non-coated nanosilver for physical hazard as it is prone to agglomerisation.
RAC's response
Agree with the DS comment that particle size and specific surface area may have a great impact on the classification for physicochemical properties of **some** substances but disagree that this applies to silver nanoforms in pure elemental form. The problem with nanoscale silver is that capping and stabilising agents are required to control and limit aggregation and agglomeration else the natural clustering of Ag^0 atoms leads to structures in excess of the nanoscale. The testing, if possible, of nano-forms of pure silver for physical hazards would add very little if any information to that already obtained with macroscale silver. The existing data for silver is considered to cover all physical forms of the pure element. Pure silver nanoforms, in the absence of stabilising/capping agents and other components that typically make up a colloidal mixture are composed of Ag^0 atoms arranged in a face-centered cubic (FCC) crystalline lattice just as found in the macroscale metal and therefore expected to have the same physical properties as pure silver metal in all its bulk forms. This naturally occurring atomic arrangement confers a very close packing order on silver atoms, more so than in other types of crystalline structure and also ensures similar physical properties to other metals that exhibit FCC crystalline geometry such as copper and gold. FCC metals are typically softer and more ductile than metals in other arrangements. RAC considers there is no requirement for testing nanoforms when applicable tests have been performed on macroscale or bulk silver metal.

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Poland	<confidential>	Company-Manufacturer	355
Comment received				
Physical hazards - never found nor observed in the <confidential>. ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Silver - <confidential> statement.docx				
Dossier Submitter's Response				
We interpret the comment as an agreement to the proposed no classification for physical hazard.				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
16.12.2020	Germany	Heraeus Deutschland GmbH & Co. KG	Company-Manufacturer	356
Comment received				
N/A				
Dossier Submitter's Response				
We interpret the comment as an agreement to the proposed no classification for physical hazard.				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
15.12.2020	France	SCHNEIDER ELECTRIC INDUSTRIES SAS	Company-Manufacturer	357
Comment received				
No comment ECHA note – An attachment was submitted with the comment above. Refer to public attachment Silver_consultation_2020_non_confidential.pdf ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Silver_consultation_2020_Schneider_Electric.pdf				
Dossier Submitter's Response				
We interpret the comment as an agreement to the proposed no classification for physical hazard.				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
15.12.2020	Germany	RAS AG	Company-Manufacturer	358
Comment received				
see comment_CLH_silver_RAS_AG.pdf attached ECHA note – An attachment was submitted with the comment above. Refer to public attachment comment_CLH_silver_RAS_AG_public.pdf ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment comment_CLH_Silver_RAS_AG.zip				
Dossier Submitter's Response				
The comment does not appear to address physical hazard.				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
02.12.2020	France	Metalor Technologies	Company-Manufacturer	359
Comment received				
-				
Dossier Submitter's Response				
We interpret the comment as an agreement to the proposed no classification for physical hazard.				
RAC's response				
Note the lack of comment.				

Date	Country	Organisation	Type of Organisation	Comment number

18.12.2020	Germany	Netzwerk NanoSilber	Industry or trade association	360
Comment received				
none ECHA note – An attachment was submitted with the comment above. Refer to public attachment CLH public consultation silver - Comments by Netzwerk NanoSilber.pdf				
Dossier Submitter's Response				
We interpret the comment as an agreement to the proposed no classification for physical hazard.				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
18.12.2020	Portugal	<confidential>	Company-Manufacturer	361
Comment received				
We are not aware of any hazard originated my metalic silver and we have been using silver for a very long time.				
Dossier Submitter's Response				
We interpret the comment as an agreement to the proposed no classification for physical hazard.				
RAC's response				
Noted.				

PUBLIC ATTACHMENTS
1. Input silver CLH - TMC - 18.12.2020.pdf [Please refer to comment No. 3]
2. RECHARGE Silver classificationPublic Consultation.pdf [Please refer to comment No. 4]
3. Aurubis comments to Silver CLH proposal 2020-12-18.pdf [Please refer to comment No. 5, 123, 174, 275, 345]
4. 2020 12 18 ECHA MdP 2020 survey CLH for Silver_VDEF.pdf [Please refer to comment No. 68, 124, 175, 209, 276, 346, 352]
5. Silver - STF comment on Muta 2 H341 - December 2020.pdf [Please refer to comment No. 125]
6. Silver - STF comment on Repr 1B H360 - December 2020.pdf [Please refer to comment No. 176]
7. su_309_StN öK Silber CLH.pdf [Please refer to comment No. 8, 128, 179, 212, 279, 348]
8. 2020-12-18_WVMetalle Comment on CLH Proposal for Silver.pdf [Please refer to comment No. 9, 80, 129, 236, 302]
9. CLH public consultation silver - Comments by Netzwerk NanoSilber.pdf [Please refer to comment No. 10, 72, 81, 130, 190, 197, 214, 234, 237, 289, 300, 303, 360]
10. Silver products.pdf [Please refer to comment No. 11, 82, 131, 238]
11. aap Implantate AG_CLH_public_consultation_non-confidential_CAS 7440-22-4.pdf [Please refer to comment No. 84, 133, 199, 240]
12. 2020 12 17 Public attachment in the questionnarie <confidential> (003).docx [Please refer to comment No. 14, 74, 86, 135, 180, 200, 217, 224, 242, 281, 291, 306, 350]
13. Bio-Gate Safety Studies.zip [Please refer to comment No. 15, 88, 137, 243, 308]
14. Comments to the silver metal CLH public consultation.pdf [Please refer to comment No. 16, 89, 138, 219, 309]

15. TD Europe CLH Consultation Silver_Dec2020_final.pdf [Please refer to comment No. 17, 76, 90, 139, 183, 202, 220, 227, 244, 283, 293, 310, 353]
16. Enclosure 2 - Overview of metal environmental classification entries including some history.zip [Please refer to comment No. 18, 311]
17. 20201218 ZVEI Silver Applications in EEE and Comments Ag CLH Consultation.pdf [Please refer to comment No. 20, 93, 143, 247, 314]
18. Heraeus Nexensos_Public Cons. Ag CLH Proposal.pdf [Please refer to comment No. 22]
19. CLH Ag Comments FINAL_201217.pdf [Please refer to comment No. 23, 95, 145, 249, 316]
20. Comments on CLH proposal for silver.pdf [Please refer to comment No. 26, 98, 148, 252]
21. FVEM comments CLH silver.pdf [Please refer to comment No. 27, 99, 149, 253, 319]
22. 20201216-comments-vbv-clh-silver.pdf [Please refer to comment No. 28, 100, 150, 254, 320]
23. Public attachment in the questionnarie.docx [Please refer to comment No. 67, 101, 151, 182, 192, 207, 226, 255, 282, 292, 321, 351]
24. CETS-comments Silver labelling CAS 7440-22-4 201217.pdf [Please refer to comment No. 30]
25. 2020-12-11 comment public consultation Ag ZVO.pdf [Please refer to comment No. 32]
26. CHL Ag- DU contribution- Hager group.docx [Please refer to comment No. 102, 152, 256, 322]
27. SAFINA_CLH public consultation_silver metal - completed.pdf [Please refer to comment No. 34, 103, 153, 257, 323]
28. Comments CLH Ag -17.12.20.pdf [Please refer to comment No. 35, 104, 154, 258, 324]
29. CAPIEL Comments.pdf [Please refer to comment No. 36]
30. H+M comments CLH silver.pdf [Please refer to comment No. 37, 105, 155, 259, 325]
31. 201214_Stellungnahme_FEEI_CAS_7440-22-4_Upload.pdf [Please refer to comment No. 39]
32. 20201214-<confidential>-clh-silver-comments.pdf [Please refer to comment No. 41, 107, 157, 260, 327]
33. 4388_001.pdf [Please refer to comment No. 44]
34. FEC response to Public consultation_Silver classification proposal.pdf [Please refer to comment No. 45]
35. Silver_consultation_2020_non_confidential.pdf [Please refer to comment No. 47, 78, 111, 161, 187, 204, 222, 231, 264, 286, 297, 331, 357]
36. comment_CLH_silver_RAS_AG_public.pdf [Please refer to comment No. 48, 79, 112, 162, 188, 205, 223, 232, 265, 287, 298, 332, 358]
37. Umicore public consultation_final 20201215.pdf [Please refer to comment No. 50, 114, 164, 267, 334]
38. AG_HMG_FM.pdf [Please refer to comment No. 52]
39. ECHA Silver 20201212.pdf [Please refer to comment No. 54]
40. Heraeus Romania SRL_Public Cons. Ag CLH Proposal_11.12.2020_signed.pdf [Please refer to comment No. 55]
41. Consultation européenne sur l'argent ERCUIS_12-2020.pdf [Please refer to comment No. 57, 168, 271, 338]
42. HPM_RC_Public Cons. Ag CLH Proposal.docx [Please refer to comment No. 59]
43. 201208_Public_Consultation_HW_comments_final.pdf [Please refer to comment No. 60]
44. LT_Comité_Colbert_ECHA.pdf [Please refer to comment No. 62, 69, 120, 171, 181, 193, 210, 225, 272, 341]
45. ARGENT.pdf [Please refer to comment No. 342]
46. HPT_Public Cons. Ag CLH Proposal_AH.pdf [Please refer to comment No. 63, 121, 172, 273, 343]

CONFIDENTIAL ATTACHMENTS
1. Silver Metal letter.pdf [Please refer to comment No. 1]
2. <confidential>.pdf [Please refer to comment No. 2]
3. Silver - <confidential> statement.docx [Please refer to comment No. 7, 70, 127, 178, 185, 195, 211, 229, 278, 284, 295, 347, 355]
4. aap Implantate AG_CLH_public_consultation_confidential_CAS 7440-22-4.pdf [Please refer to comment No. 84, 133, 199, 240]
5. comment.pdf [Please refer to comment No. 87, 136, 218, 307]
6. Bio-Gate Microsilver BG Confidential Safety Studies.zip [Please refer to comment No. 15, 88, 137, 243, 308]
7. Comments CLH Ag - <confidential> - 17.12.20 - confidential info.pdf [Please refer to comment No. 35, 104, 154, 258, 324]
8. Silver_consultation_2020_Schneider_Electric.pdf [Please refer to comment No. 47, 78, 111, 161, 187, 204, 222, 231, 264, 286, 297, 331, 357]
9. comment_CLH_Silver_RAS_AG.zip [Please refer to comment No. 48, 79, 112, 162, 188, 205, 223, 232, 265, 287, 298, 332, 358]