Assessment of regulatory needs

Authority: European Chemicals Agency

Date: 8 June 2020

Group Name: Salicylic acid, its salts and alkyl derivatives

Chemical structure: -

Revision history

Version	*Date*	*Description*
1.0	08/06/2020	

Substances within this group:

EC/List number	CAS number	Substance name	Registration type (full/OSII or TII/NONS), highest tonnage band among all the registrations (t/y))[1]
Sub-group 1: *Salicylic acid and its salts*			
200-712-3	69-72-7	Salicylic acid	Full, >1000
200-198-0	54-21-7	Sodium Salicylate	Full, 100-1000
209-421-6	578-36-9	Potassium salicylate	Full, not (publicly) available
209-011-7	552-38-5	Lithium salicylate	Full, 1-10
254-228-2	38970-76-2	Dilithium salicylate	Full, not (publicly) available
238-953-1	14882-18-9	Bismuth oxide salicylate	Full, 100-1000
218-531-3	2174-16-5	Salicylic acid, compound with 2,2',2''-nitrilotriethanol (1:1)	C&L notification
Sub-group 2: *Salicylic acid short-chain derivatives*			
200-068-3	50-85-1	2-hydroxy-p-toluic acid	Full, not (publicly) available
201-473-8	83-40-9	Hydroxytoluic acid	OSII or TII
258-753-8	53770-52-8	Zinc 3,5-bis(α-methylbenzyl)salicylate	Full, not (publicly) available
Not (publicly) available	Not (publicly) available	Reaction product of 2-hydroxybenzoic acid, styrene and oxozinc	Full, not (publicly) available
Sub-group 3: Salicylic acid ethers (Short-chain 2-alkoxylated benzoic acids)			
209-447-8	579-75-9	o-anisic acid	Full, not (publicly) available
205-130-3	134-11-2	2-ethoxybenzoic acid	Full, not (publicly) available
816-014-2	243863-88-9	2-(tert-butoxy)benzoic acid	C&L notification
608-139-4	27830-12-2	Benzoic acid, 2-(octyloxy)-	OSII or TII
Sub-group 4: Long-chain alkylated salicylic acids			
931-276-9	114959-46-5	Benzoic acid, 2-hydroxy-, mono-C14-18 alkyl derivs., calcium salts (2:1)	Full, >1000
283-049-2	84539-60-6	Benzoic acid, 2-hydroxy-, 5-C>13-alkyl derivs., sodium salts	Full, >1000
931-472-4	Not (publicly) available	Benzoic acid, 2-hydroxy-,C14-18 alkyl derivs.	Full, not (publicly) available
931-371-5	171171-80-5	Magnesium, bis(2-hydroxybenzoato-O1,O2)-, ar,ar'-di-C14-C18-alkyl derivs.	Full, not (publicly) available

This table contains also group members that are only notified under the CLP Regulation. However, the list is currently non-exhaustive. Should further regulatory risk management action on one or more substances in the group be considered, ECHA will make an additional search for related C&L notified substances to be included in the group and develop an assessment of regulatory needs for them.

[1] Note that the total aggregated tonnage band may be available on ECHA's webpage at https://echa.europa.eu/information-on-chemicals/registered-substances

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The author does not accept any liability with regard to the use that may be made of the information contained in this document. Usage of the information remains under the sole responsibility of the user. Statements made or information contained in the document are without prejudice to any further regulatory work that ECHA, the Member States or other regulatory agencies may initiate at a later stage. Assessments of regulatory needs and their conclusions are compiled on the basis of available information and may change in light of newly available information or further assessment.

Foreword

The purpose of the assessment of regulatory needs of a group of substances is to help authorities conclude on the most appropriate way to address the identified concerns for a group of substances or a single substance, i.e. the combination of the regulatory risk management instruments to be used and any intermediate steps, such as data generation, needed to initiate and introduce these regulatory measures.

An assessment of regulatory needs can conclude that regulatory risk management at EU level is required for a (group of) substance(s) (e.g. harmonised classification and labelling, Candidate List inclusion, restriction, other EU legislation) or that no regulatory action is required at EU level. While the assessment is done for a group of substances, the (no) need for regulatory action can be identified for the whole group, a subgroup or for single substance(s).

The assessment of regulatory needs is an important step under ECHA's Integrated Regulatory Strategy. However, it is not part of the formal processes defined in the legislation but aims to support them.

The assessment of regulatory needs can be applied to any group of substances or single substance, i.e., any type of hazards or uses and regardless of the previous regulatory history or lack of such. It can be done based on different level of information. A Member State or ECHA can carry out this case-by-case analysis. The starting point is available information in the REACH registrations and any other REACH and CLP information. However, more extensive set of information can be available, e.g. assessment done under REACH/CLP or other EU legislation, or can be generated in some cases (e.g. further hazard information under dossier evaluation). Uncertainties associated to the level of information used should be reflected in the documentation. It will be revisited when necessary. For example, after further information is generated and the hazard has been clarified or when new insights on uses are available. It can be revisited by the same or another authority.

The responsibility for the content of this assessment rests with the authority that developed it. It is possible that other authorities do not have the same view and may develop further assessment of regulatory needs. The assessment of regulatory needs does not yet initiate any regulatory process but any authority can consequently do so and should indicate this by appropriate means, such as the Registry of Intentions.

For more information on Assessment of regulatory needs please consult the ECHA website[2].

[2] https://echa.europa.eu/understanding-assessment-regulatory-needs

Glossary

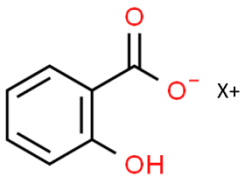
CCH	Compliance Check
CLH	Harmonised classification and labelling
CMR	Carcinogenic, mutagenic and/or toxic to reproduction
DEv	Dossier evaluation
ED	Endocrine disruptor
NONS	Notified new substances
OEL	Occupational exposure limit
OSII or TII	On-site isolated intermediate or transported isolated intermediate
PBT/vPvB	Persistent, bioaccumulative and toxic/very persistent and very bioaccumulative
RMOA	Regulatory management options analysis
RRM	Regulatory risk management
SEv	Substance evaluation
STOT RE	Specific target organ toxicity, repeated exposure
SVHC	Substance of very high concern

1. Overview of the group

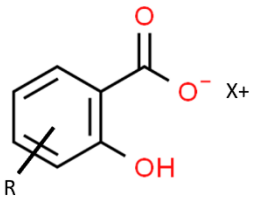
ECHA has grouped together structurally similar substances based on the presence of the salicylate moiety.

During the assessment by ECHA, the group has been further divided into four (4) sub-groups.

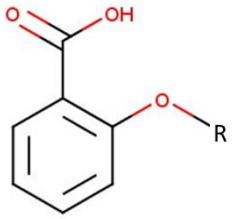
1. ***Subgroup 1: Salicylic acid and its salts*** with either lithium, potassium, sodium, bismuth or 2,2',2''-nitrilotriethanol (EC numbers: 200-712-3, 209-011-7, 254-228-2, 209-421-6, 200-198-0, 238-953-1 and 218-531-3). The sub-group is characterised by the common chemical structure shown below.



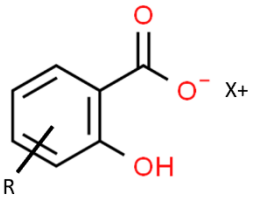
2. ***Subgroup 2: Salicylic acid short-chain derivatives***: Zinc 3,5-bis(α-methylbenzyl)salicylate, and Reaction products of 2-hydroxybenzoic acid and styrene and zinc oxide (EC numbers: 200-068-3, 201-473-8, 258-753-8 and a substance named Reaction product of 2-hydroxybenzoic acid, styrene and oxozinc). The sub-group is characterized by the common chemical structure shown below.



3. ***Subgroup 3: Salicylic acid ethers (Short-chain 2-alkoxylated benzoic acids)*** as either methoxy, ethoxy, tert-butoxy or octyloxy (EC numbers 209-447-8, 205-130-3, List numbers: 816-014-2, 608-139-4). The sub-group is characterized by the common chemical structure shown below.



4. ***Subgroup 4: Long-chain alkylated salicylic acids*** with C14-18 and their salts with either calcium, magnesium or sodium (EC numbers 931-472-4, 931-276-9, 931-371-5 and 283-049-2). The sub-group is characterized by the common chemical structure shown below.



The overall group includes 19 substances of which 17 are registered and two (2) substances are only notified to the C&L inventory. Out of the 17 registered substances two (2) are only registered as isolated transported intermediates.

Regarding relevant past or ongoing regulatory activities for substances in this group, salicylic acid (EC 200-712-3) has recently undergone a harmonised classification and labelling as Repr. 2 (suspected of damaging the unborn child) and

is currently under approval as an active substance under the Biocidal Products Regulation. An overview of main past or ongoing regulatory risk management processes is provided in Annex 3.

Based on information reported in the REACH registration dossiers, the uses have notable intra-sub-group similarities. More specifically, analysis of the substances in the different sub-groups reveal the following (see also the overview of uses provided in Annex 2):

- The substances in sub-group 1 are mainly used in cosmetic and cleaning products. Some substances are also used in fertilisers, polymer manufacture, lubricants and other technical fluids and coatings, paints and metal surface treatment products. Potential for exposure of professional users exists for most of these uses (lubricants & technical fluids, fertilisers, washing & cleaning products, cosmetics & perfumes). Consumer uses include lubricants, washing, cleaning & air care products, cosmetics & perfumes. Article service life may also be relevant. Many of these uses have the potential for releases to the environment.
- The substances in sub-group 2 are used as catalysts in the manufacture of inks and toners and as dye development agents in the preparation of paper articles. For the latter, consumer use of articles is relevant.
- The substances in sub-group 3 are used mainly as intermediates. In addition, for EC 209-447-8 only industrial use in cosmetics, perfumes and other poorly specified uses as pH regulator are reported. Limited exposure potential (low tonnage, limited uses) is expected.
- The substances in sub-group 4 are used as lubricants and other technical fluids that may lead to professional and consumer exposure as well as releases to the environment (lubricants and other technical fluids).

Note on the scope of ECHA's assessment of regulatory needs

Regarding hazards, the focus of ECHA's assessment is on CMR (carcinogenic, mutagenic and/or toxic to reproduction), sensitiser, ED (endocrine disruptor), PBT/vPvB or equivalent (e.g. substances being persistent, mobile and toxic), aquatic toxicity hazard endpoints and therefore only those are reflected in the table in section 3. This does not mean that the substances do not have other known or potential hazards. In some specific cases, where ECHA identifies a need for regulatory risk management action at EU level for other hazards (e.g. neurotoxicity, STOT RE), such additional hazards may be addressed in the assessment. An overview of classification is presented in Annex 1.

On the exposure side, ECHA is mainly using the information on uses reported in the registration dossiers (IUCLID) as a proxy for assessing the potential for exposure to humans and releases to the environment. The potential for release / exposure is generally considered high for "widespread" uses, i.e. professional and consumer uses and uses in articles. For these uses, normally happening at many places, the expected level of control is *à priori* considered limited. The chemical safety reports are not necessarily consulted and no quantitative exposure assessment is performed at this stage.

2. Justification for the need for regulatory risk management action at EU level

Note that salicylic acid (EC 200-712-3) is currently under approval as an active substance under the Biocidal Products Regulation and it is proposed to await the outcome of the ED assessment in that context before considering the need for additional regulatory risk management based on ED properties for the whole group. The actions proposed below for the different sub-groups will be revisited if based on this assessment the substances are considered to have ED properties.

Based on currently available information, there is a need for further EU regulatory risk management – namely restriction for potential PBT properties and potential releases to the environment from the professionals and consumers use of lubricants and other technical fluids for **all substances in subgroup 4*, salicylic acid long-chain derivatives***.

Based on ECHA's assessment of currently available hazard information, all substances in subgroup 4 fulfils the screening PBT criteria[3]. Based on the results of experimental study reported in the registration dossier, C18 constituents are potentially bioaccumulative while C14 and C16 constituents are just below the bioaccumulation thresholds. There is no simulation degradation data available while ready biodegradability data is inconclusive with some being not readily biodegradable. Therefore the substances in this subgroup are considered as potential PBT/vPvB substances. In addition some substances are used by professional and consumers as lubricants and other technical fluids which may lead to releases to the environment. As a consequence there is a concern that substances with potential PBT/vPvB properties would end up in the environment and EU regulatory risk management is needed to address this concern.

First, compliance check to clarify the PBT/vPvB hazard is proposed for two members (EC 931-472-4 and EC 931-276-9) of the sub-group as generated data are expected to represent constituents of all members of the sub-group.

The first step of the regulatory risk management action proposed, should the hazard exist, is the confirmation of hazard via SVHC identification.

Restriction of the uses of the substances seems to be the most appropriate risk management option at this point in time to address the concern related to the releases to the environment coming from the professional and consumer uses of lubricants and other technical fluids based on available information.

All substances in the group are also suspected to be skin sensitisers and compliance check needs to be initiated for all registered substances in the group to confirm or refute the potential skin sensitisation.

There is a concern related to skin sensitisers (potentially) present in consumer mixtures and the need to further investigate whether further regulatory actions are needed and what would be the best options to address this concern. Such concern has already been identified in other groups of substances and was brought for further discussion to Member States. Work is ongoing on this generic issue by both Member States and ECHA which may affect the regulatory actions on substances in this group. However, if the PBT properties of the substances used in those consumer uses are confirmed and further EU RRM work is initiated, the skin

[3] As defined in REACH Annex XIII and R11 Guidance on PBT assessment (https://echa.europa.eu/documents/10162/17224/information_requirements_r11_en.pdf/a8cce23f-a65a-46d2-ac68-92fee1f9e54f

sensitisation impact of the substances could also be considered as part of the restriction.

For the remaining industrial uses, it is proposed to consider what would be the most appropriate way to regulate those at a later stage once the hazards (PBT/vPvB) are clarified and the scope of the restriction better defined as actions on professional uses may also impact industrial uses.

Based on currently available information, there is a need for further EU regulatory risk management – namely restriction in combination with authorisation for potential toxic to reproduction hazard **for ECs 209-011-7 and 254-228-2 in sub-group 1, *salicylic acid and its salts*** and potential exposure to workers from the professionals and consumers use in hydraulic fluids, heat transfer fluids and lubricants.

ECHA's Risk Assessment Committee (RAC) has recently adopted its opinion[4] regarding the harmonised classification of three lithium salts (lithium content ranging from 9% to 29% w/w) under the CLP Regulation for their reproductive toxic properties. The classification is based on the intrinsic properties of the lithium cation. Based on available information it is therefore suggested that substances ECs 209-011-7 and 254-228-2 would be potentially reprotoxic based on the presence of the lithium cation and harmonised classification and labelling is proposed as next step.

It is suggested to look at the possibility to classify all lithium salts substances together rather than going one by one on the basis of the toxicity of the lithium cation to ensure that all relevant known and future substances would be classified as reprotoxic. Furthermore bioavailability may need to be taken into account in scoping the CLH entry.

CLH i) will trigger company level risk management measures (RMM) under OSH legislation for workers, ii) is needed or highly recommended for further regulatory processes under REACH and iii) is a prerequisite to restrict the presence of the substances in consumer mixtures, by means of the restriction entry 30 of REACH Annex XVII.

Professional use is typically widespread (at many sites and many users) with relatively low levels of operational controls and risk management measures. In addition, professional users may be self-employed and therefore not covered by the above mentioned Occupational Safety and Health (OSH) legislation for workers. Consumers may be co-exposed to the substances used. Therefore, a specific restriction on mixtures used by professionals is suggested after the CLH. Moreover, restricting substances in articles used by professionals or consumers (reported for both substances, ECs 209-011-7 and 254-228-2) is proposed. The choice of the restriction for professional uses over other regulatory management options (e.g. authorisation) is in line with the policy recently proposed by the European Commission under the Chemical Strategy for Sustainability that expresses the need to extend the level of protection granted under REACH to consumers also to professional users. Restriction of professional uses is preferred over authorisation as it is considered to be more efficient and effective to introduce controls at the level of placing on the market rather than at the level of uses.

In addition, the use of the most harmful substances by professional workers has been recognised as an area of concern under the European Commission's Chemicals

[4] https://echa.europa.eu/registry-of-clh-intentions-until-outcome/-/dislist/details/0b0236e18270066e

Strategy for Sustainability which aims to extend to professional users under REACH the level of protection granted to consumers.

For the remaining industrial uses where potential for exposure cannot be excluded it is suggested to use authorisation. An EU-wide exposure limit for workers under Occupational Health and Safety (OSH) legislation or REACH as an alternative risk management option to authorisation for industrial uses was also considered. Introducing EU-wide exposure limits for workers under OSH or REACH for one or both of the substances may not be a priority for relatively low or very low tonnage substances (but could be an option under REACH restriction if a restriction proposal is submitted in any case); moreover, authorisation also better promotes substitution than an OEL/DNEL would. Therefore, for the time being, even though a clear decision between the two regulatory options for uses at industrial sites is not possible, authorisation is suggested as the next regulatory risk management option. This proposal will be revisited once the hazard will be clarified after data generation, preferably based on further assessment and for instance when developing further the restrictions proposed above which should also support clarifying what are those industrial uses in need for EU RRM action.

Based on currently available information, there is a need for further EU regulatory risk management – namely harmonised classification - for toxicity to reproduction and potential for exposure of workers and consumers for **all substances in sub-group 1, *salicylic acid and its salts*** (except ECs 209-011-7 and 254-228-2).

All substances in this sub-group are used in consumer products and are suspected of developmental toxicity derived from the known hazard of salicylic acid (harmonised classification Repro 2) through read-across to its salts. They have a low environmental hazard, and they don't seem to have PBT/vPvB properties as being readily biodegradable, which is expected to be further confirmed through CCH for some substances in the group (e.g. bismuth oxide salicylate (EC 238-953-1)).

Based on currently available information it seems that the substances in this sub -group would benefit from harmonised classification as repro 2. The CLH proposal would be for a group entry covering salicylic acid and its salts (for ECs 209-011-7 and 254-228-2 see conclusion above). The harmonised classification as repro 2 would support actions under the Cosmetic Products Regulation in particular for sodium salicylate. For action under the Cosmetics Products Regulation to be triggered, harmonised classification as CMR 1/2 is required (NB. the Scientific Committee on Consumer Safety (SCCS)[5] would have to assess whether the use of sodium salicylate is safe). Sodium salicylate has the largest number of registrations and highest registration tonnages among all members of the sub-group (excluding salicylic acid). The regulatory impact of the classification as repro 2 on the other substances in this subgroup is less obvious. For instance, a Repr Cat 2 classification would not have a very extensive regulatory impact on consumer use of lubricants (additional information provided in labels of mixtures containing EC 209-011-7 and 254-228-2) or the use of EC 238-953-1 in coatings which are associated with an article service life lifecycle stage. However the development of the CLH for the group entry covering all salts would bring consistency across all the salts.

Based on currently available information, there is no need for further EU regulatory risk management for **all substances sub-groups 2 and 3**.

Sub-group 2, Salicylic acid short-chain derivatives

[5] https://ec.europa.eu/health/scientific_committees/consumer_safety_en

The substances in this sub-group are suspected of developmental toxicity and skin sensitisation. The potential for developmental toxicity is based on the known developmental toxicity of salicylic acid with read-across indicating potential hazard which means that potentially those substances would merit a repro 2 classification.

Further data generation on the reproductive endpoint is needed to clarify whether there is a potential hazard for these sub-group members, and to support classification if the results confirm developmental toxicity.

The uses of particular interest are those of zinc 3,5-bis(α-methylbenzyl)salicylate (EC 258-753-8) and the substance named reaction product of 2-hydroxybenzoic acid, styrene and oxozinc in the manufacture of paper articles as dye development agents which are present on the surface of carbon copy (pressure) paper.

It is expected that after compliance check registrants would adequately self-classify the substances and then implement the relevant RMMs which would be sufficient to ensure safe use at the workplace, and therefore it is proposed that there is no need for EU-wide action at the moment. In addition an harmonised classification as repro 2 would not impact the use of the substances in the paper articles.

The substances are also potentially skin sensitisers and compliance check needs to be initiated for all registered substances in the group to confirm or refute the potential skin sensitisation. Like substances in subgroup 4, there is a concern related to skin sensitisers (potentially) present in consumer mixtures and the need to further investigate whether further regulatory actions are needed and what would be the best options to address this concern. Such concern has already been identified in other groups of substances and was brought for further discussion to Member States. Work is ongoing on this generic issue by both Member States and ECHA which may affect the regulatory actions on substances in this group.

There is in general low concern for environment for this group, as they show no PBT/vPvB hazard and have low tonnage with uncertain (possibly limited) potential for exposure for the substance named reaction product of 2-hydroxybenzoic acid, styrene and oxozinc. There is, however, some remaining uncertainty around aquatic toxicity and PBT. Compliance check will be initiated to clarify remaining uncertainties.

Sub-group 3, Salicylic acid ethers

The overall use profile of members of this sub-group is of low concern. Substances are used as intermediates with the exception of EC 209-447-8 for which only industrial uses in cosmetics, perfumes and other poorly specified uses as pH regulator is reported. Furthermore, all substances in this sub-group are not PBT/vPvB. As for the other sub-groups, the substances are suspected of developmental toxicity and skin sensitisation for all members. The potential for skin sensitisation is based on read-across from the other sub-groups. Compliance check needs to be initiated for all registered substances in the group to confirm or refute the sensitisation concern (Annex VII dossiers). The possibility to generate further information to clarify the potential developmental toxicity is unlikely due to the low tonnage and limited uses profile. In light of the use profile, the low tonnages and the small number of registrants involved, there is currently no need for further regulatory risk management on the substances in this subgroup. Appropriate self-classification followed by implementation of adequate risk management measures should ensure sufficient protection at the workplace.

3. Summary of conclusions and actions

The conclusions and actions proposed in the table below are based on the REACH and CLP information available at the time of the assessment by ECHA. The main source of information is the registration dossiers. Relevant public assessments may also be considered. When new information (on hazard through evaluation processes or uses) will become available, the document will be updated and conclusions and actions revisited.

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
Sub-group 4: Long-chain alkylated salicylic acids					
931-276-9 ***931-472-4*** ***283-049-2*** ***931-371-5***	Known or potential hazard for skin sensitisation Inconclusive hazard for ED (assessment ongoing under BPR)	Known or potential hazard for PBT/vPvB	Professional and consumer uses (e.g. lubricants and other technical fluids) with high potential for exposure and releases to the environment.	**Need for EU RRM: Restriction** Justification: There is a concern that substances with potential PBT/vPvB properties may end up in the environment due to their use as lubricants.	**First step:** CCH **Next steps (if hazard confirmed):** SVHC identification Restriction
Sub-group 1: Salicylic acid and its salts					

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
209-011-7 ***254-228-2***	Known or potential hazard for reproductive toxicity Inconclusive hazard for ED (assessment ongoing under BPR)	No hazard or unlikely hazard	Professional and consumer uses in hydraulic fluids, heat transfer fluids and lubricants with potential for exposure	**Need for RRM: Restriction in combination with authorisation** <u>Justification</u>: The harmonised classification as Repr. Cat 1 would trigger the restriction entry 30 and by that ensure that the substances are not included in consumer mixtures above the limits specified in that entry. Professional use is typically widespread (at many sites and many users) with relatively low levels of operational controls and risk management measures but with typically frequent exposures with a long duration.	**First step:** CLH **Next steps (if hazard confirmed):** SVHC identification, restriction in combination with authorisation.

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
				Restriction of professional uses is preferred over authorisation as it is considered to be more efficient and effective to introduce controls at the level of placing on the market rather than at the level of uses. Specific restriction for use in articles as potential exposure from articles cannot be excluded. The remaining industrial uses should be addressed by authorisation to push for substitution and to ensure proper control of risks until substitution is possible.	

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
200-198-0 **200-712-3** **209-421-6** **218-531-3 (not registered)** **238-953-1**	Known or potential hazard for reproductive toxicity Inconclusive hazard for ED (assessment ongoing under BPR)	No hazard or unlikely hazard	Professional & consumer uses (e.g. cosmetics & perfumes, cleaning & air care products, fertiliser uses, coatings & paints), Article service life (metallic coated articles and lubricants), Industrial uses (e.g. polymer manufacture, laboratory chemicals) with potential for exposure.	**Need for EU RRM: CLH** Justification: The harmonised classification as Repro 2 will support regulatory actions under the Cosmetic Products regulation for sodium salicylate	CCH for EC 238-953-1 CLH for all substances (without generation of data)
Sub-group 2: Salicylic acid short-chain derivatives					
200-068-3 ***201-473-8*** ***258-753-8***	Known or potential hazard for reproductive toxicity and for skin sensitisation Inconclusive hazard for ED (assessment ongoing under BPR)	No hazard or unlikely hazard	Catalysts in the manufacture of inks and toners) and as dye development agents in the preparation of paper articles. Potential for exposure in paper articles.	**Currently no need for EU RRM** Justification: adequate self-classification of the substances after CCH followed by implementation of relevant OC/RMMs in the supply chain should be sufficient to ensure safe use at the	CCH
Reaction products of 2-		Inconclusive hazard			

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
hydroxybenzoic acid and styrene and zinc oxide		for PBT/vPvB		workplace. In addition a harmonised classification as repro 2 would not impact the use of the substances in the paper articles.	
Sub-group 3: Salicylic acid ethers					
205-130-3 ***209-447-8*** ***608-139-4 (OSII or TII, no data)*** ***816-014-2 (not registered)***	Known or potential hazard for reproductive toxicity and for skin sensitisation Inconclusive hazard for ED (assessment ongoing under BPR)	No hazard or unlikely hazard	Mainly uses as intermediate. In addition, for EC 209-447-8 only industrial use in cosmetics, perfumes and other poorly specified uses as pH regulator are reported. Limited exposure potential (low tonnage, limited uses)	**Currently no need for EU RRM** <u>Justification</u>: adequate self-classification of the substances after CCH followed by implementation of relevant OC/RMMs in the supply chain should be sufficient to ensure safe use at the workplace.	CCH

Annex 1: Harmonised classifications and self-classifications reported by registrants

Date extracted on 8 June 2020.

EC/List No	Substance name	Self-classification		
		Harmonised classification	**Self-classification in registration dossier**	**Additional classification in C&L notifications**
200-068-3	*2-hydroxy-p-toluic acid*		*Acute tox 4* *Eye irr 2* *Skin irr 2*	
200-198-0	*sodium salicylate*		*Acute tox 4* *Eye irr 2* *Repro 2*	
200-712-3	*salicylic acid*	Acute Tox. 4 Eye Dam. 1 Repr. 2	*Acute tox 4* *Eye dam 1*	
201-473-8	*hydroxytoluic acid*		*Eye dam 1*	
205-130-3	*2-ethoxybenzoic acid*		*Acute tox 4* *Eye irr 2*	
209-011-7	*lithium salicylate*		*Acute tox 4* *Eye dam 1* *Skin corr 1*	
209-421-6	*potassium salicylate*		*Acute tox 4* *Eye irr 2*	
209-447-8	*o-anisic acid*		*Eye irr 2* *Skin irr 2*	
238-953-1	*bismuth oxide salicylate*		-	
254-228-2	*dilithium salicylate*		*Acute tox 4* *Eye dam 1* *Skin corr 1*	
258-753-8	*zinc 3,5-bis(α-methylbenzyl)salicylate*		*Aqua chr 3* *Acute tox 4* *Eye Dam 1*	
283-049-2	*Benzoic acid, 2-hydroxy-, 5-C>13-alkyl derivs., sodium salts*		*Aqua chr 1* *Acute tox 4* *Eye Dam 1* *Skin sens 1A* *Skin corr 1C*	

			STOT Rep. Exp. 2 (liver)	
608-139-4	*Benzoic acid, 2-(octyloxy)*		*Acute tox 4*	
Not (publicly) available	*Reaction products of 2-hydroxybenzoic acid and styrene and zinc oxide*		*Aqua chr 2* *Skin sens 1*	
931-276-9	*Benzoic acid, 2-hydroxy-, mono-C14-18 alkyl derivs., calcium salts (2:1)*			
931-371-5	*Magnesium, bis(2-hydroxybenzoato-O1,O2)-, ar,ar'-di-C14-C18-alkyl derivs.*			
931-472-4	*Benzoic acid, 2-hydroxy-,C14-18 alkyl derivs.*		*Aqua acute 1* *Aqua chr 1* *Eye dam 1* *Skin sens 1* *STOT Rep. Exp. 2 (liver)*	

Annex 2 : Overview of uses based on information available in registration dossiers

Data extracted in April 2020.

Main types of applications structured by product or article types	Sub-group 1						Sub-group 2				Sub-group 3			Sub-group 4			
	200-712-3	200-198-0	209-421-6	209-011-7	254-228-2	238-953-1	200-068-3	201-473-8	258-753-8	Not (publicly) available	209-447-8	205-130-3	608-139-4	931-276-9	283-049-2	931-371-5	931-472-4
Lubricants, greases, release products				F, I, **P, C, A**	F, I, **P, C, A**									F, I, **P, C**		F, I, **P, C**	
Heat transfer fluids				I, **P**	I, **P**												
Hydraulic fluids				I, **P**	I, **P**									F, I, **P**		F, I, **P**	
Metalworking fluids														F, I, **P**		F	
Fertilisers	F, **P**																
Washing and cleaning products	F, **P, C**																
Polishes and wax blends	F, **C**																
Air care products	F, **C**																
Coatings and paints						F, I, **A**											
Inks and toners						I	I										
Metal surface treatment products						I											
Paper and board treatment products									I, **A**	F, I, **C, A**							

Main types of applications structured by product or article types	Sub-group 1						Sub-group 2				Sub-group 3			Sub-group 4			
	200-712-3	200-198-0	209-421-6	209-011-7	254-228-2	238-953-1	200-068-3	201-473-8	258-753-8	Not (publicly) available	209-447-8	205-130-3	608-139-4	931-276-9	283-049-2	931-371-5	931-472-4
Polymer preparations and compounds	I		I														
Fillers, putties, plasters, modelling clay	I																
Perfumes and fragrances	F, I, **P, C**	F, **C**									I						
Cosmetics and personal care products	F, I, **P, C**	F, I, **C**									I						
Products such as pH-regulators, flocculants, precipitants, neutralisation agents	I, **P**										I						
Pharmaceuticals	I, **P, C**	F, I, **C**					I										
Laboratory chemicals	I	I				I					I	I		I			
Intermediate	F, I	F, I					I	I			F, I	I	I		I		I

F: formulation, I: industrial use, P: professional use, C: consumer use, A: article service life; P, C and A are highlighted in red to indicate widespread use with potential for exposure/release

Annex 3: Overview of past and ongoing regulatory risk management activities

Data extracted on 27 March 2020.

EC/List number	RMOA	Authorisation		Restriction*	CLH	Actions not under REACH/ CLP
		Candidate list	Annex XIV	Annex XVII	Annex VI (CLP)	
200-712-3					YES	BPR: active substance approval

* Some of the broad restriction entries in the Annex XVII of REACH are not represented in the overview, e.g. when the scope of the restriction is defined by its classification or the substance identification is broad (e.g. entries 3, 28-30 and 40).

There are no relevant completed or ongoing regulatory risk management activities for the other substances.