COMPILED COMMENTS ON CLH CONSULTATION

Comments provided during consultation are made available in the table below as submitted through the web form. Please note that the comments displayed below may have been accompanied by attachments which are listed in this table and included in a zip file if non-confidential. Journal articles are not confidential; however they are not published on the website due to Intellectual Property Rights.

ECHA accepts no responsibility or liability for the content of this table.

Last data extracted on 31.05.2024

Substance name: Reaction products of diphenylamine with nonene, branched
CAS number: -
EC number: -
Dossier submitter: France

GENERAL COMMENTS

Date	Country	Organisation	Type of Organisation	Comment number
03.05.2024	Switzerland	SONGWON International AG	Company-Manufacturer	1
Comment received				
As a leading global chemical supplier of the substance that is the subject of this consultation (Bis(nonylphenyl)amine, Reaction products of diphenylamine with nonene, branched (C9 SDPA, EC: 701-385-49)), SONGWON would like to provide confidential information on its manufacturing process in order to oppose the read-across with substance Benzenamine, N-phenyl-, reaction products with 2,4,4-trimethylpentane (C4:C8 SDPA, EC: 270-128-1) that is made by the French MSCA. This information should be considered as highly confidential business information and must not be made public. It shall only be shared with the DS, ECHA, its committees and the European Commission. ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment SONGWON comment to public consultation EC 701-385-4 -3May2024 final.pdf SONGWON comment to public consultation EC 701-385-4 -3May2024 final blanked.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
03.05.2024	Germany	FUCHS SE	Company-Downstream user	2
Comment received				
FUCHS supports the proposal of ATC (ATC Document 157, April 2024) ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment 701-385-4_CLH.zip				

Date	Country	Organisation	Type of Organisation	Comment number
03.05.2024	Germany	<confidential>	Company-Manufacturer	3
Comment received				
We strongly agree with the comment given by the „Additive Technical Committee" (ATC). In addition, we want to add the following:				

C9 SDPAs are used as antioxidants in lubricants, hydraulic oils, greases, metal working fluids and anticorrosive agents.
Classification of the antioxidants as Repr. 1 will require classification of end products, resulting in restriction or even ban for consumer products from the market. In addition, professional and industrial users will strongly refuse these products due to its incompliance between calssification and corporate guidelines.
When enriched with C9 SDPAs lubricants become suitable and effective especially for transport, power generation (greases for wind turbines) and other industrial, heavy duty and energy uses that are important to reach the goals of the EU Green Deal. C9 SDPA enriched lubricants effectively and sustainably reduce friction and wear, they provide cooling and sealing properties of the fluid and add important corrosion-inhibiting effects.

Alternative antioxidants are currently not available by our suppliers. Alternatives seem to be less effective, less sustainable, less compatible with current formulations and thus much more expensive when considering the entire product developing process.

According to the registration dossier developmental toxicity studies in rabbit and rat (OECD 414) do not warrant classification of the substance for developmental toxicity under CLP regulation.

Based on the current data (see registration dossier) we do not agree with the classification Aquatic Chronic 1. First results from new tests required by ECHA are expected by Q2/Q3 2024.

The proposed CLH for C9 SDPA as Aquatic Chronic 1 (M=10) will result in most of our lubricants being classified as Dangerous Goods. This will result in significantly higher transportation and administration costs and poorer customer acceptance.

Date	Country	Organisation	Type of Organisation	Comment number
02.05.2024	Germany	<confidential>	Industry or trade association	4

Comment received

Die <confidential> stimmt mit der Bewertung des „Dossier Sumitters (DS)" nicht überein. Die Einstufung des Stoffes „Reaction products of diphenylamine with nonene, branched" als Repr. 1B (H360FD) und Aquatic Chronic 1 (H410) ist nicht gerechtfertigt. Bei der Durchsicht des Dossiers wurden diverse Unzulänglichkeiten bei den aufgeführten Daten festgestellt. Diese beeinträchtigen die Gesamtbeurteilung der toxikologischen Relevanz und des Schweregrads der beobachteten Befunde.
Eine korrekte und vollständige Zusammenfassung aller verfügbaren Nachweise und eine fundierte Datenbewertung sind die Mindestvoraussetzung für eine solide Entscheidung über die Einstufung.
<confidential> bittet daher den Dossier Submitter (DS), den Berichterstatter und das Risk Assessment Committee (RAC) die vorhandenen Daten sowie die eingereichten Informationen des ATC (Technical Committee of Petroleum Additive Manufacturers in Europe) erneut zu prüfen und in die Entscheidung in das weitere Verfahren bezüglich der Einstufung mit einzubeziehen.

ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment 2024-05-02 Profile <confidential>.pdf

Date	Country	Organisation	Type of Organisation	Comment number

02.05.2024	Belgium	ATIEL	Please select organisation type..	5
Comment received				
ATIEL is the Technical Association of the European Lubricants Industry and represents the leading European and international engine oil manufacturers and marketers. ATIEL is downstream user of the substance Benzenamine, N-phenyl-, reaction products with 2,4,4-trimethylpentene (EC 270-128-1). ATIEL is aware that our response to the CLH public consultation should focus on comments regarding the proposed classification and should be scientific in nature. However, ATIEL would like to point out the consequences if the proposed classification by the dossier submitter (DS) is adopted. The impact on the EU economy would be significant, and ATIEL strongly encourage RAC, member state authorities and the Commission to base their decision for future harmonized classification on scientifically sound weight of evidence and reliable interpretations of the available toxicology data. Classification of Benzenamine, N-phenyl-, reaction products with 2,4,4-trimethylpentene (EC 270-128-1) as Reproductive Toxicity Category 1B (H360FD) will lead to an unwarranted and generic restriction under the EU REACH Regulation on the majority of consumer uses of lubricating oils (containing the substance at ≥0.3% - by addition to REACH Annex XVII entry 30), as well as increasing the risk of a later Authorisation or wider scoping Restriction proposal under EU REACH.. Additionally, ATC members are of the view that there are currently no viable alternative antioxidants. Therefore, there will be significant impacts on ATIEL member companies who are producers of lubricants and their customers which will include Original Equipment Manufacturers (OEMs). The substituted diphenylamine's Benzenamine, N-phenyl-, reaction products with 2,4,4-trimethylpentene is a crucial antioxidant in lubricant formulations. Even if it is typically used at very low concentration in lubricant mixtures, it has a critical effect on the lifespan, durability, and technical performance of lubricants. It reduces the need for replacement/top-up of the lubricants in vehicles. It has a very important role for strategic uses in the energy transition (wind power, electrical vehicles, energy efficiency of internal combustion engines and others) and contributing to sustainability goals of the EU green deal. Currently there are no other types of antioxidant substances able to replace the substituted diphenylamines that can provide the same durability and technical performances. Just to reiterate, performance lubricants are critical for the transport sector and all types of industries and play a key role for the energy transition and sustainability. A potential classification as Reproductive Toxicity Category 1B poses substantial challenges to the lubricant industry. Many lubricant formulations in Europe will become classified as Reproductive Toxicity Category 1B, rendering them unsuitable for sale. With no current technical alternative available, reformulation would not be possible by the time of application of the harmonized classification, which will lead to a significant gap for European economy with an impact on green deal objectives. This would be particularly disruptive for automotive lubricants packed in smaller quantities (e.g., 3, 5 liters) commonly sold to both the general public and professionals such as garages. It’s important to note that while lubricants are perceived as consumer products, they are primarily for professional use. Lubricants are added when the car is produced (first fill) by the OEMs and then are recirculated in closed system in the car. In time it is possible to have to top up a part of the oil or to replace the oil completely. While consumers may occasionally top up their lubricants, the operation of complete oil replacement is typically handled by professionals due to the complexity of modern vehicle systems. Even topping up is limited in terms of frequency and duration, with minimal exposure time and infrequent occurrences (takes less than 2-3 minutes and it is done at maximum few times per year). Due to the very low vapor pressure of the substance, exposure via inhalation is negligible. Dermal exposure is of low relevance as it is very unlikely that the substance will penetrate skin barrier. Used oils are				

collected as hazardous waste by certified waste disposal companies. In most cases, disposal is by incineration. Therefore, it can be assumed that there is only very low risk of exposure to people and / or the environment.
In conclusion, in the case of classification of Benzenamine, N-phenyl-, reaction products with 2,4,4-trimethylpentene as Reproductive Toxicity Category 1B, the repercussions would be felt across the lubricant industry and not only, with high consequences for socio-economic landscape in Europe.

ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment 2024 April _ ATIEL_CLH SDPA_EC 270-128-1_V2 final.pdf

Date	Country	Organisation	Type of Organisation	Comment number
11.04.2024	United Kingdom	ATC (Additive Technical Committee)	Industry or trade association	6

Comment received

This substance has proven to be a highly effective antioxidant for lubricants which are essential for transport, power generation and a range of other industries. Use of this substance in lubricants allows equipment and vehicle manufacturers to comply with increasingly stringent fuel efficiency and emission targets, to enhance hardware durability, and to reduce the use of chemicals and mineral oils, thereby benefitting the European economy, society and environment and contributing to the sustainability goals of the EU Green Deal.

The Restriction on consumer uses (per REACH Annex XVII) of the majority of lubricating oils that would directly arise from the proposed Reprotoxicity Category 1B CLH, would lead to the loss from the market of a widely used anti-oxidant having the above benefits, without any obvious existing viable alternative of equivalent performance and safety characteristics.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment EC 701-385-4 CLH - ATC Comments Public Consultation.pdf

Date	Country	Organisation	Type of Organisation	Comment number
02.05.2024	Belgium	ATIEL	Industry or trade association	7

Comment received

ATIEL is the Technical Association of the European Lubricants Industry and represents the leading European and international engine oil manufacturers and marketers. ATIEL is downstream user of the substance 'Reaction products of diphenylamine with nonene, branched' (EC 701-385-4).
ATIEL is aware that our response to the CLH public consultation should focus on comments regarding the proposed classification and should be scientific in nature. However, ATIEL would like to point out the consequences if the proposed classification by the dossier submitter (DS) is adopted. The impact on the EU economy would be significant, and ATIEL strongly encourage RAC, member state authorities and the Commission to base their decision for future harmonized classification on scientifically sound weight of evidence and reliable interpretations of the available toxicology data.
Classification of 'Reaction products of diphenylamine with nonene, branched' (EC 701-385-4) as Reproductive Toxicity Category 1B (H360FD) will lead to an unwarranted and generic restriction under the EU REACH Regulation on the majority of consumer uses of lubricating oils (containing the substance at ≥0.3% - by addition to REACH Annex XVII entry 30), as

well as increasing the risk of a later Authorisation or wider scoping Restriction proposal under EU REACH.
If the Aquatic Chronic Category 1 / M-Factor of 10 CLH is adopted for 'Reaction products of diphenylamine with nonene, branched' (EC 701-385-4) a large number of lubricant oils will be classified as Dangerous Goods. That will result in additional costs and controls for storage and transport, potentially leading to insufficient carrying capacity for the total volumes of impacted lubricating oils in the EU market. Additionally, ATC members are of the view that there are no viable alternative antioxidants at the present time. Therefore, there will be significant impact on ATIEL member companies who are producers of lubricants and their customers including Original Equipment Manufacturers (OEMs).
The substituted diphenylamine 'Reaction products of diphenylamine with nonene, branched' (EC 701-385-4) is a crucial antioxidant in lubricant formulations. Even if it is typically used at very low concentration in lubricant mixtures, it has a critical effect on the lifespan, durability, and technical performance of lubricants. It reduces the need for replacement/top-up of the lubricants in vehicles. It has a very important role for strategic uses in the energy transition (wind power, electrical vehicles, energy efficiency of internal combustion engines and others) and contributing to sustainability goals of the EU green deal. Currently there are no other types of antioxidant substances able to replace the substituted diphenylamines that can provide the same durability and technical performances. Just to reiterate, performance lubricants are critical for the transport sector and all types of industries and play a key role for the energy transition and sustainability.
A potential classification as Reproductive Toxicity Category 1B poses substantial challenges to the lubricant industry. Many lubricant formulations in Europe will become classified as Reproductive Toxicity Category 1B, rendering them unsuitable for sale. With no current technical alternative available, reformulation would not be possible by the time of application of the harmonized classification, which will lead to a significant gap for the European economy with an impact on EU green deal objectives.
This would be particularly disruptive for automotive lubricants packed in smaller quantities (e.g., 3, 5 liters) commonly sold to both the general public and professionals such as garages. It's important to note that while lubricants are perceived as consumer products, they are primarily for professional use.
Lubricants are added when the car is produced (first fill) by the OEMs and then are recirculated in closed system in the car. In time it is possible to have to top up a part of the oil or to replace the oil completely. While consumers may occasionally top up their lubricants, the operation of complete oil replacement is typically handled by professionals due to the complexity of modern vehicle systems. Even topping up is limited in terms of frequency and duration, with minimal exposure time and infrequent occurrences (takes less than 2-3 minutes and it is done at maximum few times per year). Due to the very low vapor pressure of the substance, exposure via inhalation is negligible. Dermal exposure is of low relevance as it is very unlikely that the substance will penetrate skin barrier. Used oils are collected as hazardous waste by certified waste disposal companies. In most cases, disposal is by incineration. Therefore, it can be assumed that there is only very low risk of exposure to people and / or the environment.
In conclusion, in the case of classification of Reaction products of diphenylamine with nonene, branched as Reproductive Toxicity Category 1B, the repercussions would be felt across the lubricant industry and not only, with high consequences for socio-economic landscape in Europe.

Date	Country	Organisation	Type of Organisation	Comment number
01.05.2024	United Kingdom	<confidential>	Company-Manufacturer	8
Comment received				

The <confidential>, welcomes the opportunity to provide comments to the consultation on the Proposal for Harmonised Classification and Labelling (CLH) of reaction products of diphenylamine with nonene, branched (EC 701-384-4). <confidential> is a manufacturer of this UVCB substance, which has proven to be a highly effective antioxidant for lubricants which are essential for transport, power generation and a range of other industries. Use of this substance in lubricants allows equipment and vehicle manufacturers to comply with increasingly stringent fuel efficiency and emission targets, to enhance hardware durability, and to reduce the use of chemicals and mineral oils via extended drain intervals, thereby benefitting the European economy, society and environment and contributing to the sustainability goals of the EU Green Deal.

<confidential> would like to address comments made by the Dossier Submitter (DS) in their Assessment of the reliability of the Read-Across from the related substance "Benzenamine, N-phenyl-, reaction products with 2,4,4-trimethylpentene" (EC 270-128-1) (in line with the ECHA Read-Across Assessment Framework, RAAF) regarding impurities, specifically:
• There are no impurities that have been identified that would lead to substance classification for reproduction. As the manufacturing process is similar for both substances, and the starting material is equivalent, it is expected that the impurities profile are comparable." [Section 10.10.11 part 1 – Page 65]

The DS comments have presented a misleading representation; that "starting materials [for the two UVCB substances] are equivalent", and that "the impurities profile are comparable", aiding their arguments to justify Read-Across. This is factually incorrect. Reference to "impurities" in the context of UVCBs is not meaningful when considering the applicability of Read-Across for UVCB substances. In addition, the alkene starting materials are not equivalent, as evidenced by the fact that constituents of the two substances are fundamentally different in molecular weight and degree and type of branching (apart from residual diphenylamine), and based on the manufacturing processes, the same constituents cannot be created.

Further comments have been made in the confidential attachment.

ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment C9 SDPA Manufacturing Process - Consultation comments 1May2024.pdf

Date	Country	Organisation	Type of Organisation	Comment number
01.05.2024	United States of America	American Chemistry Council	Industry or trade association	9
Comment received				
Please accept the attached comments from the American Chemistry Council. ECHA note – An attachment was submitted with the comment above. Refer to public attachment ACC SDPA_Committee for Risk Assessment_CLH_EC 701-385-4_30April2024_redacted.pdf ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment ACC SDPA_Committee for Risk Assessment_CLH_EC 701-385-4_30April2024.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
29.04.2024	India	<confidential>	Company-Manufacturer	10
Comment received				

We hereby confirm our support for Document 156 – EC 270-128-1 CLH – ATC Comments Public Consultation and Document 157 – EC 701-385-1- ATC Public Consultation.

Date	Country	Organisation	Type of Organisation	Comment number
29.04.2024	Germany	<confidential>	Company-Downstream user	11

Comment received

Substituted diphenyl amine (SDPA) substances are one of the most effective antioxidant for the use in Lubricants. They are used for decades and have shown high performance and have proven to be the most effective antioxidant chemistry in a wide range of applications. They are used in high performance lubricants, high performance greases and also in standard lubricants and standard greases, in various applications. Such Lubricants are essential for transport, power generation and many other industrial uses. Lubricants are key to reduce energy consumption, reduce wear and therefore reduce CO2 emissions and help to extend lifetime of components. Alltogether Lubricants additised with such substances contribute to the sustainability goals of the Eurpean Green Deal and they support all industries and the EU to achieve these goals.
At the moment alternatives with the same performance are not known to us.
According to our knowledge the development and approval of alternatives in the whole supply chain takes years.
The CLH classification would have a big impact on the lubricants industry and also the industries in the supply chain
Therefore we support the Documents of ATC Europe No. 155, 157

Date	Country	Organisation	Type of Organisation	Comment number
25.04.2024	Germany	BASF SE	Company-Manufacturer	12

Comment received

CLH Dossier Reaction products of diphenylamine with nonene, branched: EC 701-385-1
Statement on page 65 regarding the impurities in the CLH report.

We would like to provide as SIEF member, additional information to the ATC Document 157 regarding the following point in the CLH report:

10.10.11Assessment of the reliability of the read-across (in line with the ECHA Read-Across Assessment Framework, RAAF). Page 63

Specifically, the statement on page 65 regarding the impurities.

"Impurities
The constituents of the two substances and the compositions of the two substances are presented in the tables 2, 3, 4 and 5 of the confidential Annex There are no impurities that have been identified that would lead to substance classification for reproduction. As the manufacturing process is similar for both substances, and the starting material is equivalent, it is expected that the impurities profile are comparable."

According to the literature, the alkylation reaction occurs from the aromatic compound (Diphenylamine, DPA) over the double bond (olefine), for that reason the kinetic of the reaction is different depending on the kind of olefine used. In addition to the olefin reactivity, the stoichiometry and reaction conditions (temperature) are different, in both processes.
Therefore, the impurities profile is not expected to be comparable, because most of it comes

from completely different alkylating agents.

ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Statement on page 65 regarding the impurities in the CLH report_Final_2024_04_24 (002).pdf

Date	Country	Organisation	Type of Organisation	Comment number
24.04.2024	Germany		MemberState	13
Comment received				
In parallel with this CLH dossier of reaction products of diphenylamine with nonene, branched ("the classified substance"), a proposal on harmonised classification of the substance reaction products of diphenylamine with 2,4,4-trimethylpentene (EC No. 270-128-1, CAS No. 68411-46-1) was submitted. The proposal for harmonised classification for effects on development of the classified substance is mainly based on read-across to the substance EC No. 270-128-1 (CAS No. 68411-46-1). We agree with the proposed classification for fertility. However, we have several reservations with respect to the read-across applied in order to classify for developmental effects (see further details given below).				

HEALTH HAZARDS – Reproductive toxicity

Date	Country	Organisation	Type of Organisation	Comment number
01.05.2024	United States of America	American Chemistry Council	Industry or trade association	14
Comment received				
Please accept the attached comments from the American Chemistry Council. ECHA note – An attachment was submitted with the comment above. Refer to public attachment ACC SDPA_Committee for Risk Assessment_CLH_EC 701-385-4_30April2024_redacted.pdf ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment ACC SDPA_Committee for Risk Assessment_CLH_EC 701-385-4_30April2024.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
02.05.2024	Belgium	ATIEL	Please select organisation type..	15
Comment received				
Taking into consideration the detailed technical comments prepared by The Additive Technical Committee (ATC) (Document 156, April 2024) on the proposed harmonised classification and labelling for EC 270-128-1, ATIEL agree with ATC in that the proposed classification as toxic to reproduction category 1B for effects on fertility (H360F) and on development (H360D) do not appear to be justified based on the available toxicology data. Please find additional comments in the attached document named "2024 April _ ATIEL_CLH SDPA_EC 270-128-1". ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment 2024 April _ ATIEL_CLH SDPA_EC 270-128-1_V2 final.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
24.04.2024	Germany		MemberState	16
Comment received				

Effects on fertility
We support the CLH proposal of the FR CA for the harmonised classification of the substance reaction products of diphenylamine with nonene, branched for effects on fertility. This is mainly based on the reduced number of implantation sites (-31 % and -24 % vs. controls) accompanied by a decreased number of pups delivered (-31 % and -19 % vs. controls) and decreased ovary weights (-40 % and -18 % vs. controls) in high- (443 mg/kg bw/day) and mid-dose (133 mg/kg bw/day) animals, resulting from a study in line with OECD TG 421 and conducted with the classified substance. Effects are statistically significant, dose-related and occur in the absence of severe maternal toxicity, and therefore warrant classification for effects on fertility, H360F.

Effects on development
PNDT studies (in rat and rabbit) conducted with the classified substance do not show effects that warrant classification for effects on developmental toxicity.

The proposal for classification for developmental effects of the classified substance is mainly based on read-across. Studies in line with OECD TG 421 (conducted with the classified substance) and OECD TG 422 (conducted with benzenamine, N-phenyl-, reaction products with 2,4,4-trimethylpentene) were used as bridging studies in which both substances induce the same type of effects (on fertility, with a similar magnitude; please see "effects on fertility"); liver and thyroid were identified as target organs.

In an EOGRTS conducted with the source substance benzenamine, N-phenyl-, reaction products with 2,4,4-trimethylpentene, DNT was observed; however, with uncertainties identified (please see DE comment on the CLH proposal for benzenamine, N-phenyl-, reaction products with 2,4,4-trimethylpentene).

Both substances show similar physicochemical properties and a metabolic simulator predicted similar breakdown products and metabolites for both substances. However, both substances are UVCBs and their constituents, with the exception of EC No. 204-539-4 (max. concentration < 2.5 %), are not the same or structurally related to each other, but do not result in the same transformation products. For EC No. 204-539-4, no classification for effects on reproductive toxicity was proposed. Furthermore, variations in concentration of constituents would represent an additional source of variation between both substances (ECHA, 2022).

As stated in the dossier, both substances demonstrate similar metabolome profiles in the plasma of fasted rats. However, the substances did not show matches that would give a clear indication for a certain toxicological mode of action. According to the DS, DNT (seen in an OECD TG 443 study) could be expected in respect to the similar effects on the thyroid axis observed with the two substances. Taking into account the bridging studies, the source substance EC No. 270-128-1 showed effects on the thyroid with a higher magnitude (↑ rel. thyroid weight in M (+32 %), ↑ TSH (+136 %) in M at 260 mg/kg bw, vs. controls), compared to the effects seen in the OECD TG 421 study conducted with the target substance (↑ rel. thyroid weight in M (+17 %), non-statistically significant ↑ TSH in M (+45 %) at 407 mg/kg bw vs. controls).

It is recommended to consider the critical points mentioned above together with the uncertainties in the classification of the source substance reaction products of

diphenylamine with 2,4,4-trimethylpentene (EC No. 270-128-1, CAS No. 68411-46-1) for effects on development (please see DE comment on the CLH proposal for benzenamine, N-phenyl-, reaction products with 2,4,4-trimethylpentene), for classification of the classified substance for developmental effects.

A RAC note (RAC/62/2022/05) is summarised in the report, which addresses developmental neurotoxicity and neurotoxicity under the current CLP hazard classes. This note has an influence on the proposal of the DS. Unfortunately, it was not included in the documents of the public consultation and could not be easily found on the internet. This RAC note is very interesting and should be made available to a wider audience to better understand the rationale of the DS.

Reference:
ECHA (2022): Advice on using read-across for UVCB substances.
https://echa.europa.eu/de/-/new-advice-for-using-read-across

Date	Country	Organisation	Type of Organisation	Comment number
02.05.2024	Belgium	ATIEL	Industry or trade association	17
Comment received				
Taking into consideration the detailed technical comments prepared by The Additive Technical Committee (ATC) (Document 157, April 2024) on the proposed harmonized classification and labelling for EC 701-385-4, ATIEL agree with ATC in that the proposed classification as toxic to reproduction category 1B for effects on fertility (H360F) and on development (H360D) do not appear to be justified based on the available toxicology data. Please find additional comments in the attached document named "2024 April _ ATIEL_CLH SDPA_EC 701-385-4".				

Date	Country	Organisation	Type of Organisation	Comment number
01.05.2024	United Kingdom	<confidential>	Company-Manufacturer	18
Comment received				
<confidential> supports the comments made by The Technical Committee of Petroleum Additive Manufacturers in Europe (ATC) that the proposed Harmonised Classification and Labelling (CLH) of Reproductive toxicity Category 1B, which if implemented will result in an unwarranted and overly conservative Restriction on consumer uses per REACH Annex XVII, is not justified based on the available toxicology data. ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment C9 SDPA Manufacturing Process - Consultation comments 1May2024.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
11.04.2024	United Kingdom	ATC (Additive Technical Committee)	Industry or trade association	19
Comment received				
ATC disagrees with the assessment of the dossier submitter and does not consider the proposed CLH of Reprotoxicity Category 1B (H360 FD) as warranted based on the available toxicology data for the reasons explained in the attached document.				

Please also note that, based on the data obtained in extended OECD TG 421 studies, the Lead Registrant submitted a testing proposal for an OECD TG 443 study with EC 701-385-4 on October 6th, 2021, as the registrants no longer supported read-across from the data available for EC 270-128-1. Following a public commenting phase, no further steps were taken by ECHA, thus prohibiting the registrants from conducting this study under EU REACH. However, since the OECD TG 443 study is also required by members of the SIEF for registration in jurisdictions outside of the EU (most immediately for registration in the Republic of Korea pursuant to the Act on the Registration and Evaluation of Chemicals ("K-REACH"), ATC members are planning to conduct an OECD TG 443 study on EC 701-385-4. Furthermore, ATC has initiated an enhanced OECD TG 421 study including additional mechanistic examinations. These studies will deliver additional data that will clarify the reproductive toxicity concerns and so are critical for establishing the CLH. ATC therefore asks the DS, Rapporteur and RAC to consider these additional data during the RAC Opinion development. It is anticipated that study reports for the OECD TG 421 study will be available in Q1 2025 and in mid-2026 for the OECD TG 443 study.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment EC 701-385-4 CLH - ATC Comments Public Consultation.pdf

Date	Country	Organisation	Type of Organisation	Comment number
03.05.2024	United Kingdom	Health and Safety Executive	National Authority	20

Comment received

'The DS has proposed a classification of Repr. 1B for developmental effects based primarily on histopathological changes in the spinal cord and impairment of acoustic startle response, both reported in cohort 2A in the EOGRTS. There are a number of uncertainties with the data and therefore we would welcome a discussion on the following points:

• Thoracic spinal cord degeneration is reported in cohort 2A males. It would be useful to discuss the severity of these effects and any likely functional consequences that are expected/observed as outlined in paragraph 83 of OECD TG 443. It would also be useful to address any functional deficiencies that are observed in any of the other available studies (90-day repeat-dose and EOGRTS), specifically those which may be attributable to thoracic spinal cord degeneration.
• In the acoustic startle response test, a decrease in mean maximal amplitude is observed in cohort 2A in conjunction with a decrease in F1 and F2 pup bw. We note that a decrease in pup bw is a covariant of the acoustic startle response (as mentioned in Section 3.2.2, Tyl et al, 2008). It would be useful to provide a comment for the decrease on pup weight and any potential effect on the acoustic startle response.'

Date	Country	Organisation	Type of Organisation	Comment number
03.05.2024	Germany	<confidential>	Company-Manufacturer	21

Comment received

As already mentioned in the general comment: Classification of the antioxidants as Repr. 1 will require classification of end products, resulting in restriction or even ban for consumer products from the market. In addition, professional and industrial users will strongly refuse these products due to its incompliance between calssification and corporate guidelines.

Date	Country	Organisation	Type of Organisation	Comment

				number
29.04.2024	Germany	<confidential>	Company-Downstream user	22
Comment received				
we support the Documents of ATC Europe No. 155, 157				

ENVIRONMENTAL HAZARDS – Hazardous to the aquatic environment

Date	Country	Organisation	Type of Organisation	Comment number
02.05.2024	Belgium	ATIEL	Please select organisation type..	23
Comment received				
Taking into consideration the detailed technical comments prepared by The Additive Technical Committee (ATC) (Document 156, April 2024) on the proposed harmonised classification and labelling for EC 270-128-1 ATIEL agree with ATC in that the proposed classifications hazardous to the aquatic environment does not appear to be justified based on the available ecotoxicology data. Please find additional comments in the attached document named "2024 April _ ATIEL_CLH SDPA_EC 270-128-1". ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment 2024 April _ ATIEL_CLH SDPA_EC 270-128-1_V2 final.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
24.04.2024	Germany		MemberState	24
Comment received				
We agree on the classification as Aquatic Chronic 1 (M=10) and support the use of the LOQ/2 for the TWA calculation.				

Date	Country	Organisation	Type of Organisation	Comment number
02.05.2024	Belgium	ATIEL	Industry or trade association	25
Comment received				
Taking into consideration the detailed technical comments prepared by The Additive Technical Committee (ATC) (Document 157, April 2024) on the proposed harmonized classification and labelling for EC 270-128-1, ATIEL agrees with ATC in that the proposed classification as hazardous to the aquatic environment does not appear to be justified based on the available ecotoxicology data. Please find additional comments in the attached document named "2024 April _ ATIEL_CLH SDPA_EC 701-385-4".				

Date	Country	Organisation	Type of Organisation	Comment number
01.05.2024	United Kingdom	<confidential>	Company-Manufacturer	26
Comment received				
<confidential> supports the comments made by The Technical Committee of Petroleum Additive Manufacturers in Europe (ATC) that the proposed Harmonised Classification and Labelling (CLH) of Aquatic Chronic Category 1 with an M Factor of 10, which will result in an unwarranted and overly conservative “Dangerous Goods” classification on formulated oils, is not supported by ecotoxicology evidence. Specifically, no aquatic toxicity was observed				

within the range of water solubility.

ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment C9 SDPA Manufacturing Process - Consultation comments 1May2024.pdf

Date	Country	Organisation	Type of Organisation	Comment number
11.04.2024	United Kingdom	ATC (Additive Technical Committee)	Industry or trade association	27
Comment received				
ATC disagrees with the assessment of the dossier submitter and does not consider the proposed CLH of Aquatic Chronic Category 1 (H410) with an M-Factor of 10 as warranted based on the available ecotoxicology data for the reasons explained in the attached document. ECHA note – An attachment was submitted with the comment above. Refer to public attachment EC 701-385-4 CLH - ATC Comments Public Consultation.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
01.05.2024	United States of America	American Chemistry Council	Industry or trade association	28
Comment received				
Please accept the attached comments from the American Chemistry Council. ECHA note – An attachment was submitted with the comment above. Refer to public attachment ACC SDPA_Committee for Risk Assessment_CLH_EC 701-385-4_30April2024_redacted.pdf ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment ACC SDPA_Committee for Risk Assessment_CLH_EC 701-385-4_30April2024.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
03.05.2024	Germany	<confidential>	Company-Manufacturer	29
Comment received				
As already mentioned in the general comment: Based on the current data (see registration dossier) we do not agree with the classification Aquatic Chronic 1. The proposed CLH for C9 SDPA as Aquatic Chronic 1 (M=10) will result in most of our lubricants being classified as Dangerous Goods. This will result in significantly higher transportation and administration costs and poorer customer acceptance.				

Date	Country	Organisation	Type of Organisation	Comment number
29.04.2024	Germany	<confidential>	Company-Downstream user	30
Comment received				
we support the Documents of ATC Europe No. 155, 157				

PUBLIC ATTACHMENTS

1. ACC SDPA_Committee for Risk Assessment_CLH_EC 701-385-4_30April2024_redacted.pdf [Please refer to comment No. 9, 14, 28]
2. EC 701-385-4 CLH - ATC Comments Public Consultation.pdf [Please refer to comment No. 6, 19, 27]

CONFIDENTIAL ATTACHMENTS
1. SONGWON comment to public consultation EC 701-385-4 -3May2024 final.pdf SONGWON comment to public consultation EC 701-385-4 -3May2024 final blanked.pdf [Please refer to comment No. 1]
2. 701-385-4_CLH.zip [Please refer to comment No. 2]
3. 2024-05-02 Profile <confidential>.pdf [Please refer to comment No. 4]
4. 2024 April _ ATIEL_CLH SDPA_EC 270-128-1_V2 final.pdf [Please refer to comment No. 5, 15, 23]
5. C9 SDPA Manufacturing Process - Consultation comments 1May2024.pdf [Please refer to comment No. 8, 18, 26]
6. ACC SDPA_Committee for Risk Assessment_CLH_EC 701-385-4_30April2024.pdf [Please refer to comment No. 9, 14, 28]
7. Statement on page 65 regarding the impurities in the CLH report_Final_2024_04_24 (002).pdf [Please refer to comment No. 12]