ATIEL COMMENTS on CLH public consultation for Benzenamine, N-phenyl-, reaction products with 2,4,4-trimethylpentene (EC 270-128-1)
2 May 2024

ATIEL is the Technical Association of the European Lubricants Industry and represents the leading European and international engine oil manufacturers and marketers. ATIEL is a 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 as toxic to reproduction category 1, for sexual function and fertility
The dossier submitter (DS) has proposed a harmonised classification for Benzenamine, N-phenyl-, reaction products with 2,4,4-trimethylpentene (EC 270-128-1) as toxic to reproduction category 1B for effects on fertility (H360F) based on lower number of implantation sites with subsequential litter sizes, decreased ovary weight and altered cyclicity.
Comments
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) does not appear to be justified based on the available toxicology data. Summary remarks: <u>Read-across proposed by DS</u> The DS has suggested conducting a read-across between EC 270-128-1 and EC 701-385-4, which is currently also proposed in the registration dossier of EC 270-128-1. However, due to divergent results obtained in OECD TG 421 bridging studies on both substances, the registrants opted to withdraw this read-across as it was not considered reliable for the proposed reproductive and developmental endpoints. According to section 3.7.2.3.1. of the CLP Regulation (EC) 1272/2008, read-across substances may be included when information on the substance is scarce. However, as a robust GLP study according to OECD TG 421 with extended study design as well as OECD TG 414 studies in two species have been conducted with EC 701-385-4, the results of these studies should not be overruled by the results from the read-across source substance EC 270-128-1.

Toxicity to reproduction: Fertility

The available studies suggest an effect of the substance on female fertility together with maternal toxicity which are likely due to a secondary, non-specific mechanism because of pronounced maternal toxicity, manifested by reduced body weight and food consumption and liver toxicity. It is well established in the literature that excessive systemic toxicity as observed in this study lead to adverse effects on fertility. The mode of action is especially relevant for this substance EC 270-128-1 (and not supported for substance EC 701-385-4) as it is most likely species-specific and of low relevance for humans. Taken together, the observed systemic toxicity concomitant with reproductive effects, the biologically plausible mode of action relevant for rats but not for humans, the review of statistical interpretation considering more accurate historical control data provided by the laboratory, provide clear evidence of an adverse effect on sexual function and fertility. In line with the criteria laid down in the CLP Regulation (EC) 1272/2008, classification as Category 2 (H361f) is considered to be more appropriate.

Classification as toxic to reproduction category 1, for development

The DS has proposed a harmonised classification for Benzenamine, N-phenyl-, reaction products with 2,4,4-trimethylpentene (EC 270-128-1) as toxic to reproduction category 1B for effects on development (H360D) based on neurodevelopmental effects.

Comments

Taking into consideration the detailed technical comments prepared by 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 development (H360D) does not appear to be justified based on the available toxicology data.

Summary remarks:

Read across proposed by DS: See comments above.

Toxicity to reproduction: Developmental Toxicity

The available studies provide some evidence for a neurotoxic effect following repeated exposure, however no correlation to the developmental period could be established. In the absence of functional impairment, classification as Category 1B (H360D) is not considered to be appropriate, and effects on pup viability and growth should be disregarded due to maternal toxicity based on the criteria laid down in the CLP Regulation (EC) 1272/2008.

In summary, the basis for the classification proposed by the DS does not appear to be sufficiently reliable and does not appear to meet the criteria under CLP Regulation (EC) 1272/2008 for classification in Category 1B.

Classification for environment

The DS has proposed a harmonised classification for Benzenamine, N-phenyl-, reaction products with 2,4,4-trimethylpentene (EC 270-128-1) as hazardous to the aquatic environment, specifically Aquatic Chronic 2 (H411).

Comments

Taking into consideration the detailed technical comments prepared by 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.
Summary remarks:

Bioaccumulation
The OECD 305 bioaccumulation study conducted with the test substance Mono-Nonyl diphenylamine (EC 248-295-7) in 2000 revealed several shortcomings when compared against today's relevant criteria. These shortcomings prevent a robust and valid evaluation of the bioaccumulation potential of the substance in fish which is why the registrants strongly recommend to reconduct the bioaccumulation study in fish.

Aquatic chronic toxicity:
In the OECD TG 211 chronic daphnia study the lowest concentrations are statistically significant, but without biological relevance. The approach of the testing laboratory to determine an EC10 value is considered the correct approach and is in line with the current regulatory guidance. When considering the EC10 approach to be valid, there is no toxicity in the range of the water solubility and therefore no classification and labelling would be required under CLP Regulation (EC) 1272/2008.

Impact of such classification of downstream users

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 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 diphenylamine's 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.