Committee for Risk Assessment
European Chemicals Agency
Annankatu 18
00120 Helsinki
Finland

April 30, 2024

Re: Proposed EU Harmonised Classification and Labelling (CLH) Benzenamine, N-phenyl-, reaction products with 2,4,4-trimethylpentene (EC 270-128-1) – C4:C8 SDPA

To Whom It May Concern:

The Substituted Diphenylamines Industry Work Group (SDPA IWG) of the American Chemistry Council (ACC)[1] writes to comment in response to the proposed harmonized classification and labeling of Benzenamine, N-phenyl-, reaction products with 2,4,4-trimethylpentene (EC 270-128-1) – C4:C8 SDPA under EU REACH. The SDPA IWG includes companies[2] with a common interest in the interpretation of the scientific information that forms the basis for regulation, including classification and labeling. The SDPA IWG is a task group under ACC's Petroleum Additives Panel. **The SDPA IWG is opposed to the proposal labeling EC 270-128-1 as a Reprotoxicity Category 1B, H361 DF and Aquatic Chronic Category 2, H411.**

ACC SDPA IWG review of available data indicates the proposed classification is not supported. The SDPA IWG supports the technical comments of the Additive Technical Committee (ATC) dated April 2024 (Document 156) and titled "ATC comments on the proposed Harmonised Classification and Labelling For: Benzenamine, N-phenyl-, reaction products with 2,4,4-trimethylpentene (EC 270-128-1)" (hereafter referred to as ATC 156). This document contains detailed review and interpretation of available toxicology and ecotoxicology data in context of the CLH classification parameters.

ATC 156 reviews toxicity to reproduction: sexual function and fertility, toxicity to reproduction: developmental toxicity, bioaccumulation, and chronic toxicity.

Regarding toxicity to reproduction: sexual function and fertility, ATC 156 concludes,

> The available studies provide some evidence for an effect of the substance on female fertility together with maternal toxicity. The mode of action proposed shows these effects are indicative of a secondary, non-specific mechanism as a consequence of pronounced maternal toxicity. The mode of action is especially relevant as it is most likely species-specific and of

[1] The American Chemistry Council (ACC) is the major trade association in the US representing leading companies engaged in the business of chemistry. ACC is committed to improved environmental, health and safety performance through Responsible Care®, regulatory advocacy to address major public policy issues, health and environmental research, and product testing.
[2] Members of the SDPA IWG include: BASF Corporation, Chemtura Corporation, Chevron Oronite, Infineum USA L.P., The Lubrizol Corporation, and R.T. Vanderbilt Holding, Inc.

> low relevance for humans. In line with the criteria laid down in Regulation (EC) 1272/2008 (CLP), classification as Category 2 (H361f) is warranted.

Regarding toxicity to reproduction: developmental toxicity, ATC 156 concludes,

> 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 inappropriate. Effects on pup viability and growth of the organism only occurred in conjunction with excessive maternal toxicity and should therefore be disregarded based on the criteria laid down in Regulation (EC) 1272/2008 (CLP).

When reviewing bioaccumulation, ATC 156 concludes,

> The performed bioaccumulation study revealed several shortcomings when compared against today's relevant criteria. In sum, these shortcomings impair a robust and valid evaluation of the bioaccumulation potential in fish. Therefore, the registrants strongly recommend to re-perform the bioaccumulation study in fish.

Considering chronic aquatic toxicity, ATC 156 concludes,

> In the available chronic daphnia study the lowest concentrations are statistically significant, but without biological relevance. The approach of the testing laboratory to determine an EC10 value was considered correct and in line with the regulatory guidance. Considering this approach to be valid, there is no toxicity in the range of the water solubility and conclusively no classification is warranted.

The SDPA IWG further supports the ATC's recommendation that the CLH process await the new information from the ongoing CORAP process.

The government of Canada has concluded this substance does not pose a risk to the environment or to human health.

In December 2017, the Final Screening Assessment for Substituted Diphenylamines[3] was released and the related notice was published in the Canada Gazette, Part I: Vol. 151, No. 49 – December 9, 2017. Benzenamine, N-phenyl-, reaction products with 2,4,4-trimethylpentene (EC 270-128-1) – C4:C8 SDPA is included in this grouping.

In the final screening assessment, the Government of Canada concluded that none of the 14 SDPAs assessed poses a risk to the environment or to human health and, therefore, do not meet any of the criteria under section 64 of CEPA 1999, stating,

[3] https://www.canada.ca/en/environment-climate-change/services/evaluating-existing-substances/screening-assessment-substituted-diphenylamines.html

> Considering all available lines of evidence presented in this screening assessment, there is low risk of harm to organisms and the broader integrity of the environment from the fourteen SDPAs considered in this assessment. It is concluded that the fourteen SDPAs do not meet the criteria under paragraphs 64(a) or (b) of CEPA as they are not entering the environment in a quantity or concentration or under conditions that have or may have an immediate or long-term harmful effect on the environment or its biological diversity or that constitute or may constitute a danger to the environment on which life depends.
>
> Based on the available information on their potential to cause harm to human health, it is concluded that the fourteen SDPAs considered in this assessment do not meet the criteria under paragraph 64(c) of CEPA as they are not entering the environment in a quantity or concentration or under conditions that constitute or may constitute a danger in Canada to human life or health.
>
> Therefore, it is concluded that the fourteen SDPAs considered in this assessment do not meet any of the criteria set out in section 64 of CEPA. This conclusion also applies to BNST, also included among the fourteen substances; this substance had previously been found to meet the criteria set out in section 64 of CEPA in a 2009 screening assessment conducted during the Challenge initiative of the Chemicals Management Plan.

SDPAs are important antioxidants for the North American transportation industry and have a global supply chain.

As described in the Canadian screening assessment, SDPAs are a subclass of amine antioxidants. Amine antioxidants are used to prevent the degradation of the materials (e.g., lubricants, foams) into which they are added. SDPAs perform as primary antioxidants and function by destroying free radicals as they form, thereby preventing degradation of the base organic compounds (Hadjuk et al. 2012)[4].

In North America, SDPAs including EC 270-128-1, play a critical role as an antioxidant in a number of industrial, professional, and consumer transportation fluids. SDPA's are formulated in fluids that contribute to the functioning of power steering, hydraulic applications, automatic and manual transmissions, off-highway drive trains and axels, motorcycle engine oil, passenger car engine oil, heavy duty vehicle engine oil, metalworking applications, refrigerants, and tractor transmissions.

While SDPAs may be produced locally in Europe and North America, their distribution and uses have global implications. A change in categorization or further restriction under EU REACH

[4] Hadjuk F, Müller S, Yang V, Yokose K. 2012. Specialty Chemicals Update Report – Antioxidants. Prepared for IHS.

would have significant impacts on downstream producers of lubricants and their customers, such as original equipment manufacturers (OEMs).

Thank you for the opportunity to comment on this proposed classification. The ACC SDPA IWG reiterates its support for the technical comments developed by the ATC in Document 156 and urges the dossier submitter and RAC to accept the conclusions on reproductive toxicity and aquatic hazard contained therein.

Please feel free to contact me at [redacted] if you have any questions or would like to discuss the proposed change in classification for this SDPA further.

Respectfully,

[redacted]

[redacted]

Manager, Petroleum Additives Panel