COMMENTS ON AN ANNEX XV DOSSIER FOR IDENTIFCATION OF A SUBSTANCE AS SVHC AND RESPONSES TO THESE COMMENTS

Disclaimer: Comments provided during the consultation are made available as submitted by the commenting parties. It was the commenting parties own responsibility to ensure that their comments do not contain confidential information. The Response to Comments table has been prepared by the competent authority of the Member State preparing the proposal for identification of a substance of very high concern.

Substance name: 2-(4-tert-butylbenzyl)propionaldehyde and its individual stereoisomers
CAS number: -
EC number: -

The substances are proposed to be identified as meeting the following SVHC criteria set out in Article 57 of the REACH Regulation: Toxic for reproduction (Article 57c)

PART I: Comments and responses to comments on the SVHC proposal and its justification

General comments on the SVHC proposal

Number / Date	Submitted by (name, submitter type, country)	Comment	Responses
5475 2021/04/22	Emerald Kalama Chemical Limited, Company, United Kingdom	Emerald Kalama Chemical Limited, as represented by Penman Consulting bvba (acting as Only Representative), is providing comments on Sweden's Proposal of March 2021 to add 2-(4-tert-butylbenzyl)propionaldehyde (the Substance) and its individual stereoisomers (EC 201-289-8/CAS 80-54-6, and its stereoisomers) to the Candidate List of Substances of Very High Concern (SVHC). As a matter of procedure, substance inclusion in the Candidate List as per REACH Article 59 requires Member States to prepare and submit an Annex XV dossier. A full Annex XV dossier needs to include a justification for the proposal of inclusion in the Candidate List and	Thank you for your comments. The substance was included in the 15th ATP to CLP Annex VI, which was published in Official Journal of the European Union on 11th August 2020 (and entered into force 20 days after its publication). Thus, Table 3 of

		information on exposures, alternative substances and risks. We therefore echo the comments submitted by the Lead Registrant for the Substance that the Proposal put forward by Sweden does not meet such requirements. Instead, the Proposal contains a reference to an entry in Part 3 of Annex VI to Regulation(EC) No 1272/2008 (CLP) while the harmonized classification of Repr. Cat. 1B for the Substance does not take effect till 1 March 2022 pursuant to the Regulation 2020/1182. The absence of justifications in relation to Annex XV Proposal therefore prevents Emerald Kalama Chemical from substantively commenting and contesting Sweden's justification and is not in line with the requirements of REACH. In light of this, we believe Sweden's proposal to include the Substance in the Candidate List for final inclusion to Annex XIV is premature and unwarranted. We understand that the basis for this nomination by Sweden is based on REACH Article 57(c) which allows for the following substances to be included in the Candidate List: • Substances meeting the criteria for classification in the hazard class reproductive toxicity category 1A or 1B, adverse effects on sexual function and fertility or on development in accordance with section 3.7 of Annex I to the CLP Regulation. However, we note our general concern as to the disagreement between the registrants of the Substance (and scientific opinions they have relied on while providing comments in relation to the proposed harmonized classification) and ECHA/the European Commission on whether harmonized classification of Repr. Cat. 1B is appropriate with respect to the Substance. There still remains doubt on the relevance to humans of the animal data used to support that	Part 3 of Annex VI to Regulation (EC) No 1272/2008 has been updated, including the substance 2-(4-tert-butylbenzyl)propionaldehyde. The harmonised classification and labelling can therefore already be applied on a voluntary basis, however, compliance with the new or updated harmonised classifications is not required immediately. The transition period for ATP 15 extends until March 1, 2022 from when it applies and is a legally binding requirement.

		classification and as a result, Repr. Cat. 2 would be more appropriate and in line with the requirements of CLP.	

Specific comments on the justification

Number / Date	Submitted by (name, submitter type, country)	Comment	Responses
5457 2021/03/18	Individual, Germany	The Candidate Listing dossier prepared by Sweden contains a reference to an entry in Part 3 of Annex VI to Regulation (EC) No 1272/2008 (CLP) as justification for including the substance on the Candidate List. However, the substance is not yet listed on Annex VI to CLP (it is included in the 15th ATP, which enters into force on 31st March 2022 – and the substance will be added to Annex VI of CLP at this date). Therefore, the proposal for listing on the Candidate List requires the preparation of an Annex XV dossier, as per Art. 59. (3) of Regulation (EC) No 1907/2006 (REACH). The report prepared does not fulfill the requirements of Annex XV REACH, and thus cannot be accepted for including the substance on the Candidate List.	Thank you for your comments. The substance was included in the 15th ATP to CLP Annex VI, which was published in Official Journal of the European Union on 11th August 2020 (and entered into force 20 days after its publication). Thus, Table 3 of Part 3 of Annex VI to Regulation (EC) No 1272/2008 has been updated, including the substance 2-(4-tert-butylbenzyl)propionaldehyde. The harmonised classification and labelling can therefore already be applied on a

			voluntary basis, however, compliance with the new or updated harmonised classifications is not required immediately. The transition period for ATP 15 extends until March 1, 2022 from when it applies and is a legally binding requirement.
5459 2021/04/13	Health and Environment Alliance (HEAL), International NGO, Belgium	The Health and Environment Alliance (HEAL) thanks Sweden for its proposal to identify 2-(4-tert-butylbenzyl)propionaldehyde and its individual stereoisomers as substances of very high concern under article 57(c) - which we fully support. Considering the existing CLP classification as toxic for reproduction 1B, we consider the SVHC identification unequivocal.	Thank you for your support.
5466 2021/04/17	CHEM Trust Europe, National NGO, Germany	CHEM Trust supports the inclusion of 2-(4-tert-butylbenzyl)propionaldehyde (lilial/lysmeral) and its individual stereoisomers in the REACH candidate list owing to its classification as reproductive toxicant 1B which fulfills the criterion of REACH article 57 c).	Thank you for your support.
5476 2021/04/22	Germany, Member State	The German CA agrees with the pro-posal for identification of 2-(4-tert-butylbenzyl)propionaldehyde and its individual stereoisomers as a substance of very high concern (SVHC) based on article 57c. The harmonised classification and labelling as Repro 1B was agreed by the EU Commission. It is included in the 15th Adaptation to Technical Progress in the Commission Delegated Regulation (EU) 2020/1182 of 19 May 2020,, entering into force from 01 March 2022.	Thank you for your support.

5484 2021/04/22	ANSES, National Authority, France	Lysmeral (racemic 1:1) has a harmonised classification Repro 1B-H360Fd. The potential mode of action and role of its metabolites in the induction of the effects have been discussed in detail in the classification dossier and in the RAC opinion but no conclusion has been made that the effect can be attributed to any specific stereoisomer. The conclusion that lysmeral and its stereoisomers fulfils the criteria to identify the substance as an SVHC under article 57(c) by meeting the criteria for classification Repro 1B and the SVHC identification are therefore supported.	Thank you for your support.
5490 2021/04/22	Norway, Member State	The Norwegian CA supports that 2-(4-tert-butylbenzyl)propionaldehyde and its individual stereoisomers should be identified as a substance of very high concern and should be included in the Candidate List.	Thank you for your support.
5504 2021/04/22	Netherlands, Member State	NL supports the proposal to include 2-(4-tert-butylbenzyl)propionaldehyde and its individual stereoisomers in the candidate list of SVHC in accordance with Article 57(c) of Regulation (EC) 1907/2006 (REACH) given the reprotoxic properties.	Thank you for your support.
5526 2021/04/23	ChemSec, International NGO, Sweden	ChemSec agrees to the identification of these substances as a Substance of Very High Concern based on it being classified as toxic to reproduction 1B.	Thank you for your support.

PART II: Comments and responses to comments on uses, exposures, alternatives and risks

Specific comments on use, exposure, alternatives and risks

Number / Date	Submitted by (name, submitter type, country)	Comment	Responses

5466 2021/04/17	CHEM Trust Europe, National NGO, Germany	CHEM Trust sees the need for additional regulatory measures to reduce the exposure of lilial/lysmeral to prevent health impacts from the reprotoxic properties of the substance. This is supported by recent human biomonitoring data from the German Environment Agency which highlight the widespread exposure of the general population: Lilial (lysmeral) was investigated in 24h-urine samples from 2000-2018 (Environmental Specimen Bank) in Scherer et al, 2021 . The two major metabolites TBBA and lysmerol were found in quantifiable concentrations in almost all samples in this study. Though concentration generally declined in the investigated time period there is remaining concern about sensitizing and adverse effects on fertility. Even more reason for concern give the results from the study Murawski et al 2020. The German Environmental Survey 2014–2017 detected lilial (lysmeral) in all 2133 children and adolescents investigted (age group 3-17 years). Given that 99% of the samples had quantifiable amounts of at least the specific metabolite Lys-OH, it can be concluded that children and adolescents in Germany were ubiquitously exposed to lysmeral. Thus, in our view exposure should be minimised through additional regulatory measures. It is not acceptable that this reprotoxic substance is still used widely in cosmetics, personal care products, laundry detergents, and air fresheners. For more details of study populations, analytical methods and results see both studies here: Scherer et al, 2021: https://www.sciencedirect.com/science/article/pii/S0045653520331520) Murawski et al: https://www.sciencedirect.com/science/article/pii/S143846392030540X	Thank you for this valuable information. The information provided may indeed be relevant for additional regulatory risk management actions and should be considered further. The recent harmonised classification as Repr.1B will also lead to several downstream effects.
5475 2021/04/22	Emerald Kalama Chemical Limited, Company, United Kingdom	While Table 5 in Part II (p. 10/14) shows that there are no active intermediate registrations, as an active (Full) registrant of the substance, we are aware of intermediate uses by downstream users. In Section 9, Table 8 on uses (p. 11/14) under "Uses at Industrial Sites", these uses are clearly referenced in "Use at industrial site as a chemical intermediate". We would like to state that should this substance proceed on to a recommendation for inclusion in the Authorisation List (Annex XIV of REACH), these intermediate uses should be excluded from that recommendation.	Thank you for your comment and the information provided.
