

## 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.

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**Last data extracted on 25.05.2020**

**Substance name: cinnamaldehyde; 3-phenylprop-2-enal; cinnamic aldehyde; cinnamal [1] (2E)-3-phenylprop-2-enal [2]  
CAS number: 104-55-2 [1] 14371-10-9 [2]  
EC number: 203-213-9 [1] 604-377-8 [2]  
Dossier submitter: Denmark**

### GENERAL COMMENTS

Date	Country	Organisation	Type of Organisation	Comment number
19.05.2020	Belgium	International Fragrance Association	Industry or trade association	1

#### Comment received

IFRA strongly disagrees with the proposed specific concentration limit (SCL) of 0.02% instead of the generic concentration limit (GCL) for a strong sensitizer of 0.1%, in particular on the following subjects:

1. Use of risk based IFRA Standard levels to derive hazard thresholds
2. Assumption that all data indicate that cinnamic aldehyde is an extreme skin sensitizer.
3. Human diagnostic patch test data cannot be used to establish the SCL of 0.02%.

We would also like to note that, consumer exposure related information (labelling) under the scope of the CLP Regulation does exclude cosmetic products, which are solely covered by the Cosmetic Regulation and this exposure is the focus of the SCCS opinion. The consumer products affected by the CLP regulation are mainly household and detergent products, with a completely different exposure scenario compared to cosmetic products. It is therefore questionable to use the SCCS opinion and exposure information from cosmetic products as basis for conclusions on other product categories. Detailed comments are provided in the attachment.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment IFRA Comments Cinnamic aldehyde CLH final.pdf

Date	Country	Organisation	Type of Organisation	Comment number
13.05.2020	Germany		MemberState	2

#### Comment received

In section 1, table 1 the first CAS and EC number belong to the unspecific Cinnamaldehyde, whereas the second CAS and EC number belong only to the trans-isomer of Cinnamaldehyde. The EC number 604-377-8 is only a list number and should not be used. Furthermore, the cis-isomer has no big significance and we assume that it is not in the scope of this CLH dossier. This assumption is underlined by the substance name (2E)-3-phenylprop-2-enal. Nevertheless, we propose to make it more clear, if the

unspecific CAS and EC number indicate that also the cis-isomer is in the scope of the CLH dossier or not.

Date	Country	Organisation	Type of Organisation	Comment number
20.05.2020	France		MemberState	3
Comment received				
<p>Ecotoxicity - The report states that environmental hazards have not been assessed in this dossier. However, data from REACH registration dossier indicates endpoints values potentially leading to an environmental classification of the substance cinnamic aldehyde. FR CA is of the opinion that reasons for no environmental classification should be clearly explained.</p>				

#### **OTHER HAZARDS AND ENDPOINTS – Skin Sensitisation Hazard**

Date	Country	Organisation	Type of Organisation	Comment number
19.05.2020	Belgium	International Fragrance Association	Industry or trade association	4
Comment received				
<p>IFRA in general agrees with the overall conclusion of classifying Cinnamic aldehyde as SS1A, which is in line with already existing industry policy, without specifically endorsing all the rationale provided in the classification dossier.</p> <p>On the other hand, IFRA strongly disagrees with the proposed specific concentration limit (SCL) of 0.02% instead of the generic concentration limit (GCL) for a strong sensitizer of 0.1%</p> <p>ECHA note – An attachment was submitted with the comment above. Refer to public attachment IFRA Comments Cinnamic aldehyde CLH final.pdf</p>				

Date	Country	Organisation	Type of Organisation	Comment number
20.05.2020	Sweden		MemberState	5
Comment received				
<p>The Swedish CA agrees with the proposed classification of cinnamaldehyde as Skin Sens 1A, H317 based on evidence of skin sensitizing properties in animals as well as in humans, with evidence of strong to extreme potency from animal studies.</p> <p>The Swedish CA suggests reviewing the basis for the proposed SCL. For example, the IFRA standards for cinnamaldehyde, which was in part used as justification by the DS for the proposed specific classification limit of 0.02, have recently been amended (January 2020, amendment 49). The DS seems to refer to the IFRA Standards from 2013 (amendment 47). With amendment 49, maximum levels range from 0.014 to 1.8% in products with various degree of skin contact (0.15% in mouthwash).</p>				

Date	Country	Organisation	Type of Organisation	Comment number
13.05.2020	Germany		MemberState	6
Comment received				

The proposed classification of cinnamaldehyde for Skin Sens. 1A is supported. The classification is based on data from animal studies (22 LLNAs, 2 LLNA BrdU-ELISA tests, 2 ex vivo LLNA:BrdU-ELISA and 3 GPMTs) as well as human data (46 patch test studies, 2 human repeated open application tests, 14 human repeat insult patch tests, 2 human maximisation tests and 3 case studies). The data show that a classification as Skin Sens. 1A is justified and that cinnamaldehyde has a strong, borderline to extreme skin sensitisation potency based on the data from LLNA studies.

An SCL of 0.02 % is proposed. The SCL setting is based on calculated limits from the International Fragrance Association (IFRA) in various product types. However, the SCL setting based on uses is unusual. Furthermore, a new version of the IFRA standards (2020) point to lower calculated limits in some product types. Data from human repeated open application tests and patch test data (Bruze et al. 2003; Johansen et al., 1996) should rather be considered for SCL setting. The data show minimum effect levels of 0.002 % and 0.02 %, respectively. The human data would support the extreme skin sensitisation potency observed in two of the LLNA tests.

Date	Country	Organisation	Type of Organisation	Comment number
20.05.2020	France		MemberState	7
Comment received				
<p>The guideline and reliable animal and human studies available in the literature confirm the sensitising properties of cinnamic aldehyde. According to the CLP criteria, the results of these tests are directly applicable for classification and sub-categorisation of skin sensitisation.</p> <p>Based on the available animal studies (22 LLNAs and 3 GPMTs) there is clear evidence for classification in sub-category 1A. This result is supporting by the high frequencies of skin sensitisation observed in 46 human patch tests leading to consider the active substance as a strong skin sensitizer in sub-category 1A.</p> <p>Besides, considering the limits 0.02%-0.4% by which different exposures entails a risk of sensitization (IFRA data), an SCL of 0.02% of the cinnamic aldehyde can be set.</p> <p>To conclude, FR agrees with the proposal classification Skin Sens 1A, H317 and the specific concentration of 0.02% for the active substance cinnamic aldehyde.</p>				

#### PUBLIC ATTACHMENTS

1. IFRA Comments Cinnamic aldehyde CLH final.pdf [Please refer to comment No. 1, 4]