COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON E-glass fibres of representative composition

COMMENTS AND RESPONSE TO COMMENTS ON CLH: PROPOSAL AND JUSTIFICATION

Comments provided during public consultation are made available in this table as submitted by the webform. Please note that some attachments received may have been copied in the table below. The attachments received have been provided in full to the dossier submitter and RAC.

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

Substance name: E-glass fibres of representative composition
CAS number: -
EC number: -
Dossier submitter: France

GENERAL COMMENTS

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Comment received

Our comments are related to the substance name [E-glass fibres of representative composition], not to the proposed classification. Our comments were partly considered at the previous consultation.

However there are changes due in order to clearly define the scope and intent of this entry and thus avoid misunderstanding by users of “E-glass fibres”. Indeed E-glass is the composition of ‘E-glass Continuous Filament Glass Fibres’ as well as ‘E-glass microfibres’. Therefore it is proposed to have the following name adopted:

Substance name: E-glass microfibres of representative composition; [Calcium-aluminium-silicate fibres with random orientation with the following representative composition (% given by weight): SiO2 50.0- 56.0%, Al2O3 13.0-16.0%, B2O3 5.8-10.0%, Na2O <0.6%, K2O <0.4%, CaO 15.0-24.0%, MgO <5.5%, Fe2O3 <0.5%, F2 <1.0% with note R. Process: typically produced by flame attenuation and rotary process. (Additional individual elements may be present at low levels; the process list does not preclude innovation)].

Justification for change of substance name:
• “E-glass fibres” term is usually associated with Continuous Filament Glass Fibre (“CFGF”) products which are used as plastic reinforcement in the composite material supply chain.
• Indeed, E-glass is the common glass composition for CFGF products. E-glass Continuous filaments fibres annual worldwide production is ca. 3 million tons whereas E-glass microfibers are produced in the magnitude of one hundred tons per year.
• The on-going CLH report consultation is already triggering inquiries by CFGF users and customers, indicating that the proposed substance name is misleading. Even downstream trade associations that know our CFGF products for many years are mislead by the substance name and have expressed concerns regarding the classification of our products.
• As emphasised in the CLH report, the substance name needs to reflect the physical characteristics (length, diameter and aspect ratio) because this is the primary criteria for fibre hazard classification. Indeed the vast majority of E-glass fibre are not carcinogenic since not respirable. Therefore ‘microfibre’ in the substance name is needed to designate adequately and clearly which E-glass fibres category is covered by the hazard classification.
• The “Note R” included in the full description is not sufficient to bring clarity and understanding in the supply chain.
• The proposed change is consistent with the actual wording used in the CLH report to
COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON E-GLASS FIBRES OF REPRESENTATIVE COMPOSITION

distinguish between ‘E-glass microfibre’ and ‘E-glass Continuous Filament Glass Fibre’. Therefore it is only consistent to change the substance name accordingly.

Conclusion
We strongly advise to replace the name ‘E-glass fibres’ by ‘E-glass microfibres’ to ensure consistency between the substance name and the actual intend of the current CLH report and proposed hazard classification. This change will better serve the purpose of the CLH dossier and avoid unfounded and detrimental concerns related E-glass Continuous Filaments Glass Fibre products.

(ECHA note: The following attachment was provided [Attachment 1a])
Proposal for Harmonised Classification and Labelling Based on Regulation (EC) No 1272/2008 (CLP Regulation), Annex VI, Part 2

Dossier Submitter's Response

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Comment received

‘These comments are related to the substance name, but NOT to the proposed classification. Our comments were partly considered at the previous consultation. However there are changes due in order to clearly define the scope of this entry and thus avoid misunderstanding by users of “E-glass fibre” because E-glass is the composition of ‘E-glass Continuous Filament Glass Fibre’ as well as ‘E-glass micro fibre’ (see attached file).

(ECHA note: The following attachment was provided [Attachment 1b])
Proposal for Harmonised Classification and Labelling Based on Regulation (EC) No 1272/2008 (CLP Regulation), Annex VI, Part 2

Dossier Submitter's Response

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Comment received

These comments are related to the substance name, but NOT to the proposed classification. Our comments were partly considered at the previous consultation. However there are changes due in order to clearly define the scope of this entry and thus avoid misunderstanding by users of “E-glass fibre” because E-glass is the composition of ‘E-glass Continuous Filament Glass Fibre’ as well as ‘E-glass micro fibre. Therefore it is proposed to have the following name adopted:

Substance name: E-glass microfibres of representative composition; [Calcium-aluminium-silicate fibres with random orientation with the following representative composition (% given by weight): SiO2 50.0- 56.0%, Al2O3 13.0-16.0%, B2O3 5.8-10.0%, Na2O <0.6%, K2O <0.4%, CaO 15.0-24.0%, MgO <5.5%, Fe2O3 <0.5%, F2 <1.0% with note R. Process: typically produced by flame attenuation and rotary process. (Additional individual elements may be present at low levels; the process list does not preclude innovation).]

The change of substance name is needed because:
COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON E-glass fibres of representative composition

- E-glass fibre is usually associated with CFGF - Continuous Filament Glass Fibre - for the reason that CFGF production ranges in the magnitude of several million tons per year, whereas E-glass microfibre is produced in the magnitude of 100 tons per year.
- The on-going CLH report consultation triggered inquiries by CFGF users already, indicating that the proposed substance name is misleading. Even downstream trade associations that know our CFGF product for many years were misled by the substance name and expressed concerns regarding the classification of our product.
- As emphasised in the CLH report, the substance name need to reflect the physical characteristics (length, diameter and aspect ratio) because this is the primary criteria for fibre hazard classification. Indeed the vast majority of E-glass fibre are not carcinogenic since not respirable. Therefore ‘microfibre’ in the substance name is needed to indicate physical characteristics.
- The proposed change is consistent with the actual wording used in the CLH report to distinguish between ‘E-glass Continuous Filament Glass Fibre’ and ‘E-glass microfibre’. Therefore it is only consistent to change the substance name accordingly.

Therefore we strongly advise to replace the name ‘E-glass fibre’ by ‘E-glass microfiber’ to ensure consistency between the substance name and the actual intend of the current CLH report.

(ECHA note: The following attachment was provided [Attachment 1c])
Proposal for Harmonised Classification and Labelling Based on Regulation (EC) No 1272/2008 (CLP Regulation), Annex VI, Part 2

Dossier Submitter’s Response

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Comment received

The Swedish CA supports classification of E-glass fibres of representative composition; [Calcium-aluminium-silicate fibres with random orientation with the following representative composition (% given by weight): SiO2 50.0-56.0%, Al2O3 13.0-16.0%, B2O3 5.8-10.0%, Na2O <0.6%, K2O <0.4%, CaO 15.0-24.0%, MgO <5.5%, Fe2O3 <0.5%, F2 <1.0% with note R. Process: typically produced by flame attenuation and rotary process. (Additional individual elements may be present at low levels; the process list does not preclude innovation).] (CAS No. not assigned) as specified in the proposal. SE agrees with the rationale for classification into the proposed hazard class and differentiation.

We assume that the date of the CLH report indicated on the front page should be February 2014.

Dossier Submitter’s Response

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Comment received

‘These comments are related to the substance name, but NOT to the proposed
Comments and response to comments on CLH PROPOSAL on E-glass fibres of representative composition

classification. Our comments were partly considered at the previous consultation. However there are changes due in order to clearly define the scope of this entry and thus avoid misunderstanding by users of “E-glass fibre” because E-glass is the composition of ‘E-glass Continuous Filament Glass Fibre’ as well as ‘E-glass micro fibre’ (see attached file).

(ECHA note: The following attachment was provided [Attachment 1d])
Proposal for Harmonised Classification and Labelling Based on Regulation (EC) No 1272/2008 (CLP Regulation), Annex VI, Part 2

Dossier Submitter’s Response

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Comment received
DE CA supports the French proposal to classify ‘E-glass fibres of representative composition’ as possibly carcinogenic to humans. The proposal of assignment of the note R is also supported. However some misrepresentations and inconsistencies in the French CLH report should be corrected.

Dossier Submitter’s Response

Date Country Organisation Type of Organisation Comment number
16.04.2014 Germany Johns Manville Europe GmbH Company-Manufacturer 7

Comment received
In 2013 we submitted comments related to the name of the substance. Although some of our comments have been considered and the name of the substance adapted, there is still a lot of potential for confusion. Therefore we suggest renaming the substance as follows: E-glass **microfibres** of representative composition; [Calcium-aluminium-silicate fibres with random orientation with the following representative composition (% given by weight): SiO2 50.0-56.0%, Al2O3 13.0-16.0%, B2O3 5.8-10.0%, Na2O <0.6%, K2O <0.4%, CaO 15.0-24.0%, MgO <5.5%, Fe2O3 <0.5%, F2 <1.0% with note R. Process: typically produced by flame attenuation and rotary process. (Additional individual elements may be present at low levels; the process list does not preclude innovation).

We only ask to add the word "microfibre" to the name in order to avoid any confusion with the Continuous Filament Glass Fibres, which are not respirable and therefore not covered by this dossier.

We support the request of our Association GlassFibreEurope and add their comment with the rationale as an attachment. Also we attach our comments from April 2013 which contains a detailed rationale for our request.

(ECHA note: The following attachment was provided [Attachment 1e and 2])
Proposal for Harmonised Classification and Labelling Based on Regulation (EC) No 1272/2008 (CLP Regulation), Annex VI, Part 2

Dossier Submitter’s Response

Date Country Organisation Type of Organisation Comment

4(7)
COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON E-Glass fibres of representative composition

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Comment received
These comments are related to the substance name, but not to the proposed classification. Our comments were partly considered at the last consultation. However there are changes due in order to clearly define the scope of this entry and thus avoid misunderstanding by users of “E-glass fibre” because E-glass is the composition of ‘E-glass Continuous Filament Glass Fibre’ as well as ‘E-glass micro fibre’ (see attached file).

(ECHA note: The following attachment was provided [Attachment 1f])
Proposal for Harmonised Classification and Labelling Based on Regulation (EC) No 1272/2008 (CLP Regulation), Annex VI, Part 2

Dossier Submitter’s Response

CARCINOGENICITY

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Comment received
The Swedish CA agrees that there is sufficient evidence from studies in several species of animals for concluding that E-glass fibres of representative composition (CAS No. not assigned) induce benign and malignant lung tumours and abdominal tumours by different routes of exposure (inhalation, intraperitoneal, intratracheal and intrapleural). Furthermore, in animals exposed to E-glass fibres by inhalation, effects which may indicate a progressive pathway to neoplastic transformation of respiratory cells (marked macrophage reaction, alveolar fibrosis and hyperplasia) were observed. A study in rats showed that the frequency of animals with abdominal tumours following intraperitoneal exposure to E-glass fibres and type “475” glass fibres was 32% and 4%, respectively, suggesting that the carcinogenic potential of two types of fibres is different. The available data warrants classification in Carc. 1B; H350i.

The Swedish CA agrees that a new specific entry is required for E-glass fibres (of special-purpose type), since, in Annex VI of CLP, the entry for fibres with a harmonised classification is man-made vitreous fibres (MMVF) subdivided into the two different entries with index number 650-016-00-2 and 650-017-00-8, referring to mineral wool (classification Carc. 2; H351) and refractory ceramic fibres/special purpose fibres (classification Carc. 1B; H350i), respectively. Neither of these entries is appropriate for E-glass fibres; with respect to “special purpose fibres”, the entry for E-glass fibres would be refractory ceramic fibres with the classification Carc. 1B; H350i and, with respect to the content of alkaline oxide and alkaline earth oxide specified for the two entries, the entry for E-glass fibres would be mineral wool with the classification Carc.2; H351. Accordingly, a new specific entry is required for E-glass fibres (of special-purpose type). The proposed classification for E-glass fibres is Carc. 1B; H350i.

The Swedish CA agrees with the naming and notes of the proposed new specific entry for E-glass fibres.


**COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON E-Glass Fibres of Representative Composition**

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‘E-glass fibres of representative composition’ show a carcinogenic potential in rats exposed by inhalation and by intra-peritoneal injection. Marked fibrosis and lung tumours were observed in rats after repeated exposure by inhalation for one year. Rats received a single intra-peritoneal injection of ‘E-glass fibres of representative composition’ developed an increased incidence of mesothelioma.

The available epidemiological data do not demonstrate sufficient evidence of carcinogenicity in human. In comparison to the given criteria for the CLP Regulation these ‘E-glass fibres of representative composition’ fulfil the criteria for a category 1B carcinogen with the hazard statement H350.

However the proposed route-specific classification for inhalation (H350i) needs a prominent statement. According to the CLP criteria a route could only be stated if proven that no other route of exposure exhibits the hazard.

Further the following misrepresentations and inconsistencies in the CLH report should be corrected:

In section 2.2, p11 it is noted that the key information for the proposal to classify ‘E-glass fibres of representative composition’ as Carc. 1B (H350i) is based on Searl et al. (1999) and Cullen et al. (2000) studies. However information from the Searl et al. (1999) study is not described in the CLH report.

In section 4.10.5, p28 it is noted that experimental data for the ‘E-glass fibres of representative composition’ have shown a clear carcinogenic effect in several species (rats, hamsters and monkeys). But data from monkeys are not described in the CLH report.

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We acknowledge that E-glass fibres cause tumours in rats as observed in Cullen study.

In order to support the classification, we would recommend the DS to substantiate its proposal by detailing the findings/the studies.

According to the guidance, Carcinogen category 1B where classification is largely based on animal evidence ... defined as a causal relationship has been established between the agent and an increased incidence of malignant neoplasms or of an appropriate combination of benign and malignant neoplasms in (a) two or more species of animals or (b) two or more independent studies in one species carried out at different times or in different laboratories or under different protocols (sufficient evidence)

The DS is proposing Carc. Cat 1B H350i ; May cause cancer by inhalation. This classification
COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON E-GLASS FIBRES OF REPRESENTATIVE COMPOSITION

Is based only on one study in one species. The DS is advised to complete its proposal in order to fulfill the criteria for Cat. 1B.

For example, the Cullen (2000) study indicates marked macrophage reaction, thickening of adjacent alveolar walls and localized but market fibrosis at the end of the 12-month exposure. However, there is no information on the number of animals presenting those effects nor if these are the same animals presenting the pulmonary tumours after the 12 months of recovery.

We recommend the DS to consider the repeated dose toxicity studies via inhalation route and specially to complete the data (number of animals affected) For example, Bellemann study (2003) indicates histological findings in a dose dependent manner (however no information on the animals) like bronchioalveolar hyperplasia which can contribute to the Weight of Evidence for carcinogenic potential.

We notice on page 28 that the DS refers to carcinogenic effects observed in monkeys however there is no study on monkeys in the proposal.

Dossier Submitter’s Response

Attachments:

1) Proposal for Harmonised Classification and Labelling Based on Regulation (EC) No 1272/2008 (CLP Regulation), Annex VI, Part 2, submitted by:
   a- European Owens Corning Fiberglas SPRL on 18/04/2014 [file name: OC Comments to CLH consultation.pdf] [please refer to comment 1]
   b- PPG Industries Fiber Glass EMEA on 18/04/2014 [file name: 14-40-E-glass fibres of representative composition.pdf] [please refer to comment 2],
   c- Saint-Gobain ADFORS on 10/04/2014 [file name: Comments Substance Name E-glass fibres.pdf] [please refer to comment 3]
   d- P-D Glasseiden GmbH Oschatz on 11/04/2014 [file name: 2014-04-10_Comments to Proposal HCL E-glass Microfibers_P-D GSO_attachment.pdf] [please refer to comment 5]
   e- Johns Manville Europe GmbH on 16/04/2014 [file name: 2014 03 24 CLH Comments.pdf] [please refer to comment 7]
   f- GlassFibreEurope on 25/03/2014 [file name: 2014 03 24 CLH Comments.pdf] [please refer to comment 8]

2) Comments to the Harmonised classification and labelling proposal from France submitted by Johns Manville Europe GmbH on 16/04/2014 [file name: Comment_JohnsManville_e_glass_20130416.pdf] [please refer to comment 7]