



**Committee for Risk Assessment
RAC**

Annex 2
Response to comments document (RCOM)
to the Opinion proposing harmonised classification and
labelling at EU level of
Glass microfibres of representative composition

**EC number: -
CAS number: -**

CLH-O-0000001412-86-35/F

Adopted

04 December 2014

COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON GLASS FIBRES OF REPRESENTATIVE COMPOSITION

COMMENTS AND RESPONSE TO COMMENTS ON CLH: PROPOSAL AND JUSTIFICATION

Comments provided during public consultation are made available in the table below as submitted through the web form. Any attachments received are referred to in this table and listed underneath, or have been copied directly into the table.

All attachments including confidential documents received during the public consultation have been provided in full to the dossier submitter, to RAC members and to the Commission (after adoption of the RAC opinion). Non-confidential attachments that have not been copied into the table directly are published after the public consultation and are also published together with the opinion (after adoption) on ECHA's website.

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Substance name: glass microfibres of representative composition

CAS number: -

EC number: -

Dossier submitter: France

GENERAL COMMENTS

Date	Country	Organisation	Type of Organisation	Comment number
14.04.2014	Sweden		MemberState	1
Comment received				
<p>The Swedish CA supports classification of glass fibres of representative composition [Calcium-aluminium-silicate fibres with random orientation with the following composition (% given by weight): SiO₂ 55.0-60.0%, Al₂O₃ 4.0-7.0%, B₂O₃ 8.0-11.0%, ZrO₂ 0.0-4.0%, Na₂O 9.5-13.5%, K₂O 0.0-4.0%, CaO 1.0-5.0%, MgO 0.0-2.0%, Fe₂O₃ <0.2%, ZnO 2.0-5.0%, BaO 3.0-6.0%, 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.</p> <p>In paragraph 2 of Section 2.2 Short summary of the scientific justification for the CLH proposal it is stated that "Tumours consist in both benign and malignant lung tumours (carcinomas, mesotheliomas and sarcomas) and abdominal tumours by different routes of exposure (inhalation, intraperitoneal, intratracheal and intrapleural)". The statement of "inhalation" is not consistent with the information given in paragraph 3 of the same section and in paragraph 4 of Section 4.9.5 Comparison with CLP criteria, i.e. No study clearly demonstrates the induction of tumour following inhalation of glass fibres of '475' type.</p>				
Dossier Submitter's Response				
<p>Thank you for your support. Indeed, the statement of "inhalation" should be deleted from the paragraph 2 of section 2.2.</p>				
RAC's response				
<p>Your support for classification of glass fibres of representative composition as Carc. 2, H351 has been noted. The word "inhalation" has been removed from the indicated sentence in section 2.2.</p>				

Date	Country	Organisation	Type of Organisation	Comment
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				number
16.04.2014	Germany		MemberState	2
Comment received				
DE CA supports the French proposal to classify 'glass fibres of representative composition' (which includes type '475' and other special purpose glass fibres) as a suspected human carcinogen. The proposal of assignment of the note R is also supported.				
Dossier Submitter's Response				
Thank you for your support.				
RAC's response				
RAC also supports that proposal				

Date	Country	Organisation	Type of Organisation	Comment number
16.04.2014	Germany	Johns Manville Europe GmbH	Company-Manufacturer	3
Comment received				
<p>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: glass **microfibers** of representative composition; [Calcium-aluminium-silicate fibres with random orientation with the following composition (% given by weight): SiO₂ 55.0-60.0%, Al₂O₃ 4.0-7.0%, B₂O₃ 8.0-11.0%, ZrO₂ 0.0-4.0%, Na₂O 9.5-13.5%, K₂O 0.0-4.0%, CaO 1.0-5.0%, MgO 0.0-2.0%, Fe₂O₃ <0.2%, ZnO 2.0-5.0%, BaO 3.0-6.0%, 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).</p> <p>We suggest changing the word "fibre" to "microfiber" in the name in order to avoid any confusion with the textile glass fibres and other Continuous Filament Glass Fibres, (CFGF) which are not respirable and therefore not covered by this dossier.</p>				
Dossier Submitter's Response				
<p>We appreciate the concerns that glass fibres is widely used as both continuous filaments and non-continuous fibers and microfibers. Filaments are not covered by the current proposal as is clear with both the method of manufacture (flame attenuation) and note R. However, because the proposed entry in Annex VI of CLP Regulation specific for microfibers, for clarity in terms of scope, we agree that it is to be included in the name.</p> <p>The revised name would then be: glass microfibers of representative composition; [Calcium-aluminium-silicate fibres with random orientation with the following composition (% given by weight): SiO₂ 55.0-60.0%, Al₂O₃ 4.0-7.0%, B₂O₃ 8.0-11.0%, ZrO₂ 0.0-4.0%, Na₂O 9.5-13.5%, K₂O 0.0-4.0%, CaO 1.0-5.0%, MgO 0.0-2.0%, Fe₂O₃ <0.2%, ZnO 2.0-5.0%, BaO 3.0-6.0%, 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).</p>				
RAC's response				
<p>RAC has adopted this proposal for rephrasing the name of the substance as:</p> <ul style="list-style-type: none"> - glass microfibres of representative composition; [Calcium-aluminium-silicate fibres with random orientation with the following composition (% given by weight): SiO₂ 55.0-60.0%, Al₂O₃ 4.0-7.0%, B₂O₃ 8.0-11.0%, ZrO₂ 0.0-4.0%, Na₂O 9.5-13.5%, K₂O 0.0-4.0%, CaO 1.0-5.0%, MgO 0.0-2.0%, Fe₂O₃ <0.2%, ZnO 2.0-5.0%, BaO 3.0-6.0%, F₂ <1.0% with note R. Process: typically produced by flame attenuation 				

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and rotary process. (Additional individual elements may be present at low levels; the process list does not preclude innovation).]

Date	Country	Organisation	Type of Organisation	Comment number
22.04.2014	Germany	Lauscha Fiber International GmbH	Company-Manufacturer	4

Comment received

The Substance Information Exchange Forum for which Lauscha Fiber International GmbH is the lead registrant agrees with the classification proposal. It confirms the existing classification already included in Annex VI (Index Number 650-016-00-2), and conforms to the decision previously taken by the Classification and Labelling group in 2007. At that time, type 475-glass special purpose fibres, referred to as "glass fibres of representative composition" in this amended and resubmitted proposal, were clearly differentiated from E-glass special purpose fibres in terms of the scientific basis and the effective classification.

The authors reference Cullen et al. 2000 and Bernstein 2007 in the report, but do not include these references in section "4.9.1.2 Carcinogenicity: inhalation". We consider these to be the most important inhalation toxicology studies on special purpose fibres, offering clear support for the classification differentiation between E-glass and 475-type special purpose fibres.

We recommend that the Committee give them particular weight in their deliberations and include them in section 4.9.1.2 Carcinogenicity: inhalation.

[Cullen RT et al. Pathogenicity of a special-purpose glass microfibre (E glass) relative to another glass microfibre and amosite asbestos. Inhal Toxicol. 2000]

[Bernstein D.M. Special-Purpose Fiber Type 475-Toxicological Assessment. Inhalation Toxicology 2007; 19:149-159.]

Dossier Submitter's Response

Your comment is noted. We agree with you concerning the inclusion of the Cullen et al (2000) and Berstein et al (2007) studies in the section "4.9.1.2 Carcinogenicity by inhalation" of the CLH report of the "glass fibers of representative composition". These key studies are in support of the classification in category 2 for carcinogenicity for 475-fibres by comparison with E-glass fibers. Besides, the study of Cullen (2000) has been taken into account in the lead registration dossier.

The same table below of the Cullen study from the E-glass CLH report should be added.

Species	Fibre: type E and 475	Conc.			Expo. Time (h/day)	Duration	Observations and Remarks	Ref.
		Total	WHO	L>20 µm				
AH/HAN rats (n=43)	104E (E) 100/475 (475)	-	1022 f/cm ³	≈ 72 f/cm ³	7h/d 5d/wk whole-	12 months + 12 months recovery	<ul style="list-style-type: none"> Clearance half-time: 7.1 months Marked macrophage reaction, thickening of adjacent alveolar walls, and localized but marked fibrosis at the end of the 12-month exposure. Wagner grade = 4. 	Cullen 2000

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					body	or lifetime obs.	<ul style="list-style-type: none"> • After 12 additional months of recovery, advanced alveolar fibrosis and bronchoalveolar hyperplasia had developed. • 10/43 rats (23.2%) developed pulmonary tumours (7 carcinomas and 3 adenomas, p=0.02) and 2 had a mesothelioma (4.7%). 	
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RAC's response

Summaries of Cullen et al (2000) and Bernstein et al (2007) studies have been incorporated in the section "4.9.1.2 Carcinogenicity by inhalation" and in the Opinion.

CARCINOGENICITY

Date	Country	Organisation	Type of Organisation	Comment number
14.04.2014	Sweden		MemberState	5

Comment received

The Swedish CA agrees that there is sufficient evidence from several studies in rats that type '475' glass fibres of representative composition (CAS No. not assigned) induce malignant abdominal tumours following intraperitoneal exposure, and that there are no studies demonstrating the induction of tumours following inhalation of such glass fibres.

Furthermore, in animals exposed to type '475' fibres by inhalation, effects which may indicate a progressive pathway to neoplastic transformation of respiratory cells (marked macrophage reaction, alveolar fibrosis and hyperplasia) were not observed.

A study in rats showed that the frequency of animals with abdominal tumours following intraperitoneal exposure to type "475" glass fibres and E-glass fibres was 4% and 32%, respectively, suggesting that the carcinogenic potential of two types of fibres is different. The available data warrants classification in Carc. 2; H351.

The Swedish CA agrees that a new specific entry is required for type '475' fibres (a special purpose type of fibres), 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 type '475' fibres; with respect to "special purpose fibres", the entry for type '475' 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 type '475' fibres would be mineral wool with the classification Carc.2; H351. Accordingly, a new specific entry is required for type '475' fibres. The proposed classification for type '475' fibres is Carc. Carc. 2; H351.

The Swedish CA agrees with the naming and notes of the proposed new specific entry for type '475'fibres.

Dossier Submitter's Response

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Thank you for your support.
RAC's response
RAC agrees with the Swedish CA proposals on classification and requirement of a new specific entry for glass microfibres of indicated representative composition

Date	Country	Organisation	Type of Organisation	Comment number
16.04.2014	Germany		MemberState	6

Comment received
The carcinogenic potential of these 'glass fibres of representative composition' has been studied in three species (rats, hamster and monkeys) under different protocols. There is limited evidence of carcinogenicity in experimental animals. The available epidemiological data do not demonstrate sufficient evidence of carcinogenicity in human. In comparison to the given criteria for the CLP Regulation these 'glass fibres of representative composition' fulfil the criteria for a category 2 carcinogen with the hazard statement H351.

Dossier Submitter's Response
Thank you for your support.
RAC's response
RAC agrees with the German CA proposal on classification of glass microfibres of indicated representative composition