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 the comments displayed below may have been accompanied by attachments which are not published in this table.

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

Substance name: Special purpose 475-glass fibres
CAS number: -
EC number: -

GENERAL COMMENTS

Date	Country	Organisation	Type of Organisation	Comment number
19.04.2013	Germany		Company-Manufacturer	1
Comment received				
We suggest changing the name of the substance to: Special purpose glass filtration fibres [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%, Na2O 9.5-13.5%, K2O 1.0-4.0%, 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: rotary fiberisation or flame attenuation. Instead of: Special purpose 475-glass fibres [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%, Na2O 9.5-13.5%, K2O 1.0-4.0%, 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: drawing or spinning the molten mix (at approx. 1500°C) from nozzles] Rationale: 475 is a proprietary name of Johns Manville for a type of glass formulation. See further details and information in the attached letter and publication. Page 9: the authors of the dossier mention that since 2006 no new relevant studies of toxicology of special purpose fibres have been published. We would like to point you attention to the publication of Bernstein D.M (2007), which we attach to this comment file. Page 9: The authors of the dossier claim that "there is no registration dossier on 475 glass fibres". This is not correct. The 475 glass fibres have been registered under EC no. 924-055-3 in 2010. Page 10: the authors of the dossier wrote: "To our knowledge, 475-glass may also be used in other type of glass fibres than special purpose fibres, such as for example continuous filaments, which have larger diameters (6 to 16 µm, CIRC 2002). Therefore, an appropriate way to identify the entries could be to specify both composition and size and to limit the entries to respirable fibres with a diameter inferior to 6 µm as specified in the note R." Continuous Filament Glass fibres are manufactured by the "drawing process". This process delivers filaments which have a precisely controlled nominal filament diameter with a narrow range of variation, obtained by a tight control of glass viscosity and a precise regulation of the linear drawing speed (Ref.: IARC Monograph Volume 81, Page 70). Continuous Filament Glass Fibres are of parallel orientation as opposed to fibres of random orientation obtained by rotary spinning or flame attenuation process. Their lowest possible diameter is limited by the fact that the glass filament will break if there are impurities in the glass creating inhomogeneity or viscosity variations and the drawing process is interrupted. When they are chopped or crushed, glass filaments keep their original "non respirable" filament diameter as the fracture plane is essentially perpendicular to their longitudinal axis. In conclusion we would like to make sure that the reference to Continuous Filament Glass Fibres is removed from this dossier and not brought into relation with the note R exemption.				

See attached letter and publication for details and more information.

ECHA note: the documents joined as attachement will be provided as separate files.

Date	Country	Organisation	Type of Organisation	Comment number
18.04.2013	Germany		Company-Manufacturer	2
Comment received				
It is recommended to indicate in the study reports whether no information is available on the concentration of fibres above 20 µm length and on concentration of WHO fibres or whether no fibres were above this length. The horizontal bar does not allow a clear interpretation.				

Date	Country	Organisation	Type of Organisation	Comment number
18.04.2013	Germany	Lauscha Fiber International GmbH	BehalfOfAnOrganisation	3
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 were clearly differentiated from E-glass special purpose fibres in terms of the scientific basis and the effective classification. In support of the proposed differentiation between 475-glass fibres and E-glass fibres we recommend that the Committee for Risk Assessment also consider the scientific publication Special-Purpose Fiber Type 475 – Toxicological Assessment, D.M. Bernstein, 2000, Inhalation Toxicology. The authors reference Cullen et al. 2000 in section 2.2 "Short summary of the scientific justification for the CLH proposal", however, it has not been included in section "4.9.1.2 Carcinogenicity: inhalation". We consider this to be the most important inhalation toxicology study on 475 glass and recommend that the Committee give it particular weight in their deliberations and include it 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]				

CARCINOGENICITY

Date	Country	Organisation	Type of Organisation	Comment number
18.04.2013	Germany		MemberState	4
Comment received				
p. 37 Due to estimated weighted half-lifes for fibres longer than 20 µm at concentrations of ≥100 fibres/cm³ it seems plausible not to apply the Nota Q. A reasoning why Nota Q (in the text passages in 4.9.4 and 4.9.6.)is helpful for transparency. p. 37 4.9.4 Summary and discussion of carcinogenicity The positive in-vitro mutagenicity studies indicating polyploidy should be discussed in the weight of evidence consideration on carcinogenicity. p. 38 4.9.5 Comparison with criteria It is said that no study clearly demonstrates the induction of tumour following inhalation of				

475-glass fibres.
It is correct that in the study of Cullen 1997 (which might be identical to those reported in Cullen, 2000) only benign lung adenomas were reported (in 4/38 rats). A clarification in the text may be considered.
The study design was limited as less than 100 fibres/cm³ > 20 µm length as recommended in the EU testing protocols[1] were tested (only 38 fibers/cm³ were longer than 20 µm). A higher tumour response or a malignant tumour response could not be excluded if adequate numbers of fibers/cm³ were tested.

It can not be concluded that the criteria for limited evidence of carcinogenicity c) the agent increases the incidence only of benign neoplasms or lesions of uncertain neoplastic potential is fulfilled, as malignant tumours (mesotheliomas, sarcomas and lung carcinomas) were observed in a number of intraperitoneal studies which are considered as predictive for the carcinogenic potential in humans.

It was concluded that the carcinogenic potential of 475-glass fibres was lower than for E-glass fibres which is classified as 1B based on the tumour incidences of studies with intraperitoneal applications. Differences in potency are not a clear cut argument to support Cat 2 for 475 fibres according to the CLP criteria.
Although Cat. 3, R40 has been concluded in 2006 following the DSD criteria, the appropriateness of translation into Cat 2 according to CLP needs scrutiny.

p. 39
Nota R refers to fibre diameters of 6 µm instead of 3 µm.

[1] http://tsar.jrc.ec.europa.eu/documents/Testing-Methods/mmmfweb.pdf

Date	Country	Organisation	Type of Organisation	Comment number
19.04.2013	Sweden		MemberState	5
Comment received				
SE supports classification of 475-glass special purpose fibers as specified in the proposal. SE agrees with the rationale for classification into the proposed hazard class.				

Attachment:

1. **Special-Purpose Fiber Type 475—Toxicological Assessment** submitted by Company-Manufacturer from Germany on 19/04/2013

Confidential Attachment:

1. **Comments to the Harmonised classification and labelling of France – substance n ame: Special purpose 475-glass fibers**, submitted by Company-Manufacturer from Germany on 19/04/2013