

CLH report

Proposal for Harmonised Classification and Labelling

**Based on Regulation (EC) No 1272/2008 (CLP Regulation),
Annex VI, Part 2**

**Substance Name: 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).]**

EC Number: Not assigned

CAS Number: Not assigned

Index Number: Not assigned

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Part A.

1 PROPOSAL FOR HARMONISED CLASSIFICATION AND LABELLING

1.1 Substance

Table 1: Substance identity

Substance name:	E-glass fibres of representative composition; [Calcium-aluminium-silicate fibres with random orientation with the following representative composition (% given by weight): SiO ₂ 50.0-56.0%, Al ₂ O ₃ 13.0-16.0%, B ₂ O ₃ 5.8-10.0%, Na ₂ O <0.6%, K ₂ O <0.4%, CaO 15.0-24.0%, MgO <5.5%, Fe ₂ O ₃ <0.5%, F ₂ <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).]
EC number:	-
CAS number:	-
Annex VI Index number:	¹
Degree of purity:	100%
Impurities:	N/A for UVCB substance

1.2 Harmonised classification and labelling proposal

Table 2: The current Annex VI entry and the proposed harmonised classification

	CLP Regulation
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¹Index numbers 650-016-00-2 and 650-017-00-8 in Annex VI of CLP are not applicable

Current entry in Annex VI, CLP Regulation	
Current proposal for consideration by RAC	Carc. 1B – H350i (with note R)
Resulting harmonised classification (future entry in Annex VI, CLP Regulation)	Carc. 1B – H350i (with note R)

* The text of the notes is given in section 2.1 of the CLH report.

1.3 Proposed harmonised classification and labelling based on CLP Regulation

Table 3: Proposed classification according to the CLP Regulation

CLP Annex I ref	Hazard class	Proposed classification	Proposed SCLs and/or M-factors	Current classification ¹⁾	Reason for no classification ²⁾
2.1.	Explosives	None		None	Not evaluated
2.2.	Flammable gases	None		None	Not evaluated
2.3.	Flammable aerosols	None		None	Not evaluated
2.4.	Oxidising gases	None		None	Not evaluated
2.5.	Gases under pressure	None		None	Not evaluated
2.6.	Flammable liquids	None		None	Not evaluated
2.7.	Flammable solids	None		None	Not evaluated
2.8.	Self-reactive substances and mixtures	None		None	Not evaluated
2.9.	Pyrophoric liquids	None		None	Not evaluated
2.10.	Pyrophoric solids	None		None	Not evaluated
2.11.	Self-heating substances and mixtures	None		None	Not evaluated
2.12.	Substances and mixtures which in contact with water emit flammable gases	None		None	Not evaluated
2.13.	Oxidising liquids	None		None	Not evaluated
2.14.	Oxidising solids	None		None	Not evaluated
2.15.	Organic peroxides	None		None	Not evaluated
2.16.	Substance and mixtures corrosive to metals	None		None	Not evaluated
3.1.	Acute toxicity - oral	None		None	Not evaluated
	Acute toxicity - dermal	None		None	Not evaluated
	Acute toxicity - inhalation	None		None	Not evaluated
3.2.	Skin corrosion / irritation	None		None	Not evaluated
3.3.	Serious eye damage / eye irritation	None		None	Not evaluated
3.4.	Respiratory sensitisation	None		None	Not evaluated
3.4.	Skin sensitisation	None		None	Not evaluated
3.5.	Germ cell mutagenicity	None		None	Not evaluated
3.6.	Carcinogenicity	Carc. 1B – H350i		Carc. 1B – H350i	
3.7.	Reproductive toxicity	None		None	Not evaluated
3.8.	Specific target organ toxicity –single exposure	None		None	Not evaluated

3.9.	Specific target organ toxicity – repeated exposure	None		None	Not evaluated
3.10.	Aspiration hazard	None		None	Not evaluated
4.1.	Hazardous to the aquatic environment	None		None	Not evaluated
5.1.	Hazardous to the ozone layer	None		None	Not evaluated

¹⁾ Including specific concentration limits (SCLs) and M-factors

²⁾ Data lacking, inconclusive, or conclusive but not sufficient for classification

Labelling: Signal word: “Danger”
 Hazard statements: H350i
 Precautionary statements: not harmonised
 Pictogram: SGH08

Proposed notes assigned to an entry: Note R; the text of the note is detailed in section 2.1 of the CLH report.

2 BACKGROUND TO THE CLH PROPOSAL

2.1 History of the previous classification and labelling

In annex VI of Regulation 1272/2008 (CLP), fibres with a harmonised classification are man-made vitreous fibres (MMVF) which are subdivided in two different entries (see table below). The two entries 650-016-00-2 and 650-017-00-8 in CLP refer to “mineral wool” and “refractory ceramic fibres” (RCFs) respectively. These entries are differentiated by name and the chemical composition with respect to the content of alkali/alkali earth metal oxides with 18 % being the cut-off point. Their hazardous properties and harmonised classifications (C&L) also vary from ‘suspected carcinogen to humans’ (Carc. 2, entry 650-016-00-2) to ‘presumed to have carcinogenic potential for humans’ (Carc. 1B, entry 650-017-00-8).

Although “special purpose fibres” are explicitly mentioned in the phrasing of the current Refractory Ceramic Fibres entry (index number 650-017-00-8), the appropriate entry for E-glass fibres regarding the alkaline oxide and alkaline earth oxide content (K_{NB} index) should be for “Mineral wool”. However, E-glass fibres are proposed to be classified as Carc. 1B – H350i and the classification assigned to the entry with index number 650-016-00-2 is therefore not appropriate (Carc. 2 – H351). These discrepancies of the appropriate entry for E-glass fibres requires a new specific entry.

Index number	Substance Name	Classification	Nota
650-016-00-2	Mineral wool, with the exception of those specified elsewhere in this Annex; [Man-made vitreous (silicate) fibres with random orientation with alkaline oxide and alkali earth oxide ($Na_2O+K_2O+CaO+MgO+BaO$) content greater than 18 % by weight]	Carc. 2 – H351	A, Q, R
650-017-00-8	Refractory Ceramic Fibres; Special Purpose Fibres , with the exception of those specified elsewhere in this Annex; [Man-made vitreous (silicate) fibres with random orientation with alkaline oxide and alkali earth oxide ($Na_2O+K_2O+CaO+MgO+BaO$) content less or equal to 18 % by weight]	Carc. 1B – H350i	A, R

In its evaluation, IARC (2002) concluded that there is sufficient evidence in experimental animals for special-purpose glass fibres including E-glass and ‘475’ glass fibres and classified them together as possibly carcinogenic to humans (group 2B). In addition, IARC reported that current average exposure levels to MMVF are generally less than 0.5 respirable fibre/cm³ (500 000 respirable fibres/m³) as an 8-h time-weighted average but that higher levels have been measured in production of special-purpose glass fibres, increasing the concern for workers.

In November 2005, a French proposal was submitted at the TC C&L for a classification of special purpose fibres E and 475 as Carc. Cat.2; R45 (Carc. 1B under CLP). However, in October 2006, the

TC C&L agreed to classify 'E-glass fibres' with Carc. Cat. 2; R49 (currently Carc. 1B under CLP) (Follow-up III of TC C&L October 2006; doc ECBI/09/07). Indeed, largely based on animal evidence, E-glass fibres are presumed to have carcinogenic potential for humans. TC C&L discussions (2005, 2006) are added in annex of this dossier. This decision was however not included in an ATP before the entry into force of CLP (2008).

In March 2013, a French proposal for classification was submitted on 'E-glass special purpose fibres' to ECHA followed by a public consultation (PC) from 5 March 2013 until 19 April 2013. During PC, a number of issues were raised by a manufacturer including the incorrect composition and manufacturing process, the confusion in the name between continuous filament glass fibres (not 'respirable') and microfibers ('respirable'). In addition, the manufacturer proposed an alternative name for the substance. In January 2014, the French proposal on 'special purpose E-glass fibres' was withdrawn. The name of the fibres under the CLH proposal has been revised in the present proposal to clarify the scope of the proposal and of the future entry in Annex VI of CLP.

Since TC C&L discussions (2006), there were no new relevant studies of toxicology published on E-fibres with the exception of a review by Bernstein (2007). There is a joint REACH registration dossier on E-glass fibres (E-glass microfibers) which has been taken into account for the completion of this CLH report (registration number 01-2119488048-29-00XX). The registered classification for E-glass microfibres is Carc. 1B – H350i,

In this proposal for harmonised classification, E-glass fibres are proposed to be classified as Carc. 1B – H350i.

Justification for the proposal of a new specific entry:

For the reasons described above, it is therefore proposed to clarify the scope of the original entry to cover E-glass fibres. These fibres are characterized by their chemical composition and physical characteristics (i.e length, diameter and aspect ratio). They are manufactured as continuous filaments, as general purpose insulation fibres with diameters ranging from ca. 5-15 µm and as special purpose fibres of smaller diameters ca. 1-5 microns. It is acknowledged that the meaning of 'special purpose' in this context implies that the fibres are used in applications where a small fibre diameter is required unlike general purpose insulation fibres.

The proposed new entry only refers to E-glass fibres that are respirable. Filaments and non-respirable fibres are not covered by this entry. Note R is therefore included to capture the physical characteristics of the fibres relevant for this classification proposal.

The following naming of the new specific entry is proposed:

'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)].'

Proposal of notes:

The notes A and Q are not proposed for the specific entry of E-glass fibres.

Note A applies in order to give the exact name of the substance on the label and not the name of the entry in the cases of generic entries. The new entry proposed is not a generic entry and note A is therefore not relevant.

Note Q applies for the general entry for fibres (index 650-016-00-2) to be able to distinguish fibres that are of less concern and should be exempted from the carcinogenic classification. The available data as shown in this dossier demonstrate the carcinogenic potential of these fibres and it is not relevant to include exemption conditions.

The note R is proposed for this new specific entry. The note R applies for the fibres with a length weighted geometric mean diameter inferior to 6 µm.

Text of notes (CLP Regulation):

A: Without prejudice to Article 17(2), the name of the substance must appear on the label in the form of one of the designations given in Part 3. In Part 3, use is sometimes made of a general description such as "... compounds" or "... salts". In this case, the supplier is required to state on the label the correct name, due account being taken of section 1.1.1.4.

Q: The classification as a carcinogen need not to apply if it can be shown that the substance fulfils one of the following conditions:

- a short term biopersistence test by inhalation has shown that the fibres longer than 20 µm have a weighted half-life less than 10 days; or
- a short term biopersistence test by intratracheal instillation has shown that the fibres longer than 20 µm have a weighted half-life less than 40 days; or
- an appropriate intra-peritoneal test has shown no evidence of excess carcinogenicity; or
- absence of relevant pathogenicity or neoplastic changes in a suitable long term inhalation test.

R: carcinogenic classification need not to apply to fibres with a length weighted geometric mean diameter – 2 standard geometric errors > 6 µm.

2.2 Short summary of the scientific justification for the CLH proposal

In its evaluation, IARC (2002) concluded that there is sufficient evidence in experimental animals for special-purpose glass fibres including E-glass and classified them as possibly carcinogenic to humans (group 2B). In addition, IARC reported that current average exposure levels to MMVF are generally less than 0.5 respirable fibre/cm³ (500 000 respirable fibres/m³) as an 8-h time-weighted average but that higher levels have been measured in production of special-purpose glass fibres, increasing the concern for workers.

Respirable fibres are those that can penetrate into the alveolar region of the lung upon inhalation; in humans, a fibre with an aerodynamic diameter of less than 5 µm is respirable according to EPA (2001). Aerodynamic diameter, unlike geometric diameter, takes into account fiber density and aspect ratio (ratio of length to diameter). The World Health Organization (WHO) defines respirable fibres as less than 3 µm in diameter and over 5 µm long, with an aspect ratio of at least 3:1 (WHO 2000).

Nevertheless, carcinogenic differences seem to exist between type '475' and E-glass fibres (Bernstein, 2007). IARC (2002) further reported that the advanced fibrosis induced by E-glass fibres (code 104/E) compared to microfibrils (code 100/475) from Cullen *et al.* (2000) were due to the higher number of long fibres of E-glass and their greater biopersistence compared with that of other fibre types.

Indeed, E-glass fibres show a carcinogenic potential by the intraperitoneal route and by inhalation in a well-designed study. On the basis of animal studies by inhalation, E-glass fibres induce marked macrophage reaction, alveolar fibrosis and hyperplasia which may indicate a progressive pathway to neoplastic transformation of respiratory cells. Besides, comparison between the carcinogenic potential of both fibres by intraperitoneal route (Pott 1984) shows that 32% of rats has abdominal tumours with E-glass.

The key information used in the REACH registration dossier concluding on Carc. 1B (H350i) is based on Searl *et al.* (1999) and Cullen *et al.* (2000) studies. It is emphasised that ‘the studies showed that E-glass microfibre induced fibrosis, carcinomas, adenomas and mesotheliomas in the rat.

Overall, it is concluded that E-glass fibres of representative composition and physical characteristics are presumed to be human carcinogens and should be classified as Carc. 1B (H350) under the CLP Regulation.

2.3 Current harmonised classification and labelling

Not applicable.

2.4 Current self-classification and labelling

2.4.1 Current self-classification and labelling based on the CLP Regulation criteria

There is a joint REACH registration dossier on E-glass fibres (E-glass microfibers) which has been taken into account for the completion of this CLH report (registration number 01-2119488048-29-00XX). The registered classification for E-glass microfibres is Carc. 1B – H350i,

For information, other fibres have also been registered using various chemical identifiers as shown in the table below (ECHA dissemination database accessed on 10 February 2014).

Information given in the registration dossier	CAS Number	EC/ListNumber	Proposed C&L	Registration No	Notifications in the C&L inventory
Glass, oxide, chemicals	65997-17-3	266-046-0	Carc. 1B, H350i	01-2119488048-29-XXXX	yes
No name given (Not technically possible following IUPAC rules) <i>Description: Refractories, alumino-silicate, fibres</i> Relates to alumino-silicate wools (ASW)	142844-00-6	604-314-4	Carc. 1B, H350	01-2119458050-50-XXXX	Yes (CAS only)
No name given (Not technically possible following IUPAC rules) <i>Description: Synthetic fibers, alk. earth silicate</i> Relates to alkaline-earth silicate (AES) fibres	436083-99-7	610-130-5	NC (note Q)	01-2119457644-32-XXXX	Yes (CAS only)

No name given (Not technically possible following IUPAC rules) <i>Description: Aluminium chloride, basic, reaction products with silica</i>	675106-31-7	614-074-2	NC	01-2119456884-25-XXXX	No
Man-made vitreous (silicate) fibres with random orientation with alkaline oxide and alkali earth oxide (Na ₂ O+K ₂ O+CaO+ MgO+BaO) content greater than 18 % by weight	-	924-055-3	Carc. 2, H351	01-2119615609-34-XXXX	No
No name given (No IUPAC name allocated) <i>Description: Man-made vitreous (silicate) fibres with random orientation with alkaline oxide and alkali earth oxide (Na₂O+K₂O+CaO+MgO+BaO) content greater than 18% by weight and fulfilling one of the note Q conditions</i> Relates to high alumina, low silica stone wools (HT wools)	-	926-099-9	NC (note Q)	01-2119472313-44-XXXX	No
Amorphous glass product formed from the melting and fiberisation of dipotassium oxide, oxo(oxo-alumanyloxy) alumane and dioxosilane Potassium alumino silicate glass fibre	675106-31-7	931-219-8	NC (note Q)	01-2119962882-26-XXXX	No

NC, not classified

An overview of fibres notified in the C&L inventory (accessed on 10/02/2014) is presented in the table below. For some of these entries, the classification varies from 'not classified' to 'Carc. 1B'. The list number 924-055-3 using the name 'Man-made vitreous (silicate) fibres with random orientation with alkaline oxide and alkali earth oxide (Na₂O+K₂O+CaO+ MgO+BaO) content greater than 18 % by weight' has not been used by notifiers.

Index Number	EC/list Number	CAS Number	Name	Overview of Notifications of classification according to CLP
650-016-00-2	-	-	Mineral wool, with the exception of those specified elsewhere in this Annex [Man-made vitreous (silicate) fibres with random orientation with alkaline oxide and alkali earth oxide (Na ₂ O+K ₂ O+CaO+MgO+BaO) content greater than 18 % by weight]	None [CLP: Carc. 2 (H351) (with notes R, Q and A)]
650-017-00-8	-	-	Refractory Ceramic Fibres, Special Purpose Fibres, with the exception of those specified elsewhere in this Annex [Man-made vitreous (silicate) fibres with random orientation with alkaline oxide and alkali earth oxide (Na ₂ O+K ₂ O+CaO+ MgO+BaO) content less or equal to 18 % by weight]	None [CLP: Carc. 1B (H350i) (with notes R and A)]
-	-	142844-00-6	Aluminosilicate (ceramic) fiber Aluminosilicate refractory ceramic fibres Refractories, fibers, aluminosilicate not technically possible following IUPAC rules	Carc. 1B (H350) with or without notes (70 notifications)

-	-	436083-99-7	Alkaline Earth Silicate Fibres	NC or Carc. 2 (H351) with or without notes (25 notifications)
-	-	-	Man-made vitreous (silicate) fibres with random orientation with alkaline oxide and alkali earth oxide (Na ₂ O+K ₂ O+CaO+ MgO+BaO) content greater than 18 % by weight Man-made vitreous (silicate) fibres with random orientation with alkaline oxide and alkali earth oxide (Na ₂ O+K ₂ O+CaO+ MgO+BaO) content greater than 18 % by weight	Carc. 2 (H351) with or without notes (2 notifications)
-	-	-	Man-made vitreous (silicate) fibres with random orientation with alkaline oxide and alkali earth oxide (Na ₂ O+K ₂ O+CaO+MgO+BaO) content greater than 18 % by weight No IUPAC name assigned	Carc. 2 (H351) with or without notes (11 notifications)
-	-	-	Man-made vitreous (silicate) fibres with random orientation with alkaline oxide and alkali earth oxide (Na ₂ O+K ₂ O+CaO+ MgO+BaO) Reaction mass of aluminium oxide and silicon dioxide	NC or Carc. 1B (H350) with or without notes (5 notifications)
-	-	-	Aluminosilicate Refractory Ceramic Fibres	Carc. 1B (H350) with notes R & A (2 notifications)
-	-	-	Zirconia Aluminosilicate Refractory Ceramic Fibres	Carc. 1B (H350) with notes R & A (1 notification)
-	266-046-0	65997-17-3	glass, oxide, chemicals (other names include fiberglass),	NC to Carc. 1B (H350) with no note (> 500 notifications)

2.4.2 Current self-classification and labelling based on DSD criteria

See above.

3 JUSTIFICATION THAT ACTION IS NEEDED AT COMMUNITY LEVEL

E-glass fibres of representative composition and physical characteristics have CMR properties, i.e. carcinogenic property, that justifies a harmonised classification and labelling according to article 36 of CLP.

Considering the recommendations of IARC (2002), TC C&L (2006) and the REACH registration dossier (registration number 01-2119615609-34-XXXX), harmonisation of classification is considered to be required for this endpoint (carcinogenicity) .

Part B.

SCIENTIFIC EVALUATION OF THE DATA

1 IDENTITY OF THE SUBSTANCE

1.1 Name and other identifiers of the substance

E-glass is a member of the family calcium-aluminium-silicate glasses. Boron oxide is generally a major additive of E-glass. E-glass fibres are E-glass fibres with special properties e.g. high corrosion resistance, high strength, low dielectric constant. In order to provide such special properties the composition is manipulated by adding or reducing specific oxide content. The physical characteristics (length, diameter, aspect ratio) determine the applications in which they are used. The proposed entry is specific to those E-glass fibres that are respirable. Continuous filaments and non-respirable fibres are outside the scope of the entry.

Table 4: Substance identity

EC number:	-
EC name:	-
CAS number (EC inventory):	-
CAS number:	-
CAS name:	-
Name(s) in the IUPAC nomenclature or other international chemical name(s)	E-glass special purpose fibres of representative composition; [Calcium-aluminium-silicate fibres with random orientation with the following representative composition (% given by weight): SiO ₂ 50.0-56.0%, Al ₂ O ₃ 13.0-16.0%, B ₂ O ₃ 5.8-10.0%, Na ₂ O <0.6%, K ₂ O <0.4%, CaO 15.0-24.0%, MgO <5.5%, Fe ₂ O ₃ <0.5%, F ₂ <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).]
CLP Annex VI Index number:	Not applicable
Molecular formula:	Not applicable (a generic molecular formula cannot be provided for E-glass fibres as it is a UVCB substance)
Molecular weight range:	Not applicable

Structural formula: Not applicable

1.2 Composition of the substance

Table 5: Constituents (non-confidential information)

Constituent	Typical concentration	Concentration range	Remarks
<i>E-glass fibres</i>	Ca 100%	-	-

Table 6: Impurities (non-confidential information)

Impurity	Typical concentration	Concentration range	Remarks
None	-	-	-

Table 7: Additives (non-confidential information)

Additive	Function	Typical concentration	Concentration range	Remarks
None	-	-	-	-

1.2.1 Composition of test material

Not relevant.

1.3 Physico-chemical properties

Table 8: Summary of physico - chemical properties

Property	Value	Reference	Comment (e.g. measured or estimated)
State of the substance at 20°C and 101,3 kPa	Inorganic, solid, white odourless fibrous glass in bulk or blanket form	ATSDR, 2004	measured
Melting/freezing point	ca. 800 °C	GE Healthcare, 2010	estimated
Boiling point	Not applicable		
Relative density	2.6 g/cm ³ at 20°C	AFSSET, 2007	measured
Softening point	850 °C	AFSSET, 2007	measured
Maximal temperature of use	600 °C	AFSSET, 2007	measured
Devitrification temperature	800 °C	AFSSET, 2007	measured
Not fibrous particles or shot	minimal	AFSSET, 2007	measured
Refractive index	1.55	AFSSET, 2007	measured
Vapour pressure	Not applicable		
Surface tension	Not applicable		
Water solubility	Not soluble in water	ATSDR, 2004	measured
Partition coefficient n-octanol/water	Not applicable		
Flash point	Not applicable		
Flammability	Not applicable		
Explosive properties	Not applicable		
Self-ignition temperature	Not applicable		
Oxidising properties	Not applicable		
Granulometry	aerodynamic diameters corresponding to the fibre density, diameter and length < 4 µm	Cullen, 2000	measured
Stability in organic solvents and identity of relevant degradation products	Not applicable		
Dissociation constant	Not applicable		
Viscosity	Not applicable		

2 MANUFACTURE AND USES

2.1 Manufacture

Two European production sites are located for the one in Belgium (Hollingsworth & Vose) and the other one in Germany (Lauscha) (AFSSET, 2007)

2.2 Identified uses

Industrial: air and liquid filtration (ASHRAE, HEPA, ULPA filter) in automotive applications and electronic industry (clean room filter), separation (battery) and insulation in aeronautical applications.

General public: In the filtration of high-efficiency air, the major application is the general ventilation of buildings (offices, schools, airports, hotels, department stores, residences, conference center). Otherwise, the domestic applications of special purpose fibres are filters for vacuum cleaners and the purifiers of air.

Secondary filters HEPA in vacuum cleaners and high-efficiency filtration of the air in residential buildings.

3 CLASSIFICATION FOR PHYSICO-CHEMICAL PROPERTIES

Not evaluated in this dossier.

4 HUMAN HEALTH HAZARD ASSESSMENT

4.1 Toxicokinetics (absorption, metabolism, distribution and elimination)

No data available.

4.2 Acute toxicity

No data available.

4.3 Specific target organ toxicity – single exposure (STOT SE)

No data available.

4.4 Irritation

4.4.1 Skin irritation

Discussions took place on this endpoint at the TC C&L, leading to the conclusion that the classification for the skin irritation is not necessary.

No classification proposed.

4.4.2 Respiratory tract irritation

No data available.

4.5 Corrosivity

No data available.

4.6 Sensitisation

No data available.

4.7 Repeated dose toxicity (including biopersistence)

This endpoint is presented only for information and is not proposed for harmonised classification.

4.7.1 Non-human information**4.7.1.1 Repeated dose toxicity: oral**

No data available.

4.7.1.2 Repeated dose toxicity: inhalation

Species	Fibre type	Conc.			Expo. time (h/day)	Duration	Observations and Remarks	Ref.
		Total	WHO	L>20 µm				
Male Fischer rats (n=74 / group)	MMVF3 2(E)	38±9 mg/m ³	316±50 f/cm ³	146±28 f/cm ³	6h/d nose-only	5 days + 1 year recovery	<u>E-glass:</u> <ul style="list-style-type: none"> Geometric mean dimension: length: 16.1±2.4 µm, diameter: 0.81±1.98 µm Weighted half-time of fibres longer than 20µm: 79 days (95% CI: 62-96) 90% clearance of fibres longer than 20µm: 371days (95% CI: 272-506) k_{dis} = 11 ng/cm²/h 	Hesterberg 1998 (Eastes 2000)
	MMVF3 3 (475)	36±8 mg/m ³	371±55 f/cm ³	163±25 f/cm ³			<u>475-glass:</u> <ul style="list-style-type: none"> Geometric mean dimension: length: 16.2±2.3 µm, diameter: 	

							<p>0.74±2.20 µm</p> <ul style="list-style-type: none"> Weighted half-time of fibres longer than 20µm: 49 days (95% CI: 40-58) 90% clearance of fibres longer than 20µm: 240 days (95% CI: 195-300) $k_{dis} = 17 \text{ ng/cm}^2/\text{h}$ 	
Male Wistar rats	E-glass	<p>2.4 mg/m³</p> <p>7.0 mg/m³</p> <p>17.3 mg/m³</p>	<p>197.9 f/cm³</p> <p>623.1 f/cm³</p> <p>1886.5 f/cm³</p>	<p>16.8 f/cm³</p> <p>50.9 f/cm³</p> <p>142.3 f/cm³</p>	<p>6h/d</p> <p>5d/wk</p>	<p>3 months</p> <p>+</p> <p>3 months recovery</p>	<ul style="list-style-type: none"> Dose-dependent and significant increase of lung wet weight at weeks 1, 7 and 14 post-exposure in the mid- and high-dose groups. Biochemical parameters in BALF: increase of LDH and β-glu 1 wk after the end of exposure in high-dose group. Increase in both mid- and high-dose groups of protein after 1, 7 and 14 wk, LDH and β-glu after 7 wk post-exposure. Histopathological findings: all rats (n=5/dose) exhibited dose-dependent very slight to slight accumulation of fibre-laden macrophages, bronchioalveolar hyperplasia, microgranulomas and interstitial fibrosis at wk 14 post-exposure. 	Bellmann 2003

4.7.1.3 Repeated dose toxicity: dermal

No data available.

4.7.1.4 Repeated dose toxicity: other routes

No data available.

4.7.1.5 Human information

No data available.

4.7.1.6 Other relevant information

No data available.

4.7.1.7 Summary and discussion of repeated dose toxicity

This endpoint is presented only for information and is not proposed for harmonised classification.

4.7.1.8 Summary and discussion of repeated dose toxicity findings relevant for classification according to DSD

This endpoint is presented only for information and is not proposed for harmonised classification.

4.7.1.9 Comparison with criteria of repeated dose toxicity findings relevant for classification according to DSD

This endpoint is presented only for information and is not proposed for harmonised classification.

4.7.1.10 Conclusions on classification and labelling of repeated dose toxicity findings relevant for classification according to DSD

This endpoint is presented only for information and is not proposed for harmonised classification.

4.8 Specific target organ toxicity (CLP Regulation) – repeated exposure (STOT RE)

No data available.

4.9 Germ cell mutagenicity (Mutagenicity)

No data available.

4.10 Carcinogenicity

4.10.1 Non-human information

4.10.1.1 Carcinogenicity: oral

No data available.

4.10.1.2 Carcinogenicity: inhalation

Species	Fibre: type E	Conc.			Expo. Time (h/day)	Duration	Observations and Remarks	Ref.
		Total	WHO	L>20 µm				
AH/HA N rats (n=43)	104E (E)	-	1022 f/cm ³	≈ 72 f/cm ³	7h/d 5d/wk whole-body	12 months + 12 months recovery or lifetime	<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. After 12 additional months of recovery, advanced alveolar fibrosis 	Cullen 2000

						obs.	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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4.10.1.3 Carcinogenicity: intraperitoneal

Species	Fibre type	Dose			Injection schedule	Duration of observation	Observations and Remarks	Ref.
		Total	WHO	L>20 µm				
Male Wistar rats (n=24)	104E (E)	-	Target: 10 ⁹ f	-	1 x 2 ml saline	lifetime	<ul style="list-style-type: none"> Median survival: 642 days. Tumour-associated deaths occurred more quickly than in amosite or 100/475 groups (reported in the Davis 1996 study). 21/24 rats (88%) treated with 104E had mesothelioma. 	Cullen 2000
Female Sprague-Dawley rats	104E (E)	5 mg			1 injection (in 2 ml saline)	lifetime	<ul style="list-style-type: none"> Dimensions: median length=4.8 µm and median diameter=0.29 µm Abdominal tumours were seen in 44/54 (81%) animals Control (5 mg titanium dioxide): 2/52 (4%) rats had tumours 	Pott 1987 Pott 1988
Wistar rats	104E (E)	5 mg			1 injection (in 2 ml saline)	lifetime	<ul style="list-style-type: none"> Dimensions: median length=4.8 µm and median diameter=0.29 µm Abdominal tumours were seen in 20/45 (44%) animals Control (5 mg titanium dioxide): 0/47 rats had tumours 	Pott 1987
Female Wistar rats (n=44)	JM104/E (E) JM 475 (475)	2 or 10 mg 2 mg	-	-	2 or 10 mg 2 mg	lifetime	<ul style="list-style-type: none"> E-glass: 14/44 (32%) and 29/44 (66%) rats with abdominal tumours at doses of 2 and 10 mg, respectively 475-glass: 2/44 (4%) rats with abdominal tumours (dimensions: median length=10 µm and median diameter=0.2 µm) Chrysotile: 9/44 (20%), 26/44 (59%) and 35/44 (79%) rats with abdominal tumours at doses of 0.4, 2 and 10 mg, respectively 	Pott 1984
Female Wistar	JM104 (475,				2, 10 or 2x25 mg	lifetime	<ul style="list-style-type: none"> Dimensions: median length=10 µm and median diameter=0.2 µm 	Pott 1976

rats	753, E)						<ul style="list-style-type: none"> • 2 mg-dose: 17 rats had mesothelioma, 3 a sarcoma (n=37). Total tumour rate: 27.4% • 10 mg-dose: 36 rats had mesothelioma, 4 a sarcoma and 1 a carcinoma (n=77). Total tumour rate: 53.2% • 2x25 mg-dose: 47 rats had mesothelioma, 8 a sarcoma (n=77). Total tumour rate: 71.4% • crocidolite group (2 mg): 15/39 abdominal tumours (38%) 	
Rats	JM106 (475, 753, E)				2, 10 or 4x25 mg	lifetime	<ul style="list-style-type: none"> • Dimensions: median length = 3 µm and median diameter = 0.4 µm • 2 mg-dose: 1 rat had a mesothelioma (n = 34). Total tumour rate: 2.9% • 10 mg-dose: 2 rats had mesothelioma, 2 a sarcoma (n = 36). Total tumour rate: 11.0% • 4x25 mg-dose: 20 rats had mesothelioma, 3 a sarcoma (n = 32). Total tumour rate: 72% 	Pott 1976

4.10.1.4 Carcinogenicity: intra-tracheal

Species	Fibre type	Dose			Injection schedule	Duration of observation	Observations and Remarks	Ref.
		Total	WHO	L>20 µm				
Syrian golden hamster (n=35 / sex)	JM 104 (475, 753, E)	26 mg			26 x 1mg in 0.2 mL 0.005% gelatine in saline (every 2 wk for 52 wk)	85 wk	<ul style="list-style-type: none"> • Dimensions: 58% < 5 µm in length, 88% < 1.0 µm in diameter • No mesothelioma or pulmonary tumour in JM104- or crocidolite-treated groups 	Feron 1985

Male Syrian golden hamster	JM 104 (475, 753, E)	8 mg			8 x 1mg in 0.15 mL saline (weekly)	113 wk	<ul style="list-style-type: none"> Group with median length= 7 µm: 48/136 animals (35%) developed a tumour (5 lung carcinomas, 37 mesotheliomas, 6 sarcomas) Group with median length= 4.2 µm: 38/138 animals (27%) developed a tumour (6 lung carcinomas, 26 mesotheliomas, 6 sarcomas) Crocidolite: 18/42 rats (13%) had a tumour (9 lung carcinomas, 8 mesotheliomas, 1 sarcomas) Control (TiO₂): 2/135 rats (1.5%) had sarcoma 	Mohr 1984
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4.10.1.5 Carcinogenicity: intra-pleural

Species	Fibre type	Dose			Injection schedule	Duration of observation	Observations and Remarks	Ref.
		Total	WHO	L>20 µm				
Sprague Dawley rats (n=32-45)	JM 104 (475, 753, E)	20 mg			1 x 20 mg in 2 mL saline	Lifetime	<ul style="list-style-type: none"> Dimensions: mean length=5.89 µm and mean diameter=0.229 µm 6/45 animals (13%) had mesothelioma. Chrysotile : 14/33 (42%), and crocidolite: 21/39 (54%) mesotheliomas No thoracic tumours in 32 control animals. 	Monchaux 1981

4.10.1.6 Carcinogenicity: dermal

No data.

4.10.2 Human information

Study type	Fibre type	End point	Population	Exposure assessment	Observations and Remarks	Ref.
Case-control	Microfibre s	Larynx and hypopharynx cancers	<p>Patients recruited from 15 hospitals in 6 French cities.</p> <p>Larynx cancers: n=296 subjects</p>	<p>Job history was collected by face to face interview.</p> <p>Exposure was</p>	<ul style="list-style-type: none"> Results adjusted for age, smoking and alcohol consumption Laryngeal cancers: 16 cases/9 controls ever exposed; OR=1.28 (95% CI: 0.51-3.22) 	Marchand 2000

			Hypopharynx cancers: n=201 subjects Controls: n=295 with non-respiratory cancers	assessed using a job-exposure matrix and 2 categories were defined: Ever exposed or Never exposed	<ul style="list-style-type: none"> Hypopharynx cancers: 7 cases/9 controls ever exposed; OR=0.78 (95% CI: 0.26-2.38) No significant association between laryngeal or hypopharyngeal cancers and exposure to microfibrils but exposure concerned only a few subjects. 	
Historical cohort	Fibre glass including 2/10 plants producing special-application glass fibres	Respiratory system cancers	32,110 production or maintenance workers employed for 1 year or more between 1945 and 1992. Control: US or local county mortality rates	Quantitative estimation of fibre exposure.	<ul style="list-style-type: none"> No evidence of excess mortality risks for all causes of death, all cancer death or non malignant respiratory disease mortality. General cohort: a 6% (SMR=1.06, 95% CI: 1.00-1.14, p=0.05) and 16% (SMR=1.16, 95% CI: 1.08-1.24, p<0.01) excess of respiratory system cancer mortality was observed compared to respectively local and national rates. Duration of exposure and cumulative exposure were not associated with an increased risk of respiratory system cancer. Possible co-exposure to arsenic, asbestos, asphalt, epoxy, formaldehyde, PAH, phenolics, silica, styrene and urea. Special-purpose glass fibres exposure category: SMR=1.09, 95% CI: 0.87-1.36 (n=81 cases) 	Marsh 2001 (IARC 2002)

4.10.3 Other relevant information

Test	Fibre type	Cell system	Protocol	Conc. (mg/l)	Observations and Remarks	Ref.
Cell activation	100/475 (475) 104E (E)	Rat alveolar macrophages	24 h	8.2 x 10 ⁶ fibres (WHO)	<ul style="list-style-type: none"> Both microfibrils showed an intermediate activity with a TNF-α production of 60 (475-glass) and 71 (E-glass) TNF-α unit/10⁶ cells. Two silicon carbide whiskers and two asbestos samples were more active while RCF and other MMVF tested were inactive. 	Cullen 1997

4.10.4 Summary and discussion of carcinogenicity

Summary for E-Glass fibres:

Rats were exposed by **inhalation** to **E-glass** in one single study (Cullen *et al.*, 2000). E-glass fibres clearly induced marked fibrosis and lung tumours in spite of a short 1-year exposure time and the short size of groups.

By **intraperitoneal** exposure, Cullen *et al.* (2000) showed an increase in the incidence of mesothelioma. Besides, all studies from Pott (1984, 1987 and 1988) clearly report an increased incidence of abdominal tumours following exposure to E-glass fibres by intraperitoneal way. It is observed a dose-response related effect in the studies of Pott (1976, 1984). It should however be noted that the type of glass (475, E or 753) is not indicated in Pott (1976).

By **intratracheal** exposure, studies were performed with the “JM 104” fibre, corresponding with the both **475 and E-glass fibres**. There is no specific study on the **single E-glass fibre**. In one study (Feron 1985), no lung tumour were found in the hamster but in this study, the crocidolite control-group was also negative. On the other hand, two others studies reported an increase in lung carcinomas in 15% of the animals in rats (Pott 1987) and 27% or 35% of the animals in hamster (Mohr 1984) with an increased incidence with longer fibres.

By **intrapleural route**, there is one study on JM 104 fibres, so it englobes 475, 753 and **E-glass** fibres but it is not specific to **E-glass** fibre (Monchaux 1981). An increase of 13% in mesotheliomas was found in rat with 42% and 54% respectively for chrysotile and crocidolite.

The reach registration dossiers do not reported additional key studies.

Classification by IARC in 2002:

In its evaluation, IARC (2002) concluded that there is sufficient evidence in experimental animals for special-purpose glass fibres (E-glass) and classified them as possibly carcinogenic to humans (group 2B), as for refractory ceramic fibres.

Human data:

A case-control study did not show any association between laryngeal or hypopharyngeal cancers and microfibre exposure (Marchand 2000) but the study included a very small number of microfibre-exposed subjects. In an historical cohort study (Marsh 2001), an excess of respiratory cancer was observed in the general fibre glass group but not in the special-purpose glass fibres sub-group. The size of this sub-group was also limited. Overall, these data are not considered sufficient to draw any conclusion on the potential carcinogenic effects in humans.

4.10.5 Comparison with CLP criteria

The **epidemiological data** do not bring sufficient evidence of carcinogenicity in human.

For experimental data, the CLP criteria for classification establish different levels of evidence:

— “**sufficient evidence of carcinogenicity**: 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. An increased incidence of tumours in both sexes of a single species in a

well-conducted study, ideally conducted under Good Laboratory Practices, can also provide sufficient evidence. A single study in one species and sex might be considered to provide sufficient evidence of carcinogenicity when malignant neoplasms occur to an unusual degree with regard to incidence, site, type of tumour or age at onset, or when there are strong findings of tumours at multiple sites;

*— **limited evidence of carcinogenicity:** the data suggest a carcinogenic effect but are limited for making a definitive evaluation because, e.g. (a) the evidence of carcinogenicity is restricted to a single experiment; (b) there are unresolved questions regarding the adequacy of the design, conduct or interpretation of the studies; (c) the agent increases the incidence only of benign neoplasms or lesions of uncertain neoplastic potential; or (d) the evidence of carcinogenicity is restricted to studies that demonstrate only promoting activity in a narrow range of tissues or organs.”*

Experimental data for the E-glass fibres clearly provide evidence of a carcinogenic effect in several species (rats, hamsters and monkeys) and in both sexes in numerous independent studies in different laboratories. 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).

Indeed, special-purpose (respirable) fibres E show a carcinogenic potential by the intraperitoneal route and by inhalation in a well-designed study. Fibre biopersistence may enable their migration further inhalation into the pleural cavity and emphasise the relevance of positive results by the intrapleural route.

On the basis of animal studies by inhalation, E-glass fibres induce marked macrophage reaction, alveolar fibrosis and hyperplasia which may indicate a progressive pathway to neoplastic transformation of respiratory cells, whereas 475-glass fibres do not exhibit such effects by inhalation (Cullen, 2000). Besides, comparison between the carcinogenic potential of the both fibres by intraperitoneal route (Pott 1984) shows that 32% of rats has abdominal tumours with E-glass although only 4% of rats has abdominal tumours with 475-glass tumours.

E-glass fibres are characterized by their chemical composition and physical characteristics (i.e length, diameter and aspect ratio). They are manufactured as continuous filaments, as general purpose insulation fibres with diameters ranging from ca. 5-15 µm and as special purpose fibres of smaller diameters ca. 1-5 microns. It is acknowledged that the meaning of ‘special purpose’ in this context implies that the fibres are used in applications where a small fibre diameter is required unlike general purpose insulation fibres.

The proposed new entry only refers to E-glass fibres that are respirable. Filaments and non-respirable fibres are not covered by this entry. Note R is therefore included to capture the physical characteristics of the fibres relevant for this classification proposal. Respirable fibers are those that can penetrate into the alveolar region of the lung upon inhalation; in humans, a fibre with an aerodynamic diameter of less than 5 µm is respirable according to EPA (2001). Aerodynamic diameter, unlike geometric diameter, takes into account fiber density and aspect ratio (ratio of length to diameter). The World Health Organization (WHO) defines respirable fibres as less than 3 µm in diameter and over 5 µm long, with an aspect ratio of at least 3:1 (WHO 2000).

4.10.6 Conclusions on classification and labelling

Overall, largely based on animal evidence, E-glass fibres are presumed to have carcinogenic potential for humans. E-glass fibres clearly induced malign lung tumours after inhalation.

A classification as Carc. 1B; H350i is therefore warranted for respirable E-glass fibres of representative composition (Carc. Cat. 2 – R49 according to the DSD) with the addition of Note R.

4.11 Toxicity for reproduction

No data available.

4.12 Other effects

No data available.

5 ENVIRONMENTAL HAZARD ASSESSMENT

Not relevant for this dossier.

6 OTHER INFORMATION

No other information.

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8 ANNEXES

Discussions at the TC C&L:

Summary records – TC C&L November 2005 (doc ECBI/60/05 Rev. 3)

In **November 2005** a preliminary discussion took place.

Discussion of this substance was introduced by France, which reported that special purpose fibres were incorrectly regarded in the same Annex I entry as mineral wool. In fact they should be in the same entry as refractory ceramic fibres as a result of their known carcinogenicity. The French proposal was for a classification of special purpose fibres as Carc. Cat.2; R45.

Industry spoke to their paper (Add 1). They argued that special purpose fibres fell into two broad sub-Groups one of which (E glass) should be classified as a category 2 carcinogen. However the second sub-Group (identified as 475) did not have the same properties and should be considered as a category 3 carcinogen.

In the course of discussion member states raised a number of concerns. France drew attention to the difficulty of inhalation studies as a valid test for eliminating concerns over the carcinogenicity of fibres. Germany pointed out the importance of IP studies. The United Kingdom asked for further information, particularly the arguments that observations of mesothelioma in hamsters were not relevant to humans.

Industry promised to provide further information, particularly the relationship between inhalation and IP studies. The Chair said the discussion would be taken up again at the next meeting.

Summary records – TC C&L Mars 2006 (doc ECBI/90/06 Rev. 8)

[ECBI/10/05](#) F, classification proposal.
ECBI/10/05 Add. 1, 2,3,4 IND, response to proposal

In **November 2005** a preliminary discussion took place and industry promised to provide further information on a number of issues. Carcinogenicity

The Chair introduced this substance by reporting that industry said it preferred to keep the existing Annex 1 entry with the Carc Cat 3 classification. France was invited to react to the industry comments on their proposal.

France reported that it maintained the view that the existing classification was unsatisfactory. The fibres covered by the entry are persistent with a half-life similar to E glass. This suggested similar properties and it was appropriate to classify both special purpose fibres and E glass as a Carcinogen Category 2.

In responding to these comments Industry said the database on the substance had not changed since the original classification. There was no statistical difference in the frequency of adenocarcinomas and there was an absence of fibrosis. Bio-persistence was not a valid inclusion criterion for

carcinogenicity; it had only been used in the past to enable exoneration. The only valid data were the complex inhalation studies which had been carried out prior to the 1977 classification decision.

During the subsequent discussion the United Kingdom indicated that they preferred keeping the original Carc. Cat 3 classification. However other Member States noted the confusion in relation to the description of the substance in the current entry which appeared to include E glass for which there was good evidence for Carc Cat 2. This led Germany and the Netherlands to suggest that a split entry might be appropriate. However they acknowledged there would be difficulties in developing a suitable characterisation of the substance.

Conclusion:

In drawing the discussion to a close the Chair suggested Member States needed to reflect on the issue. There appeared to be three possibilities; to maintain the status quo, to adopt the French proposal, or to develop split entries. Industry commented that the latter option would be extremely difficult to introduce.

Summary records – TC C&L October 2006 (doc ECBI/13/07 Rev. 2)

ECBI/10/05

ECBI/10/05 Add. 1, 2, 3, 4

ECBI/10/05 Add. 5

F, classification proposal.

IND, response to proposal

IND, summary of chemistry and key toxicological issues

In **November 2005** a preliminary discussion took place and industry promised to provide further information on a number of issues.

In **March 2006**, it was agreed to delete the Xi; R38 classification for both entries 650-016-00-2 (including CAS number 65997-17-3) and 650-017-00-8. The Chair suggested Member States needed to reflect on the carcinogenicity issue. There appeared to be three possibilities; to maintain the status quo, to adopt the French proposal, or to develop split entries. Industry commented that the latter option would be extremely difficult to introduce. Carcinogenicity:

ECB summarised the conclusions from the last meeting. Re-classification was needed for E-glass fibres. IND had sent additional information on 'E-glass' and 'Type 475 special purpose fibres' and wanted them to be considered as different. Epidemiology data did not warrant a Carc. Cat. 2 classification for the Type 475 fibres, according to IND. There was no significant fibrosis in the Cullen study, therefore no carcinogenicity classification warranted. A further paper was published the week prior the meeting and would be distributed to the TC C&L during the Follow-up period. The Type 475 special purpose fibres should be classified with Carc. Cat. 3, according to IND.

ECB said at the last meeting there were split opinions between Carc. Cat. 3 and Carc. Cat. 2. We had a discussion to split the fibres amongst 2 entries.

F commented on the bio-persistence and bio-availability. The two types of fibres had different composition. The 'Type 475 special purpose fibres' and 'E-glass fibres' had different dissolution rates. Both fibres could be grouped on this basis and no split entry was needed. The E-glass fibres induced fibrosis. Also very slight fibrosis was found with 'Type 475 special purpose fibres' at short exposure. For F this was enough evidence for Carc. Cat. 2, for both fibre categories.

NL asked said that they had looked at dissolution rate and then at fibrosis, but they did not see the relation between dissolution rates and the category.

IND said the dissolution rate is an interesting concept. When developed, nobody felt that this could be used for C&L purposes. It was an indication of a relative category of where the fibres belong. The difference between Carc. Cat. 2 and Carc. Cat. 3, however, must be determined by toxicological studies. In this case the inhalation study was negative. There was also not significant fibrosis. Therefore we need different categories for 'Type 475 special purpose fibres' and 'E-glass fibres'.

UK agreed with IND that the two fibre types are different. Thus Carc. Cat. 3 for 'Type 475 special purpose fibres'. NL also agreed to this.

DE said there was a different potency between the fibres. However, also 'Type 475 special purpose fibres' could still be classified as Carc. Cat. 2. A practical problem was also how to present the classification in Annex I because both fibres had the same CAS number. F confirmed the CAS number covers many fibres.

ECB summarised the TC C&L agreed to classify the 'Type 475 special purpose fibres' in Cat. 3. IND was asked to provide the chemical identification for both entries in the Follow up procedure. The TC C&L agreed to classify the 'Type 475 special purpose fibres' in Carc. Cat. 3 and the E-glass fibres in Carc. Cat. 2, and the only remaining issue was then how to identify the substances in the two different entries.

IND confirmed that they would provide further information in the Follow up procedure.

F asked IND what the percentage of oxide was in the fibres. IND responded: greater than 18 % but close to the limit.

Conclusion:

The TC C&L agreed to classify 'Type 475 Special purpose fibres' with Carc. Cat. 3; R40 while 'E-glass fibres' would remain with the current Carc. Cat. 2; R49 classification.

Follow-up:

IND sent in ECBI/10/05 Add. 6 for identification of the substances to be covered by the two entries.

F proposed to define following four entries for fibres:

- To keep the current entries Index 650-017-00-8 and Index 650-016-00-2 as they are.
- To create one additional entry for E-fibres (with a new index number) and one additional entry for 475-fibres (which will differ from index 650-016-00-2 by the absence of nota Q).

Follow-up conclusion:

The definition of the new entries should be confirmed at the March 2007 meeting.

Follow-up III of TC C&L October 2006 (doc ECBI/09/07)

IND sent in ECBI/10/05 Add. 6 for identification of the substances to be covered by the two entries.

Member States were invited to react in case they did not agree with the entries as identified.

FR: The current index 650-017-00-8 also covers refractory ceramic fibres (RCF) and should therefore not be restricted to E-fibres.

Besides, the current index 650-016-00-2 which is classified Carc. Cat. 3; R40 and could apply by default to 475-type fibres, is specific because of nota Q which allows exemption of the carcinogenic classification under certain circumstances.

For these reasons, we propose to have the following entries:

- To keep the current entries Index 650-017-00-8 and Index 650-016-00-2 as they are.
- To create one additional entry for E-fibres (with a new index number) and one additional entry for 475-fibres (which will differ from index 650-016-00-2 by the absence of nota Q).

Besides, the chemical composition of the glass may not be sufficient to characterise appropriately the entries. To our knowledge, E-glass may also be used in other type of glass fibres than special purpose fibres, such as continuous glass filaments for example. Therefore, an appropriate way to identify the entries could be to specify both composition and size and to limit the entries to fibres with a mean diameter of less than 3 µm.

IND sent documents ECBI/10/05 Add. 8 parts I, II and III. The values of the type 475 fibres are corrected in correspondence with the table of document 10/05 Add. 8 part II.

MS were asked to react in written in case they do not agree to the new IND proposal prior 31 August 2007. In case no reactions no further detailed discussion is foreseen to take place at the September meeting, but the entry as defined here can be considered confirmed.

No further comments were received.

Final Conclusion:

TC C&L has then confirmed the entry as written here, and there will be no further discussion.

After FUII:

ECB: The CAS No 65997-17-3 is coupled to EC No 266-046-0 with the substance name *Glass, oxide, chemicals* and a description starting with "This category encompasses the various chemical substances manufactured in the production of inorganic glasses.....". Whether the CAS and EC Numbers should be assigned to the more specified entry *Type 475 Special purpose fibres* still has to be decided before this entry is included in the next ATP.