



Substance name: Aluminosilicate Refractory Ceramic Fibres

EC number: -

CAS number: -

**MEMBER STATE COMMITTEE
SUPPORT DOCUMENT FOR IDENTIFICATION OF
ALUMINOSILICATE REFRACTORY CERAMIC FIBRES
AS A SUBSTANCE OF VERY HIGH CONCERN BECAUSE OF ITS
CMR¹ PROPERTIES**

Adopted on 9 December 2011

¹ CMR means carcinogenic, mutagenic or toxic for reproduction

CONTENTS

JUSTIFICATION	3
1 IDENTITY OF THE SUBSTANCE AND PHYSICAL AND CHEMICAL PROPERTIES	3
1.1 Name and other identifiers of the substance	4
1.2 Composition of the substance	5
1.3 Physico-chemical properties	6
2 HARMONISED CLASSIFICATION AND LABELLING	7
3 ENVIRONMENTAL FATE PROPERTIES	8
4 HUMAN HEALTH HAZARD ASSESSMENT	8
5 ENVIRONMENTAL HAZARD ASSESSMENT	8
6 CONCLUSIONS ON THE SVHC PROPERTIES	8
6.1 PBT, vPvB assessment	8
6.2 CMR assessment.....	8
6.3 Substances of equivalent level of concern assessment.	8
REFERENCES	9
ABBREVIATIONS	10

TABLES

Table 1: Physical size characteristics of stock RCF.....	4
Table 2: Substance identity.....	4
Table 3: Starting material of the UVCB substance.....	5
Table 4: Impurities.....	5
Table 5: Additives.....	5
Table 6: Overview of physicochemical properties	6
Table 7: RCF entry in Table 3.1 of Annex VI of EC Regulation (No.) 1272/2008 as amended by the 1 st ATP.	7
Table 8: RCF entry in Table 3.2 of Annex VI of EC Regulation (No.) 1272/2008 as amended by the 1 st ATP	7

Substance Name(s): Aluminosilicate Refractory Ceramic Fibres

EC Number(s): -

CAS number(s): -

Aluminosilicate Refractory Ceramic Fibres

are fibres covered by index number 650-017-00-8 in Annex VI, part 3, table 3.1 of Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, and fulfil the three following conditions:

a) oxides of aluminium and silicon are the main components present (in the fibres) within variable concentration ranges

b) fibres have a length weighted geometric mean diameter less two standard geometric errors of 6 or less micrometres (μm)

c) alkaline oxide and alkali earth oxide ($\text{Na}_2\text{O}+\text{K}_2\text{O}+\text{CaO}+\text{MgO}+\text{BaO}$) content less or equal to 18% by weight

- The substance is identified as substance meeting the criteria of Article 57 (a) of Regulation (EC) 1907/2006 (REACH) owing to its classification as carcinogen 1B² which corresponds to classification as carcinogen category 2³.

Summary of how the substance meets the Carcinogen 1B criteria

Man-made vitreous (silicate) fibres with random orientation and with alkaline oxide and alkali earth oxide ($\text{Na}_2\text{O}+\text{K}_2\text{O}+\text{CaO}+\text{MgO}+\text{BaO}$) content less or equal to 18 % by weight and a length weighted geometric mean diameter less two standard geometric errors of 6 or less micrometres (μm) are covered by Index No 650-017-00-8 and classified as carcinogen 1B in Annex VI, Part3, Table 3.1 (list of harmonised classification and labelling of hazardous substances) of Regulation (EC) No 1272/2008. This corresponds to a classification as carcinogen (Carc. Cat. 2) in Annex VI, Part 3, Table 3.2 (the list of harmonised classification and labelling of hazardous substances from Annex I to Directive 67/548/EEC) of Regulation (EC) No 1272/2008

Therefore, this classification of aluminosilicate refractory ceramic fibres in Regulation (EC) No 1272/2008 shows that the substance meets the criteria for classification as carcinogen in accordance with Article 57 (a) of REACH.

Registrations received for this substance: yes

² Classification in accordance with Regulation (EC) No 1272/2008 Annex VI, part 3, Table 3.1 List of harmonised classification and labelling of hazardous substances.

³ Classification in accordance with Regulation (EC) No 1272/2008, Annex VI, part 3, Table 3.2 List of harmonised classification and labelling of hazardous substances (from Annex I to Council Directive 67/548/EEC).

JUSTIFICATION

In 2009 an Annex XV Dossier has been submitted to identify aluminosilicate refractory ceramic fibres (RCF) as substances of very high concern (SVHC). These fibres are manufactured by melting approximately equal amounts of silicon dioxide and aluminium oxide; in some cases further metal oxides are added. In this Annex XV document the composition of the fibres was indicated according to a publication of the association of the producers of the fibre material.

This Annex XV Dossier was discussed and accepted during MSC-10 (Dec. 2009) and aluminosilicate refractory ceramic fibres were included in the Candidate List⁴.

In 2010 some registrations for RCF were submitted to ECHA which did not match the chemical composition indicated in this Annex XV dossier. These substances are, therefore, not covered by the existing entry in the Candidate List. Nevertheless, those substances have the same properties concerning their biodurability and toxicological profile (i.e. classification as Carc. 1B according to Regulation (EC) No 1272/2008) as the RCF already included in the Candidate List.

Therefore, DE has now prepared a new Annex XV dossier for RCF covering fibre materials based on variable amounts of aluminium oxide and silicon dioxide. In order to cover not only the already submitted but also possible future registration dossiers, it is intended to identify the substances by their typical constitution without specifying the exact amounts of the components (UVCB substance).

1 IDENTITY OF THE SUBSTANCE AND PHYSICAL AND CHEMICAL PROPERTIES

Aluminosilicate refractory ceramic fibres belong to the group of the refractory ceramic fibres (RCF⁵). Refractory ceramic fibres are a special category of synthetic vitreous fibres (SVFs, or, more commonly known as man-made vitreous fibres (MMVF)). A complete chemical identification is not possible as they are UVCB substances (substances of Unknown or Variable composition, Complex reaction products or Biological materials). According to the guidance for identification and naming of substances under REACH these UVCB substances are specified with the IUPAC name of their starting materials. In the case of aluminosilicate RCF those are Al₂O₃ and SiO₂ with variable concentrations.

Generally, four types of RCF are being distinguished (RCF 1, 2, 3 and 4). RCF 1 are kaolin-based ceramic fibres and RCF 3 are high-purity fibres.

RCF 2 contain beside silicon oxide and aluminium oxide also zirconium oxide as main starting materials and are therefore not identical with aluminosilicate RCF in the sense of the substance definition according to REACH. For this type of fibre a separate Annex XV proposal for identification as substance of very high concern has been developed.

RCF 4 have actually no commercial importance. These so called “after-service fibres” are fibres of type 1 which had been previously heated at 1300 °C for 24 h, in order to determine properties of the products after longer use.

⁴ http://echa.europa.eu/chem_data/authorisation_process/candidate_list_table_en.asp

⁵ Abbreviations are summarized and explained at the end of the dossier

Therefore, this document refers to the aluminosilicate RCF of type 1 and 3.

Due to the physical properties of the bulk material and the manifold mechanical forces during the production process a broad spectrum of fibre sizes (length/diameter) is generated. The size characteristics of RCF stock ⁶ are presented in table 1 [Mast, 1995 a].

Table 1: Physical size characteristics of stock RCF

	RCF 1	RCF 3
	Stock fibre ^a	Stock fibre ^a
Diameter range (µm)	0.10 - 4.2	0.17 - 2.91
Length range (µm)	2.1 - 67.8	1.5 - 58.7
AMD ± SD (µm)	1.06 ± 0.7	1.17 ± 0.79
AML ± SD (µm)	24.0 ± 18.5	25.7 ± 19.1
GMD ± GSD (µm)	0.86 ± 1.96	0.94 ± 2.0
GML ± GSD (µm)	16.5 ± 2.6	17.7 ± 2.7
Median diameter ± SD (µm)	0.88 ± 0.02	1.03 ± 0.01
Median length ± SD (µm)	17.8 ± 1.5	20.1 ± 0.3

^anumber of samples analyzed = 3

1.1 Name and other identifiers of the substance

Table 2: Substance identity

EC number:	-
EC name:	-
CAS number (in the EC inventory):	-
CAS number:	-
CAS name:	-
IUPAC name:	aluminosilicate refractory ceramic fibres
Index number in Annex VI of the CLP Regulation	650-017-00-8
Molecular formula:	-
Molecular weight range:	-
Synonyms:	-

Structural formula:

Aluminosilicate RCF are fibrous, inorganic, vitreous materials formed by high temperature fusion of sources of silica and alumina into a mass which is cooled to a rigid condition without

⁶ RCF fibres as they derive from production

crystallization and formed into fibres. The silicon and aluminium oxides are present in glassy matrix in variable concentrations.

Other oxides like potassium oxide (< 0.01 %), sodium oxide (0.5 %), magnesium oxide (< 0.1 %), calcium oxide (< 0.1 %), titanium oxide (2 %), zirconium oxide (0.1 %), iron oxide (1 %) and chromium oxide (< 0.03 %) are sometimes incorporated to change the fibre properties.

Annex VI entry of Regulation (EC) No 1272/2008 focuses on a content of Na₂O+K₂O+CaO+MgO+BaO less or equal to 18 % by weight. That means that the condition for these substances to be classified as Carc. 1B according to Regulation (EC) No 1272/2008 (or Carc. Cat 2, R49 according to Regulation 67/548/EEC respectively) is fulfilled.

Therefore, the substance aluminosilicate Refractory Ceramic Fibres (SiO₂, Al₂O₃) as described in this document is a subset of the group of substances which are defined by the refractory ceramic fibres in Annex VI of the Regulation (EC) No 1272/2008.

1.2 Composition of the substance

Name: aluminosilicate refractory ceramic fibres
Description: refractory ceramic fibres, special purpose fibres
Degree of purity: 100% w/w

Table 3: Starting material of the UVCB substance

Starting material	Typical concentration	Concentration range	Remarks
silicon dioxide, EC no. 231-545-4	present in variable concentrations	variable	-
aluminium trioxide, EC no. 215-691-6	present in variable concentrations	variable	-

Table 4: Impurities

Impurities	Typical concentration	Concentration range	Remarks
-			

Table 5: Additives

Additives	Typical concentration	Concentration range	Remarks
-			.

1.3 Physico-chemical properties

For aluminosilicate RCF no specific data are available. The physico-chemical properties listed in Table 6 belong to RCF in general:

Table 6: Overview of physicochemical properties⁷

Property	Value	Remarks	Reference
Physical state at 20 °C and 101.3 kPa	White fibrous solid		[Mast, 1995a]
Melting/freezing point	1740 – 1800 °C		[Glass, 1995]
Boiling point	Not applicable		
Vapour pressure	Not applicable		
Water solubility	Not applicable		
Partition coefficient n-octanol/water (log value)	Not applicable		
Dissociation constant	Not applicable		

⁷ The references of the values reported in Table 6 will be available in the technical dossier. In case references need to be included an additional column could be added manually to Table 6.

2 HARMONISED CLASSIFICATION AND LABELLING

All refractory ceramic fibres are covered by entries under index number 650-017-00-8 in Annex VI, part 3, table 3.1 (list of harmonised classification and labelling of hazardous substances) and table 3.2 (list of harmonised classification and labelling of hazardous substances from Annex I to Directive 67/548/EEC) of Regulation (EC) No 1272/2008. These entries were amended by a Commission Regulation amending, for the purposes of its adaptation to technical progress, for the first time Regulation (EC) No. 1272/2008. This Commission Regulation was adopted on August 10th, 2009. Subject of the amendment was deletion of the hazard class skin irritation. The amended entries, as they were included in tables 3.2 and 3.1 of Annex VI of Regulation (EC) No 1272/2008, are listed in Table 7 and Table 8.

According to the IARC (2002) refractory ceramic fibres are the only fibres that match these entries. Actually, only two different categories of RCF are on the market: those fibres with a content of zirconium dioxide up to 18 % by weight (RCF 2) and those with an amount on zirconium dioxide of approx. 0.1 % (RCF 1 or 3). A separate dossier is submitted for RCF 2 fibres.

Table 7: RCF entry in Table 3.1 of Annex VI of EC regulation (no.) 1272/2008 as amended by the 1st ATP.

Index No	International Chemical Identification	EC No	CAS No	Classification	Labelling				Conc. Limits	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)		
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]	-	-	Carc. 1B	H350i	GHS08 Dgr	H350i			AR

Table 8: RCF entry in Table 3.2 of Annex VI of EC regulation (no.) 1272/2008 as amended by the 1st ATP

Index No	International Chemical Identification	EC No	CAS No	Classification	Labelling	Concentration Limits	Notes
650-017-00-8	Refractory Ceramic Fibres, Special Purpose Fibres, with the exception of those specified elsewhere in this Annex;	-	-	Carc. Cat. 2; R49	T R: 49 S: 53-45		AR

	[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]					
--	---	--	--	--	--	--

3 ENVIRONMENTAL FATE PROPERTIES

Not relevant for the identification of the substance as SVHC in accordance with Article 57(a).

4 HUMAN HEALTH HAZARD ASSESSMENT

Human health hazard has been assessed in the context of classification and labelling and it has been classified as carcinogen 1B as seen in section 6.2 below.

5 ENVIRONMENTAL HAZARD ASSESSMENT

Not relevant for the identification of the substance as SVHC in accordance with Article 57(a).

6 CONCLUSIONS ON THE SVHC PROPERTIES

6.1 PBT, vPvB assessment

Not relevant for the identification of the substance as SVHC in accordance with Article 57(a).

6.2 CMR assessment

Fibres with a content of 18 % of weight or less of Na₂O+K₂O+CaO+ MgO+BaO were classified as Carc. 1B according to Regulation (EC) No 1272/2008. The refractory ceramic fibres are the only fibres that meet this definition and therefore refractory ceramic fibres are listed as carcinogens (Carc. 1B) in Annex VI, part 3, Table 3.1 of Regulation (EC) No 1272/2008 (list of harmonised classification and labelling of hazardous substances). This corresponds to a classification as carcinogen (Carc. Cat. 2) in Annex VI, part 3, Table 3.2 (the list of harmonised classification and labelling of hazardous substances from Annex I to Directive 67/548/EEC) of Regulation (EC) No 1272/2008⁸ - see section 3 of this document for full details on classification and labelling. Actually, only two types of RCF both differing by the amount of zirconium dioxide are on the market and therefore an additional dossier is submitted for the other fibre type. Therefore, this classification of the substance in Regulation (EC) No 1272/2008 shows that the substance meets the criteria for classification as carcinogen in accordance with Article 57 (a) of REACH.

6.3 Substances of equivalent level of concern assessment.

Not relevant for the identification of the substance as SVHC in accordance with Article 57(a).

⁸ Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

REFERENCES

- Chiazze, L., Watkins, D.K. and Fryar, C. (1997): Historical cohort mortality study of a continuous filament fibreglass manufacturing plant. I. White men. *J. occup. environ. Med.*, 39, 432–441
- Glass, L.R., Brown, R.C., and Hoskins, J.A (1995): Health effects of refractory ceramic fibres: scientific issues and policy considerations. *Occup. Environ. Med.*, 52; 433-440
- IARC (2002): IARC monographs on the evaluation of carcinogenic risks to humans. Man-made vitreous fibres, Lyon, IARC Press Vol.81
- Lemasters G.K.; Lockey J.E.; Yiin J.H.; Hilbert T.J.; Levin L.S. and Rice, C.H. (2003): Mortality of workers occupationally exposed to refractory ceramic fibres. *J. Occup. Environ. Med.* 45, 440-450
- Lemasters, G.K., Lockey, J., Levin, L., Yiin, J., Reutman, S., Papes, D. and Rice, C. (2001): A longitudinal study of chest radiographic changes and mortality of workers in the refractory ceramic fibre industry (Abstract at the 2001 Congress of Epidemiology) (Abstract No. 986). *Am. J. Epidemiol.*, 153 (Suppl. 264)
- Mast, R. W., McConnell, E. E., Anderson, R., Chevalier, J., Kotin, P., Bernstein, D. M., Thevenaz, P., Glass, L. R., Miiller, W. C. and Hesterberg, T. W. (1995a): Studies on the Chronic Toxicity (Inhalation) Of Four Types of Refractory Ceramic Fibre in Male Fischer 344 Rats, *Inhalation Toxicology*, 7 (4), 425-467
- Mast, R.W., McConnell, E.E., Hesterberg, T.W., Chevalier, J., Kotin, P., Thévenaz, P., Bernstein, D.M., Glass, L.R., Miiller, W.C. and Anderson, R. (1995b): Multiple-dose chronic inhalation toxicity study of size-separated kaolin refractory ceramic fibre in male Fischer 344 rats. *Inhal. Toxicol.*, 7, 469–502
- Walker, A.M., Maxim, L.D. and Utell, M. (2002): Risk analysis for mortality from respiratory tumors in a cohort of refractory ceramic fibre workers. *Regul. Toxicol. Pharmacol.* 35, 95-104

ABBREVIATIONS

AMD	Arithmetic Mean Diameter
AML	Arithmetic Mean Length
CAS	Chemical Abstract Service
CMR	Carcinogen, Mutagen, toxic for Reproduction
GHS	Globally Harmonized System of Classification and Labelling of Chemicals
GMD	Geometric Mean Diameter
GSD	Geometric Standard Deviation
GML	Geometric Mean Length
IARC	International Agency for Research on Cancer
MMVF	Man-Made Vitreous Fibres
RCF	Refractory Ceramic Fibre (aluminium silicate wool)
SD	Standard Deviation
SVF	Synthetic Vitreous Fibres
TWA	allowable time-weighted average concentration for a normal 8-hour workday or 40-hour week to which a person can be repeatedly exposed for 8 hours a day, day after day, without adverse effect