Annex XV dossier

PROPOSAL FOR IDENTIFICATION OF A SUBSTANCE AS A CMR CAT 1A OR 1B, PBT, vPvB OR A SUBSTANCE OF AN EQUIVALENT LEVEL OF CONCERN

Substance Name(s): **Zirconia Aluminosilicate Refractory Ceramic Fibres**

EC Number(s): **-**

CAS Number(s): **-**

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CONTENTS

TABLES

FIGURES

PROPOSAL FOR IDENTIFICATION OF A SUBSTANCE AS A CMR CAT 1A OR 1B, PBT, VPVB OR A SUBSTANCE OF AN EQUIVALENT LEVEL OF CONCERN

Substance Name(s): Zirconia Aluminosilicate Refractory Ceramic Fibres

EC Number(s): -

CAS number(s): -

- The substance is proposed to be identified as substance meeting the criteria of Article 57 (a) of Regulation (EC) 1907/2006 (REACH) owing to its classification as carcinogen 1B[1] which corresponds to classification as carcinogen category 2[2].

Summary of how the substance meets the CMR (1A or 1B) criteria

Man-made vitreous (silicate) fibres with random orientation and with alkaline oxide and alkali earth oxide (Na_2O+K_2O+CaO+MgO+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 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.

Registrations received for this substance

yes

1 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.

2 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).

PART I

JUSTIFICATION

In 2009 an Annex XV Dossier has been submitted to identify zirconia 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 and also zirconium 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 zirconia aluminosilicate refractory ceramic fibres were included in the Candidate List[3].

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, silicon dioxide and zirconium oxide. 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

Zirconia aluminosilicate refractory ceramic fibres belong to the group of the refractory ceramic fibres (RCF[4]). 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 zirconia aluminosilicate RCF those are Al_2O_3, SiO_2 and ZrO_2 in variable concentrations.

Generally, four types of RCF are being distinguished. The present document deals with type 2 RCF, which are the zirconia aluminosilicate refractory ceramic fibres.

RCF 1 are kaolin-based ceramic fibres and RCF 3 are high-purity fibres. In the sense of the guidance document for identification and naming of substances under REACH the fibres RCF 1, RCF 3 and RCF 4 are covered by one common definition of substance namely “aluminosilicate RCF” with the two

[3] http://echa.europa.eu/chem_data/authorisation_process/candidate_list_table_en.asp

[4] Abbreviations are summarized and explained at the end of the dossier

starting materials SiO_2 and Al_2O_3. For this type of fibres 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.

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[5] are presented in the table below [Mast et al., 1995 a].

Table 1: Physical size characteristics of stock zirconia aluminosilicate RCF

	RCF 2
	Stock fibre[a]
Diameter range (µm)	0.12 - 3.21
Length range (µm)	1.2 - 54.5
AMD ± SD (µm)	1.14 ± 0.8
AML ± SD (µm)	21.8 ± 17.2
GMD ± GSD (µm)	0.91 ± 1.99
GML ± GSD (µm)	14.6 ± 2.7
Median diameter ± SD (µm)	0.86 ± 0.11
Median length ± SD (µm)	15.9 ± 3.1

[a]number of samples analyzed = 3

5 RCF fibres as they derive from production

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:	zirconia 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:
Zirconia aluminosilicate RCF are fibrous, inorganic, vitreous materials formed by high temperature fusion of sources of silica, alumina and zirconia into a mass which is cooled to a rigid condition without crystallization and formed into fibres. The silicon, aluminium and zirconium oxides are present in glassy matrix in variable concentrations.

Other oxides like potassium oxide (< 0.01 %), sodium oxide (< 0.3 %), magnesium oxide (0.01 %), calcium oxide (< 0.05 %), titanium oxide (0 04 %), iron oxide (< 0.05 %) and chromium oxide (< 0.01 %) are sometimes added to change the fibre properties.

Annex VI entry of Regulation (EC) No 1272/2008 focuses on a content of Na_2O+K_2O+CaO+ MgO+BaO less or equal to 18 % by weight. The content of the alkaline and alkaline earth oxides is lower than 1 %. That means that the condition for these substances to be classified as Carc. Cat 2, R49 according to Directive 67/548/EEC (or Carc. 1B according to Regulation (EC) No 1272/2008 respectively) is fulfilled.

Therefore, the substance zirconia aluminosilicate refractory ceramic fibres (SiO_2, Al_2O_3, ZrO_2) as described in this document are 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: zirconia 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

Constituents	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	
zirconium dioxide, EC no. 215-227-2	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 zirconia aluminosilicate RCFs no specific data are available. The physicochemical properties listed in Table 6 belong to RCFs in general:

Table 6: Overview of physicochemical properties[6]

Property	Value	Remarks	Reference
Physical state at 20℃ and 101.3 kPa	White fibrous solid		[Mast et al., 1995]
Melting/freezing point	1740 – 1800 ℃		[Glass et al., 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		

6 *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 tables 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 1 and RCF 3 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)	Suppl. 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_2O+K_2O+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; [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. Cat. 2; R49	T R: 49 S: 53-45		AR

3 ENVIRONMENTAL FATE PROPERTIES

4 HUMAN HEALTH HAZARD ASSESSMENT

4.1 Toxicokinetics (absorption, metabolism, distribution and elimination)

Not relevant

4.2 Acute toxicity

Not relevant

4.3 Irritation

Not relevant

4.4 Corrosivity

Not relevant

4.5 Sensitisation

Not relevant

4.6 Repeated dose toxicity

Not relevant

4.7 Mutagenicity

Not relevant

4.8 Carcinogenicity

4.8.1 Non-human information

Not relevant

4.8.2 Human information

The following text is taken from IARC monograph, volume 81 [IARC, 2002] which describes the available epidemiological data:

"The results of studies on mortality among workers in the refractory ceramic fibre industry have also been published since the last IARC Monograph. However, the epidemiological data for refractory ceramic fibres are still very limited. Radiographic evidence indicating pleural plaques has been reported for refractory ceramic fibres workers. Although the prognostic significance of pleural plaques is unclear, such plaques are common in workers exposed to asbestos.

[…]

Cohort study

A cohort study of workers at two plants in the USA that produced refractory ceramic fibres included 927 male workers employed for one year or more between 1952 and 1997. The mortality data were presented in a conference abstract [Lemasters et al., 2001] and in a paper addressing risk analysis [Walker et al., 2002]. The estimated exposure ranged from 10 fibres/mL (8-h TWA) in the 1950s to < 1 fibre/mL in the 1990s. No significant increase in cancer mortality was reported. [The Working Group noted that neither the observed nor the expected numbers of cancers other than lung cancer were given.] Six deaths from lung cancer were observed versus 9.35 expected, SMR, 0.64 (95% CI [0.24–1.27]). No cases of mesothelioma were observed. [The Working Group noted that the details of cohort definition and period of follow up were not clear, and there was no analysis of risk in relation to time since first exposure or exposure surrogates. The small number of study subjects, especially those with adequate latency, limits the informativeness of the study.]

Case–control study

A case–control study including 45 men with lung cancer and 122 controls was nested within a cohort of 2933 white men employed in a plant manufacturing continuous glass filament [Chiazze et al., 1997]. Exposure to respirable glass fibres, asbestos, refractory ceramic fibres (used at the plant for high-temperature heat insulation, but not manufactured there), and a number of other sources of exposure was assessed by a procedure of reconstruction of historical exposure conditions. The risk of lung cancer was lower in workers exposed to a cumulative dose of refractory ceramic fibres of 0.01–1 fibre/mL–days (odds ratio, 0.36 (95% CI, [0.04–3.64]); 1 case), and those exposed to 1-40 fibres/mL–days (odds ratio, 0.30 (95% CI, [0.11–0.77]); 7 cases), than in workers not exposed to fibres. The odds ratios were not adjusted for exposure in the workplace to other fibres or for tobacco smoking, but the trends in odds ratios were similar when the analysis was restricted to smokers. [The Working Group noted that exposure to refractory ceramic fibres may have been difficult to separate from other sources of exposure in the workplace in view of the small number of cases and the large number of sources of exposure.]

[…]

There is inadequate evidence in humans for the carcinogenicity of refractory ceramic fibres."

Note: The mortality data presented in a conference abstract [Lemasters et al., 2001] and in a paper addressing risk analysis [Walker et al., 2002] were published as full paper in 2003 [Lemasters et al., 2003]. This paper could not be referenced by IARC [2002]. In [Lemasters et al., 2003], a statistically significant association with cancers of the urinary organs with a standardized mortality ratio of 344.8 (95% CL of 111.6, 805.4) was reported. On the basis on mode of toxicological action (the fibre principle) this effect cannot be plausibly explained by exposure to refractory ceramic fibres.

4.8.3 Summary and discussion of carcinogenicity

Not relevant

4.9 Toxicity for reproduction

Not relevant

4.10 Other effects

Not relevant

5 ENVIRONMENTAL HAZARD ASSESSMENT

Not relevant

6 CONCLUSIONS ON THE SVHC PROPERTIES

6.1 PBT, vPvB assessment

Not relevant

6.2 CMR assessment

Fibres with a content of 18 % of weight or less of Na_2O+K_2O+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 1272/2008[7] - 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

[7] 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.

PART II

INFORMATION ON USE, EXPOSURE, ALTERNATIVES AND RISKS

INFORMATION ON MANUFACTURE, IMPORT/EXPORT AND USES –CONCLUSIONS ON EXPOSURE

According to the registration dossiers provided in 2011 the described exposure assessment based on registration information is not very different compared to the assessment provided in the annex XV dossier of zirconia aluminosilicate refractory ceramic fibres, submitted to ECHA in 2009. Therefore the exposure assessment part of this dossier was maintained.

Refractory ceramic fibres, RCF are amorphous synthetic vitreous fibres (SVF) produced from melting and spinning/blowing calcined kaolin or a mixture of alumina (Al_2O_3) and silica (SiO_2). The basic composition of refractory ceramic fibres has not changed appreciably since their initial formulation in the 1940s, but modifications to the composition such as raising the content of alumina and the addition of other oxides, such as ZrO_2 or TiO_2 are sometimes added to alter the properties of the material, f. e. to create fibres that tolerate higher maximum end-use temperatures.

Production and uses of RCF products

An overview about percentage distribution of the RCF-applications in Europe is given in Table 9 [Wimmer, 2002].

Table 9: Percentage distribution of RCF-applications in Europe

Application	Percentage
Furnace Insulation	66.7 %
High Temperature Insulation	5 %
Automotive	8 %
Metal Treatment	8 %
Fire Protection	2 %
Appliance	0.3 %

The largest single use of RCF is for furnace linings and related applications; accounting for approximately 67 % of consumption.

The global production of RCF amounts to about 150 000 - 200 000 tonnes [NAIMA/EURIMA, 2001], the production of RCF in the EU was 50 000 tonnes, undertaken by three companies in 1999 [ECFIA, 1999], and has been reduced to 25 000 tonnes in 2008 [Wimmer, 2008].

Occupational exposure

It is estimated that in the United States approximately 30 000 workers are exposed to RCF in manufacturing, processing, or end-uses [Maxim, 2008].

The European Chemical Fibre Industry Association (ECFIA) estimates that the workforce dealing with RCF in Europe amounts to approximately 25 000 employees.

The conversion of RCF into other processing forms (boards etc.) is performed by numerous independent companies (convertors). The breakdown by industry segments is shown in Table 10 [ECFIA, 1999].

Table 10: Workforce dealing with RCF in Europe

Industry segment	Basis for estimate	Total number of employees	Estimation of exposure duration
Primary production	ECFIA member companies	750	Regularly
Convertors	35 major companies, 10 employees 100 minor companies, 5 employees	350 500	Regularly Regularly
Distributors / Agents	50 companies, 5 employees	250	No
Installation contractors	150 companies, 10 employees	1500	Sporadically
End users	700 major companies, 10 employees 2800 minor companies, 5 employees	7000 14000	Sporadically Sporadically

The RCF production process consists of blowing an air stream on the molten material flowing from an orifice at the bottom of the melting furnace (blowing process) or by directing the molten material onto a series of spinning wheels (spinning process). Both methods are known by the generic name “melt fibreisation process”. The bulk fibre can be further processed to blankets, which may be needled to improve handling of the material. The bulk material can also be converted into several types of products. Using processes similar to those in the paper industry, bulk can be processed into boards, shapes, felts and papers. It can also be used for textiles and mixed into cements and putties. Blankets are often used directly, (e.g. as a furnace insulation material), but is also converted into modules used for furnace lining, gaskets and other products or articles.

Processing and handling of RCF can be classified into eight major functional job categories: fibre manufacturing, mixing/forming, finishing, assembly, installation, removal, auxiliary operations, others (NEC) [Maxim et al, 2000]. In Table 11 the functional job categories are characterised.

Table 11: Characterisation of functional job categories in relation to workplace exposure [ECFIA, 1999]

Industrial Group	Functional job category	Description	Workplace concentration [f / mL; geometric mean]*
Primary production	Fibre Production	all jobs on lines producing bulk or blankets	0.17
Secondary production	Mixing-Forming	wet-end production of vacuum-cast shapes, boards, felt, paper; includes mixing RCF putties, compounds or castables	0.26
Secondary production	Finishing:	cutting or machining RCF material after fibre manufacture	0.58
Secondary production	Assembly	combining or assembling RCF material with other material	0.31
Furnace related uses (Installation / Removal)	Installation	building or manufacturing at end-user locations industrial furnaces or boilers, refinery or petrochemical plant equipment, kilns, foundry equipment, electric power generators; includes furnace maintenance.	0.46
Furnace related uses (Installation / Removal)	Removal	removal of after-service RCF from an industrial furnace etc	0.98
Other uses	Auxiliary	jobs in which employees may be passively exposed	0.13
Other uses	Other	not covered in any of the foregoing category	0.09

* European Care Programme: August 1996 - July 1998; CARE: "Controlled and Reduced Exposure": workplace control methods and monitor personal concentrations of fibrous dust. Workplace monitoring was carried out using the WHO-EURO method (German method ZH1/120.31). Personal samplers are used to measure concentrations in the workers' breathing zone. Fibre counting was done by using phase-contrast optical microscopy (PCOM) in accordance with WHO counting rules. Average concentrations were recorded for the monitoring period (from 50 to 500 min.) and reported as Actual Time-Weighted Averages (ATWA) In the first two years of the CARE programme, a total of 1442 ATWA measurements were made.

Table 12 shows measured workplace concentrations for the four industrial groups. Since the concentrations are log-normally distributed, both the geometric and arithmetic means are given. The ATWA *(Actual Time-Weighted Averages)* values reported correspond to concentrations averaged over the monitoring period. Time profiles were not established. Instantaneous concentrations can obviously be higher or lower than the mean.

Table 12: Average concentration of fibrous dust in the industrial groups producing or using refractory ceramic fibres

Industrial group	Mean arithmetic [f/mL]	Mean geometric [f/mL]	Min. [f/mL]	Max. [f/mL]	Average duration [minutes]	Number of observations
Primary production	0.23	0.13	<0.01	1.82	411	420
Secondary production	0.61	0.36	0.01	5.60	356	593
Furnace removal/ Installation	2.71	0.62	<0.01	53.6	244	100
Other uses	0.31	0.16	0.01	5.28	283	240

The ladder diagram shown in Figure 1 presents the distributions of ATWAs in the four industrial groups [ECFIA, 1999].

In Germany, a concept has been established to quantify cancer risk for workers after exposure to carcinogens in order to derive appropriate workplace measures [AGS, 2008]. Currently, working life time cancer risks shall range between 4:1000 (tolerance level) and 4:10 000 (acceptance level) while exposures are aimed to approach the acceptance level. According to this concept, the tolerance level range for refractory ceramic fibres lies between $62.5 * 10^{-3}$ - $93.0 * 10^{-3}$ fibres/mL (see Table 17) and the acceptance level would be one order of magnitude lower, i.e. roughly 0.1 fibres/mL (tolerance level) and 0.01 fibres/mL (acceptance level), respectively. In 2018, it is planned to lower the acceptance level to a cancer risk of 1:100 000.

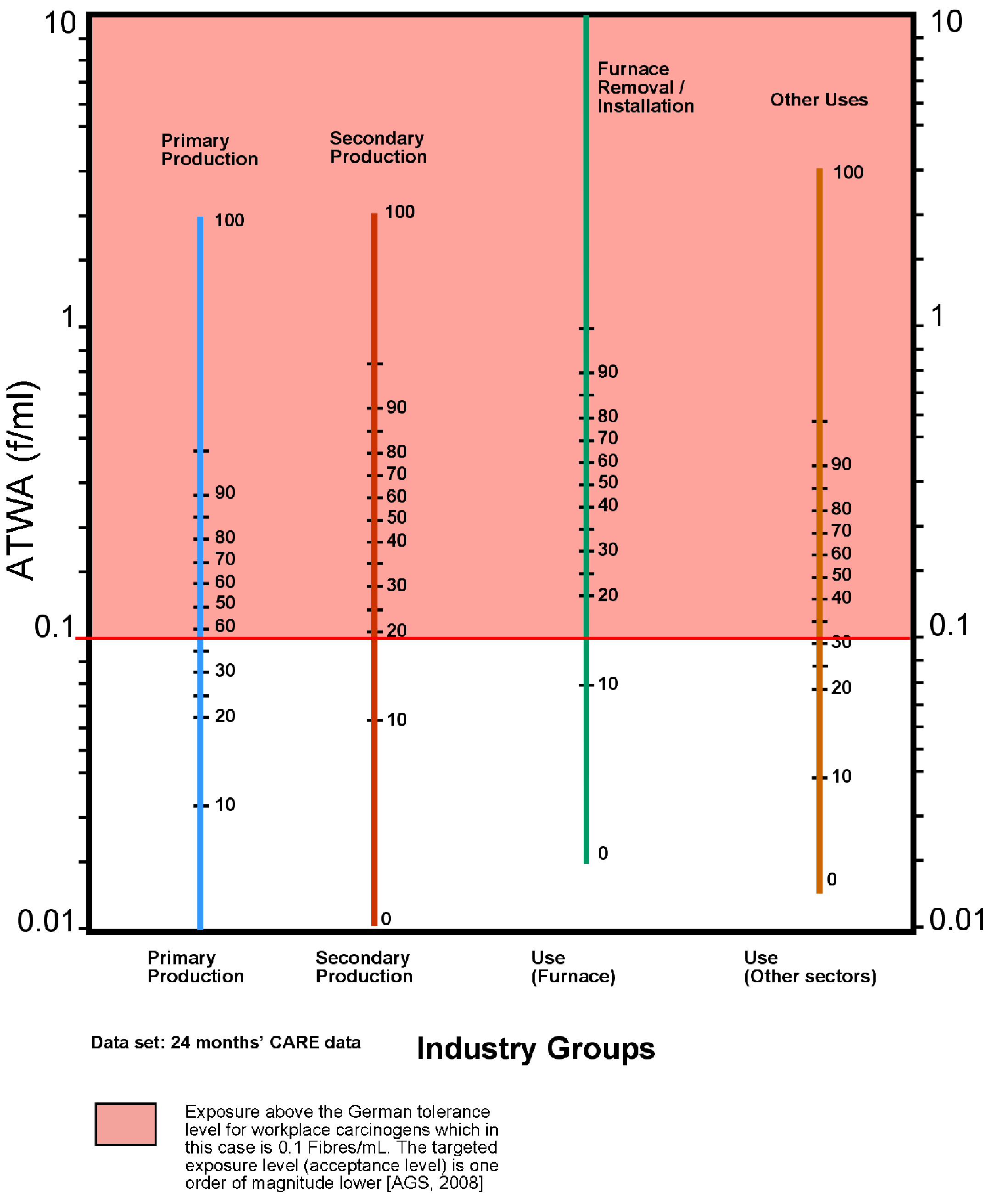

Figure 1: Ladder diagram showing proportion (%) of concentrations of ATWAs in each industrial group [ECFIA, 1999].

Dermal irritation caused by RCF is not due to a chemical reaction with the skin or body fluids, but rather is a temporary mechanical irritation caused by fibre morphology (the physical size and shape of the fibres). Sensitivity to mechanical fibre irritation tends to decrease over time. It is known that SVF (synthetic vitreous fibre) irritation is directly related to fibre size and the degree of exposure [Stam-Westerveld et al., 1994].

<u>Consumer exposure</u>

RCF use in articles is not restricted by European law and not affected by labelling requirements of Regulation (EC) No 1272/2008.

RCF may be used in electrical and domestic appliances, like glass ceramic hobs, electric ovens, electric grills, microwave ovens, in gas-fired apparatus or other devices with “open” flames and in kilns (for enamels, ceramics, or clay) for leisure and hobby use. RCF use in electrical and domestic appliances has been reduced from 20% of the total European production in 1994 to 0.3% in 2008 [Supplementary Text to Notification 2004/370/D, Wimmer, 2008].

In construction products for fire protection, RCF are used for seals for fireproof glazing (fire protection windows and doors) and in insulating materials that create foam in the event of fire. Since 1998, ceramic fibres in this field have increasingly been replaced by high-temperature glass fibre. [Supplementary Text to Notification 2004/370/D]

RCF are used in the construction of motor and other vehicles and their use in the automotive industry accounts to 8% of the European production volume. [Wimmer 2008]. In these applications, it is not possible to absolutely exclude the possibility of the vehicles’ users being exposed. According to the manufacturers, newly introduced friction coatings like brake pads no longer contain fibres classified as carcinogens in Category 2. [Supplementary Text to Notification 2004/370/D]. In the context of a petition to the European Parliament on RCF from catalytic converters, the Commission has called on the automobile industry to provide scientific data on release into the environment of inorganic ceramic fibres from catalytic converters during their use. [European Parliament, 2007]

Data on consumer exposure to RCF from imported articles are lacking.

CURRENT KNOWLEDGE ON ALTERNATIVES

<u>Alternative substances</u>

In principle the replacement of aluminium silicate wool is possible for a wide range of applications. In domestic appliances, products for fire protection and for automotive engineering substitutes for aluminium silicate wool are already widely used.

Further attention should also be directed to products essentially used for thermal insulation in furnace and firing system construction, in heating installations and exhaust gas systems for motor vehicles, especially at application temperatures above 900 °C. For such applications descriptive profiles for selecting a substitute already exist [TRGS 619, 2007].

Substitutes with a lower health risk include both fibrous and fibre-free refractory products.

Fibrous products for application in the temperature range to 300 °C generally comprise glass and mineral wools. For the temperature range from 300 °C to approx. 600 °C, mineral wools or alkaline earth silicate (AES) wools can be used depending on the specific requirements of the application. From 600 °C to approx. 900 °C, generally AES wool products can be used.

Above 900 °C to max. 1200 °C, the possibility for using AES wool products may be reduced owing to technological constraints. This temperature range is the main application range for aluminium silicate wool products. On the other hand current product developments indicate that the upper temperature limit of AES wool products could be increased significantly.

Non-fibrous substitutes are refractory materials such as calcium silicate or vermiculite panels and mouldings, thermal insulation bricks and concretes, lightweight refractory bricks and concretes, thermal insulation refractory compounds and other non-fibrous products that meet the application requirements as substitute products.

In conclusion, there are several possible substitutes for aluminium silicate wool products on the market depending on the temperature range of application.

RISK-RELATED INFORMATION

The information provided in this Annex XV document is focused on the most critical endpoint, which is carcinogenicity after inhalation.

Carcinogenicity

Length, diameter, and biopersistence are the main determinants of the carcinogenic activity of fibres. This concept is called the fibre principle [Pott & Friedrich, 1972; Stanton & Wrench, 1972]. It was further specified by development of criteria for characterisation of the subset of fibres most relevant for mediation of carcinogenicity subsumed under the term “WHO fibres”. WHO fibres are any particle that has a length greater than 5 µm, a fibre diameter less than 3 µm and a length : diameter ratio larger than 3:1. This definition was initially established to characterise asbestos fibres. The use of this terminology also makes sense for RCF fibres as fibres with a diameter of > 3 µm will not be inhaled any more. The different chemical composition of the commercially relevant types of refractory ceramic fibres does not have an impact on their dimension and biopersistence. Thus, the risk-related information given below does not discriminate between different types of fibres.

Inhalation

Epidemiological studies

An IARC working group concluded in 2002 that there is inadequate evidence in humans for the carcinogenicity of refractory ceramic fibres as no elevated incidences of lung tumours or mesothelioma could be found in the exposed individuals [IARC, 2002]. The cumulative exposure to refractory ceramic fibres (RCF) in the only cohort study available showed a median of 12.1 fibre-months and an average of 45.3 fibre-months (roughly 4 fibre-years, i.e. 4 fibres/mL/yr) [Walker et al., 2002]. Pulmonary pleural plaques but no increase in lung cancer or mesothelioma had been reported in this study. Although the prognostic significance of pleural plaques is unclear, such plaques are common in workers exposed to asbestos.

In summary, from the negative epidemiological studies with refractory ceramic fibres (also see section 5.8.4 of this document) it is not possible to derive cancer or mesothelioma risk estimates.

Animal studies

Refractory ceramic fibres (RCF) were shown to cause lung cancer in chronic inhalation studies in rats and mesothelioma in Syrian hamsters [Davis et al., 1984; Mast et al., 1995 a, b; McConnell et al., 1995; Smith et al., 1987].

Due to the following reasons these studies were not deemed adequate for the derivation of cancer or mesothelioma risk estimates for RCF:

1. The fibre samples used in all the chronic inhalation studies had relevant portions of non-fibrous particles (50 - 75% related to numeric comparison). These particles were postulated to have an influence on lung carcinogenicity. Thus, it is not clear which portion of lung tumours in the chronic inhalation studies is assignable to fibre exposure.
2. Moreover, there is scientific controversy on the point whether the rat is a sensitive species for the detection of inhalative fibre carcinogenicity [Muhle and Pott, 2000; Maxim and McConnell, 2001].
3. Non-fibrous granular particles do not induce mesothelioma. Thus, it could seem plausible to use the data from the RCF inhalation study with hamsters to derive cancer risk estimates. However, this study had used only one exposure concentration so that it is not suitable for dose-response and potency analysis. Moreover, the data with various other carcinogens show that the Syrian hamster does not seem to be a valid model for inhalation carcinogenicity [Mauderly et al., 1997].

Intraperitoneal (ip) application:
carcinogenic potency of crocidolite asbestos vs refractory ceramic fibres

Bernstein et al. [2001a, b] published a comparative analysis of the available data from studies with synthetic mineral fibres that used intraperitoneal injection, chronic inhalation and measures of biopersistence. These authors came to the conclusion that the studies that used intraperitoneal injection provide a ranking comparable to that obtained in studies of carcinogenicity following chronic inhalation of fibres of similar biopersistence and length.

Based on this conclusion, the strategy to derive risk-related information for the inhalation carcinogenicity of refractory ceramic fibres is to compare the potencies of RCF to asbestos fibres in the intraperitoneal test. The information obtained from this cancer potency comparison will be used to relate the quantitative risk derived from asbestos epidemiology to the cancer risk of refractory ceramic fibres.

To ensure an optimum comparability of intraperitoneal tests with respect to potency assessment the following parameters have to be taken into account: fibre biopersistence, dimension and dose. In contrast to serpentine asbestos, refractory ceramic fibres tend to break transversely rather than cleaving along the fibre axis. The behaviour to cleave along the fibre axis is associated with the fact that numerous new fibres are being generated intraperitoneally, which may increase the dose and have an impact on the test outcome. Thus, only results from ip tests with amphibole asbestos (i.e. crocidolite), which does not cleave along the fibre axis, were used to assess the comparative carcinogenic potency of asbestos and refractory ceramic fibres.

Table 13 contains data from the ip studies which were used to derive potency information. Benchmark doses for a 10 % incidence of cancer (BMD_{10}) and the T_{10} value were calculated. The T_{10} value represents the dose causing a 10 % incidence of cancer derived according to the T_{25}

concept which is based on linear extra-/interpolation [Dybing et al., 1997]. The BMD calculation is based on the US EPA benchmark dose software (BMDS), the preferred basis for derivation was the multistage or the gamma models [US EPA, 2008]. As there was no evidence for a sex-dependent susceptibility, data from male and female rats of the similar treatment groups were pooled. Granular silicon carbide (SiC) did not induce mesothelioma and these data were pooled with the controls.

Table 13: Injected number of fibres and tumour incidence (crocidolite vs refractory ceramic fibres (RCF))

Treatment	Dose	Animals		Lenth (µm)[a]	Dia-meter (µm)[a]	Fibre definition	Reference
	[Fibres * 10^9]	No.	Tumours[d]				
Control NaCl[b]	0	433	2	-	-	L > 5 µm D < 3 µm L/D > 3/1	[Roller et al. 1996]
Crocidolite[b]	0.042	273	170	1.4	0.19		
Control NaCl	0	102	2	-	-	L > 5 µm D < 3 µm L/D > 5/1	[Pott et al. 1989]
Ceramic Fibrefrax (RCF)	0.15	47	33	13	0.89		
Ceramic MAN (RCF)	0.021	54	12	16	1.4		
Control NaCl	0	32	2	-	-	L > 5 µm D < 2 µm L/D > 5/1	[Pott et al. 1987]
Crocidolite (SA)[c]	0.042	32	18	2.1	0.20		
	0.169	32	28	2.1	0.20		
Control NaCl	0	84	2	-	-	L > 5 µm D < 2 µm L/D > 5/1	[Pott et al. 1991]
Ceramic Fibrefrax II (RCF)	0.021	36	17	13.1	0.84		
	0.069	36	29	13.1	0.84		
Ceramic Manville (RCF)	0.009	36	6	16.4	1.35		
Ceramic Fibrefrax I (RCF)	0.029	35	15	5.5	0.47		

[a] median value;
[b] including treatment with granular SiC;
[c] data for injected fibre numbers and fibre definition: personal communication Dr. Roller, February 6th,.2008;
[d] histologically proven, primary epitheloid and sarcomatous mesothelioma in Roller et al. 1996; described in Pott et al. 1989, 1987, 1991 as mesothelioma and sarcoma (casually histologically proven carcinoma were included as treatment-related).

In Table 14, the results of the BMDS analyses where the best fits were obtained are shown, T_{10} values are given in parallel. In case where there were similar fibre dimensions, results for refractory ceramic fibres were combined. It was assured during the evaluation that this combination did not have a relevant impact on the results. It can be seen that the potency indicators BMD_{10} and the T_{10} values are rather similar for crocidolite and RCF ranging between 0.0047 to 0.0079*10^9 fibres.

Table 14: BMD_{10} and T_{10} values (for fibre definition see Table 13)

Type of fibre	Length [µm][a]	Diameter [µm][a]	$BMD_{10} \times 10^9$	$T_{10} \times 10^9$	Ref.
Crocidolite	1.4	0.19	-[b]	0.007	[Roller et al. 1996]
Crocidolite	2.1	0.20	0.007	0.0079	[Pott et al. 1987]
Refractory ceramic fibres	5.5	0.47	-[b]	0.007	[Pott et al. 1991]
Refractory ceramic fibres	~ 14	~ 1.0	0.0047	0.006	[Pott et al. 1989; 1991]

[a] median value
[b] no BMD calculation possible, either only 1 dose tested or inadequate curve fit

<u>Fibre dimension at workplaces vs. fibres used in the experiments with intraperitoneal application</u>

The data described in Table 15 compare the fibre dimensions found at workplaces to fibre dimensions used in the experiments with intraperitoneal applications. The data are taken from Rödelsperger and Woitowitz [1993] and IARC [2002]. The crocidolite samples tested intraperitoneally were by trend thicker but had a similar length when compared to the workplace samples. The RCF samples tested ip tended to be more slim but in the length range typical for workplaces. These differences are such that the samples tested intraperitoneally can be considered as representative for fibres found at workplaces.

Table 15: Comparison of the fibre dimensions found in workplace atmospheres and the fibres used in the experiments with intraperitoneal application

	Diameter [µm]		Length [µm]	
Type of fibre	workplace	experiment	workplace	Experiment
Crocidolite (SA)	0.075 - 0.12[a]	0.19[a]	0.9 - 1.7[a]	1.4[a]/2.1[a]
RCF	0.84 - 1.2[b]	0.47[a]/~ 1.0[a]	11 - 19[b]	5.5 [a] /~14[a]

[a] median value
[b] geometric mean

<u>Human cancer risk estimates for asbestos fibres</u>

Asbestos is a collective name given to fibrous minerals that occur naturally as fibre bundles. Two basic mineral groups -serpentine and amphibole- contain asbestos minerals. Actinolite, Amosite, Anthophyllite, Crocidolite, and Tremolite are amphiboles. Chrysotile is a serpentine asbestos.

Elevated risks for lung tumours and mesothelioma are statistically significant associated with exposure to asbestos, a causal relationship is scientific consensus. Malign mesothelioma are rare and very clearly assignable to exposure to asbestos. The epidemiological literature related to the forms of asbestos which have technical significance is extensive and includes quantitative risk assessments. One report was published in 1991 by the Health Effects Institute - Asbestos Research (HEI-AR) comprising and analyzing the relevant data available by that time [HEI-AR, 1991].

Further similar analyses are available [US EPA, 2008; OSHA, 1999; Hodgson & Darnton, 2000]. All these analyses estimated rather similar average cancer risk estimates for cumulative exposures to asbestos. In all these analyses, similar models for the exposure-cancer risk relationship were applied and it was generally differentiated between lung cancer and mesothelioma in the mathematical modelling. This is mainly caused by the different background rates of lung cancer and mesothelioman the general population. One difference in the analysis published by Hodgson & Darnton [2000] is that the variability in cancer risks found in the different epidemiological studies was assigned to variable carcinogenic potencies of different forms of asbestos.

Table 16 shows an extract from table 6-3 given in HEI-AR [1991]. The maximum exposure duration which is given in HEI-AR [1991] is 20 years. This scenario is taken as a basis for cancer risk estimation of the total working life, i.e. 40 years of workplace exposure, roughly between the 20^{th} and the 60^{th} year of lifetime.

Table 16: Results for the absolute lifetime cancer risk (up to the age of 80)

Age at start of exposure	Tumour type	Excess lifetime risk, exposure 0.0001 fibre/mL (calculated until the age of 80)	
		Exposure 5 years	Exposure 20 years
20 years	Lung cancer	0.3 / 1000000	1.3 / 1000000
	Mesothelioma	0.3 / 1000000	0.9 / 1000000
	Sum	0.6 / 1000000	2.2 / 1000000

The HEI-AR data are related to a very low exposure concentration. As there is no data available justifying a deviation from a linear risk extrapolation for the cumulative human exposures both for lung cancer as well as for mesothelioma a linear exposure-effect relationship was taken as basis to extrapolate to higher exposure. For 20 years of exposure to asbestos to an average workplace concentration of 0.1 fibre/mL, i.e. a cumulative exposure of 2 fibre-years a cancer risk of 2.2 to 1000 results. Basically, table 12 is only related to a 20-year exposure. This is due to the theoretical model on which mesothelioma induction is based. According to this model exposure duration and level are mathematically not equally weighted. Taking into account this mathematical background the difference to 40 years of exposure to 0.1 fibre/mL is not substantial which could be mathematically demonstrated. Thus, cumulative exposures to asbestos estimate an excess lifetime cancer risk (sum of lung cancer and mesothelioma) in humans of 4.3 % assuming a working lifetime exposure to 1 fibre/mL, i.e. 40 fibre-years [HEI-AR, 1991].

It should be noted that these risk estimates were derived from different studies and different types of asbestos and exposures were mainly determined by light microscopy. In case of estimating potencies for specific different types of asbestos, the risk estimate given above is an underestimate for the amphibole asbestos crocidolite which is deemed to possess a higher carcinogenic potency than chrysotile asbestos.

Exposure-risk comparison: crocidolite vs RCF on the basis of the BMD_{10} - / T_{10} - relationship

When comparing asbestos fibres and refractory ceramic fibres it has to be taken into account that asbestos fibres are generally thinner and shorter. As a consequence, the portion of fibres which are too small to be visible by light microscopy is higher for asbestos fibres than it is for refractory ceramic fibres. A comparative analysis came to the conclusion that the difference in fibre detection rate varies by a factor of 4 when comparing the results of light microscopy and transmission electron microscopy [Riedinger, 1984]. However, the percentage of fibres detected by light microscopy is not generally constant. According to more recent results the number of chrysotile fibres detected by transmission electron microscopy was twice as high when compared to WHO fibres detected by light microscopy [Dement et al., 2008; Stayner et al., 2008].

As a consequence, in case of comparing asbestos and RCF fibre quantifications carried out by light microscopy the cancer risk of RCF may be overestimated. However, it has to be taken into account that the human cancer risk estimate for asbestos is an average value obtained from various forms of asbestos and numerous epidemiological studies. All these uncertainties cannot be quantified exactly but they lie within one order of magnitude. They are neither additive nor multiplicative but will more or less outweigh each other. Thus, no additional safety factor was applied in the potency comparison between asbestos and RCF. Table 17 shows the results of the comparison of cancer risk estimates (sum of lung cancer and mesothelioma) of crocidolite and RCF. The superfine RCF show a cancer risk estimate similar to crocidolite, the calculated risk estimate for RCF is slightly higher.

Table 17: Risk calculation for WHO fibres on the basis of the BMD10 - / T10 –relationship and the resulting air concentrations.

Type of fibre	BMD_{10} / T_{10} [f x 10^9]	Factor cf. crocidolite	risk per 40 fibre-years	Cancer risk 4:1000 [f / mL]	Cancer risk 4:10 000 [f / mL]
Crocidolite	0.007	1.0	4.3 : 100	93.0 * 10^{-3}	9.30 * 10^{-3}
RCF (superfine)	0.007	1.0	4.3 : 100	93.0 * 10^{-3}	9.30 * 10^{-3}
RCF	0.0047	0.67	6.4 : 100	62.5 * 10^{-3}	6.25 * 10^{-3}

In conclusion, the comparative analysis performed in the present paper shows that refractory ceramic fibres possess a carcinogenic potency (sum of lung cancer and mesothelioma) which is similar to (crocidolite) asbestos.

In Germany, a concept has been established to quantify cancer risk figures for workers after exposure to carcinogens in order to derive appropriate workplace measures [AGS, 2008]. Currently, working life time cancer risks shall range between 4:1000 (tolerance level) and 4:10 000 (acceptance level) while exposures are aimed to approach the acceptance level. According to this concept, the tolerance level range for refractory ceramic fibres lies between 62.5 * 10^{-3} - 93.0 * 10^{-3} fibres/mL (see Table 17) and the acceptance level would be one order of magnitude lower, i.e. roughly 0.1 fibres/mL (tolerance level) and 0.01 fibres/mL (acceptance level), respectively. In 2018, it is planned to lower the acceptance level to a cancer risk of 1:100 000.

OTHER INFORMATION

This dossier is based on the former dossier on zirconia aluminosilicate refractory ceramic fibres. Part two of the report has been left unchanged although new information on alternatives is being discussed in Germany by an expert working group (AGS). This group will produce an updated version of the TRGS 619 (Technical Rule on Hazardous Substances) based on recent developments on the market for insulating material. As soon as this report is completed, the German CA will forward this information to ECHA.

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ABBREVIATIONS

AES wool	Alkaline Earth Silicate wool
AGS	German Committee on Hazardous Substances (**A**usschuss für **G**efährliche **S**toffe)
AMD	Arithmetic Mean Diameter
AML	Arithmetic Mean Length
ATWA	Actual Time-Weighted Average
BMD	Benchmark Dose
CAS	Chemical Abstract Service
CMR	Carcinogen, Mutagen, toxic for Reproduction
ECFIA	European Chemical Fibre Industry Association
EURIMA	European Insulation Manufacturers' Association
FARIMA	Fibreglass and Rockwool Insulation Manufacturers'
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
ip	intraperitoneal
MMVF	Man-Made Vitreous Fibres
NAIMA	North American Insulation Manufacturers' Association
NEC	Not Elsewhere Classified
RCF	Refractory Ceramic Fibre (aluminium silicate wool)
SD	Standard Deviation
SVF	Synthetic Vitreous Fibres
TRGS	Technische Regeln für Gefahrstoffe (Technical Rules for Hazardous Substances)
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