

KERAMAB® CERAMIC FIBRE TEXTILES

According to (EC) No 1907/2006 and (EC) No1272/2008

1. IDENTIFICATION OF THE SUBSTANCE AND OF THE COMPANY

Identification of the product

Trade names: Keramab® Ceramic fibre textile products

Keramab textile products contain Refractory Ceramic Fibres (RC/alumina-silicate wools (ASW) ((RCF/ASW)).

Index Number : 650-017-00-8 of Annex VI
CAS-Number : 142844-00-6
CAS-Name : Refractories, fibres, aluminosilicate
Registration Nr : 01-2119458050-50-0001

Other components: Keramab textile products contain viscose (maximum20%). Viscose is organic and not classified as dangerous.

CAS-Number : 9004-34-6
CAS-Name : Viscose (C₆H₁₀O₅)_n

Identified Use

Use of the products is restricted to “professional users” for application as thermal insulation, heat shields, heat containment, gaskets and expansion joints at temperatures up to 1400°C in industrial furnaces, ovens, kilns, boilers and other process equipment and in the aerospace and automotive industries. Products are not intended for direct sale to the general public

- Primary Use: Manufacture of fibre (refers to the initial production of the fibre and is therefore not relevant to the downstream user, secondary and tertiary use are relevant to users).
- Secondary Use: Conversion into wet and dry mixtures and articles (refer to section 8).
- Tertiary Use: Installation, removal (industrial and professional) / Maintenance and service life (industrial and professional) (refer to section 8).

Identification of the company

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2. HAZARD IDENTIFICATION

Classification of the substance/mixture

Classification according to Regulation (EC) No 1272/2008

Under the CLP-Regulation (classification, labelling and packaging of substances and mixtures) RCF/ASW has been classified as a 1B carcinogen (“presumed to have carcinogenic potential for humans, classification is largely based on animal evidence”).



Classification according to directive 67/548/EEC

RCF/ASW have been classified as a category 2 carcinogen (“substances which should be regarded as if they are carcinogenic to man”)

Additional information

The International Agency for Research on Cancer (IARC) reaffirmed that group 2B (“possibly carcinogenic to humans”) remains the appropriate classification for RCF/ASW. In accordance with 31st Adaptation to Technical Progress (ATP) of Directive 67/548/ECC as published 15th January 2009 the classification as “irritant” has been removed for all types of man made vitreous fibres (MMVFs). The 1st Adaptation to Technical Progress (ATP) to Regulation (EC) No 1272/2008 entered into force on 25 September 2009. It transfers the 30th and 31st ATPs of Directive 67/548/EEC to the Regulation (EC) No 1272/2008.

Labelling elements

Component	Classification	Hazard pictogram & Symbol	R Phrase & H Statement
Refractory ceramic fibres (Alumino-silicate wools)	(EC)No. 1272/2008	GHS 08 	H350i
	Directive 67/548/EEC	T 	R49

Signal Word

Danger

Hazard Statements

May cause cancer by inhalation (H350i), Causes skin irritation (H315)

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Do not handle until all safety instructions have been read and understood. (P202)
Use personal protective equipment as required. (P281)

Other hazards which do not result in classification:

Mild mechanical irritation to skin, eyes and these effects are usually temporary.

3. COMPOSITION / INFORMATION ON INGREDIENTS**Composition**

Chemical composition of Refractory Ceramic Fibres (RCF/ASW): SiO₂ 45-60% - Al₂O₃ 28-55%,
ZrO₂ <18%. None of the components are radioactive under the terms of European Directive Euratom 96/29

COMPONENT	CAS NUMBER	Index number in CLP Annex VI	% by weight
Refractory ceramic fibres Alumino-silicate wools	142 844-00-6	650-017-00-8	Min. 80%
Viscose (C ₆ H ₁₀ O ₅) _n	900 43 4-6		Max. 20%

4. FIRST AID MEASURES**Skin**

In case of skin irritation rinse affected areas with water and wash gently. Do not rub or scratch exposed skin.

Eyes

In case of eye contact flush abundantly with water; have eye bath available. Do not rub eyes.

Nose and throat

If these become irritated move to a dust free area, drink water and blow nose.
If symptoms persist, seek medical advice.

5. FIRE FIGHTING MEASURES

Non combustible products. Packaging and surrounding materials may be combustible. Use extinguishing agent suitable for surrounding combustible materials. Keramab textile products can contain viscose (max. 20%). This organic fibre will burn out at a low temperature (aprox. at 200°C). This can cause smoke, however this will happen only once.

6. ACCIDENTAL RELEASE MEASURES

**Personal precautions, protective
equipment and emergency procedures**
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Where abnormally high dust concentrations occur, provide workers with appropriate protective equipment as detailed in section 8.

Restrict access to the area to a minimum number of workers required.
Restore the situation to normal as quickly as possible.

Environmental precautions

Prevent further dust dispersion for example by damping the materials.
Do not flush spillage to drain.
Check for local regulations, which may apply.

Methods for cleaning up

Pick up large pieces and use a vacuum cleaner fitted with high efficiency filter (HEPA)
If brushing is used, ensure that the area is wetted down first.
Do not use compressed air for clean-up.
Do not allow to be wind blown.

7. HANDLING AND STORAGE

Handling / techniques to reduce dust emissions during handling

Handling

Handling can be a source of dust emission and therefore the process should be designed to limit the amount of handling. Whenever possible, handling should be carried out under controlled conditions (i.e., use dust exhaust system).

Regular good housekeeping will minimise secondary dust dispersal.

Conditions for safe storage

Store in original packaging in dry area whilst awaiting use.

Always use sealed and visibly labelled containers.

Avoid damaging containers.

Reduce dust emission during unpacking.

Emptied containers, which may contain debris, should be cleaned before disposal or recycling.

Recyclable cardboard and/or plastic films are recommended for packaging.

The specific end use

The main application of these products is as thermal insulation. Use of the products is restricted to “professional users”. Please refer to section 8 and the relevant exposure scenario.

8. RISK MANAGEMENT MEASURES / EXPOSURE CONTROL / PERSONAL PROTECTION

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Control parameters

Industrial hygiene standards and occupational exposure limits vary between countries and local jurisdictions. Check which exposure levels apply to your facility and comply with local regulations. If no regulatory dust or other standards apply, a qualified industrial hygienist can assist with a specific workplace evaluation including recommendations for respiratory protection.

National Limit Values

Examples of national OELs (December 2010) are given in the table below. Additional references and/or updates can be found on the following websites:

http://www.dguv.de/ifa/en/gestis/limit_values,

<http://osha.europa.eu/en/publications/reports/548OELs/view>

Country	OEL*
Austria	0.5 f/ml
Belgium	0.5 f/ml
Czech Republic	1.0 f/ml
Denmark	1.0 f/ml
Finland	0.2 f/ml
France***	0.1 f/ml
Germany***	0.2 f/ml (max. tolerance-concentration)**
Italy	0.2 f/ml
Poland	0.5 f/ml
Spain	0.5 f/ml
Sweden	0.2 f/ml
The Netherlands	0.5 f/ml
UK***	1.0 f/ml

Note:

* 8-hr time weighted average concentrations of airborne respirable fibres measured using the conventional membrane filter method.

** In Germany, OELs were replaced by concentration ranges following a risk based concept. The maximum "tolerance-concentration" is 0.2 f/ml following TRGS 558 in combination with BekGS 910.

*** Source of OEL is detailed in section 15.

The Scientific Committee on Occupational Exposure Limit Values (**SCOEL**) as set up by a Commission.

Recommended monitoring program

France has a monitoring program in line with test method reference number XP X43-269 dated March 2002, which is used to check for compliance with the OEL of 0.1 f/ml. The UK follow MDHS 59 specific for MMVF: "Man-made mineral fibre - Airborne number concentration by phase-contrast light microscopy" and MDHS 14/3 "General methods for sampling and gravimetric analysis of respirable and inhalable dust". Germany recommends following the rules as laid out in TRGS 402 and describes applicable sampling / analytical methods in BGI 505-31 and BGI 505-46.

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WHO-EURO method: Determination of airborne fibre number concentrations; A recommended method, by phase-contrast optical microscopy (membrane filter method); World Health Organisation Geneva 1997 ISBN 92 4 154496 1.

DNEL/DMEL

The calculation of DMELs for fibres alone is not possible; a precautionary value is assigned based on fibrosis. An inhalation DMEL of 0.5 mg/m³ with an assessment factor of 25 can be calculated based on repeated dose toxicity, this value in the correct units would give a DMEL of 4 f/ml.

Exposure Controls. controls

Review your application(s) and assess situations with the potential for dust release.

Where practical, enclose dust sources and provide dust extraction at source.
Designate work areas and restrict access to informed and trained workers.
Use operating procedures that will limit dust production and exposure of workers.
Keep the workplace clean. Use a vacuum cleaner fitted with a HEPA filter; avoid using brooms and compressed air.
If necessary, consult an industrial hygienist to design workplace controls and practices.
The use of products specially tailored to your application(s) will help to control dust. Some products can be delivered ready for use to avoid further cutting or machining. Some could be pre-treated or packaged to minimise or avoid dust release during handling.
Consult your supplier for further details.

Personal Protective Equipment

Skin Protection

If working with virgin material, wear industrial leather gloves and work clothes, which are loose fitting at the neck and wrists. Soiled clothes should be cleaned to remove excess dust before being taken off (e.g. use vacuum cleaner, not compressed air). Each worker should be provided with two lockers in an appropriate changing and washing area. It is good hygiene practice to ensure work clothes are washed separately by the employer. Work clothes should not be taken home.

Eye Protection

As necessary, wear goggles or safety glasses with side shields

Respiratory Protection

For dust concentrations below the exposure limit value, RPE is not required but FFP2 respirators may be used on a voluntary basis. For short term operations where excursions are less than ten times the limit value, use FFP3 respirators. In case of higher concentrations or where the concentration is not known, please seek advice from your company and/or your supplier.

You may also refer to the ECFIA code of practice available on the ECFIA's web site: www.ecfia.eu

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Information and Training of workers

This should include:

- The applications involving RCF/ASW-containing products;
- The potential risk to health resulting from the exposure to fibrous dust;
- The requirements regarding smoking, eating and drinking at the workplace;
- The requirements for protective equipment and clothing;
- The good working practices to limit dust release;
- The proper use of protective equipment.

Environmental Exposure Controls

Keramab textile products are at least 80% inorganic, inert and stable and are not soluble in water (solubility <1mg/litre) and as such does not pose a detrimental effect on the environment.

Keramab textile product can contain viscose (max. 20%).

Processes involving the manufacturing or use of RCF/ASW should be filtered to minimise fibre emissions to air. Waste RCF/ASW should be stored in closed containers and placed in to deep landfills, giving therefore little opportunity for release.

General good practice for spills and waste is to prevent products from being wind blown, by covering and damping the waste materials. Contain spillages to prevent access to drain.

Refer to local, national or European applicable environmental standards for release to air water and soil. *For waste, refer to section 13*

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state	: White solid
Partition coefficient	: Not applicable
Boiling point	: Not applicable
Flash point	: Not applicable
Auto flammability	: Not applicable
Oxidising properties	: Not applicable
Specific gravity	: Not applicable
Solubility	: Less than 1 mg/l
Odour	: None
Melting point	: > 1650°C
Flammability	: Not applicable
Explosive properties	: Not applicable
Vapour pressure	: Not applicable
pH	: Not applicable

Length weighted geometric mean diameter of fibres contained in the product: 1.4 - 3 µm

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Other safety Information

These fibres are dense materials and so will settle rapidly from both air and liquid.

10. STABILITY AND REACTIVITY

Reactivity

Keramab textile products are stable and non reactive.

Chemical stability

Keramab textile products are at least 80% inorganic, inert and stable. Keramab textile product can contain viscose (max. 20%).

Possibility of hazardous reactions

None

Conditions to avoid

Please refer to handling and storage advice in Section 7

Incompatible materials

None

Hazardous decomposition products

Upon heating above 900°C for sustained periods, this amorphous material can begin to transform to mixtures of crystalline phases. For further information please refer to Section 16.

11. TOXICOLOGICAL INFORMATION

Toxicokinetics, metabolism and distribution

Basic toxicokinetic

Exposure is predominantly by inhalation or ingestion. Man made vitreous fibres of a similar size to RCF/ASW have not been shown to migrate from the lung and/or gut and do not become located in other parts of the body When compared to many naturally occurring minerals, RCF/ASW has a low ability to persist and accumulate in the body (half-life of long fibres (> 20 µm) in 3 week rat inhalation test is approx. 60 days).

Human Toxicological data

In order to determine possible human health effects following RCF exposure, the University of Cincinnati has been conducting medical surveillance studies on RCF workers in the U.S. The Institute of Occupational Medicine (IOM) has conducted medical surveillance studies on RCF workers in European manufacturing facilities. Pulmonary morbidity studies among production workers in Europe and USA have demonstrated an absence of interstitial fibrosis and no decrement in lung function associated with current exposures, but have indicated a reduction of lung capacity among smokers.

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A statistically significant correlation between pleural plaques and cumulative RCF exposure was evidenced in the USA longitudinal study.

The USA mortality study did not show evidence of increased lung tumour development either in the lung parenchyma or in the pleura.

Information on Toxicological effects

- *Acute toxicity: short term inhalation*
 - No data available: Short term tests have been undertaken to determine fibre (bio) solubility rather than toxicity; repeat dose inhalation tests have been undertaken to determine chronic toxicity and carcinogenicity.
- *Acute toxicity: oral*
 - No data available: Repeated dose studies have been carried out using gavage. No effect was found.
- *Skin corrosion/irritation:*
 - Not possible to obtain acute toxicity information due to the nature of the substance.
- *Serious eye damage/irritation:*
 - Not possible to obtain acute toxicity information due to the nature of the substance.
- *Respiratory or skin sensitization*
 - No evidence from human epidemiological studies of any respiratory or skin sensitisation potential.
- *Germ cell mutagenicity*
 - Method: In vitro micronucleus test.
 - Species: Hamster (CHO).
 - Dose: 1-35 mg/ml.
 - Routes of administration: In suspension.
 - Results: Negative.
- *Carcinogenicity*
 - Method: Inhalation. Multi-dose.
 - Species: Rat.
 - Dose: 3 mg/m³, 9 mg/m³ and 16 mg/m³
 - Routes of administration: Nose only inhalation
 - Results: Fibrosis just reached significant levels at 16 and 9 mg/m³ but not at 3 mg/m³. None of the parenchymal tumour incidences were higher than the historical control values for this strain of animal.
 - Method: Inhalation. Single dose.
 - Species: Rat.

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- Dose: 30 mg/m³
- Routes of administration: Nose only inhalation.
- Results: This study was designed to test the chronic toxicity and carcinogenicity of RCF at extreme exposures. Tumour incidence (incl. mesothelioma) was raised at this dose level. The presence of overload conditions (only detected after the experiment was completed), whereby the delivered dose exceeded the clearance capability of the lung, makes meaningful conclusions in terms of hazard and risk assessment difficult.
- Method: Inhalation. Single dose.
- Species: Hamster.
- Dose: 30 mg/m³
- Routes of administration: Nose only inhalation
- Results: This low quality study in hamsters (no justification for exposure concentration used and pre existing and concurrent infections in the test animals) produced mesothelial lesions of uncertain significance. Subsequent studies in hamsters with glass fibres indicated that the lung burdens of RCF in this experiment were between 5 and 10 times more than that needed to produce overload, and the results are therefore difficult to interpret.

There are reports of injection studies with some similar materials. While some intraperitoneal injection (IP) studies reported the development of tumours in rats, the relationship of these results to classification remains controversial.

- *Reproductive toxicity;*

- Method: Gavage.
- Species: Rat
- Dose: 250mg/kg/day
- Routes of administration: Oral
- Results: No effects were seen in an OECD 421 screening study. There are no reports of any reproductive toxic effects of mineral fibres. Exposure to these fibres is via inhalation and effects seen are in the lung. Clearance of fibres is via the gut and the faeces, so exposure of the reproductive organs is extremely unlikely.

- STOT-Single exposure; NA
- STOT-Repeated exposure; NA
- Aspiration hazard: NA

Irritant Properties

Negative results have been obtained in animal studies (EU method B 4) for skin irritation. Inhalation exposures using the nose only route produce simultaneous heavy exposures to the eyes, but no reports of excess eye irritation exist. Animals exposed by inhalation similarly show no evidence of respiratory tract irritation.

Human data confirm that only mechanical irritation, resulting in itching, occurs in humans, Screening at manufacturers' plants in the UK has failed to show any human cases of skin conditions related to fibre exposure.

12. ECOLOGICAL INFORMATION

These products are inert materials, which remain stable overtime. These products are insoluble in the natural environment and are chemically identical to inorganic compounds found in the soil and sediment. RCF/ASW is inorganic and a dense material, which will settle rapidly from both air and liquid. No adverse effects of this material on the environment are anticipated.

13. DISPOSAL CONSIDERATIONS

Waste treatment

Waste containing > 0.1% RCF/ASW is categorised as a stable non-reactive hazardous waste, which can generally be disposed of at landfill sites licensed for this purpose. Unless wetted, such a waste is normally dusty and so should be properly sealed in clearly labelled containers for disposal. At some authorised disposal sites, dusty wastes may be treated differently in order to ensure they are dealt with promptly to avoid them being wind blown.

Please refer to the European list (Decision no 2000/532/CE as modified) to identify your appropriate European Waste Code (EWC) and ensure national and or regional regulation are complied with.

Additional information

When disposing of waste and assigning European Waste Code (EWC) any possible contamination during use will need to be considered and expert guidance sought as necessary.

14. TRANSPORT INFORMATION

Not classified as dangerous goods under relevant international transport regulations (ADR, RID, IATA, IMDG, ADN).

Ensure that dust is not wind blown during transportation.

Definitions:

ADR	Transport by road, Council Directive 94/55/EC
IMDG	Regulations relating to transport by sea
RID	Transport by rail, Council Directive 96/49/EC
ICAO/IATA	Regulations relating to transport by air
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways

15. REGULATORY INFORMATION

Safety, health and environment regulations/legislation specific for the substances or mixtures

EU regulations:

- Council Directive 67/548/EEC “on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances as modified and adapted to the technical progress” (OJEC L 196 of 16 August 1967, p.1 and its modifications and adaptations to technical progress).
- Council Directive 1999/45/EC of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations.
- Regulation (EC) No 1907/2006 dated 18th December 2006 on Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).
- Regulation (EC) No 1272/2008 dated 20th January 2009 on classification, labeling and packaging of substances and mixtures (OJ L 353).
- Commission Directive 97/69/EC of 5 December 1997 adapting to technical progress for the 23rd time Council Directive 67/548/EEC (OJEC of 13 December 1997, L 343).
- Commission regulation (EC) No 790/2009 of 10 August 2009 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labeling and packaging of substances and mixtures.
- The 1st Adaptation to Technical Progress (ATP) to Regulation (EC) No 1272/2008 enters into force on 25 September 2009. It transfers the 30th and 31st ATPs of Directive 67/548/EEC to the Regulation (EC) No 1272/2008.

Inclusion of RCF/ASW on the Candidate List of SVHC:

RCF are classified as a carcinogenic substance CLP 1B. On the 13th of January 2010 ECHA updated the Candidate List (containing substances of very high concern – SVHC – potentially qualifying for authorisation) and added 14 new substances in this list including aluminosilicate refractory ceramic fibres and zirconia aluminosilicate refractory ceramic fibres. As a consequence, EU (European Union) or EEA (European Economical Area) suppliers of articles which contain aluminosilicate refractory ceramic fibres and zirconia aluminosilicate refractory ceramic fibres in a concentration above 0.1% (w/w) have to provide sufficient information, available to them, to their customers or upon requests to a consumer within 45 days of the receipt of the request. This information must ensure safe use of the article and as minimum contains the name of the substance.

Restriction on Marketing of RCF/ASW

Marketing and use of RCF/ASW is controlled by Directive 76/769/EEC relating to restrictions on the marketing and use of certain dangerous substances and preparations as modified (21st amending, Directive 2001/41/EC, 19 June 2001) and is restricted to professional use only.

Protection of workers

Shall be in accordance with several European Directives as amended and their implementations by the Member States:

- Council Directive 89/391/EEC dated 12 June 1989 "on the introduction of measures to encourage improvement in the safety and health of workers at work (OJEC (Official Journal of the European Community) L 183 of 29 June 1989, p.1).
- Council Directive 98/24/EC dated 7 April 1997 "on the protection of workers from the risks related to chemical agents at work" (OJEC L 131 of 5 May 1998, p.11).
- Council Directive 2004/37/EC of 29 April 2004 on the protection of workers from risks related to exposure to carcinogens mutagens and reprotoxics at work (OJEC L 158 of 30 April 2004).

Other EU Regulations:

Member states are in charge of implementing European directives into their own national regulation within a period of time normally given in the directive. Member States may impose more stringent requirements. Please always refer to national regulations.

Source of reference for the OELs:

- UK** : HSE EH40 Workplace Exposure Limit.
- France** : Décret N°2007-1539 du 26 octobre 2007 fixant des valeurs limites d'exposition professionnelle contraignantes pour certains agents chimiques et modifiant le code du travail.
- Germany** : Änderung und Ergänzung der Bekanntmachung BekGS 910 / TRGS 558 and TRGS 905.

Chemical Safety Assessment

A Chemical Safety Assessment has been carried out for RCF/ASW and CSR can be provided on request.

16. OTHER INFORMATION

Useful references

(the directives which are cited must be considered in their amended version)

- Hazards from the use of Refractory Ceramic Fibre. Health and Safety Executive: Information document, HSE 267 (1998).
- Working with High Temperature Insulation wools 2006.
- ECFIA; Code of Practice.

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- Maxim LD et al (1998). CARE – A European programme for monitoring and reducing Refractory Ceramic Fibre dust at the workplace initial results; Gefahrstoffe – Reinhaltung der Luft, 58:3,97-103.
- Recognition and control of exposure to RCF, ECFIA, April 2009
- TRGS 619 – Technical Rules for Hazardous substances: Substitution Products for Aluminium silicate wools.

Additional information and precautions to be considered upon removal of after service material

In almost all applications RCF/ASW is used as an insulating material helping to maintain a temperature of 900°C or more in a closed space. As only a thin layer of the insulation (hot face side) is exposed to high temperatures, respirable dust generated during removal operations does not contain detectable levels of crystalline silica (CS). In applications where the material is heat soaked, duration of heat exposure is normally short and a significant devitrification allowing CS to build up does not occur. This is the case for waste mould casting for instance. Toxicological evaluation of the effect of the presence of CS in artificially heated RCF/ASW material has not shown any increased toxicity *in vitro*. Combinations of factors such as increased brittleness of fibres, or microcrystals being embedded in the glass structure of the fibre and therefore not being biologically available may explain the lack of toxicological effects. The IARC evaluation as provided in Monograph 68 is not relevant as CS is not biologically available in afterservice RCF/ASW.

High concentrations of fibres and other dusts may be generated when after-service products are mechanically disturbed during operations such as wrecking. Therefore ECFIA recommends:

- a) control measures are taken to reduce dust emissions;
- b) all personnel directly involved wear an appropriate respirator to minimise exposure; and
- c) Compliance with local regulatory limits.

Care programme

ECFIA, representing the high temperature insulation wool (HTIW) industry, has undertaken an extensive industrial hygiene program to provide assistance to the users of all products containing HTIW.

The objectives are twofold:

- to monitor workplace dust concentrations at both manufacturers' and customers' premises.
- to document manufacturing and use of RCF products from an industrial hygiene perspective in order to establish appropriate recommendations to reduce exposures.

If you wish to participate in the CARE programme, contact ECFIA or your supplier.

Spraying

ECFIA recommends that this fibre is not used for spraying

Websites

European Industry Association Representing HTIW (ECFIA): 3, Rue du Colonel Moll, 75017 Paris

Tel. +33 (0) 31 48 74 26

www.ecfia.eu