Revision Date 16/12/2014 SDS No. 11074

Revision 9

SAFETY DATA SHEET

Hyflo™ Super-Cel™

According to Regulation (EU) No 453/2010
According to Regulation (EC) No 1907/2006

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

Product name	Hyflo™ Super-Cel™
REACH Registration number	01-2119488518-22-0004
CAS-No.	68855-54-9
EC No.	272-489-0

1.2. Relevant identified uses of the substance or mixture and uses advised against

Identified uses	A filter aid
Uses advised against	None

1.3. Details of the supplier of the safety data sheet

Supplier

Imerys Filtration France
7 rue de stade - BP 42
FR - 15300 Murat
France
Tel. +33 (0) 4 71 20 00 49
Fax. +33 (0) 4 71 20 32 28
SDS.expert@imerys.com

1.4. Emergency telephone number

CHEMTREC + 1 703 527 3887

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

Classification (EC 1272/2008)

Physical and Chemical Hazards	Not classified.
Human health	Not classified.
Environment	Not classified.

Classification (67/548/EEC) Not classified.

The Full Text for all R-Phrases and Hazard Statements are Displayed in Section 16.

Human health

This product does not meet the criteria for classification as hazardous as defined in the Regulation EC 1272/2008 and in Directive 67/548/EEC. Depending on the type of handling and use (e.g. grinding, drying), airborne respirable crystalline silica may be generated. Prolonged and/or massive inhalation of respirable crystalline silica dust may cause lung fibrosis, commonly referred to as silicosis. Principal symptoms of silicosis are cough and breathlessness. Occupational exposure to respirable crystalline silica dust should be monitored and controlled.

Environment

The product is not expected to be hazardous to the environment.

Physical and Chemical Hazards

This product is an inorganic substance and does not meet the criteria for PBT or vPvB in accordance with Annex XIII of REACH. This product should be handled with care to avoid dust generation.

2.2. Label elements

EC No. 272-489-0

Label In Accordance With (EC) No. 1272/2008

No pictogram required.

Hyflo™ Super-Cel™

2.3. Other hazards

Not Classified as PBT/vPvB by current EU criteria.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substances

Diatomaceous Earth, Flux Calcined		100%
CAS-No.: 68855-54-9	EC No.: 272-489-0	Registration Number: 01-2119488518-22-0005

Classification (EC 1272/2008)	Classification (67/548/EEC)
Not classified.	Not classified.

The Full Text for all R-Phrases and Hazard Statements are Displayed in Section 16.

REACH Registration number 01-2119488518-22-0004

CAS-No. 68855-54-9

EC No. 272-489-0

Composition Comments

Impurities:

Cristobalite: CAS-No.: 14464-46-1 EC No.: 238-455-4

This product contains less than 1% cristobalite (fine fraction); cristobalite (fine fraction) is classified as STOT RE1.

SECTION 4: FIRST AID MEASURES

4.1. Description of first aid measures

General information

No acute and delayed symptoms and effects are observed.

Inhalation

Move into fresh air and keep at rest. Get medical attention if any discomfort continues.

Ingestion

Rinse mouth thoroughly. Get medical attention if any discomfort continues. Do not induce vomiting.

Skin contact

Wash skin with soap and water. Use suitable lotion to moisturise skin.

Eye contact

Do not rub eye. Rinse with copious quantities of water and seek medical attention if irritation persists.

4.2. Most important symptoms and effects, both acute and delayed

Inhalation

Breathing dust containing crystalline silica over a prolonged period of time may cause lung damage. Crystalline silica (Cristobalite) is a known cause of silicosis, a progressive, sometimes fatal lung disease.

4.3. Indication of any immediate medical attention and special treatment needed

No specific first aid measures noted.

SECTION 5: FIREFIGHTING MEASURES

5.1. Extinguishing media

Extinguishing media

This product is non-combustible. No specific extinguishing media is needed.

5.2. Special hazards arising from the substance or mixture

Specific hazards

Non combustible. No hazardous thermal decomposition.

5.3. Advice for firefighters

Hyflo™ Super-Cel™

Special Fire Fighting Procedures

No specific fire-fighting protection is required. Use an extinguishing agent suitable for the surrounding fire.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Avoid airborne dust generation, wear personal protective equipment in compliance with national legislation. Provide adequate ventilation.

6.2. Environmental precautions

Do not discharge into drains, water courses or onto the ground. Avoid spreading dust or contaminated materials.

6.3. Methods and material for containment and cleaning up

Avoid dry sweeping and use water spraying or vacuum cleaning systems to prevent airborne dust generation. Wear personal protective equipment in compliance with national legislation.

6.4. Reference to other sections

For personal protection, see section 8. For waste disposal, see section 13.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

Avoid airborne dust generation. Provide appropriate exhaust ventilation at places where airborne dust is generated. In case of insufficient ventilation, wear suitable respiratory protective equipment. Handle packaged products carefully to prevent accidental bursting. If you require advice on safe handling techniques, please contact your supplier or check the Good Practice Guide referred to in section 16. Do not to eat, drink and smoke in work areas; wash hands after use; remove contaminated clothing and protective equipment before entering eating areas.

7.2. Conditions for safe storage, including any incompatibilities

Store in a dry covered area. Minimise airborne dust generation and prevent wind dispersal during loading and unloading. Keep containers closed and store packaged products so as to prevent accidental bursting.

7.3. Specific end use(s)

For further information see attached Exposure Scenario.

Usage Description

If you require advice on specific uses, please contact your supplier or check the Good Practice Guide referred to in section 16.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

Name	STD	TWA - 8 Hrs		STEL - 15 Min		Notes
Cristobalite	WEL		0,1 mg/m3			
Inorganic dust	WEL		4 mg/m3 resp.dust			

WEL = Workplace Exposure Limit.

DNEL				
Industry	Inhalation.	Long Term	0.33	mg/m3
Consumer	Inhalation.	Long Term	0.08	mg/m3
Consumer	Oral	Long Term	3.5	mg/kg/day
PNEC				
STP	NOAEL value AF=100			
Sediment	n/a			
Water	n/a			

8.2. Exposure controls

Engineering measures

Refer to exposure scenarios in Annex I and Section 7. Minimise airborne dust generation. Use process enclosures, local exhaust ventilation or other engineering controls to keep airborne levels below specified exposure limits. If user operations generate dust, fumes or mist, use ventilation to keep exposure to airborne particles below the exposure limit. Apply organisational measures, e.g. by isolating personnel from dusty areas. Remove and wash soiled clothing. .

Respiratory equipment

In case of prolonged exposure to airborne dust concentrations, wear a respiratory protective equipment that complies with the requirements of European or national legislation.

Hand protection

For prolonged or repeated skin contact use suitable protective gloves. PVC or rubber gloves are recommended.

Eye protection

Use eye protection. Goggles/face shield are recommended. Contact lenses should not be worn when working with this product.

Hygiene measures

When using do not eat, drink or smoke. Wash hands at the end of each work shift and before eating, smoking and using the toilet. Use appropriate skin cream to prevent drying of skin.

Skin protection

No specific requirement. Appropriate protection (e.g. protective clothing, barrier cream) is recommended for workers who suffer from dermatitis or sensitive skin.

Environmental Exposure Controls

Dispose of waste in accordance with local and national regulations.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Appearance	Powder
Colour	White / off-white.
Odour	Almost odourless.
Solubility	Insoluble in water EU Method A6

Initial boiling point and boiling range (°C)

Not applicable.

Melting point (°C)	> 450
	EU Method A1
Relative density	2.4
	OECD 109

Vapour pressure

Not applicable.

pH-Value, Conc. Solution

Not applicable.

Viscosity

Not applicable.

Decomposition temperature (°C)

Not applicable.

Flash point (°C)

Not applicable.

Auto Ignition Temperature (°C)

Not applicable.

Flammability Limit - Lower(%)

Not applicable.

Flammability Limit - Upper(%)

Not applicable.

Partition Coefficient
(N-Octanol/Water)

Not applicable.

Oxidising properties

Not relevant

9.2. Other information

None.

SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity

No specific reactivity hazards associated with this product.

10.2. Chemical stability

Hyflo™ Super-Cel™

Stable under normal temperature conditions and recommended use.

10.3. Possibility of hazardous reactions

Not applicable.

10.4. Conditions to avoid

No particular incompatibility.

10.5. Incompatible materials

Materials To Avoid

No incompatible groups noted.

10.6. Hazardous decomposition products

None under normal conditions.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

Acute toxicity:

Acute Toxicity (Oral LD50)

> 2000 mg/kg Rat

OECD 401

Acute Toxicity (Dermal LD50)

Not applicable.

Acute Toxicity (Inhalation LC50)

> 2.6 mg/l (dust/mist) Rat

OECD 403

Skin Corrosion/Irritation:

Dose Rabbit

Dose

Rabbit

OECD 404

Not irritating.

Serious eye damage/irritation:

Not applicable. Not Irritating. OECD 405

Respiratory or skin sensitisation:

Skin sensitisation

Not applicable. Guinea Pig

OECD 429

Not Sensitising.

Germ cell mutagenicity:

Genotoxicity - In Vitro

Not applicable.

OECD 471. OECD 473. OECD 476.

Negative.

Carcinogenicity:

Carcinogenicity

Not applicable.

Reproductive Toxicity:

Reproductive Toxicity - Fertility

Not applicable.

Specific target organ toxicity - single exposure:

STOT - Single exposure

Not applicable.

General information

This product has low toxicity. Only large volumes may have adverse impact on human health.

Inhalation

No acute effects were seen in an animal study following acute inhalation exposure. A 90 day repeated dose inhalation study has been proposed. Calcined diatomaceous earth (Kieselgur) contains crystalline silica, which is a known cause of silicosis, a progressive, sometimes fatal lung disease. In a 1997 monograph (Volume 68, "Silica, Some Silicates, Coal Dust and Para-aramid Fibrils"), the International Agency for Research on cancer (IARC) has classified "inhaled crystalline silica from occupational sources" in Group 1 as a substance "carcinogenic to humans". In making the overall evaluation, the IARC Working Group noted that carcinogenicity in humans was not detected in all industrial circumstances studied. Crystalline silica has also been classified by the German MAK Commission as a human carcinogen (Category A1). Dust in high concentrations may irritate the respiratory system.

Ingestion

No harmful effects expected in amounts likely to be ingested by accident. No acute or long term effects were seen in animal studies following oral exposure.

Skin contact

No acute effects were seen in an animal study following acute dermal exposure. Kieselguhr soda ash flux calcined is not a skin irritant. Prolonged contact may cause dryness of the skin.

Eye contact

Kieselguhr soda ash flux calcined is not an eye irritant.

Health Warnings

Prolonged and/or massive exposure to respirable crystalline silica-containing dust may cause silicosis, a nodular pulmonary fibrosis caused by deposition in the lungs of fine respirable particles of crystalline silica.

In 1997, IARC (the International Agency for Research on Cancer) concluded that crystalline silica inhaled from occupational sources can cause lung cancer in humans. However it pointed out that not all industrial circumstances, nor all crystalline silica types, were to be incriminated. (IARC Monographs on the evaluation of the carcinogenic risks of chemicals to humans, Silica, silicates dust and organic fibres, 1997, Vol. 68, IARC, Lyon, France.)

In June 2003, SCOEL (the EU Scientific Committee on Occupational Exposure Limits) concluded that the main effect in humans of the inhalation of respirable crystalline silica dust is silicosis. "There is sufficient information to conclude that the relative risk of lung cancer is increased in persons with silicosis (and, apparently, not in employees without silicosis exposed to silica dust in quarries and in the ceramic industry). Therefore preventing the onset of silicosis will also reduce the cancer risk…" (SCOEL SUM Doc 94-final, June 2003).
So there is a body of evidence supporting the fact that increased cancer risk would be limited to people already suffering from silicosis. Worker protection against silicosis should be assured by respecting the existing regulatory occupational exposure limits and implementing additional risk management measures where required (see section 16 below).

SECTION 12: ECOLOGICAL INFORMATION

Ecotoxicity

The product components are not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

12.1. Toxicity

Acute Toxicity - Fish

96 hours Onchorhynchus mykiss (Rainbow trout)

OECD 203

Acute Toxicity - Aquatic Invertebrates

48 hours Daphnia magna

Exceeds maximum solubility of substance OECD 202

Acute Toxicity - Aquatic Plants

72 hours Desmondesmus subspicatus

Exceeds maximum solubility of substance OECD 201

Acute Toxicity - Microorganisms

3 hours > 1000 mg/l Activated sludge

Harmless to STP microorganisms OECD 209

12.2. Persistence and degradability

Hyflo™ Super-Cel™

Degradability

The product solely consists of inorganic compounds which are not biodegradable.

12.3. Bioaccumulative potential

Bioaccumulative potential

The product does not contain any substances expected to be bioaccumulating.

Partition coefficient

Not applicable.

12.4. Mobility in soil

Mobility:

Not relevant, due to the form of the product. The product is insoluble in water.

12.5. Results of PBT and vPvB assessment

Not Classified as PBT/vPvB by current EU criteria.

12.6. Other adverse effects

Not known.

SECTION 13: DISPOSAL CONSIDERATIONS

General information

This mineral can be disposed of as a non toxic/inactive material in approved landfill sites in accordance with local regulations. Dust formation from residues in packaging should be avoided and suitable worker protection assured. Store used packaging in enclosed receptacles. Recycling and disposal of packaging should be carried out in compliance with local regulations. The re-use of packaging is not recommended. Recycling and disposal of packaging should be carried out by an authorised waste management company.

13.1. Waste treatment methods

Where possible, recycling is preferable to disposal. Can be disposed of in compliance with local regulations.

SECTION 14: TRANSPORT INFORMATION

General	No special precautions. The product is not covered by international regulation on the transport of dangerous goods (IMDG, IATA, ADR/RID).

14.1. UN number

No information required.

14.2. UN proper shipping name

No information required.

14.3. Transport hazard class(es)

No information required.

14.4. Packing group

No information required.

14.5. Environmental hazards

Environmentally Hazardous Substance/Marine Pollutant

No.

14.6. Special precautions for user

Not applicable.

14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

No information required.

SECTION 15: REGULATORY INFORMATION

Hyflo™ Super-Cel™

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

Uk Regulatory References

Health and Safety at Work Act 1974. The Control of Substances Hazardous to Health Regulations 2002 (S.I 2002 No. 2677) with amendments.

Statutory Instruments

The Chemicals (Hazard Information and Packaging for Supply) Regulations 2009 (S.I 2009 No. 716).

Approved Code Of Practice

Safety Data Sheets for Substances and Preparations. Classification and Labelling of Substances and Preparations Dangerous for Supply.

EU Legislation

Dangerous Substance Directive 67/548/EEC.

National Regulations

Workplace Exposure Limits 2005 (EH40)

Water hazard classification

NWG

15.2. Chemical Safety Assessment

A chemical safety assessment has been carried out.

SECTION 16: OTHER INFORMATION

Abbreviations and acronyms used in the safety data sheet

AF = Assessment factor
BCF = Bioconcentration factor
CAS = Chemical Abstracts Service
C & L= Classification and labelling
RCS = Respirable crystalline silica
DNEL= Derived no effect level
LC50 = Median lethal concentration
LD50 = Medial lethal dose
EC = European Commission
NOAEL = No observed adverse effect level
PBT = Persistent bioaccumulative toxic
PEC = Predicted effect level
PNEC = Predicted no effect level
SDS = Safety data sheet
STOT = Specific target organ toxicity
STP = Sewage treatment plant
vPvB = Very persistent very bioaccumulative

.

General information

Workers must be informed of the presence of crystalline silica and trained in the proper use and handling of this product as required under applicable regulations.

A multi-sectoral social dialogue agreement on Workers Health Protection through the Good Handling and Use of Crystalline Silica and Products Containing it was signed on 25 April 2006. This autonomous agreement, which receives the European Commission's financial support, is based on a Good Practices Guide. The requirements of the Agreement came into force on 25 October 2006. The Agreement was published in the Official Journal of the European Union (2006/C 279/02). The text of the Agreement and its annexes, including the Good Practices Guide, are available from http://www.nepsi.eu and provide useful information and guidance for the handling of products containing crystalline silica (fine fraction). Literature references are available on request from EUROSIL, the European Association of Industrial Silica Producers.

Health & Safety Executive: Detailed reviews of the scientific evidence on the health effects of crystalline silica have been published by HSE (Health and Safety Executive, UK) in the Hazard Assessment Documents EH75/4 (2002) and EH75/5 (2003). The HSE points out on its website that "Workers exposed to fine dust containing quartz are at risk of developing a chronic and possibly severely disabling lung disease known as "silicosis"." In addition to silicosis, there is now evidence that heavy and prolonged workplace exposure to dust containing crystalline silica can lead to an increased risk of lung cancer. The evidence suggests that an increased risk of lung cancer is likely to occur only in those workers who have developed silicosis.
The above information describes exclusively the safety requirements of the product and is based on our present-day knowledge. The information is intended to give you advice about the safe handling of the product named in this safety data sheet, for storage, processing, transport and disposal. The information cannot be transferred to other products. In the case of mixing the product with other products or in the case of processing, the information on this safety data sheet is not necessarily valid for the new made-up material.

.

Hyflo™ Super-Cel™

Insofar as materials not manufactured or supplied by (the supplier)., are used in conjunction with, or instead of (the supplier), materials, it is the responsibility of the customer himself to obtain, from the manufacturer or supplier, all technical data and other properties relating to these and other materials and to obtain all necessary information relating to them. No liability can be accepted in respect of the use of (the supplier), Kieselguhr soda-ash flux calcined in conjunction with materials from another supplier.

.

Revision Date	16/12/2014
Revision	9
Risk Phrases In Full	
NC	Not classified.
Hazard Statements In Full	

Annex I

Exposure Scenario 1: Manufacture of Kieselguhr soda ash flux-calcined

1. Short title of exposure scenario 1	
Manufacture of Kieselguhr soda ash flux-calcined	
2. Description of activities and processes covered in the exposure scenario	
Sector of use (SU)	SU 3: Industrial uses: uses of substances as such or in preparations at industrial sites .
Product category (PC)	PC 0: (adsorbent, filling material) PC 14: Metal surface treatment products, including galvanic and electroplating products (This covers substances permanently binding with the metal surface)
Process category (PROC)	PROC 2: Use in closed, continuous process with occasional controlled exposure. PROC 3: Use in closed batch process PROC 4: Use in batch or other process where opportunity for exposure arises. Industrial setting PROC 8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities. PROC 9: Transfer of substance or preparation into small containers (dedicated filling line, including weighing).
Article category (AC)	Not applicable
Environmental release category (ERC)	ERC 1: Manufacture of substances
3. Operational conditions	
3. 1 Operational conditions related with frequency and quantities of use	
Duration of exposure at workplace:	8 hours per day
Frequency of exposure at workplace:	5 days/week for each worker

Annual amount used per site:	The actual tonnage handled per shift is not considered to influence the exposure as such for this scenario
3.2 Operational conditions related with substance/ product	
Physical state	Solid ranging from a fine powder with high dustiness to coarser granules with low dustiness
Concentration of substance in mixture	100% w/w
3.3 Other relevant operational conditions	
No information about frequency and duration of the various tasks is available.	
4. Risk Management Measures	
4.1 RMMs related to workers	
Organisational measures	Local exhaust ventilation is installed at manufacturing sites. The employer has also to ascertain that the required PPE is available and used according to instructions.
Technical measures	Safe conditions were defined by taking into account local exhaust ventilation in the present scenario
Respiratory protection	Workers may use half-face masks (P2 or P3) with an efficiency of at least 90% in situations with elevated dust concentrations in the air (Refered to as PRE)
Hand protection	Workers use gloves during the handling of the pure, solid substance
Eye protection	Workers use safety glasses during the handling of the pure, solid substance
Skin and body protection	Wearing of suitable protective clothing.
Hygiene measures	Standard occupational hygiene measures should be adopted.
4.2 RMMs related to the environment	
Organisational measures	Waste gases are cleaned by passage through cyclones or scrubber units or by filtration with bag filters. Solid and liquid wastes are disposed of in landfills or may be incinerated
Abatement measures related with	The wastewater resulting from manufacturing of the substance can be treated by sedimentation to remove the solid parts of the substance. The sedimentation is very efficient with a reduction efficacy of 99% or more.

wastewater	
Abatement measures waste air and solid waste	It is recommended to pass waste gas through bag filters, scrubbers or cyclones to reduce the amount of solid substance in the waste gas.
4.3 Waste related measures	
Type of waste	Solid and liquid waste
Disposal technique	Solid and liquid wastes are disposed of in landfills or may be incinerated.
Fraction released to environment during waste treatment	Any wastewater relreased from the sedimentation step is expected not to contain more than 3.87 mg/L (saturated solution).
5. Prediction of exposure resulting from the conditions described above and the substance properties.	
5.1. Human exposure	
Workers (oral)	Good hygiene practice will minimise oral exposure
Workers (inhalation) *DNEL: Worker, long-term, systemic, inhalation: 0.05 mg/m^3*	The workers' inhalation exposure to kieselguhr soda ash flux-calcined is estimated with the ECETOC TRA tool (ECETOC 2010). The assessment of exposure concentrations was performed with the three grades of dustiness that can be selected in the TRA tool: low, medium and high. The modelled long-term exposure concentrations are compared to the DNEL for chronic inhalation exposure to obtain risk characterisation ratios. RCRs above 1 indicate that the potential risk is not adequately controlled. Safe conditions of use are described in the table for all activities. It is concluded that the manufacture of solid kieselguhr soda ash flux-calcined exhibiting different grades of dustiness is safe for workers under the specified conditions of exposure. This applies also to storage, repackaging and distribution of the substance. Safe conditions were defined by taking into account local exhaust ventilation in the present scenario. To achieve acceptable airborne concentrations of kieselguhr soda ash flux-calcined the efficiency of LEV and the duration of exposure were modified. Safe conditions can also be achieved by the use of personal respiratory equipment (PRE) in addition or as an alternative to LEV. Consequently, the presentation of safe conditions is not exhaustive in the present ES. **Safe conditions for industrial activities performed during the manufacture of kieselguhr soda ash flux-calcined**

Process Category	**LEV**	**Duration**	**PRE**	**Inhalation exposure (mg/m3) RCS content < 1%**	**Inhalation exposure (mg/m^3) RCS content < 10 %**	**Inhalation exposure (mg/m^3) RCS content <30 %**	**RCR (RCS content < 1%)**	**RCR (RCS content < 10 %)**	**RCR (RCS content <30 %)**
INDUSTRIAL USE WITH SUBSTANCE EXIHIBITING HIGH DUSTINESS									

1 – Use in closed process, no likelihood of exposure	No	4 to 8	No	0.0001	0.001	0.003	0.002	0.02	0.06
2 – Use in closed, continuous process with occasional controlled exposure	No	4 to 8	No	0.01			0.2		
	90%	4 to 8	No		0.01	0.03		0.2	0.6
3 – Use in closed batch process (synthesis or formulation)	No	4 to 8	No	0.01			0.2		
	90%	4 to 8	No		0.01	0.03		0.2	0.6
4 – Use in batch and other process (synthesis) where opportunity for exposure arises	90%	4 to 8	No	0.025			0.5		
	90%	Up to 4	90%		0.015			0.3	
	90%	Up to 1	90%			0.015			0.3
5 – Mixing or blending in batch processes (multistage and/or significant contact)	90%	4 to 8	No	0.025			0.5		
	90%	Up to 4	90%		0.015			0.3	
	90%	Up to 1	90%			0.015			0.3
8a – Transfer of chemicals from/to vessels/ large containers at non dedicated facilities	90%	Up to 4	No	0.03			0.6		
	90%	Up to 1	90%		0.01	0.03		0.2	0.6
8b – Transfer of chemicals from/to vessels/ large containers at dedicated facilities	90%	4 to 8	No	0.025			0.5		
	90%	Up to 4	90%		0.015			0.3	
	90%	Up to 1	90%			0.015			0.3
9 – Transfer of chemicals into small containers (dedicated filling line)	90%	4 to 8	No	0.02			0.4		
	90%	Up to 4	90%		0.012	0.036		0.24	0.72
15 – Use of laboratory reagents in small scale laboratories	90%	4 to 8	No	0.005			0.1		
	90%	Up to 1	No		0.01	0.03		0.2	0.6
19 – Hand-mixing with intimate contact (only PPE available)	No	Up to 1	90%	0.005			0.1		
	No	Up to 1	95%		0.025			0.5	
	No	Up to 15 minutes	95%			0.0375			0.75
INDUSTRIAL USE WITH SUBSTANCE EXIHIBITING MEDIUM DUSTINESS									
1 – Use in closed process, no likelihood of exposure	No	4 to 8	No	0.0001	0.001	0.003	0.002	0.02	0.06
2 – Use in closed, continuous process with occasional controlled exposure	No	4 to 8	No	0.01			0.2		
	90%	4 to 8	No		0.01	0.03		0.2	0.6
3 – Use in closed batch process (synthesis or formulation)	No	4 to 8	No	0.01			0.20		
	90%	4 to 8	No		0.01	0.03		0.2	0.6
4 – Use in batch and other process (synthesis) where opportunity for exposure arises	90%	4 to 8	No	0.005			0.1		
	90%	Up to 4	No		0.03			0.6	
	90%	Up to 4	90%			0.009			0.18
5 – Mixing or blending in batch processes (multistage and/or significant contact)	90%	4 to 8	No	0.005			0.1		
	90%	Up to 4	No		0.03			0.6	
	90%	Up to 4	90%			0.009			0.18
8a – Transfer of chemicals from/to vessels/ large containers at non dedicated facilities	90%	4 to 8	No	0.005			0.1		
	90%	Up to 4	No		0.025			0.5	
	90%	Up to 1	No			0.03			0.6

8b – Transfer of chemicals from/to vessels/ large containers at dedicated facilities	90%	4 to 8	No	0.005			0.1		
	90%	Up to 4	No		0.025			0.5	
	90%	Up to 1	No			0.03			0.6
9 – Transfer of chemicals into small containers (dedicated filling line)	90%	4 to 8	No	0.005			0.1		
	90%	Up to 4	No		0.025			0.5	
	90%	Up to 1	No			0.03			0.6
15 – Use of laboratory reagents in small scale laboratories	No	4 to 8	No	0.005			0.1		
	90%	4 to 8	No		0.005	0.015		0.1	0.3
19 – Hand-mixing with intimate contact (only PPE available)	No	Up to 1	90%	0.001	0.01	0.03	0.02	0.2	0.6
INDUSTRIAL USE WITH SUBSTANCE EXIHIBITING LOW DUSTINESS									
1 – Use in closed process, no likelihood of exposure	No	4 to 8	No	0.0001	0.001	0.003	0.002	0.02	0.06
2 – Use in closed, continuous process with occasional controlled exposure	No	4 to 8	No	0.0001	0.001	0.003	0.002	0.02	0.06
3 – Use in closed batch process (synthesis or formulation)	No	4 to 8	No	0.001	0.01	0.03	0.02	0.2	0.6
4 – Use in batch and other process (synthesis) where opportunity for exposure arises	No	4 to 8	No	0.005			0.1		
	90%	4 to 8	No		0.005	0.015		0.1	0.3
5 – Mixing or blending in batch processes (multistage and/or significant contact)	No	4 to 8	No	0.005			0.1		
	90%	4 to 8	No		0.005	0.015		0.1	0.3
8a – Transfer of chemicals from/to vessels/ large containers at non dedicated facilities	No	4 to 8	No	0.005			0.1		
	90%	4 to 8	No		0.005	0.015		0.1	0.3
8b – Transfer of chemicals from/to vessels/ large containers at dedicated facilities	No	4 to 8	No	0.001	0.01	0.03	0.02	0.2	0.6
9 – Transfer of chemicals into small containers (dedicated filling line)	No	4 to 8	No	0.001	0.01	0.03	0.02	0.2	0.6
15 – Use of laboratory reagents in small scale laboratories	No	4 to 8	No	0.001	0.01	0.03	0.02	0.2	0.6
19 – Hand-mixing with intimate contact (only PPE available)	No	4 to 8	No	0.005			0.1		
	No	4 to 8	90%		0.005	0.015		0.1	0.3

Workers (dermal)	Dermal exposure was not assessed, as no risks are anticipated with dermal exposure.
Indirect exposure via the	It is expected that emissions of kieselguhr soda ash flux-calcined from its identified uses will not significantly increase the naturally occurring concentrations of kieselguhr or other compounds in the environment. The potential of kieselguhr soda ash flux-calcined for bioaccumulation is low. The substance has a low solubility in water and thus is essentially unavailable to organisms.

environment	
Consumer exposure	No direct consumer exposure is resulting from the manufacture of kieselguhr soda ash flux-calcined.
5.2. Environmental exposure (qualitative assessment)	
Waste water treatment plants (WWTP)	According to unpublished monitoring data, wastewater released at manufacturing sites may contain up to 100 mg kieselguhr soda ash flux-calcined per litre. This is exceeding the amount that can be dissolved in one litre of water at saturation (3.87 mg/L at 20°C), indicating that suspended particles of kieselguhr soda ash flux-calcined may be present in the wastewater. Before entering the local sewage treatment plant (STP), the wastewater resulting from manufacturing of the substance can be treated by sedimentation to remove the solid parts of kieselguhr soda ash flux-calcined. The sedimentation is very efficient with a reduction efficacy of 99% or more. Any wastewater released from the sedimentation step is expected to contain not more than 3.87 mg kieselguhr soda ash flux-calcined per litre wastewater (saturated solution). No further degradation of the substance in the course of wastewater treatment is taken into account in the present assessment and the reasonable worst-case concentration of kieselguhr soda ash flux-calcined in the effluent of a local STP is 3.87 mg/L.
Aquatic pelagic compartment	To calculate the reasonable worst-case concentration of kieselguhr soda ash flux-calcined in surface water that may be due to emissions from the manufacture of the substance, the concentration of 3.87 mg/L in the effluent of the local STP is taken and a dilution factor of 10 is taken into account at the point of mixing of the wastewater with surface water (default EUSES). This leads to a surface water concentration of 0.387 mg/L. For releases of the wastewater to coastal sites, a dilution factor of 100 (EUSES default) is taken into account which leads to a concentration of 0.0387 mg/L in marine waters
Sediments	The wastewater released to the environment may contain suspended particles of kieselguhr soda ash flux-calcined. These solid parts will settle down at the bottom of the receiving water. As kieselguhr is a naturally occurring sedimentary rock consisting of the shells of diatoms and is naturally formed in water bodies this not considered to cause a potential hazard to the receiving water. Kieselguhr is a naturally occurring sedimentary rock consisting of the shells of diatoms which is formed in water bodies and is therefore considered a natural part of the ecosystem. Therefore, no risk is anticipated with kieselguhr soda ash flux-calcined in sediments and no exposure assessment for sediment is carried out.
Soil and groundwater	Kieselguhr soda ash flux-calcined may be released to soil via atmospheric deposition and via sewage sludge brought to agricultural fields and grassland. Kieselguhr is a naturally occurring sedimentary rock which is essentially a mineral fraction of soil already. Only the accidental release of a significant quantity kieselguhr soda ash flux-calcined is expected to alter the physical and chemical characteristics of a soil. As atmospheric deposition to soil is regarded as minor and the deposition of sewage sludge to fields takes place under controlled conditions no risk is anticipated with the release of kieselguhr soda ash flux-calcined to soil from the use described in this scenario and thus, no further assessment of the exposure concentrations in soil is undertaken
Atmospheric compartment	Emissions of kieselguhr soda ash flux-calcined into the atmosphere are low during the manufacture of the substance and waste air is expected to be filtered before released to the environment. The atmospheric concentrations of the substance are expected to be low. It is recommended to pass waste gas from manufacturing processes through bag filters, scrubbers or cyclones to reduce the amount of solid substance in the waste gas. No further assessment of the exposure concentrations in the atmosphere is undertaken.
Secondary poisoning	The potential of kieselguhr soda ash flux-calcined for bioaccumulation is low. The substance has a low solubility in water and thus is essentially unavailable to organisms.

Exposure Scenario 2: Use as filter aid in industrial settings

1. Short title of exposure scenario 2	
Use as a filter aid in industrial settings	
2. Description of activities and processes covered in the exposure scenario	
Sector of use (SU)	SU 3: Industrial uses: uses of substances as such or in preparations at industrial sites SU 4: Manufacture of food products SU 6: Manufacture of pulp, paper and paper products SU 8: Manufacture of bulk, large scale chemicals SU 10: Formulation mixing) of preparations and/or re-packaging SU 14: Manufacture of basic metals SU 17: General manufacturing, eg machner, equipment, vehicles, other transport equipment .
Product category (PC)	PC 2: Adsorbents PC 14: Metal surface treatment products, including galvanic and electroplating products PC 20: Products such as ph-regulators, flocculants, precipitants, neutralisation agents PC 25: Metal working fluids PC 35: Washing and cleaning products (including solvent based products) PC 0: Other: Filtration material
Process category (PROC)	PROC 1: Use in closed process, no likelihood of exposure PROC 2: Use in closed, continuous process with occasional controlled exposure PROC 3: Use in closed batch process (synthesis or formulation) PROC 4: Use in batch and other process (synthesis) where opportunity for exposure arises PROC 5: Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) PROC 8a: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities PROC 8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities PROC 9: Transfer of substance or preparation into small containers (dedicated filling line, including weighing) PROC 15: Use as laboratory reagent PROC 19: Hand-mixing with intimate contact and only PPE available.

Article category (AC)	Not applicable
Environmental release category (ERC)	ERC 1: Manufacture of substances ERC 2: Formulation of preparations ERC 4: Industrial use of processing aids in processes and products, not becoming part of articles ERC 6b: Industrial use of reactive processing aids ERC 7: Industrial use of substances in closed systems
3. Operational conditions	
3. 1 Operational conditions related with frequency and quantities of use	
Duration of exposure at workplace:	4-8 hours per day
Frequency of exposure at workplace:	5 days/week for each worker
Annual amount used per site:	The daily and annual amount/emission per site is not considered to be the main determinant for environmental exposure.
3.2 Operational conditions related with substance/ product	
Physical state	Solid and liquid
Concentration of substance in mixture	A concentration of 100% w/w was used to assess exposure to the solid substance. The exposure concentrations due to contact with liquid mixtures were calculated by taking into account a concentration of the substance in the liquid phase ranging from 5% to 25%.
3.3 Other relevant operational conditions	
No information about frequency and duration of the various tasks is available.	
4. Risk Management Measures	
4.1 RMMs related to workers	
Organisational measures	Solid substance: Local exhaust ventilation is installed at the manufacturing sites. The employer has also to ascertain that the required PPE is available and used according to instructions.
Technical measures	Solid substance: Safe conditions were defined by taking into account local exhaust ventilation in the present scenario

	Liquid substance: Outdoor activity – natural ventilation
Respiratory protection	In addition, workers may use half-face masks (P2 or P3) with an efficiency of at least 90% in situations with elevated dust concentrations in the air. Liquid substance: N/A
Hand protection	Skin protection may be used.
Eye protection	Eye protection may be used.
Skin and body protection	Wearing of suitable protective clothing.
Hygiene measures	Standard occupational hygiene measures should be adopted.
4.2 RMMs related to the environment	
Organisational measures	Waste gases are cleaned by passage through cyclones or scrubber units or by filtration with bag filters. Solid and liquid wastes are disposed of in landfills or may be incinerated
Abatement measures related with wastewater	The wastewater can be treated by sedimentation to remove the solid parts of the substance. The sedimentation is very efficient with a reduction efficacy of 99% or more.
Abatement measures waste air and solid waste	Waste air may be filtered eg by bag filters or scrubber units.
4.3 Waste related measures	
Type of waste	Solid and liquid waste.
Disposal technique	Solid and liquid waste may be incinerated or disposed of in landfills.
Fraction released to environment during waste treatment	Any wastewater released from the sedimentation step is expected not to contain more than 3.87 mg/L (saturated solution).

5. Prediction of exposure resulting from the conditions described above and the substance properties.

5.1. Human exposure

Workers (oral)	Good hygiene practice will minimise oral exposure
Workers (inhalation) *DNEL: Worker, long-term, systemic, inhalation: 0.05 mg/m^3*	Safe conditions for the handling of solid kieselguhr soda ash flux-calcined are given in for the manufacture of the substance. These apply also to the use of the substance as filter aid covered in exposure scenario 2. The modelled long-term exposure concentrations resulting from the handling of liquid mixtures containing the substance are compared to the DNEL for chronic inhalation exposure to obtain risk characterisation ratios. RCRs above 1 indicate that the potential risk is not adequately controlled. Safe conditions of use are described for all activities described in exposure scenario 1. It is concluded that the manufacture of solid kieselguhr soda ash flux-calcined exhibiting different grades of dustiness is safe for workers under the specified conditions of exposure.

Safe conditions for industrial activities performed during the use of kieselguhr soda ash flux-calcined as a filter aid

Process Category	LEV	Duration	PRE	Content (%)	Inhalation exposure (ppm)	Inhalation exposure (mg/m3)
INDUSTRIAL USE OF LIQUID DISPERSIONS						
2 – Use in closed, continuous process with occasional controlled exposure	No	4 to 8	No	5 to 25	0.00	0.00
3 – Use in closed batch process (synthesis or formulation)	No	4 to 8	No	5 to 25	0.00	0.00
4 – Use in batch and other process (synthesis) where opportunity for exposure arises	No	4 to 8	No	5 to 25	0.00	0.00
5 – Mixing or blending in batch processes (multistage and/or significant contact)	No	4 to 8	No	5 to 25	0.00	0.00
8a –Transfer of chemicals from/to vessels/ large containers at non dedicated facilities	No	4 to 8	No	5 to 25	0.00	0.00
8b –Transfer of chemicals from/to vessels/ large containers at dedicated facilities	No	4 to 8	No	5 to 25	0.00	0.00

9 – Transfer of chemicals into small containers (dedicated filling line)	No	4 to 8	No	5 to 25	0.00	0.00	
15 – Use of laboratory reagents in small scale laboratories	No	4 to 8	No	5 to 25	0.00	0.00	
19 – Hand-mixing with intimate contact (only PPE available)	No	4 to 8	No	5 to 25	0.00	0.00	

Workers (dermal)	Dermal exposure was not assessed, as no risks are anticipated with dermal exposure.
Indirect exposure via the environment	It is expected that emissions of kieselguhr soda ash flux-calcined from its identified uses will not significantly increase the naturally occurring concentrations of kieselguhr or other compounds in the environment. The potential of kieselguhr soda ash flux-calcined for bioaccumulation is low. The substance has a low solubility in water and thus is essentially unavailable to organisms.
Consumer exposure	No direct consumer exposure is resulting from the manufacture of kieselguhr soda ash flux-calcined.
5.2. Environmental exposure (qualitative assessment)	
Waste water treatment plants (WWTP)	The amount of kieselguhr soda ash flux-calcined present in the wastewater may exceed the amount that can be dissolved at saturation (3.87 mg/L at 20°C), indicating that suspended particles of kieselguhr soda ash flux-calcined may be present in the wastewater. Before entering a sewage treatment plant (STP), the wastewater should be treated by sedimentation to remove the greatest portion of solids. Sedimentation is very efficient with a reduction efficacy of 99% or more. Any wastewater released from the sedimentation step is expected to contain not more than 3.87 mg kieselguhr soda ash flux-calcined per litre wastewater (saturated solution). No further degradation of the substance in the course of wastewater treatment is taken into account in the present assessment and the reasonable worst-case concentration of kieselguhr soda ash flux-calcined in the effluent of a local STP is 3.87 mg/L.
Aquatic pelagic compartment	To calculate the reasonable worst-case concentration of kieselguhr soda ash flux-calcined in surface water that may be due to emissions from the manufacture of the substance, the concentration of 3.87 mg/L in the effluent of the local STP is taken and a dilution factor of 10 is taken into account at the point of mixing of the wastewater with surface water (default EUSES). This leads to a surface water concentration of 0.387 mg/L. For releases of the wastewater to coastal sites, a dilution factor of 100 (EUSES default) is taken into account which leads to a concentration of 0.0387 mg/L in marine waters
Sediments	The wastewater released to the environment may contain suspended particles of kieselguhr soda ash flux-calcined. These solid parts will settle down at the bottom of the receiving water. As kieselguhr is a naturally occurring sedimentary rock consisting of the shells of diatoms and is naturally formed in water bodies this not considered to cause a potential hazard to the receiving water. Kieselguhr is a naturally occurring sedimentary rock consisting of the shells of diatoms which is

	formed in water bodies and is therefore considered a natural part of the ecosystem. Therefore, no risk is anticipated with kieselguhr soda ash flux-calcined in sediments and no exposure assessment for sediment is carried out
Soil and groundwater	Kieselguhr soda ash flux-calcined may be released to soil via atmospheric deposition and via sewage sludge brought to agricultural fields and grassland. Kieselguhr is a naturally occurring sedimentary rock which is essentially a mineral fraction of soil already. Only the accidental release of a significant quantity kieselguhr soda ash flux calcined is expected to alter the physical and chemical characteristics of a soil. As atmospheric deposition to soil is regarded as minor and the deposition of sewage sludge to fields takes place under controlled conditions no risk is anticipated with the release of kieselguhr soda ash flux-calcined to soil from the use described in this scenario and thus, no further assessment of the exposure concentrations in soil is undertaken
Atmospheric compartment	Emissions of kieselguhr soda ash flux-calcined into the atmosphere are low during the use of kieselguhr soda ash flux-calcined as a filter aid in industrial settings. The atmospheric concentrations of the substance are expected to be low. No further assessment of the exposure concentrations in the atmosphere is undertaken
Secondary poisoning	The potential of kieselguhr soda ash flux-calcined for bioaccumulation is low. The substance has a low solubility in water and thus is essentially unavailable to organisms.

Exposure Scenario 3: Use as additive in formulation of liquid, viscous or solid mixtures

1. Short title of exposure scenario 3	
Use as an additive in formulation of liquids, viscous or solid mixtures	
2. Description of activities and processes covered in the exposure scenario	
Sector of use (SU)	SU 3: Industrial uses: uses of substances as such or in preparations at industrial sites SU 10: Formulation mixing) of preparations and/or re-packaging SU 11: Manufacture of rubber products SU 13: Manufacture of other non-metallic mineral products, eg plasters, cement .
Product category (PC)	PC 2: Adsorbents

	PC 9: Coatings and paints, fillers, putties, thinners PC 21: Laboratory chemicals PC 29: Pharmaceuticals PC 35: Washing and cleaning products (including solvent based products)
Process category (PROC)	PROC 1: Use in closed process, no likelihood of exposure PROC 2: Use in closed, continuous process with occasional controlled exposure PROC 3: Use in closed batch process (synthesis or formulation) PROC 4: Use in batch and other process (synthesis) where opportunity for exposure arises PROC 5: Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) PROC 8a: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities PROC 8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities PROC 9: Transfer of substance or preparation into small containers (dedicated filling line, including weighing) PROC 14: Production of preparations or articles by tabletting, compression, extrusion, pelletisation PROC 15: Use as laboratory reagent PROC 19: Hand-mixing with intimate contact and only PPE available.
Article category (AC)	AC 10: Rubber products AC 13: Plastic products
Environmental release category (ERC)	ERC 2: Formulation of preparations ERC 4: Industrial use of processing aids in processes and products, not becoming part of articles ERC 7: Industrial use of substances in closed systems ERC 8b: Wide dispersive indoor use of reactive substances in open systems
3. Operational conditions	
3. 1 Operational conditions related with frequency and quantities of use	
Duration of exposure at workplace:	8 hours per day
Frequency of exposure at workplace:	5 days/week for each worker
Annual amount used per site:	The daily and annual amount/emission per site is not considered to be the main determinant for environmental exposure.

3.2 Operational conditions related with substance/ product	
Physical state	Solid and liquid
Concentration of substance in mixture	The concentration of the substance in the final mixtures may range from <1 % (liquid) to 60 % (dental fillings).
3.3 Other relevant operational conditions	
No information about frequency and duration of the various tasks is available.	
4. Risk Management Measures	
4.1 RMMs related to workers	
Organisational measures	The employer has also to ascertain that the required PPE is available and used according to instructions.
Technical measures	LEV may be present and/or respiratory masks (P2 or P3) may be used in situations with elevated dust concentrations in the air. Skin protection and eye protection may be used
Respiratory protection	LEV may be present and/or respiratory masks (P2 or P3) may be used in situations with elevated dust concentrations in the air.
Hand protection	Skin protection may be used.
Eye protection	Eye protection may be used.
Skin and body protection	Wearing of suitable protective clothing.
Hygiene measures	Standard occupational hygiene measures should be adopted.
4.2 RMMs related to the environment	
Organisational measures	Waste gases are cleaned by passage through cyclones or scrubber units or by filtration with bag filters. Solid and liquid wastes are disposed of in landfills or may be incinerated
Abatement measures related with wastewater	The wastewater resulting from manufacturing of the substance can be treated by sedimentation to remove the solid parts of the substance. The sedimentation is very efficient with a reduction efficacy of 99% or more.

Abatement measures waste air and solid waste	It is recommended to pass waste gas through bag filters, scrubbers or cyclones to reduce the amount of solid substance in the waste gas.
4.3 Waste related measures	
Type of waste	Solid and liquid waste.
Disposal technique	Solid and liquid waste may be incinerated or disposed of in landfills.
Fraction released to environment during waste treatment	Any wastewater released from the sedimentation step is expected not to contain more than 3.87 mg/L (saturated solution).
5. Prediction of exposure resulting from the conditions described above and the substance properties.	
5.1. Human exposure	
Workers (oral)	Good hygiene practice will minimise oral exposure
Workers (inhalation) *DNEL: Worker, long-term, systemic, inhalation: 0.05mg/m^3*	The workers' inhalation exposure to kieselguhr soda ash flux-calcined that may occur during the formulation of liquid, viscous or solid preparations described in the present exposure scenario ES 3 is covered by the exposure concentrations calculated in the exposure scenarios ES 1 and ES 2.
Workers (dermal)	Dermal exposure was not assessed, as no risks are anticipated with dermal exposure.
Indirect exposure via the environment	It is expected that emissions of kieselguhr soda ash flux-calcined from its identified uses will not significantly increase the naturally occurring concentrations of kieselguhr or other compounds in the environment. The potential of kieselguhr soda ash flux-calcined for bioaccumulation is low. The substance has a low solubility in water and thus is essentially unavailable to organisms.
Consumer exposure	No direct consumer exposure is resulting from the use of kieselguhr soda-ash flux calcined as an additive in the formulation of liquid, viscous or solid mixtures.
5.2. Environmental exposure (qualitative assessment)	

Waste water treatment plants (WWTP)	The amount of kieselguhr soda ash flux-calcined present in the wastewater may exceed the amount that can be dissolved at saturation (3.87 mg/L at 20°C), indicating that suspended particles of kieselguhr soda ash flux-calcined may be present in the wastewater. Before entering a sewage treatment plant (STP), the wastewater should be treated by sedimentation to remove the greatest portion of solids. Sedimentation is very efficient with a reduction efficacy of 99% or more. Any wastewater released from the sedimentation step is expected to contain not more than 3.87 mg kieselguhr soda ash flux-calcined per litre wastewater (saturated solution). No further degradation of the substance in the course of wastewater treatment is taken into account in the present assessment and the reasonable worst-case concentration of kieselguhr soda ash flux-calcined in the effluent of a local STP is 3.87 mg/L.
Aquatic pelagic compartment	To calculate the reasonable worst-case concentration of kieselguhr soda ash flux-calcined in surface water that may be due to emissions from the manufacture of the substance, the concentration of 3.87 mg/L in the effluent of the local STP is taken and a dilution factor of 10 is taken into account at the point of mixing of the wastewater with surface water (default EUSES). This leads to a surface water concentration of 0.387 mg/L. For releases of the wastewater to coastal sites, a dilution factor of 100 (EUSES default) is taken into account which leads to a concentration of 0.0387 mg/L in marine waters
Sediments	The wastewater released to the environment may contain suspended particles of kieselguhr soda ash flux-calcined. These solid parts will settle down at the bottom of the receiving water. As kieselguhr is a naturally occurring sedimentary rock consisting of the shells of diatoms and is naturally formed in water bodies this not considered to cause a potential hazard to the receiving water. Kieselguhr is a naturally occurring sedimentary rock consisting of the shells of diatoms which is formed in water bodies and is therefore considered a natural part of the ecosystem. Therefore, no risk is anticipated with kieselguhr soda ash flux-calcined in sediments and no exposure assessment for sediment is carried out
Soil and groundwater	Kieselguhr soda ash flux-calcined may be released to soil via atmospheric deposition and via sewage sludge brought to agricultural fields and grassland. Kieselguhr is a naturally occurring sedimentary rock which is essentially a mineral fraction of soil already. Only the accidental release of a significant quantity kieselguhr soda ash flux calcined is expected to alter the physical and chemical characteristics of a soil. As atmospheric deposition to soil is regarded as minor and the deposition of sewage sludge to fields takes place under controlled conditions no risk is anticipated with the release of kieselguhr soda ash flux-calcined to soil from the use described in this scenario and thus, no further assessment of the exposure concentrations in soil is undertaken
Atmospheric compartment	Emissions of kieselguhr soda ash flux-calcined into the atmosphere are low during the use of kieselguhr soda ash flux-calcined as a filter aid in industrial settings. The atmospheric concentrations of the substance are expected to be low. No further assessment of the exposure concentrations in the atmosphere is undertaken
Secondary poisoning	The potential of kieselguhr soda ash flux-calcined for bioaccumulation is low. The substance has a low solubility in water and thus is essentially unavailable to organisms.

Exposure Scenario 4: Use as process aid in manufacture of chemicals, resins, rubbers and plastics

1. Short title of exposure scenario 4	
Use as an additive in formulation of liquids, viscous or solid mixtures	
2. Description of activities and processes covered in the exposure scenario	
Sector of use (SU)	SU 3: Industrial uses: uses of substances as such or in preparations at industrial sites SU 8: Manufacture of bulk, large scale chemicals SU 9: Manufacture of fine chemicals SU 11: Manufacture of rubber products SU 12: Manufacture of plastics products, including compound and conversion .
Product category (PC)	PC 16: Heat transfer fluids PC 17: Hydraulic fluids PC 20: Products such as ph-regulators, flocculants, precipitants, neutralisation agents PC 24: Lubricants, greases, release products PC 25: Metal working fluids PC 32: Polymer preparations and compounds
Process category (PROC)	PROC 1: Use in closed process, no likelihood of exposure PROC 2: Use in closed, continuous process with occasional controlled exposure PROC 3: Use in closed batch process (synthesis or formulation) PROC 4: Use in batch and other process (synthesis) where opportunity for exposure arises PROC 5: Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) PROC 8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities PROC 15: Use as laboratory reagent PROC 19: Hand-mixing with intimate contact and only PPE available.
Article category (AC)	Not applicable
Environmental release category (ERC)	ERC 1: Manufacture of substances ERC 2: Formulation of preparations ERC 4: Industrial use of processing aids in processes and products, not becoming part of articles
3. Operational conditions	
3. 1 Operational conditions related with frequency and quantities of use	

Duration of exposure at workplace:	8 hours per day
Frequency of exposure at workplace:	360 days/year for each worker
Annual amount used per site:	The daily and annual amount/emission per site is not considered to be the main determinant for environmental exposure.
3.2 Operational conditions related with substance/ product	
Physical state	Solid and liquid
Concentration of substance in mixture	100% w/w
3.3 Other relevant operational conditions	
No information about frequency and duration of the various tasks is available.	
4. Risk Management Measures	
4.1 RMMs related to workers	
Organisational measures	The employer has also to ascertain that the required PPE is available and used according to instructions.
Technical measures	LEV may be present and/or respiratory masks (P2 or P3) may be used in situations with elevated dust concentrations in the air. Skin protection and eye protection may be used
Respiratory protection	LEV may be present and/or respiratory masks (P2 or P3) may be used in situations with elevated dust concentrations in the air.
Hand protection	Skin protection may be used.
Eye protection	Eye protection may be used.
Skin and body protection	Wearing of suitable protective clothing.
Hygiene measures	Standard occupational hygiene measures should be adopted.
4.2 RMMs related to the environment	

Organisational measures	Not applicable
Abatement measures related with wastewater	The wastewater resulting from manufacturing of the substance can be treated by sedimentation to remove the solid parts of the substance. The sedimentation is very efficient with a reduction efficacy of 99% or more.
Abatement measures waste air and solid waste	It is recommended to pass waste gas through bag filters, scrubbers or cyclones to reduce the amount of solid substance in the waste gas.
4.3 Waste related measures	
Type of waste	Solid and liquid waste.
Disposal technique	Solid and liquid waste may be incinerated or disposed of in landfills.
Fraction released to environment during waste treatment	Any wastewater released from the sedimentation step is expected not to contain more than 3.87 mg/L (saturated solution).
5. Prediction of exposure resulting from the conditions described above and the substance properties.	
5.1. Human exposure	
Workers (oral)	Good hygiene practice will minimise oral exposure
Workers (inhalation) *DNEL: Worker, long-term, systemic, inhalation: 0.05mg/m^3*	The workers' inhalation exposure to kieselguhr soda ash flux-calcined that may occur during the formulation of liquid, viscous or solid preparations described in the present exposure scenario ES 4 is covered by the exposure concentrations calculated in the exposure scenarios ES 1 and ES 2.
Workers (dermal)	Dermal exposure was not assessed, as no risks are anticipated with dermal exposure.
Indirect exposure via	It is expected that emissions of kieselguhr soda ash flux-calcined from its identified uses will not significantly increase the naturally occurring concentrations of kieselguhr or other compounds in

the environment	the environment. The potential of kieselguhr soda ash flux-calcined for bioaccumulation is low. The substance has a low solubility in water and thus is essentially unavailable to organisms.
Consumer exposure	No direct consumer exposure is resulting from the use of kieselguhr soda ash flux-calcined as a process aid in the manufacture of chemicals, resins, rubbers and plastics
5.2. Environmental exposure (qualitative assessment)	
Waste water treatment plants (WWTP)	The amount of kieselguhr soda ash flux-calcined present in the wastewater may exceed the amount that can be dissolved at saturation (3.87 mg/L at 20°C), indicating that suspended particles of kieselguhr soda ash flux-calcined may be present in the wastewater. Before entering a sewage treatment plant (STP), the wastewater should be treated by sedimentation to remove the greatest portion of solids. Sedimentation is very efficient with a reduction efficacy of 99% or more. Any wastewater released from the sedimentation step is expected to contain not more than 3.87 mg kieselguhr soda ash flux-calcined per litre wastewater (saturated solution). No further degradation of the substance in the course of wastewater treatment is taken into account in the present assessment and the reasonable worst-case concentration of kieselguhr soda ash flux-calcined in the effluent of a local STP is 3.87 mg/L.
Aquatic pelagic compartment	To calculate the reasonable worst-case concentration of kieselguhr soda ash flux-calcined in surface water that may be due to emissions from the manufacture of the substance, the concentration of 3.87 mg/L in the effluent of the local STP is taken and a dilution factor of 10 is taken into account at the point of mixing of the wastewater with surface water (default EUSES). This leads to a surface water concentration of 0.387 mg/L. For releases of the wastewater to coastal sites, a dilution factor of 100 (EUSES default) is taken into account which leads to a concentration of 0.0387 mg/L in marine waters
Sediments	The wastewater released to the environment may contain suspended particles of kieselguhr soda ash flux-calcined. These solid parts will settle down at the bottom of the receiving water. As kieselguhr is a naturally occurring sedimentary rock consisting of the shells of diatoms and is naturally formed in water bodies this not considered to cause a potential hazard to the receiving water. Kieselguhr is a naturally occurring sedimentary rock consisting of the shells of diatoms which is formed in water bodies and is therefore considered a natural part of the ecosystem. Therefore, no risk is anticipated with kieselguhr soda ash flux-calcined in sediments and no exposure assessment for sediment is carried out
Soil and groundwater	Kieselguhr soda ash flux-calcined may be released to soil via atmospheric deposition and via sewage sludge brought to agricultural fields and grassland. Kieselguhr is a naturally occurring sedimentary rock which is essentially a mineral fraction of soil already. Only the accidental release of a significant quantity kieselguhr soda ash flux calcined is expected to alter the physical and chemical characteristics of a soil. As atmospheric deposition to soil is regarded as minor and the deposition of sewage sludge to fields takes place under controlled conditions no risk is anticipated with the release of kieselguhr soda ash flux-calcined to soil from the use described in this scenario and thus, no further assessment of the exposure concentrations in soil is undertaken

Atmospheric compartment	Emissions of kieselguhr soda ash flux-calcined into the atmosphere are low during the use of the substance as a process aid in the manufacture of chemicals, resins, rubbers and plastics. The atmospheric concentrations of the substance are expected to be low. It is recommended to pass waste gas through bag filters, scrubbers or cyclones to reduce the amount of solid substance in the waste gas. No further assessment of the exposure concentrations in the atmosphere is undertaken
Secondary poisoning	The potential of kieselguhr soda ash flux-calcined for bioaccumulation is low. The substance has a low solubility in water and thus is essentially unavailable to organisms.

Exposure Scenario 5: Professional use by dental technicians and dentists

1. Short title of exposure scenario 4	
Use as an additive in formulation of liquids, viscous or solid mixtures	
2. Description of activities and processes covered in the exposure scenario	
Sector of use (SU)	SU 9: Manufacture of fine chemicals SU 10: Formulation mixing) of preparations and/or re-packaging SU 12: Manufacture of plastics products, including compound and conversion SU 20: Health surfaces .
Product category (PC)	PC 32: Polymer preparations and compounds
Process category (PROC)	PROC 5: Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) PROC 19: Hand-mixing with intimate contact and only PPE available.
Article category (AC)	Not applicable
Environmental release category (ERC)	ERC 2: Formulation of preparations ERC 3: Formulation in materials ERC 8f: Wide dispersive outdoor use resulting in inclusion into or onto a matrix
3. Operational conditions	
3. 1 Operational conditions related with frequency and quantities of use	

Duration of exposure at workplace:	Up to 1 h/day
Frequency of exposure at workplace:	Performed on up to 220 days/year
Annual amount used per site:	The daily and annual amount emission per site is not considered to be the main determinant for environmental exposure.
3.2 Operational conditions related with substance/ product	
Physical state	Solid and liquid
Concentration of substance in mixture	Such materials can contain the substance at levels up to 60% w/w
3.3 Other relevant operational conditions	
No information about frequency and duration of the various tasks is available.	
4. Risk Management Measures	
4.1 RMMs related to workers	
Organisational measures	The employer has also to ascertain that the required PPE is available and used according to instructions.
Technical measures	Professionals normally do the mixing in the absence of LEV.
Respiratory protection	N/A
Hand protection	Skin protection may be used.
Eye protection	Eye protection may be used.
Skin and body protection	Wearing of suitable protective clothing.
Hygiene measures	Standard occupational hygiene measures should be adopted.
4.2 RMMs related to the environment	

<table>
<tr><td>Organisational measures</td><td>Any liquid waste that results from cleaning of equipment will be disposed of via the public sewer. Solid waste may be incinerated or deposited in landfills</td></tr>
<tr><td>Abatement measures related with wastewater</td><td>Any liquid waste that results from cleaning of equipment will be disposed of via the public sewer</td></tr>
<tr><td>Abatement measures waste air and solid waste</td><td>Solid waste may be incinerated or deposited in landfills. Emissions of kieselguhr soda ash flux-calcined into the atmosphere are low during the use of the substance in dental practices. The atmospheric concentrations of the substance are expected to be low. No further assessment of the exposure concentrations in the atmosphere is undertaken.</td></tr>
<tr><td colspan="2">4.3 Waste related measures</td></tr>
<tr><td>Type of waste</td><td>Solid and liquid waste.</td></tr>
<tr><td>Disposal technique</td><td>Solid waste may be incinerated or deposited in landfills. Any liquid waste that results from cleaning of equipment will be disposed of via the public sewer.</td></tr>
<tr><td>Fraction released to environment during waste treatment</td><td>Emissions from filling and alginate impression material may occur on 260 days per year. About 300 tonnes kieselguhr soda ash flux-calcined are used per year for dental filling and impression material in the EU. A fraction of 10%, i.e. 30 t/year, is considered for regional use. For the local use, 0.2% of the regional tonnage is considered, i.e. 60 kg/year. Part of the substance may be release to the wastewater when cleaning materials, which were in contact with preparations containing kieselguhr soda ash, flux-calcined. It is expected that at most 10% of the filling and impression materials are released to the sewer, i.e. 6 kg per year on the local scale. This results in a reasonable worst-case emission of substance into the wastewater of 0.023 kg/day. Emissions of the substance into the atmosphere or the soil compartment are negligible
<table>
<tr><th>Parameter</th><th>Value</th></tr>
<tr><td>Tonnage in EU per year</td><td>300 t</td></tr>
<tr><td>Regional tonnage per year</td><td>30 t</td></tr>
<tr><td>Local tonnage per year</td><td>60 kg</td></tr>
<tr><td>Fraction of main local source</td><td>0.002</td></tr>
<tr><td>Number of days</td><td>260 d</td></tr>
<tr><td></td><td></td></tr>
<tr><td>Fraction of tonnage released to air</td><td>0</td></tr>
</table>
</td></tr>
</table>

Fraction of tonnage released to wastewater	0.1	
Fraction of tonnage released to soil	0	
Local emissions to wastewater	0.023 kg/day	

5. Prediction of exposure resulting from the conditions described above and the substance properties.

5.1. Human exposure

Workers (oral)	Good hygiene practice will minimise oral exposure
Workers (inhalation) *DNEL: Worker, long-term, systemic, inhalation:0.05 mg/m^3*	The modelled reasonable worst-case long-term exposure concentrations resulting from the handling of small amounts of dental filling or impression materials (about 50 g/application) is 0.0072 mg/m^3 (based on a product containing 10% of kieselguhr soda ash flux-calcined with a RCS content of 30%). The RCR obtained by comparing this concentration of the long-term inhalation DNEL of 0.05 mg/m^3 is 0.144 showing that the potential health risk for workers is controlled for the professional use of kieselguhr soda ash flux-calcined as dental filling and impression material by dental technicians and dentists.
Workers (dermal)	Dermal exposure was not assessed, as no risks are anticipated with dermal exposure.
Indirect exposure via the environment	It is expected that emissions of kieselguhr soda ash flux-calcined from its identified uses will not significantly increase the naturally occurring concentrations of kieselguhr or other compounds in the environment. The potential of kieselguhr soda ash flux-calcined for bioaccumulation is low. The substance has a low solubility in water and thus is essentially unavailable to organisms. It is concluded that indirect human exposure to kieselguhr soda ash flux-calcined via the environment is not relevant
Consumer exposure	Patients may ingest small amounts of substance during dental treatment. In general exposure is expected to be negligibe as the dental treatment is performed under professional surveillance.

5.2. Environmental exposure (qualitative assessment)

Waste water treatment plants (WWTP)	In the present assessment, the wastewater passes through a sewage treatment plant (STP) which has a capacity of 2000000 L/day. No removal of kieselguhr soda ash flux-calcined during wastewater treatment is taken into account for the present exposure scenario. The resulting reasonable worst-case concentration of the substance in the effluent of a local STP is 23000/2000000=0.012 mg/L

Aquatic pelagic compartment	A dilution factor of 10 is taken into account at the point of mixing of the wastewater with surface water, leading to a surface water concentration of 0.0012 mg/L. For coastal areas a dilution factor of 100 is taken into account, leading to a concentration of 0.00012 mg/L in marine waters
Sediments	The wastewater released to the environment may contain suspended particles of kieselguhr soda ash flux-calcined. These solid parts will settle down at the bottom of the receiving water. As kieselguhr is a naturally occurring sedimentary rock consisting of the shells of diatoms and is naturally formed in water bodies this not considered to cause a potential hazard to the receiving water. Kieselguhr is a naturally occurring sedimentary rock consisting of the shells of diatoms which is formed in water bodies and is therefore considered a natural part of the ecosystem. Therefore, no risk is anticipated with kieselguhr soda ash flux-calcined in sediments and no exposure assessment for sediment is carried out.
Soil and groundwater	Kieselguhr soda ash flux-calcined may be released to soil via atmospheric deposition and via sewage sludge brought to agricultural fields and grassland. Kieselguhr is a naturally occurring sedimentary rock which is essentially a mineral fraction of soil already. Only the accidental release of a significant quantity kieselguhr soda ash flux-calcined is expected to alter the physical and chemical characteristics of a soil. As atmospheric deposition to soil is regarded as minor and the deposition of sewage sludge to fields takes place under controlled conditions no risk is anticipated with the release of kieselguhr soda ash flux-calcined to soil from the use described in this scenario and thus, no further assessment of the exposure concentrations in soil is undertaken
Atmospheric compartment	Emissions of kieselguhr soda ash flux-calcined into the atmosphere are low during the use of the substance in dental practices. The atmospheric concentrations of the substance are expected to be low. No further assessment of the exposure concentrations in the atmosphere is undertaken
Secondary poisoning	The potential of kieselguhr soda ash flux-calcined for bioaccumulation is low. The substance has a low solubility in water and thus is essentially unavailable to organisms.

Exposure Scenario 6: Industrial, professional and private use of substance or mixtures containing the substance

1. Short title of exposure scenario 6

Use as an additive in formulation of liquids, viscous or solid mixtures	
2. Description of activities and processes covered in the exposure scenario	
Sector of use (SU)	SU 3: Industrial uses: uses of substances as such or in preparations at industrial sites SU 21: Consumer uses: Private households (= general public = consumers) SU22: Professional uses: Public domain (administration, education, entertainment, services, craftsmen)
Product category (PC)	PC 35: Washing and cleaning products (including solvent based products) PC 37: Water treatment chemicals
Process category (PROC)	PROC 2: Use in closed, continuous process with occasional controlled exposure PROC 3: Use in closed batch process (synthesis or formulation) PROC 4: Use in batch and other process (synthesis) where opportunity for exposure arises PROC 5: Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) PROC 7: Industrial spraying PROC 8a: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities PROC 10: Roller application or brushing PROC 11: Non industrial spraying PROC 13: Treatment of articles by dipping and pouring PROC 19: Hand-mixing with intimate contact and only
Article category (AC)	AC 10: Rubber products AC 13: Plastic products
Environmental release category (ERC)	ERC 1: Manufacture of substances ERC 2: Formulation of preparations ERC 8a: Wide dispersive indoor use of processing aids in open systems ERC 8c: Wide dispersive indoor use resulting in inclusion into or onto a matrix ERC 8d: Wide dispersive outdoor use of processing aids in open systems ERC 8f: Wide dispersive outdoor use resulting in inclusion into or onto a matrix ERC 10b: Wide dispersive outdoor use of long-life articles and materials with high or intended release (including abrasive processing)
3. Operational conditions	
3. 1 Operational conditions related with frequency and quantities of use	
Duration of exposure at workplace:	Use of coatings and paints containing kieselguhr soda ash flux-calcined: 4-8 hours Use of kieselguhr soda ash flux calcined for filtering water: Approximately 1 hour per day. Use of cleaners containing kieselguhr soda-ash flux calcined: Professionals up to 60 minutes per use, consumers up to 20 minutes per day.
Frequency of exposure at workplace:	Use of coatings and paints containing kieselguhr soda ash flux-calcined: Up to 225 days per year Use of kieselguhr soda ash flux calcined for filtering water: Weekly for professional use and monthly consumer use

	Use of cleaners containing kieselguhr soda-ash flux calcined: Professionals up to 8 times a day.
Annual amount used per site:	The daily and annual amount emission per site is not considered to be the main determinant for environmental exposure.
3.2 Operational conditions related with substance/ product	
Physical state	Solid and liquid
Concentration of substance in mixture	A variety of articles made from rubbers or plastics contain the substance. The average weight fraction of kieselguhr soda ash flux-calcined in such articles is about 7% w/w and the maximum weight fraction is approximately 15% w/w.
3.3 Other relevant operational conditions	
No information about frequency and duration of the various tasks is available.	
4. Risk Management Measures	
4.1 RMMs related to workers	
Organisational measures	The employer has also to ascertain that the required PPE is available and used according to instructions.
Technical measures	Safe conditions were defined by considering that workers use respiratory equipment during industrial spraying to protect themselves against elevated airbourne concentrations of coatings or paints. Alternatively safe conditions may also be achieved by ensuring very good ventilation in the workplace. The use of articles made from rubbers or plastics containing the substance is considered safe as no release of kieselguhr is expected.
Respiratory protection	If elevated exposure is to be expected LEV may be present and industrial and professional users may wear breathing masks (P2 or P3) reducing the amount of inhaled aerosols
Hand protection	Skin protection may be used.
Eye protection	Eye protection may be used.
Skin and body protection	Wearing of suitable protective clothing.
Hygiene measures	Standard occupational hygiene measures should be adopted.
4.2 RMMs related to the environment	
Organisational measures	Kieselguhr soda ash flux-calcined used for the filtering of drinking and swimming pool water and kieselguhr soda ash flux-calcined present in surface cleaners may be released to the sewer and subsequently pass a municipal sewage treatment plant (STP).

Abatement measures related with wastewater	Any liquid waste that results will be disposed of via the public sewer
Abatement measures waste air and solid waste	Solid waste may be disposed of as industrial, commercial or common household waste and may be incinerated or disposed of in landfills Waste air at industrial and professional sites may be filtered before released to the atmosphere.
4.3 Waste related measures	
Type of waste	Liquid/solid waste.
Disposal technique	Wastewater that is generated during cleaning operations may be treated in an onsite treatment plant or be released to the public sewer system and treated in a municipal STP. Solid waste may be disposed of as industrial, commercial or common household waste and may be incinerated or disposed of in landfills.
Fraction released to environment during waste treatment	A worst-case is considered in the present assessment in that 10% of the total tonnage placed on the EU market ends up in municipal STPs
5. Prediction of exposure resulting from the conditions described above and the substance properties.	
5.1. Human exposure	
Workers (oral)	Good hygiene practice will minimise oral exposure
Workers (inhalation) *DNEL: Worker, long-term, systemic, inhalation 0.05: mg/m^3*	The modelled long-term exposure concentrations are compared to the DNEL for chronic inhalation exposure to obtain risk characterisation ratios. RCRs above 1 indicate that the potential risk is not adequately controlled. Safe conditions of use are described in exposure scenario 5. Safe conditions for additional activities are shown in the table below Safe conditions were defined by considering that workers use personal respiratory equipment during industrial spraying to protect themselves against elevated airborne concentrations of coatings or paints. Alternatively, safe conditions may also be achieved by ensuring very good ventilation of the workplace. The use of articles made from rubbers or plastics containing the substance is considered safe as no release of kieselguhr soda ash flux-calcined is anticipated. It is concluded that the industrial use of mixtures containing kieselguhr soda ash flux-calcined is safe for workers under the specified conditions of exposure. **Safe conditions for industrial activities performed during the use of mixtures containing kieselguhr soda ash flux-calcined**

Process Category	**LEV**	**Duration**	**PRE**	**Inhalation exposure (mg/m3) RCS content < 1%**	**Inhalation exposure (mg/m^3) RCS content < 10 %**	**Inhalation exposure (mg/m^3) RCS content <30 %**	**RCR RCS content < 1%**	**RCR RCS content < 10 %**	**RCR RCS content <30 %**
INDUSTRIAL AND PROFESSIONAL USE OF LIQUID									

DISPERSIONS									
	No	Up to 6	No	0.0035	0.035		0.07	0.7	
7 – Industrial spraying	No	Up to 6	90%			0.011			0.22
	No	Up to 8	No	0.0016	0.016	0.048	0.032	0.32	
10 – Roller application or brushing	No	Up to 8	90%		0.0016	0.0048		0.032	0.096
13 –Treatment of articles by dipping and pouring	No	4 to 8	No	0.000015	0.00015	0.00045	0.003	0.03	0.09

The modelled long-term exposure concentrations are compared to the DNEL for chronic inhalation exposure to obtain risk characterisation ratios. RCRs above 1 indicate that the potential risk is not adequately controlled. Safe conditions of use are described in the tables above. Safe conditions were defined by considering that workers use personal respiratory equipment during non-industrial spraying to protect themselves against elevated airborne concentrations of coatings or paints. Alternatively, safe conditions may also be achieved by ensuring very good ventilation of the workplace. The reasonable worst-case airborne concentration of the substance resulting from professional cleaning was 1.86E-05 mg/m^3. The RCR obtained by comparing this concentration of the long-term inhalation DNEL of 0.05 mg/m^3 is 3.72E-04 showing that the potential health risk for workers is controlled for the professional use of cleaners. The use of articles made from rubbers or plastics containing the substance is considered safe as no release of kieselguhr soda ash flux-calcined is anticipated. It is concluded that the professional use of mixtures containing kieselguhr soda ash flux-calcined is safe for workers under the specified conditions of exposure

Safe conditions for professional activities performed during the use of mixtures containing kieselguhr soda ash flux-calcined

Process Category	**LEV**	**Duration**	**PRE**	**Inhalation exposure (mg/m3) RCS content < 1%**	**Inhalation exposure (mg/m^3) RCS content < 10 %**	**Inhalation exposure (mg/m^3) RCS content <30 %**	**RCR (RCS content < 1%)**	**RCR (RCS content < 10 %)**	**RCR (RCS content <30 %)**
PROFESSIONAL USE WITH SUBSTANCE EXIHIBITING MEDIUM DUSTINESS									
1 – Use in closed process, no likelihood of exposure	No	4 to 8	No	0.0001	0.001	0.003	0.002	0.02	0.06
2 – Use in closed, continuous process with occasional controlled exposure	No	4 to 8	No	0.01			0.2		
	90%	4 to 8	No		0.01	0.03		0.2	0.6
3 – Use in closed batch process (synthesis or formulation)	No	4 to 8	No	0.01			0.20		
	90%	4 to 8	No		0.01	0.03		0.2	0.6
4 – Use in batch and other process (synthesis) where opportunity for exposure arises	90%	4 to 8	No	0.005			0.1		
	90%	Up to 4	No		0.03			0.6	
	90%	Up to 4	90%			0.009			0.18
5 – Mixing or blending in batch processes (multistage and/or significant contact)	90%	4 to 8	No	0.005			0.1		
	90%	Up to 4	No		0.03			0.6	
	90%	Up to 4	90%			0.009			0.18
8a – Transfer of chemicals from/to vessels/ large containers at non dedicated facilities	90%	4 to 8	No	0.005			0.1		
	90%	Up to 4	No		0.025			0.5	
	90%	Up to 1	No			0.03			0.6

8b – Transfer of chemicals from/to vessels/ large containers at dedicated facilities	90%	4 to 8	No	0.005			0.1		
	90%	Up to 4	No		0.025			0.5	
	90%	Up to 1	No			0.03			0.6
9 – Transfer of chemicals into small containers (dedicated filling line)	90%	4 to 8	No	0.005			0.1		
	90%	Up to 4	No		0.025			0.5	
	90%	Up to 1	No			0.03			0.6
19 – Hand-mixing with intimate contact (only PPE available)	No	Up to 1	90%	0.001	0.01	0.03	0.02	0.2	0.6

Safe conditions for professional activities performed during use of kieselguhr soda ash flux-calcined as filter aid

Process Category	LEV	Duration	PRE	Content (%)	Inhalation exposure (mg/m3)	RCR
PROFESSIONAL USE OF LIQUID DISPERSIONS						
2 – Use in closed, continuous process with occasional controlled exposure	No	4 to 8	No	5 to 25	0	0
3 – Use in closed batch process (synthesis or formulation)	No	4 to 8	No	5 to 25	0	0
4 – Use in batch and other process (synthesis) where opportunity for exposure arises	No	4 to 8	No	5 to 25	0	0
5 – Mixing or blending in batch processes (multistage and/or significant contact)	No	4 to 8	No	5 to 25	0	0
8a – Transfer of chemicals from/to vessels/ large containers at non dedicated facilities	No	4 to 8	No	5 to 25	0	0
8b – Transfer of chemicals from/to vessels/ large containers at dedicated facilities	No	4 to 8	No	5 to 25	0	0
9 – Transfer of chemicals into small containers (dedicated filling line)	No	4 to 8	No	5 to 25	0	0
15 – Use of laboratory reagents in small scale laboratories	No	4 to 8	No	5 to 25	0	0
19 – Hand-mixing with intimate contact (only PPE available): modelled with ConsExpo	No	8	No	10	0	0

Workers (dermal)	Dermal exposure was not assessed, as no risks are anticipated with dermal exposure.
Indirect exposure via the	No indirect exposure of humans to kieselguhr soda ash flux-calcined is anticipated.

environment	
Consumer exposure (inhalation) *DNEL: Consumerr, long-term, systemic, inhalation 0.05: mg/m^3*	Consumer exposure to kieselguhr soda ash flux-calcined resulting from the use of mixtures was described as long-term exposure in the case of use of paints and cleaning products and as short-term exposure in the case of spray painting and use of filtration materials. The long-term and acute airborne concentrations of the substance for the different uses are given in the table below. The RCRs for all consumer uses resulting in long-term exposure to the substance are well below 1 indicating that potential health risks for consumers are adequately controlled. Spray painting may result in relatively high acute exposure to kieselguhr soda ash flux-calcined and should be performed only in well-ventilated areas. It is recommended that particles of the substance used in spray paints available to consumers exhibit diameters greater than 0.015 mm. As particles with larger diameters generally are not inhaled this helps to avoid elevated consumer exposure to particles of kieselguhr soda ash flux-calcined during spray painting. The use of articles made from rubbers or plastics containing the substance is considered safe as no release of kieselguhr soda ash flux-calcined is anticipated. It is concluded that the potential health risks for consumers are adequately controlled for the uses of the substance described in the present exposure scenario.

Consumer use	**Mean inhalation concentration (long-term) in mg/m^3**	**Mean inhalation concentration (acute) in mg/m^3**	**RCR**
Use of high-solid paints	0.000122		0.0024
Use of water-based paints	0.000186		0.0037
Use of solvent-based paints	0.000864		0.017
Use of water-based wall paints	0.00044		0.0088
Spray painting (trigger cans)	Not applicable	37.5	Not applicable
Spray painting (pneumatic sprayer)	Not applicable	0.676	Not applicable
Filtration material	Not applicable	0.14	Not applicable
Cleaning products	0.00002		0.0004

5.2. Environmental exposure (qualitative assessment)

Waste water treatment plants (WWTP)	Kieselguhr soda ash flux-calcined used for the filtering of drinking and swimming pool water and kieselguhr soda ash flux-calcined present in surface cleaners may be released to the sewer and subsequently pass a municipal sewage treatment plant (STP). As the tonnages of kieselguhr soda ash flux-calcined for these uses are not known, a worst-case is considered in the present assessment in that 10% of the total tonnage placed on the EU market ends up in municipal STPs due to industrial, professional and private use of mixtures containing the substance and not covered by other exposure scenarios. The total EU tonnage is 120,000 tonnes per year resulting in 12,000 tonnes of kieselguhr soda ash flux-calcined released to municipal STPs in the present scenario. This amount is evenly distributed over the EU as dispersive use of mixtures containing the substance can be assumed. The EU has approximately 500 millions inhabitants. The average volume of wastewater per inhabitant equivalent is 200 L per day (EUSES default). The concentration in a municipal STP can then be calculated as: $$C_{STP} = \frac{AMOUNT_{STP}}{DAYS \cdot INHAB \cdot WASTEW_{inhab}}$$, where $AMOUNT_{STP}$: amount of kieselguhr soda ash flux-calcined released to municipal STPs in the EU per year (1.2E13 mg/year),

	$DAYS$: number of release days (365 days/year), $INHAB$: number of inhabitants in EU (500 millions inhabitants), $WASTEW_{inhab}$: wastewater per inhabitant (200 L/d) , C_{STP} : concentration of kieselguhr soda ash flux-calcined in municipal STP (mg/L). The predicted concentration of kieselguhr soda ash flux-calcined in municipal sewage treatment plants is then: $$C_{STP} = \frac{1.2E13}{365 \cdot 500000000 \cdot 200} = 0.329 \frac{mg}{L}.$$
Aquatic pelagic compartment	A dilution factor of 10 is taken into account at the point of mixing of the waste water with surface water, leading to a surface water concentration of 0.033 mg/L. For coastal areas a dilution factor of 100 is taken into account, leading to a concentration of 0.00033 mg/L in marine waters
Sediments	Kieselguhr is a naturally occurring sedimentary rock consisting of the shells of diatoms which is formed in water bodies and is therefore considered a natural part of the ecosystem. Therefore, no risk is anticipated with kieselguhr soda ash flux-calcined in sediments and no exposure assessment for sediment is carried out
Soil and groundwater	If paints containing soda ash flux-calcined are used outdoors small amounts of kieselguhr soda ash flux-calcined may leach to the soil. Further, kieselguhr soda ash flux-calcined may be released to soil via atmospheric deposition and via sewage sludge brought to agricultural fields and grassland. Kieselguhr is a naturally occurring sedimentary rock which is essentially a mineral fraction of soil already. Only the accidental release of a significant quantity kieselguhr soda ash flux-calcined is expected to alter the physical and chemical characteristics of a soil. As leaching from paints and atmospheric deposition to soil is regarded as minor and the deposition of sewage sludge to fields takes place under controlled conditions no risk is anticipated with the release of kieselguhr soda ash flux-calcined to soil from the use described in this scenario and thus, no further assessment of the exposure concentrations in soil is undertaken
Atmospheric compartment	Emissions of kieselguhr soda ash flux-calcined into the atmosphere are low during the use of mixtures containing the substances by industrial workers, professionals or consumers. The atmospheric concentrations of the substance are expected to be low. No further assessment of the exposure concentrations in the atmosphere is undertaken.
Secondary poisoning	It is expected that emissions of the substance resulting from the industrial, professional or private use of the substance or mixtures containing the substance will not significantly increase the naturally occurring concentrations of kieselguhr or other compounds in the environment. The potential of kieselguhr soda ash flux-calcined for bioaccumulation is low. The substance has a low solubility in water and thus is essentially unavailable to organisms. Therefore, it is not necessary to assess secondary poisoning via the food chain