LB MINERALS, s.r.o.

Safety Data Sheet in accordance with Regulation (EC) No 1907/2006 and Regulation (EC) No 1272/2008

Version **09.0**

Revision date **September 2023**

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Kieselguhr, flux-calcined

REACH Registration number: **01-2119488518-22-0003** Reference date: 25/10/2010 17:56

Trade names:

Material	Identification
MF CK05 M	Filter kieselguhr F 5
MF CK10 M	Filter kieselguhr F 10
MF CK15 M	Filter kieselguhr F 15
MF CK20 M	Filter kieselguhr F 20
MF CK25 M	Filter kieselguhr F 25
MF CK50 M	Filter kieselguhr F 50
MF CK60 M	Filter kieselguhr F 60
MF CK70 M	Filter kieselguhr F 70
MF CK100 M	Filter kieselguhr F 100

Other identification means: diatomaceous earth, diatomite

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

The substance is used for various purposes, especially in the production of:

- Fillers
- Excipient not listed anywhere else
- Filter material
- Laboratory chemical
- Agent to control pH
- Plating compositions for treating metal surfaces
- Solvents
- Filter agent
- Functional filler
- Functional additive
- Industrial professional and private

1.2.1. Identified uses specified

Industrial, professional and consumer use.

1.2.2. Uses advised against

No use specified in section 1.2 is inadvisable.

1.3. Details of the supplier of the Material Safety Data Sheet

Name:	LB MINERALS, s.r.o. www.lb-minerals.cz
Address:	Tovarni 431, CZ 330 12 Horni Briza
Phone number:	+420 378 071 111
Identification number (CRN)/VAT Reg No:	27994929/CZ27994929
E-mail of a competent person responsible for MSDS in the Member States and the EU:	msds@lb-minerals.cz

1.4. Emergency telephone number

Single European emergency number: *112*
Emergency telephone number: National Health Service (NHS) 111
Available outside the office hours: ☒ Yes ❑ No

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification pursuant to Regulation (EC) No. 1272/2008:
Not classified as hazardous
See section 16 for the full text of the classifications and hazard statements.

2.2. Label elements

None

2.3. Other hazards

This product is an inorganic substance and does not meet the criteria for PBT or vPvB in accordance with Annex XIII of regulation (EC) No 1907/2006 (REACH). The substance is not considered to be an endocrine disruptor for human health or the environment in accordance with Annex I of Regulation (EC) No. 1272/2008 (CLP).
Depending on the application and processing method, airborne dust containing RCS may be formed.

SECTION 3: Composition/information on ingredients

3.1. Substances

Identification No.	Name of substance
CAS number: 68855-54-9 EC number: 272-489-0	Kieselguhr, flux-calcined

Kieselguhr, flux-calcined is UVCB, subtype 4. The product purity is 100 wt. %.
This product contains less than 1% of respirable silica (RCS), which is classified as STOT RE 1.

SECTION 4: First aid measures

4.1. Description of first aid measures

Pay attention to your own safety. No special personal protective equipment is recommended for first aid personnel.

Following inhalation
It is recommended to move the affected persons from the area to fresh air. If the problem persists, seek a medical advice.

Following skin contact
Wash the skin with water and soap and use protective ointment.

Following eye contact
Rinse with a large amount of water and seek medical attention if irritation persists.

Following ingestion
Rinse mouth with a large amount of water. Do not induce vomiting.

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

The acute symptoms would give pain in the eyes because of dust entry. No delayed effects are anticipated if first aid treatment is applied and is effective.

4.3. Indication of immediate medical attention and special treatment needed

Immediate medical attention is not required; follow the instructions in section 4.1.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Adapt the fire extinguishing agent to the fire surroundings.

5.2. Special hazards arising from the substance or mixture

The material is not flammable, and it does not lead to hazardous thermal decomposition products.

5.3. Advice for fire-fighters

Avoid generation of dust. Use breathing apparatus. Self-contained breathing apparatus may be required due to other substances but is not required due to possible exposure to kieselguhr.
Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Product on floor when wetted will become slippery and may present a hazard; wear anti-slip boots.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment, and emergency procedures

Avoid the formation of airborne dust, wear personal protective equipment in accordance with local legislation, and see EN 143.

6.2. Environmental precautions

Prevent the spread of leaked material. Remove leaked material with suction systems.

6.3. Methods and materials for containment and cleaning up

Avoid sweeping and ensure disposal without any airborne dust formation. Store it in suitable closed containers. Torn packages must be taped or wrapped in another package. Wear personal protective equipment in accordance with the local regulations.

6.4. Reference to other sections

See sections 8 and 13 of this MSDS.

SECTION 7: Handling and storage

7.1. Safe handling measures

7.1.1. Recommendations

Keep dust concentrations to a minimum. Minimize dust formation.
In places where airborne dust forms, use suitable exhaust ventilation. The packed product should be handled with care to prevent accidental bursting. Spilled powder should be removed by vacuuming or wet sweeping. To advise on the safe handling, please contact your supplier or check the Good Practice Guide which is referred to in section 16.

7.1.2. Advice on general occupational hygiene

Not drink, eat, and smoke at the workplace. Wash your hands and change contaminated clothing before entering dining room.

7.2 Conditions for safe storage, including any incompatibilities

Minimise airborne dust formation. Keep shipping containers closed and prevent wind blowing during loading and unloading. Store in a dry place protected from moisture. Do not store petroleum substances, oils, or chemicals that have a characteristic odour/smell near the product due to the high diatomaceous earth sorption capacity.
If the product is stored in a dry covered place, it can be stored indefinitely. Its storage temperature is not prescribed. Pallets cannot be stacked.

7.3. Specific end Use(s)

Exposure scenarios for humans and the environment are attached in Annex I to this Material Safety Data Sheet.

SECTION 8: Exposure controls/ personal protection

8.1. Control parameters

8.1.1. Occupational exposure limit values

Follow workplace regulatory exposure limits for all types of airborne dust (e.g. total dust, respirable dust, respirable crystalline silica dust).
The occupational exposure limit values (OEL) in the Czech Republic are set by Government Decree No. 361/2007 Coll. on requirements for occupational health protection (measured as the 8-hour time-weighted average):

Substance (ingredient) name	Type	Value ($mg*m^{-3}$)
Other silicates (excluding asbestos)	**OEL_r */OEL_t** ** SiO_2 content in respirable fraction ≤ 5% (valid in the CZ)*	2 / 10
	OEL_r **/OEL_c *** SiO_2 content in respirable fraction > 5% (valid in the CZ)*	10 : F_r / 10

F_r — Fibrogenic component content in the respirable fraction in %
The permissible RCS exposure limit can be specified by the national legislation of the EU Member State.

8.1.2. Recommended monitoring procedures

None.

8.1.3. Occupational Exposure Limits and/or biological limits when forming air pollutants

Not applicable.

8.1.4. DNEL/DMEL and PNEC

DNEL/DMEL

Route of exposure	Exposure frequency	DNEL (employees)
Inhalation	Prolonged repetitive	0.05 mg/m^3

Route of exposure	Exposure frequency	DNEL (population)
Inhalation	Prolonged repetitive	0.05 mg/m^3
Oral	Prolonged repetitive	18.7 mg/kg/ body weight /day

PNECS

Environment	PNEC	Remarks
Water (surface water)	n/a	LC_{50} studies for fish, daphnia, and algae in a supersaturated solution >100 vol.% (i.e. higher concentration than the maximum solubility of the substance).
WWTP microorganisms	100	NOAEL value (AF = 100)
Terrestrial	n/a	Naturally occurring inert substance
Sediment	n/a	Naturally occurring inert substance

8.2. Exposure controls

Reference to Exposure Scenario in Annex I of this MSDS.

8.2.1. Appropriate engineering controls

Reference to Exposure Scenarios in Annex I of this MSDS.

8.2.2. Individual protection measures, such as personal protective equipment

Eye/face protection
Do not wear contact lenses. For powders, tight fitting goggles with side shields, or wide vision full goggles. It is also advisable to have individual pocket eyewash.

Skin/hands protection
For skin, normal work clothes are appropriate. After finishing work, wash the skin with soap and water, or use a greasy cream - the products may dry the skin.

Respiratory protection
In case of prolonged exposure to airborne dust concentrations, wear respiratory protective equipment with the requirements of national legislation is recommended.

Thermal hazards
None

8.2.3. Environmental exposure controls

Avoid any release into the environment. Avoid any leaked product spreading.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	Solid
Colour	White, beige, ochre, light grey
Odour	Odourless
Melting point/freezing point	> 450 °C (EU A1 method)
Boiling point or initial boiling point and boiling range	Not applicable to solids
Flammability	Substance is not flammable
Lower and upper explosion limit	Not applicable to solids
Flash point	Not applicable to solids
Auto-ignition temperature	Not applicable to solids
Decomposition temperature	Not applicable to solids
pH (20°C) suspension – 1 part dry matter : 7	6 – 9
Kinematic viscosity	Not applicable to solids
Solubility	Low, max 3.7 mg/l (EU A6 method)
Partition coefficient: n-octanol/water (log value)	Not applicable to solids
Vapour pressure	Not applicable to solids
Density and/or relative density	Not applicable to solids
Relative vapour density	2,360 kg/m^3 (OECD 109 method)
Particle characteristics	Solid particles, granules, rest on screen max. 15% (0.045 mm), does not contain a nanoform as defined in Annex VI of Regulation REACH

9.2. Other information

Bulk density	200 - 350 kg/m^3

SECTION 10: Stability and reactivity

10.1. Reactivity Inert, not reactive

10.2. Chemical stability Chemically stable under normal conditions.

10.3. Possibility of hazardous reactions Products may react violently with hydrofluoric acid and its products.

10.4. Conditions to avoid None

10.5. Incompatible materials Hydrofluoric acid products

10.6. Hazardous decomposition products None

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Hazard classes	Outcome of the effect assessments
Acute toxicity	
Oral	LD_{50} > 2000 mg/kg body weight (OECD 401, rat)
Dermal	Based on the available data, the classification criteria are not met.
Inhalation	LC_{50} > 2,6 mg/l (4h) (OECD 403, rat)
Skin corrosion/irritation	Kieselguhr does not irritate the skin (OECD 431)
Serious eye damage/irritation	Kieselguhr does not irritate the eyes (HCE, SkinEthic Laboratories, Nice, France)
Respiratory or skin sensitization	Kieselguhr does not cause skin sensitization (OECD 429, mouse)
Germ cell mutagenicity	Kieselguhr does not mutagenic (in vitro test OECD 471, OECD 473, OECD 476)
Carcinogenicity	Based on the available data, the classification criteria are not met.
Reproductive toxicity	Based on the available data, the classification criteria are not met.

STOT - single exposure	Based on the available data, the classification criteria are not met.	
STOT - repeated exposure	STOT RE 1 (if the respirable silica content > 10%) STOT RE 2 (if the respirable silica content > 1% to < 10%)	see section 11.2
Aspiration hazard	Based on the available data, the classification criteria are not met.	

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

No data available

11.2.2. Other information

Repeated dose toxicity

Oral	NOAEL (rat, OECD 408)	3,737.9 mg/kg of body weight/day
Inhalation	NOAEC (rat, OECD 413)	1.3 mg/m^3
	NOEC (rat, OECD 413)	1.3 mg/m^3
	LOAEC (rat, OECD 413a)	5.9 mg/m^3
Dermal	-	Scientifically unjustified

SECTION 12: Ecological information

12.1. Toxicity

12.1.1. Acute/short-term toxicity for fish	LC_{50} (96 h) for freshwater fish (rainbow trout Oncorhynchus mykiss): >100% v/v saturated solution (OECD 203 method)
12.1.2. Acute/short-term toxicity for aquatic invertebrates	EC_{50} (48 h) for aquatic invertebrates (Daphnia magna): > 100% v/v saturated solution (OECD 202 method)
12.1.3. Acute toxicity for aquatic plants	EC_{50} (72 h) for fresh water algae (Desmodesmus subspicatus): > 100% v/v saturated solution (OECD 201 method)
12.1.4. Toxicity for microorganisms, e.g. bacteria	EC_{50} (3 h) for microorganisms (activated sludge): > 1,000 mg/l (OECD method 209)
12.1.5. Chronic toxicity to aquatic organisms	No data available
12.1.6. Toxicity to soil dwelling organisms	No data available
12.1.7. Toxicity to terrestrial plants	No data available
12.1.8. General effect	No specific adverse effects known
12.2. Persistence and degradability	No data available
12.3. Bioaccumulative potential	No data available
12.4. Mobility in soil	Negligible
12.5. Results of PBT and vPvB assessment	This substance does not meet the criteria for classification as PBT or vPvB.
12.6. Endocrine disrupting properties	No data available
12.7. Other adverse effects	No other adverse effects are identified.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

The substance is not hazardous waste. The diatomaceous earth can be reused if it is not contaminated or otherwise damaged. Waste disposal methods are not applicable here.

Product treatment – unused remains or spilled material
Collect dry unused remains or spilled dry material. The material can be reused, taking into consideration its shelf life and the requirement to prevent dustiness.
In case of any product contamination, liquidate it in line with the waste legislation.
Prevent its penetration into any wastewater system.

Further details are provided in the Exposure Scenario - see Annex I.

Packaging treatment - completely empty, remove in accordance with the applicable legislation.

Waste legislation – Decree 2000/532/EC establishing a list of wastes, as amended.

SECTION 14: Transport information

14.1.	**UN number or ID number**	Not relevant
14.2.	**UN proper shipping name**	Not relevant
14.3.	**Transport hazard class(es)**	ADR: Not classified IMDG: Not classified ICAO/IATA: Not classified RID: Not classified
14.4.	**Packaging group**	Not applicable
14.5.	**Environmental hazards**	Not relevant
14.6.	**Special precautions for users**	Not specified
14.7.	**Maritime transport in bulk according to IMO instruments**	Not relevant

SECTION 15: Regulatory information

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

Regulation (EC) No **1907/2006** of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorization and Restriction of Chemicals, establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Regulation Council Regulation (EEC) No. 793/93, Commission Regulation (EC) No. 1488/94, Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC, and 2000/21/EC, as amended.

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

15.2. Chemical safety assessment

For this substance, the chemical safety assessment is provided in Annex I.

SECTION 16: Other information

16.1. Indication of changes made to the previous MSDS version

Regulation (EC) No 1272/2008 and Regulation (EC) No 453/2010
Version 7.1 - ch. 2.1.2 – removed, chap. 15.1
Version 07.2 - In full compliance with Regulation (EC) No 830/2015
Version 07.3 - trademark expansion and logo change
Version 08.0 - Change of 1.1, 8.1, 9.1, 9.2, 11.2, 13.1, 15.1, 16.3, and 16.7, most of the 16 sections were updated in accordance with revised Annex II to the REACH Decree
Version 08.1 - Change of 1.1
Version 09.0 – 2.1., 2.3., 7.1.1., 9.1., 11.2., 12.6., 14.1.

Reasons to change the safety data sheet version:

COMMISSION REGULATION (EU) 2020/878 of 18 June 2020 amending Annex II to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation, and Restriction of Chemicals (REACH).

16.2. Abbreviations and acronyms

AF	Assessment Factor

DNEL	The concentration at which no adverse effects to human health occur
EC_{50}	Median effective concentration
LC_{50}	Median lethal concentration
LOAEC	Lowest-observed-adverse-effect concentration
NOAEC	No-observed-adverse-effect concentration
NOAEL	No-observed-adverse-effect level
NOEC	No-observed-effect concentration
OEL	Occupational exposure limit
OEL_c	Occupational exposure limit for total concentration
OEL_r	Occupational exposure limit for respirable dust fraction
PBT	Permanently Bioaccumulatively Toxic
PNEC	Safe concentration at which little or no effects on human health can be expected
RCS	Respirable Crystalline Silica
REACH	Regulation (EC) No 1907/2006
STOT RE	Toxicity for specific target organs - repeated
WWTP	Waste water treatment plant
vPvB	Very Persistent Very Bioaccumulative
UVCB	Substances of unknown or variable composition

16.3. Relevant H-phrases (number and full text)

EUH066: Repeated exposure may cause skin dryness or cracking.
EUH210: Safety data sheet available on request.
EUH212: Caution! Hazardous respirable dust may form during use. Do not inhale dust.

16.4. Third Party Materials

If materials not manufactured or supplied by LB MINERALS, s.r.o. are used in conjunction with materials from LB MINERALS, s.r.o, or instead of them, it is the responsibility of the customer to ensure that the manufacturer or supplier provides all technical data and other documents relating to those and other materials and ensure all necessary information relating to them. No responsibility with regard to the use of an LB MINERALS, s.r.o.'s material in conjunction with materials from other suppliers shall be accepted.

16.5. Liability

The given information is the best that LB MINERALS, s.r.o has at that date and is believed to be accurate and reliable. However, no representation, warranty or guarantee of its accuracy, reliability or completeness exists. It is the user's responsibility to satisfy themselves as to the suitability and completeness of such information for their own particular use.

16.6. Training

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

16.7. Additional information

The permissible exposure limit for the total concentration (respirable fraction) of dust (particle size 1–100 µm) is called PEL_c, for the respirable dust fraction PEL_r. The inhalable dust fraction is an aggregate of particles of airborne dust, which can be inhaled through the nose or mouth. Respirable fraction means the mass fraction of inhaled particles (size less than 5 µm) that penetrate the part of the airways where there is no ciliated epithelium and into the alveoli according to EN 1540 Occupational exposure - Terminology.

Prolonged or massive exposure to respirable fraction of crystalline silica may cause silicosis, which is a nodular pulmonary fibrosis caused by deposition of fine respirable crystalline silica particles in the lungs.

In 1997, IARC (International Agency for Research on Cancer) concluded that crystalline silica inhaled in the workplace may cause lung cancer in humans. They stressed, however, that not all industrial environments, nor all crystalline silica types, are to blame. (IARC Monograph on the assessment of risk of cancer in humans caused by chemicals, silicon, quartz dust and organic fibres, 1997, Vol. 68, IARC, Lyon, France.) In 2009, in the Monograph 100 series IARC confirmed its classification of powdered quartz, crystalline in form of quartz and cristobalite (IARC Monographs, Volume 100C, 2012).

In June 2003, the EU Scientific Committee on Occupational Exposure Limits to chemical agents (SCOEL) concluded that the main result of inhalation of respirable crystalline silica dust in humans is silicosis. "There is sufficient information to conclude that the relative lung cancer risk is increased in persons with silicosis (and it does not seem to occur in

employees without silicosis exposed to silica dust in quarries and in the ceramic industry). Preventing silicosis thus at the same time reduces the risk of cancer ...” (SCOEL SUM Doc-94-final, June 2003). So there is evidence supporting the fact that increased carcinoma risk would be limited to people already suffering from silicosis. Protection of workers against silicosis should be assured by respecting the existing occupational exposure limits and implementing additional risk management measures where required (see Section 16 below).

Multisectoral Social 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 received a financial support from the European Commission, is based on the 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 at http://www.nepsi.eu and provide useful information and guidance for handling products that may release respirable crystalline silica. Literature references are available upon request with the EUROSIL Association, the European Association of Industrial Silica Producers.

Disclaimer

This Material Safety Data Sheet (MSDS) has been prepared in accordance with the legal provisions of the REACH Regulation (EC 1907/2006; Article 31 and Annex II), as amended. Its content is intended as a guide for appropriate precautionary measures when handling the material. The responsibility of recipients of this Material Safety Data Sheet is to ensure that the information contained therein is properly read and correctly understood by all personnel who may use or process the product, handle it or come into contact with it in any way. The information and instructions provided in this Material Safety Data Sheet is based on the present state of scientific and technical knowledge at the time of publication. This document does not assume responsibility for the technical design and processing of the material, suitability for specific applications, and does not replace legally valid contractual relationship. This version of the MSDS supersedes all previous versions.

End of the Material Safety Data Sheet

Annex I
Exposure Scenario 1: Manufacture of kieselguhr, flux-calcined

1. Short title of exposure scenario 1	
Manufacture of kieselguhr, 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 condition 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 considering 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.

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 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 wastes are disposed of in landfills or may be incinerated.
Fraction released to environment during waste treatment	Any wastewater released from the sedimentation step is expected not to contain more than 3.7 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 minimize oral exposure.
Workers (inhalation) *DNEL: Worker, long-term, systemic, inhalation: 0.05 mg/m^3*	The workers' inhalation exposure to kieselguhr, 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 characterization 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, 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 considering local exhaust ventilation in the present scenario. To achieve acceptable airborne concentrations of kieselguhr, flux-calcined the efficiency of LEV and the duration of exposure were modified. Safe conditions can also be achieved using personal respiratory equipment in addition or as an alternative to LEV. Consequently, the presentation of safe conditions is not exhaustive in the present ES.

Process Category	LEV	Duration	PRE	Content (%)	Inhalation exposure (mg/m3)	RCR
INDUSTRIAL USE WITH SUBSTANCE EXIHIBITING HIGH DUSTINESS						
1 – Use in closed process, no likelihood of exposure	No	4 to 8	No	100	0.01	0.2
2 – Use in closed, continuous process with occasional controlled exposure	90%	4 to 8	No	100	0.1	2.0
3 – Use in closed batch process (synthesis or formulation)	90%	4 to 8	No	100	0.1	2.0
4 – Use in batch and other process (synthesis) where opportunity for exposure arises	95%	Up to 1	No	100	0.25	5.0
5 – Mixing or blending in batch processes (multistage and/or significant contact)	95%	Up to 1	No	100	0.25	5.0
8a – Transfer of chemicals from/to vessels/ large containers at non dedicated facilities	95%	Up to 1	No	100	0.25	5.0
8b – Transfer of chemicals from/to vessels/ large containers at dedicated facilities	95%	Up to 1	No	100	0.25	5.0
9 – Transfer of chemicals into small containers (dedicated filling line)	95%	Up to 1	No	100	0.2	4.0
15 – Use of laboratory reagents in small scale laboratories	95%	4 to 8	No	100	0.25	5.0
19 – Hand-mixing with intimate contact (only PPE available	95%	Up to 1	No	100	0.25	5.0
INDUSTRIAL USE WITH SUBSTANCE EXIHIBITING MEDIUM DUSTINESS						
1 – Use in closed process, no likelihood of exposure	No	4 to 8	No	100	0.01	0.2
2 – Use in closed, continuous process with occasional controlled exposure	90%	4 to 8	No	100	0.1	2.0
3 – Use in closed batch process (synthesis or formulation)	80%	4 to 8	No	100	0.2	4.0
4 – Use in batch and other process (synthesis) where opportunity for exposure arises	95%	4 to 8	No	100	0.25	5.0
5 – Mixing or blending in batch processes (multistage and/or significant contact)	95%	4 to 8	No	100	0.25	5.0
8a – Transfer of chemicals from/to vessels/ large containers at non dedicated facilities	95%	4 to 8	No	100	0.25	5.0
8b – Transfer of chemicals from/to vessels/ large containers at dedicated facilities	95%	4 to 8	No	100	0.25	5.0
9 – Transfer of chemicals into small containers (dedicated filling line)	95%	4 to 8	No	100	0.25	5.0
15 – Use of laboratory reagents in small scale laboratories	50%	4 to 8	No	100	0.25	5.0
19 – Hand-mixing with intimate contact (only PPE available	95%	4 to 8	No	100	0.25	5.0

	INDUSTRIAL USE WITH SUBSTANCE EXIHIBITING LOW DUSTINESS						
	1 – Use in closed process, no likelihood of exposure	No	4 to 8	No	100	0.01	0.2
	2 – Use in closed, continuous process with occasional controlled exposure	No	4 to 8	No	100	0.01	0.2
	3 – Use in closed batch process (synthesis or formulation)	No	4 to 8	No	100	0.1	2.0
	4 – Use in batch and other process (synthesis) where opportunity for exposure arises	50%	4 to 8	No	100	0.25	5.0
	5 – Mixing or blending in batch processes (multistage and/or significant contact)	50%	4 to 8	No	100	0.25	5.0
	8a – Transfer of chemicals from/to vessels/ large containers at non dedicated facilities	50%	4 to 8	No	100	0.25	5.0
	8b – Transfer of chemicals from/to vessels/ large containers at dedicated facilities	No	4 to 8	No	100	0.1	2.0
	9 – Transfer of chemicals into small containers (dedicated filling line)	No	4 to 8	No	100	0.1	2.0
	15 – Use of laboratory reagents in small scale laboratories	No	4 to 8	No	100	0.1	2.0
	19 – Hand-mixing with intimate contact (only PPE available	50%	4 to 8	No	100	0.25	5.0

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, 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, 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, flux-calcined.
5.2. Environmental exposure (qualitative assessment)	
Wastewater treatment plants (WWTP)	According to unpublished monitoring data, wastewater released at manufacturing sites may contain up to 100 mg kieselguhr, flux-calcined per liter. This is exceeding the amount that can be dissolved in one liter of water at saturation (3.7 mg/L at 20°C), indicating that suspended particles of kieselguhr, 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, 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 no more than 3.7 mg kieselguhr, flux-calcined per liter wastewater (saturated solution). No further degradation of the substance during wastewater treatment is considered in the present assessment and the reasonable worst-case concentration of kieselguhr, flux-calcined in the effluent of a local STP is 3.7 mg/L.
Aquatic pelagic compartment	To calculate the reasonable worst-case concentration of kieselguhr, flux-calcined in surface water that may be due to emissions from the manufacture of the substance, the concentration of 3.7 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 0.37 mg/L. For releases of the wastewater to coastal sites, a dilution factor of 100 (EUSES default) is considered which leads to a concentration of 0.037 mg/L in marine waters
Sediments	The wastewater released to the environment may contain suspended particles of kieselguhr, 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, flux-calcined in sediments and no exposure assessment for sediment is carried out.
Soil and groundwater	Kieselguhr, 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, 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, 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, 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, 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, e.g. 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, neutralization 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 condition 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 considering 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 considering 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 e.g. 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 3.7 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/m³*	Safe conditions for the handling of solid kieselguhr, 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 characterization ratios. RCRs above 1 indicate that the potential risk is not adequately controlled. Safe conditions of use are described in for all activities described in exposure scenario 1. It is concluded that the manufacture of solid kieselguhr, flux-calcined exhibiting different grades of dustiness is safe for workers under the specified conditions of exposure.

Process Category	LEV	Duration	PRE	Content (%)	Inhalation exposure (mg/m3)	RCR
INDUSTRIAL USE OF LIQUID MATERIAL						
2 – Use in closed, continuous process with occasional controlled exposure	No	4 to 8	No	5 to 25	0.147	2.94
3 – Use in closed batch process (synthesis or formulation)	No	4 to 8	No	5 to 25	0.147	2.94
4 – Use in batch and other process (synthesis) where opportunity for exposure arises	No	4 to 8	No	5 to 25	0.147	2.94
5 – Mixing or blending in batch processes (multistage and/or significant contact)	No	4 to 8	No	5 to 25	0.147	2.94
8a – Transfer of chemicals from/to vessels/ large containers at non dedicated facilities	No	4 to 8	No	5 to 25	0.147	2.94
8b – Transfer of chemicals from/to vessels/ large containers at dedicated facilities	No	4 to 8	No	5 to 25	0.147	2.94
9 – Transfer of chemicals into small containers (dedicated filling line)	No	4 to 8	No	5 to 25	0.147	2.94
15 – Use of laboratory reagents in small scale laboratories	No	4 to 8	No	5 to 25	0.147	2.94
19 – Hand-mixing with intimate contact (only PPE available): modelled with ConsExpo	No	8	No	10	0.0002	0.004

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, 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, 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, flux-calcined.
5.2. Environmental exposure (qualitative assessment)	
Wastewater treatment plants (WWTP)	The amount of kieselguhr, flux-calcined present in the wastewater may exceed the amount that can be dissolved at saturation (3.7 mg/L at 20°C), indicating that suspended particles of kieselguhr, 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 no more than 3.7 mg kieselguhr, flux-calcined per liter wastewater (saturated solution). No further degradation of the substance during wastewater treatment is considered in the present assessment and the reasonable worst-case concentration of kieselguhr, flux-calcined in the effluent of a local STP is 3.7 mg/L.
Aquatic pelagic compartment	To calculate the reasonable worst-case concentration of kieselguhr, flux-calcined in surface water that may be due to emissions from the manufacture of the substance, the concentration of 3.7 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 0.37 mg/L. For releases of the wastewater to coastal sites, a dilution factor of 100 (EUSES default) is considered which leads to a concentration of 0.037 mg/L in marine waters
Sediments	The wastewater released to the environment may contain suspended particles of kieselguhr, 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, flux-calcined in sediments and no exposure assessment for sediment is carried out
Soil and groundwater	Kieselguhr, 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, 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, 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, flux-calcined into the atmosphere are low during the use of kieselguhr, 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, 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, e.g. 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 tableting, compression, extrusion, palletization. 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 condition related with frequency and quantities of use	
Duration of exposure at workplace:	8 hrs/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 (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 (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 3.7 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, 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, 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, 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, flux calcined as an additive in the formulation of liquid, viscous or solid mixtures.
5.2. Environmental exposure (qualitative assessment)	
Wastewater treatment plants (WWTP)	The amount of kieselguhr, flux-calcined present in the wastewater may exceed the amount that can be dissolved at saturation (3.7 mg/L at 20°C), indicating that suspended particles of kieselguhr, 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 no more than 3.7 mg kieselguhr, flux-calcined per liter wastewater (saturated solution). No further degradation of the substance during wastewater treatment is considered in the present assessment and the reasonable worst-case concentration of kieselguhr, flux-calcined in the effluent of a local STP is 3.7 mg/L.
Aquatic pelagic compartment	To calculate the reasonable worst-case concentration of kieselguhr, flux-calcined in surface water that may be due to emissions from the manufacture of the substance, the concentration of 3.7 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 0.37 mg/L. For releases of the wastewater to coastal sites, a dilution factor of 100 (EUSES default) is considered which leads to a concentration of 0.037 mg/L in marine waters
Sediments	The wastewater released to the environment may contain suspended particles of kieselguhr, 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, flux-calcined in sediments and no exposure assessment for sediment is carried out
Soil and groundwater	Kieselguhr, 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, 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, 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, flux-calcined into the atmosphere are low during the use of kieselguhr, 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, 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 process aid in manufacture of chemicals, resins, rubbers, and plastics	
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, neutralization 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 condition 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 (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 (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	Wearing of suitable protective clothing.

protection	
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 3.7 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, 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 the environment	It is expected that emissions of kieselguhr, 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, 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, flux-calcined as a process aid in the manufacture of chemicals, resins, rubbers and plastics
5.2. Environmental exposure (qualitative assessment)	
Wastewater treatment plants (WWTP)	The amount of kieselguhr, flux-calcined present in the wastewater may exceed the amount that can be dissolved at saturation (3.7 mg/L at 20°C), indicating that suspended particles of kieselguhr, 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 no more than 3.7 mg kieselguhr, flux-calcined per liter wastewater (saturated solution). No further degradation of the substance during wastewater treatment is considered in the present assessment and the reasonable worst-case concentration of kieselguhr, flux-calcined in the effluent of a local STP is 3.7 mg/L.

Aquatic pelagic compartment	To calculate the reasonable worst-case concentration of kieselguhr, flux-calcined in surface water that may be due to emissions from the manufacture of the substance, the concentration of 3.7 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 0.37 mg/L. For releases of the wastewater to coastal sites, a dilution factor of 100 (EUSES default) is considered which leads to a concentration of 0.037 mg/L in marine waters
Sediments	The wastewater released to the environment may contain suspended particles of kieselguhr, 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, flux-calcined in sediments and no exposure assessment for sediment is carried out
Soil and groundwater	Kieselguhr, 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, 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, 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, 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, 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 5	
Professional use by dental technicians and dentists	
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 condition 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	
Organisational measures	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
Abatement measures related with wastewater	Any liquid waste that results from cleaning of equipment will be disposed of via the public sewer
Abatement measures waste air and solid waste	Solid waste may be incinerated or deposited in landfills. Emissions of kieselguhr, 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.
4.3 Waste related measures	
Type of waste	Solid and liquid waste.
Disposal technique	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.

Fraction released to environment during waste treatment	Emissions from filling and alginate impression material may occur on 260 days per year. About 300 tonnes kieselguhr, 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, 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

Parameter	**Value**
Tonnage in EU per year	300 t
Regional tonnage per year	30 t
Local tonnage per year	60 kg
Fraction of main local source	0.002
Number of days	260 d
Fraction of tonnage released to air	0
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 0.024 mg/m^3. The RCR obtained by comparing this concentration of the long-term inhalation DNEL of 0.05 mg/m^3 is 0.48 showing that the potential health risk for workers is controlled for the professional use of kieselguhr, 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, 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, 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, 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 negligible as the dental treatment is performed under professional surveillance.

5.2. Environmental exposure (qualitative assessment)

Wastewater 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, flux-calcined during wastewater treatment is considered 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 considered 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 considered, 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, 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, flux-calcined in sediments and no exposure assessment for sediment is carried out.
Soil and groundwater	Kieselguhr, 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, 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, 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, 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, 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	
Industrial, professional and private use of substance or mixtures containing the substance	
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 (= public = consumers) SU 22: 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: Nonindustrial 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 condition related with frequency and quantities of use	
Duration of exposure at workplace:	Use of coatings and paints containing kieselguhr, flux-calcined: 4-8 hours Use of kieselguhr, flux-calcined for filtering water: Approximately 1 hour per day. Use of cleaners containing kieselguhr, 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, flux-calcined: Up to 225 days per year. Use of kieselguhr, flux-calcined for filtering water: Weekly for professional use and monthly consumer use. Use of cleaners containing kieselguhr, 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, 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 airborne 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 reducing the number 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, flux-calcined used for the filtering of drinking and swimming pool water and kieselguhr, 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/m³

Process Category	LEV	Duration	PRE	Content (%)	Inhalation exposure (mg/m3)	RCR
INDUSTRIAL USE OF LIQUID MATERIAL						
7 – Industrial spraying based on TNsG (European Commission 2002)	No	Up to 6	95%	10	0.325	6.5
10 – Roller application or brushing	No	4 to 8	No	5 to 25	0.125	2.5
13 – Treatment of articles by dipping and pouring	No	4 to 8	No	5 to 25	0.147	2.94

The modelled long-term exposure concentrations are compared to the DNEL for chronic inhalation exposure to obtain risk characterization 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, flux-calcined is anticipated. It is concluded that the industrial use of mixtures containing kieselguhr, 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, flux-calcined

The modelled long-term exposure concentrations are compared to the DNEL for chronic inhalation exposure to obtain risk characterization ratios. RCRs above 1 indicate that the potential risk is not adequately controlled. Safe conditions of use are described in the table above. Safe condition was 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 3.7E-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, flux-calcined is anticipated. It is concluded that the professional use of mixtures containing kieselguhr, flux-calcined is safe for workers under the specified conditions of exposure.

Process Category	LEV	Duration	PRE	Content (%)	Inhalation exposure (mg/m3)	RCR
PROFESSIONAL USE OF SOLID MATERIAL WITH MEDIUM DUSTINESS						
2 – Use in closed, continuous process with occasional controlled exposure	75%	4 to 8	No	100	0.25	5.0
3 – Use in closed batch process (synthesis or formulation)	75%	4 to 8	No	100	0.25	5.0
4 – Use in batch and other process (synthesis) where opportunity for exposure arises	95%	4 to 8	No	100	0.25	5.0
5 – Mixing or blending in batch processes (multistage and/or significant contact)	95%	4 to 8	No	100	0.25	5.0
8a – Transfer of chemicals from/to vessels/ large containers at non dedicated facilities	95%	4 to 8	No	100	0.25	5.0
8b – Transfer of chemicals from/to vessels/ large containers at dedicated facilities	95%	4 to 8	No	100	0.25	5.0
9 – Transfer of chemicals into small containers (dedicated filling line)	95%	4 to 8	No	100	0.25	5.0
19 – Hand-mixing with intimate contact (only PPE available)	95%	4 to 8	No	100	0.25	5.0
PROFESSIONAL USE OF LIQUID MATERIAL						
2 – Use in closed, continuous process with occasional controlled exposure	No	4 to 8	No	5 to 25	0.15	3.0
3 – Use in closed batch process (synthesis or formulation)	No	4 to 8	No	5 to 25	0.15	3.0
4 – Use in batch and other process (synthesis) where opportunity for exposure arises	No	4 to 8	No	5 to 25	0.15	3.0
5 – Mixing or blending in batch processes (multistage and/or significant contact)	No	4 to 8	No	5 to 25	0.15	3.0
8a – Transfer of chemicals from/to vessels/ large containers at non dedicated facilities	No	4 to 8	No	5 to 25	0.15	3.0
8b – Transfer of chemicals from/to vessels/ large containers at dedicated facilities	No	4 to 8	No	5 to 25	0.15	3.0
9 – Transfer of chemicals into small containers (dedicated filling line)	No	4 to 8	No	5 to 25	0.15	3.0
10 – Roller application or brushing	No	4 to 8	No	5 to 25	0.125	2.5
11 – Nonindustrial spraying based on TNsG (European Commission 2002)	No	Up to 6	95%	10	0.325	6.5
13 – Treatment of articles by dipping and pouring	No	4 to 8	No	5 to 25	0.15	3.0
15 – Use of laboratory reagents in small scale laboratories	No	4 to 8	No	5 to 25	0.15	3.0
19 – Hand-mixing with intimate contact (only PPE available): modelled with ConsExpo	No	8	No	10	0.0002	0.004

Workers (dermal)	Dermal exposure was not assessed, as no risks are anticipated with dermal exposure.
Indirect exposure via the environment	No indirect exposure of humans to kieselguhr, flux-calcined is anticipated.
Consumer	Consumer exposure to kieselguhr, flux-calcined resulting from the use of mixtures was described

exposure (inhalation)

DNEL: Consumer, long-term, systemic, inhalation 0.05: mg/m³

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, 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, 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, flux-calcined is anticipated. It is concluded that the potential health risks for consumers are adequately for the uses of the substance described in the present exposure scenario.

Consumer use	**Mean inhalation concentration (long-term) in mg/m³**	**Mean inhalation concentration (acute) in mg/m³**	**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		0.0173
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)

Wastewater treatment plants (WWTP)

Kieselguhr, flux-calcined used for the filtering of drinking and swimming pool water and kieselguhr, 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, 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, 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 million 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, 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 million inhabitants),

$WASTEW_{inhab}$: wastewater per inhabitant (200 L/d),

C_{STP} : concentration of kieselguhr, flux-calcined in municipal STP (mg/L).

The predicted concentration of kieselguhr, 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 considered at the point of mixing of the wastewater with surface water, leading to a surface water concentration of 0.033 mg/L. For coastal areas a dilution factor of 100 is considered, leading to a concentration of 0.0033 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, flux-calcined in sediments and no exposure assessment for sediment is carried out.
Soil and groundwater	If paints containing kieselguhr, flux-calcined are used outdoors small amounts of kieselguhr, flux-calcined may leach to the soil. Further, kieselguhr, 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, 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, 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, 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, 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.