Revision: 4.1 Date: 29.01.2021

Minerals<sup>®</sup>

ACCORDING TO EC-REGULATIONS 1907/2006 (REACH), 1272/2008 (CLP) & 2015/830

Diatomaceous Earth Flux-Calcined, Kieselguhr Flux-Calcined Celatom® FW-6, FW-12, FW-14, FW-18, FW-20, FW-40, FW-50, FW-60, FW-70, FW-80, SP, AW-12, AW-14, AW-18, AW-20

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

4.4	Product identifier		
1.1	Product Identifier Product Name	Celatom® FW-6, FW-12, FW-14, FW-18, FW-20, FW-40, FW-50, FW-60	FW-70
	1 roddot ridino	FW- 80, SP, AW-12, AW-14, AW-18, AW-20	, , , , , , , , , , , , , , , , , , , ,
	Trade names	Celatom® FW-6, FW-12, FW-14, FW-18, FW-20, FW-40, FW-50, FW-	
		60, FW-70, FW- 80, SP, AW-12, AW-14, AW-18, AW-20	
	Chemical Name	Diatomaceous Earth Flux-Calcined, Kieselguhr Flux-Calcined	
	CAS No.	68855-54-9	
		14464-46-1	
	EINECS No.	272-489-0	
		238-455-4	
	REACH Registration No.	01-2119488518-22-0002	
1.2	Recommended use of the chemical and restrictions on use		
	Identified Use(s)	Used as a carrier, a silica source or as a functional additive for paint, cos	metics,
	(,	plastics, rubber or other applications. Use as filter aid in industrial setting	
	Exposure Scenario	No.	Page:
	·	1 Manufacture of kieselguhr soda ash flux calcined	10
		2 Use as filter aid in industrial settings	13
		3 Industrial, professional and private use of substance or mixtures	16
		containing the substance	
		4 Consumer use; Cosmetics, personal care products	20
	Uses Advised Against	Anything other than the above.	
1.3	Details of the supplier of the safety data sheet	,	
	Manufacturer	EP Minerals, LLC	
		9785 Gateway Drive	
		Reno,	
		Nevada 89521	
		USA	
	Telephone	+1-775-824-7600	
	Fax	+1-775-824-7601	
	E-Mail (competent person)	inquiry.minerals@epminerals.com	
	Importer	EP Minerals Europe GmbH & Co,	
		KG Rehrhofer Weg 115 D-29633,	
		Munster,	
		Germany	
	Telephone	+49 51 92 98970	
	Fax	+49-51 92 989715	
	E-Mail (competent person)	EPME@epminerals.com	
1.4	Emergency Phone No.	Europe: +49 51 92 98970 (08:00- 17:00 CET)	
		Languages spoken: English, French and German	

#### **SECTION 2: HAZARDS IDENTIFICATION**

2.1	Classification of the substance or mixture	This product contains cristobalite (fine fraction) at: < 1%
		Depending on the type of handling and use (e.g. grinding, drying), airborne fine fraction crystalline silica may be generated. Prolonged and/or massive inhalation
		, , , ,
		of fine fraction crystalline silica dust may cause lung fibrosis, commonly referred
		to as silicosis. Principal symptoms of silicosis are cough and breathlessness.
		Occupational exposure to fine fraction crystalline silica dust should be monitored
		and controlled.
2.1.1	Regulation (FC) No. 1272/2008 (CLP)	Not classified as hazardous for supply/use

USA: +1-775-824-7600 (08:00- 17:00 PST)

Page: 1 of 20

Revision: 4.1 Date: 29.01.2021



ACCORDING TO EC-REGULATIONS 1907/2006 (REACH), 1272/2008 (CLP) & 2015/830

Diatomaceous Earth Flux-Calcined, Kieselguhr Flux-Calcined Celatom® FW-6, FW-12, FW-14, FW-18, FW-20, FW-40, FW-50, FW-60, FW-70, FW-80, SP, AW-12, AW-14, AW-18, AW-20

2.2 Label elements According to Regulation (EC) No. 1272/2008 (CLP)

Product Name Celatom® FW-6, FW-12, FW-14, FW-18, FW-20, FW-40, FW-50, FW-60, FW-

70, FW- 80, SP, AW-12, AW-14, AW-18, AW-20

Contains: Diatomaceous Earth , Flux-Calcined (Kieselguhr)

(< 1% Crystalline Silica- Cristobalite (Respirable Dust))

Hazard Pictogram(s)

None assigned.

Signal Word(s) None assigned.

Hazard Statement(s)

None assigned.

Precautionary Statement(s)

None assigned.

2.3 Other hazards None

#### **SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS**

#### 3.1 Substances

EC Classification Regulation (EC) No. 1272/2008 (CLP)

Chemical identity of the substance	%W/W	CAS No.	EC No.
Diatomaceous Earth , Flux-Calcined (Kieselguhr)	circa.100	68855-54-9	272-489-0
Contains: Cristobalite (Respirable Dust), <1 Fine Fraction Crystalline silica per SWeRF calculation	< 1	14464-46-1	238-455-4

3.2 Mixtures - Not applicable.

#### **SECTION 4: FIRST AID MEASURES**



#### 4.1 Description of first aid measures

Eye Contact

Inhalation If breathing is difficult, remove victim to fresh air and keep at rest in a position

comfortable for breathing. If irritation develops and persists, get medical

attention. Blow nose to evacuate dust.

Skin Contact Remove clothing and wash thoroughly before use. Wash affected skin with soap

and water. If skin irritation or rash occurs: Get medical advice/attention. Flush eyes with water for at least 15 minutes while holding eyelids open. Get

medical attention if eye irritation develops or persists.

Ingestion Rinse mouth. Give plenty of water to drink. Get medical attention.

4.2 Most important symptoms and effects, both acute and Prolonged and/or massive exposure to fine fraction crystalline silica-containing

delayed dust may cause silicosis, a nodular pulmonary fibrosis caused by deposition in the lungs of fine respirable particles of crystalline silica. Acute inhalation can

cause dryness of the nasal passage and lung congestion, coughing and general throat irritation. Chronic inhalation of dust should be avoided. May cause

irritation to the respiratory system.

4.3 Indication of any immediate medical attention and

special treatment needed

Unlikely to be required but if necessary treat symptomatically. There is no specific antidote. Remove person to fresh air and keep comfortable for

breathing.

Revision: 4.1 Date: 29.01.2021



ACCORDING TO EC-REGULATIONS 1907/2006

(REACH), 1272/2008 (CLP) & 2015/830

Diatomaceous Earth Flux-Calcined, Kieselguhr Flux-Calcined Celatom® FW-6, FW-12, FW-14, FW-18, FW-20, FW-40, FW-50, FW-60, FW-70, FW-80, SP, AW-12, AW-14, AW-18, AW-20

#### **SECTION 5: FIREFIGHTING MEASURES**

**Extinguishing media** 5.1

> Suitable Extinguishing media Non-flammable. Extinguish with carbon dioxide, dry chemical, foam or

> > None.

waterspray. As appropriate for surrounding fire.

Unsuitable extinguishing media

Special hazards arising from the substance or mixture

5.3 Advice for fire-fighters

5.2

6.2

7.3

Non-flammable, Non-combustible, Not explosive.

Fight fire with normal precautions from a reasonable distance. Fire fighters should wear complete protective clothing including self-contained breathing

apparatus.

#### **SECTION 6: ACCIDENTAL RELEASE MEASURES**

6.1 Personal precautions, protective equipment and

emergency procedures

Ensure adequate ventilation. Avoid generation of dust. Do not breathe dust. Wear appropriate personal protective equipment, avoid direct contact. Where engineering controls are not fitted or inadequate wear suitable respiratory

**Environmental precautions** 

protective equipment. No special requirements.

Methods and material for containment and cleaning 6.3

Sweep spilled substances into containers if appropriate moisten first to prevent dusting. Use vacuum equipment for collecting spilt materials, where practicable.

Transfer to a container for disposal.

6.4 Reference to other sections See Section: 8, 13

#### **SECTION 7: HANDLING AND STORAGE**

7.1 Precautions for safe handling Handle packaged products carefully to prevent accidental bursting. If you require advice on safe handling techniques, please contact your supplier or check the Good Practice Guide referred to in section 16. Avoid generation of dust. In case of inadequate ventilation wear respiratory protection. Do not breathe dust. Wear protective gloves/protective clothing/eye protection/face protection. Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke when using this product. Wash hands before breaks and after work.

Atmospheric concentrations should be minimised and kept as low as reasonably

7.2 Conditions for safe storage, including any incompatibilities

Storage life

Incompatible materials Specific end use(s)

practicable below the occupational exposure limit.

Stable under normal conditions. Store in a dry place.

Keep away from: Hydrofluoric Acid See Section: 1.2

#### SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

#### 8.1 **Control parameters**

#### Occupational Exposure Limits 811

SUBSTANCE	CAS No.	LTEL (8 hr	LTEL (8 hr	STEL	STEL	Note
		TWA ppm)	TWA mg/m³)	(ppm)	(mg/m³)	
Silica, Respirable	-	-	0.1	=	-	WEL: Workplace Exposure Limit (UK
Crystalline						HSE EH40)
Nuisance Dust	-	-	10	-	-	Inhalable Dust. WEL: Workplace
						Exposure Limit (UK HSE EH40)
Nuisance Dust	-	-	4	=	-	Respirable Dust. WEL: Workplace
						Exposure Limit (UK HSE EH40)

Source: WEL: Workplace Exposure Limit (UK HSE EH40)

Note: For the equivalent limits in other countries, please consult a competent occupational hygienist or the local regulatory authority.

8.1.2 **Biological limit value**  Not established.

PNECs and DNELs 8.1.3

Diatomaceous Earth (Kieselguhr): Not harmful to aquatic organisms. Insoluble in water. On this basis the PNECs for the aquatic compartment have not been derived.

Page: 3 of 20

Revision: 4.1 Date: 29.01.2021



ACCORDING TO EC-REGULATIONS 1907/2006 (REACH), 1272/2008 (CLP) & 2015/830

Diatomaceous Earth Flux-Calcined, Kieselguhr Flux-Calcined Celatom® FW-6, FW-12, FW-14, FW-18, FW-20, FW-40, FW-50, FW-60, FW-70, FW-80, SP, AW-12, AW-14, AW-18, AW-20

Diatomaceous Earth (Kieselguhr) DNELs	Oral	Inhalation	Dermal
Industry - Long Term - Systemic effects	-	0.05 mg/m <sup>3</sup>	-
Consumer - Long Term - Systemic effects	18.7 mg/kg bw/day	0.05 mg/m <sup>3</sup>	-

8.2 Exposure controls

8.2.1 Appropriate engineering controls

8.2.2 Individual protection measures, such as personal protective equipment (PPE)

Ensure adequate ventilation. Atmospheric levels should be controlled in compliance with the occupational exposure limit. Avoid dust generation. Use personal protective equipment as required. Wash contaminated clothing before reuse. Avoid contact with skin and eyes. Do not breathe dust.

Eye/ face protection

Wear eye protection with side protection (EN166).

Skin protection



Use skin barrier cream before handling the product. Wear suitable gloves if prolonged skin contact is likely - Wear impervious gloves (EN374). Unsuitable gloves materials

Respiratory protection



8.2.3

9.2

Atmospheric levels should be controlled in compliance with the occupational exposure limit. In case of inadequate ventilation wear respiratory protection. Recommended: Half-face mask (DIN EN 140), Filter type P2/P3 - efficiency of at least 90%

Thermal hazards
Environmental Exposure Controls

Not applicable. Avoid wind dispersal.

#### **SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES**

9.1 Information on basic physical and chemical properties

Appearance Light pink to white powder

Odour Odourless
Odour threshold Not available.

pH (10% Suspension) 10

Melting point/freezing point Not applicable.

Initial boiling point and boiling range Decomposes below boiling point at (°C): >1300°C

Flash point Non-flammable.

Evaporation rate Not applicable.

Flammability (solid, gas) Non-flammable.

Upper/lower flammability or explosive limits Non-flammable.

Vapour pressure Not applicable.

Vapour pressure Not applicable. Vapour density Not applicable. Relative density 2.3 g/cm $^3$  (H $_2$ O = 1) Solubility(ies) <1% Water

Soluble in: Hydrofluoric Acid

Partition coefficient: n-octanol/water

Auto-ignition temperature

Decomposition Temperature

Viscosity

Viscosity

Explosive properties

Oxidising properties

Not available.

Not applicable, Solid.

Not explosive.

Not oxidising.

**SECTION 10: STABILITY AND REACTIVITY** 

Other information

10.1 Reactivity Stable under normal conditions.

None.

Revision: 4.1 Date: 29.01.2021



ACCORDING TO EC-REGULATIONS 1907/2006 (REACH), 1272/2008 (CLP) & 2015/830

Diatomaceous Earth Flux-Calcined, Kieselguhr Flux-Calcined Celatom® FW-6, FW-12, FW-14, FW-18, FW-20, FW-40, FW-50, FW-60, FW-70, FW-80, SP, AW-12, AW-14, AW-18, AW-20

10.2 Chemical stability

10.3 Possibility of hazardous reactions

10.4 Conditions to avoid

10.5 Incompatible materials

10.6 Hazardous decomposition product(s)

Stable under normal conditions. Stable under normal conditions.

Avoid contact with: Hydrofluoric Acid. Do not leave in enclosed spaces when mixed with highly flammable material, as heat can build up over long periods of

time and flammable material may eventually ignite.

Reacts violently with - Hydrofluoric Acid

No hazardous decomposition products known.

#### **SECTION 11: TOXICOLOGICAL INFORMATION**

## 11.1 Information on toxicological effects Acute toxicity

Ingestion Inhalation Skin Contact Eye Contact

Skin corrosion/irritation
Serious eye damage/irritation
Respiratory or skin sensitization
Germ cell mutagenicity
Carcinogenicity
Reproductive toxicity
STOT - single exposure
STOT - repeated exposure

11.2 Other information

Aspiration hazard

Based upon the available data, the classification criteria are not met. Based upon the available data, the classification criteria are not met. Based upon the available data, the classification criteria are not met. Based upon the available data, the classification criteria are not met. Based upon the available data, the classification criteria are not met. Based upon the available data, the classification criteria are not met. Based upon the available data, the classification criteria are not met. Based upon the available data, the classification criteria are not met. Based upon the available data, the classification criteria are not met. Based upon the available data, the classification criteria are not met. Based upon the available data, the classification criteria are not met. Based upon the available data, the classification criteria are not met. Based upon the available data, the classification criteria are not met. Prolonged and/or massive exposure to fine fraction crystalline silica-containing dust may cause silicosis, a nodular pulmonary fibrosis caused by deposition in the lungs of fine respirable particles of crystalline silica.

In 1997, IARC (the International Agency for Research on Cancer) concluded that crystalline silica inhaled from occupational sources can cause lung cancer in humans (human carcinogen category 1). However it pointed out that not all industrial circumstances, nor all crystalline silica types, were to be incriminated. (IARC Monographs on the evaluation of the carcinogenic risks of chemicals to humans, Silica, silicates dust and organic fibres, 1997, Vol. 68, IARC, Lyon, France.) In 2009, in the Monographs 100 series, IARC confirmed its classification of Silica Dust, Crystalline, in the form of Quartz and Cristobalite (IARC Monographs, Volume 100C, 2012). In June 2003, SCOEL (the EU Scientific Committee on Occupational Exposure Limits) concluded that the main effect in humans of the inhalation of fine fraction crystalline silica dust is silicosis. "There is sufficient information to conclude that the relative risk of lung cancer is increased in persons with silicosis (and, apparently, not in employees without silicosis exposed to silica dust in quarries and in the ceramic industry). Therefore preventing the onset of silicosis will also reduce the cancer risk..." (SCOEL SUM Doc 94-final, June 2003). So there is a body of evidence supporting the fact that increased cancer risk would be limited to people already suffering from silicosis. Worker protection against silicosis should be assured by respecting the existing regulatory occupational exposure limits and implementing additional risk management measures where required (see section 16 below).

## **SECTION 12: ECOLOGICAL INFORMATION**

12.1 Toxicity

12.2 Persistence and degradability

12.3 Bioaccumulative potential

12.4 Mobility in soil

12.5 Results of PBT and vPvB assessment

Not classified as a Marine Pollutant.

Not applicable.

The product has no potential for bioaccumulation. Some organisms accumulate Si(OH)4.

The product is predicted to have low mobility in soil.

This product is an inorganic substance and does not meet the criteria for PBT or

Revision: 4.1 Date: 29.01.2021

Other adverse effects



ACCORDING TO EC-REGULATIONS 1907/2006 (REACH), 1272/2008 (CLP) & 2015/830

Diatomaceous Earth Flux-Calcined, Kieselguhr Flux-Calcined Celatom® FW-6, FW-12, FW-14, FW-18, FW-20, FW-40, FW-50, FW-60, FW-70, FW-80, SP, AW-12, AW-14, AW-18, AW-20

vPvB in accordance with Annex XIII of REACH.

None known.

12.6

#### **SECTION 13: DISPOSAL CONSIDERATIONS**

**13.1** Waste treatment methods Dispose of empty containers and wastes safely. Dispose of contents in

accordance with local, state or national legislation. Ensure all waste water is

collected and treated via a waste water treatment plant.

**13.2** Additional Information Packaging waste: Remove all packaging for recovery or disposal. Make sure

that packaging is completely empty before recycling. Inform consumer about possible hazards of unclean empty packaging for recycling or disposal.

#### **SECTION 14: TRANSPORT INFORMATION**

Not classified according to the United Nations 'Recommendations on the Transport of Dangerous Goods'.

ADR/RID / IMDG / ICAO/IATA

14.1UN numberNot applicable.14.2UN proper shipping nameNot applicable.14.3Transport hazard class(es)Not applicable.14.4Packing groupNot applicable.

**14.5 Environmental hazards** Not classified as a Marine Pollutant.

14.6 Special precautions for user Not applicable.

14.7 Transport in bulk according to Annex II of MARPOL Diatomaceous Earth , No special measures are required.

73/78 and the IBC Code

14.8 Additional Information None.

#### **SECTION 15: REGULATORY INFORMATION**

15.1 Safety, health and environmental

regulations/legislation specific for the substance or

mixture

15.1.1 EU regulations

Authorisations and/or Restrictions On Use None.

15.1.2 National regulations

Germany Water hazard class: nwg

15.2 Chemical Safety Assessment Subject to REACH Registration, A REACH chemical safety assessment has

been carried out.

#### **SECTION 16: OTHER INFORMATION**

The following sections contain revisions or new statements: 15.1.2

References: Existing Safety Data Sheet (SDS), Existing ECHA registration(s) for Diatomaceous Earth (Kieselguhr), Soda Flux-Calcined (CAS No. 68855-54-9).

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

#### LEGEND

**PNEC** 

LTEL Long Term Exposure Limit
STEL Short Term Exposure Limit
DNEL Derived No Effect Level

Predicted No Effect Concentration

Revision: 4.1 Date: 29.01.2021



ACCORDING TO EC-REGULATIONS 1907/2006 (REACH), 1272/2008 (CLP) & 2015/830

Diatomaceous Earth Flux-Calcined, Kieselguhr Flux-Calcined Celatom® FW-6, FW-12, FW-14, FW-18, FW-20, FW-40, FW-50, FW-60, FW-70, FW-80, SP, AW-12, AW-14, AW-18, AW-20

PBT PBT: Persistent, Bioaccumulative and Toxic PvB PBT: very Persistent and very Toxic

OECD Organisation for Economic Cooperation and Development
SCOEL The EU Scientific Committee on Occupational Exposure Limits

IARC International Agency for Research on Cancer

SWeRF Size-Weighted Fine Fraction

#### **Disclaimers**

Information contained in this publication or as otherwise supplied to Users is believed to be accurate and is given in good faith, but it is for the Users to satisfy themselves of the suitability of the product for their own particular purpose. EP Minerals, LLC gives no warranty as to the fitness of the product for any particular purpose and any implied warranty or condition (statutory or otherwise) is excluded except to the extent that exclusion is prevented by law. EP Minerals, LLC accepts no liability for loss or damage (other than that arising from death or personal injury caused by defective product, if proved), resulting from reliance on this information. Freedom under Patents, Copyright and Designs cannot be assumed.

#### Annex to the extended Safety Data Sheet (eSDS)

The following scenarios were addressed in the chemical safety report (CSR) for Kieselguhr, Soda Ash Flux-Calcined Fine Cristobalite Fraction as prepared as part of the registration dossier required by the EU REACH Regulation:

Exposure scenario 1 Manufacture of kieselguhr soda ash flux calcined

Exposure scenario 2 Use as filter aid in industrial settings

Exposure scenario 3 Industrial, professional and private use of substance or mixtures containing the substance

Exposure scenario 4 Consumer use; Cosmetics, personal care products

Revision: 4.1 Date: 29.01.2021



ACCORDING TO EC-REGULATIONS 1907/2006 (REACH), 1272/2008 (CLP) & 2015/830

Diatomaceous Earth Flux-Calcined, Kieselguhr Flux-Calcined Celatom® FW-6, FW-12, FW-14, FW-18, FW-20, FW-40, FW-50, FW-60, FW-70, FW-80, SP, AW-12, AW-14, AW-18, AW-20

# **Kieselguhr, Soda Ash Flux-Calcined Fine Cristobalite Fraction < 1%**

CAS No. 68855-54-9 EC No. 272-489-0

#### **Summary of Parameters**

Physical Parameters		
Melting point/freezing point	> 450 °C	
Partition Coefficient (log K <sub>OW</sub> )	Not applicable	
Solubility (Water) (mg/l)	3.7 mg/l @ 20 °C	
Molecular weight	66.0843	
Biodegradability	The methods for determining the biological degradability are not applicable to inorganic substances.	

Human Health (DNEL)				
	Short term	Inhalation (mg/m³)	0.05 mg/m³	
Workers		Dermal (mg/kg bw/day)	Not determined	
Workers	Long Term	Inhalation (mg/m³)	Not determined	
	Long Term	Dermal (mg/kg bw/day)	Not determined	
Consumer		Inhalation (mg/m³)	0.05 mg/m³	
		Dermal (mg/kg bw/day)	Not determined	
		Oral (mg/kg bw/day)	3.5 mg/kg bw/day	

Environmental Parameters (PNECs)				
Exposure Scenario	PEC Environment Reasonable worst case	PNEC STP		
ES1 Manufacture of kieselguhr soda ash flux calcined	Not defined	Not defined		
ES2 Use as filter aid in industrial settings	3.87 mg/l	100 mg/l		
ES3 Industrial, professional and private use of substance or mixtures containing the substance	0.329 mg/l	100 mg/l		

Revision: 4.1 Date: 29.01.2021



ACCORDING TO EC-REGULATIONS 1907/2006 (REACH), 1272/2008 (CLP) & 2015/830

Diatomaceous Earth Flux-Calcined, Kieselguhr Flux-Calcined Celatom® FW-6, FW-12, FW-14, FW-18, FW-20, FW-40, FW-50, FW-60, FW-70, FW-80, SP, AW-12, AW-14, AW-18, AW-20

#### **Contents**

Exposure scenario	Title	Page:
Exposure scenario 1	Manufacture of kieselguhr soda ash flux calcined	10
Exposure scenario 2	Use as filter aid in industrial settings	13
Exposure scenario 3	Industrial, professional and private use of substance or mixtures containing the substance	16
Exposure scenario 4	Consumer use; Cosmetics, personal care products	20

#### **Contributing Scenarios**

#### **PROC Codes**

- PROC1 Use in closed process, no likelihood of exposure
- PROC2 Use in closed, continuous process with occasional controlled exposure
- PROC3 Use in closed batch process (synthesis or formulation)
- PROC4 Use in batch and other process (synthesis) where opportunity for exposure arises
- PROC5 Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact)
- PROC7 Industrial spraying
- PROC8a Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities
- PROC8b Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities
- PROC9 Transfer of substance or preparation into small containers (dedicated filling line, including weighing)
- PROC10 Roller application or brushing
- PROC11 Non industrial spraying
- PROC13 Treatment of articles by dipping and pouring
- PROC15 Use as laboratory reagent
- PROC19 Hand-mixing with intimate contact and only PPE available

Revision: 4.1 Date: 29.01.2021



ACCORDING TO EC-REGULATIONS 1907/2006 (REACH), 1272/2008 (CLP) & 2015/830

Diatomaceous Earth Flux-Calcined, Kieselguhr Flux-Calcined Celatom® FW-6, FW-12, FW-14, FW-18, FW-20, FW-40, FW-50, FW-60, FW-70, FW-80, SP, AW-12, AW-14, AW-18, AW-20

Error! Not a valid bookmark self-reference. Exposure Scenario 1 – Manufacture of kieselguhr soda ash flux calcined

1.0 Contributing Scenarios	
Sector of uses SU	SU3 Industrial uses: Uses of substances as such or in preparations at industrial sites
Process category [PROC]	PROC2 Use in closed, continuous process with occasional controlled exposure PROC3 Use in closed batch process (synthesis or formulation) PROC4 Use in batch and other process (synthesis) where opportunity for exposure arises PROC8b Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities PROC9 Transfer of substance or preparation into small containers (dedicated filling line, including weighing)
Chemical product category [PC]	PC0 Other Adsorbents, Filling material PC14 Metal surface treatment products, including galvanic and electroplating products
Article Categories [AC]	Not applicable
Environmental release categories [ERC]	ERC1 Manufacture of substances
Specific Environmental Release Categories SPERC	Not applicable

2.1 Control of worker exposure				
Product characteristics				
Physical form of product	White/Beige Powder			
Concentration of substance in product	Covers concentrations up to	100%		
Human factors not influenced by risk m	anagement			
Potential exposure area	Not defined			
Frequency and duration of use				
Exposure duration per day	Covers daily exposures up to	8 hours (unless stated differently).		
Exposure time per week	Covers frequency up to: 5 da	ays per week.		
Other operational conditions affecting v	vorker exposure			
Area of use	All contributing scenarios	Indoor		
Characteristics of the surroundings	Not defined			
General measures applicable to all activ				
Assumes a good basic standard of occupa	tional hygiene is implemented. As	sumes use at not more than 20°C above ambient temperature, unless		
stated differently. Do not breathe dust. Avo	oid dust generation. Clear spills im	mediately. After contact with skin, wash immediately with plenty of:		
Water. Provide basic employee training to	prevent / minimize exposures.			
Organisational measures	T	re using measures such as contained or enclosed systems, properly		
All contributing scenarios	designed and maintained facilities and a good standard of general ventilation. Drain down systems and clear transfer lines prior to breaking containment. Drain down and flush equipment where possible prior to maintenance. Where there is potential for exposure: Ensure relevant staff are informed of the nature of exposure and aware of basic actions to minimise exposures; Ensure suitable personal protective equipment is available; Clear up spills and dispose of waste in accordance with regulatory requirements; monitor effectiveness of control measures; consider the need for health surveillance; identify and implement corrective actions.			
Technical conditions of use	<u> </u>	· · · · · · · · · · · · · · · · · · ·		
PROC4, PROC5, PROC8a, PROC8b, PROC9, PROC15, PROC19	Local exhaust ventilation is r	Local exhaust ventilation is required.		
PROC1, PROC2, PROC3	Use in closed systems. Loca	l exhaust ventilation is required.		
Risk management measures related to I	human health			
Respiratory protection	PROC4, PROC8b, PROC9	Half-face mask (DIN EN 140), Filter type P2/P3 - efficiency of at least 90%		
	PROC2, PROC3	No special measures are required.		
Hand and/or Skin protection	All contributing scenarios	Wear impervious gloves (EN374). Wear suitable coveralls to preven exposure to the skin.		
Eye Protection	All contributing scenarios	Wear eye protection with side protection (EN166).		
Other operational conditions affecting v	vorker exposure	· · · · · ·		
Assumes a good basic standard of occupa	tional hygiene is implemented.			
2.2 Control of environmental exposure				
Amounts used				
Fraction of EU tonnage used in region:	Niet	sidered to influence the eveneurs of such for this coors		
Regional use tonnage (tons/year):	NOT CONS	sidered to influence the exposure as such for this scenario		

Revision: 4.1 Date: 29.01.2021



ACCORDING TO EC-REGULATIONS 1907/2006 (REACH), 1272/2008 (CLP) & 2015/830

Diatomaceous Earth Flux-Calcined, Kieselguhr Flux-Calcined Celatom® FW-6, FW-12, FW-14, FW-18, FW-20, FW-40, FW-50, FW-60, FW-70, FW-80, SP, AW-12, AW-14, AW-18, AW-20

Frantism of Danismal termona wood levelly temply on				
Fraction of Regional tonnage used locally: tons/year				
Annual site tonnage (tons/year):				
Maximum daily site tonnage (kg/day):				
Environment factors not influenced by risk management				
Flow rate of receiving surface water (m³/d):	Not defined (default = 18,000)			
Local freshwater dilution factor:	10			
Local marine water dilution factor:	100			
Operational conditions				
Emission days (days/year):	Not defined			
Release fraction to air from process (initial release prior to RMM):	No risk is anticipated: Atmospheric concentrations are expected to be low.			
Release fraction to wastewater from process (initial release prior to RMM):	100 mg/l			
Release fraction to soil from process (initial release prior to RMM):	No risk is anticipated: Deposition is expected to be low.			
Technical onsite conditions and measures to reduce or limit of	discharges, air emissions and releases to soil			
	Not defined. It is recommended to pass waste gas from manufacturing			
Treat air emission to provide a typical removal efficiency of (%):	processes through bag filters, scrubbers or cyclones.			
Treat onsite wastewater (prior to receiving water discharge) to provide the required removal efficiency of (%):	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.			
If discharging to domestic sewage treatment plant, provide the required onsite wastewater removal efficiency of (%):	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.			
Treat soil emission to provide a typical removal efficiency of (%):	Not defined			
Note: Common practices vary across sites thus conservative process.	ess release estimates used.			
Organisational measures to prevent/limit release from site				
Prevent discharge of undissolved substance to or recover from on Do not apply industrial sludge to natural soils. Sludge should be incinerated, contained or reclaimed.	site wastewater.			
Conditions and measures related to municipal sewage treatment	ent plant			
Size of municipal sewage system/treatment plant (m³/d)	Not defined			
Degradation effectiveness (%)	Not defined			
Conditions and measures related to external treatment of waste for disposal				
Type of waste	Solid and Liquid and Gas			
Disposal technique	Bury on an authorised landfill site or incinerate under approved controlled conditions. It is recommended to pass waste gas from manufacturing processes through bag filters, scrubbers or cyclones.			
Substance release quantities after risk management measures				
Release to waste water from process (mg/l)	< 3.87 mg/l			
Maximum allowable site tonnage (MSafe) (kg/d):	Not defined			

#### 3. Exposure estimation and reference to its source

3.1	Human	exposure	prediction

Exposure assessment (method/calculation model) ECETOC TRA 2010

			Inf	nalation
Process category [PROC]	Duration	Local Exhaust Ventilation	inhalation exposure (mg/m³)	Risk characterisation ratio (RCR)
PROC1	4 – 8	None	0.01	0.028
PROC2	4 – 8	90%	0.1	0.278
PROC3	4 – 8	90%	0.1	0.278
PROC4	<u>&lt;</u> 1	95%	0.25	0.694
PROC5	<u>&lt;</u> 1	95%	0.25	0.694
PROC8a	<u>&lt;</u> 1	95%	0.25	0.694
PROC8b	<u>&lt;</u> 1	95%	0.25	0.694
PROC9	<u>&lt;</u> 1	95%	0.2	0.556
PROC15	4 – 8	95%	0.25	0.694
PROC19	< 1	95%	0.25	0.694

Dermal exposure is considered to be not relevant.

Oral exposure is not expected to occur.

3.2 Environmental exposure prediction

Exposure assessment (method/calculation model) EUSES

Revision: 4.1 Date: 29.01.2021



ACCORDING TO EC-REGULATIONS 1907/2006 (REACH), 1272/2008 (CLP) & 2015/830

Risk characterisation ratio	
Waste water treatment	Not defined: After sedimentation, wastewater sent to the waste water treatment plant contains: < 3.87 mg/l. No effects are observed at this level.
Aquatic Compartment (Pelagic)	Not defined: Reasonable worst-case local PECs are below the no effect level (3.87 mg/l): 0.387/0.039 mg/l
freshwater sediment/marine sediment	No risk is anticipated: Kieselguhr is naturally occurring and is considered a natural part of ecosystems.
Soil	No risk is anticipated: Deposition is expected to be low.
Atmospheric Compartment	No risk is anticipated: Atmospheric concentrations are expected to be low.
Indirect exposure to humans via the environment / Secondary Poisoning	The substance has a low solubility in water and thus is essentially unavailable to organisms.

4. Evaluation guidance to downstream user				
For scaling see	are managed to at least equivalen. Available hazard data do not supp Further details on scaling and cont industries-libraries.html).	ort the need for a DNEL to be established for other health effects. trol technologies are provided in SpERC factsheet (http://cefic.org/en/reach-formendations, the "worst case" approach has been taken and only the most stringent te of exposure have been taken.		
Exposure assessment	Workers	ECETOC TRA 2010		
instrument/tool/method	Environmental exposure	EUSES		

Revision: 4.1 Date: 29.01.2021

Minerals<sup>®</sup>

ACCORDING TO EC-REGULATIONS 1907/2006 (REACH), 1272/2008 (CLP) & 2015/830

Diatomaceous Earth Flux-Calcined, Kieselguhr Flux-Calcined Celatom® FW-6, FW-12, FW-14, FW-18, FW-20, FW-40, FW-50, FW-60, FW-70, FW-80, SP, AW-12, AW-14, AW-18, AW-20

## Exposure Scenario 2 – Use as filter aid in industrial settings

1.0 Contributing Scenarios	
Sector of uses SU	SU3 Industrial uses: Uses of substances as such or in preparations at industrial sites SU4 Manufacture of food products SU6a Manufacture of wood and wood products SU6b Manufacture of pulp, paper and paper products SU8 Manufacture of bulk, large scale chemicals (including petroleum products) SU9 Manufacture of fine chemicals SU15 Manufacture of fabricated metal products, except machinery and equipment SU19 Building and construction work
Process category [PROC]	PROC1 Use in closed process, no likelihood of exposure PROC2 Use in closed, continuous process with occasional controlled exposure PROC3 Use in closed batch process (synthesis or formulation) PROC4 Use in batch and other process (synthesis) where opportunity for exposure arises PROC5 Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) PROC8a Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities PROC8b Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities PROC9 Transfer of substance or preparation into small containers (dedicated filling line, including weighing) PROC15 Use as laboratory reagent PROC19 Hand-mixing with intimate contact and only PPE available
Chemical product category [PC]	PC0 Other Filtration material PC2 Adsorbents PC14 Metal surface treatment products, including galvanic and electroplating products PC20 Products such as ph-regulators, flocculants, precipitants, neutralization agents PC25 Metal working fluids PC35 Washing and cleaning products (including solvent based products)
Article Categories [AC]	Not applicable
Environmental release categories [ERC]	ERC1 Manufacture of substances ERC2 Formulation of preparations ERC4 Industrial use of processing aids in processes and products, not becoming part of articles. ERC6b Industrial use of reactive processing aids ERC7 Industrial use of substances in closed systems
Specific Environmental Release Categories SPERC	Not applicable

2.0 Operational conditions and risk management measures				
2.1 Control of worker exposure				
Product characteristics				
Physical form of product	Light pink to white powder			
Concentration of substance in product	White/Beige Powder Covers of	oncentrations up to 100%		
Human factors not influenced by risk mana	agement			
Potential exposure area	Not defined			
Frequency and duration of use				
Exposure duration per day	Covers daily exposures up to	8 hours (unless stated differently).		
Exposure time per week	Covers frequency up to: 5 day	s per week.		
Other operational conditions affecting wor	ker exposure			
Area of use	All contributing scenarios	Indoor		
Characteristics of the surroundings	Room volume	50 m <sup>3</sup>		
Characteristics of the surroundings	Ventilation rate	0.6 / 1 hour(s)		
General measures applicable to all activities  Assumes a good basic standard of occupational hygiene is implemented. Assumes use at not more than 20°C above ambient temperature, unless stated differently. Do not breathe dust. Avoid dust generation. Clear spills immediately. After contact with skin, wash immediately with plenty of:  Water. Provide basic employee training to prevent / minimize exposures.				
Organisational measures				
Control any potential exposure using measures such as contained or enclosed systems, properly designed and maintained facilities and a good standard of general ventilation. Drain down systems and clear transfer lines prior to breaking containment. Drain down and flush equipment where possible prior to maintenance. Where there is potential for exposure: Ensure relevant staff are informed of the nature of exposure and aware of basic actions to minimise exposures; Ensure				

Revision: 4.1 Date: 29.01.2021



ACCORDING TO EC-REGULATIONS 1907/2006 (REACH), 1272/2008 (CLP) & 2015/830

	suitable personal	protective ed	quipment is available; Clear up spills and dispose of waste in		
	accordance with regulatory requirements; monitor effectiveness of control measures; consider the need for health surveillance; identify and implement corrective actions.				
Technical conditions of use	110001011100111100		and implement conscient design.		
PROC4, PROC5, PROC8a, PROC8b, PROC9, PROC15, PROC19	C4, PROC5, PROC8a, PROC8b,				
PROC2, PROC3	Use in closed syst	ems.			
Risk management measures related to hu					
PROC4, PROC5, P			Wear respiratory protection.		
Respiratory protection	PROC15, PROC1 PROC2, PROC3	9	No special measures are required.		
Hand and/or Skin protection	All contributing sce	enarios	Wear impervious gloves (EN374). Wear suitable coveralls to prevent exposure to the skin.		
Eye Protection	All contributing sco	enarios	Wear eye protection with side protection (EN166).		
Other operational conditions affecting wo	rker exposure				
Assumes a good basic standard of occupation	onal hygiene is impler	nented.			
2.2 Control of environmental exposure					
Amounts used					
Fraction of EU tonnage used in region:					
Regional use tonnage (tons/year):		Not consid	dered to influence the exposure as such for this scenario		
Fraction of Regional tonnage used locally: to	ns/year		·		
Annual site tonnage (tons/year):	-	2 - 12500			
Maximum daily site tonnage (kg/day):		Not deterr	nined.		
Environment factors not influenced by ris	k management	•			
Flow rate of receiving surface water (m³/d):	<b></b>	Not define	d (default = 18,000)		
Local freshwater dilution factor:		10	(43.55.6.1		
Local marine water dilution factor:		100			
Operational conditions					
Emission days (days/year):		Not define	Not defined		
Release fraction to air from process (initial re	lease prior to				
RMM):		No risk is	anticipated: Atmospheric concentrations are expected to be low.		
Release fraction to wastewater from process (initial release prior to RMM):		100 mg/l			
Release fraction to soil from process (initial RMM):			anticipated: Deposition is expected to be low.		
Technical onsite conditions and measure	s to reduce or limit				
Treat air emission to provide a typical remov	al efficiency of (%):	processes	d. It is recommended to pass waste gas from manufacturing through bag filters, scrubbers or cyclones.		
Treat onsite wastewater (prior to receiving water discharge) to provide the required removal efficiency of (%):		sedimenta	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.		
If discharging to domestic sewage treatment required onsite wastewater removal efficience		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.			
Treat soil emission to provide a typical remo	val efficiency of (%)	Not defined			
Note: Common practices vary across sites the					
Organisational measures to prevent/limit		230 1010400			
Prevent discharge of undissolved substance	to or recover from on	site wastewa	ater.		
Do not apply industrial sludge to natural soils Sludge should be incinerated, contained or r	eclaimed.				
Conditions and measures related to municipal sewage treatmen					
Size of municipal sewage system/treatment plant (m³/d)		Not defined			
8			Not defined		
Conditions and measures related to exter	nal treatment of was				
Type of waste			Liquid and Gas		
Disposal technique		Bury on an authorised landfill site or incinerate under approved controlled conditions. It is recommended to pass waste gas from manufacturing processes through bag filters, scrubbers or cyclones.			
Substance release quantities after risk m	anagement measure		•		
Release to waste water from process (mg/l)		< 3.87 mg	Л		
Maximum allowable site tonnage (MSafe) (kg	g/d):	Not defined			
1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1					

Revision: 4.1 Date: 29.01.2021



ACCORDING TO EC-REGULATIONS 1907/2006 (REACH), 1272/2008 (CLP) & 2015/830

Diatomaceous Earth Flux-Calcined, Kieselguhr Flux-Calcined Celatom® FW-6, FW-12, FW-14, FW-18, FW-20, FW-40, FW-50, FW-60, FW-70, FW-80, SP, AW-12, AW-14, AW-18, AW-20

3.1	Human	exposure	prediction

Exposure assessment (method/calculation model) ECETOC TRA 2010

			Inf	nalation
Process category [PROC]	Duration	Local Exhaust Ventilation	inhalation exposure (mg/m³)	Risk characterisation ratio (RCR)
PROC2	4 – 8	None	0.147	0.408
PROC3	4 – 8	None	0.147	0.408
PROC4	4 – 8	None	0.147	0.408
PROC5	4 – 8	None	0.147	0.408
PROC8a	4 – 8	None	0.147	0.408
PROC8b	4 – 8	None	0.147	0.408
PROC9	4 – 8	None	0.147	0.408
PROC15	4 – 8	None	0.147	0.408
PROC19	8	None	0.147	0.408

Dermal exposure is considered to be not relevant.

Oral exposure is not expected to occur.

Oral exposure is not expected to occur.	
3.2 Environmental exposure prediction	
Exposure assessment (method/calculation model)	EUSES
Risk characterisation ratio	
Waste water treatment	Not defined: After sedimentation, wastewater sent to the waste water treatment plant contains: < 3.87 mg/l. No effects are observed at this level.
Aquatic Compartment (Pelagic)	Not defined: Reasonable worst-case local PECs are below the no effect level (3.87 mg/l): 0.387/0.0387 mg/l
freshwater sediment/marine sediment	No risk is anticipated: Kieselguhr is naturally occurring and is considered a natural part of ecosystems.
Soil	No risk is anticipated: Deposition is expected to be low.
Atmospheric Compartment	No risk is anticipated: Atmospheric concentrations are expected to be low.
Indirect exposure to humans via the environment / Secondary Poisoning	The substance has a low solubility in water and thus is essentially unavailable to organisms.

4. Evaluation guidance to downstream user				
For scaling see	Where other Risk Management Measures/Operational Conditions are adopted, then users should ensure that risks are managed to at least equivalent levels.  Available hazard data do not support the need for a DNEL to be established for other health effects.  Further details on scaling and control technologies are provided in SpERC factsheet (http://cefic.org/en/reach-for-industries-libraries.html).  In accordance with ECHAs recommendations, the "worst case" approach has been taken and only the most stringent RMMs recommended for each route of exposure have been taken.			
Exposure assessment	Workers	ECETOC TRA 2010		
instrument/tool/method	Environmental exposure	EUSES		

Revision: 4.1 Date: 29.01.2021



ACCORDING TO EC-REGULATIONS 1907/2006 (REACH), 1272/2008 (CLP) & 2015/830

Diatomaceous Earth Flux-Calcined, Kieselguhr Flux-Calcined Celatom® FW-6, FW-12, FW-14, FW-18, FW-20, FW-40, FW-50, FW-60, FW-70, FW-80, SP, AW-12, AW-14, AW-18, AW-20

# Exposure Scenario 3 – Industrial, professional and private use of substance or mixtures containing the substance

1.0 Contributing Scenarios	
Sector of uses SU	SU3 Industrial uses: Uses of substances as such or in preparations at industrial sites SU21 Consumer uses: Private households (= general public = consumers) SU22 Professional uses: Public domain (administration, education, entertainment, services, craftsmen)
Process category [PROC]	PROC2 Use in closed, continuous process with occasional controlled exposure PROC3 Use in closed batch process (synthesis or formulation) PROC4 Use in batch and other process (synthesis) where opportunity for exposure arises PROC5 Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) PROC7 Industrial spraying PROC8a Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities PROC10 Roller application or brushing PROC11 Non industrial spraying PROC13 Treatment of articles by dipping and pouring PROC19 Hand-mixing with intimate contact and only PPE available
Chemical product category [PC]	PC35 Washing and cleaning products (including solvent based products) PC37 Water treatment chemicals
Article Categories [AC]	AC10 Rubber articles AC13 Plastic articles
Environmental release categories [ERC]	ERC1 Manufacture of substances ERC2 Formulation of preparations ERC8a Wide dispersive indoor use of processing aids in open systems ERC8c Wide dispersive indoor use resulting in inclusion into or onto a matrix ERC8d Wide dispersive outdoor use of processing aids in open systems ERC8f Wide dispersive outdoor use resulting in inclusion into or onto a matrix ERC10b Wide dispersive outdoor use of long-life articles and materials with high or intended release (including abrasive processing)
Specific Environmental Release Categories SPERC	Not applicable

2.0 Operational conditions and risk management measures					
2.1 Control of worker exposure					
Product characteristics					
Physical form of product	Solid and Liquid				
Concentration of substance in product	Covers concentrations up to 1	5%			
Human factors not influenced by risk man	agement				
Potential exposure area	Not defined				
Frequency and duration of use					
	Use of coatings and paints con soda ash flux-calcined	ntaining kieselguhr	4 – 8 hours		
Exposure duration	Use of kieselguhr soda ash flu filtering water	x calcined for	1 hour/days		
	Use of cleaners containing kieselguhr soda-ash flux calcined		Professional: 60 min/Use Consumer: 20 min/Days		
	Use of coatings and paints containing kieselguhr soda ash flux-calcined		225 days per year		
Exposure frequency	Use of kieselguhr soda ash flux calcined for filtering water		Professional: Weekly Consumer: Monthly		
	Use of cleaners containing kie flux calcined		Professional: ≤ 8 Uses per day Consumer: 1 Uses per day		
Other operational conditions affecting wo	rker exposure				
Area of use	All contributing scenarios	All contributing scenarios Indoor			
	Professional: Use of	Room volume	1 m <sup>3</sup>		
Characteristics of the surroundings	coatings and paints	Ventilation rate	0.6 / 1 hour(s)		
	containing kieselguhr soda ash flux-calcined	Release area	200 cm <sup>2</sup>		
	Professional use of hand	Room volume	2.5 m³		
	cleaners	Ventilation rate	2 / 1 hour(s)		

Revision: 4.1 Date: 29.01.2021



ACCORDING TO EC-REGULATIONS 1907/2006 (REACH), 1272/2008 (CLP) & 2015/830

			Release area	5 m <sup>2</sup>
	All other uses		Not defined	
General measures applicable to all activities				
Assumes a good basic standard of occupational hygiene is implemented. Assumes use at not more than 20°C above ambient temperature, unless stated differently. Do not breathe dust. Avoid dust generation. Clear spills immediately. After contact with skin, wash immediately with plenty of: Water. Provide basic employee training to prevent / minimize exposures.				
Organisational measures	. о. н. ,			
All contributing scenarios	designed and mair and clear transfer possible prior to m informed of the na suitable personal p accordance with re	ntained facili lines prior to aintenance. ture of expo- protective eq egulatory rec	ties and a good star breaking containme Where there is pote sure and aware of b uipment is available quirements; monitor	ich as contained or enclosed systems, properly indard of general ventilation. Drain down systems ent. Drain down and flush equipment where ential for exposure: Ensure relevant staff are easic actions to minimise exposures; Ensure e; Clear up spills and dispose of waste in effectiveness of control measures; consider the int corrective actions.
Technical conditions of use				
All contributing scenarios	Local exhaust reco	ommended.		
Risk management measures related to hun				
Respiratory protection	All contributing sce	enarios	Wear respiratory p	
Hand and/or Skin protection	All contributing sce	enarios	exposure to the sk	
Eye Protection	All contributing sce	enarios	Wear eye protecti	on with side protection (EN166).
Other operational conditions affecting work				
Assumes a good basic standard of occupation		nented.		
2.2 Control of environmental exposure				
Amounts used				
Tonnage in EU per year		120, tonne	s	
Fraction of EU tonnage used in region:		10 %		
Regional use tonnage (tons/year):		12 tonnes		
Fraction of Regional tonnage used locally:		Not define	d	
Annual site tonnage (tons/year):		Not defined		
Maximum daily site tonnage (kg/day):		Not defined		
Environment factors not influenced by risk	management			
Flow rate of receiving surface water (m³/d):		2000		
Local freshwater dilution factor:		10		
Local marine water dilution factor:		100		
Operational conditions				
Emission days (days/year):		260		
Release fraction to air from process (initial release RMM):	ease prior to	0		
Release fraction to wastewater from process (initial release prior to RMM):		0.1		
Release fraction to soil from process (initial release prior to RMM):		0		
Technical onsite conditions and measures	to reduce or limit of	discharaes.	air emissions and	releases to soil
Treat air emission to provide a typical removal		Not define		
Treat onsite wastewater (prior to receiving war provide the required removal efficiency of (%):	er discharge) to	The waste sedimenta very efficie	water resulting from tion to remove the s ent with a reduction	n manufacturing of the substance can be treated by solid parts of the substance. The sedimentation is efficacy of 99% or more.
If discharging to domestic sewage treatment plant, provide the required onsite wastewater removal efficiency of (%):		sedimenta very efficie	tion to remove the sent with a reduction	n manufacturing of the substance can be treated by solid parts of the substance. The sedimentation is efficacy of 99% or more.
Treat soil emission to provide a typical removal efficiency of (%):				
Note: Common practices vary across sites thu		ess release	estimates used. No	wastewater treatment required.
Organisational measures to prevent/limit re				
Vent waste air only via suitable separators or				
Prevent discharge of undissolved substance to or recover from onsite wastewater.  Do not apply industrial sludge to natural soils.				
Sludge should be incinerated, contained or red		ont plant		
Conditions and measures related to municipal sewage treatments of municipal sewage treatments			d	
Size of municipal sewage system/treatment plant (m³/d)		Not define		
Degradation effectiveness (%)  Conditions and measures related to external treatment of waste for disposal				
	ai ireaunent oi Was			
Type of waste		Solid and I		site or incinerate under approved controlled
Disposal technique		conditions		site or incinerate under approved controlled

Revision: 4.1 Date: 29.01.2021



ACCORDING TO EC-REGULATIONS 1907/2006 (REACH), 1272/2008 (CLP) & 2015/830

Diatomaceous Earth Flux-Calcined, Kieselguhr Flux-Calcined Celatom® FW-6, FW-12, FW-14, FW-18, FW-20, FW-40, FW-50, FW-60, FW-70, FW-80, SP, AW-12, AW-14, AW-18, AW-20

	Discharge cleaning water into sewer. Do not discharge cleaning water into small water bodies.
Substance release quantities after risk management measures	
Release to waste water from process (mg/l)	0.012 mg/l
Maximum allowable site tonnage (MSafe) (kg/d):	Not defined

3. Exposure estimation and reference to its source		
3.1 Human exposure prediction		
Exposure assessment (method/calculation model)	ECETOC TRA 2010	
Risk characterisation ratio		

						Inhalation
Туре	Content	Local Exhaust Ventilation	Duration	Process category [PROC]	inhalation exposure (mg/m³)	Risk characterisation ratio (RCR)
Industrial	10%	NO	6	PROC7	0.325	0.903
Professional	95%	NO	6	PROC11	0.325	0.903

Consumer use	Long Term inhalation exposure (mg/m³)	Short term inhalation exposure (mg/m³)	Risk characterisation ratio (RCR)
Use of high-solid paints	0.000122		0.0015
Use of water-based paints	0.000186		0.0023
Use of solvent-based paints	0.000864		0.011
Use of water-based wall paints	0.00044		0.0055
Spray painting (trigger cans)		37.5	-
Spray painting (pneumatic sprayer)		0.676	
Filtration material		0.14	
Cleaning products	0.00002		0.00025

3.2 Environmental exposure prediction		
Exposure assessment (method/calculation model)	EUSES	
Risk characterisation ratio		
Waste water treatment	$C$ – $AMOUNT_{STP}$	
	$C_{STP} = \frac{AMOUNT_{STP}}{DAYS \cdot INHAB \cdot WASTEW_{inhab}}$	
	$AMOUNT_{\it STP}$ Amount of kieselguhr soda ash flux-calcined released to municipal STPs in the EU per year (1.2E13 mg/Year(s),	
	DAYS Number of release days (365 Days//Year(s)),	
	INHAB Number of inhabitants in EU (500 million inhabitants)	
	WASTEW <sub>inhab</sub> Wastewater per inhabitant (200 L/day)	
	$C_{\it STP}$ Concentration of kieselguhr soda ash flux-calcined in municipal STP (mg/l).	
	Estimated STP Concentration (g/L):	
	$C_{STP} = \frac{1.2E13}{365 \cdot 500000000 \cdot 200} = 0.329 \frac{mg}{L}$	
Aquatic Compartment (Pelagic)	Surface Water: 0.333 mg/l marine water: 0.00033 mg/l	
freshwater sediment/marine sediment	No risk is anticipated: Kieselguhr is naturally occurring and is considered a natural part of ecosystems.	
Soil	No risk is anticipated: Kieselguhr is naturally occurring and is considered a natural part of ecosystems.	
Atmospheric Compartment	No risk is anticipated: Deposition is expected to be low.	
Secondary Poisoning	No risk is anticipated: Atmospheric concentrations are expected to be low.	
Indirect exposure to humans via the environment / Seconda Poisoning	The substance has a low solubility in water and thus is essentially unavailable to organisms.	

Page: 18 of 20

Revision: 4.1 Date: 29.01.2021



ACCORDING TO EC-REGULATIONS 1907/2006 (REACH), 1272/2008 (CLP) & 2015/830

4. Evaluation guidance to downstream user		
For scaling see	are managed to at least equivalent Available hazard data do not supp Further details on scaling and cont industries-libraries.html).	ort the need for a DNEL to be established for other health effects. trol technologies are provided in SpERC factsheet (http://cefic.org/en/reach-formendations, the "worst case" approach has been taken and only the most stringent te of exposure have been taken.
Exposure assessment	Workers	ECETOC TRA 2010 / RIVM 2008
instrument/tool/method	Consumer	RIVM 2008
	Environmental exposure	EUSES

Revision: 4.1 Date: 29.01.2021



ACCORDING TO EC-REGULATIONS 1907/2006 (REACH), 1272/2008 (CLP) & 2015/830

Diatomaceous Earth Flux-Calcined, Kieselguhr Flux-Calcined Celatom® FW-6, FW-12, FW-14, FW-18, FW-20, FW-40, FW-50, FW-60, FW-70, FW-80, SP, AW-12, AW-14, AW-18, AW-20

#### Exposure Scenario 4 – Consumer use; Cosmetics, personal care products

1.0 Contributing Scenarios	
Sector of uses SU	SU21 Consumer uses: Private households (= general public = consumers)
Process category [PROC]	Not applicable
Chemical product category [PC]	PC39 Cosmetics, personal care products
Article Categories [AC]	Not applicable
Environmental release categories [ERC]	ERC8a Wide dispersive indoor use of processing aids in open systems
Specific Environmental Release Categories SPERC	Not applicable

2.0 Operational conditions and risk management measures					
2.1 Control of worker exposure	2.1 Control of worker exposure				
Product characteristics					
Physical form of product	Not defined				
Concentration of substance in product	Not defined				
Conditions of use affecting exposure					
	In accordance to the Article 14 (5b) of the REACh Regulation (EC) No 1907/2006, exposure estimation and risk characterisation for human health does not need to be performed for end uses in cosmetic products within the scope of Directive 76/768/EEC.				
Risk management measures					
Respiratory protection	espiratory protection No specific measures identified.				
Hand/Skin protection	No specific measures identified.				
Eye Protection	No specific measures identified.				
2.2 Control of environmental exposure					
Conditions of use affecting exposure					
Daily local widespread use amount ≤ 300 g/Day					
Dispose of waste product or used containers according to local regulations. Waste water of facility is assumed to be treated in municipal waste water treatment.					

#### 3. Exposure estimation and reference to its source

2 4	LI.Imaan		muadiation	
J. I	numan	exposure	prediction	

In accordance to the Article 14 (5b) of the REACh Regulation (EC) No 1907/2006, exposure estimation and risk characterisation for human health does not need to be performed for end uses in cosmetic products within the scope of Directive 76/768/EEC.

#### 3.2 Environmental exposure prediction

Exposure assessment (method/calculation model)		EUSES
Environmental Release		
	Water	0.302 kg/day (ERC)
	Air	0.302 kg/day (ERC)
	Soil	0 kg/day (ERC)

#### Risk characterisation ratio

Protection target	Exposure estimation	Risk characterisation ratio
Sewage Treatment Plant	0.151 mg/l (EUSES 2.1.2)	< 0.01
Man via environment - Inhalation	2.06E-6 mg/m³ (EUSES 2.1.2)	< 0.01
Man via environment - Oral	5.67E-4 mg/kg bw/day (EUSES 2.1.2)	< 0.01
Man via environment - Combined	-	< 0.01

#### 4. Evaluation guidance to downstream user

If safe use conditions stated in the exposure scenario cannot be enforced, alternatives measures must be equivalent or better than those stated in this exposure scenario.

For scaling see EUSES v. 2.1.2

Guidance is based on assumed operating conditions which may not be applicable to all sites; thus, scaling may be necessary to define appropriate site-specific risk management measures.