

SAFETY DATA SHEET

Revision: 27 Date: 08.02.2018



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

Diatomaceous Earth Flux-Calcined, Kieselguhr Flux-Calcined
CelaBrite®, Celatom® MW-25, MW-27, MW-31

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

1.1 Product identifier

Product Name CelaBrite®, Celatom® MW-25, MW-27, MW-31
Trade names CelaBrite®, Celatom® MW-25, MW-27, MW-31
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, cosmetics, plastics, rubber or other applications.

Exposure Scenario

No.		Page:
1	Manufacture of kieselguhr soda ash flux calcined	10
2	Use as additive in formulation of liquid, viscous or solid mixtures	13
3	Use as process aid in manufacture of chemicals, resins, rubbers and plastics	16
4	Professional use by dental technicians	19
5	Industrial, professional and private use of substance or mixtures containing the substance	22
6	Consumer use; Cosmetics, personal care products	26

1.3 Details of the supplier of the safety data sheet

Uses Advised Against Anything other than the above.
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
USA: +1-775-824-7600 (08:00– 17:00 PST)

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

This product contains cristobalite (fine fraction) between 1 and 10%. 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


SAFETY DATA SHEET

Revision: 27 Date: 08.02.2018



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1272/2008 (CLP) & 2015/830

Diatomaceous Earth Flux-Calcined, Kieselguhr Flux-Calcined
CelaBrite®, Celatom® MW-25, MW-27, MW-31

2.1.1	Regulation (EC) No. 1272/2008 (CLP)	STOT RE 2 Inhalation (Specific target organ toxicity — repeated exposure 2)
2.1.2	Directive 67/548/EEC & Directive 1999/45/EC	Not classified According to Directive 67/548/EEC & Directive 1999/45/EC
2.2	Label elements Product Name Contains: Hazard Pictogram(s)	According to Regulation (EC) No. 1272/2008 (CLP) CelaBrite®, Celatom® MW-25, MW-27, MW-31 Diatomaceous Earth ,Flux-Calcined (Kieselguhr) (1-10% Crystalline Silica– Cristobalite (Fine Fraction Dust)) 
	Signal Word(s)	Warning
	Hazard Statement(s)	H373: May cause damage to organs through prolonged or repeated exposure: Inhalation into Lungs
	Precautionary Statement(s)	P260: Do not breathe dust. P285: In case of inadequate ventilation wear respiratory protection. P501: Dispose of contents/container to: Disposal should be in accordance with local, state or national legislation.
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 (Fine Fraction Dust), 1-10% Fine Fraction Crystalline silica per SWeRF calculation	1 - 10	14464-46-1	238-455-4

3.2 Mixtures - Not applicable.

SECTION 4: FIRST AID MEASURES



4.1 Description of first aid measures

Inhalation	IF INHALED: If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. Blow nose to evacuate dust.
Skin Contact	IF ON SKIN (or hair): After contact with skin, wash immediately with plenty of soap and water.
Eye Contact	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.
Ingestion	If swallowed, rinse mouth with water (only if the person is conscious). Drink two glasses of water. If irritation develops and persists, get medical attention.

SAFETY DATA SHEET

Revision: 27 Date: 08.02.2018



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CelaBrite®, Celatom® MW-25, MW-27, MW-31

- 4.2 Most important symptoms and effects, both acute and delayed** 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. 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** There is no specific antidote. Remove person to fresh air and keep comfortable for breathing. Treat symptomatically.

SECTION 5: FIREFIGHTING MEASURES

- 5.1 Extinguishing media**
Suitable Extinguishing media Non-flammable. Extinguish with carbon dioxide, dry chemical, foam or waterspray. As appropriate for surrounding fire.
Unsuitable extinguishing media None.
- 5.2 Special hazards arising from the substance or mixture** Non-flammable, Non-combustible, Not explosive.
- 5.3 Advice for fire-fighters** 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 protective equipment.
- 6.2 Environmental precautions** No special requirements.
- 6.3 Methods and material for containment and cleaning up** 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.
- 7.2 Conditions for safe storage, including any incompatibilities** Atmospheric concentrations should be minimised and kept as low as reasonably practicable below the occupational exposure limit.
Storage life Stable under normal conditions. Store in a dry place.
Incompatible materials Keep away from: Hydrofluoric Acid, concentrated caustic solutions
- 7.3 Specific end use(s)** See Section: 1.2

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

- 8.1 Control parameters**
8.1.1 Occupational Exposure Limits

SUBSTANCE	CAS No.	LTEL (8 hr TWA ppm)	LTEL (8 hr TWA mg/m ³)	STEL (ppm)	STEL (mg/m ³)	Note
Silica, Respirable Crystalline	-	-	0.1	-	-	WEL: Workplace Exposure Limit (UK HSE EH40)
Nuisance Dust	-	-	10	-	-	Inhalable Dust. WEL: Workplace

SAFETY DATA SHEET

Revision: 27 Date: 08.02.2018



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1272/2008 (CLP) & 2015/830

Diatomaceous Earth Flux-Calcined, Kieselguhr Flux-Calcined
CelaBrite®, Celatom® MW-25, MW-27, MW-31

						Exposure Limit (UK HSE EH40)
Nuisance Dust	-	-	4	-	-	Respirable Dust. 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.

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

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

8.2 Exposure controls

8.2.1 Appropriate engineering controls

Ensure adequate ventilation. Atmospheric levels should be controlled in compliance with the occupational exposure limit. Avoid dust generation.

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

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).



Respiratory protection

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

Not applicable.

8.2.3 Environmental Exposure Controls

Avoid wind dispersal.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance	White Powder
Odour	Odourless
Odour threshold	Not available.
pH	8 – 10.5
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 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	Not available.
Auto-ignition temperature	Not applicable

SAFETY DATA SHEET

Revision: 27 Date: 08.02.2018



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

Diatomaceous Earth Flux-Calcined, Kieselguhr Flux-Calcined
CelaBrite®, Celatom® MW-25, MW-27, MW-31

Decomposition Temperature	Not available.
Viscosity	Not applicable, Solid.
Explosive properties	Not explosive.
Oxidising properties	Not oxidising.
9.2 Other information	None.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity	Stable under normal conditions.
10.2 Chemical stability	Stable under normal conditions.
10.3 Possibility of hazardous reactions	Stable under normal conditions.
10.4 Conditions to avoid	Avoid contact with: Hydrofluoric Acid, concentrated caustic solutions 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.
10.5 Incompatible materials	Reacts violently with - Hydrofluoric Acid concentrated caustic solutions
10.6 Hazardous decomposition product(s)	No hazardous decomposition products known.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects	
Acute toxicity	
Ingestion	Based upon the available data, the classification criteria are not met.
Inhalation	Based upon the available data, the classification criteria are not met.
Skin Contact	Based upon the available data, the classification criteria are not met.
Eye Contact	Based upon the available data, the classification criteria are not met.
Skin corrosion/irritation	Based upon the available data, the classification criteria are not met.
Serious eye damage/irritation	Based upon the available data, the classification criteria are not met.
Respiratory or skin sensitization	Based upon the available data, the classification criteria are not met.
Germ cell mutagenicity	Based upon the available data, the classification criteria are not met.
Carcinogenicity	Based upon the available data, the classification criteria are not met.
Reproductive toxicity	Based upon the available data, the classification criteria are not met.
STOT - single exposure	Based upon the available data, the classification criteria are not met.
STOT - repeated exposure	Based upon the available data, the classification criteria are not met. Kieselguhr Flux-calcined with between 1% and 10% of respirable cristobalite is classified as STOT RE 2 According to Regulation (EC) No. 1272/2008 (CLP). 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

SAFETY DATA SHEET

Revision: 27 Date: 08.02.2018



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11.2 **Aspiration hazard** section 16 below).
Other information Based upon the available data, the classification criteria are not met.
None.

SECTION 12: ECOLOGICAL INFORMATION

12.1 **Toxicity** Based upon the available data, the classification criteria are not met. Not classified as a Marine Pollutant.

12.2 **Persistence and degradability** Not applicable.

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

12.4 **Mobility in soil** The product is predicted to have low mobility in soil.

12.5 **Results of PBT and vPvB assessment** This product is an inorganic substance and does not meet the criteria for PBT or vPvB in accordance with Annex XIII of REACH.

12.6 **Other adverse effects** None known.

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.

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

14.1 **UN number** Not applicable.

14.2 **UN proper shipping name** Not applicable.

14.3 **Transport hazard class(es)** Not applicable.

14.4 **Packing group** Not 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 73/78 and the IBC Code** Diatomaceous Earth , No special measures are required.

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: 1

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:

Section 1 Addition of - Exposure Scenario 6 Title
Section 16 Addition of - Exposure Scenario 6

References: Existing Safety Data Sheet (SDS), Existing ECHA registration(s) for Diatomaceous Earth (Kieselguhr), Soda Flux-Calcined (CAS#

SAFETY DATA SHEET



Revision: 27 Date: 08.02.2018

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1272/2008 (CLP) & 2015/830

Diatomaceous Earth Flux-Calcined, Kieselguhr Flux-Calcined
CelaBrite®, Celatom® MW-25, MW-27, MW-31

68855-54-9).

Classification of the substance or mixture According to Regulation (EC) No. 1272/2008 (CLP)	Classification Procedure
STOT RE 2; H373	CLP Threshold Calculation

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.

Date of Last Change: 06th February 2018

LEGEND

LTEL	Long Term Exposure Limit
STEL	Short Term Exposure Limit
DNEL	Derived No Effect Level
PNEC	Predicted No Effect Concentration
PBT	PBT: Persistent, Bioaccumulative and Toxic
vPvB	vPvT: 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

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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 additive in formulation of liquid, viscous or solid mixtures
Exposure scenario 3	Use as process aid in manufacture of chemicals, resins, rubbers and plastics
Exposure scenario 4	Professional use by dental technicians
Exposure scenario 5	Industrial, professional and private use of substance or mixtures containing the substance

SAFETY DATA SHEET

Revision: 27 Date: 08.02.2018



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1272/2008 (CLP) & 2015/830

Diatomaceous Earth Flux-Calcined, Kieselguhr Flux-Calcined
CelaBrite®, Celatom® MW-25, MW-27, MW-31

Kieselguhr, Soda Ash Flux-Calcined Fine Cristobalite Fraction

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 _{ow})	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)			
Workers	Short term	Inhalation (mg/m ³)	0.05 mg/m ³
		Dermal (mg/kg bw/day)	Not determined
	Long Term	Inhalation (mg/m ³)	Not determined
		Dermal (mg/kg bw/day)	Not determined
Consumer		Inhalation (mg/m ³)	0.05 mg/m ³
		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
ES 2 Use as additive in formulation of liquid, viscous or solid mixtures	3.87 mg/l	100 mg/l
ES 3 Use as process aid in manufacture of chemicals, resins, rubbers and plastics	3.87 mg/l	100 mg/l
ES 4 Professional use by dental technicians	0.012 mg/l	100 mg/l
ES 5 Industrial, professional and private use of substance or mixtures containing the substance	0.329 mg/l	100 mg/l

SAFETY DATA SHEET

Revision: 27 Date: 08.02.2018



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1272/2008 (CLP) & 2015/830

Diatomaceous Earth Flux-Calcined, Kieselguhr Flux-Calcined
CelaBrite®, Celatom® MW-25, MW-27, MW-31

Contents

Number of the ES	Title	Page:
Exposure scenario 1	Manufacture of kieselguhr soda ash flux calcined	10
Exposure scenario 2	Use as additive in formulation of liquid, viscous or solid mixtures	13
Exposure scenario 3	Use as process aid in manufacture of chemicals, resins, rubbers and plastics	16
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Exposure scenario 6	Consumer use; Cosmetics, personal care products	26

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
PROC14 Production of preparations or articles by tableting, compression, extrusion, pelletisation
PROC15 Use as laboratory reagent
PROC19 Hand-mixing with intimate contact and only PPE available

SAFETY DATA SHEET

Revision: 27 Date: 08.02.2018



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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

2.0 Operational conditions and risk management measures		
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 management		
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 days per week.	
Other operational conditions affecting worker exposure		
Area of use	All contributing scenarios Indoor	
Characteristics of the surroundings	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		
All contributing scenarios	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 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		
PROC4, PROC5, PROC8a, PROC8b, PROC9, PROC15, PROC19	Local exhaust ventilation is required.	
PROC1, PROC2, PROC3	Use in closed systems. Local exhaust ventilation is required.	
Risk management measures related to 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 prevent exposure to the skin.
Eye Protection	All contributing scenarios	Wear eye protection with side protection (EN166).
Other operational conditions affecting worker exposure		
Assumes a good basic standard of occupational hygiene is implemented.		
2.2 Control of environmental exposure		
Amounts used		
Fraction of EU tonnage used in region:	Not considered to influence the exposure as such for this scenario	
Regional use tonnage (tons/year):		
Fraction of Regional tonnage used locally: tons/year		

SAFETY DATA SHEET



Revision: 27 Date: 08.02.2018

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

Diatomaceous Earth Flux-Calcined, Kieselguhr Flux-Calcined
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Annual site tonnage (tons/year):	
Maximum daily site tonnage (kg/day):	
Environmental 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 discharges, air emissions and releases to soil	
Treat air emission to provide a typical removal efficiency of (%):	Not defined. It is recommended to pass waste gas from manufacturing 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 release estimates used.	
Organisational measures to prevent/limit release from site	
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 reclaimed.	
Conditions and measures related to municipal sewage treatment 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

Process category [PROC]	Duration	Local Exhaust Ventilation	Inhalation	
			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	≤ 1	95%	0.25	0.694
PROC5	≤ 1	95%	0.25	0.694
PROC8a	≤ 1	95%	0.25	0.694
PROC8b	≤ 1	95%	0.25	0.694
PROC9	≤ 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

Risk characterisation ratio

SAFETY DATA SHEET

Revision: 27 Date: 08.02.2018



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

Diatomaceous Earth Flux-Calcined, Kieselguhr Flux-Calcined
CelaBrite®, Celatom® MW-25, MW-27, MW-31

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	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 instrument/tool/method	Workers	ECETOC TRA 2010
	Environmental exposure	EUSES

SAFETY DATA SHEET

Revision: 27 Date: 08.02.2018



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

Diatomaceous Earth Flux-Calcined, Kieselguhr Flux-Calcined
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Exposure Scenario 2 – Use as additive in formulation of liquid, viscous or solid mixtures

1.0 Contributing Scenarios	
Sector of uses SU	SU3 Industrial uses: Uses of substances as such or in preparations at industrial sites SU10 Formulation [mixing] of preparations and/or re-packaging (excluding alloys) SU11 Manufacture of rubber products SU12 Manufacture of plastics products, including compounding and conversion SU13 Manufacture of other non-metallic mineral products, e.g. plasters, cement
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) PROC14 Production of preparations or articles by tableting, compression, extrusion, pelletisation PROC15 Use as laboratory reagent PROC19 Hand-mixing with intimate contact and only PPE available
Chemical product category [PC]	PC2 Adsorbents PC9 Coatings and paints, thinners, paint removers, Fillers, putties, plasters, modelling clay PC21 Laboratory chemicals PC29 Pharmaceuticals PC35 Washing and cleaning products (including solvent based products)
Article Categories [AC]	AC10 Rubber articles AC13 Plastic articles
Environmental release categories [ERC]	ERC2 Formulation of preparations ERC4 Industrial use of processing aids in processes and products, not becoming part of articles ERC7 Industrial use of substances in closed systems ERC8b Wide dispersive indoor use of reactive substances in open 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	White/Beige Powder Liquid
Concentration of substance in product	Powder: Covers concentrations up to 60% Liquid: Covers concentrations up to < 1%
Human factors not influenced by risk management	
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 days per week.
Other operational conditions affecting worker exposure	
Area of use	All contributing scenarios Indoor
Characteristics of the surroundings	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	
All contributing scenarios	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 suitable personal protective equipment is available; Clear up spills and dispose of waste in

SAFETY DATA SHEET



Revision: 27 Date: 08.02.2018

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

Diatomaceous Earth Flux-Calcined, Kieselguhr Flux-Calcined
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	accordance with regulatory requirements; monitor effectiveness of control measures; consider the need for health surveillance; identify and implement corrective actions.	
Technical conditions of use		
All contributing scenarios	Local exhaust recommended.	
Risk management measures related to human health		
Respiratory protection	All contributing scenarios	Recommended: Wear respiratory protection. Filter type: P3
Hand and/or Skin protection	All contributing scenarios	Wear impervious gloves (EN374). Wear suitable coveralls to prevent exposure to the skin.
Eye Protection	All contributing scenarios	Wear eye protection with side protection (EN166).
Other operational conditions affecting worker exposure		
Assumes a good basic standard of occupational hygiene is implemented.		
2.2 Control of environmental exposure		
Amounts used		
Fraction of EU tonnage used in region:	Not considered to influence the exposure as such for this scenario	
Regional use tonnage (tons/year):		
Fraction of Regional tonnage used locally: tons/year		
Annual site tonnage (tons/year):	3 - 200 tons/year	
Maximum daily site tonnage (kg/day):	Not defined	
Environment factors not influenced by risk management		
Flow rate of receiving surface water (m ³ /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 discharges, air emissions and releases to soil		
Treat air emission to provide a typical removal efficiency of (%):	Not defined	
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 release estimates used. No wastewater treatment required.		
Organisational measures to prevent/limit release from site		
Vent waste air only via suitable separators or scrubbers. 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 reclaimed.		
Conditions and measures related to municipal sewage treatment plant		
Size of municipal sewage system/treatment plant (m ³ /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
Risk characterisation ratio	
Workers	No risk is anticipated: Use described in this exposure scenario is safe under the specified conditions of exposure.
Consumers	No risk is anticipated: Consumers are not exposed.

SAFETY DATA SHEET

Revision: 27 Date: 08.02.2018



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

Diatomaceous Earth Flux-Calcined, Kieselguhr Flux-Calcined
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3.2 Environmental exposure prediction	
Exposure assessment (method/calculation model)	EUSES
Risk characterisation ratio	
Waste water treatment	0.0039
Aquatic Compartment (Pelagic)	Not defined: Reasonable worst-case local PECs are below the no effect level (3.87 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).	
Exposure assessment instrument/tool/method	Workers	ECETOC TRA 2010
	Environmental exposure	EUSES

SAFETY DATA SHEET

Revision: 27 Date: 08.02.2018



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

Diatomaceous Earth Flux-Calcined, Kieselguhr Flux-Calcined
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Exposure Scenario 3 – Use as process aid in manufacture of chemicals, resins, rubbers and plastics

1.0 Contributing Scenarios	
Sector of uses SU	SU3 Industrial uses: Uses of substances as such or in preparations at industrial sites SU8 Manufacture of bulk, large scale chemicals (including petroleum products) SU9 Manufacture of fine chemicals SU11 Manufacture of rubber products SU12 Manufacture of plastics products, including compounding and conversion
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) PROC8b Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities PROC15 Use as laboratory reagent PROC19 Hand-mixing with intimate contact and only PPE available
Chemical product category [PC]	PC16 Heat transfer fluids PC17 Hydraulic fluids PC20 Products such as ph-regulators, flocculants, precipitants, neutralization agents PC24 Lubricants, greases, release products PC25 Metal working fluids PC32 Polymer preparations and compounds
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
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	White/Beige Powder
Concentration of substance in product	Covers concentrations up to 100%
Human factors not influenced by risk management	
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	Not defined
Exposure time per year	360 days per year/Worker
Other operational conditions affecting worker exposure	
Area of use	All contributing scenarios Indoor
Characteristics of the surroundings	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	
All contributing scenarios	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 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	
All contributing scenarios	Local exhaust recommended.
Risk management measures related to human health	

SAFETY DATA SHEET

Revision: 27 Date: 08.02.2018



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

Diatomaceous Earth Flux-Calcined, Kieselguhr Flux-Calcined
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Respiratory protection	All contributing scenarios	Wear respiratory protection.
Hand and/or Skin protection	All contributing scenarios	Wear impervious gloves (EN374). Wear suitable coveralls to prevent exposure to the skin.
Eye Protection	All contributing scenarios	Wear eye protection with side protection (EN166).
Other operational conditions affecting worker exposure		
Assumes a good basic standard of occupational hygiene is implemented.		
2.2 Control of environmental exposure		
Amounts used		
Fraction of EU tonnage used in region:	Not considered to influence the exposure as such for this scenario	
Regional use tonnage (tons/year):		
Fraction of Regional tonnage used locally: tons/year		
Annual site tonnage (tons/year):	10 - 100 tons/year	
Maximum daily site tonnage (kg/day):	Not defined	
Environment factors not influenced by risk management		
Flow rate of receiving surface water (m ³ /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	
Release fraction to wastewater from process (initial release prior to RMM):	No risk is anticipated	
Release fraction to soil from process (initial release prior to RMM):	No risk is anticipated	
Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil		
Treat air emission to provide a typical removal efficiency of (%):	Not defined	
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 release estimates used. No wastewater treatment required.		
Organisational measures to prevent/limit release from site		
Vent waste air only via suitable separators or scrubbers. 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 reclaimed.		
Conditions and measures related to municipal sewage treatment plant		
Size of municipal sewage system/treatment plant (m ³ /d)	Not defined	
Degradation effectiveness (%)	Not defined	
Conditions and measures related to external treatment of waste for disposal		
Type of waste	Solid and Liquid	
Disposal technique	Bury on an authorised landfill site or incinerate under approved controlled conditions.	
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
Risk characterisation ratio	
Workers	No risk is anticipated: Use described in this exposure scenario is safe under the specified conditions of exposure.
Consumers	No risk is anticipated: Consumers are not exposed.

3.2 Environmental exposure prediction

Exposure assessment (method/calculation model)	EUSES
Risk characterisation ratio	
Waste water treatment	0.0039
Aquatic Compartment (Pelagic)	Not defined: Reasonable worst-case local PECs are below the no effect level (3.87 mg/l).

SAFETY DATA SHEET



Revision: 27 Date: 08.02.2018

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

Diatomaceous Earth Flux-Calcined, Kieselguhr Flux-Calcined
CelaBrite®, Celatom® MW-25, MW-27, MW-31

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.	
	Workers	ECETOC TRA 2010
Exposure assessment instrument/tool/method	Environmental exposure	EUSES

SAFETY DATA SHEET

Revision: 27 Date: 08.02.2018



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

Diatomaceous Earth Flux-Calcined, Kieselguhr Flux-Calcined
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Exposure Scenario 4 – Professional use by dental technicians

1.0 Contributing Scenarios		
Sector of uses SU	SU9 Manufacture of fine chemicals SU10 Formulation [mixing] of preparations and/or re-packaging (excluding alloys) SU12 Manufacture of plastics products, including compounding and conversion SU20 Health services	
Process category [PROC]	PROC5 Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) PROC19 Hand-mixing with intimate contact and only PPE available	
Chemical product category [PC]	PC32 Polymer preparations and compounds	
Article Categories [AC]	Not applicable	
Environmental release categories [ERC]	ERC2 Formulation of preparations ERC3 Formulation in materials ERC8f Wide dispersive outdoor use resulting in inclusion into or onto a matrix	
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	
Concentration of substance in product	Covers concentrations up to 60%	
Human factors not influenced by risk management		
Potential exposure area	Not defined	
Frequency and duration of use		
Exposure duration per day	Covers exposure up to 1 hour/days	
Exposure time per week	Not defined	
Exposure time per year	220 days per year	
Other operational conditions affecting worker exposure		
Area of use	All contributing scenarios	Indoor
Characteristics of the surroundings	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		
All contributing scenarios	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 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		
All contributing scenarios	No LEV required.	
Risk management measures related to human health		
Respiratory protection	All contributing scenarios	Not determined.
Hand and/or Skin protection	All contributing scenarios	Wear impervious gloves (EN374). Wear suitable coveralls to prevent exposure to the skin.
Eye Protection	All contributing scenarios	Wear eye protection with side protection (EN166).
Other operational conditions affecting worker exposure		
Assumes a good basic standard of occupational hygiene is implemented.		
2.2 Control of environmental exposure		
Amounts used		
Tonnage in EU per year	300 tonnes	
Fraction of EU tonnage used in region:	10 %	
Regional use tonnage (tons/year):	30 tonnes	
Fraction of Regional tonnage used locally:	60 kg	
Annual site tonnage (tons/year):	Not defined	

SAFETY DATA SHEET



Revision: 27 Date: 08.02.2018

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

Diatomaceous Earth Flux-Calcined, Kieselguhr Flux-Calcined
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Maximum daily site tonnage (kg/day):	Not defined
Environment factors not influenced by risk management	
Flow rate of receiving surface water (m ³ /d):	Not defined (default = 18,000)
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 prior to RMM):	0
Release fraction to wastewater from process (initial release prior to RMM):	0.023 kg/day
Release fraction to soil from process (initial release prior to RMM):	0
Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil	
Treat air emission to provide a typical removal efficiency of (%):	Not defined
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 release estimates used. No wastewater treatment required.	
Organisational measures to prevent/limit release from site	
Vent waste air only via suitable separators or scrubbers. 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 reclaimed.	
Conditions and measures related to municipal sewage treatment plant	
Size of municipal sewage system/treatment plant (m ³ /d)	Not defined
Degradation effectiveness (%)	Not defined
Conditions and measures related to external treatment of waste for disposal	
Type of waste	Solid and Liquid
Disposal technique	Bury on an authorised landfill site or incinerate under approved controlled conditions.
Substance release quantities after risk management measures	
Release to waste water from process	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	
Workers	
Inhalation	Risk characterisation ratio (RCR): 0.067 Exposure prediction: Reasonable worst case (50 g/Use): 0.024 mg/m ³ default DNEL: 0.36 mg/m ³
Dermal	No risk is anticipated.
Oral	No risk is anticipated: Oral exposure is not expected to occur.
Consumers	Exposure assessment: Negligible. Dental treatment is performed under professional surveillance.
Indirect exposure to humans via the environment / Secondary Poisoning	The substance has a low solubility in water and thus is essentially unavailable to organisms.

3.2 Environmental exposure prediction

Exposure assessment (method/calculation model)	EUSES
Risk characterisation ratio	
Waste water treatment	Reasonable worst case (mg/l): 0.012
Aquatic Compartment (Pelagic)	Surface Water: 0.0012 mg/l marine water: 0.00012 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	The substance has a low solubility in water and thus is essentially unavailable to

SAFETY DATA SHEET

Revision: 27 Date: 08.02.2018



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

Diatomaceous Earth Flux-Calcined, Kieselguhr Flux-Calcined
CelaBrite®, Celatom® MW-25, MW-27, MW-31

Poisoning	organisms.
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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.	
	Workers	RIVM 2007
Exposure assessment instrument/tool/method	Environmental exposure	EUSES

SAFETY DATA SHEET

Revision: 27 Date: 08.02.2018



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

Diatomaceous Earth Flux-Calcined, Kieselguhr Flux-Calcined
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Exposure Scenario 5 – 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 15%	
Human factors not influenced by risk management		
Potential exposure area	Not defined	
Frequency and duration of use		
Exposure duration	Use of coatings and paints containing kieselguhr soda ash flux-calcined	4 – 8 hours
	Use of kieselguhr soda ash flux calcined for filtering water	1 hour/days
	Use of cleaners containing kieselguhr soda-ash flux calcined	Professional: 60 min/Use Consumer: 20 min/Days
Exposure frequency	Use of coatings and paints containing kieselguhr soda ash flux-calcined	225 days per year
	Use of kieselguhr soda ash flux calcined for filtering water	Professional: Weekly Consumer: Monthly
	Use of cleaners containing kieselguhr soda-ash flux calcined	Professional: ≤ 8 Uses per day Consumer: 1 Uses per day
Other operational conditions affecting worker exposure		
Area of use	All contributing scenarios	Indoor
Characteristics of the surroundings	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		

SAFETY DATA SHEET

Revision: 27 Date: 08.02.2018



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

Diatomaceous Earth Flux-Calcined, Kieselguhr Flux-Calcined
CelaBrite®, Celatom® MW-25, MW-27, MW-31

All contributing scenarios	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 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		
All contributing scenarios	Local exhaust recommended.	
Risk management measures related to human health		
Respiratory protection	All contributing scenarios	Half-face mask (DIN EN 140), Filter type P2/P3 - efficiency of at least 90%
Hand and/or Skin protection	All contributing scenarios	Wear impervious gloves (EN374). Wear suitable coveralls to prevent exposure to the skin.
Eye Protection	All contributing scenarios	Wear eye protection with side protection (EN166).
Other operational conditions affecting worker exposure		
Assumes a good basic standard of occupational hygiene is implemented.		
2.2 Control of environmental exposure		
Amounts used		
Tonnage in EU per year	120, tonnes	
Fraction of EU tonnage used in region:	10 %	
Regional use tonnage (tons/year):	12 tonnes	
Fraction of Regional tonnage used locally:	Not defined	
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 prior to RMM):	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 discharges, air emissions and releases to soil		
Treat air emission to provide a typical removal efficiency of (%):	Not defined	
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 release estimates used. No wastewater treatment required.		
Organisational measures to prevent/limit release from site		
Vent waste air only via suitable separators or scrubbers. 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 reclaimed.		
Conditions and measures related to municipal sewage treatment 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	
Disposal technique	Bury on an authorised landfill site or incinerate under approved controlled conditions. 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	

SAFETY DATA SHEET

Revision: 27 Date: 08.02.2018



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1272/2008 (CLP) & 2015/830

Diatomaceous Earth Flux-Calcined, Kieselguhr Flux-Calcined
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3. Exposure estimation and reference to its source

3.1 Human exposure prediction

Exposure assessment (method/calculation model)	ECETOC TRA 2010
Risk characterisation ratio	

Type	Content	LEV	Duration	Process category [PROC]	Inhalation	
					inhalation exposure (mg/m ³)	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/m ³)	Short term inhalation exposure (mg/m ³)	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	$C_{STP} = \frac{AMOUNT_{STP}}{DAYS \cdot INHAB \cdot WASTEW_{inhab}}$ <p> <i>AMOUNT_{STP}</i> Amount of kieselguhr soda ash flux-calcined released to municipal STPs in the EU per year (1.2E13 mg/Year(s)), <i>DAYS</i> Number of release days (365 Days//Year(s)), <i>INHAB</i> Number of inhabitants in EU (500 million inhabitants) <i>WASTEW_{inhab}</i> Wastewater per inhabitant (200 L/day) <i>C_{STP}</i> Concentration of kieselguhr soda ash flux-calcined in municipal STP (mg/l). </p> <p>Estimated STP Concentration (g/L):</p> $C_{STP} = \frac{1.2E13}{365 \cdot 500000000 \cdot 200} = 0.329 \frac{mg}{L}$
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 / 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.
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SAFETY DATA SHEET

Revision: 27 Date: 08.02.2018



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	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 instrument/tool/method	Workers	ECETOC TRA 2010 / RIVM 2008
	Consumer	RIVM 2008
	Environmental exposure	EUSES

SAFETY DATA SHEET

Revision: 27 Date: 08.02.2018



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Exposure Scenario 6 – 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

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	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
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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

3.1 Human 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
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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/m ³ (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.
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