

Revision nr. 5 Dated 06/06/2023

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

1.1. Product identifier

Mixture identification:

Product Name: OCCLUFAST ROCK - BASE Code: C200726, C200727, C203220

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

For professional use only. Addition silicone for bite registration.

1.3. Details of the supplier of the safety data sheet

Name

Zhermack S.p.a

Via Bovazecchino 100

45021 Badia Polesine (RO)

Italy

tel. +39 0425-597611

fax +39 0425-597689

Competent person responsible for the safety data sheet:

msds@zhermack.com

1.4. Emergency telephone number

+39 0425 597611 (office hours)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

EC regulation criteria 1272/2008 (CLP)

The product is not classified as dangerous according to Regulation EC 1272/2008 (CLP).

Adverse physicochemical, human health and environmental effects:

No other hazards

2.2. Label elements

The Regulation EC 1272/2008, on classification, labelling and packaging of substances and mixtures (CLP), shall not apply to a medical device in the finished state used in direct physical contact with the human body according to art. 1.5, letter d). Therefore the product is exempted from the CLP labeling requirements.

The product is not classified as dangerous according to Regulation EC 1272/2008 (CLP).

Hazard pictograms:

None

Hazard statements:

None

Precautionary statements:

None

Special Provisions:

EUH210 Safety data sheet available on request.

Special provisions according to Annex XVII of REACH and subsequent amendments:

None

2.3. Other hazards

There is no exposure to breathable free crystalline silica during normal use of this product. For more information see section 11.

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No PBT, vPvB or endocrine disruptor substances present in concentration >= 0.1% Other Hazards:

No other hazards

SECTION 3: Composition/information on ingredients

3.1. Substances

Not Applicable

3.2. Mixtures

Hazardous components within the meaning of the CLP regulation and related classification:

Qty	Name	Ident. Numb	er	Classification	
>= 13% - < 20%	Cristobalite	CAS: EC:	14464-46-1 238-455-4	STOT RE 1 H372 Causes damage to organs (lungs) through prolonged or repeated exposure if inhaled.	
<0,05%	octamethylcyclotetrasil oxane; [D4]	Index number: CAS: EC: REACH No.:	014-018-00-1 556-67-2 209-136-7 01-21195292 38-36-XXXX	Flam. Liq. 3 H226 Flammable liquid and vapour. Repr. 2 H361f Suspected of damaging fertility. Aquatic Chronic 1 H410 Very toxic to aquatic life with long lasting effects. M=10.	
<0,05%	octamethylcyclotetrasil oxane; [D4]	Index 014-018-00-1 number: CAS: 556-67-2 EC: 209-136-7		 Flam. Liq. 3 H226 Flammable liquid and vapour. Repr. 2 H361f Suspected of damaging fertility. Aquatic Chronic 1 H410 Very toxic to aquatic life with long lasting effects. M=10. 	

Substances in nanoform:

>= 10% - < 12,5% Silicon dioxide, amorphous

REACH No.: 01-2119379499-16-XXXX, CAS: 7631-86-9, EC: 231-545-4

>=0,05% - <0,1% 2-(3,6-dihydroxy-2,4,5,7-tetraiodoxanthen-9- yl)benzoic acid, aluminium salt - Nanoform

CAS: 12227-78-0, EC: 235-440-4

>=0,05% - <0,1% Aluminium,

2-(1,3-dihydro-3-oxo-5-sulfo-2H-indol-2-ylidene)-2,3-dihydro-3-oxo-1H-indole-5-s ulfonic acid complex - nanoform

CAS: 16521-38-3, EC: 240-589-3

SECTION 4: First aid measures

4.1. Description of first aid measures

In case of skin contact:

Wash with plenty of water and soap.

In case of eyes contact:

In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. In case of Ingestion:

Do not under any circumstances induce vomiting. OBTAIN A MEDICAL EXAMINATION IMMEDIATELY.

In case of Inhalation:

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Remove casualty to fresh air and keep warm and at rest.

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

None

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

Treatment:

None

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media:

Water.

Carbon dioxide (CO2).

Extinguishing media which must not be used for safety reasons:

None in particular.

5.2. Special hazards arising from the substance or mixture

Do not inhale explosion and combustion gases.

Burning produces heavy smoke.

5.3. Advice for firefighters

Use suitable breathing apparatus.

Collect contaminated fire extinguishing water separately. This must not be discharged into drains.

Move undamaged containers from immediate hazard area if it can be done safely.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

For non emergency personnel:

Wear personal protection equipment.

Remove persons to safety.

See protective measures under point 7 and 8.

For emergency responders:

Wear personal protection equipment.

6.2. Environmental precautions

Do not allow to enter into soil/subsoil. Do not allow to enter into surface water or drains.

Retain contaminated washing water and dispose it.

In case of gas escape or of entry into waterways, soil or drains, inform the responsible authorities.

Suitable material for taking up: absorbing material, organic, sand

6.3. Methods and material for containment and cleaning up

Wash with plenty of water.

6.4. Reference to other sections

See also section 8 and 13

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Avoid contact with skin and eyes, inhalation of vapours and mists.

See also section 8 for recommended protective equipment.

Advice on general occupational hygiene:

Do not eat or drink while working.

7.2. Conditions for safe storage, including any incompatibilities

Keep away from food, drink and feed.

Incompatible materials:

See section 10.5.

Instructions as regards storage premises:

Adequately ventilated premises.

7.3. Specific end use(s)

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See section 1.2.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

OCCLUFAST ROCK - BASE Cristobalite - CAS: 14464-46-1

OEL Type	TWA	Duratio	STEL	Duratio	Notes	Country
		n		n		
EU	0.1 mg/m3	8h			Respirable	
TLV	0.1 mg/m3	8h			Respirable	ITALY
ACGIH	0.025 mg/m3	8h			(R), A2 - Pulm fibrosis, lung cancer	

octamethylcyclotetrasiloxane; [D4] - CAS: 556-67-2

OEL Type	TWA	Duratio	STEL	Duratio	Notes	Country
		n		n		
No data available						

octamethylcyclotetrasiloxane; [D4] - CAS: 556-67-2

OEL Type	TWA		Duratio	STEL	Duratio	Notes	Country
			n		n		
No data available		·					

DNEL Exposure Limit Values

octamethylcyclotetrasiloxane; [D4] - CAS: 556-67-2

Consumer: 13 mg/m3 - Exposure: Human Inhalation - Frequency: Long Term, local

effects

Worker Professional: 73 mg/m3 - Exposure: Human Inhalation - Frequency: Long

Term, local effects

Consumer: 3.7 mg/kg bw/d - Exposure: Human Oral - Frequency: Long Term, systemic

effects

Consumer: 13 mg/m3 - Exposure: Human Inhalation - Frequency: Long Term, systemic

effects

Worker Professional: 73 mg/m3 - Exposure: Human Inhalation - Frequency: Long

Term, systemic effects

PNEC Exposure Limit Values

octamethylcyclotetrasiloxane; [D4] - CAS: 556-67-2

Target: Fresh Water - Value: 0.0015 mg/l Target: Marine water - Value: 1.5E-5 mg/l

Target: Freshwater sediments - Value: 0.64 mg/kg Target: Marine water sediments - Value: 0.064 mg/kg

Target: Microorganisms in sewage treatments - Value: 10 mg/l

Target: Food chain - Value: 41 mg/kg

Target: Soil (agricultural) - Value: 0.48 mg/kg

8.2. Exposure controls

Precautionary measures:

Give adequate ventilation to the premises where the product is stored and/or handled.



Eye protection:

Wear airtight protective goggles (EN 166).

Protection for skin:

Wear professional overalls and safety footwear (EN 14605).

Protection for hands:

Protect hands with work gloves (EN 374).

The following should be considered when choosing work glove material (EN 374): compatibility, degradation, failure time and permeability.

The work gloves' resistance to chemical agents should be checked before use, as it can be unpredictable. The gloves' wear time depends on the duration and type of use.

Respiratory protection:

Use respiratory protection where ventilation is insufficient or exposure is prolonged. Respiratory protection devices must be used if the technical measures adopted are not suitable for restricting the worker's exposure to the threshold values considered (e.g. TLV-TWA).

Thermal Hazards:

None

Environmental exposure controls:

None

Appropriate engineering controls:

None

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Properties	Value	Method:	Notes
Physical state:	Liquid		
Colour:	Violet		
Odour:	Odourless		
Melting point/freezing	Not Relevant		
point:			
Boiling point or initial	Not Relevant		
boiling point and boiling			
range:			
Flammability:	Not available		
Lower and upper explosion	Not available		
limit:			
Flash point:	>135 ° C	EN ISO	
		3679	
Auto-ignition temperature:	Not available		
Decomposition	Not available		
temperature:			
pH:	Not Relevant		
Kinematic viscosity:	Not available		
Solubility in water:	Insoluble		
Solubility in oil:	Not available		
Partition coefficient	Not Relevant		
n-octanol/water (log value):			
Vapour pressure:	Not available		
Density and/or relative	1.50		
density:			
Relative vapour density:	Not available		

Particle characteristics:



Particle size:	Not available	

9.2. Other information

No other relevant information

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

None

10.4. Conditions to avoid

Stable under normal conditions.

10.5. Incompatible materials

None in particular.

10.6. Hazardous decomposition products

None

SECTION 11: Toxicological information

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

"For the purposes of classification of health hazards (part 3), the route of exposure, information on mechanisms and metabolism studies are useful for determining the relevance of effects in humans. If this information raises doubts as to their relevance in humans, in spite of the indisputable data legitimacy and quality, a lower classification may be justified. When there is scientific evidence that the mechanism or mode of action is not relevant to humans, the substance or mixture should not be classified" (annex I, section 1.1.1.5, EC Regulation 1272/2008).

Monitoring activities conducted at the company related to possible inhalation exposure, in accordance with industrial hygiene standards for paste and fluid products, showed levels of exposure to free crystalline silica (breathable part) below the limit of quantification of the method, therefore exposure is not expected during the use indicated in section 1.2 for this specific product. However, the actual levels of free crystalline silica (breathable part) present in the workplace must be obtained through monitoring as required by regulations for the safety and health of workers.

Toxicological information of the product:

OCCLUFAST ROCK - BASE

- a) acute toxicity
 - Not classified
- b) skin corrosion/irritation Not classified
- c) serious eye damage/irritation Not classified
- d) respiratory or skin sensitisation Not classified
- e) germ cell mutagenicity Not classified
- f) carcinogenicity Not classified



- g) reproductive toxicity Not classified
- h) STOT-single exposure Not classified
- i) STOT-repeated exposure Not classified
- j) aspiration hazard Not classified

Toxicological information of the main substances found in the product:

Cristobalite - CAS: 14464-46-1

i) STOT-repeated exposure:

Route: Inhalation - Notes: Silicosis, pulmonary fibrosis; Target organ: lungs - Source: (MSDS supplier).

octamethylcyclotetrasiloxane; [D4] - CAS: 556-67-2

a) acute toxicity:

Test: LC50 - Route: Inhalation - Species: Rat 36 mg/l - Duration: 4h - Source: (OECD 403, GLP, ECHA dossier).

Test: LD50 - Route: Skin - Species: Rat > 2375 mg/kg - Source: (similar to OECD 402, ECHA dossier).

Test: LD50 - Route: Oral - Species: Rat 4800 mg/kg - Source: (similar to OECD 401, ECHA dossier)

b) skin corrosion/irritation:

Species: Rabbit - Based on available data, the classification criteria are not met - Source: (OECD 404, ECHA dossier).

c) serious eye damage/irritation:

Species: Rabbit - Based on available data, the classification criteria are not met - Source: (OECD 405, ECHA dossier).

d) respiratory or skin sensitisation:

Test: Skin Sensitization - Based on available data, the classification criteria are not met - Source: (OECD 406, ECHA dossier).

e) germ cell mutagenicity:

Test: In vitro - Negative - Source: (OECD 476, OECD 471, OECD 473; ECHA dossier). Test: In vivo - Species: Rat - Negative - Source: (OECD 474; OECD 478, ECHA dossier).

f) carcinogenicity:

Test: 18201_NOAEC - Route: Inhalation - Species: Rat > 700 ppm - Notes: male rat - Source: (OECD 453, ECHA dossier).

Test: 18201_NOAEC - Route: Inhalation Vapour - Species: Rat = 150 ppm - Notes: female rat - Source: OECD 453, MSDS supplier

g) reproductive toxicity:

Test: NOAEL - Route: Inhalation Vapour - Species: Rat = 300 ppm - Source: EPA OPPTS 870.3800, MSDS supplier

Test: 18201_NOAEC - Route: Inhalation Vapour - Species: Rabbit > 6.1 mg/l - Notes: developmental - Source: OECD 414, MSDS supplier

Test: 18201_NOAEC - Route: Inhalation Vapour - Species: Rabbit > 3.6 mg/l - Notes: maternal - Source: OECD 414, MSDS supplier

Test: 18201_NOAEC - Route: Inhalation Vapour - Species: Rat > 6.1 mg/l - Notes: developmental - Source: OECD 414, MSDS supplier

Test: 18201_NOAEC - Route: Inhalation Vapour - Species: Rat = 3.6 mg/l - Notes: maternal - Source: OECD 414, MSDS supplier

i) STOT-repeated exposure:



Test: 18201_NOAEC - Route: Inhalation Vapour - Species: Rat 1.8 mg/l - Notes: Systemic effect, chronic nephropathy - Source: OECD 453, MSDS supplier

Test: LOAEC - Route: Inhalation Vapour - Species: Rat = 8.5 mg/l - Notes: Systemic effect, chronic nephropathy - Source: OECD 453, MSDS supplier

Test: 18201_NOAEC - Route: Inhalation Vapour - Species: Rat = 1.8 mg/l - Notes: local effects, inflammatory processes of the lungs - Source: OECD 453, MSDS supplier Test: LOAEC - Route: Inhalation Vapour - Species: Rat = 8.5 mg/l - Notes: local

effects, inflammatory processes of the lungs - Source: OECD 453, MSDS supplier octamethylcyclotetrasiloxane; [D4] - CAS: 556-67-2

a) acute toxicity:

Test: LC50 - Species: Rat 36 mg/l - Source: (OECD 403, GLP, rat, 4 h, ECHA dossier). Test: LD50 - Route: Skin - Species: Rat > 2000 mg/kg - Source: (similar to OECD 402, rat, ECHA dossier).

Test: LD50 - Route: Oral - Species: Rat 4800 mg/kg - Source: (similar to OECD 401, rat, ECHA dossier).

11.2. Information on other hazards

Endocrine disrupting properties:

No endocrine disruptor substances present in concentration >= 0.1%

SECTION 12: Ecological information

The product is not classified for chronic aquatic hazard: a test based on the bioavailability / release of D4 by the polymer silicone was performed with the OECD 29 method. It was found that the quantity of D4 released by 100mg of polymer is at least below the quantification limit of the method (i.e. 4.4 ppb), a value significantly lower than the limit that would result in the classification for chronic aquatic toxicity, i.e. NOEC of 0.0044 mg / L for fish and 0.0079 mg / L for aquatic invertebrates. Therefore, the product is not classified for this hazard class..

12.1. Toxicity

Adopt good working practices, so that the product is not released into the environment. OCCLUFAST ROCK - BASE

The product is classified: -

octamethylcyclotetrasiloxane; [D4] - CAS: 556-67-2

a) Aquatic acute toxicity:

Endpoint: EC50 - Species: Daphnia > 0.015 mg/l - Duration h: 48h (publication, GLP, Daphnia magna, ECHA dossier).

Endpoint: IC50 - Species: Algae > 0.022 mg/l - Duration h: 72h (EPA OTS 797.1050, Selenastrum capricornutum, freshwater, ECHA dossier).

Endpoint: LC50 - Species: Fish > 0.022 mg/l (publication, Oncorhynchus mykiss, ECHA dossier).

Endpoint: NOEC - Species: Fish > 0.044 mg/l (publication, Oncorhynchus mykiss, GLP, ECHA dossier).

octamethylcyclotetrasiloxane; [D4] - CAS: 556-67-2

a) Aquatic acute toxicity:

Endpoint: IC50 - Species: Algae > 0.0022 mg/l - Duration h: 72h (EPA OTS 797.1050, Selenastrum capricornutum, freshwater, ECHA dossier).

Endpoint: LC50 - Species: Fish > 0.0022 mg/l (Oncorhynchus mykiss, GLP, ECHA dossier).

Endpoint: NOEC - Species: Fish > 0.0044 mg/l (publication, Oncorhynchus mykiss, GLP, ECHA dossier).

Long-term toxicity to aquatic invertebrates:

Endpoint: NOEC - Species: Daphnia = $7.9 \mu g/L$ - Duration h: 21d EPA OTS 797.1330, Daphnia magna, ECHA dossier

12.2. Persistence and degradability

Cristobalite - CAS: 14464-46-1

Biodegradability: Non-readily biodegradable

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octamethylcyclotetrasiloxane; [D4] - CAS: 556-67-2 Biodegradability: Non-readily biodegradable

12.3. Bioaccumulative potential

Cristobalite - CAS: 14464-46-1

Not bioaccumulative

octamethylcyclotetrasiloxane; [D4] - CAS: 556-67-2

Test: Kow - Partition coefficient 6.49 - Notes:)

(Log Pow. ECHA dossier).

octamethylcyclotetrasiloxane; [D4] - CAS: 556-67-2

Test: Kow - Partition coefficient 6.49 - Notes: (Log Pow, ECHA dossier).

12.4. Mobility in soil

Not available

12.5. Results of PBT and vPvB assessment

vPvB Substances: None - PBT Substances: None

12.6. Endocrine disrupting properties

No endocrine disruptor substances present in concentration >= 0.1%

12.7. Other adverse effects

None

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Recover if possible. In so doing, comply with the local and national regulations currently in force.

SECTION 14: Transport information

14.1. UN number or ID number

Not classified as dangerous in the meaning of transport regulations.

14.2. UN proper shipping name

Not available

14.3. Transport hazard class(es)

Not available

14.4. Packing group

Not available

14.5. Environmental hazards

ADR-Enviromental Pollutant: No IMDG-Marine pollutant: No

14.6. Special precautions for user

Not available

14.7. Maritime transport in bulk according to IMO instruments

Not Applicable

SECTION 15: Regulatory information

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

Dir. 98/24/EC (Risks related to chemical agents at work)

Dir. 2000/39/EC (Occupational exposure limit values)

Regulation (EC) n. 1907/2006 (REACH)

Regulation (EC) n. 1272/2008 (CLP)

Regulation (EC) n. 790/2009 (ATP 1 CLP) and (EU) n. 758/2013

Regulation (EU) n. 2020/878

Regulation (EU) n. 286/2011 (ATP 2 CLP)

Regulation (EU) n. 618/2012 (ATP 3 CLP)

Regulation (EU) n. 487/2013 (ATP 4 CLP)

Regulation (EU) n. 944/2013 (ATP 5 CLP)

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Regulation (EU) n. 605/2014 (ATP 6 CLP)

Regulation (EU) n. 2015/1221 (ATP 7 CLP)

Regulation (EU) n. 2016/918 (ATP 8 CLP)

Regulation (EU) n. 2016/1179 (ATP 9 CLP)

Regulation (EU) n. 2017/776 (ATP 10 CLP)

Regulation (EU) n. 2018/669 (ATP 11 CLP)

Regulation (EU) n. 2018/1480 (ATP 13 CLP)

Regulation (EU) n. 2019/521 (ATP 12 CLP)

Regulation (EU) n. 2020/217 (ATP 14 CLP)

Regulation (EU) n. 2020/1182 (ATP 15 CLP)

Regulation (EU) n. 2021/643 (ATP 16 CLP)

Restrictions related to the product or the substances contained according to Annex XVII Regulation (EC) 1907/2006 (REACH) and subsequent modifications:

Restrictions related to the product:

No restriction.

Restrictions related to the substances contained:

No restriction.

Provisions related to directive EU 2012/18 (Seveso III):

Seveso III category according to Annex 1, part 1

None

WGK Classification (Water hazard class - Verwaltungsvorschrift wassergefährdende Stoffe) WGK1 - Slightly hazardous for water

Lagerklasse according to TRGS 510:

LGK 10: Combustible liquids

Substances subject to exportation reporting pursuant to (EC) Reg. 649/2012:

None.

California Proposition 65

Substance(s) listed under California Proposition 65:

Cristobalite - Listed as carcinogen.

15.2. Chemical safety assessment

No Chemical Safety Assessment has been carried out for the mixture. Substances for which a Chemical Safety Assessment has been carried out: octamethylcyclotetrasiloxane; [D4]

SECTION 16: Other information

Hazard class and hazard category	Code	Description
Flam. Liq. 3	2.6/3	Flammable liquid, Category 3
Repr. 2	3.7/2	Reproductive toxicity, Category 2
STOT RE 1	3.9/1	Specific target organ toxicity - repeated exposure, Category 1
Aquatic Chronic 1	4.1/C1	Chronic (long term) aquatic hazard, category 1
Aquatic Chronic 3	4.1/C3	Chronic (long term) aquatic hazard, category 3

This safety data sheet has been completely updated in compliance to Regulation 2020/878. Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:

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Classification according to Regulation (EC) Nr. 1272/2008	Classification procedure
Aquatic Chronic	According to Article 12 of the CLP Regulation, "Where, as a result of the evaluation carried out pursuant to Article 9, the following properties or effects are identified, manufacturers, importers and downstream users shall take them into account for the purposes of classification: [] (b) conclusive scientific experimental data show that the substance or mixture is not biologically available and those data have been ascertained to be adequate and reliable." Following a release study of D4 through the OECD 29 test on polymeric products representative for quantity of D4, the limit that would result in the classification for chronic aquatic toxicity (NOEC of 0.0044 mg / L for fish and 0.0079 mg / L for invertebrates aquatic) is not reached.

This document was prepared by a competent person who has received appropriate training. Main bibliographic sources:

ECHA - European Chemical Agency

GESTIS - Information system on hazardous substances of the German Social Accident Insurance

IARC - International Agency for Research on Cancer

IPCS INCHEM - International Programme on Chemical Safety

ISS - Istituto Superiore di Sanità

PubChem - open chemistry database at the National Institutes of Health (NIH)

A safety data sheet is not required for this product under article 31 of Regulation 1907/2006/EC. This safety data sheet has been created on a voluntary basis.

The information contained herein is based on our state of knowledge at the above-specified date. It refers solely to the product indicated and constitutes no guarantee of particular quality. It is the duty of the user to ensure that this information is appropriate and complete with respect to the specific use intended.

This MSDS cancels and replaces any preceding release.

ADR: European Agreement concerning the International Carriage of

Dangerous Goods by Road.

ATE: Acute Toxicity Estimate

ATEmix: Acute toxicity Estimate (Mixtures)

CAS: Chemical Abstracts Service (division of the American Chemical

Society).

CLP: Classification, Labeling, Packaging.

DNEL: Derived No Effect Level.

EINECS: European Inventory of Existing Commercial Chemical Substances.

GefStoffVO: Ordinance on Hazardous Substances, Germany.

GHS: Globally Harmonized System of Classification and Labeling of

Chemicals.

IATA: International Air Transport Association.

IATA-DGR: Dangerous Goods Regulation by the "International Air Transport

Association" (IATA).

ICAO: International Civil Aviation Organization.

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ICAO-TI: Technical Instructions by the "International Civil Aviation Organization"

(ICAO).

IMDG: International Maritime Code for Dangerous Goods. INCI: International Nomenclature of Cosmetic Ingredients.

KSt: Explosion coefficient.

LC50: Lethal concentration, for 50 percent of test population.

LD50: Lethal dose, for 50 percent of test population.

PNEC: Predicted No Effect Concentration.

RID: Regulation Concerning the International Transport of Dangerous Goods

by Rail.

STEL: Short Term Exposure limit.
STOT: Specific Target Organ Toxicity.
TLV: Threshold Limiting Value.
TWA: Time-weighted average
WGK: German Water Hazard Class.



Revision nr. 5 Dated 06/06/2023

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

1.1. Product identifier

Mixture identification:

Product Name: OCCLUFAST ROCK - CATALYST Code: C200726, C200727, C203220

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

For professional use only. Addition silicone for bite registration.

1.3. Details of the supplier of the safety data sheet

Name

Zhermack S.p.a

Via Bovazecchino 100

45021 Badia Polesine (RO)

Italy

tel. +39 0425-597611

fax +39 0425-597689

Competent person responsible for the safety data sheet:

msds@zhermack.com

1.4. Emergency telephone number

+39 0425 597611 (office hours)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

EC regulation criteria 1272/2008 (CLP)

The product is not classified as dangerous according to Regulation EC 1272/2008 (CLP).

Adverse physicochemical, human health and environmental effects:

No other hazards

2.2. Label elements

The Regulation EC 1272/2008, on classification, labelling and packaging of substances and mixtures (CLP), shall not apply to a medical device in the finished state used in direct physical contact with the human body according to art. 1.5, letter d). Therefore the product is exempted from the CLP labeling requirements.

The product is not classified as dangerous according to Regulation EC 1272/2008 (CLP).

Hazard pictograms:

None

Hazard statements:

None

Precautionary statements:

None

Special Provisions:

EUH210 Safety data sheet available on request.

Special provisions according to Annex XVII of REACH and subsequent amendments:

None

2.3. Other hazards

There is no exposure to breathable free crystalline silica during normal use of this product. For more information see section 11.

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No PBT, vPvB or endocrine disruptor substances present in concentration >= 0.1% Other Hazards:

No other hazards

SECTION 3: Composition/information on ingredients

3.1. Substances

Not Applicable

3.2. Mixtures

Hazardous components within the meaning of the CLP regulation and related classification:

Qty	Name	Ident. Numb	er	Classification		
>= 8% - < 10%	Cristobalite	CAS: EC:	14464-46-1 238-455-4	STOT RE 1 H372 Causes damage to organs (lungs) through prolonged or repeated exposure if inhaled.		
<0,05%	octamethylcyclotetrasil oxane; [D4]	Index number: CAS: EC: REACH No.:	014-018-00-1 556-67-2 209-136-7 01-21195292 38-36-XXXX	Flam. Liq. 3 H226 Flammable liquid and vapour. Repr. 2 H361f Suspected of damaging fertility. Aquatic Chronic 1 H410 Very toxic to aquatic life with long lasting effects. M=10.		
<0,05%	octamethylcyclotetrasil oxane; [D4]	Index 014-018-00-1 number: CAS: 556-67-2 EC: 209-136-7				

Substances in nanoform:

>= 10% - < 12,5% Silicon dioxide, amorphous

REACH No.: 01-2119379499-16-XXXX, CAS: 7631-86-9, EC: 231-545-4

SECTION 4: First aid measures

4.1. Description of first aid measures

In case of skin contact:

Wash with plenty of water and soap.

In case of eyes contact:

In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. In case of Ingestion:

Do not under any circumstances induce vomiting. OBTAIN A MEDICAL EXAMINATION IMMEDIATELY.

In case of Inhalation:

Remove casualty to fresh air and keep warm and at rest.

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

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

Treatment:

None

SECTION 5: Firefighting measures

5.1. Extinguishing media

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Suitable extinguishing media:

Water.

Carbon dioxide (CO2).

Extinguishing media which must not be used for safety reasons:

None in particular.

5.2. Special hazards arising from the substance or mixture

Do not inhale explosion and combustion gases.

Burning produces heavy smoke.

5.3. Advice for firefighters

Use suitable breathing apparatus.

Collect contaminated fire extinguishing water separately. This must not be discharged into drains.

Move undamaged containers from immediate hazard area if it can be done safely.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

For non emergency personnel:

Wear personal protection equipment.

Remove persons to safety.

See protective measures under point 7 and 8.

For emergency responders:

Wear personal protection equipment.

6.2. Environmental precautions

Do not allow to enter into soil/subsoil. Do not allow to enter into surface water or drains.

Retain contaminated washing water and dispose it.

In case of gas escape or of entry into waterways, soil or drains, inform the responsible authorities.

Suitable material for taking up: absorbing material, organic, sand

6.3. Methods and material for containment and cleaning up

Wash with plenty of water.

6.4. Reference to other sections

See also section 8 and 13

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Avoid contact with skin and eyes, inhalation of vapours and mists.

See also section 8 for recommended protective equipment.

Advice on general occupational hygiene:

Do not eat or drink while working.

7.2. Conditions for safe storage, including any incompatibilities

Keep away from food, drink and feed.

Incompatible materials:

See section 10.5.

Instructions as regards storage premises:

Adequately ventilated premises.

7.3. Specific end use(s)

See section 1.2.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

OCCLUFAST ROCK - CATALYST Cristobalite - CAS: 14464-46-1

OEL Type	TWA	Durati	STEL	Du	ıratio N	lotes	Country
		n		n			



EU	0.1	8h	Respirable
	mg/m3		
TLV	0.1	8h	Respirable ITALY
	mg/m3		
ACGIH	0.025	8h	(R), A2 -
	mg/m3		Pulm
			fibrosis,
			lung
			cancer

octamethylcyclotetrasiloxane; [D4] - CAS: 556-67-2

OEL Type	TWA	Duratio	STEL	Duratio	Notes	Country
		n		n		
No data available						

octamethylcyclotetrasiloxane; [D4] - CAS: 556-67-2

OEL Type	TWA	Duratio	STEL	Duratio	Notes	Country
		n		n		
No data available						

DNEL Exposure Limit Values

octamethylcyclotetrasiloxane; [D4] - CAS: 556-67-2

Consumer: 13 mg/m3 - Exposure: Human Inhalation - Frequency: Long Term, local

effects

Worker Professional: 73 mg/m3 - Exposure: Human Inhalation - Frequency: Long

Term, local effects

Consumer: 3.7 mg/kg bw/d - Exposure: Human Oral - Frequency: Long Term, systemic

effects

Consumer: 13 mg/m3 - Exposure: Human Inhalation - Frequency: Long Term, systemic

effects

Worker Professional: 73 mg/m3 - Exposure: Human Inhalation - Frequency: Long

Term, systemic effects

PNEC Exposure Limit Values

octamethylcyclotetrasiloxane; [D4] - CAS: 556-67-2

Target: Fresh Water - Value: 0.0015 mg/l

Target: Marine water - Value: 1.5E-5 mg/l

Target: Freshwater sediments - Value: 0.64 mg/kg

Target: Marine water sediments - Value: 0.064 mg/kg

Target: Microorganisms in sewage treatments - Value: 10 mg/l

Target: Food chain - Value: 41 mg/kg

Target: Soil (agricultural) - Value: 0.48 mg/kg

8.2. Exposure controls

Precautionary measures:

Give adequate ventilation to the premises where the product is stored and/or handled.

Eye protection:

Wear airtight protective goggles (EN 166).

Protection for skin:

Wear professional overalls and safety footwear (EN 14605).

Protection for hands:

Protect hands with work gloves (EN 374).

The following should be considered when choosing work glove material (EN 374):

compatibility, degradation, failure time and permeability.



The work gloves' resistance to chemical agents should be checked before use, as it can be unpredictable. The gloves' wear time depends on the duration and type of use.

Respiratory protection:

Use respiratory protection where ventilation is insufficient or exposure is prolonged. Respiratory protection devices must be used if the technical measures adopted are not suitable for restricting the worker's exposure to the threshold values considered (e.g. TLV-TWA).

Thermal Hazards:

None

Environmental exposure controls:

None

Appropriate engineering controls:

None

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Properties	Value	Method:	Notes
Physical state:	Liquid		
Colour:	White		
Odour:	Odourless		
Melting point/freezing point:	Not Relevant		
Boiling point or initial boiling point and boiling range:	Not Relevant		
Flammability:	Not available		
Lower and upper explosion limit:	Not available		
Flash point:	>135 ° C	EN ISO 3679	
Auto-ignition temperature:	Not available		
Decomposition	Not available		
temperature:			
pH:	Not Relevant		
Kinematic viscosity:	Not available		
Solubility in water:	Insoluble		
Solubility in oil:	Not available		
Partition coefficient	Not Relevant		
n-octanol/water (log value):			
Vapour pressure:	Not available		
Density and/or relative density:	1.45		
Relative vapour density:	Not available		
	Particle characteristics:		
Particle size:	Not available		

9.2. Other information

No other relevant information

SECTION 10: Stability and reactivity

10.1. Reactivity

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Stable under normal conditions

10.2. Chemical stability

Stable under normal conditions

10.3. Possibility of hazardous reactions

None

10.4. Conditions to avoid

Stable under normal conditions.

10.5. Incompatible materials

None in particular.

10.6. Hazardous decomposition products

None.

SECTION 11: Toxicological information

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

"For the purposes of classification of health hazards (part 3), the route of exposure, information on mechanisms and metabolism studies are useful for determining the relevance of effects in humans. If this information raises doubts as to their relevance in humans, in spite of the indisputable data legitimacy and quality, a lower classification may be justified. When there is scientific evidence that the mechanism or mode of action is not relevant to humans, the substance or mixture should not be classified" (annex I, section 1.1.1.5, EC Regulation 1272/2008).

Monitoring activities conducted at the company related to possible inhalation exposure, in accordance with industrial hygiene standards for paste and fluid products, showed levels of exposure to free crystalline silica (breathable part) below the limit of quantification of the method, therefore exposure is not expected during the use indicated in section 1.2 for this specific product. However, the actual levels of free crystalline silica (breathable part) present in the workplace must be obtained through monitoring as required by regulations for the safety and health of workers.

Toxicological information of the product:

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a) acute toxicity

Not classified

b) skin corrosion/irritation Not classified

- c) serious eye damage/irritation Not classified
- d) respiratory or skin sensitisation Not classified
- e) germ cell mutagenicity Not classified
- f) carcinogenicity Not classified
- g) reproductive toxicity Not classified
- h) STOT-single exposure Not classified
- i) STOT-repeated exposure
 Not classified



j) aspiration hazard Not classified

Toxicological information of the main substances found in the product:

Cristobalite - CAS: 14464-46-1

i) STOT-repeated exposure:

Route: Inhalation - Notes: Silicosis, pulmonary fibrosis; Target organ: lungs - Source: (MSDS supplier).

octamethylcyclotetrasiloxane; [D4] - CAS: 556-67-2

a) acute toxicity:

Test: LC50 - Route: Inhalation - Species: Rat 36 mg/l - Duration: 4h - Source: (OECD 403, GLP, ECHA dossier).

Test: LD50 - Route: Skin - Species: Rat > 2375 mg/kg - Source: (similar to OECD 402, ECHA dossier).

Test: LD50 - Route: Oral - Species: Rat 4800 mg/kg - Source: (similar to OECD 401, ECHA dossier)

b) skin corrosion/irritation:

Species: Rabbit - Based on available data, the classification criteria are not met - Source: (OECD 404, ECHA dossier).

c) serious eye damage/irritation:

Species: Rabbit - Based on available data, the classification criteria are not met - Source: (OECD 405, ECHA dossier).

d) respiratory or skin sensitisation:

Test: Skin Sensitization - Based on available data, the classification criteria are not met - Source: (OECD 406, ECHA dossier).

e) germ cell mutagenicity:

Test: In vitro - Negative - Source: (OECD 476, OECD 471, OECD 473; ECHA dossier). Test: In vivo - Species: Rat - Negative - Source: (OECD 474; OECD 478, ECHA dossier).

f) carcinogenicity:

Test: 18201_NOAEC - Route: Inhalation - Species: Rat > 700 ppm - Notes: male rat - Source: (OECD 453, ECHA dossier).

Test: 18201_NOAEC - Route: Inhalation Vapour - Species: Rat = 150 ppm - Notes: female rat - Source: OECD 453, MSDS supplier

g) reproductive toxicity:

Test: NOAEL - Route: Inhalation Vapour - Species: Rat = 300 ppm - Source: EPA OPPTS 870.3800, MSDS supplier

Test: 18201_NOAEC - Route: Inhalation Vapour - Species: Rabbit > 6.1 mg/l - Notes: developmental - Source: OECD 414, MSDS supplier

Test: 18201_NOAEC - Route: Inhalation Vapour - Species: Rabbit > 3.6 mg/l - Notes: maternal - Source: OECD 414, MSDS supplier

Test: 18201_NOAEC - Route: Inhalation Vapour - Species: Rat > 6.1 mg/l - Notes: developmental - Source: OECD 414, MSDS supplier

Test: 18201_NOAEC - Route: Inhalation Vapour - Species: Rat = 3.6 mg/l - Notes: maternal - Source: OECD 414, MSDS supplier

i) STOT-repeated exposure:

Test: 18201_NOAEC - Route: Inhalation Vapour - Species: Rat 1.8 mg/l - Notes: Systemic effect, chronic nephropathy - Source: OECD 453, MSDS supplier Test: LOAEC - Route: Inhalation Vapour - Species: Rat = 8.5 mg/l - Notes: Systemic effect, chronic nephropathy - Source: OECD 453, MSDS supplier

Test: 18201_NOAEC - Route: Inhalation Vapour - Species: Rat = 1.8 mg/l - Notes: local effects, inflammatory processes of the lungs - Source: OECD 453, MSDS supplier Test: LOAEC - Route: Inhalation Vapour - Species: Rat = 8.5 mg/l - Notes: local effects, inflammatory processes of the lungs - Source: OECD 453, MSDS supplier

octamethylcyclotetrasiloxane; [D4] - CAS: 556-67-2



a) acute toxicity:

Test: LC50 - Species: Rat 36 mg/l - Source: (OECD 403, GLP, rat, 4 h, ECHA dossier).

Test: LD50 - Route: Skin - Species: Rat > 2000 mg/kg - Source: (similar to OECD 402,

rat, ECHA dossier).

Test: LD50 - Route: Oral - Species: Rat 4800 mg/kg - Source: (similar to OECD 401, rat, ECHA dossier).

11.2. Information on other hazards

Endocrine disrupting properties:

No endocrine disruptor substances present in concentration >= 0.1%

SECTION 12: Ecological information

The product is not classified for chronic aquatic hazard; a test based on the bioavailability / release of D4 by the polymer silicone was performed with the OECD 29 method. It was found that the quantity of D4 released by 100mg of polymer is at least below the quantification limit of the method (i.e. 4.4 ppb), a value significantly lower than the limit that would result in the classification for chronic aquatic toxicity, i.e. NOEC of 0.0044 mg / L for fish and 0.0079 mg / L for aquatic invertebrates. Therefore, the product is not classified for this hazard class..

12.1. Toxicity

Adopt good working practices, so that the product is not released into the environment.

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The product is classified: -

octamethylcyclotetrasiloxane; [D4] - CAS: 556-67-2

a) Aquatic acute toxicity:

Endpoint: EC50 - Species: Daphnia > 0.015 mg/l - Duration h: 48h (publication, GLP, Daphnia magna, ECHA dossier).

Endpoint: IC50 - Species: Algae > 0.022 mg/l - Duration h: 72h (EPA OTS 797.1050, Selenastrum capricornutum, freshwater, ECHA dossier).

Endpoint: LC50 - Species: Fish > 0.022 mg/l (publication, Oncorhynchus mykiss, ECHA dossier).

Endpoint: NOEC - Species: Fish > 0.044 mg/l (publication, Oncorhynchus mykiss, GLP, ECHA dossier).

octamethylcyclotetrasiloxane; [D4] - CAS: 556-67-2

a) Aquatic acute toxicity:

Endpoint: IC50 - Species: Algae > 0.0022 mg/l - Duration h: 72h (EPA OTS 797.1050, Selenastrum capricornutum, freshwater, ECHA dossier).

Endpoint: LC50 - Species: Fish > 0.0022 mg/l (Oncorhynchus mykiss, GLP, ECHA dossier).

Endpoint: NOEC - Species: Fish > 0.0044 mg/l (publication, Oncorhynchus mykiss, GLP, ECHA dossier).

Long-term toxicity to aquatic invertebrates:

Endpoint: NOEC - Species: Daphnia = 7.9 μg/L - Duration h: 21d EPA OTS 797.1330, Daphnia magna, ECHA dossier

12.2. Persistence and degradability

Cristobalite - CAS: 14464-46-1

Biodegradability: Non-readily biodegradable octamethylcyclotetrasiloxane; [D4] - CAS: 556-67-2 Biodegradability: Non-readily biodegradable

12.3. Bioaccumulative potential

Cristobalite - CAS: 14464-46-1

Not bioaccumulative

octamethylcyclotetrasiloxane; [D4] - CAS: 556-67-2

Test: Kow - Partition coefficient 6.49 - Notes:)

(Log Pow. ECHA dossier).

octamethylcyclotetrasiloxane; [D4] - CAS: 556-67-2



Test: Kow - Partition coefficient 6.49 - Notes: (Log Pow, ECHA dossier).

12.4. Mobility in soil

Not available

12.5. Results of PBT and vPvB assessment

vPvB Substances: None - PBT Substances: None

12.6. Endocrine disrupting properties

No endocrine disruptor substances present in concentration >= 0.1%

12.7. Other adverse effects

None

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Recover if possible. In so doing, comply with the local and national regulations currently in force.

SECTION 14: Transport information

14.1. UN number or ID number

Not classified as dangerous in the meaning of transport regulations.

14.2. UN proper shipping name

Not available

14.3. Transport hazard class(es)

Not available

14.4. Packing group

Not available

14.5. Environmental hazards

ADR-Enviromental Pollutant: No **IMDG-Marine** pollutant: Nο

14.6. Special precautions for user

Not available

14.7. Maritime transport in bulk according to IMO instruments

Not Applicable

SECTION 15: Regulatory information

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

Dir. 98/24/EC (Risks related to chemical agents at work)

Dir. 2000/39/EC (Occupational exposure limit values)

Regulation (EC) n. 1907/2006 (REACH)

Regulation (EC) n. 1272/2008 (CLP)

Regulation (EC) n. 790/2009 (ATP 1 CLP) and (EU) n. 758/2013

Regulation (EU) n. 2020/878

Regulation (EU) n. 286/2011 (ATP 2 CLP)

Regulation (EU) n. 618/2012 (ATP 3 CLP)

Regulation (EU) n. 487/2013 (ATP 4 CLP)

Regulation (EU) n. 944/2013 (ATP 5 CLP)

Regulation (EU) n. 605/2014 (ATP 6 CLP)

Regulation (EU) n. 2015/1221 (ATP 7 CLP)

Regulation (EU) n. 2016/918 (ATP 8 CLP)

Regulation (EU) n. 2016/1179 (ATP 9 CLP)

Regulation (EU) n. 2017/776 (ATP 10 CLP)

Regulation (EU) n. 2018/669 (ATP 11 CLP) Regulation (EU) n. 2018/1480 (ATP 13 CLP)

Regulation (EU) n. 2019/521 (ATP 12 CLP)

Regulation (EU) n. 2020/217 (ATP 14 CLP)



Regulation (EU) n. 2020/1182 (ATP 15 CLP) Regulation (EU) n. 2021/643 (ATP 16 CLP)

Restrictions related to the product or the substances contained according to Annex XVII Regulation (EC) 1907/2006 (REACH) and subsequent modifications:

Restrictions related to the product:

No restriction.

Restrictions related to the substances contained:

No restriction.

Provisions related to directive EU 2012/18 (Seveso III):

Seveso III category according to Annex 1, part 1
None

WGK Classification (Water hazard class - Verwaltungsvorschrift wassergefährdende Stoffe) WGK1 - Slightly hazardous for water

Lagerklasse according to TRGS 510:

LGK 10: Combustible liquids

Substances subject to exportation reporting pursuant to (EC) Reg. 649/2012: None.

California Proposition 65

Substance(s) listed under California Proposition 65:

Cristobalite - Listed as carcinogen.

15.2. Chemical safety assessment

No Chemical Safety Assessment has been carried out for the mixture. Substances for which a Chemical Safety Assessment has been carried out: octamethylcyclotetrasiloxane; [D4]

SECTION 16: Other information

Hazard class and hazard category	Code	Description
Flam. Liq. 3	2.6/3	Flammable liquid, Category 3
Repr. 2	3.7/2	Reproductive toxicity, Category 2
STOT RE 1	3.9/1	Specific target organ toxicity - repeated exposure, Category 1
Aquatic Chronic 1	4.1/C1	Chronic (long term) aquatic hazard, category 1
Aquatic Chronic 3	4.1/C3	Chronic (long term) aquatic hazard, category 3

This safety data sheet has been completely updated in compliance to Regulation 2020/878. Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:

Classification according to Regulation (EC) Nr. 1272/2008	Classification procedure
Aquatic Chronic	According to Article 12 of the CLP Regulation, "Where, as a result of the evaluation carried out pursuant to Article 9, the following properties or effects are identified, manufacturers, importers and downstream users shall take them into account for the purposes of classification: [] (b) conclusive

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scientific experimental data show that the substance or mixture is not biologically available and those data have been ascertained to be adequate and reliable." Following a release study of D4 through the OECD 29 test on polymeric products representative for quantity of D4, the limit that would result in the classification for chronic aquatic toxicity (NOEC of 0.0044 mg / L for fish and 0.0079 mg / L for inverted to the control of the c
invertebrates aquatic) is not reached.

This document was prepared by a competent person who has received appropriate training. Main bibliographic sources:

ECHA – European Chemical Agency

GESTIS - Information system on hazardous substances of the German Social Accident Insurance

IARC - International Agency for Research on Cancer

IPCS INCHEM - International Programme on Chemical Safety

ISS - Istituto Superiore di Sanità

PubChem - open chemistry database at the National Institutes of Health (NIH)

A safety data sheet is not required for this product under article 31 of Regulation 1907/2006/EC. This safety data sheet has been created on a voluntary basis.

The information contained herein is based on our state of knowledge at the above-specified date. It refers solely to the product indicated and constitutes no guarantee of particular quality. It is the duty of the user to ensure that this information is appropriate and complete with respect to the specific use intended.

This MSDS cancels and replaces any preceding release.

ADR: European Agreement concerning the International Carriage of

Dangerous Goods by Road.

ATE: Acute Toxicity Estimate

ATEmix: Acute toxicity Estimate (Mixtures)

CAS: Chemical Abstracts Service (division of the American Chemical

Society).

CLP: Classification, Labeling, Packaging.

DNEL: Derived No Effect Level.

EINECS: European Inventory of Existing Commercial Chemical Substances.

GefStoffVO: Ordinance on Hazardous Substances, Germany.

GHS: Globally Harmonized System of Classification and Labeling of

Chemicals.

IATA: International Air Transport Association.

IATA-DGR: Dangerous Goods Regulation by the "International Air Transport

Association" (IATA).

ICAO: International Civil Aviation Organization.

ICAO-TI: Technical Instructions by the "International Civil Aviation Organization"

(ICAO).

IMDG: International Maritime Code for Dangerous Goods. INCI: International Nomenclature of Cosmetic Ingredients.

KSt: Explosion coefficient.

LC50: Lethal concentration, for 50 percent of test population.

LD50: Lethal dose, for 50 percent of test population.

PNEC: Predicted No Effect Concentration.

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RID: Regulation Concerning the International Transport of Dangerous Goods

by Rail.

STEL: Short Term Exposure limit.
STOT: Specific Target Organ Toxicity.
TLV: Threshold Limiting Value.
TWA: Time-weighted average

WGK: German Water Hazard Class.

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