

**Safety Data Sheet  
OCCLUFAST+ COLOR - BASE****Revision nr. 2  
Dated 09/05/2022****SECTION 1: Identification of the substance/mixture and of the company/undertaking****1.1. Product identifier**

Mixture identification:

Product Name: OCCLUFAST+ COLOR - BASE

Code: C200780, C200781, C200782

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

Intended use 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**

UK Emergency number: 999 (24 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.

Hazard pictograms:

None

Hazard statements:

None

Precautionary statements:

None

Special Provisions:

EUH210 Safety data sheet available on request.

EUH208 Contains (R)-p-mentha-1,8-diene; d-limonene. May produce an allergic reaction.

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.

No PBT, vPvB or endocrine disruptor substances present in concentration  $\geq 0.1\%$ 

Other Hazards:

No other hazards

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#### 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. Number                                                                                         | Classification                                                                                                                                                                                                                                                                                                                                                       |
|---------------------|------------------------------------|-------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| >= 10% -<br>< 12,5% | Cristobalite                       | CAS: 14464-46-1<br>EC: 238-455-4                                                                      | STOT RE 1 H372 Causes damage to organs (lungs) through prolonged or repeated exposure if inhaled.                                                                                                                                                                                                                                                                    |
| >= 0,1% -<br>< 0,3% | (R)-p-mentha-1,8-diene; d-limonene | Index number: 601-029-00-7<br>CAS: 5989-27-5<br>EC: 227-813-5<br>REACH No.: 01-21195292<br>23-47-XXXX | Skin Sens. 1B H317 May cause an allergic skin reaction.<br>Asp. Tox. 1 H304 May be fatal if swallowed and enters airways.<br>Aquatic Acute 1 H400 Very toxic to aquatic life. M=1.<br>Aquatic Chronic 3 H412 Harmful to aquatic life with long lasting effects. M=1.<br>Flam. Liq. 3 H226 Flammable liquid and vapour.<br>Skin Irrit. 2 H315 Causes skin irritation. |

#### 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

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 (CO<sub>2</sub>).

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.

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### 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.  
 Don't use empty container before they have been cleaned.  
 Before making transfer operations, assure that there aren't any incompatible material residuals in the containers.  
 See also section 8 for recommended protective equipment.  
 Advice on general occupational hygiene:  
 Contaminated clothing should be changed before entering eating areas.  
 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+ COLOR - BASE  
 Cristobalite - CAS: 14464-46-1

| OEL Type | TWA          |  | Duratio<br>n | STEL |  | Duratio<br>n | Notes      | Country |
|----------|--------------|--|--------------|------|--|--------------|------------|---------|
| EU       | 0.1<br>mg/m3 |  | 8h           |      |  |              | Respirable |         |
| TLV      | 0.1<br>mg/m3 |  | 8h           |      |  |              | Respirable | ITALY   |

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|       |                         |  |    |  |  |  |                                      |  |
|-------|-------------------------|--|----|--|--|--|--------------------------------------|--|
| ACGIH | 0.025 mg/m <sup>3</sup> |  | 8h |  |  |  | (R), A2 - Pulm fibrosis, lung cancer |  |
|-------|-------------------------|--|----|--|--|--|--------------------------------------|--|

(R)-p-mentha-1,8-diene; d-limonene - CAS: 5989-27-5

| OEL Type | TWA                   |        | Duratio<br>n | STEL                  |        | Duratio<br>n | Notes | Country     |
|----------|-----------------------|--------|--------------|-----------------------|--------|--------------|-------|-------------|
| AGW      | 28 mg/m <sup>3</sup>  | 5 ppm  | 8h           | 112 mg/m <sup>3</sup> | 20 ppm | 15min        |       | GERMANY     |
| MAK      | 28 mg/m <sup>3</sup>  | 5 ppm  | 8h           | 110 mg/m <sup>3</sup> | 20 ppm | 15min        |       | GERMANY     |
| HTP      | 140 mg/m <sup>3</sup> | 25 ppm | 8h           | 280 mg/m <sup>3</sup> | 50 ppm | 15min        |       | FINLAND     |
| MAK      | 40 mg/m <sup>3</sup>  | 7 ppm  | 8h           | 80 mg/m <sup>3</sup>  | 14 ppm | 15min        |       | SWITZERLAND |

#### DNEL Exposure Limit Values

(R)-p-mentha-1,8-diene; d-limonene - CAS: 5989-27-5

Consumer: 4.8 mg/kg/d - Exposure: Human Oral - Frequency: Long Term, systemic effects

Consumer: 16.6 mg/m<sup>3</sup> - Exposure: Human Inhalation - Frequency: Long Term, systemic effects

Worker Professional: 66.7 mg/m<sup>3</sup> - Exposure: Human Inhalation - Frequency: Long Term, systemic effects

Consumer: 4.8 mg/kg bw/d - Exposure: Human Dermal - Frequency: Short Term, systemic effects

Worker Professional: 9.5 mg/kg bw/d - Exposure: Human Dermal - Frequency: Short Term, systemic effects

#### PNEC Exposure Limit Values

(R)-p-mentha-1,8-diene; d-limonene - CAS: 5989-27-5

Target: Fresh Water - Value: 0.014 mg/l

Target: Marine water - Value: 0.0014 mg/l

Target: Freshwater sediments - Value: 3.85 mg/kg

Target: Marine water sediments - Value: 0.385 mg/kg

Target: Microorganisms in sewage treatments - Value: 1.8 mg/l

Target: Soil (agricultural) - Value: 0.763 mg/kg

Target: Food chain - Value: 133 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.

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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:                                           | Fluid         | --          | --    |
| Colour:                                                   | Green         | --          | --    |
| Odour:                                                    | Lemon         | --          | --    |
| 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 temperature:                                | Not available | --          | --    |
| pH:                                                       | Not Relevant  | --          | --    |
| Kinematic viscosity:                                      | Not available | --          | --    |
| Solubility in water:                                      | Insoluble     | --          | --    |
| Solubility in oil:                                        | Not available | --          | --    |
| Partition coefficient n-octanol/water (log value):        | Not available | --          | --    |
| Vapour pressure:                                          | Not available | --          | --    |
| Density and/or relative density:                          | 1.53          | --          | --    |
| 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

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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+ COLOR - 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

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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).

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

In June 2003, SCOEL (the EU Scientific Committee on Occupational Exposure Limits) concluded that the main effect in humans of the inhalation of respirable crystalline silica dust is silicosis. "There is sufficient information to conclude that the relative risk of lung cancer is increased in persons with silicosis (and, apparently, not in employees without silicosis exposed to silica dust in quarries and in the ceramic industry). Therefore preventing the onset of silicosis will also reduce the cancer risk..." (SCOEL SUM Doc 94-final, June 2003).

There is a body of evidence supporting the fact that increased cancer risk would not be limited to people already suffering from silicosis. According to the current state of the art, worker protection against silicosis can be consistently assured by respecting the existing regulatory occupational exposure limits. Occupational exposure to nuisance dust (total and respirable) and respirable crystalline silica should be monitored and controlled.

(R)-p-mentha-1,8-diene; d-limonene - CAS: 5989-27-5

a) acute toxicity:

Test: LD50 - Route: Oral - Species: Rat > 2000 mg/kg - Source: (OECD 423, ECHA dossier).

b) skin corrosion/irritation:

Species: Rabbit - Skin Irritant - Source: (comparable to OECD 404, in vivo, ECHA dossier).

c) serious eye damage/irritation:

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

d) respiratory or skin sensitisation:

Test: Skin Sensitization - Species: Mouse - Positive - Source: (OECD 429, in vivo, Mouse local lymphnode assay, ECHA dossier).

e) germ cell mutagenicity:

Test: In vitro - Negative - Source: (OECD 476, 473, 479, ECHA dossier).

Test: In vivo - Route: Oral - Species: Rat - Negative - Source: (publication, ECHA dossier).

f) carcinogenicity:

Species: Rat - Notes: Mechanism of nephrocarcinogenicity male-rat specific. Not relevant for humans. - Positive - Source: (similar to OECD 451, GLP, ECHA dossier).

g) reproductive toxicity:

Insufficient data

i) STOT-repeated exposure:

Test: NOAEL - Species: Rat 1650 mg/kg - Source: (similar to OECD 407, GLP, ECHA dossier).

j) aspiration hazard:

No data available for the product

#### 11.2. Information on other hazards

Endocrine disrupting properties:

No endocrine disruptor substances present in concentration  $\geq 0.1\%$

**Safety Data Sheet  
OCCLUFAST+ COLOR - BASE****SECTION 12: Ecological information****12.1. Toxicity**

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

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Not classified for environmental hazards

Based on available data, the classification criteria are not met

(R)-p-mentha-1,8-diene; d-limonene - CAS: 5989-27-5

a) Aquatic acute toxicity:

Endpoint: EC50 - Species: Daphnia 0.307 mg/l - Duration h: 48h (OECD 202, Daphnia magna, static, freshwater, ECHA dossier).

Endpoint: LC50 - Species: Fish < 1 mg/l - Duration h: 96h (similar or equivalent to OECD 203, Pimephales promelas, freshwater, ECHA dossier).

Endpoint: IC50 - Species: Algae < 0.32 mg/l - Duration h: 72h (OECD 201, Pseudokirchneriella subcapitata, ECHA dossier).

**12.2. Persistence and degradability**

Cristobalite - CAS: 14464-46-1

Biodegradability: Non-readily biodegradable

(R)-p-mentha-1,8-diene; d-limonene - CAS: 5989-27-5

Biodegradability: Readily biodegradable

**12.3. Bioaccumulative potential**

Cristobalite - CAS: 14464-46-1

Not bioaccumulative

**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  $\geq$  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-Environmental 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



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**OCCLUFAST+ COLOR - BASE****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:

Restriction 40

Restrictions related to the substances contained:

Restriction 28

Restriction 70

Restriction 72

Restriction 75

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)

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:

None

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| <b>Hazard class and hazard category</b> | <b>Code</b> | <b>Description</b>                                             |
|-----------------------------------------|-------------|----------------------------------------------------------------|
| Flam. Liq. 3                            | 2.6/3       | Flammable liquid, Category 3                                   |
| Asp. Tox. 1                             | 3.10/1      | Aspiration hazard, Category 1                                  |
| Skin Irrit. 2                           | 3.2/2       | Skin irritation, Category 2                                    |
| Skin Sens. 1B                           | 3.4.2/1B    | Skin Sensitisation, Category 1B                                |
| STOT RE 1                               | 3.9/1       | Specific target organ toxicity - repeated exposure, Category 1 |
| Aquatic Acute 1                         | 4.1/A1      | Acute aquatic hazard, category 1                               |
| Aquatic Chronic 3                       | 4.1/C3      | Chronic (long term) aquatic hazard, category 3                 |

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.                                                               |

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|       |                                                                                  |
|-------|----------------------------------------------------------------------------------|
| 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<br>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.                                                       |

Changes from the previous revision.

Changes have been made to the following sections:  
01/02/03/04/05/06/07/08/09/10/11/12/13/14/15/16.