

Safety Data Sheet OCCLUFAST+ COLOR - BASE

Revision nr. 3
Dated 03/04/2024

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

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)

Details of Australian Distributor / Sponsor

Name: Durodent Dental Supplies

Full Address: Unit 6 / 51 Jersey Road, Bayswater
Victoria

Australia 3153

Ph: (03) 9720 6700

Email: sales@durodent.com.au

Australian Emergency Telephone Number

Durodent Office Ph: (03) 9720 6700 Mon-Thurs

09:00 - 17:00 / Friday 09:00 - 16.30 AEST

Australian Poisons Information Centre (National)

Ph: 13 11 26 - 24 Hours / 7 Days

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

EC regulation criteria 1272/2008 (CLP)

The product is not classified as hazardous 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 hazardous 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.

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

here is no exposure to breathable free crystalline silica and treated silanamine 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 $\geq 0.1\%$
 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. Number	Classification
$\geq 13\%$ - $< 20\%$	Cristobalite	CAS: 14464-46-1 EC: 238-455-4	STOT RE 1 H372 Causes damage to organs (lungs) through prolonged or repeated exposure if inhaled.
$\geq 1\%$ - $< 3\%$	silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica; pyrogenic, synthetic amorphous, nano, surface treated silicon dioxide	Index number: 014-052-00-7 CAS: 68909-20-6 EC: 272-697-1	STOT RE 2 H373 May cause damage to organs (lungs) through prolonged or repeated exposure if inhaled. EUH066 Repeated exposure may cause skin dryness or cracking.
$\geq 0,5\%$ - $< 2,5\%$	silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica; pyrogenic, synthetic amorphous, nano, surface treated silicon dioxide	Index number: 014-052-00-7 CAS: 68909-20-6 EC: 272-697-1	STOT RE 2 H373 May cause damage to organs (lungs) through prolonged or repeated exposure if inhaled. EUH066 Repeated exposure may cause skin dryness or cracking.
$\geq 0,1\%$ - $< 0,3\%$	(R)-p-mentha-1,8-diene; d-limonene	Index number: 601-096-00-2 CAS: 5989-27-5 EC: 227-813-5 REACH No.: 01-21195292 23-47-XXXX	Skin Sens. 1B H317 May cause an allergic skin reaction. Asp. Tox. 1 H304 May be fatal if swallowed and enters airways. Aquatic Acute 1 H400 Very toxic to aquatic life. M=1. Aquatic Chronic 3 H412 Harmful to aquatic life with long lasting effects. Flam. Liq. 3 H226 Flammable liquid and vapour. Skin Irrit. 2 H315 Causes skin irritation.

Substances in nanoform:

$\geq 1\%$ - $< 3\%$ silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica; pyrogenic, synthetic amorphous, nano, surface treated silicon dioxide
 Index number: 014-052-00-7, CAS: 68909-20-6, EC: 272-697-1

$\geq 0,5\%$ - $< 2,5\%$ silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica; pyrogenic, synthetic amorphous, nano, surface treated silicon dioxide
 Index number: 014-052-00-7, CAS: 68909-20-6, EC: 272-697-1

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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 (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

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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

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Cristobalite - CAS: 14464-46-1

OEL Type	TWA		Duration	STEL		Duration	Notes	Country
EU	0.1 mg/m ³		8h				Respirable	
TLV	0.1 mg/m ³		8h				Respirable	ITALY
ACGIH	0.025 mg/m ³		8h				(R), A2 - Pulm fibrosis, lung cancer	

silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica; pyrogenic, synthetic amorphous, nano, surface treated silicon dioxide - CAS: 68909-20-6
silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica; pyrogenic, synthetic amorphous, nano, surface treated silicon dioxide - CAS: 68909-20-6
(R)-p-mentha-1,8-diene; d-limonene - CAS: 5989-27-5

OEL Type	TWA		Duration	STEL		Duration	Notes	Country
AGW	28 mg/m ³	5 ppm	8h	112 mg/m ³	20 ppm	15min		GERMANY
MAK	28 mg/m ³	5 ppm	8h	110 mg/m ³	20 ppm	15min		GERMANY
HTP	140 mg/m ³	25 ppm	8h	280 mg/m ³	50 ppm	15min		FINLAND
MAK	40 mg/m ³	7 ppm	8h	80 mg/m ³	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/m³ - Exposure: Human Inhalation - Frequency: Long Term, systemic effects

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Worker Professional: 66.7 mg/m³ - 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.

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:	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	Not available	--	--

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limit:			
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	--	--
Nanoforms:	See Nanoform information in Section 3.	--	--

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) and treated silanamine 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 dust present in the workplace must be obtained through monitoring as required by regulations for the safety and health of workers.

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Toxicological information of the product:

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a) acute toxicity

Not classified

b) skin corrosion/irritation

Not classified

Not classified for EUH066. Based on the 2100-RAZ-23128 assessment report, the product does not cause dryness or cracking of the skin.

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).

silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica; pyrogenic, synthetic amorphous, nano, surface treated silicon dioxide - CAS: 68909-20-6

a) acute toxicity:

Test: LD50 - Route: Oral > 2000 mg/kg - Source: OECD 401, MSDS supplier

b) skin corrosion/irritation:

Based on available data, the classification criteria are not met - Source: OECD 404, MSDS supplier

c) serious eye damage/irritation:

Based on available data, the classification criteria are not met - Source: OECD 405, MSDS supplier

d) respiratory or skin sensitisation:

Based on available data, the classification criteria are not met - Source: OECD 406, MSDS supplier

e) germ cell mutagenicity:

Based on available data, the classification criteria are not met - Source: MSDS supplier

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f) carcinogenicity:

Based on available data, the classification criteria are not met - Source: MSDS supplier

(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 $\geq 0.1\%$

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

silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica; pyrogenic, synthetic amorphous, nano, surface treated silicon dioxide - CAS: 68909-20-6

a) Aquatic acute toxicity:

Endpoint: LC50 - Species: rerio > 1000 mg/l - Duration h: 96h MSDS supplier

Endpoint: EC50 - Species: Daphnia > 100 mg/l - Duration h: 48h MSDS supplier

Endpoint: EC50 - Species: Microorganisms > 1000 mg/l MSDS supplier

(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

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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

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)

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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 29

Restriction 30

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

SECTION 16: Other information

Hazard class and hazard category	Code	Description
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
STOT RE 2	3.9/2	Specific target organ toxicity - repeated exposure, Category 2
Aquatic Acute 1	4.1/A1	Acute aquatic hazard, category 1
Aquatic Chronic 3	4.1/C3	Chronic (long term) aquatic hazard, category 3

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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.
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.