

SAFETY DATA SHEETS

This SDS packet was issued with item:

074484069

The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).

074483947 074483954 074483970 074483988 074483996 074484002 074484010 074484028 074484036 074484044
074484051 074484077 074484085 074484093 074484101 074484119 074484127 074484135 074484143 074484150
074484168 074484176 074484184 074484192 074484200 074484218 074484226 074484234 074490124 074490132
074490140 074490157 074490165 074490173 074490181 074490199 074490207 074490231 074490355 074490363
074490397 074490413 074490421 074490439 074490447 074490454

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 26.10.2015

Revision: 20.10.2015

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

- **1.1 Product identifier**
 - **Trade name:** **Durafill VS**
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**

No further relevant information available.

 - **Application of the substance / the mixture** Dental filling material
- **1.3 Details of the supplier of the safety data sheet**
 - **Manufacturer/Supplier:**
Heraeus Kulzer GmbH
Grüner Weg 11, D-63450 Hanau
 - Tel.: 0800 4372522
 - **Informing department:** E-Mail: msds@kulzer-dental.com
- **1.4 Emergency telephone number:**
Emergency CONTACT (24-Hour-Number): GBK GmbH +49 (0)6132-84463

SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
 - **Classification according to Regulation (EC) No 1272/2008**
Skin Sens. 1 H317 May cause an allergic skin reaction.
- **2.2 Label elements**
 - **Labelling according to Regulation (EC) No 1272/2008**
The product is classified and labelled according to the CLP regulation.
 - **Hazard pictograms**



GHS07

- **Signal word** Warning
- **Hazard-determining components of labelling:**
triethylenglycoldimethacrylate
- **Hazard statements**
H317 May cause an allergic skin reaction.
- **Precautionary statements**
 - P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
 - P280 Wear protective gloves/protective clothing/eye protection/face protection.
 - P321 Specific treatment (see on this label).
 - P363 Wash contaminated clothing before reuse.
 - P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
 - P501 Dispose of contents/container in accordance with local/regional/national/international regulations.
- **2.3 Other hazards -**
 - **Results of PBT and vPvB assessment**
 - **PBT:** Not applicable.
 - **vPvB:** Not applicable.

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SECTION 3: Composition/information on ingredients

- **3.2 Chemical characterisation: Mixtures**
 - **Description:** Product based on methacrylates
 - **Dangerous components:** Void
 - **Additional information** For the wording of the listed risk phrases refer to section 16.

SECTION 4: First aid measures

- **4.1 Description of first aid measures**
 - **General information** No special measures required.
 - **After skin contact** The product is not skin irritating.
 - **After eye contact** Rinse opened eye for several minutes under running water.
 - **After swallowing**
Rinse out mouth and then drink plenty of water.
In case of persistent symptoms consult doctor.
- **4.2 Most important symptoms and effects, both acute and delayed**
No further relevant information available.
- **4.3 Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

SECTION 5: Firefighting measures

- **5.1 Extinguishing media**
 - **Suitable extinguishing agents**
CO₂, extinguishing powder or water jet. Fight larger fires with water jet or alcohol-resistant foam.
Use fire fighting measures that suit the environment.
- **5.2 Special hazards arising from the substance or mixture** No further relevant information available.
- **5.3 Advice for firefighters**
 - **Protective equipment:** No special measures required.
 - **Additional information** -

SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures** Not required.
- **6.2 Environmental precautions:** No special measures required.
- **6.3 Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (diatomite, universal binders, for small amounts tissues).
- **6.4 Reference to other sections**
No dangerous materials are released.
See Section 8 for information on personal protection equipment.

SECTION 7: Handling and storage

- **7.1 Precautions for safe handling** No special measures required.
- **Information about protection against explosions and fires:** No special measures required.

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- **7.2 Conditions for safe storage, including any incompatibilities**
 - **Storage**
 - **Requirements to be met by storerooms and containers:** No special requirements.
 - **Information about storage in one common storage facility:** Not required.
 - **Further information about storage conditions:** Store cool (not above 25 °C).
- **7.3 Specific end use(s)** No further relevant information available.

SECTION 8: Exposure controls/personal protection

- **Additional information about design of technical systems:** No further data; see item 7.
- **8.1 Control parameters**
 - **Components with critical values that require monitoring at the workplace:**
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
 - **Additional information:** The lists that were valid during the compilation were used as basis.
- **8.2 Exposure controls**
 - **Personal protective equipment**
 - **General protective and hygienic measures**
The usual precautionary measures should be adhered to in handling the chemicals.
 - **Breathing equipment:** Not required.
 - **Protection of hands:** recommended
 - **Material of gloves**
The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer.
 - **Penetration time of glove material**
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
 - **For the permanent contact in work areas without heightened risk of injury (e.g. Laboratory) gloves made of the following material are suitable:**
Butyl rubber, BR
Nitrile rubber, NBR
 - **Eye protection:** Safety glasses
 - **Body protection:** Light weight protective clothing

SECTION 9: Physical and chemical properties

- **9.1 Information on basic physical and chemical properties**
 - **General Information**
 - **Appearance:**
 - **Form:** Pasty
 - **Colour:** Different according to colour
 - **Smell:** Odourless
 - **Change in condition**
 - **Melting point/Melting range:** Not determined
 - **Boiling point/Boiling range:** 250 °C
 - **Flash point:** 151 °C

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· Self-inflammability:	Product is not selfigniting.
· Danger of explosion:	Product is not explosive.
· Density at 20 °C	0 g/cm ³
· Solubility in / Miscibility with	
· Water:	Not miscible or difficult to mix
· Viscosity:	
· dynamic at 20 °C:	10000 mPas
· Solvent content:	
· VOC EU	g/l
· Solids content:	75.3 %
· 9.2 Other information	No further relevant information available.

SECTION 10: Stability and reactivity

- **10.1 Reactivity** No further relevant information available.
- **10.2 Chemical stability**
 - **Conditions to be avoided:** No decomposition if used and stored according to specifications.
- **10.3 Possibility of hazardous reactions** No dangerous reactions known
- **10.4 Conditions to avoid** No further relevant information available.
- **10.5 Incompatible materials:** No further relevant information available.
- **10.6 Hazardous decomposition products:** None
 - **Additional information:**
If stored longer than recommended and/or above recommended temperature, product may polymerize generating heat.

SECTION 11: Toxicological information

- **11.1 Information on toxicological effects**
 - **Acute toxicity** Based on available data, the classification criteria are not met.
 - **Primary irritant effect:**
 - **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
 - **Serious eye damage/irritation** Based on available data, the classification criteria are not met.
 - **Respiratory or skin sensitisation**
May cause an allergic skin reaction.
 - **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
 - **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
 - **Carcinogenicity** Based on available data, the classification criteria are not met.
 - **Reproductive toxicity** Based on available data, the classification criteria are not met.
 - **STOT-single exposure** Based on available data, the classification criteria are not met.
 - **STOT-repeated exposure** Based on available data, the classification criteria are not met.
 - **Aspiration hazard** Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

- **12.1 Toxicity**
 - **Aquatic toxicity:** No further relevant information available.

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- **12.2 Persistence and degradability** No further relevant information available.
- **12.3 Bioaccumulative potential** No further relevant information available.
- **12.4 Mobility in soil** No further relevant information available.
 - **Additional ecological information:**
 - **General notes:**

Do not allow product to reach ground water, water bodies or sewage system.
Danger to drinking water if even small quantities leak into soil.
- **12.5 Results of PBT and vPvB assessment**
 - **PBT:** Not applicable.
 - **vPvB:** Not applicable.
- **12.6 Other adverse effects** No further relevant information available.

SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**
 - **Recommendation** Smaller quantities can be disposed with household garbage.

· **European waste catalogue**

18 01 07 chemicals other than those mentioned in 18 01 06

- **Uncleaned packagings:**
 - **Recommendation:** Disposal must be made according to official regulations.

SECTION 14: Transport information

- | | |
|--|-----------------|
| · 14.1 UN-Number | |
| · ADR, ADN, IMDG, IATA | Void |
| · 14.2 UN proper shipping name | |
| · ADR, ADN, IMDG, IATA | Void |
| · 14.3 Transport hazard class(es) | |
| · ADR, ADN, IMDG, IATA | |
| · Class | Void |
| · 14.4 Packing group | |
| · ADR, IMDG, IATA | Void |
| · 14.5 Environmental hazards: | |
| · Marine pollutant: | No |
| · 14.6 Special precautions for user | Not applicable. |
| · 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code | Not applicable. |
| · Transport/Additional information: | - |
| · UN "Model Regulation": | Void |

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SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
No further relevant information available.
- **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

These data are based on our present knowledge. However, they shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· **Abbreviations and acronyms:**

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

VOCV: Lenkungsabgabe auf flüchtigen organischen Verbindungen, Schweiz (Swiss Ordinance on volatile organic compounds)

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

Skin Sens. 1: Sensitisation - Skin, Hazard Category 1

- *** Data compared to the previous version altered.**

GB



Safety Data Sheet
acc. to OSHA HCS

Printing date 06/03/2017

Reviewed on 06/03/2017

1 Identification

· **Product identifier**

· **Trade name:** **Durafill VS**

· **Application of the substance / the mixture** Dental filling material

· **Details of the supplier of the safety data sheet**

· **Manufacturer/Supplier:**

Kulzer GmbH

Leipziger Straße 2, 63450 Hanau (Germany)

Tel.: +49 (0)800 4372522

· **Information department:**

Tel. +1 (800) 431-1785 Fax: +1 (800) 522-1545

e-mail: customer.servicehkna@kulzer-dental.com

· **Emergency telephone number:**

Emergency CONTACT (24-Hour-Number)

GBK/Infotrac ID 105860: (domestic) 1 800 535 5053 or international (001) 352 323 3500

2 Hazard(s) identification

· **Classification of the substance or mixture**

Skin Sens. 1 H317 May cause an allergic skin reaction.

· **Label elements**

· **GHS label elements**

The product is classified and labeled according to the Globally Harmonized System (GHS).

· **Hazard pictograms**



GHS07

· **Signal word** Warning

· **Hazard-determining components of labeling:**

triethylen glycol dimethacrylate

· **Hazard statements**

May cause an allergic skin reaction.

· **Precautionary statements**

Avoid breathing dust/fume/gas/mist/vapors/spray

Wear protective gloves.

Specific treatment (see on this label).

Wash contaminated clothing before reuse.

If skin irritation or rash occurs: Get medical advice/attention.

IF ON SKIN: Wash with plenty of water.

· **Classification system**

· **NFPA ratings for USA (scale 0-4)**



Health = 1

Fire = 1

Reactivity = 1

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acc. to OSHA HCS

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Trade name: Durafill VS

· **HMIS-Ratings (Scale 0-4)**

HEALTH	0	Health = 0
FIRE	1	Fire = 1
REACTIVITY	1	Reactivity = 1

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· **Results of PBT and vPvB assessment**

- **PBT:** Not applicable.
- **vPvB:** Not applicable.

3 Composition/information on ingredients

· **Chemical characterization: Mixtures**

- **Description:** Composition based on methacrylates

· **Dangerous components:**

109-16-0 triethylen glycol dimethacrylate	Skin Sens. 1B, H317	5-10%
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- **Additional information** For the wording of the listed hazard phrases refer to section 16.

4 First-aid measures

· **Description of first aid measures**

- **General information** No special measures required.
- **After skin contact** Generally the product does not irritate the skin.
- **After eye contact** Rinse opened eye for several minutes under running water.
- **After swallowing**
Rinse out mouth and then drink plenty of water.
If symptoms persist consult doctor.

· **Information for doctor**

- **Most important symptoms and effects, both acute and delayed**
No further relevant information available.
- **Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

5 Fire-fighting measures

· **Extinguishing media**

· **Suitable extinguishing agents**

CO₂, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

Use fire fighting measures that suit the environment.

- **Special hazards arising from the substance or mixture** No further relevant information available.

· **Advice for firefighters**

- **Protective equipment:** No special measures required.

· **Additional information -**

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Printing date 06/03/2017

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Trade name: Durafill VS

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6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures** Not required.
- **Environmental precautions:** No special measures required.
- **Methods and material for containment and cleaning up:**
Absorb with liquid binding material (diatomite, universal binders, for small amounts tissues).
- **Reference to other sections**
No dangerous substances are released.
See Section 8 for information on personal protection equipment.
-

7 Handling and storage

- **Handling**
 - **Precautions for safe handling** No special measures required.
 - **Information about protection against explosions and fires:** No special measures required.
- **Conditions for safe storage, including any incompatibilities**
 - **Storage**
 - **Requirements to be met by storerooms and receptacles:** No special requirements.
 - **Information about storage in one common storage facility:** Not required.
 - **Further information about storage conditions:** Keep cool, if possible (not above 25 °C).
- **Specific end use(s)** No further relevant information available.

8 Exposure controls/personal protection

- **Additional information about design of technical systems:** No further data; see item 7.
- **Control parameters**
 - **Components with limit values that require monitoring at the workplace:**
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
 - **Additional information:** The lists that were valid during the creation were used as basis.
- **Exposure controls**
 - **Personal protective equipment**
 - **General protective and hygienic measures** Wash hands before breaks and at the end of work.
 - **Breathing equipment:** Not required.
 - **Protection of hands:**
Check protective gloves prior to each use for their proper condition.
recommended
 - **Material of gloves**
The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.
 - **Penetration time of glove material**
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

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acc. to OSHA HCS

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Trade name: Durafill VS

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- **For the permanent contact of a maximum of 15 minutes gloves made of the following materials are suitable:**
 - Butyl rubber, BR
 - Nitrile rubber, NBR
- **Eye protection:** Safety glasses
- **Body protection:** Light weight protective clothing

9 Physical and chemical properties

· **Information on basic physical and chemical properties**

· **General Information**

· **Appearance:**

- **Form:** Pasty
- **Color:** Different according to coloring
- **Odor:** Odorless
- **Odor threshold:** Not determined.

· **pH-value:** Not determined.

· **Change in condition**

- **Melting point/Melting range:** undetermined
- **Boiling point/Boiling range:** 250 °C (482 °F)

· **Flash point:** 151 °C (304 °F)

· **Flammability (solid, gaseous)** Not applicable.

· **Ignition temperature:**

- **Decomposition temperature:** Not determined.

· **Auto igniting:** Product is not selfigniting.

· **Danger of explosion:** Product does not present an explosion hazard.

· **Explosion limits:**

- **Lower:** Not determined.
- **Upper:** Not determined.

· **Vapor pressure:** Not determined.

· **Density at 20 °C (68 °F):** 0 g/cm³ (0 lbs/gal)

- **Relative density** Not determined.
- **Vapor density** Not determined.
- **Evaporation rate** Not determined.

· **Solubility in / Miscibility with**

- **Water:** Not miscible or difficult to mix

· **Partition coefficient (n-octanol/water):** Not determined.

· **Viscosity:**

- **dynamic at 20 °C (68 °F):** 10000 mPas
- **kinematic:** Not determined.

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· **Solvent content:**

· **Solids content:**

75.3 %

· **Other information**

No further relevant information available.

10 Stability and reactivity

- **Reactivity** No further relevant information available.
- **Possibility of hazardous reactions** No dangerous reactions known
- **Conditions to avoid** No further relevant information available.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** none
- **Additional information:**
Product might polymerize after considerable exceeding of recommended storage time or temperature.

11 Toxicological information

· **Information on toxicological effects**

· **Acute toxicity:**

· **LD/LC50 values that are relevant for classification:**

Pyrogenic silica, silanized

Oral LD50 10000 mg/kg (rat)

1565-94-2 Bisphenol A-bis(hydroxypropylmethacrylate)

Oral LD50 >5110 mg/kg (rat)

109-16-0 triethylen glycol dimethacrylate

Oral LD50 > 5000 mg/kg (rat)

Dermal LD50 > 2000 mg/kg (mouse)

41137-60-4 diurethandimethacrylate

Oral LD50 >5000 mg/kg (rat)

24650-42-8 2,2-dimethoxy-1,2-diphenylethan-1-one

Oral LD50 >6000 mg/kg (rat)

Dermal LD50 > 7100 mg/kg (rat)

· **Primary irritant effect:**

· **on the skin:** No irritant effect.

· **on the eye:** No irritating effect.

· **Sensitization:** No sensitizing effects known.

· **Additional toxicological information:**

The product is not subject to classification according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version:

When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

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· **Carcinogenic categories**

· **IARC (International Agency for Research on Cancer)**

Butyl-hydroxy-toluol

3

· **NTP (National Toxicology Program)**

None of the ingredients is listed.

· **OSHA-Ca (Occupational Safety & Health Administration)**

None of the ingredients is listed.

12 Ecological information

· **Toxicity**

· **Aquatic toxicity:**

109-16-0 triethylen glycol dimethacrylate

EC50/72h > 100 mg/l (algae)

· **Persistence and degradability** No further relevant information available.

· **Behavior in environmental systems:**

· **Bioaccumulative potential** No further relevant information available.

· **Mobility in soil** No further relevant information available.

· **Additional ecological information:**

· **General notes:**

Do not allow product to reach ground water, water course or sewage system.

Danger to drinking water if even small quantities leak into the ground.

· **Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

· **Other adverse effects** No further relevant information available.

13 Disposal considerations

· **Waste treatment methods**

· **Recommendation** Smaller quantities can be disposed of with household waste.

· **Uncleaned packagings:**

· **Recommendation:** Disposal must be made according to official regulations.

14 Transport information

· **UN-Number**

· **DOT, ADR, ADN, IMDG, IATA**

Void

· **UN proper shipping name**

· **DOT, ADR, ADN, IMDG, IATA**

Void

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- | | |
|--|-----------------|
| · Transport hazard class(es) | |
| · DOT, ADR, ADN, IMDG, IATA | |
| · Class | Void |
| · Packing group | |
| · DOT, ADR, IMDG, IATA | Void |
| · Environmental hazards: | |
| · Marine pollutant: | No |
| · Special precautions for user | Not applicable. |
| · Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code | Not applicable. |
| · Transport/Additional information: | - |
| · UN "Model Regulation": | Void |

15 Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**

- **SARA Section 355 (extremely hazardous substances)**

None of the ingredients is listed.

- **Carcinogeny categories**

- **TLV (Threshold Limit Value established by ACGIH)**

Butyl-hydroxy-toluol

A4

- **GHS label elements**

The product is classified and labeled according to the Globally Harmonized System (GHS).

- **Hazard pictograms**



GHS07

- **Signal word** Warning

- **Hazard-determining components of labeling:**

triethylen glycol dimethacrylate

- **Hazard statements**

May cause an allergic skin reaction.

- **Precautionary statements**

Avoid breathing dust/fume/gas/mist/vapors/spray

Wear protective gloves.

Specific treatment (see on this label).

Wash contaminated clothing before reuse.

If skin irritation or rash occurs: Get medical advice/attention.

IF ON SKIN: Wash with plenty of water.

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acc. to OSHA HCS

Printing date 06/03/2017

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Trade name: Durafill VS

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· **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

16 Other information

These data are based on our present knowledge. However, they shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· **Relevant phrases**

H317 May cause an allergic skin reaction.

· **Date of preparation / last revision** 06/03/2017 / 1

· **Abbreviations and acronyms:**

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation

IATA: International Air Transport Association

ACGIH: American Conference of Governmental Industrial Hygienists

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

NFPA: National Fire Protection Association (USA)

HMIS: Hazardous Materials Identification System (USA)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

OSHA: Occupational Safety & Health

TLV: Threshold Limit Value

PEL: Permissible Exposure Limit

REL: Recommended Exposure Limit

Skin Sens. 1: Skin sensitisation – Category 1

Skin Sens. 1B: Skin sensitisation – Category 1B

· *** Data compared to the previous version altered.**

USA