

SAFETY DATA SHEETS

This SDS packet was issued with item:

074562153

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).

074562120 074562138 074562146

**Safety Data Sheet
acc. to OSHA HCS**

Printing date 05/12/2015

Reviewed on 05/12/2015

1 Identification

· **Product identifier**

· **Trade name:** **Venus Bulk Fill**

· **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

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

· **Manufacturer/Supplier:**

Heraeus Kulzer GmbH
Grüner Weg 11, D-63450 Hanau

Tel.: 0800 4372522

· **Information department:**

Marc Henn
Tel. +1 (574) 2995444 / Fax: +1 (574) 2912542
e-mail: marc.henn@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 Irrit. 2 H315 Causes skin irritation.

Eye Irrit. 2A H319 Causes serious eye irritation.

· **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 statements**

Causes skin irritation.

Causes serious eye irritation.

· **Precautionary statements**

Wear protective gloves/protective clothing/eye protection/face protection.

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Specific treatment (see on this label).

Take off contaminated clothing and wash before reuse.

If skin irritation occurs: Get medical advice/attention.

If eye irritation persists: Get medical advice/attention.

· **Classification system**

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



Health = 0

Fire = 1

Reactivity = 0

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Trade name: Venus Bulk Fill

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· HMIS-Ratings (Scale 0-4)

HEALTH	0
FIRE	1
REACTIVITY	0

Health = 0

Fire = 1

Reactivity = 0

· Results of PBT and vPvB assessment**· PBT:** Not applicable.**· vPvB:** Not applicable.**3 Composition/information on ingredients****· Chemical characterization:** Mixtures**· Description:** -**· Dangerous components:** Void**4 First-aid measures****· Description of first aid measures****· General information** No special measures required.**· After inhalation** Supply fresh air; consult doctor in case of complaints.**· After skin contact** Immediately wash with water and soap and rinse thoroughly.**· After eye contact** Rinse opened eye for several minutes under running water.**· After swallowing** Rinse out mouth and then drink plenty of water.**· 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** -**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:** Pick up mechanically.**· Reference to other sections**

See Section 13 for disposal information.

See Section 8 for information on personal protection equipment.

7 Handling and storage**· Precautions for safe handling** No special measures required.

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Trade name: **Venus Bulk Fill**

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- **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:**
Store in dry conditions.
Keep cool, if possible (not above 25 °C).
- **Specific end use(s)** No further relevant information available.

8 Exposure controls/personal protection

- **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**
The usual precautionary measures for handling chemicals should be followed.
 - **Breathing equipment:** Not required.
 - **Protection of hands:**
The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation
 - **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 of a maximum of 15 minutes gloves made of the following materials are suitable:**
PVC or PE gloves
Natural rubber, NR
 - **Eye protection:**
Protective goggles are recommended.
Not absolutely necessary.
 - **Body protection:** Light weight protective clothing

9 Physical and chemical properties

- **Information on basic physical and chemical properties**
 - **General Information**
 - **Appearance:**
 - **Form:** Pasty
 - **Color:** White
Yellowish
 - **Odor:** Odorless
 - **Change in condition**
 - **Melting point/Melting range:** undetermined
 - **Boiling point/Boiling range:** undetermined
 - **Flash point:** > 100 °C (> 212 °F)

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Trade name: Venus Bulk Fill

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· Auto igniting:	Product is not selfigniting.
· Danger of explosion:	Product does not present an explosion hazard.
· Density at 20 °C (68 °F):	1.9 g/cm ³ (15.856 lbs/gal)
· Solubility in / Miscibility with	
· Water:	Not miscible or difficult to mix
· Other information	No further relevant information available.

10 Stability and reactivity

- **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:** -

11 Toxicological information

- **Information on toxicological effects**
 - **Acute toxicity:**
 - **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.

- **Carcinogenic categories**

· IARC (International Agency for Research on Cancer)		
7631-86-9	silicon dioxide, chemically prepared	3
	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:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.
- **Additional ecological information:**
 - **General notes:** Avoid transfer into the environment.
- **Results of PBT and vPvB assessment**
 - **PBT:** Not applicable.
 - **vPvB:** Not applicable.

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· **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
- **UN proper shipping name**
 - DOT, ADR, ADN, IMDG, IATA
- **Transport hazard class(es)**
 - DOT, ADR, ADN, IMDG, IATA
 - Class
- **Packing group**
 - DOT, ADR, IMDG, IATA
- **Environmental hazards:**
 - **Marine pollutant:**
- **Special precautions for user**
- **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code**
- **Transport/Additional information:**
- **UN "Model Regulation":**

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.**
- **TSCA (Toxic Substances Control Act)** Medical devices are exempted from TSCA.
- **Carcinogenity categories**
 - **TLV (Threshold Limit Value established by ACGIH)**
- **Butyl-hydroxy-toluol**
- **GHS label elements**
 - **The product is classified and labeled according to the Globally Harmonized System (GHS).**
 - **Hazard pictograms**



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Trade name: Venus Bulk Fill

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· **Signal word** Warning· **Hazard statements**

Causes skin irritation.

Causes serious eye irritation.

· **Precautionary statements**

Wear protective gloves/protective clothing/eye protection/face protection.

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Specific treatment (see on this label).

Take off contaminated clothing and wash before reuse.

If skin irritation occurs: Get medical advice/attention.

If eye irritation persists: Get medical advice/attention.

· **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.

· **Date of preparation / last revision** 05/12/2015 / -· **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)

Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2

Eye Irrit. 2A: Serious eye damage/eye irritation, Hazard Category 2A

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

USA



Safety Data Sheet
acc. to OSHA HCS

Printing date 06/03/2017

Reviewed on 06/03/2017

1 Identification

· **Product identifier**

· **Trade name:** **Venus Bulk Fill**

· **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 Irrit. 2 H315 Causes skin irritation.

Eye Irrit. 2A H319 Causes serious eye irritation.

· **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 statements**

Causes skin irritation.

Causes serious eye irritation.

· **Precautionary statements**

Wear protective gloves.

Wear eye protection / face protection.

If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Specific treatment (see on this label).

If skin irritation occurs: Get medical advice/attention.

If eye irritation persists: Get medical advice/attention.

· **Classification system**

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



Health = 1

Fire = 1

Reactivity = 0

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Trade name: Venus Bulk Fill

· **HMIS-Ratings (Scale 0-4)**

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

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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: -**

· **Dangerous components:**

13760-80-0	ytterbium trifluoride Skin Irrit. 2, H315; Eye Irrit. 2A, H319; STOT SE 3, H335	10-25%
109-16-0	triethylen glycol dimethacrylate Skin Sens. 1B, H317	< 1%

4 First-aid measures

· **Description of first aid measures**

- **General information** No special measures required.
- **After inhalation** Supply fresh air; consult doctor in case of complaints.
- **After skin contact** Immediately wash with water and soap and rinse thoroughly.
- **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.

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Trade name: Venus Bulk Fill

· **Additional information -**

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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:** Pick up mechanically.
- **Reference to other sections**
See Section 13 for disposal information.
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:**
Store in dry conditions.
Keep cool, if possible (not above 25 °C).
- **Specific end use(s)** No further relevant information available.

8 Exposure controls/personal protection

- **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:**
The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation
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

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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.

· **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:**

White

Yellowish

· **Odor:**

Odorless

· **Odor threshold:**

Not determined.

· **pH-value:**

Not determined.

· **Change in condition**

· **Melting point/Melting range:**

undetermined

· **Boiling point/Boiling range:**

undetermined

· **Flash point:**

> 100 °C (> 212 °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):**

1.9 g/cm³ (15.856 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

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Trade name: Venus Bulk Fill

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- **Partition coefficient (n-octanol/water):** Not determined.
- **Viscosity:**
 - **dynamic:** Not determined.
 - **kinematic:** Not determined.
- **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:** -

11 Toxicological information

- **Information on toxicological effects**

- **Acute toxicity:**

· LD/LC50 values that are relevant for classification:		
56744-60-6 Bisphenol-A-ethoxylat(4)dimethacrylat		
Oral	LD50	>2000 mg/kg (rat)
41137-60-4 diurethandimethacrylate		
Oral	LD50	>5000 mg/kg (rat)
109-16-0 triethylen glycol dimethacrylate		
Oral	LD50	> 5000 mg/kg (rat)
Dermal	LD50	> 2000 mg/kg (mouse)

- **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.

- **Carcinogenic categories**

· IARC (International Agency for Research on Cancer)		
7631-86-9	silicon dioxide, chemically prepared	3
	Butyl-hydroxy-toluol	3

- **NTP (National Toxicology Program)**

None of the ingredients is listed.

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Trade name: Venus Bulk Fill

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· 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: Avoid transfer into the environment.

· 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

· Transport hazard class(es)

· DOT, ADR, ADN, IMDG, IATA
· Class Void

· Packing group

· DOT, ADR, IMDG, IATA Void

· Environmental hazards:

· Marine pollutant: No

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Reviewed on 06/03/2017

Trade name: Venus Bulk Fill

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- | | |
|--|-----------------|
| · 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.

- **TSCA (Toxic Substances Control Act)** Medical devices are exempted from TSCA.

- **Cancerogenity 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 statements**

Causes skin irritation.

Causes serious eye irritation.

- **Precautionary statements**

Wear protective gloves.

Wear eye protection / face protection.

If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Specific treatment (see on this label).

If skin irritation occurs: Get medical advice/attention.

If eye irritation persists: Get medical advice/attention.

- **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**

H315 Causes skin irritation.

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USA



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Reviewed on 06/03/2017

Trade name: Venus Bulk Fill

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H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.

H335 May cause respiratory irritation.

• **Date of preparation / last revision** 06/03/2017 / 2

• **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 Irrit. 2: Skin corrosion/irritation – Category 2

Eye Irrit. 2A: Serious eye damage/eye irritation – Category 2A

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

STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

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

USA