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Safety Data Sheet acc. to OSHA HCS

Printing date 11/16/2022 Reviewed on 11/16/2022 1 Identification · Product identifier · Trade name: VENUS Pearl · Application of the substance / the mixture Dental filling material · Details of the supplier of the safety data sheet Manufacturer/Supplier: Kulzer GmbH Tel.: +49 (0)800 4372522 Leipziger Straße 2, 63450 Hanau (Germany) · 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) ID 105860: (domestic) 1 800 535 5053 or international (001) 352 323 3500 2 Hazard(s) identification Classification of the substance or mixture Sensitization - Skin 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: 2-Propenoic acid, 1,1'-[(octahydro-4,7-methano-1H-indene-5,?-diyl) bis(methyleneoxycarbonylamino-2,1-ethanediyl)] ester 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate triethylen glycol dimethacrylate Hazard statements May cause an allergic skin reaction. · Precautionary statements Avoid release to the environment. Wear protective gloves/protective clothing/eye protection/face protection. If on skin: Wash with plenty of soap and water. If skin irritation or rash occurs: Get medical advice/attention. Classification system NFPA ratings for USA (scale 0-4) Health = 0Fire = 1Reactivity = 0(Contd. on page 2)

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FIRE

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· HMIS-Ratings (Scale 0-4)

HEALTH 0

Health = 0 1 Fire = 1 REACTIVITY 0 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:

945656-78-0	945656-78-0 2-Propenoic acid, 1,1'-[(octahydro-4,7-methano-1H-indene-5,?-diyl bis(methyleneoxycarbonylamino-2,1-ethanediyl)] ester			
	Sensitization - Skin 1, H317			
72869-86-4	7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane- 1,16-diyl bismethacrylate	≥0.1-<1%		
	Sensitization - Skin 1B, H317			
109-16-0	triethylen glycol dimethacrylate	<i>≥</i> 0.1-<1%		
	Sensitization - Skin 1B, H317			
. Additions	information For the wording of the listed becard phrases refer to section 1	6		

Additional information For the wording of the listed hazard phrases refer to section 16.

4 First-aid measures

· Description of first aid measures

After inhalation Supply fresh air; consult doctor in case of complaints.

- After skin contact
- Immediately wash with water and soap and rinse thoroughly.
- If skin irritation continues, consult a doctor.
- After eye contact
- Rinse opened eye for several minutes under running water. Then consult a doctor.
- 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
- Use fire fighting measures that suit the environment.

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

[·] Special hazards arising from the substance or mixture

Formation of toxic gases is possible during heating or in case of fire.

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- · Advice for firefighters
- Protective equipment: No special measures required.
- · Additional information -

6 Accidental release measures

Personal precautions, protective equipment and emergency procedures Wear protective equipment. Keep unprotected persons away. · Environmental precautions: Do not allow to enter sewers/ surface or ground water. Do not allow to penetrate the ground/soil. Methods and material for containment and cleaning up: Absorb with liquid binding material (diatomite, universal binders, for small amounts tissues). Dispose of the collected material according to regulations. Reference to other sections See Section 7 for information on safe handling See Section 8 for information on personal protection equipment. See Section 13 for disposal information. · Protective Action Criteria for Chemicals · PAC-1: 112945-52-5 Amorphous silica 18 mg/m³ 72869-86-4 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-120 mg/m³ 1,16-diyl bismethacrylate 33 ma/m³ 109-16-0 triethylen glycol dimethacrylate 2530-85-0 3-trimethoxysilylpropyl methacrylate 71 mg/m³ 7775-14-6 sodium dithionite 30 mg/m³ 579-07-7 1-Phenyl-1,2-propandion 0.4 mg/m³ 80-62-6 methyl methacrylate 17 ppm 64-19-7 acetic acid 5 ppm · PAC-2: 100 mg/m³ 112945-52-5 Amorphous silica 72869-86-4 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,300 mg/m³ 1,16-diyl bismethacrylate 109-16-0 triethylen glycol dimethacrylate 360 mg/m³ 2530-85-0 3-trimethoxysilylpropyl methacrylate 780 mg/m³ 7775-14-6 sodium dithionite 330 mg/m³ 579-07-7 1-Phenyl-1,2-propandion 4.5 mg/m³ 80-62-6 methyl methacrylate 120 ppm 64-19-7 acetic acid 35 ppm · PAC-3: 112945-52-5 Amorphous silica 630 mg/m³ 72869-86-4 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-7,900 mg/m³ 1,16-diyl bismethacrylate 109-16-0 triethylen glycol dimethacrylate 2,100 mg/m³ 2530-85-0 3-trimethoxysilylpropyl methacrylate 4,700 mg/m³ 7775-14-6 sodium dithionite 2,000 mg/m³ 579-07-7 1-Phenyl-1,2-propandion 27 mg/m³ (Contd. on page 4)

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570 ppm

250 ppm

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80-62-6 methyl methacrylate

64-19-7 acetic acid

7 Handling and storage

· Handling

• **Precautions for safe handling** Ensure good ventilation/exhaustion at the workplace. • **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: None.

• 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.

Not required.

• Additional information: The lists that were valid during the creation were used as basis.

· Exposure controls

- ¹Personal protective equipment
 - General protective and hygienic measures
 - Immediately remove all soiled and contaminated clothing
 - Wash hands before breaks and at the end of work.
 - · Breathing equipment: Not required.
 - Protection of hands:

If skin contact cannot be avoided, protective gloves are recommended to

avoid possible sensitization.

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.

- 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: Not absolutely necessary.
- · Body protection: Light weight protective clothing

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9 Physical and chemical properti	es
· Information on basic physical and che	
General Information	
Appearance: Form:	Pastv
· 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: 	undetermined
· Flash point:	>100 °C (>212 °F)
· Flammability (solid, gaseous)	Not applicable.
· 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):	2.1 g/cm³ (17.5245 lbs/gal)
· Relative density	Ňot determined.
· Vapor density	Not determined.
Evaporation rate	Not determined.
 Solubility in / Miscibility with 	
· Water:	Not miscible or difficult to mix
· Partition coefficient (n-octanol/wat	er): 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: -

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· Acute tox	on toxicological effects
	50 values that are relevant for classification:
-	7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diy
	pismethacrylate
	0 >5000 mg/kg (rat) (OECD 401)
	0 >2000 mg/kg (rat) (OECD 402)
	thylen glycol dimethacrylate
	0 8300 mg/kg (rat)
Dermal LD5	0 >2000 mg/kg (mouse)
	ry irritant effect:
	the skin: No irritant effect.
	the eye: No irritating effect. fization: No sensitizing effects known.
· Additiona	al toxicological information:
	nogenic categories
	RC (International Agency for Research on Cancer)
	ngredients is listed.
	•
	P (National Toxicology Program) ngredients is listed.
	•
	HA-Ca (Occupational Safety & Health Administration)
None of the i	ngredients is listed.
None of the i	
None of the i	ngredients is listed.
None of the i · Rej	ngredients is listed. productive toxicity Based on available data, the classification criteria are not met.
None of the in Rep 2 Ecologica	ngredients is listed.
None of the i Rep 2 Ecologica Toxicity	ngredients is listed. productive toxicity Based on available data, the classification criteria are not met. I information
None of the i Rep 2 Ecologica Toxicity Aquatic t	ngredients is listed. productive toxicity Based on available data, the classification criteria are not met. I information oxicity:
None of the i Rep 2 Ecologica Toxicity Aquatic t 72869-86-4 7	ngredients is listed. productive toxicity Based on available data, the classification criteria are not met. I information oxicity:
None of the i Rep 2 Ecologica Toxicity Aquatic t 72869-86-4 7	ngredients is listed. productive toxicity Based on available data, the classification criteria are not met. I information oxicity: 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diy
None of the in Rep 2 Ecologica Toxicity Aquatic t 72869-86-4 7 k EC50/48h	ngredients is listed. productive toxicity Based on available data, the classification criteria are not met. I information oxicity: 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diy oismethacrylate
None of the in Rep 2 Ecologica Toxicity Aquatic t 72869-86-4 7 k EC50/48h LC50/96h	ngredients is listed. productive toxicity Based on available data, the classification criteria are not met. I information oxicity: 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diy pismethacrylate >1.2 mg/l (daphnia) (OECD 202)
None of the in Rep 2 Ecologica Toxicity Aquatic t 72869-86-47 k EC50/48h LC50/96h ErC50 / 72 h	ngredients is listed. productive toxicity Based on available data, the classification criteria are not met. I information oxicity: 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diy pismethacrylate >1.2 mg/l (daphnia) (OECD 202) 10.1 mg/l (fish) (OECD 203)
None of the in Rej 2 Ecologica Toxicity Aquatic t 72869-86-4 7 EC50/48h LC50/96h ErC50 / 72 h NOEC / 72h	ngredients is listed. productive toxicity Based on available data, the classification criteria are not met. I information oxicity: 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diy pismethacrylate >1.2 mg/l (daphnia) (OECD 202) 10.1 mg/l (fish) (OECD 203) >0.68 mg/l (algae) (OECD 201)
None of the in Rej 2 Ecologica Toxicity Aquatic t 72869-86-4 7 EC50/48h LC50/96h ErC50 / 72 h NOEC / 72h	ngredients is listed. productive toxicity Based on available data, the classification criteria are not met. I information oxicity: 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diy pismethacrylate >1.2 mg/l (daphnia) (OECD 202) 10.1 mg/l (fish) (OECD 203) >0.68 mg/l (algae) (OECD 201) 0.21 mg/l (algae) (OECD 201)
None of the in Rep 2 Ecologica Toxicity Aquatic t 72869-86-4 7 k EC50/48h LC50/96h ErC50 / 72 h NOEC / 72h 109-16-0 trie	ngredients is listed. productive toxicity Based on available data, the classification criteria are not met. I information oxicity: 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diy pismethacrylate >1.2 mg/l (daphnia) (OECD 202) 10.1 mg/l (fish) (OECD 203) >0.68 mg/l (algae) (OECD 201) 0.21 mg/l (algae) (OECD 201) othylen glycol dimethacrylate
None of the in Rep 2 Ecologica Toxicity Aquatic t 72869-86-47 EC50/48h LC50/96h ErC50 / 72 h NOEC / 72h 109-16-0 trie EC50/21d LC50/96h	ngredients is listed. productive toxicity Based on available data, the classification criteria are not met. I information oxicity: 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diy pismethacrylate >1.2 mg/l (daphnia) (OECD 202) 10.1 mg/l (fish) (OECD 203) >0.68 mg/l (algae) (OECD 201) 0.21 mg/l (algae) (OECD 201) 0.21 mg/l (algae) (OECD 201) 0.21 mg/L (daphnia) (OECD 211) 16.4 mg/l (fish) (OECD 203)
None of the in Rep 2 Ecologica Toxicity Aquatic t 72869-86-47 k EC50/48h LC50/96h ErC50 / 72 h NOEC / 72h 109-16-0 trie EC50/21d LC50/96h NOEC / 21d	ngredients is listed. productive toxicity Based on available data, the classification criteria are not met. I information oxicity: 7,79(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diy pismethacrylate >1.2 mg/l (daphnia) (OECD 202) 10.1 mg/l (fish) (OECD 203) >0.68 mg/l (algae) (OECD 201) 0.21 mg/l (algae) (OECD 201) thylen glycol dimethacrylate 51.9 mg/L (daphnia) (OECD 211) 16.4 mg/l (fish) (OECD 203) 32 mg/l (daphnia) (OECD 211)
None of the in Rep 2 Ecologica Toxicity Aquatic t 72869-86-4 7 EC50/48h LC50/96h ErC50 / 72 h NOEC / 72h 109-16-0 trie EC50/21d LC50/96h NOEC / 21d ErC50 / 72 h	ngredients is listed. productive toxicity Based on available data, the classification criteria are not met. I information oxicity: 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diy pismethacrylate >1.2 mg/l (daphnia) (OECD 202) 10.1 mg/l (fish) (OECD 203) >0.68 mg/l (algae) (OECD 201) 0.21 mg/l (algae) (OECD 201) 0.21 mg/l (algae) (OECD 201) thylen glycol dimethacrylate 51.9 mg/L (daphnia) (OECD 211) 16.4 mg/l (fish) (OECD 203) 32 mg/l (daphnia) (OECD 211) >100 mg/l (algae) (OECD 201)
None of the in Rep 2 Ecologica Toxicity Aquatic t 72869-86-4 7 k EC50/48h LC50/96h ErC50 / 72 h NOEC / 72h NOEC / 21d ErC50 / 72 h NOEC / 21d ErC50 / 72 h NOEC / 72h	ngredients is listed. productive toxicity Based on available data, the classification criteria are not met. I information oxicity: 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diy bismethacrylate >1.2 mg/l (daphnia) (OECD 202) 10.1 mg/l (fish) (OECD 203) >0.68 mg/l (algae) (OECD 201) 0.21 mg/l (algae) (OECD 201) 0.21 mg/l (algae) (OECD 201) thylen glycol dimethacrylate 51.9 mg/L (daphnia) (OECD 211) 16.4 mg/l (fish) (OECD 203) 32 mg/l (daphnia) (OECD 211) >100 mg/l (algae) (OECD 201) 18.6 mg/l (algae) (OECD 201)
None of the in Rep 2 Ecologica Toxicity Aquatic t 72869-86-47 EC50/48h LC50/96h ErC50 / 72 h NOEC / 72h 109-16-0 trie EC50/21d LC50/96h NOEC / 21d ErC50 / 72 h NOEC / 72h EbC50 / 72h	ngredients is listed. productive toxicity Based on available data, the classification criteria are not met. I information oxicity: 7,79(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diy bismethacrylate >1.2 mg/l (daphnia) (OECD 202) 10.1 mg/l (fish) (OECD 203) >0.68 mg/l (algae) (OECD 201) 0.21 mg/l (algae) (OECD 201) thylen glycol dimethacrylate 51.9 mg/L (daphnia) (OECD 211) 16.4 mg/l (fish) (OECD 203) 32 mg/l (daphnia) (OECD 211) >100 mg/l (algae) (OECD 201) 18.6 mg/l (algae) (OECD 201) 72.8 mg/l (algae) (OECD 201)
None of the in Rep 2 Ecologica Toxicity Aquatic t 72869-86-47 EC50/48h LC50/96h ErC50 / 72 h NOEC / 72h 109-16-0 trie EC50/21d LC50/96h NOEC / 21d ErC50 / 72 h NOEC / 72h EbC50 / 72h	ngredients is listed. productive toxicity Based on available data, the classification criteria are not met. I information oxicity: 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diy bismethacrylate >1.2 mg/l (daphnia) (OECD 202) 10.1 mg/l (fish) (OECD 203) >0.68 mg/l (algae) (OECD 201) 0.21 mg/l (algae) (OECD 201) 0.21 mg/l (algae) (OECD 201) thylen glycol dimethacrylate 51.9 mg/L (daphnia) (OECD 211) 16.4 mg/l (fish) (OECD 203) 32 mg/l (daphnia) (OECD 211) >100 mg/l (algae) (OECD 201) 18.6 mg/l (algae) (OECD 201)



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72869-86-4 7.7.9(or 7.9.9)-trimethyl-4.13-dioxo-3.14-dioxa-5.12-diazahexadecane-1.16-diyl bismethacrylate

biodegradability 22 % /28d (not defined) (OECD 301B; ISO/ 9439/ EEC 92/69/V. C.4-C)

109-16-0 triethylen glycol dimethacrylate

biodegradability 85 % /28d (not defined) (OECD 301B; ISO/ 9439/ EEC 92/69/V, C.4-C)

- 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

Small quantities can be polymerized by light and the cured solid material can be disposed of with the regular garbage. Larger quantities must be disposed of following the regulations of the local authorities.

· Uncleaned packagings:

Recommendation: Disposal must be made according to official regulations.

UN-Number · DOT, ADR, ADN, IMDG, IATA	Void	
	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	
Special precautions for user	Not applicable.	
Transport in bulk according to Annex MARPOL73/78 and the IBC Code	II of Not applicable.	
Transport/Additional information:	-	
UN "Model Regulation":	Void	

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5 Regulatory information	
 Safety, health and environmental regulations/legislation specific for the substan No further relevant information available. Sara 	nce or mixtu
· SARA Section 355 (extremely hazardous substances)	
None of the ingredients is listed.	
· SARA Section 313 (specific toxic chemical listings)	
80-62-6 methyl methacrylate	
· Hazardous Air Pollutants	
80-62-6 methyl methacrylate	
Proposition 65	
Prop 65 - Chemicals known to cause cancer	
None of the ingredients is listed.	
• Chemicals known to cause reproductive toxicity for females:	
None of the ingredients is listed.	
• Chemicals known to cause reproductive toxicity for males:	
None of the ingredients is listed.	
· Chemicals known to cause developmental toxicity:	
None of the ingredients is listed.	
· Cancerogenity categories	
· EPA (Environmental Protection Agency)	
80-62-6 methyl methacrylate	E, N
· TLV (Threshold Limit Value)	
None of the ingredients is listed.	
· NIOSH-Ca (National Institute for Occupational Safety and Health)	
None of the ingredients is listed.	
· Chemical safety assessment: A Chemical Safety Assessment has not been carried	out.
6 Other information	
These data are based on our present knowledge. However, they shall not constitute any specific product features and shall not establish a legally valid contractual relation • Relevant phrases H317 May cause an allergic skin reaction. • Date of preparation / last revision 11/16/2022	a guarantee Iship.

 Date of preparation rast revision 11/10/2022
 Abbreviations and acronyms:
 ADR: Accord relatif au transport international 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
 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) CAS: Chemical Abstracts Service (division of the American Chemical Society) NFPA: National Fire Protection Association (USA) HMIS: Hazardous Materials Identification (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 (Contd. on page 9)



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NIOSH: National Institute for Occupational Safety OSHA: Occupational Safety & Health TLV: Threshold Limit Value PEL: Permissible Exposure Limit REL: Recommended Exposure Limit Sensitization - Skin 1: Skin sensitisation – Category 1 Sensitization - Skin 1B: Skin sensitisation – Category 1B • * **Data compared to the previous version altered.**

US