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

Printing date 29.07.2020

Version number 4

Revision: 29.07.2020

1.1 Product id	
· Trade name	e: Paladur liquid
	dentified uses of the substance or mixture and uses advised against vant information available.
 Application 	of the substance / the mixture Manufacture of dental prothesis
1.3 Details of t	he supplier of the safety data sheet
· Manufactur	er/Supplier:
Kulzer Gmb	H raße 2, 63450 Hanau (Germany)
, .	
	lepartment: E-Mail: msds@kulzer-dental.com / telephone number: Emergency CONTACT (24-Hour-Number): +49 (0)6132-8446.
SECTION 2:	Hazards identification
	ion of the substance or mixture
	on according to Regulation (EC) No 1272/2008
Flam. Liq. 2	
Skin Irrit. 2	
Skin Sens.	
STOT SE 3	
Aquatic Chr	onic 3 H412 Harmful to aquatic life with long lasting effects.
The product	ents ccording to Regulation (EC) No 1272/2008 is classified and labelled according to the CLP regulation. pictograms
 Labelling a The product 	ccording to Regulation (EC) No 1272/2008 is classified and labelled according to the CLP regulation.
 Labelling a The product 	ccording to Regulation (EC) No 1272/2008 is classified and labelled according to the CLP regulation.
• Labelling a The product • Hazard p GHS02	ccording to Regulation (EC) No 1272/2008 is classified and labelled according to the CLP regulation. pictograms
Labelling a The product Hazard J GHS02 Signal w Hazard-d	ccording to Regulation (EC) No 1272/2008 This classified and labelled according to the CLP regulation. Dictograms GHS07 Ford Danger Determining components of labelling:
• Labelling a The product • Hazard J GHS02 • Signal w • Hazard-u methyl m	ccording to Regulation (EC) No 1272/2008 T is classified and labelled according to the CLP regulation. Dictograms GHS07 Ford Danger Contemponents of labelling: Diethacrylate
• Labelling a The product • Hazard J GHS02 • Signal w • Hazard- methyl m tetrameti	ccording to Regulation (EC) No 1272/2008 ris classified and labelled according to the CLP regulation. Dictograms GHS07 rord Danger determining components of labelling: methacrylate mylene dimethacrylate
• Labelling a The product • Hazard p GHS02 • Signal w • Hazard-o methyl m tetrameti 2-(2H-Be	ccording to Regulation (EC) No 1272/2008 is classified and labelled according to the CLP regulation. Dictograms
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Labelling a The product Hazard J GHS02 Signal w Hazard- methyl m tetrameth 2-(2H-Be Hazard s H225 Hig	ccording to Regulation (EC) No 1272/2008 is classified and labelled according to the CLP regulation. Dictograms
Labelling a The product Hazard f GHS02 Signal w Hazard-c methyl m tetrameth 2-(2H-Be Hazard s H225 Hig H315 Ca H317 Ma	ccording to Regulation (EC) No 1272/2008 is classified and labelled according to the CLP regulation. Dictograms
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Labelling a The product Hazard J GHS02 Signal w Hazard-o methyl m tetrameth 2-(2H-Be Hazard s H225 Hig H315 Ca H317 Ma H335 Ma H412 Ha	ccording to Regulation (EC) No 1272/2008 is classified and labelled according to the CLP regulation. bictograms
Labelling a The product Hazard J GHS02 Signal w Hazard- methyl m tetrameth 2-(2H-Be Hazard s H225 Hig H315 Ca H317 Ma H315 Ca H317 Ma H315 Ma H412 Ha Precauth P210 P260	ccording to Regulation (EC) No 1272/2008 is classified and labelled according to the CLP regulation. bictograms
Labelling a The product Hazard J GHS02 Signal w Hazard- methyl m tetrameth 2-(2H-Be Hazard s H225 Hig H315 Ca H317 Ma H315 Ca H317 Ma H335 Ma H412 Ha Precauth P210 P260 P273	cording to Regulation (EC) No 1272/2008 is classified and labelled according to the CLP regulation. bictograms GHS07 rord Danger determining components of labelling: nethacrylate hylene dimethacrylate hylene dimethacrylat
Labelling a The product Hazard J GHS02 Signal w Hazard- methyl m tetrameth 2-(2H-Be Hazard s H225 Hig H315 Ca H317 Ma H315 Ca H317 Ma H315 Ca H317 Ma H315 Ca H317 Ma H325 Ma H412 Ha	cording to Regulation (EC) No 1272/2008 is classified and labelled according to the CLP regulation. bictograms
Labelling a The product Hazard J GHS02 Signal w Hazard- methyl m tetrameth 2-(2H-Be Hazard s H225 Hig H315 Ca H317 Ma H315 Ca H317 Ma H315 Ca H317 Ma H315 Ca H317 Ma H325 Ma H412 Ha	cording to Regulation (EC) No 1272/2008 is classified and labelled according to the CLP regulation. bictograms GHS07 rord Danger determining components of labelling: hethacrylate hylene dimethacrylate enzotriazol-2-yl)-4-methylphenol statements hyly flammable liquid and vapour. uses skin irritation. y cause an allergic skin reaction. y cause and the long lasting effects. ionary statements Keep away from heat, hot surfaces, sparks, open flames and other ignitic sources. No smoking. Do not breathe dust/fume/gas/mist/vapours/spray. Avoid release to the environment. Wear protective gloves/protective clothing/eye protection/face protection. 813 If skin irritation or rash occurs: Get medical advice/attention.



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Results of PBT and vPvB assessment

· PBT: Not applicable.

vPvB: Not applicable.

SECTION 3: Composition/information on ingredients

· 3.2 Chemical characterisation: Mixtures Description:

Product based on methacrylates

 Dangerous components: 		
CAS: 80-62-6 EINECS: 201-297-1 Reg.nr.: 01-2119452498-28-XXXX	methyl methacrylate Flam. Liq. 2, H225 Skin Irrit. 2, H315; Skin Sens. 1, H317; STOT SE 3, H335	>90%
CAS: 2082-81-7 EINECS: 218-218-1 Reg.nr.: 02-2119849716-25	tetramethylene dimethacrylate Skin Sens. 1B, H317	<i>≥1-≤</i> 5%
CAS: 2440-22-4 Reg.nr.: 01-2119583811-34-0000 01-2119583811-34-0001	2-(2H-Benzotriazol-2-yl)-4-methylphenol Aquatic Chronic 1, H410 Skin Sens. 1, H317	<i>≥</i> 0.25-<1%
CAS: 99-97-8 EINECS: 202-805-4 Reg.nr.: 01-2119956633-31-xxxx	N,N-dimethyl-p-toluidine Acute Tox. 3, H301; Acute Tox. 3, H311; Acute Tox. 2, H330 STOT RE 2, H373 Aquatic Chronic 3, H412	<1%

SECTION 4: First aid measures

· 4.1 Description of first aid measures

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

- After skin contact If skin irritation continues, consult a doctor.
- After eye contact
- Rinse opened eye for several minutes under running water. Then consult doctor.
- 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 Allergic reactions
- **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, sand, extinguishing powder. Do not use water. For safety reasons unsuitable extinguishing agents Water.

• 5.2 Special hazards arising from the substance or mixture

Can form explosive gas-air mixtures.

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

- 5.3 Advice for firefighters
 - Protective equipment: No special measures required.

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· Additional information -

SECTION 6: Accidental release measures 6.1 Personal precautions, protective equipment and emergency procedures Wear protective equipment. Keep unprotected persons away. • 6.2 Environmental precautions: Prevent material from reaching sewage system, holes and cellars. · 6.3 Methods and material for containment and cleaning up: Absorb with liquid-binding material (diatomite, universal binders, for small amounts tissues). Do not flush with water or aqueous cleansing agents Send for recovery or disposal in suitable containers. · 6.4 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 information on disposal. SECTION 7: Handling and storage · 7.1 Precautions for safe handling Keep containers tightly sealed. Ensure good ventilation/exhaustion at the workplace. Prevent formation of aerosols. Ensure good interior ventilation, especially at floor level. (Fumes are heavier than air). Information about protection against explosions and fires: Keep ignition sources away - Do not smoke. Protect against electrostatic charges. · 7.2 Conditions for safe storage, including any incompatibilities Storage Requirements to be met by storerooms and containers: Store in cool location. · Information about storage in one common storage facility: Not required. · Further information about storage conditions: Store cool (not above 25 °C). Store in cool, dry conditions in well sealed containers. • 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: 80-62-6 methyl methacrylate WEL (Great Britain) Short-term value: 416 mg/m³, 100 ppm Long-term value: 208 mg/m³, 50 ppm Short-term value: 100 ppm IOELV (European Union) Long-term value: 50 ppm · DNELs 80-62-6 methyl methacrylate worker industr., I.te., syst. 74.3 mg/Kg/d (human) Dermal Inhalative worker industr., I.te., syst. 210 mg/m3 (human) (Contd. on page 4)



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2440-22-4	4 2-(2H-Ber	zotriazol-2-vl)-	4-methylphenol (Contd. of pag
Oral	ge.pop., I.t		1.2 mg/Kg (nd)
Dermal		-	2.5 mg/Kg/d (nd)
	ge.pop., I.t	-	1.2 mg/Kg/d (nd)
Inhalative		lustr., l.te., syst.	
	PNECs	ustr., 1.to., syst.	
	nethyl meth	hacrulato	
freshwate	-	0.94 mg/l (aqua	(6
			4-methylphenol
freshwate		0.00026 mg/l (r	
marine wa		0.000026 mg/l	,
	at. release	1 mg/l (nd)	(14)
STP		1 mg/l (nd) 1 mg/l (nd)	
-	w fro wot		
	w, fre.wat.	0.136 mg/Kg (n 0.0136 mg/Kg (
	w, mar.wat.		na)
soil,dw		11 mg/Kg (nd)	ists that were valid during the compilation were used as basis
Ins Wa Avo	tantly remov ash hands di oid contact v	ve any soiled an uring breaks and with the eyes an	e nic measures verages and food. d impregnated garments. d at the end of the work. d skin.
Ins Wa Avo Bre Not pro Pro Sel the If s ser	tantly removes ash hands described to the second the second to the second to the second the second to the second to the second to the second to the test of the second to	ve any soiled an uring breaks and with the eyes an upment: y with efficient lo k (filter A). hands: terial has to be e glove material n t cannot be avo	verages and food. d impregnated garments. d at the end of the work.
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Ins Wa Avo Bre Not pro The pre Sel the If s ser Sol Cho	tantly removes ash hands de- bid contact we athing equ t neccessar otective mas otection of the glove material of the paration. degradation skin contact of the selection further man preparation calculated in Penetration	ve any soiled an uring breaks and with the eyes an ipment: y with efficient lo k (filter A). hands: terial has to be e glove material n t cannot be avo t cannot be avo t gloves ve gloves prior to gloves ve gloves prior to gloves on of the suital ks of quality and n of several su n advance and h n time of glove	verages and food. d impregnated garments. d at the end of the work. d skin. ocal exhaust. If exposition to vapours is possible, use breath impermeable and resistant to the product/ the substance/ on consideration of the penetration times, rates of diffusion a bided, protective gloves are recommended to avoid possi be each use for their proper condition. be gloves does not only depend on the material, but also d varies from manufacturer to manufacturer. As the product for bistances, the resistance of the glove material can not mas therefore to be checked prior to the application. material
Ins. Wa Avo Bre Not pro The pre Sel the If s ser Sol Cho rec	tantly removes ash hands de- bid contact we ash hands de- bid contact we athing equ t neccessar of the contact of the selection of the selection further man preparation calculated in Penetration The exact gloves and For the pen materials a	ve any soiled an uring breaks and with the eyes an upment: y with efficient lo k (filter A). hands: terial has to be e glove material n t cannot be avo t cannot be avo t cannot be avo t gloves ve gloves prior to gloves ve gloves prior to t advance and h n time of glove break trough tin has to be obser tranent contac ore suitable:	verages and food. d impregnated garments. d at the end of the work. d skin. ocal exhaust. If exposition to vapours is possible, use breath impermeable and resistant to the product/ the substance/ on consideration of the penetration times, rates of diffusion a bided, protective gloves are recommended to avoid possi to each use for their proper condition. ble gloves does not only depend on the material, but also d varies from manufacturer to manufacturer. As the product is bistances, the resistance of the glove material can not mas therefore to be checked prior to the application. material me has to be found out by the manufacturer of the protect
Ins Wa Avo Bre Not pro Pro Sel the If s ser Sol Cho rec	tantly removes ash hands de- bid contact we athing equ t neccessar otective mas otection of e glove materiation. Intection of the degradation skin contact of the selection further man preparation calculated in preparation calculated in Penetration The exact gloves and For the penetration For the penetration	ve any soiled an uring breaks and with the eyes an ipment: y with efficient lo k (filter A). hands: terial has to be e glove material n t cannot be ave to anot be ave y gloves prior to gloves on of the suital ks of quality and n of several su n advance and h n time of glove break trough tin has to be obser rmanent contac tre suitable: r, BR	verages and food. d impregnated garments. d at the end of the work. d skin. ocal exhaust. If exposition to vapours is possible, use breath impermeable and resistant to the product/ the substance/ on consideration of the penetration times, rates of diffusion a bided, protective gloves are recommended to avoid possi o each use for their proper condition. ble gloves does not only depend on the material, but also d varies from manufacturer to manufacturer. As the product is obstances, the resistance of the glove material can not mas therefore to be checked prior to the application. material me has to be found out by the manufacturer of the protect ved.



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• *Eye protection: Tightly sealed safety glasses.* • *Body protection: Light weight protective clothing*

SECTION 9: Physical and cher	nical properties
• 9.1 Information on basic physical and • General Information • Appearance:	d chemical properties
· Form:	Fluid
· Colour:	Colourless
· Smell:	Characteristic
 Odour threshold: 	Not determined.
· pH-value:	Not determined.
 Change in condition Melting point/freezing point: Initial boiling point and boiling 	Not determined range: 100 °C
· Flash point:	10 °C
Inflammability (solid, gaseous)	Not applicable.
· Ignition temperature:	430 °C
 Decomposition temperature: 	Not determined.
· Self-inflammability:	Product is not selfigniting.
• Explosive properties:	Product is not explosive. However, formation o explosive air/vapour mixtures is possible.
 Critical values for explosion: Lower: Upper: 	2.1 Vol % 12.5 Vol %
· Steam pressure at 20 °C:	47 hPa
· Density at 20 °C	0.94613 g/cm³
· Relative density	Not determined.
· Vapour density	Not determined.
· Evaporation rate	Not determined.
 Solubility in / Miscibility with Water: 	Not miscible or difficult to mix
· Partition coefficient: n-octanol/wa	
· Viscosity:	
dynamic at 20 °C:	1 mPas
· kinematic:	Not determined.
· Solvent content:	
· Solids content:	1.0 %
9.2 Other information	No further relevant information available.

SECTION 10: Stability and reactivity

• 10.1 Reactivity No further relevant information available.

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· 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.

11.1 Info	rmation or	toxicological effects
·Acute	e toxicity Ba	ased on available data, the classification criteria are not met.
·LE	0/LC50 valu	es that are relevant for classification:
80-62-6	methyl met	hacrylate
Oral	LD50	~7,900 mg/kg (rat)
Dermal	LD50	>5,000 mg/kg (rab) (OECD 402)
Inhalative	e LC50/4 h	29.8 mg/l (rat)
2082-81-	7 tetrametl	nylene dimethacrylate
Oral	LD50	10,066 mg/kg (rat) (OECD 401)
2440-22-	4 2-(2H-Be	nzotriazol-2-yl)-4-methylphenol
Oral	LD50	>10,000 mg/kg (rat) (OECD 423)
99-97-8	N,N-dimeth	yl-p-toluidine
Oral	LD50	139 mg/kg (rat)
	imary irrita	
	Skin corro Causes ski	sion/irritation
		re damage/irritation
	Based on a	available data, the classification criteria are not met.
· Re	espiratory o	or skin sensitisation
Ma	ay cause an	allergic skin reaction.
	Germ cell Carcinoge Reproduc	(carcinogenity, mutagenicity and toxicity for reproduction) mutagenicity Based on available data, the classification criteria are not met nicity Based on available data, the classification criteria are not met. tive toxicity Based on available data, the classification criteria are not met.
	()T cinalo	exposure
· S1		spiratory irritation.

SECTION 12: Ecological information	
· 12.1 Toxicity	
· Aquatic toxicity:	
80-62-6 methyl methacrylate	
EC50/48h 69 mg/l (daphnia)	
LC50/96h 191 mg/l (fish)	
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2440-22-4	2-(2H-Benzotriazol-2-yl)-4-methylphenol	
EC50/72h	>100 mg/l (algae)	
LC50/96h	>0.17 mg/l (fish)	
99-97-8 N	N-dimethyl-p-toluidine	
LC50/96h	100 mg/l (fish)	
12.3 Bioa 12.4 Mob Additi Do Da 12.5 Resu PBT: N vPvB:	istence and degradability No further relevant information available. ccumulative potential No further relevant information available. ility in soil No further relevant information available. onal ecological information: neral notes: not allow product to reach ground water, water bodies or sewage system. nger to drinking water if even small quantities leak into soil. Ilts of PBT and vPvB assessment Not applicable. Not applicable. Not applicable.	
SECTIO	N 13: Disposal considerations	
Recon	te treatment methods imendation ot be disposed of together with household garbage. Do not allow product t	to reach sewage

system. Disposal must be made according to official regulations.

· European waste catalogue

18 01 06* chemicals consisting of or containing hazardous substances

· Uncleaned packagings:

· Recommendation:

Disposal must be made according to official regulations. Non contaminated packagings can be used for recycling.

14.1 UN-Number · ADR, IMDG, IATA	UN1247
14.2 UN proper shipping name · ADR	1247 METHYL METHACRYLATI MONOMER, STABILIZED solution
· IMDG, IATA	METHYL METHACRYLATE MONOMER STABILIZED solution
14.3 Transport hazard class(es)	
ADR	
Class	3 (F1) Flammable liquids.
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· Label	3
· IMDG, IATA	
· Class · Label	3 Flammable liquids. 3
· 14.4 Packing group · ADR, IMDG, IATA	11
14.5 Environmental hazards: Marine pollutant:	No
 14.6 Special precautions for user Kemler Number: EMS Number: Stowage Category Stowage Code 	Warning: Flammable liquids. 339 F-E,S-D B SW2 Clear of living quarters.
 14.7 Transport in bulk according to A Marpol and the IBC Code 	Annex II of Not applicable.
 Transport/Additional information: 	
• ADR • Limited quantities (LQ) • Excepted quantities (EQ) • Transport category	1L Code: E2 Maximum net quantity per inne packaging: 30 ml Maximum net quantity per oute packaging: 500 ml 2
ADR Limited quantities (LQ) Excepted quantities (EQ)	1L Code:E2 Maximum net quantity per inne packaging:30ml Maximum net quantity per oute
• ADR • Limited quantities (LQ) • Excepted quantities (EQ) • Transport category	1L Code: E2 Maximum net quantity per inne packaging: 30 ml Maximum net quantity per oute packaging: 500 ml 2

SECTION 15: Regulatory information

· 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

Directive 2012/18/EU

· Named dangerous substances - ANNEX I None of the ingredients is listed.

- Named dangerous substances ANNEA I Note of the inglescence Seveso category P5c FLAMMABLE LIQUIDS Qualifying quantity (tonnes) for the application of lower-tier requirements 5.000 t (Contd. on page 9)

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(Contd. of page 8) • Qualifying quantity (tonnes) for the application of upper-tier requirements 50.000 t • REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3 • 15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

These data are based on our present knowledge. However, they shall not constitute a guarantee any specific product features and shall not establish a legally valid contractual relationship. • Relevant phrases H225 Highly flammable liquid and vapour. H301 Toxic if swallowed. H311 Toxic in contact with skin. H315 Causes skin irritation. H317 May cause an allergic skin reaction. H330 Fatal if inhaled. H335 May cause respiratory irritation. H373 May cause damage to organs through prolonged or repeated exposure. H410 Very toxic to aquatic life with long lasting effects. H412 Harmful to active thansport Association GHS: Globally Harmonised System of Classification and Labelling of Chemicals EINECS: European Inventory of Existing Commercial Chemical Substances ELINCS: European Inventory of Existing of the American Chemical Society) DNEL: Derived No-Effect Level (REACH) L50: Lethal dose; 50 percent L50: Lethal dose; 50 percent L50: Lethal dose; 50 percent H20: Fredicted No-Effect Concentration (REACH) Kin Sens. 1: Skin sensitisation – Category 2 Skin Intt. 2: Skin corrosion/irritation – Category 2 Skin Sens. 1: Skin sensitisation – Category 1 Skin Sens. 1: Skin sensitisation – Category 1 Skin Sens. 1: Skin sensit	SECTION 16:	Other information
 Relevant phrases H225 Highly flammable liquid and vapour. H301 Toxic if swallowed. H311 Toxic in contact with skin. H315 Causes skin irritation. H317 May cause an allergic skin reaction. H330 Fatal if inhaled. H335 May cause respiratory irritation. H373 May cause damage to organs through prolonged or repeated exposure. H410 Very toxic to aquatic life with long lasting effects. H412 Harmful to aquatic life with long lasting effects. Abbreviations and acronyms: ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concern the International Carriage of Dangerous Goods by Road) IMDG: International Martime Code for Dangerous Goods IATA: International Air Transport Association GHS: Globally Harmonised System of Classification and Labelling of Chemicals ELINCS: European list of Notified Chemical Substances CAS: Chemical Abstracts Service (division of the American Chemical Society) DNEL: Derived No-Effect Level (REACH) PNEC: Predicted No-Effect Level (REACH) PNEC: Predicted No-Effect Level (REACH) LC50: Lethal concentration, 50 percent DB51: Persistent, Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative Flam. Liq. 2: Flammable liquids – Category 2 Akute Tox. 3: Acute toxicity - inhalation – Category 2 Skin Sens. 11: Skin sensitisation – Category 1 Skin Sens. 11: Skin sensitisation – Category 1 Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard – Category 1 Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 1 		
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• * Data compared to the previous version altered.		