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

· **1.1 Product identifier**

· **Trade name:** **Gluma 2Bond**

· **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 bonding material

· **1.3 Details of the supplier of the safety data sheet**
· **Manufacturer/Supplier:**
Kulzer GmbH
Leipziger Straße 2, 63450 Hanau (Germany) Tel.: +49 (0)800 4372522

· **Informing department:** E-Mail: msds@kulzer-dental.com
· **1.4 Emergency telephone number:** Emergency CONTACT (24-Hour-Number): +49 (0)6132-84463

SECTION 2: Hazards identification

· **2.1 Classification of the substance or mixture**
· **Classification according to Regulation (EC) No 1272/2008**

Flam. Liq. 3	H226 Flammable liquid and vapour.
Skin Irrit. 2	H315 Causes skin irritation.
Eye Irrit. 2	H319 Causes serious eye irritation.
Resp. Sens. 1	H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Skin Sens. 1	H317 May cause an allergic skin reaction.
STOT SE 3	H335 May cause respiratory irritation.
Aquatic Chronic 2	H411 Toxic to aquatic life with long lasting effects.

· **2.2 Label elements**
· **Labelling according to Regulation (EC) No 1272/2008**
The product is classified and labelled according to the GB CLP regulation.
· **Hazard pictograms**

GHS02 GHS07 GHS08 GHS09

· **Signal word** Danger

· **Hazard-determining components of labelling:**
7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate
glutaral
2-hydroxyethyl methacrylate
Homopolymer, reaction product of glycidyl methacrylate with polyacrylic acid
4-methacryloxyethyltrimellitic acid anhydride
· **Hazard statements**
H226 Flammable liquid and vapour.
H315 Causes skin irritation.
H319 Causes serious eye irritation.
H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.

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H317 May cause an allergic skin reaction.
H335 May cause respiratory irritation.
H411 Toxic to aquatic life with long lasting effects.

· **Precautionary statements**

P210	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P261	Avoid breathing mist/vapours/spray.
P273	Avoid release to the environment.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P342+P311	If experiencing respiratory symptoms: Call a POISON CENTER/doctor.

· **Additional information:**
Contains isocyanates. May produce an allergic reaction.

· **2.3 Other hazards** -

· **Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

SECTION 3: Composition/information on ingredients

· **3.2 Mixtures**

· **Description:** -

· **Dangerous components:**

CAS: 72869-86-4 EINECS: 276-957-5 Index number: 607-134-00-4 Reg.nr.: 01-2120751202-68-xxxx	7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate Aquatic Chronic 2, H411 Skin Sens. 1B, H317 EUH204	25-50%
CAS: 64-17-5 EINECS: 200-578-6 Index number: 603-002-00-5 Reg.nr.: 01-2119457610-43-xxxx	ethanol Flam. Liq. 2, H225 Eye Irrit. 2, H319 Specific concentration limit: Eye Irrit. 2; H319: C ≥ 50 %	≥25-<50%
CAS: 868-77-9 EINECS: 212-782-2 Index number: 607-124-00-X Reg.nr.: 01-2119490169-29-xxxx	2-hydroxyethyl methacrylate Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317	10-25%
	Homopolymer, reaction product of glycidyl methacrylate with polyacrylic acid Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317	≥1-≤5%

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CAS: 70293-55-9	4-methacryloxyethyltrimellitic acid anhydride Acute Tox. 4, H302; Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317; STOT SE 3, H335	≥1-<5%
CAS: 111-30-8 EINECS: 203-856-5 Index number: 605-022-00-X	glutaral Acute Tox. 3, H301; Acute Tox. 2, H330 Resp. Sens. 1, H334 Skin Corr. 1B, H314 Aquatic Acute 1, H400; Aquatic Chronic 2, H411 Skin Sens. 1A, H317; STOT SE 3, H335 EUH071 Specific concentration limit: STOT SE 3; H335: C ≥ 0.5 %	≥2.5-<5%

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

SECTION 4: First aid measures

· **4.1 Description of first aid measures**
· **General information**
Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident.
· **After inhalation** Supply fresh air; consult doctor in case of symptoms.
· **After skin contact** Instantly wash with water and soap and rinse thoroughly.
· **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.
Instantly call for 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.
· **For safety reasons unsuitable extinguishing agents** Water with a full water jet.
· **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:** Put on breathing apparatus.
· **Additional information** -

SECTION 6: Accidental release measures

· **6.1 Personal precautions, protective equipment and emergency procedures**
Wear protective equipment. Keep unprotected persons away.

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· ***6.2 Environmental precautions:*** *Do not allow to enter the ground/soil.*
· ***6.3 Methods and material for containment and cleaning up:***
Absorb with liquid-binding material (diatomite, universal binders, for small amounts tissues).
Send for recovery or disposal in suitable containers.
· ***6.4 Reference to other sections***
See Section 13 for information on disposal.
See Section 8 for information on personal protection equipment.
-

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.
Please observe the additional instructions in the product's instructions for use.
· ***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:*** *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

· ***8.1 Control parameters***

· **Components with critical values that require monitoring at the workplace:**	
64-17-5 ethanol	
WEL (Great Britain)	Long-term value: 1920 mg/m³, 1000 ppm
111-30-8 glutaral	
WEL (Great Britain)	Short-term value: 0.2 mg/m³, 0.05 ppm Long-term value: 0.2 mg/m³, 0.05 ppm Sen

· **DNELs**		
72869-86-4 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate		
Oral	general population, long term, systemic	0.3 mg/Kg (not defined)
Dermal	worker industrial, long term, systemic	1.3 mg/Kg/d (not defined)
	general population, long term, systemic	0.7 mg/Kg/d (not defined)
Inhalative	worker industrial, long term, systemic	3.3 mg/m3 (not defined)
	general population, long term, systemic	0.6 mg/m3 (not defined)

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64-17-5 ethanol		
Oral	general population, long term, systemic	87 mg/Kg (not defined)
Dermal	worker industrial, long term, systemic	343 mg/Kg/d (not defined)
	general population, long term, systemic	206 mg/Kg/d (not defined)
Inhalative	worker industrial, long term, systemic	950 mg/m3 (not defined)
	general population, long term, systemic	114 mg/m3 (not defined)
868-77-9 2-hydroxyethyl methacrylate		
Oral	general population, long term, systemic	0.83 mg/Kg (not defined)
Dermal	worker industrial, long term, systemic	1.3 mg/Kg/d (not defined)
	general population, long term, systemic	0.83 mg/Kg/d (not defined)
Inhalative	worker industrial, long term, systemic	4.9 mg/m3 (not defined)
	general population, long term, systemic	2.9 mg/m3 (not defined)

· **PNECs**

72869-86-4 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate	
freshwater	0.01 mg/l (not defined)
marine water	0.001 mg/l (not defined)
sewage treatment plant	3.61 mg/l (not defined)
sediment, dry weight, freshwater	4.56 mg/Kg (not defined)
sediment, dry weight, marine water	0.46 mg/Kg (not defined)
soil, dry weight	0.91 mg/Kg (not defined)
64-17-5 ethanol	
freshwater	0.96 mg/l (not defined)
marine water	0.79 mg/l (not defined)
sewage treatment plant	580 mg/l (not defined)
sediment, dry weight, freshwater	3.6 mg/Kg (not defined)
sediment, dry weight, marine water	2.9 mg/Kg (not defined)
soil, dry weight	0.63 mg/Kg (not defined)
868-77-9 2-hydroxyethyl methacrylate	
freshwater	0.482 mg/l (not defined)
marine water	0.482 mg/l (not defined)
sewage treatment plant	10 mg/l (not defined)
sediment, dry weight, freshwater	3.79 mg/Kg (not defined)
sediment, dry weight, marine water	3.79 mg/Kg (not defined)
soil, dry weight	0.476 mg/Kg (not defined)

· **Additional information:** The lists that were valid during the compilation were used as basis.

· **8.2 Exposure controls**
· **Appropriate engineering controls** No further data; see section 7.
· **Individual protection measures, such as personal protective equipment**
· **General protective and hygienic measures**
Keep away from foodstuffs, beverages and food.

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Instantly remove any soiled and impregnated garments.
Wash hands during breaks and at the end of the work.
Do not inhale gases / fumes / aerosols.
Avoid contact with the eyes and skin.
· **Breathing equipment:** Breathing protection recommended.
· **Hand protection**
If skin contact cannot be avoided, protective gloves are recommended to avoid possible sensitization.
Solvent resistant gloves
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 trough 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/face protection** Tightly sealed 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**

· **Physical state**	Fluid
· **Colour:**	Yellowish
· **Smell:**	Characteristic
· **Odour threshold:**	Not determined.
· **Melting point/freezing point:**	Not determined
· **Boiling point or initial boiling point and boiling range**	78 °C (64-17-5 ethanol)
· **Flammability**	Not applicable.
· **Lower and upper explosion limit**	
· **Lower:**	Not determined.
· **Upper:**	Not determined.
· **Flash point:**	23.5 °C
· **Decomposition temperature:**	Not determined.
· **SADT**	
· **pH**	Not determined.
· **Viscosity:**	
· **Kinematic viscosity**	Not determined.

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· **Kinematic viscosity**	
· **dynamic:**	Not determined.
· **Solubility**	
· **Water:**	Partly soluble
· **Partition coefficient n-octanol/water (log value)**	Not determined.
· **Steam pressure:**	Not determined.
· **Vapour pressure:**	
· **Density and/or relative density**	
· **Density at 20 °C**	1 g/cm³
· **Relative density**	Not determined.
· **Vapour density**	Not determined.

· **9.2 Other information**	No further relevant information available.
· **Appearance:**	
· **Form:**	Fluid
· **Important information on protection of health and environment, and on safety.**	
· **Self-inflammability:**	Product is not selfigniting.
· **Explosive properties:**	Product is not explosive. However, formation of explosive air/vapour mixtures is possible.
· **Change in condition**	
· **Evaporation rate**	Not determined.

· **Information with regard to physical hazard classes**	
· **Explosives**	Void
· **Flammable gases**	Void
· **Aerosols**	Void
· **Oxidising gases**	Void
· **Gases under pressure**	Void
· **Flammable liquids**	Flammable liquid and vapour.
· **Flammable solids**	Void
· **Self-reactive substances and mixtures**	Void
· **Pyrophoric liquids**	Void
· **Pyrophoric solids**	Void
· **Self-heating substances and mixtures**	Void
· **Substances and mixtures, which emit flammable gases in contact with water**	Void
· **Oxidising liquids**	Void
· **Oxidising solids**	Void
· **Organic peroxides**	Void
· **Corrosive to metals**	Void
· **Desensitised explosives**	Void

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:** -

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SECTION 11: Toxicological information

· **11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008**
· **Acute toxicity** Based on available data, the classification criteria are not met.

· LD/LC50 values that are relevant for classification:		
72869-86-4 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate		
Oral	LD50	>5,000 mg/kg (rat) (OECD 401)
Dermal	LD50	>2,000 mg/kg (rat) (OECD 402)
64-17-5 ethanol		
Oral	LD50	10,470 mg/kg (rat) (OECD 401)
868-77-9 2-hydroxyethyl methacrylate		
Oral	LD50	5,564 mg/kg (rat)
Dermal	LD50	>5,000 mg/kg (rabbit)
70293-55-9 4-methacryloxyethyltrimellitic acid anhydride		
Oral	LD50	>2,000 mg/kg (mouse)
Dermal	LD50	>2,000 mg/kg (mouse)
111-30-8 glutaral		
Oral	LD50	77 mg/kg (rat)

· **Skin corrosion/irritation**
Causes skin irritation.
· **Serious eye damage/irritation**
Causes serious eye irritation.
· **Respiratory or skin sensitisation**
May cause allergy or asthma symptoms or breathing difficulties if inhaled.
May cause an allergic skin reaction.
· **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**
May cause respiratory irritation.
· **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.

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· **11.2 Information on other hazards**

· **Endocrine disrupting properties**		
128-37-0	2,6-di-tert-butyl-p-cresol	List II

SECTION 12: Ecological information

· **12.1 Toxicity**

· **Aquatic toxicity:**	
72869-86-4 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate	
EC50/48h	>1.2 mg/l (daphnia) (OECD 202)
LC50/96h	10.1 mg/l (fish) (OECD 203)
ErC50 / 72 h	>0.68 mg/l (algae) (OECD 201)
NOEC / 72h	0.21 mg/l (algae) (OECD 201)
64-17-5 ethanol	
LC50/96h	14,200 mg/l (fish)
ErC50 / 72 h	275 mg/l (algae) (OECD 201)
EC50/96h	129,000 mg/L (fish)
LC50/48h	5,012 mg/L (daphnia)
ErC10/72h	11.5 mg/L (algae) (OECD 201)
NOEC 5d	250 mg/L (fish) (OECD 212)
NOEC 10d	9.6 mg/L (daphnia)
868-77-9 2-hydroxyethyl methacrylate	
EC50/72h	345 mg/l (algae) (OECD 201)
EC50/21d	90.1 mg/L (daphnia) (OECD 211)
EC50/48h (static)	380 mg/l (daphnia) (OECD 202)
LC50/96h	>100 mg/l (fish) (OECD 203)
NOEC / 21d	24.1 mg/l (daphnia) (OECD 211)
ErC50 / 72 h	836 mg/l (algae) (OECD 201)
NOEC / 72h	400 mg/l (algae) (OECD 201)
NOEC / 48h	171 mg/l (daphnia) (OECD 202)

· **12.2 Persistence and degradability**	
72869-86-4 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate	
Biodegradation	22 % /28d (not defined) (OECD 301B; ISO/ 9439/ EEC 92/69/V, C.4-C)
64-17-5 ethanol	
Biodegradation	84 % /20d (not defined)
868-77-9 2-hydroxyethyl methacrylate	
Biodegradation	92-100 % /14d (not defined) (OECD 301C)

· **12.3 Bioaccumulative potential** No further relevant information available.
· **12.4 Mobility in soil** No further relevant information available.

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· **12.5 Results of PBT and vPvB assessment**
· **PBT:** Not applicable.
· **vPvB:** Not applicable.
· **12.6 Endocrine disrupting properties**
For information on endocrine disrupting properties see section 11.
· **12.7 Other adverse effects**
· **Additional ecological information:**
· **General notes:** Avoid transfer into the environment.

SECTION 13: Disposal considerations

· **13.1 Waste treatment methods**
· **Recommendation**
Must not be disposed of together with household garbage. Do not allow product to reach sewage system.
Disposal must be made according to official regulations.

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

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SECTION 14: Transport information

· **14.1 UN number or ID number**
· **ADR, IMDG, IATA** UN1993

· **14.2 UN proper shipping name**
· **ADR** 1993 FLAMMABLE LIQUID, N.O.S. (ethanol)
· **IMDG, IATA** FLAMMABLE LIQUID, N.O.S. (ethanol)

· **14.3 Transport hazard class(es)**

· **ADR**

· **Class** 3 (F1) Flammable liquids.
· **Label** 3

· **IMDG, IATA**

· **Class** 3 Flammable liquids.
· **Label** 3

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· **14.4 Packing group**	
· **ADR, IMDG, IATA**	III
· **14.5 Environmental hazards:**	
· **Marine pollutant:**	No
· **Special marking (ADR):**	Symbol (fish and tree)
· **14.6 Special precautions for user**	Warning: Flammable liquids.
· **Kemler Number:**	30
· **EMS Number:**	F-E,S-E
· **Stowage Category**	A
· **14.7 Maritime transport in bulk according to IMO instruments**	Not applicable.
· **Transport/Additional information:**	-
· **ADR**	
· **Limited quantities (LQ)**	5L
· **Excepted quantities (EQ)**	Code: E1 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 1000 ml
· **Transport category**	3
· **Tunnel restriction code**	D/E
· **IMDG**	
· **Limited quantities (LQ)**	5L
· **Excepted quantities (EQ)**	Code: E1 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 1000 ml
· **UN "Model Regulation":**	UN 1993 FLAMMABLE LIQUID, N.O.S. (ETHANOL), 3, III

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.
· **Seveso category** P5c FLAMMABLE LIQUIDS
· **Qualifying quantity (tonnes) for the application of lower-tier requirements** 5.000 t
· **Qualifying quantity (tonnes) for the application of upper-tier requirements** 50.000 t

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

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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.

· **Relevant phrases**

H225 Highly flammable liquid and vapour.
H301 Toxic if swallowed.
H302 Harmful if swallowed.
H314 Causes severe skin burns and eye damage.
H315 Causes skin irritation.
H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.
H330 Fatal if inhaled.
H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H335 May cause respiratory irritation.
H400 Very toxic to aquatic life.
H411 Toxic to aquatic life with long lasting effects.
EUH071 Corrosive to the respiratory tract.
EUH204 Contains isocyanates. May produce an allergic reaction.

· **Abbreviations and acronyms:**

SADT: Self Accelerating Decomposition Temperature
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
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)
DNEL: Derived No-Effect Level (UK REACH)
PNEC: Predicted No-Effect Concentration (UK REACH)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
Flam. Liq. 2: Flammable liquids – Category 2
Flam. Liq. 3: Flammable liquids – Category 3
Acute Tox. 3: Acute toxicity – Category 3
Acute Tox. 4: Acute toxicity – Category 4
Acute Tox. 2: Acute toxicity – Category 2
Skin Corr. 1B: Skin corrosion/irritation – Category 1B
Skin Irrit. 2: Skin corrosion/irritation – Category 2
Eye Irrit. 2: Serious eye damage/eye irritation – Category 2
Resp. Sens. 1: Respiratory sensitisation – Category 1
Skin Sens. 1: Skin sensitisation – Category 1
Skin Sens. 1A: Skin sensitisation – Category 1A
Skin Sens. 1B: Skin sensitisation – Category 1B
STOT SE 3: Specific target organ toxicity (single exposure) – Category 3
Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard – Category 1
Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard – Category 2

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