

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 13.04.2021

Version number 2104

Revision: 13.04.2021

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

1.1 Product identifier

Trade name: **Dentatec**
 Article number: 5360-0421

1.2 Relevant identified uses of the substance or mixture and uses advised against

Application of the substance / the mixture: No further relevant information available.
 Milling additive

1.3 Details of the supplier of the safety data sheet

Manufacturer/Supplier: SIRONA Dental Systems GmbH
 Fabrikstraße 31
 D-64625 Bensheim
 Germany
<http://www.dentsplysirona.com>
 T.: +49 (0) 6251/16-1670

Hersteller/Manufacturer:
 Graichen Produktions- und Vertriebs-GmbH
 Darmstädter Str. 127
 D-64625 Bensheim
 Tel.: +49(0)6251/7707880
 Fax: +49(0)6251/77901
 e-mail: ehs@graichen-bensheim.de
<http://www.graichen.net>

Further information obtainable from: Environment protection department

1.4 Emergency telephone number:

Advice centre for poisoning university Mainz phone +49(0)6131/19240
 or poison information: +49(0)700/GIFTINFO

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008
 Skin Irrit. 2 H315 Causes skin irritation.
 Eye Irrit. 2 H319 Causes serious eye irritation.
 Skin Sens. 1 H317 May cause an allergic skin reaction.
 Aquatic Chronic 2 H411 Toxic to aquatic life with long lasting effects.

2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008
 Hazard pictograms

The product is classified and labelled according to the CLP regulation.



GHS07 GHS09

Signal word

Warning

Hazard-determining components of labelling:

mixture of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2-isothiazol-3-one [EC no. 220-239-6] (3:1)

Hazard statements

H315 Causes skin irritation.
 H319 Causes serious eye irritation.
 H317 May cause an allergic skin reaction.

Precautionary statements

H411 Toxic to aquatic life with long lasting effects.
 P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
 P264 Wash thoroughly after handling.
 P273 Avoid release to the environment.
 P280 Wear protective gloves / 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.
 P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
 P337+P313 If eye irritation persists: Get medical advice/attention.
 P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

2.3 Other hazards

Results of PBT and vPvB assessment

PBT: Not applicable.
 vPvB: Not applicable.

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SECTION 3: Composition/information on ingredients

3.2 Chemical characterisation: Mixtures

Dangerous components:

| | | |
|-----------------------------------|---|--------|
| CAS: 52-51-7 EINECS: 200-143-0 | bronopol (INN) ☠ Eye Dam. 1, H318; ☠ Aquatic Acute 1, H400 (M=10); ☠ Acute Tox. 4, H302; Acute Tox. 4, H312; Skin Irrit. 2, H315; STOT SE 3, H335 | < 2.5% |
| CAS: 55965-84-9 | mixture of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H-isothiazol-3-one [EC no. 220-239-6] (3:1) ☠ Acute Tox. 3, H301; Acute Tox. 2, H310; Acute Tox. 2, H330; ☠ Skin Corr. 1C, H314; Eye Dam. 1, H318; ☠ Aquatic Acute 1, H400 (M=100); Aquatic Chronic 1, H410 (M=100); ☠ Skin Sens. 1A, H317 | < 2.5% |

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.

Position and transport stably in side position.

After inhalation:

Supply fresh air; consult doctor in case of complaints.

After skin contact:

If skin irritation continues, consult a doctor.

After eye contact:

Immediately wash with water and soap and rinse thoroughly.

Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.

After swallowing:

Rinse out mouth and then drink plenty of water.

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, powder or water spray. Fight larger fires with water spray or alcohol resistant foam. Use fire extinguishing methods suitable to surrounding conditions.

5.2 Special hazards arising from the substance or mixture

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

Sulphur dioxide (SO₂)

Hydrogen chloride (HCl)

Nitrogen oxides (NO_x)

Carbon monoxide (CO)

5.3 Advice for firefighters

Protective equipment:

Wear self-contained respiratory protective device.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Use respiratory protective device against the effects of fumes/dust/aerosol.

6.2 Environmental precautions:

Do not allow to enter sewers/ surface or ground water.

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

Inform respective authorities in case of seepage into water course or sewage system.

Dilute with plenty of water.

6.3 Methods and material for containment and cleaning up:

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

Ensure adequate ventilation.

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 disposal information.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Information about fire - and explosion protection:

No special precautions are necessary if used correctly.

No special measures required.

7.2 Conditions for safe storage, including any incompatibilities

Requirements to be met by storerooms and receptacles:

Store only in the original receptacle.

Information about storage in one common storage facility:

Store away from foodstuffs.

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- . Further information about storage conditions: Store receptacle in a well ventilated area.
- . **7.3 Specific end use(s)** No further relevant information available.

SECTION 8: Exposure controls/personal protection

- . **8.1 Control parameters**
- . Additional information about design of technical facilities: No further data; see item 7.

. Ingredients with limit values that require monitoring at the workplace:

CAS: 56-81-5 glycerol (50 – 100%)

WEL Long-term value: 10 mg/m³

. DNELs

CAS: 56-81-5 glycerol

Inhalative DNEL Long-term - local effects 56 mg/m³ (Workers (Arbeitnehmer))

. PNECs

CAS: 56-81-5 glycerol

| | |
|---|-------------------|
| PNEC Soil (Boden) | 0.141 mg/kg (---) |
| PNEC fresh water sediment (Süßwassersediment) | 3.3 mg/kg (---) |
| PNEC fresh water (Süßwasser) | 0.885 mg/l (---) |
| PNEC marine water sediment | 0.33 mg/kg (---) |
| PNEC Marine water | 0.0885 mg/l (---) |
| PNEC mikrobiological activity in waste water | 1,000 mg/l (---) |

. Additional Occupational Exposure Limit Values for possible hazards during processing:

| Country | Components | Categorie | mg/m ³ |
|---------|---------------------------------------|-----------|-------------------|
| Germany | 2-methyl-4-isothiazolin-3-on | MAK | 0,05 |
| | 5-chloro-2-methyl-4-isothiazolin-3-on | MAK | 0,05 |

. Additional information:

The lists valid during the making were used as basis.

. **8.2 Exposure controls**

. Personal protective equipment:

. General protective and hygienic measures:

Keep away from foodstuffs, beverages and feed.
Immediately remove all soiled and contaminated clothing
Wash hands before breaks and at the end of work.
Avoid contact with the eyes and skin.

. Respiratory protection:

Not required.

. Protection of hands:

Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

. Material of gloves

Nitrile rubber, NBR

Recommended thickness of the material: ≥ 0.7 mm

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

Value for the permeation: Level $\leq 0,7$ mm 480min (8h) EN374

The determined penetration times according to EN 16523-1:2015 are not performed under practical conditions. Therefore a maximum wearing time, which corresponds to 50% of the penetration time, is recommended.

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

. Not suitable are gloves made of the following materials:

Natural rubber, NR

PVA gloves

. Eye protection:

Tightly sealed goggles

SECTION 9: Physical and chemical properties

. **9.1 Information on basic physical and chemical properties**

. General Information

. Appearance:

Form: Fluid

Colour: Colourless

. Odour: Characteristic

. Odour threshold: Not determined.

. pH-value at 20 °C: $> 2 - \leq 2.8$

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| | |
|---|--|
| . pH-value 10% aqu. solution | < 4.5 |
| . Change in condition Initial boiling point and boiling range: 100 °C | |
| . Flash point: | > 100 °C |
| . Flammability (solid, gas): | Not applicable. |
| . Ignition temperature: | 400 °C |
| . Decomposition temperature: | Not determined. |
| . Auto-ignition temperature: | Product is not selfigniting. |
| . Explosive properties: | Not determined. |
| . Explosion limits: Lower: Upper: | 0.9 Vol % Not determined. |
| . Vapour pressure at 20 °C: | < 0.1 hPa |
| . Density at 20 °C: . Relative density . Vapour density . Evaporation rate | 1.2135 – 1.2165 g/cm ³ Not determined. Not determined. Not determined. |
| . Solubility in / Miscibility with water: | Fully miscible. |
| . Partition coefficient: n-octanol/water: | Not determined. |
| . Viscosity: Dynamic: | Not determined. |
| . Solvent content: Organic solvents: Water: VOC (EC) VOC (EU) (%) | 81.3 % 18.2 % -0.0 g/l 0.0 % |
| . Solids content: | 0.6 % |
| . 9.2 Other information | No further relevant information available. |

SECTION 10: Stability and reactivity

- . **10.1 Reactivity** No further relevant information available.
- . **10.2 Chemical stability**
- . Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.
- . **10.3 Possibility of hazardous reactions** Forms explosive gas mixture with air.
Reacts with strong oxidising agents.
- . **10.4 Conditions to avoid** No further relevant information available.
- . **10.5 Incompatible materials:** No further relevant information available.
- . **10.6 Hazardous decomposition products:** Hydrogen chloride (HCl)
Nitrogen oxides
Sulphur dioxide

SECTION 11: Toxicological information

- . **11.1 Information on toxicological effects**
- . Acute toxicity Based on available data, the classification criteria are not met.

LD/LC50 values relevant for classification:

CAS: 56-81-5 glycerol

| | | |
|--------|------|-------------------------|
| Oral | LD50 | 12,600 mg/kg (rat) |
| Dermal | LD50 | > 10,000 mg/kg (rabbit) |

CAS: 52-51-7 bronopol (INN)

| | | |
|------------|---------|---------------------|
| Oral | LD50 | 307 mg/kg (rat) |
| Dermal | LD50 | > 2,000 mg/kg (rat) |
| Inhalative | LC50/4h | 800 mg/l (rat) |

CAS: 55965-84-9 mixture of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2Hisothiazol-3-one [EC no. 220-239-6] (3:1)

| | | |
|------------|---------|-------------------------|
| Oral | LD50 | 550 mg/kg (rat) |
| Dermal | LD50 | 200 – 1,000 mg/kg (rat) |
| | | 660 mg/kg (rabbit) |
| Inhalative | LC50/4h | 0.31 mg/l (rat) |

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. Primary irritant effect:

. Skin corrosion/irritation

CAS: 52-51-7 bronopol (INN)

Ätz-/Reizwirkung auf die Haut (rab)

CAS: 55965-84-9 mixture of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2Hisothiazol-3-one [EC no. 220-239-6] (3:1)

Ätz-/Reizwirkung auf die Haut (rab)

. Serious eye damage/irritation

CAS: 52-51-7 bronopol (INN)

Irritation of eyes | Augenreiz- und -ätzwirkung (rab)

. Respiratory or skin sensitisation

CAS: 52-51-7 bronopol (INN)

Sensitisation | Sensibilisierung (Guinea Pigs)

CAS: 55965-84-9 mixture of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2Hisothiazol-3-one [EC no. 220-239-6] (3:1)

Sensitisation | Sensibilisierung (Guinea Pigs)

. Additional toxicological information:

CAS: 55965-84-9 mixture of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2Hisothiazol-3-one [EC no. 220-239-6] (3:1)

Oral NOAEL (subchronisch, 90d) < 5 mg/kg (rat)

Dermal NOAEL (subchronisch, 28d) < 3 mg/kg (rat)

. CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)

. Germ cell mutagenicity

Based on available data, the classification criteria are not met.

. Carcinogenicity

Based on available data, the classification criteria are not met.

. Reproductive toxicity

Based on available data, the classification criteria are not met.

. STOT-single exposure

CAS: 52-51-7 bronopol (INN)

STOT SE cat. 3, Atemwegsreizung ()

. STOT-repeated exposure

Based on available data, the classification criteria are not met.

. Aspiration hazard

Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

. 12.1 Toxicity

. Aquatic toxicity:

CAS: 56-81-5 glycerol

LC50 (24h) > 5,000 mg/l (Carassius auratus)

IC50 (16h) > 10,000 mg/l (scenedesmus quadricauda)

CAS: 52-51-7 bronopol (INN)

EC50 (48h) 1.08 mg/l (daphnia magna/gr. Wasserfloh)

EC50 (72h) 0.4 – 2.8 mg/l (Algae)

LC50 (96h) 41.2 mg/l (Oncorhynchus mykiss)

NOEC (21d) 0.03 mg/l /chron. (Desmodesmus subspicatus/Grünalge)

0.06 mg/l /akut (daphnia magna/gr. Wasserfloh)

CAS: 55965-84-9 mixture of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2Hisothiazol-3-one [EC no. 220-239-6] (3:1)

LC50 acute (96h) 0.58 mg/l (danio rerio/ Zebrafisch)

EC50 (48h) 0.16 mg/l (daphnia magna/gr. Wasserfloh)

EC50 (72h) 0.018 mg/l (Desmodesmus subspicatus/Grünalge)

0.379 mg/l (Pseudokirchnerella subcapitata - Algen)

EC50 (96h) 0.47 mg/l (Pseudokirchnerella subcapitata - Algen)

EC50 (16h) 5.7 mg/l (Pseudomonas putida)

LC50 (96h) 0.19 mg/l (Oncorhynchus mykiss)

EC50 acute (21d) > 1 mg/l (daphnia magna/gr. Wasserfloh)

EC50 acute (48h) 1.02 mg/l (daphnia magna/gr. Wasserfloh)

EC50 chron. (3h) 31.7 mg/l (Mikroorganismus)

LOEL chron. (34d) 1.6 mg/l (danio rerio/ Zebrafisch)

NOEC chron. (34d) 0.5 mg/l (danio rerio/ Zebrafisch)

NOEC (96h) 0.032 mg/l (Pseudokirchnerella subcapitata - Algen)

. 12.2 Persistence and degradability

CAS: 56-81-5 glycerol

CSB (chem. Sauerstoffbedarf) 95 mg/l (---)

theor. O2 consumption (theor. Sauerstoffverbrauch) 1.217 g/g (---)

Biodegradability 14d 63 % (---) (Ready Biodegradability)

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CAS: 52-51-7 bronopol (INN)

Biodegradability 28d | 51 – 57 % (Biodegradability - CO2 Evolution Test)

CAS: 55965-84-9 mixture of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2Hisothiazol-3-one [EC no. 220-239-6] (3:1)

Biodegradability | < 50 % /10 Tage

. 12.3 Bioaccumulative potential**CAS: 56-81-5 glycerol**

Log Pow | ≤ 4 (---)

CAS: 52-51-7 bronopol (INN)

Log Pow | 0.17 (---)

. 12.4 Mobility in soil

No further relevant information available.

. Additional ecological information:**. General notes:**

Water hazard class 3 (German Regulation) (Self-assessment): extremely hazardous for water

Do not allow product to reach ground water, water course or sewage system, even in small quantities.

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

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

. 12.5 Results of PBT and vPvB assessment**. PBT:**

Not applicable.

. vPvB:

Not applicable.

. 12.6 Other adverse effects

No further relevant information available.

SECTION 13: Disposal considerations**. 13.1 Waste treatment methods****. Recommendation**

Must be specially treated adhering to official regulations.

. European waste catalogue

HP14 | Ecotoxic

. Uncleaned packaging:**. Recommendation:**

Dispose of packaging according to regulations on the disposal of packagings.

. Recommended cleansing agents:

Water, if necessary together with cleansing agents.

SECTION 14: Transport information**. 14.1 UN-Number****. ADR, IMDG, IATA**

UN3082

. 14.2 UN proper shipping name**. ADR**

3082 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (mixture of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2Hisothiazol-3-one [EC no. 220-239-6] (3:1), 2-BROMO-2-NITROPROPANE-1,3-DIOL)

. IMDG

ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (mixture of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2Hisothiazol-3-one [EC no. 220-239-6] (3:1), 2-BROMO-2-NITROPROPANE-1,3-DIOL), MARINE POLLUTANT

. IATA

ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (mixture of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2Hisothiazol-3-one [EC no. 220-239-6] (3:1), 2-BROMO-2-NITROPROPANE-1,3-DIOL)

. 14.3 Transport hazard class(es)**. ADR****. Class**

9 (M6) Miscellaneous dangerous substances and articles.

. Label

9

. IMDG, IATA**. Class**

9 Miscellaneous dangerous substances and articles.

. Label

9

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| | |
|--|---|
| . 14.4 Packing group . ADR, IMDG, IATA | III |
| . 14.5 Environmental hazards: | Product contains environmentally hazardous substances: mixture of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2Hisothiazol-3-one [EC no. 220-239-6] (3:1) |
| . Marine pollutant: | No |
| . Special marking (ADR): | Symbol (fish and tree) |
| . Special marking (IATA): | Symbol (fish and tree) |
| . 14.6 Special precautions for user | Warning: Miscellaneous dangerous substances and articles. |
| . Hazard identification number (Kemler code): | 90 |
| . EMS Number: | F-A,S-F |
| . Stowage Category | A |
| . 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code | Not applicable. |
| . Transport/Additional information: | Not dangerous according to the above specifications. |
| . ADR | 5L |
| . Limited quantities (LQ) | Code: E1 |
| . Excepted quantities (EQ) | Maximum net quantity per inner packaging: 30 ml |
| | Maximum net quantity per outer packaging: 1000 ml |
| . Transport category | 3 |
| . Tunnel restriction code | - |
| . IMDG | 5L |
| . Limited quantities (LQ) | Code: E1 |
| . Excepted quantities (EQ) | Maximum net quantity per inner packaging: 30 ml |
| | Maximum net quantity per outer packaging: 1000 ml |
| . UN "Model Regulation": | UN 3082 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (MIXTURE OF: 5-CHLORO-2-METHYL-4-ISOTHIAZOLIN-3-ONE [EC NO. 247-500-7] AND 2-METHYL-2HISOTHIAZOL-3-ONE [EC NO. 220-239-6] (3:1), 2-BROMO-2-NITROPROPANE-1,3-DIOL), 9, 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 | E2 Hazardous to the Aquatic Environment |
| . Qualifying quantity (tonnes) for the application of lower-tier requirements | 200 t |
| . Qualifying quantity (tonnes) for the application of upper-tier requirements | 500 t |
| . 15.2 Chemical safety assessment: | A Chemical Safety Assessment has not been carried out. |

SECTION 16: Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

| | |
|-------------------------------|--|
| . Department issuing SDS: | Environment protection department. |
| . 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 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) VOC: Volatile Organic Compounds (USA, EU) DNEL: Derived No-Effect Level (REACH) PNEC: Predicted No-Effect Concentration (REACH) LC50: Lethal concentration, 50 percent LD50: Lethal dose, 50 percent PBT: Persistent, Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative Acute Tox. 3: Acute toxicity – Category 3 Acute Tox. 4: Acute toxicity – Category 4 Acute Tox. 2: Acute toxicity – Category 2 Skin Corr. 1C: Skin corrosion/irritation – Category 1C Skin Irrit. 2: Skin corrosion/irritation – Category 2 Eye Dam. 1: Serious eye damage/eye irritation – Category 1 |

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Eye Irrit. 2: Serious eye damage/eye irritation – Category 2
Skin Sens. 1: Skin sensitisation – Category 1
Skin Sens. 1A: Skin sensitisation – Category 1A
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 1: Hazardous to the aquatic environment - long-term 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.

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