

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 26.10.2017

Version number 1801

Revision: 26.10.2017

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 Milling additive
 No further relevant information available.

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.sirona.de>
 Tel.: +49 (0) 6251/16-1670
 Fax: +49 (0) 6251/16-1818

Manufacturer: Graichen Produktions-und Vertriebs-GmbH
 Darmstädterstraße 127-129
 D-64625 Bensheim
 Germany
 Tel.: +49 6251 73103
 Fax: +49 6251 77901
 E-Mail: ehs@graichen-bensheim.de
www.graichen.net

Further information obtainable from: Environment protection department
 Advice centre for poisoning university Mainz phone +49(0)6131/19240
 or poison information:+49(0)700/GIFTINFO

1.4 Emergency telephone number:

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008
 Skin Sens. 1 H317 May cause an allergic skin reaction.

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

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-isothiazolin-3-one [EC no. 220-239-6] (3:1)

Hazard statements

H317 May cause an allergic skin reaction.

Precautionary statements

P262 Do not get in eyes, on skin, or on clothing.
 P280 Wear protective gloves/protective clothing/eye protection/face protection.
 P281 Use personal protective equipment as required.
 P301+P330+P331 IF SWALLOWED: rinse mouth. Do NOT induce vomiting.
 P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
 P315 Get immediate medical advice/attention.
 P363 Wash contaminated clothing before reuse.
 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.

SECTION 3: Composition/information on ingredients

3.2 Chemical characterisation: Mixtures watery solution of salts, stabilizers and preservatives

Dangerous components:

CAS: 56-81-5	glycerol	50-100%
EINECS: 200-289-5	substance with a Community workplace exposure limit	

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CAS: 52-51-7 EINECS: 200-143-0	bronopol (INN) ☠ Eye Dam. 1, H318; ☠ Aquatic Acute 1, H400; ☠ 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. 3, H311; Acute Tox. 3, H331; ☠ Skin Corr. 1B, H314; ☠ Aquatic Acute 1, H400; Aquatic Chronic 1, H410; ☠ Skin Sens. 1, 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.
Immediately wash with water and soap and rinse thoroughly.
- 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.
Call for a doctor immediately.

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.

- For safety reasons unsuitable extinguishing agents: Water with full jet

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.

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

No special precautions are necessary if used correctly.

- Information about fire - and explosion protection:

No special measures required.

7.2 Conditions for safe storage, including any incompatibilities

Storage:

- 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.

- 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

- Additional information about design of technical facilities:

No further data; see item 7.

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8.1 Control parameters

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

56-81-5 glycerolWEL | Long-term value: 10 mg/m³

· DNELs

56-81-5 glycerolInhalative | DNEL Long-term - local effects | 56 mg/m³ (worker (Arbeitnehmer))

· PNECs

56-81-5 glycerol

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

· CAS No. Designation of material % Type Value Unit

· 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
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 374 part III 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: > 4

· Change in condition

Initial boiling point and boiling range: 100 °C

· Flash point: > 100 °C

· Flammability (solid, gas): Not applicable.

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- Ignition temperature: 400 °C
- Decomposition temperature: Not determined.
- Auto-ignition temperature: Product is not selfigniting.
- Explosive properties: Not determined.
- Explosion limits:
 - Lower: 0,9 Vol %
 - Upper: Not determined.
- Vapour pressure at 20 °C: 0,1 hPa
- Density at 20 °C: 1,2324 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/water: Not determined.
- Viscosity:
 - Dynamic: Not determined.
- **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:

56-81-5 glycerol

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

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)

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)

- Primary irritant effect:
- Skin corrosion/irritation: Based on available data, the classification criteria are not met.
- Serious eye damage/irritation: Based on available data, the classification criteria are not met.
- Respiratory or skin sensitisation: May cause an allergic skin reaction.

· Subacute to chronic toxicity:

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 (carcinogenity, 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.

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· STOT-single exposure

52-51-7 bronopol (INN)

STOT SE cat. 3, Atemwegsreizung ()

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

· 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:

56-81-5 glycerol

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

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

52-51-7 bronopol (INN)

EC50 (48h) 1.4 mg/l (daphnia magna/gr. Wasserfloh)

EC50 (72h) 0.4-2.8 mg/l (Algae)

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

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/ Zebraabärbling)

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) 0.166 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/ Zebraabärbling)

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

· 12.2 Persistence and degradability**56-81-5 glycerol**

CSB (chem. Sauerstoffbedarf) 95 % (---)

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

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

· 12.3 Bioaccumulative potential**56-81-5 glycerol**

Log Pow ≤4 (---)

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 2 (German Regulation) (Self-assessment): hazardous for water

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

· 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.

· Uncleaned packaging:

· Recommendation:

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

SECTION 14: Transport information**· 14.1 UN-Number**

· ADR, ADN, IMDG, IATA

Void

· 14.2 UN proper shipping name

· ADR, ADN, IMDG, IATA

Void

· 14.3 Transport hazard class(es)

· ADR, ADN, IMDG, IATA

· Class

Void

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- **14.4 Packing group**
 - ADR, IMDG, IATA
 - **14.5 Environmental hazards:**
 - Marine pollutant:
 - **14.6 Special precautions for user**
 - **14.7 Transport in bulk according to Annex II of Marpol and the IBC Code**
 - Transport/Additional information:
 - UN "Model Regulation":
- | | |
|--|--|
| | Void |
| | No |
| | Not applicable. |
| | Not applicable. |
| | Not dangerous according to the above specifications. |
| | Void |

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
- REGULATION (EC) No 1907/2006 ANNEX XVII

None of the ingredients is listed.

- **15.2 Chemical safety assessment:**

Conditions of restriction: 3

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:
 - Abbreviations and acronyms:
- | | |
|--|--|
| | Environment protection department. |
| | ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road) |
| | IMDG: International Maritime Code for Dangerous Goods |
| | 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 (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 |
| | Skin Corr. 1B: Skin corrosion/irritation – Category 1B |
| | Skin Irrit. 2: Skin corrosion/irritation – Category 2 |
| | Eye Dam. 1: Serious eye damage/eye irritation – Category 1 |
| | Skin Sens. 1: Skin sensitisation – Category 1 |
| | 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 |

- * Data compared to the previous version altered.

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