

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

#### 1.1. Product identifier

Product name : Dentamet

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

##### 1.2.1. Relevant identified uses

Use of the mixture : Fertilisers

##### 1.2.2. Uses advised against

Any other unidentified use is not recommended.

#### 1.3. Details of the supplier of the safety data sheet

Manufacturer/Supplier: Diachem S.p.A

Registered office: Via Tonale 15, 24061 - Albano Sant'Alessandro (BG), Italy

Plant and offices: Via Mozzanica 9/11, 24043 - Caravaggio (BG), Italy

T 0363/355611 - F 0363/355610

E-mail address of competent person: [infosds@diachemagro.com](mailto:infosds@diachemagro.com)

#### 1.4. Emergency telephone number

Country	Body / company	Address	Emergency number
Italy	Centro Antiveleni di Bergamo Azienda Ospedaliera Papa Giovanni XXII	Piazza OMS - Organizzazione Mondiale della Sanità, 1 24127 Bergamo	800 88 33 00
Italy	Centro Antiveleni di Milano Ospedale Niguarda Ca' Granda	Piazza Ospedale Maggiore 3 20162 Milano	+39 02 6610 1029
Italy	Centro Antiveleni di Roma CAV Policlinico "A. Gemelli", Dipartimento di Tossicologia Clinica Universita Cattolica del Sacro Cuore	Largo Agostino Gemelli, 8 00168 Roma	+39 06 305 4343
Italy	Centro Antiveleni di Roma CAV Policlinico "Umberto I", Università di Roma	Viale del Policlinico, 155 00161 Roma	+39 06 4997 8000
Italy	Centro Antiveleni di Firenze Az. Osp. "Careggi" U.O. Tossicologia Medica, S.O.D. di Tossicologia Clinica	Largo Brambilla, 3 50134 Firenze	+39 055 794 7819
Italy	Centro Antiveleni di Pavia CAV Centro Nazionale di Informazione Tossicologica, IRCCS Fondazione Maugeri	Via Salvatore Maugeri, 10 27100 Pavia	+39 03 822 4444
Italy	Centro Antiveleni di Roma CAV "Osp. Pediatrico Bambino Gesù" Dip. Emergenza e Accettazione DEA	Piazza Sant'Onofrio, 4 00165 Roma	+39 06 6859 3726
Italy	Centro Antiveleni di Foggia Az. Osp. Univ. Foggia	V.le Luigi Pinto, 1 71122 Foggia	+39 800 183 459
Italy	Centro Antiveleni di Napoli Az. Osp. "A. Cardarelli"	Via A. Cardarelli, 9 80131 Napoli	+39 081 54 53 333
Italy	Centro Antiveleni di Verona Azienda Ospedaliera Integrata Verona	Piazzale Aristide Stefani, 1 37126 Verona	+39 800 011 858

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### SECTION 2: Hazards identification

#### 2.1. Classification of the substance or mixture

##### Classification according to Regulation (EC) No. 1272/2008 [CLP]

Skin corrosion/irritation, Category 1	H314
Serious eye damage/eye irritation, Category 1	H318
Specific target organ toxicity – Single exposure, Category 3, Respiratory tract irritation	H335
Hazardous to the aquatic environment – Acute Hazard, Category 1	H400
Hazardous to the aquatic environment – Chronic Hazard, Category 1	H410
Full text of H-statements: see section 16	

##### Adverse physicochemical, human health and environmental effects

Causes severe skin burns and eye damage. May cause respiratory irritation. Very toxic to aquatic life with long lasting effects.

#### 2.2. Label elements

##### Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP)



Signal word (CLP)

: Danger

Contains

: Zinc sulphate eptahydrate; Citric acid monohydrate; copper sulphate pentahydrate

Hazard statements (CLP)

: H314 - Causes severe skin burns and eye damage.  
H335 - May cause respiratory irritation.  
H410 - Very toxic to aquatic life with long lasting effects.  
P260 - Do not breathe vapours, fume.  
P264 - Wash hands thoroughly after handling.  
P273 - Avoid release to the environment.  
P303+P361+P353+P310 - IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower. Immediately call a POISON CENTER, a doctor.  
P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  
P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

Precautionary statements (CLP)

#### 2.3. Other hazards

This mixture does not meet the PBT criteria of REACH regulation, annex XIII

This mixture does not meet the vPvB criteria of REACH regulation, annex XIII

The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %

### SECTION 3: Composition/information on ingredients

#### 3.1. Substances

Not applicable

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### 3.2. Mixtures

Name	Product identifier	Conc. % w/w	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Zinc sulphate eptahydrate	CAS-No.: 7446-19-7 EC-No.: 231-793-3 EC Index-No.: 030-006-00-9 REACH-no: 01-2119474684-27	<20	Acute Tox. 4 (Oral), H302 (ATE=926 mg/kg bodyweight) Eye Dam. 1, H318 Aquatic Acute 1, H400 Aquatic Chronic 1, H410
Citric acid monohydrate	CAS-No.: 77-92-9 (anhydrous form) 5949-29-1 (monohydrate form) EC-No.: 201-069-1 REACH-no: 01-2119457026-42	<25	Eye Irrit. 2, H319 STOT SE 3, H335
copper sulphate pentahydrate (of which Cu metallic 25%)	CAS-No.: 7758-99-8 EC-No.: 231-847-6 EC Index-No.: 029-023-00-0 REACH-no: 01-2119520566-40	5-10 (1.25 - 2.5)	Acute Tox. 4 (Oral), H302 (ATE=500 mg/kg bodyweight) Eye Dam. 1, H318 Aquatic Acute 1, H400 (M=10) Aquatic Chronic 1, H410 (M=10)

Full text of H-statements: see section 16

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

First-aid measures after inhalation	: Remove the injured person from the area of exposure and transfer to a well-ventilated area. Call a doctor.
First-aid measures after skin contact	: Remove contaminated clothing and wash with plenty of soap and water. Call a doctor.
First-aid measures after eye contact	: Wash off immediately with plenty of water and/or isotonic solution for at least 15 minutes. Call a doctor.
First-aid measures after ingestion	: Do not administer anything by mouth and do not induce vomiting if the injured person is unconscious. Call a doctor.

For people providing first aid: Use self-contained breathing equipment for airway protection, suitable clothing and gloves for skin protection.

### 4.2. Most important symptoms and effects, both acute and delayed

Symptoms/effects after inhalation	: May cause respiratory irritation.
Symptoms/effects after skin contact	: Causes severe burns.
Symptoms/effects after eye contact	: Causes serious eye damage.

### 4.3. Indication of any immediate medical attention and special treatment needed

Symptomatic treatment. Consult a poison center.

## SECTION 5: Firefighting measures

### 5.1. Extinguishing media

Suitable extinguishing media	: Use fractionated water, chemical powder, foam or carbon dioxide.
Unsuitable extinguishing media	: No unsuitable extinguishing media were identified.

### 5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire	: Thermal decomposition or combustion may cause the release of toxic and hazardous fumes containing CO <sub>x</sub> , SO <sub>x</sub> , and other substances in the event of incomplete decomposition.
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### 5.3. Advice for firefighters

Precautionary measures fire	: Cool the containers with jet water, even after the fire is extinguished. Remove the containers from the fire area if this can be done safely.
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Protection during firefighting : Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.

### SECTION 6: Accidental release measures

#### 6.1. Personal precautions, protective equipment and emergency procedures

##### 6.1.1. For non-emergency personnel

Emergency procedures : Ventilate spillage area. Avoid contact with skin and eyes. Avoid breathing vapours, mist, fume. Leave the area if you are not in possession of the protective equipment listed in Section 8. Alert the personnel responsible for the management of such emergencies.

##### 6.1.2. For emergency responders

Protective equipment : Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".

#### 6.2. Environmental precautions

Very toxic to aquatic life with long lasting effects. Avoid release to the environment. In case of accidental release or spillage, do not allow the mixture to reach drains and surface or ground water. If the product has escaped into a water course, into the drainage system, or has contaminated the ground or vegetation, notify the competent authorities.

#### 6.3. Methods and material for containment and cleaning up

For containment : Collect spillage. Stop leak without risks if possible.  
Methods for cleaning up : Mechanically recover the product. Cover the contaminated area with absorbent material such as sand or sepiolite.  
Other information : Dispose of materials or solid residues at an authorized site.

#### 6.4. Reference to other sections

For further information refer also to sections 8 and 13.

### SECTION 7: Handling and storage

#### 7.1. Precautions for safe handling

Precautions for safe handling : Ensure good ventilation of the work station. Handle in a well-ventilated space. Wear suitable Personal Protective Equipment (see section 8). Use protective glasses during the mixing / loading phase of the product. Avoid contact with skin and eyes. Avoid breathing vapours, mist, fume.  
Hygiene measures : Remove contaminated clothing and personal protective equipments (PPE) before entering eating areas.

#### 7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in original containers, well-sealed and labelled with the product name, in a cool, dry place, away from sources of ignition. Avoid exposure to light and protect against moisture. Keep away from incompatible materials. Empty containers may also be hazardous due to product residues. Ventilation of the room/area: well-ventilated room. Keep away from food and drink.

#### 7.3. Specific end use(s)

Consult the product label.

### SECTION 8: Exposure controls/personal protection

#### 8.1. Control parameters

##### 8.1.1 National occupational exposure and biological limit values

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<b>Copper sulphate pentahydrate (7758-99-8)</b>	
<b>EU - Indicative Occupational Exposure Limit (IOEL)</b>	
Local name	Copper(II) sulfate pentahydrate
IOEL TWA	0.01 mg/m <sup>3</sup> (respirable fraction)
Remark	(Year of adoption 2014)
Regulatory reference	SCOEL Recommendations

### 8.1.2. Recommended monitoring procedures

<b>Monitoring methods</b>	
Monitoring methods	The measurement of substances in the workplace must be carried out with standardized methods (e.g. UNI EN 689:2019: Workplace atmospheres - Guide for assessment of exposure by inhalation to chemical agents for comparison with limit values and measurement strategy; UNI EN 482:2015: Workplace exposure - General requirements for the performance of procedures for the measurement of chemical agents) or, failing that, with appropriate methods.

### 8.1.3. Air contaminants formed

No additional information available

### 8.1.4. DNEL and PNEC

<b>Zinc sulphate eptahydrate (7446-19-7)</b>	
<b>DNEL/DMEL (Workers)</b>	
Long-term - systemic effects, dermal	8.3 mg/kg bodyweight/day
Long-term - systemic effects, inhalation	1 mg/m <sup>3</sup>
<b>DNEL/DMEL (General population)</b>	
Long-term - systemic effects, oral	0.83 mg/kg bodyweight/day
Long-term - systemic effects, inhalation	1.25 mg/m <sup>3</sup>
Long-term - systemic effects, dermal	8.3 mg/kg bodyweight/day
<b>PNEC (Water)</b>	
PNEC aqua (freshwater)	20.6 µg/L
PNEC aqua (marine water)	6.1 µg/L
<b>PNEC (Sediment)</b>	
PNEC sediment (freshwater)	117.8 mg/kg dwt
PNEC sediment (marine water)	56.5 mg/kg dwt
<b>PNEC (Soil)</b>	
PNEC soil	35.6 mg/kg dwt
<b>PNEC (STP)</b>	
PNEC sewage treatment plant	100 µg/L
<b>Citric acid monohydrate (77-92-9 (anhydrous form) 5949-29-1 (monohydrate form))</b>	
<b>PNEC (Water)</b>	
PNEC aqua (freshwater)	0.44 mg/l
PNEC aqua (marine water)	0.044 mg/l
<b>PNEC (Sediment)</b>	
PNEC sediment (freshwater)	34.6 mg/kg dwt

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<b>Citric acid monohydrate (77-92-9 (anhydrous form) 5949-29-1 (monohydrate form))</b>	
PNEC sediment (marine water)	3.46 mg/kg dwt
<b>PNEC (Soil)</b>	
PNEC soil	33.1 mg/kg dwt
<b>PNEC (STP)</b>	
PNEC sewage treatment plant	1000 mg/l
<b>copper sulphate pentahydrate (7758-99-8)</b>	
<b>DNEL/DMEL (Workers)</b>	
Long-term - systemic effects, dermal	137 mg/kg bodyweight/day
Long-term - systemic effects, inhalation	1 mg/m <sup>3</sup>
Long-term - local effects, inhalation	1 mg/m <sup>3</sup>
<b>DNEL/DMEL (General population)</b>	
Acute - systemic effects, oral	0.082 mg/kg bodyweight
Long-term - systemic effects, oral	0.041 mg/kg bodyweight/day
<b>PNEC (Water)</b>	
PNEC aqua (freshwater)	7.8 µg/L
PNEC aqua (marine water)	5.2 µg/L
<b>PNEC (Sediment)</b>	
PNEC sediment (freshwater)	87 mg/kg dwt
PNEC sediment (marine water)	676 mg/kg dwt
<b>PNEC (Soil)</b>	
PNEC soil	65 mg/kg dwt
<b>PNEC (STP)</b>	
PNEC sewage treatment plant	230 mg/kg dwt

### 8.1.5. Control banding

No additional information available

## 8.2. Exposure controls

### 8.2.1. Appropriate engineering controls

#### Appropriate engineering controls:

Ensure good ventilation of the work station.

### 8.2.2. Personal protection equipment

#### 8.2.2.1. Eye and face protection

##### Eye protection:

Wear protective tightly fitting glasse or protective visor (EN 166).

#### 8.2.2.2. Skin protection

##### Skin and body protection:

Wear category II professional long-sleeved overalls and safety footwear (EN 344). Wash with soap and water after removing protective clothing.

##### Hand protection:

Wear impervious gloves, resistant to chemical agents (eg rubber, neoprene, PVC), complying with EN 374 standard. Take note of the information given by the producer concerning permeability and break through times, and of special workplace conditions (mechanical strain, duration of contact).

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### 8.2.2.3. Respiratory protection

#### Respiratory protection:

Use suitable respiratory protection systems, such as FFP2 class filters (EN 149).

### 8.2.2.4. Thermal hazards

No additional information available

### 8.2.3. Environmental exposure controls

#### Environmental exposure controls:

Avoid release to the environment.

## SECTION 9: Physical and chemical properties

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

Physical state	: Liquid
Colour	: Blue.
Odour	: No data available, experimental evaluation not conducted
Odour threshold	: No data available, experimental evaluation not conducted
Melting point	: No data available, experimental evaluation not conducted
Freezing point	: No data available, experimental evaluation not conducted
Boiling point	: No data available, experimental evaluation not conducted
Flammability	: No data available, experimental evaluation not conducted
Explosive properties	: Not explosive.
Oxidising properties	: Not oxidiser.
Explosive limits	: No data available, experimental evaluation not conducted
Lower explosion limit	: No data available, experimental evaluation not conducted
Upper explosion limit	: No data available, experimental evaluation not conducted
Flash point	: No data available, experimental evaluation not conducted
Auto-ignition temperature	: Not applicable
Decomposition temperature	: No data available, experimental evaluation not conducted
pH	: 1 at 25°C
Viscosity, kinematic	: No data available, experimental evaluation not conducted
Solubility	: No data available, experimental evaluation not conducted
Partition coefficient n-octanol/water (Log Kow)	: No data available, experimental evaluation not conducted
Vapour pressure	: No data available, experimental evaluation not conducted
Vapour pressure at 50°C	: No data available, experimental evaluation not conducted
Density	: No data available, experimental evaluation not conducted
Relative density	: No data available, experimental evaluation not conducted
Relative vapour density at 20°C	: No data available, experimental evaluation not conducted
Particle characteristics	: Not applicable

### 9.2. Other information

#### 9.2.1. Information with regard to physical hazard classes

No additional information available

#### 9.2.2. Other safety characteristics

No additional information available

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

### 10.2. Chemical stability

The mixture is stable under normal temperature and pressure conditions and if stored in closed containers in a cool and well-ventilated place.

### 10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

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### 10.4. Conditions to avoid

None under recommended storage and handling conditions (see section 7).

### 10.5. Incompatible materials

Avoid contact with oxidizers, acids and metals.

### 10.6. Hazardous decomposition products

Thermal decomposition or combustion may cause the release of toxic and hazardous fumes containing CO<sub>x</sub>, SO<sub>x</sub>, and other substances in the event of incomplete decomposition.

## SECTION 11: Toxicological information

### 11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity (oral) : Not classified (Based on available data, the classification criteria are not met)  
Acute toxicity (dermal) : Not classified (Based on available data, the classification criteria are not met)  
Acute toxicity (inhalation) : Not classified (Based on available data, the classification criteria are not met)

#### Zinc sulphate eptahydrate (7446-19-7)

LD50 oral rat	926 mg/kg equivalent to 337 mg Zn/kg, according to OECD 401, measured on mouse
LD50 dermal rat	> 2000 mg/kg bodyweight
STA CLP (oral)	926 mg/kg bodyweight

#### Citric acid monohydrate (77-92-9 (anhydrous form) 5949-29-1 (monohydrate form))

LD50 oral	5400 mg/kg bodyweight Animal: mouse, Guideline: OECD Guideline 401 (Acute Oral Toxicity), 95% CL: 4500 - 6400
LD50 dermal rat	> 2000 mg/kg bodyweight Animal: rat, Guideline: OECD Guideline 402 (Acute Dermal Toxicity)
Additional information	Exposure to citric acid aerosol causes coughing (test on guinea pigs)

#### copper sulphate pentahydrate (7758-99-8)

LD50 oral rat	482 mg/kg
LD50 dermal rat	> 2000 mg/kg

Skin corrosion/irritation : Causes severe skin burns. (Based on available data, the classification criteria are not met)  
pH: 1 at 25°C

Additional information : *Zinc sulphate eptahydrate*: In skin irritation/corrosion study, conducted according OECD guideline 404, zinc sulphate heptahydrate was not found irritant on rabbit skin.  
*Citric acid*: non-irritant to slightly irritant (in vivo test on rabbits).  
*Copper sulfate pentahydrate*: Considered a skin irritant.

#### Citric acid monohydrate (77-92-9 (anhydrous form) 5949-29-1 (monohydrate form))

Citric acid	non-irritant to slightly irritant (in vivo test on rabbits).
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Serious eye damage/irritation : Causes serious eye damage. (Based on available data, the classification criteria are not met)  
pH: 1 at 25°C

Additional information : *Zinc sulphate eptahydrate*: In an eye irritation/corrosion study, conducted according to OECD guideline 405, zinc sulphate heptahydrate was not found irritant on rabbit eyes.  
Effects on eye irritation: moderately irritating  
*Copper sulfate pentahydrate*: The test substance is severely irritating to rabbit eyes (OECD 405)

#### Citric acid monohydrate (77-92-9 (anhydrous form) 5949-29-1 (monohydrate form))

Citric acid	the substance resulted an eye irritant in an in vivo test on rabbits.
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Respiratory or skin sensitisation : Not classified (Based on available data, the classification criteria are not met)



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<b>Zinc sulphate eptahydrate (7446-19-7)</b>	
Additional information	The substance was tested in an in vivo non-LLNA (OECD 406) and in a in vivo LLNA tests. Both lead to conclude that the substance does not induce skin sensitisation.
<b>Citric acid monohydrate (77-92-9 (anhydrous form) 5949-29-1 (monohydrate form))</b>	
Citric acid	low sensitising potential on skin (test on rabbits and on humans).
<b>copper sulphate pentahydrate (7758-99-8)</b>	
Additional information	Copper II sulfate pentahydrate did not produce a delayed contact sensitization response in guinea pigs and is not considered a skin sensitizer under the study conditions used (in vivo test, non-LLNA).
Germ cell mutagenicity	: Not classified (Based on available data, the classification criteria are not met)
Additional information	: <i>Zinc sulphate eptahydrate</i> : Zinc soluble compounds did not show any mutagenic effect both in in vitro and in vivo studies, such as the Ames test, the chromosomal aberrations, micronucleus test, the exchange of brothers chromatides and in a dominant lethal mutation assay. <i>Copper sulfate pentahydrate</i> : Based on in vivo and in vitro studies, copper and its compounds were not genotoxic
<b>Citric acid monohydrate (77-92-9 (anhydrous form) 5949-29-1 (monohydrate form))</b>	
Citric acid	in vitro and in vivo tests (on rats) did not show any mutagenic effect.
Carcinogenicity	: Not classified (Based on available data, the classification criteria are not met)
<b>Zinc sulphate eptahydrate (7446-19-7)</b>	
Additional information	There are a range of epidemiological studies that investigated the association between zinc exposure either through occupational activities or food supplementation and increased cancer risks. While no associations were found between occupational zinc exposure and excess cancer risk, the main association that has been made in this context is related to dietary/supplemental zinc and prostate cancer risk. Anyway, these epidemiological studies have not established a relationship for any effect or lack thereof of dietary/supplemental zinc on the risk of prostate cancer.
<b>Citric acid monohydrate (77-92-9 (anhydrous form) 5949-29-1 (monohydrate form))</b>	
Citric acid	tests on animals (rats) did not show carcinogenic effects.
<b>copper sulphate pentahydrate (7758-99-8)</b>	
Additional information	The available data for copper compounds do not meet the criteria requiring classification for carcinogenicity.
Reproductive toxicity	: Not classified (Based on available data, the classification criteria are not met)
<b>Zinc sulphate eptahydrate (7446-19-7)</b>	
Additional information	The reproductive toxicity of zinc compounds was assessed using existing human studies which examined the responses of healthy women to zinc supplementation during pregnancy: the reviewers concluded that zinc at a rate of 20 and 30 mg/kg bw/day did not result in any adverse reproductive effects during pregnancy. A NOAEL of 20 mg/kg bw/day was established. For the effects on foetuses a NOAEL of 50 mg/kg bw/day was established.
<b>Citric acid monohydrate (77-92-9 (anhydrous form) 5949-29-1 (monohydrate form))</b>	
Citric acid	tests on animals (rats, mice, hamsters) did not show toxic effects on reproduction.
<b>copper sulphate pentahydrate (7758-99-8)</b>	
NOAEL (animal/male, F0/P)	24 mg/kg bodyweight
Additional information	It is considered inappropriate to consider copper compounds and copper itself as potential teratogenic compounds due to the complex role of copper in regulating normal fetal development in humans.
STOT-single exposure	: May cause respiratory irritation.

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### Citric acid monohydrate (77-92-9 (anhydrous form) 5949-29-1 (monohydrate form))

STOT-single exposure	May cause respiratory irritation.
STOT-repeated exposure	: Not classified (Based on available data, the classification criteria are not met)
Additional information	: The pivotal repeat-dose study is a 90-day oral study with copper sulfate pentahydrate. In rats and mice, ingestion of copper sulfate pentahydrate caused stomach lesions which could be due to the irritant effects of the compound. The NOAEL for this effect was 16.7 mg Cu/kg bw/day in rats and 97 and 126 mg Cu/kg bw/day in male and female mice, respectively.

### Zinc sulphate eptahydrate (7446-19-7)

NOAEL (oral, rat, 90 days)	13.3 mg/kg bodyweight/day At higher doses the most important effects in the rats were the development of hypocupremia, significant changes in the pancreas (i.e., degeneration and necrosis) and a decreased number of pigmented macrophages in spleen.
NOAEC (inhalation, rat, dust/mist/fume, 90 days)	2.7 mg/m <sup>3</sup> of ultrafine ZnO, which resulted in changes in neutrophils and activities of lactate dehydrogenase and alkaline phosphatase in the pulmonary fluid

### Citric acid monohydrate (77-92-9 (anhydrous form) 5949-29-1 (monohydrate form))

LOAEL (oral, rat, 90 days)	8000 mg/kg bodyweight Animal: rat
NOAEL (oral, rat, 90 days)	4000 mg/kg bodyweight Animal: rat
Citric acid	NOAEL = 1200 mg/kg bw/d (2 years study on rats, oral administration through diet). Main adverse effects observed: alterations in the hematic levels and in the excretion kinetics of metals.

Aspiration hazard	: Not classified (Based on available data, the classification criteria are not met)
Additional information	: No aspiration toxicity hazards reported for humans.

## 11.2. Information on other hazards

### 11.2.1. Endocrine disrupting properties

Adverse health effects caused by endocrine disrupting properties	: The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605
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### 11.2.2. Other information

Potential adverse human health effects and symptoms	: Causes severe skin burns and eye damage, May cause respiratory irritation.
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## SECTION 12: Ecological information

### 12.1. Toxicity

Hazardous to the aquatic environment, short-term (acute)	: Very toxic to aquatic life.
Hazardous to the aquatic environment, long-term (chronic)	: Very toxic to aquatic life with long lasting effects.

### Zinc sulphate eptahydrate (7446-19-7)

LC50 - Fish	0.169 – 0.78 mg/l of Zn, on Pimephales promelas (96 h)
EC50 - Other aquatic organisms	0.147 – 0.228 mg/l of Zn, on Ceriodapnia dubia (48h)
EC50 72h - Algae	≥ 0.136 mg/l of Zn, on Selenastrum capricornutum (96h)
NOEC chronic fish	< 0.53 mg/l of Zn, on Salvelinus fontinalis (36 months)
NOEC chronic crustacea	< 0.4 mg/l of Zn (on Paracentrotus lividus)
NOEC chronic algae	0.019 mg/l of Zn, on Pseudokirchneriella subcapitata

### Citric acid monohydrate (77-92-9 (anhydrous form) 5949-29-1 (monohydrate form))

LC50 - Fish	440 – 760 mg/l in 96h, on Leuciscus idus
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### Citric acid monohydrate (77-92-9 (anhydrous form) 5949-29-1 (monohydrate form))

EC50 - Crustacea	120 mg/l
EC50 72h - Algae	425 mg/l for 168h, lethal effect on Scenedesmus quadricauda

### copper sulphate pentahydrate (7758-99-8)

EC50 - Crustacea	25 µg/l
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## 12.2. Persistence and degradability

### Zinc sulphate eptahydrate (7446-19-7)

Persistence and degradability	Zinc is an element and does not degrade after the dissociation of zinc sulphate in the environment. The same is valid for the sulphate ion. Zinc does not bioaccumulate in water and soil and is an essential element for the optimal development of living organisms.
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### Citric acid monohydrate (77-92-9 (anhydrous form) 5949-29-1 (monohydrate form))

Biodegradation	97 % in 28 days
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### copper sulphate pentahydrate (7758-99-8)

Persistence and degradability	Copper ions derived from tribasic copper sulphate cannot be degraded. The fate of copper ions in the water column was modelled using the Ticket Unit World Model. Removal was also assessed using data from one mesocosm and three field studies. "Rapid" removal was demonstrated, defined as 70% removal within 28 days. Literature data confirm the strong binding of copper ions to sediment, with the formation of stable Cu-S complexes. Re-mobilisation of copper ions to the water column is therefore not expected. Copper does not meet the criteria as "persistent".
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## 12.3. Bioaccumulative potential

### Zinc sulphate eptahydrate (7446-19-7)

Bioaccumulative potential	The Kp for the distribution between sediment and water (Kpsed) was estimated in the RAR from that for particulate matter, as follows: $K_{psed} = K_{psusp} / 1.5$ , based on the average difference in concentrations of zinc and other metals in both media. For zinc this results in a Kpsed of 73,000 l/kg.
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### Citric acid monohydrate (77-92-9 (anhydrous form) 5949-29-1 (monohydrate form))

Bioaccumulative potential	On the basis of the partition coefficient n-octanol/water (Kow) or the bioconcentration factor (BCF) it was foreseen that citric acid (Log Kow = between -1.61 and -1.80); BCF(calc.) = 0.5) does not bioaccumulate.
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### copper sulphate pentahydrate (7758-99-8)

Bioaccumulative potential	As sulfur is an inorganic substance, it will not have any significant potential for bioaccumulation.
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## 12.4. Mobility in soil

### copper sulphate pentahydrate (7758-99-8)

Ecology - soil	Copper ions bond strongly to the ground. The average water / soil partition coefficient (Kp) is 2120 L / Kg.
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## 12.5. Results of PBT and vPvB assessment

### Dentamet

This mixture does not meet the PBT criteria of REACH regulation, annex XIII

This mixture does not meet the vPvB criteria of REACH regulation, annex XIII

# Dentamet

## Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878

### 12.6. Endocrine disrupting properties

Adverse effects on the environment caused by endocrine disrupting properties

: The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605.

### 12.7. Other adverse effects

No additional information available

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods




Waste treatment methods

: If wastes and/or containers cannot be disposed of according to the product label directions, disposal of this material must be in accordance with your local or area regulatory authorities. This information presented below only applies to the material as supplied. The identification based on characteristic(s) or listing may not apply if the material has been used or otherwise contaminated. It is the responsibility of the waste generator to determine the toxicity and physical properties of the material generated to determine the proper waste identification and disposal methods in compliance with applicable regulations. If the material as supplied becomes a waste, follow all applicable regional, national and local laws.

The definitive assignment of this material to the appropriate EWC group and thus its proper EWC code will depend on the use that is made of this material. Contact the authorized waste disposal services.

## SECTION 14: Transport information

In accordance with ADR / IMDG / IATA / RID

ADR	IMDG	IATA
<b>14.1. UN number or ID number</b>		
UN 1760	UN 1760	UN 1760
<b>14.2. UN proper shipping name</b>		
CORROSIVE LIQUID, N.O.S. (Citric acid monohydrate ; copper sulphate pentahydrate)	CORROSIVE LIQUID, N.O.S. (Citric acid monohydrate ; copper sulphate pentahydrate)	Corrosive liquid, n.o.s. (Citric acid monohydrate ; copper sulphate pentahydrate)
<b>Transport document description</b>		
UN 1760 CORROSIVE LIQUID, N.O.S. (Citric acid monohydrate ; copper sulphate pentahydrate), 8, III, (E), ENVIRONMENTALLY HAZARDOUS	UN 1760 CORROSIVE LIQUID, N.O.S. (Citric acid monohydrate ; copper sulphate pentahydrate), 8, III, MARINE POLLUTANT/ENVIRONMENTALLY HAZARDOUS	UN 1760 Corrosive liquid, n.o.s. (Citric acid monohydrate ; copper sulphate pentahydrate), 8, III, ENVIRONMENTALLY HAZARDOUS
<b>14.3. Transport hazard class(es)</b>		
8	8	8
		
<b>14.4. Packing group</b>		
III	III	III

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ADR	IMDG	IATA
<b>14.5. Environmental hazards</b>		
Dangerous for the environment: Yes	Dangerous for the environment: Yes Marine pollutant: Yes	Dangerous for the environment: Yes
No supplementary information available		

### 14.6. Special precautions for user

#### Overland transport

Classification code (ADR)	: C9
Limited quantities (ADR)	: 5I
Excepted quantities (ADR)	: E1
Transport category (ADR)	: 3
Hazard identification number (Kemler No.)	: 80

#### Transport by sea

Limited quantities (IMDG)	: 5 L
Excepted quantities (IMDG)	: E1

#### Air transport

PCA Excepted quantities (IATA)	: E1
PCA Limited quantities (IATA)	: Y841
PCA limited quantity max net quantity (IATA)	: 1L
PCA packing instructions (IATA)	: 852
PCA max net quantity (IATA)	: 5L
CAO packing instructions (IATA)	: 856
CAO max net quantity (IATA)	: 60L
Special provisions (IATA)	: A3, A803
ERG code (IATA)	: 8L

### 14.7. Maritime transport in bulk according to IMO instruments

Not applicable

## SECTION 15: Regulatory information

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

#### 15.1.1. EU-Regulations

Other information, restriction and prohibition regulations : Regulation RECh (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals.

#### REACH Annex XVII (Restriction List)

Contains no substance(s) listed on REACH Annex XVII (Restriction Conditions)

#### REACH Annex XIV (Authorisation List)

Contains no substance(s) listed on REACH Annex XIV (Authorisation List)

#### REACH Candidate List (SVHC)

Contains no substance(s) listed on the REACH Candidate List

#### Seveso Directive (Disaster Risk Reduction)

Seveso Additional information : Seveso III: Directive 2012/18/EU of the European Parliament and of the Council of 4 July 2012 on the control of major-accident hazards involving dangerous substances, transposed in Italy with D. Lgs. 105/2015. Section: E Category: E1

### 15.2. Chemical safety assessment

No chemical safety assessment has been carried out

# Dentamet

## Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878

### SECTION 16: Other information

#### Indication of changes:

Edition: 2 Revision: 0 dated 12/16/2022 (17° ATP, Regulation 2020/878).

Abbreviations and acronyms:	
ACGIH	American Conference of Governmental Industrial Hygienists
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
BCF	Bioconcentration factor
CAS	Chemical Abstract Service (division of the American Chemical Society)
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008
DMEL	Derived Minimal Effect level
DNEL	Derived-No Effect Level
EC50	Median effective concentration
IARC	International Agency for Research on Cancer
IATA	International Air Transport Association
IMDG	International Maritime Dangerous Goods
LC50	Median lethal concentration
LD50	Median lethal dose
LOAEL	Lowest Observed Adverse Effect Level
NOAEC	No-Observed Adverse Effect Concentration
NOAEL	No-Observed Adverse Effect Level
NOEC	No-Observed Effect Concentration
OEL	Occupational Exposure Limit
PBT	Persistent Bioaccumulative Toxic
PNEC	Predicted No-Effect Concentration
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
SDS	Safety Data Sheet
STP	Sewage treatment plant
TLV/TWA	Threshold Limit Value/Threshold Weighted Average
vPvB	Very Persistent and Very Bioaccumulative

Data sources

: ECHA Database. GESTIS International Limit Values, available on [http://limitvalue.ifa.dguv.de/WebForm\\_ueliste.aspx](http://limitvalue.ifa.dguv.de/WebForm_ueliste.aspx).

Training advice

: Training instructions: Comply with the provisions of Directive 98/24/EC and subsequent amendments and national implementations.

#### Full text of H-statements:

H302	Harmful if swallowed.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
H400	Very toxic to aquatic life.

# Dentamet

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### Full text of H-statements:

H410	Very toxic to aquatic life with long lasting effects.
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### Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:

Skin Corr. 1	H314	On basis of test data
Eye Dam. 1	H318	On basis of test data
STOT SE 3	H335	Calculation method
Aquatic Acute 1	H400	Calculation method
Aquatic Chronic 1	H410	Calculation method

#### Safety Data Sheet (SDS), EU

The document aims to provide guidance for appropriate handling and precaution of this product by qualified personnel or operating under the supervision of personnel trained in handling chemicals. The product should not be used for purposes other than those mentioned in section 1, unless they are given adequate written information received on how to handle the material.

The provider of this document cannot provide any warnings related to the dangers of using, interaction with other materials or chemicals or user's safe use of the product, the suitability of the product for which is applied or its proper disposal. The information above should not be considered a declaration or guarantee, either expressed or implied, of merchantability, fitness for a particular purpose, quality, or any other.