

1 Identification

- **Product identifier**
- **Trade name:** Dilucap PSD
- **Article number:** 106360
- **Relevant identified uses of the substance or mixture and uses advised against**
No further relevant information available.
- **Application of the substance / the mixture** Pharma excipient

- **Details of the supplier of the safety data sheet**

- **Manufacturer/Supplier:**

Fagron Services B.V.
Molenwerk 13, UITGEEST, 1911DB
Netherlands
Phone: +31251361400

Supplier
Azelis Australia
Suite 217
117 Old Pittwater Road
Brookvale
NSW 2100
Australia
Phone: +61 0299392188
Fax: +61 0299392799
e-mail: info@azelis.com.au

- **Further information obtainable from:** info@fagron.com.au

- **Emergency telephone number:**

In case of emergency, please call your local poisons:
Emergency Australia: 13 11 26
Emergency NZ: 0800 764 766 (0800 POISON)

1800 127 406 (24 h, Australia) | +64 4 917 9888 (24 h, Worldwide) CareChem 24x7 : EUROPE:
+44 1235 239670 | USA: +1 202 464 2554 | CANADA - +1 800 579 7421 (Toll Free)| ASIA - +65
3158 1074 | MOROCCO - +44 1235 239671 | REST OF THE WORLD - +44 1865 407333
(English only)

2 Hazard(s) Identification

- **Classification of the substance or mixture**
Eye Irritation 2A H319 Causes serious eye irritation.

- **Label elements**

- **GHS label elements**

The product is classified and labelled according to the Globally Harmonised System (GHS).

- **Hazard pictograms**



GHS07

- **Signal word** Warning
- **Hazard statements**
Causes serious eye irritation.

(Contd. on page 2)

AUS

Trade name: Dilucap PSD

(Contd. of page 1)

- **Precautionary statements**
Wash thoroughly after handling.
Wear eye protection / face protection.
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
If eye irritation persists: Get medical advice/attention.
- **Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

3 Composition and Information on Ingredients

- **Chemical characterisation: Mixtures**
- **Description:** Mixture of substances listed below with nonhazardous additions.

• Dangerous components:		
CAS: 9004-34-6	Microcrystalline Cellulose 102	50–≤100%
CAS: 112926-00-8	Silicon dioxide (amorphous silica, precipitated silica) Tixosil	1–≤3%
CAS: 151-21-3	Dodecyl Sulfate Sodium Salt Natrii laurilsulfas Acute Tox. 3, H311; Eye Dam. 1, H318; Acute Tox. 4, H302; Skin Irrit. 2, H315; STOT SE 3, H335	1%

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

4 First Aid Measures

- **Description of first aid measures**
- **General information:**
In case of irregular breathing or respiratory arrest provide artificial respiration.
- **After inhalation:** Supply fresh air; consult doctor in case of complaints.
- **After skin contact:**
Immediately wash with water and soap and rinse thoroughly.
If skin irritation continues, consult a doctor.
- **After eye contact:**
Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
- **After swallowing:** Seek immediate medical advice.
- **Information for doctor:**
- **Most important symptoms and effects, both acute and delayed**
No further relevant information available.
- **Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

5 Fire Fighting Measures

- **Extinguishing media**
- **Suitable extinguishing agents:**
Use fire extinguishing methods suitable to surrounding conditions.
Foam
Carbon dioxide
Water
- **Special hazards arising from the substance or mixture**
In case of fire, the following can be released:

(Contd. on page 3)

AUS

Trade name: Dilucap PSD

(Contd. of page 2)

- Carbon monoxide (CO)
- **Advice for firefighters**
- **Protective equipment:**
Wear self-contained respiratory protective device.
Wear fully protective suit.

6 Accidental Release Measures

- **Personal precautions, protective equipment and emergency procedures**
Avoid formation of dust.
Wear protective equipment. Keep unprotected persons away.
- **Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:**
Ensure adequate ventilation.
Dispose of the material collected according to regulations.
Dispose contaminated material as waste according to item 13.
- **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.

7 Handling and Storage

- **Handling:**
- **Precautions for safe handling**
Ensure good ventilation/exhaustion at the workplace.
Prevent formation of dust.
- **Information about fire - and explosion protection:** No special measures required.
- **Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** No special requirements.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:**
Keep container tightly sealed.
Store in cool, dry conditions in well sealed receptacles.
Protect from heat and direct sunlight.
- **Specific end use(s)** No further relevant information available.

8 Exposure controls and personal protection

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

- **Ingredients with limit values that require monitoring at the workplace:**

CAS: 9004-34-6 Microcrystalline Cellulose 102

WES Long-term value: 10 mg/m³

CAS: 112926-00-8 Silicon dioxide (amorphous silica, precipitated silica)
Tixosil

WES Long-term value: 10 mg/m³

- **Additional information:** The lists valid during the making were used as basis.

(Contd. on page 4)

AUS

Trade name: Dilucap PSD

(Contd. of page 3)

- **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.
 - Avoid contact with the eyes and skin.
- **Respiratory protection:** Suitable respiratory protective device recommended.
- **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**

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 through time has to be found out by the manufacturer of the protective gloves and has to be observed.
- **Eye protection:**



Tightly sealed goggles

- **Body protection:** Protective work clothing

9 Physical and Chemical Properties

- | | |
|--|-----------------|
| · Information on basic physical and chemical properties | |
| · General Information | |
| · Appearance: | |
| Form: | Powder |
| Colour: | White |
| · Odour: | Characteristic |
| · Odour threshold: | Not determined. |
| · pH-value: | Not applicable. |
| · Change in condition | |
| Melting point/freezing point: | Undetermined. |
| Initial boiling point and boiling range: | Undetermined. |
| · Flash point: | Not applicable. |
| · Flammability (solid, gas): | Not determined. |

(Contd. on page 5)

AUS

Trade name: Dilucap PSD

(Contd. of page 4)

· Ignition temperature:	340°C
· Decomposition temperature:	Not determined.
· Auto-ignition temperature:	Product is not selfigniting.
· Explosive properties:	Product does not present an explosion hazard.
· Explosion limits:	
Lower:	Not determined.
Upper:	Not determined.
· Vapour pressure:	Not applicable.
· Density:	Not determined.
· Relative density	Not determined.
· Vapour density	Not applicable.
· Evaporation rate	Not applicable.
· Solubility in / Miscibility with water:	Insoluble.
· Partition coefficient: n-octanol/water:	Not determined.
· Viscosity:	
Dynamic:	Not applicable.
Kinematic:	Not applicable.
· Solvent content:	
Solids content:	100.0 %
· Other information	No further relevant information available.

10 Stability and Reactivity

- **Reactivity** No further relevant information available.
- **Chemical stability**
- **Thermal decomposition / conditions to be avoided:**
No decomposition if used according to specifications.
- **Possibility of hazardous reactions** No dangerous reactions known.
- **Conditions to avoid** No further relevant information available.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** Carbon monoxide and carbon dioxide

11 Toxicological Information

- Information on toxicological effects
- Acute toxicity

· LD/LC50 values relevant for classification:		
ATE (Acute Toxicity Estimates)		
Oral	LD50	120000 mg/kg (rat)
Dermal	LD50	>50000 mg/kg (rabbit)
CAS: 112926-00-8 Silicon dioxide (amorphous silica, precipitated silica)		
Tixosil		
Oral	LD50	>5000 mg/kg (rat)

(Contd. on page 6)

AUS

Trade name: Dilucap PSD

(Contd. of page 5)

Dermal	LD50	>5000 mg/kg (rabbit)
CAS: 151-21-3 Dodecyl Sulfate Sodium Salt Natrii laurilsulfas		
Oral	LD50	1200 mg/kg (rat)
Dermal	LD50	>500 mg/kg (rabbit)

- **Primary irritant effect:**
- **Serious eye damage/irritation** Irritating effect.
- **Additional toxicological information:**
The product shows the following dangers according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version:
Irritant

12 Ecological Information

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Behaviour in environmental systems:**
- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.
- **Additional ecological information:**
- **General notes:**
Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

13 Disposal considerations

- **Waste treatment methods**
- **Recommendation**
Must not be disposed together with household garbage. Do not allow product to reach sewage system.
- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

14 Transport information

· UN-Number	
· ADG, IMDG, IATA	not regulated
· UN proper shipping name	
· ADG, IMDG, IATA	not regulated
· Transport hazard class(es)	
· ADG, ADN, IMDG, IATA	
· Class	not regulated

(Contd. on page 7)

AUS

Trade name: Dilucap PSD

(Contd. of page 6)

- | | |
|---|-----------------|
| · Packing group | |
| · ADG, IMDG, IATA | not regulated |
| · Environmental hazards: | Not applicable. |
| · Special precautions for user | Not applicable. |
| · Transport in bulk according to Annex II of Marpol and the IBC Code | Not applicable. |
| · UN "Model Regulation": | not regulated |

15 Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**

- **Australian Inventory of Industrial Chemicals**

All ingredients are listed.

- **Standard for the Uniform Scheduling of Medicines and Poisons**

None of the ingredients is listed.

- **Australia: Priority Existing Chemicals**

None of the ingredients is listed.

- **Directive 2012/18/EU**

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

- **National regulations:**

- **Other regulations, limitations and prohibitive regulations**

Therapeutic goods are listed on the Australian Register of Therapeutic Goods (ARTG)

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

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.

- **Relevant phrases**

H302 Harmful if swallowed.
H311 Toxic in contact with skin.
H315 Causes skin irritation.
H318 Causes serious eye damage.
H335 May cause respiratory irritation.

- **Department issuing SDS:** Product Safety Department

- **Contact:**

- **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

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)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

(Contd. on page 8)

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Safety Data Sheet

according to WHS Regulations

Page 8/8

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Trade name: Dilucap PSD

(Contd. of page 7)

Acute Tox. 4: Acute toxicity – Category 4
Acute Tox. 3: Acute toxicity – Category 3
Skin Irrit. 2: Skin corrosion/irritation – Category 2
Eye Dam. 1: Serious eye damage/eye irritation – Category 1
Eye Irritation 2A: Serious eye damage/eye irritation – Category 2A
STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

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