

1 Identification

- **Product identifier**
- **Trade name:** DILUCAP OD
- **Article number:** 106382
- **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, UITGEEEST, 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**
The product is not classified, according to the Globally Harmonised System (GHS).
- **Label elements**
- **GHS label elements** Void
- **Hazard pictograms** Void
- **Signal word** Void
- **Hazard statements** Void
- **Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

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3 Composition and Information on Ingredients

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

- **Dangerous components:**

CAS: 77-92-9	citric acid Skin Irrit. 2, H315; Serious eye damage/irritation – Category 2A, H319; STOT SE 3, H335	3–≤5%
CAS: 57-55-6	Propylene glycol	1–≤3%
CAS: 64-17-5	Ethanol / Alcohol 99,5% v/v (absolute Flam. Liq. 2, H225; Serious eye damage/irritation – Category 2A, H319	1–≤3%

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

4 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

- **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:
Carbon monoxide (CO)
- **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.

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- **Methods and material for containment and cleaning up:**
Pick up mechanically.
Dispose of the material collected according to regulations.
Dispose contaminated material as waste according to section 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** Prevent formation of dust.
- **Information about fire - and explosion protection:** No special measures required.
- **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 section 7.

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

CAS: 57-55-6 Propylene glycol	
WES	Long-term value: 474* 10** mg/m ³ , 150* ppm *vapour&particulates;**particulates only
CAS: 64-17-5 Ethanol / Alcohol 99,5% v/v (absolute)	
WES	Long-term value: 1880 mg/m ³ , 1000 ppm

- **Additional information:** The lists valid during the making were used as basis.
- **Personal protective equipment:**
- **General protective and hygienic measures:** Wash hands before breaks and at the end of work.
- **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

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• **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:** Safety glasses

• **Body protection:** Protective work clothing

9 Physical and Chemical Properties

• **General Information**

• **Appearance:**

• **Form:** Powder

• **Colour:** Yellowish

• **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.

• **Decomposition temperature:** Not determined.

• **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:** Soluble.

• **Partition coefficient: n-octanol/water:** Not determined.

• **Viscosity:**

• **Dynamic:** Not applicable.

• **Kinematic:** Not applicable.

• **Solvent content:**

• **Organic solvents:** 4.9 %

• **Other information** No further relevant information available.

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10 Stability and Reactivity

- **Reactivity** No further relevant information available.
- **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** Based on available data, the classification criteria are not met.

• LD/LC50 values relevant for classification:

CAS: 77-92-9 citric acid

Oral	LD50	5400 mg/kg (rat)
Dermal	LD50	>2000 mg/kg (rat)

CAS: 57-55-6 Propylene glycol

Oral	LD50	>10400 mg/kg (rat)
Dermal	LD50	20800 mg/kg (rabbit)

CAS: 64-17-5 Ethanol / Alcohol 99,5% v/v (absolute)

Oral	LD50	7060 mg/kg (rat)
Inhalative	LC50/4 h	20000 mg/l (rat)

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

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.

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- **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.
- **Recommended cleansing agents:** Water, if necessary together with cleansing agents.

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
· 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	
CAS: 9050-36-6	Maltodextrin
CAS: 77-92-9	citric acid
CAS: 9063-38-1	Sodium Starch Glycolate
CAS: 57-55-6	Propylene glycol
CAS: 64-17-5	Ethanol / Alcohol 99,5% v/v (absolute)

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CAS: 8002-43-5	Lecithins Soy lecithin
CAS: 112926-00-8	Silicon dioxide (amorphous silica, precipitated silica) Tixosil
CAS: 138-86-3	dipentene
CAS: 6381-92-6	Edetate Disodium
CAS: 57817-89-7	Stevioside
CAS: 78-70-6	Linalool
CAS: 53850-34-3	Proteins, thaumatins

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

CAS: 64-17-5	Ethanol / Alcohol 99,5% v/v (absolute)	Not scheduled
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- **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**
H225 Highly flammable liquid and vapour.
H315 Causes skin irritation.
H319 Causes serious eye irritation.
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
Flam. Liq. 2: Flammable liquids – Category 2
Skin Irrit. 2: Skin corrosion/irritation – Category 2
Serious eye damage/irritation – Category 2A: Serious eye damage/eye irritation – Category 2A
STOT SE 3: Specific target organ toxicity (single exposure) – Category 3
- *** Data compared to the previous version altered.**

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