

## 1 Identification

- **Product identifier**
- **Trade name:** DILUCAP OD
- **Article number:** 106382
- **Application of the substance / the mixture** Pharma excipient
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**  
Fagron Inc  
2400 Pilot Knob Road  
St. Paul, MN 55120  
www.fagron.us  
QA@fagron.us
- **Information department:**  
Tel.: 800-423-6967  
Fax: 800-339-1596
- **Emergency telephone number:**  
Emergency Telephone:  
US: 1-800-535-5053  
International: 1-352-323-3500

## 2 Hazard(s) identification

- **Classification of the substance or mixture**  
Sensitization - Skin 1 H317 May cause an allergic skin reaction.  
Carcinogenicity 1A H350 May cause cancer.
- **Label elements**
- **GHS label elements**  
The product is classified and labeled according to the Globally Harmonized System (GHS).
- **Hazard pictograms**



GHS07 GHS08

- **Signal word** Danger
- **Hazard-determining components of labeling:**  
Ethanol / Alcohol 99,5% v/v (absolute  
dipentene
- **Hazard statements**  
May cause an allergic skin reaction.  
May cause cancer.
- **Precautionary statements**  
Obtain special instructions before use.  
Do not handle until all safety precautions have been read and understood.  
Avoid breathing dust/fume/gas/mist/vapors/spray  
Contaminated work clothing must not be allowed out of the workplace.  
Wear protective gloves/protective clothing/eye protection/face protection.  
If on skin: Wash with plenty of water.  
If exposed or concerned: Get medical advice/attention.

(Contd. on page 2)

**Trade name: DILUCAP OD**

(Contd. of page 1)

Specific treatment (see on this label).

If skin irritation or rash occurs: Get medical advice/attention.

Wash contaminated clothing before reuse.

Store locked up.

Dispose of contents/container in accordance with local/regional/national/international regulations.

• **Classification system:**

• **NFPA ratings (scale 0 - 4)**



Health = 0  
Fire = 0  
Reactivity = 0

• **HMIS-ratings (scale 0 - 4)**



Health = \*1  
Fire = 0  
Reactivity = 0

• **Other hazards**

• **Results of PBT and vPvB assessment**

• **PBT:** Not applicable.

• **vPvB:** Not applicable.

## 3 Composition/information on ingredients

• **Chemical characterization: Mixtures**

• **Description:** Mixture of the substances listed below with nonhazardous additions.

• **Dangerous components:**

CAS: 77-92-9	citric acid	3–≤5%
CAS: 9063-38-1	Sodium Starch Glycolate	3–≤5%
CAS: 57-55-6	Propylene glycol	1–≤3%
CAS: 64-17-5	Ethanol / Alcohol 99,5% v/v (absolute)	1–≤3%
CAS: 8002-43-5	Lecithins Soy lecithin	1–≤3%
CAS: 138-86-3	dipentene	≤0.1%

## 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.

(Contd. on page 3)

USA

Trade name: DILUCAP OD

(Contd. of page 2)

- **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 fighting measures that suit the environment.  
Foam  
Carbon dioxide  
Water
- **Special hazards arising from the substance or mixture**  
In case of fire, the following can be released:  
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:**  
Pick up mechanically.  
Dispose of the collected material 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.
- **Protective Action Criteria for Chemicals**

### • PAC-1:

CAS: 57-55-6	Propylene glycol	30 mg/m <sup>3</sup>
CAS: 64-17-5	Ethanol / Alcohol 99,5% v/v (absolute	1,800 ppm
CAS: 112926-00-8	Silicon dioxide (amorphous silica, precipitated silica) Tixosil	18 mg/m <sup>3</sup>
CAS: 6381-92-6	Edetate Disodium	30 mg/m <sup>3</sup>

### • PAC-2:

CAS: 57-55-6	Propylene glycol	1,300 mg/m <sup>3</sup>
CAS: 64-17-5	Ethanol / Alcohol 99,5% v/v (absolute	3300* ppm
CAS: 112926-00-8	Silicon dioxide (amorphous silica, precipitated silica) Tixosil	200 mg/m <sup>3</sup>
CAS: 6381-92-6	Edetate Disodium	330 mg/m <sup>3</sup>

### • PAC-3:

CAS: 57-55-6	Propylene glycol	7,900 mg/m <sup>3</sup>
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(Contd. on page 4)

USA

# Safety Data Sheet

acc. to OSHA HCS

Page 4/9

Printing date 07/28/2023  
Reviewed on 06/20/2023

Trade name: DILUCAP OD

CAS: 64-17-5	Ethanol / Alcohol 99,5% v/v (absolute	(Contd. of page 3) 15000* ppm
CAS: 112926-00-8	Silicon dioxide (amorphous silica, precipitated silica) Tixosil	1,200 mg/m <sup>3</sup>
CAS: 6381-92-6	Edetate Disodium	2,000 mg/m <sup>3</sup>

## 7 Handling and storage

- **Handling:**
- **Precautions for safe handling** Prevent formation of dust.
- **Information about protection against explosions and fires:** 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 receptacle 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/personal protection

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

### • Components with limit values that require monitoring at the workplace:

#### CAS: 57-55-6 Propylene glycol

WEEL Long-term value: 10 mg/m<sup>3</sup>

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

PEL Long-term value: 1900 mg/m<sup>3</sup>, 1000 ppm

REL Long-term value: 1900 mg/m<sup>3</sup>, 1000 ppm

TLV Short-term value: 1000 ppm  
A3

#### CAS: 138-86-3 dipentene

WEEL Long-term value: 30 ppm

- **Additional information:** The lists that were valid during the creation were used as basis.
- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:** Wash hands before breaks and at the end of work.
- **Breathing equipment:** Suitable respiratory protective device recommended.
- **Protection of hands:**



Protective gloves

(Contd. on page 5)

USA

Trade name: DILUCAP OD

(Contd. of page 4)

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:** Safety glasses

• **Body protection:** Protective work clothing

## 9 Physical and chemical properties

• **Information on basic physical and chemical properties**

• **General Information**

• **Appearance:**

Form: Powder

Color: Yellowish

• **Odor:** Characteristic

• **Odor threshold:** Not determined.

• **pH-value:** Not applicable.

• **Change in condition**

Melting point/Melting range: Undetermined.

Boiling point/Boiling range: Undetermined.

• **Flash point:** Not applicable.

• **Flammability (solid, gaseous):** Not determined.

• **Decomposition temperature:** Not determined.

• **Ignition temperature:** Product is not selfigniting.

• **Danger of explosion:** Product does not present an explosion hazard.

• **Explosion limits:**

Lower: Not determined.

Upper: Not determined.

• **Vapor pressure:** Not applicable.

• **Density:** Not determined.

• **Relative density** Not determined.

• **Vapor density** Not applicable.

• **Evaporation rate** Not applicable.

(Contd. on page 6)

USA

# Safety Data Sheet

acc. to OSHA HCS

Page 6/9

Printing date 07/28/2023  
Reviewed on 06/20/2023

Trade name: DILUCAP OD

(Contd. of page 5)

- |   |  |
|---|--|
| · <b>Solubility in / Miscibility with Water:</b>  | Soluble.                                   |
| · <b>Partition coefficient (n-octanol/water):</b> | Not determined.                            |
| · <b>Viscosity:</b>                               |  |
| <b>Dynamic:</b>                                   | Not applicable.                            |
| <b>Kinematic:</b>                                 | Not applicable.                            |
| · <b>Solvent content:</b>                         |  |
| <b>Organic solvents:</b>                          | 4.9 %                                      |
| <b>VOC content:</b>                               | 4.90 %                                     |
| · <b>Other information</b>                        | 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 that are 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)

- **Additional toxicological information:**
- **Carcinogenic categories**
- **IARC (International Agency for Research on Cancer)**

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

1

- **NTP (National Toxicology Program)**

None of the ingredients is listed.

(Contd. on page 7)

USA

# Safety Data Sheet

acc. to OSHA HCS

Page 7/9

Printing date 07/28/2023  
Reviewed on 06/20/2023

Trade name: DILUCAP OD

(Contd. of page 6)

· **OSHA-Ca (Occupational Safety & Health Administration)**

None of the ingredients is listed.

## 12 Ecological information

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Behavior 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 (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 of together with household garbage. Do not allow product to reach sewage system.
- **Uncleaned packagings:**
- **Recommendation:** Disposal must be made according to official regulations.
- **Recommended cleansing agent:** Water, if necessary with cleansing agents.

## 14 Transport information

- |                                       |                 |
|---------------------------------------|-----------------|
| · <b>UN-Number</b>                    |                 |
| · <b>DOT, IMDG, IATA</b>              | not regulated   |
| · <b>UN proper shipping name</b>      |                 |
| · <b>DOT, IMDG, IATA</b>              | not regulated   |
| · <b>Transport hazard class(es)</b>   |                 |
| · <b>DOT, ADN, IMDG, IATA</b>         |                 |
| · <b>Class</b>                        | not regulated   |
| · <b>Packing group</b>                |                 |
| · <b>DOT, IMDG, IATA</b>              | not regulated   |
| · <b>Environmental hazards:</b>       | Not applicable. |
| · <b>Special precautions for user</b> | Not applicable. |

(Contd. on page 8)

USA

Trade name: DILUCAP OD

(Contd. of page 7)

- **Transport in bulk according to Annex II of MARPOL73/78 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**  
No further relevant information available.
- **Sara**

### · Section 355 (extremely hazardous substances):

None of the ingredients is listed.

### · Section 313 (Specific toxic chemical listings):

None of the ingredients is listed.

### · TSCA (Toxic Substances Control Act):

CAS: 9050-36-6	Maltodextrin	ACTIVE
CAS: 77-92-9	citric acid	ACTIVE
CAS: 9063-38-1	Sodium Starch Glycolate	ACTIVE
CAS: 57-55-6	Propylene glycol	ACTIVE
CAS: 64-17-5	Ethanol / Alcohol 99,5% v/v (absolute	ACTIVE
CAS: 8002-43-5	Lecithins Soy lecithin	ACTIVE
CAS: 138-86-3	dipentene	ACTIVE
CAS: 78-70-6	Linalool	ACTIVE

### · Hazardous Air Pollutants

None of the ingredients is listed.

### · Proposition 65

#### · Chemicals known to cause cancer:

None of the ingredients is listed.

#### · Chemicals known to cause reproductive toxicity for females:

None of the ingredients is listed.

#### · Chemicals known to cause reproductive toxicity for males:

None of the ingredients is listed.

#### · Chemicals known to cause developmental toxicity:

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

### · Carcinogenic categories

#### · EPA (Environmental Protection Agency)

None of the ingredients is listed.

#### · TLV (Threshold Limit Value)

CAS: 64-17-5 Ethanol / Alcohol 99,5% v/v (absolute A3

#### · NIOSH-Ca (National Institute for Occupational Safety and Health)

None of the ingredients is listed.

(Contd. on page 9)



Trade name: DILUCAP OD

(Contd. of page 8)

- **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.

- **Department issuing SDS:**

Fagron US  
Quality Assurance

- **Contact:** QA@fagron.us

- **Date of preparation / last revision** 06/20/2023

- **Abbreviations and acronyms:**

IMDG: International Maritime Code for Dangerous Goods  
DOT: US Department of Transportation  
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)  
NFPA: National Fire Protection Association (USA)  
HMIS: Hazardous Materials Identification System (USA)  
VOC: Volatile Organic Compounds (USA, EU)  
LC50: Lethal concentration, 50 percent  
LD50: Lethal dose, 50 percent  
PBT: Persistent, Bioaccumulative and Toxic  
vPvB: very Persistent and very Bioaccumulative  
NIOSH: National Institute for Occupational Safety  
OSHA: Occupational Safety & Health  
TLV: Threshold Limit Value  
PEL: Permissible Exposure Limit  
REL: Recommended Exposure Limit  
Sensitization - Skin 1: Skin sensitisation – Category 1  
Carcinogenicity 1A: Carcinogenicity – Category 1A

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