

1 Identification

- **Product identifier**
- **Trade name:** Dilucap PSD
- **Article number:** 106360
- **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**
Eye Irritation 2A H319 Causes serious eye irritation.
- **Label elements**
- **GHS label elements**
The product is classified and labeled according to the Globally Harmonized System (GHS).
- **Hazard pictograms**



GHS07

- **Signal word** Warning
- **Hazard statements**
Causes serious eye irritation.
- **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.
- **Classification system:**
- **NFPA ratings (scale 0 - 4)**



Health = 2
Fire = 0
Reactivity = 0

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· HMIS-ratings (scale 0 - 4)

HEALTH	*2
FIRE	0
REACTIVITY	0

Health = *2

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: 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	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.
- 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.

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Wear fully protective suit.

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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 collected material 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.

Protective Action Criteria for Chemicals

PAC-1:

CAS: 112926-00-8	Silicon dioxide (amorphous silica, precipitated silica) Tixosil	18 mg/m ³
CAS: 151-21-3	Dodecyl Sulfate Sodium Salt Natrii laurilsulfas	3.9 mg/m ³

PAC-2:

CAS: 112926-00-8	Silicon dioxide (amorphous silica, precipitated silica) Tixosil	200 mg/m ³
CAS: 151-21-3	Dodecyl Sulfate Sodium Salt Natrii laurilsulfas	43 mg/m ³

PAC-3:

CAS: 112926-00-8	Silicon dioxide (amorphous silica, precipitated silica) Tixosil	1,200 mg/m ³
CAS: 151-21-3	Dodecyl Sulfate Sodium Salt Natrii laurilsulfas	260 mg/m ³

7 Handling and storage

Handling:

Precautions for safe handling

Ensure good ventilation/exhaustion at the workplace.

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.

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8 Exposure controls/personal protection

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

· **Components with limit values that require monitoring at the workplace:**

CAS: 9004-34-6 Microcrystalline Cellulose 102

PEL Long-term value: 15* 5** mg/m³
*total dust **respirable fraction

REL Long-term value: 10* 5** mg/m³
*total dust **respirable fraction

TLV Long-term value: 10 mg/m³

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

PEL 20mppcf or 80mg/m³ /%SiO₂

REL Long-term value: 6 mg/m³
See Pocket Guide App. C

TLV TLV withdrawn

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

- **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.

- **Breathing equipment:** 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

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- **Body protection:** Protective work clothing

9 Physical and chemical properties

· Information on basic physical and chemical properties	
· General Information	
· Appearance:	
Form:	Powder
Color:	White
· 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.
· Ignition temperature:	340°C (644°F)
· Decomposition temperature:	Not determined.
· Auto igniting:	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.
· Solubility in / Miscibility with	
Water:	Insoluble.
· Partition coefficient (n-octanol/water):	
Not determined.	
· Viscosity:	
Dynamic:	Not applicable.
Kinematic:	Not applicable.
· Solvent content:	
VOC content:	0.00 %
· Solids content:	
100.0 %	
· Other information	No further relevant information available.

10 Stability and reactivity

- **Reactivity** No further relevant information available.

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- **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:**

ATE (Acute Toxicity Estimate)

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)
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:**
- **on the eye:** Irritating effect.
- **Additional toxicological information:**
The product shows the following dangers according to internally approved calculation methods for preparations:
Irritant
- **Carcinogenic categories**

- **IARC (International Agency for Research on Cancer)**

None of the ingredients is listed.

- **NTP (National Toxicology Program)**

None of the ingredients is listed.

- **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

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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.

14 Transport information

· **UN-Number**

· **DOT, IMDG, IATA** not regulated

· **UN proper shipping name**

· **DOT, IMDG, IATA** not regulated

· **Transport hazard class(es)**

· **DOT, ADN, IMDG, IATA**

· **Class** not regulated

· **Packing group**

· **DOT, IMDG, IATA** not regulated

· **Environmental hazards:** Not applicable.

· **Special precautions for user** Not applicable.

· **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: 9004-34-6 Microcrystalline Cellulose 102

ACTIVE

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CAS: 151-21-3	Dodecyl Sulfate Sodium Salt Natrii laurilsulfas	ACTIVE
CAS: 67701-03-5	Stearic acid Acidum stearicum Fatty acids, C16-18	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:**

None of the ingredients is listed.

· **Carcinogenic categories**

· **EPA (Environmental Protection Agency)**

None of the ingredients is listed.

· **TLV (Threshold Limit Value)**

None of the ingredients is listed.

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

None of the ingredients is listed.

· **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** 06/15/2023

· **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

Eye Irritation 2A: Serious eye damage/eye irritation – Category 2A