

1 Identification

- **Product identifier**
- **Trade name:** Dilucap Antioxi
- **Article number:** 106386
- **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**
The product is not classified, according to the Globally Harmonized System (GHS).
- **Label elements**
- **GHS label elements** Void
- **Hazard pictograms** Void
- **Signal word** Void
- **Hazard statements** Void
- **Classification system:**
- **NFPA ratings (scale 0 - 4)**



- **HMIS-ratings (scale 0 - 4)**



- **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.

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· Dangerous components:		
CAS: 9004-34-6	Microcrystalline Cellulose 102	50–≤100%
CAS: 9005-25-8	Starch Amylum Potato starch Solani amyllum Mazize starch Maydis amyllum Rice starch Oryzae amyllum Wheat starch Tritici amyllum	25–≤50%
CAS: 112926-00-8	Silicon dioxide (amorphous silica, precipitated silica) Tixosil	0.1–≤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.
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.

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- **Environmental precautions:** No special measures required.
- **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 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
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· **PAC-2:**

CAS: 112926-00-8	Silicon dioxide (amorphous silica, precipitated silica) Tixosil	200 mg/m ³
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· **PAC-3:**

CAS: 112926-00-8	Silicon dioxide (amorphous silica, precipitated silica) Tixosil	1,200 mg/m ³
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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:**
Store in cool, dry conditions in well sealed receptacles.
Keep receptacle tightly sealed.
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 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/m ³ *total dust **respirable fraction
REL	Long-term value: 10* 5** mg/m ³ *total dust **respirable fraction

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TLV	Long-term value: 10 mg/m ³
CAS: 9005-25-8 Starch Amylum Potato starch Solani amyllum Mazize starch Maydis amyllum Rice starch Oryzae amyllum Wheat starch Tritici amyllum	
PEL	Long-term value: 15* 5** mg/m ³ *total dust **respirable fraction
REL	Long-term value: 10* 5** mg/m ³ *total dust **respirable fraction
TLV	Long-term value: 10 mg/m ³ A4
CAS: 112926-00-8 Silicon dioxide (amorphous silica, precipitated silica) Tixosil	
PEL	20mppcf or 80mg/m ³ /%SiO ₂
REL	Long-term value: 6 mg/m ³ 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:**

The usual precautionary measures for handling chemicals should be followed.

Wash hands before breaks and at the end of work.

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:** Safety glasses

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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.
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· Partition coefficient (n-octanol/water): Not determined.

· Viscosity:

Dynamic:	Not applicable.
Kinematic:	Not applicable.

· Solvent content:

VOC content:	0.00 %
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Solids content:	100.0 %
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· 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:**

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

Oral	LD50	>5000 mg/kg (rat)
Dermal	LD50	>5000 mg/kg (rabbit)

- **Additional toxicological information:**

The product is not subject to classification according to internally approved calculation methods for preparations:

When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

- **Carcinogenic categories**

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

CAS: 128-37-0 Butylated hydroxytoluene

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- **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:** Not hazardous for water.
- **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:** Smaller quantities can be disposed of with household waste.

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- **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
CAS: 9005-25-8	Starch Amylum Potato starch Solani amyllum Mazize starch Maydis amyllum Rice starch Oryzae amyllum Wheat starch Tritici amyllum	ACTIVE
CAS: 7695-91-2	Vitamin E Acetate	ACTIVE
CAS: 137-66-6	Ascorbyl palmitate Ascorbylis palmitas	ACTIVE
CAS: 128-37-0	Butylated hydroxytoluene	ACTIVE

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· **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)**

CAS: 9005-25-8	Starch Amylum Potato starch Solani amyllum Mazize starch Maydis amyllum Rice starch Oryzae amyllum Wheat starch Tritici amyllum	A4
CAS: 128-37-0	Butylated hydroxytoluene	A4

· **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

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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

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