

Safety Data Sheet

acc. to OSHA HCS

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Printing date 09/23/2021
Reviewed on 09/23/2021

1 Identification

- **Product identifier**
- **Trade name:** Pentravan®
- **Article number:** 613691
- **Application of the substance / the mixture** Pharmaceutical intermediate
- **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

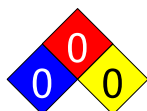
Distributor: Bella Corp Trading Pty Ltd
6/34 Dominions Rd, Ashmore QLD 4214
Australia | T: 07 5597 4169
E: bellacorp@bellacorp.com.au

IN CASE OF EMERGENCY: Chemtrec
Outside USA and Canada:
+1 703-527-3887
NSW Poisons Information
Centre: 131 126 (24 hours)

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)**



Health = 0
Fire = 0
Reactivity = 0

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



Health = 0
Fire = 0
Reactivity = 0

- **Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

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3 Composition/information on ingredients

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

- **Dangerous components:**

CAS: 504-63-2	propane-1,3-diol	1–≤3%
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4 First-aid measures

- **Description of first aid measures**
- **General information:** No special measures required.
- **After inhalation:** Supply fresh air; consult doctor in case of complaints.
- **After skin contact:** Generally the product does not irritate the skin.
- **After eye contact:** Rinse opened eye for several minutes under running water.
- **After swallowing:** If symptoms persist consult doctor.
- **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.
- **Special hazards arising from the substance or mixture** No further relevant information available.
- **Advice for firefighters**
- **Protective equipment:** No special measures required.

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures** Not required.
- **Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:** Pick up mechanically.
- **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: 110-27-0	isopropyl myristate	81 mg/m ³
CAS: 31566-31-1	Glycerol Monostearate (40-55) Glyceroli monostearas 40-55	0.66 mg/m ³
CAS: 504-63-2	propane-1,3-diol	7.8 mg/m ³
CAS: 36653-82-4	Cetylalcohol Alcohol cetylicus	1.6 mg/m ³
CAS: 112-92-5	Stearylalkohol octadecan-1-ol	5.4 ppm

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CAS: 65-85-0	Benzoic Acid Crystal	13 mg/m ³
CAS: 6381-92-6	Edetate Disodium	30 mg/m ³
CAS: 7647-01-0	hydrogen chloride	1.8 ppm

· **PAC-2:**

CAS: 110-27-0	isopropyl myristate	900 mg/m ³
CAS: 31566-31-1	Glycerol Monostearate (40-55) Glyceroli monostearas 40-55	7.2 mg/m ³
CAS: 504-63-2	propane-1,3-diol	86 mg/m ³
CAS: 36653-82-4	Cetylalcohol Alcohol cetylicus	18 mg/m ³
CAS: 112-92-5	Stearylalkohol octadecan-1-ol	60 ppm
CAS: 65-85-0	Benzoic Acid Crystal	140 mg/m ³
CAS: 6381-92-6	Edetate Disodium	330 mg/m ³
CAS: 7647-01-0	hydrogen chloride	22 ppm

· **PAC-3:**

CAS: 110-27-0	isopropyl myristate	5,400 mg/m ³
CAS: 31566-31-1	Glycerol Monostearate (40-55) Glyceroli monostearas 40-55	43 mg/m ³
CAS: 504-63-2	propane-1,3-diol	520 mg/m ³
CAS: 36653-82-4	Cetylalcohol Alcohol cetylicus	110 mg/m ³
CAS: 112-92-5	Stearylalkohol octadecan-1-ol	360 ppm
CAS: 65-85-0	Benzoic Acid Crystal	830 mg/m ³
CAS: 6381-92-6	Edetate Disodium	2,000 mg/m ³
CAS: 7647-01-0	hydrogen chloride	100 ppm

7 Handling and storage

- **Handling:**
- **Precautions for safe handling** No special measures required.
- **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:** None.
- **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.

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- **Control parameters**
- **Components with limit values that require monitoring at the workplace:**
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
- **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.
- **Breathing equipment:** Not required.
- **Protection of hands:**
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:** Not required.
- **Body protection:** Protective work clothing

9 Physical and chemical properties

- | | |
|----------------------------------------------------------------|------------------------------------|
| · Information on basic physical and chemical properties | |
| · General Information | |
| · Appearance: | |
| Form: | Solid |
| Color: | According to product specification |
| · 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. |
| · Auto igniting: | Product is not selfigniting. |

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· 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:	Soluble.
· Partition coefficient (n-octanol/water):	Not determined.
· Viscosity:	
Dynamic:	Not applicable.
Kinematic:	Not applicable.
· Solvent content:	
Organic solvents:	1.9 %
Water:	61.6 %
VOC content:	1.90 %
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:** No dangerous decomposition products known.

11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity:**

· LD/LC50 values that are relevant for classification:
CAS: 504-63-2 propane-1,3-diol
Oral LD50 4773 mg/kg (mouse)

- **Primary irritant effect:**
- **on the skin:** No irritant effect.
- **on the eye:** No irritating effect.
- **Sensitization:** No sensitizing effects known.

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· **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	3
CAS: 9003-01-4	Carbomer Carbomera Carbomerum (974 / 980 NF) polymer	3
CAS: 7647-01-0	hydrogen chloride	3

· **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

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:** Smaller quantities can be disposed of with household waste.

· **Uncleaned packagings:**

· **Recommendation:** Disposal must be made according to official regulations.

· **Recommended cleansing agent:** Water, if necessary with cleansing agents.

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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):

CAS: 7647-01-0 hydrogen chloride

· Section 313 (Specific toxic chemical listings):

CAS: 7647-01-0 hydrogen chloride

· TSCA (Toxic Substances Control Act):

CAS: 7732-18-5	water, distilled, conductivity or of similar purity	ACTIVE
CAS: 110-27-0	isopropyl myristate	ACTIVE
CAS: 9004-99-3	Polyethylene glycol stearate	ACTIVE
CAS: 31566-31-1	Glycerol Monostearate (40-55) Glyceroli monostearas 40-55	ACTIVE
CAS: 67701-03-5	Fatty acids, C16-18	ACTIVE
CAS: 142-91-6	Isopropyl palmitate	ACTIVE
CAS: 8002-43-5	Lecithins	ACTIVE
CAS: 504-63-2	propane-1,3-diol	ACTIVE
CAS: 36653-82-4	Cetylalcohol Alcohol cetylicus	ACTIVE
CAS: 112-92-5	Stearylalkohol octadecan-1-ol	ACTIVE
CAS: 65-85-0	Benzoic Acid Crystal	ACTIVE
CAS: 24634-61-5	potassium (E,E)-hexa-2,4-dienoate	ACTIVE

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	Sorbic acid Acidum Sorbicum	ACTIVE
CAS: 128-37-0	Butylated hydroxytoluene	ACTIVE
CAS: 9003-01-4	Carbomer Carbomera Carbomerum (974 / 980 NF) polymer	ACTIVE
CAS: 7647-01-0	hydrogen chloride	ACTIVE

· **Hazardous Air Pollutants**

CAS: 7647-01-0 | hydrogen chloride

· **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)**

CAS: 65-85-0 | Benzoic Acid Crystal

D

· **TLV (Threshold Limit Value)**

CAS: 128-37-0 | Butylated hydroxytoluene

A4

CAS: 7647-01-0 | hydrogen chloride

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** 09/23/2021 / -

· **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

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)

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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

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