

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

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.

(Contd. on page 2)

USA

Trade name: Pentravan®

(Contd. of page 1)

· Dangerous components:

CAS: 504-63-2 propane-1,3-diol

1-≤3%

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	Stearylalcohol octadecan-1-ol	5.4 ppm
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
---------------	---------------------	-----------------------

(Contd. on page 3)

USA

Trade name: Pentravan®

		(Contd. of page 2)
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	Stearylalcohol 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	Stearylalcohol 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.
- **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.

(Contd. on page 4)

USA

Trade name: Pentravan®

(Contd. of page 3)

- **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. |
|------------------|------------------------------|

- | | |
|------------------------|---|
| · 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. |
|--|-----------------|

(Contd. on page 5)

USA

Trade name: Pentravan®

(Contd. of page 4)

· 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.

- **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	3
-------------------------	---

Carbomera

Carbomerum (974 / 980 NF) polymer

CAS: 7647-01-0 hydrogen chloride	3
----------------------------------	---

- **NTP (National Toxicology Program)**

None of the ingredients is listed.

(Contd. on page 6)

USA

Trade name: Pentravan®

(Contd. of page 5)

- **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.

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

USA
(Contd. on page 7)

Trade name: Pentravan®

(Contd. of page 6)

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	Stearylalcohol octadecan-1-ol	ACTIVE
CAS: 65-85-0	Benzoic Acid Crystal	ACTIVE
CAS: 24634-61-5	Potassium sorbate Kalii sorbas	ACTIVE
	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.

(Contd. on page 8)

USA

Trade name: Pentravan®

(Contd. of page 7)

· **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)

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

USA