

1 Identification

- **Product identifier**
- **Trade name:** SEPIPLUS 400
- **Article number:** 103304
- **Application of the substance / the mixture** Additive for cosmetic or pharmaceutic preparations
- **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.

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3 Composition/information on ingredients

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

4 First-aid measures

- **Description of first aid measures**
- **After inhalation:**
Supply fresh air. If required, provide artificial respiration. Keep patient warm. Consult doctor if symptoms persist.
In case of unconsciousness place patient stably in side position for transportation.
- **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:**
Rinse out mouth and then drink plenty of water.
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**
Formation of toxic gases is possible during heating or in case of fire.
Carbon monoxide (CO)
Nitrogen oxides (NO_x)
Sulphur dioxide (SO₂)
- **Advice for firefighters**
- **Protective equipment:** Wear self-contained respiratory protective device.

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures**
Wear protective equipment. Keep unprotected persons away.
Particular danger of slipping on leaked/spilled product.
- **Environmental precautions:**
Do not allow product to reach sewage system or any water course.
Inform respective authorities in case of seepage into water course or sewage system.
Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

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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:**

None of the ingredients is listed.

- **PAC-2:**

None of the ingredients is listed.

- **PAC-3:**

None of the ingredients is listed.

7 Handling and storage

- **Handling:**

- **Precautions for safe handling** Ensure good ventilation/exhaustion at the workplace.

- **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.

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:**

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:** Wash hands before breaks and at the end of work.

- **Breathing equipment:**

Suitable respiratory protective device recommended.

Filter P1

- **Protection of hands:**



Protective gloves

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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**

Nitrile rubber, NBR

Fluorocarbon rubber (Viton)

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

• **Body protection:** Protective work clothing

9 Physical and chemical properties

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

• **General Information**

• **Appearance:**

Form:	Liquid
Color:	Yellowish
Odor:	Characteristic
Odor threshold:	Not determined.

• **pH-value at 20°C (68°F):** 5–6.5

• **Change in condition**

Melting point/Melting range:	Undetermined.
Boiling point/Boiling range:	>100°C (>212°F)

• **Flash point:** >100°C (>212°F)

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

• **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 determined.

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- | | |
|----------------------------------|-------------------------------------|
| · Density at 20°C (68°F): | 1 g/cm ³ (8.345 lbs/gal) |
| · Relative density | Not determined. |
| · Vapor density | Not determined. |
| · Evaporation rate | Not determined. |

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|--|--------------|
| · Solubility in / Miscibility with Water: | Dispersible. |
|--|--------------|

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

- | | |
|---------------------|-----------------|
| · Viscosity: | |
| Dynamic: | Not determined. |
| Kinematic: | Not determined. |

- | | |
|---------------------------|-----------------------|
| · Solvent content: | |
| Water: | 0–10 % |
| VOC content: | 0.00 % |
| | 0.0 g/l / 0.00 lb/gal |

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|----------------------------|--|
| · 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** Reacts with strong oxidizing agents.
- **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: |
|---|

Oral	LD50	>5000 mg/kg (rat)
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- **Primary irritant effect:**
- **on the skin:** No irritant effect.
- **Sensitization:** No sensitizing effects known.
- **Additional toxicological information:**

- **Carcinogenic categories**

- | |
|---|
| · IARC (International Agency for Research on Cancer) |
|---|

None of the ingredients is listed.

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|--|
| · NTP (National Toxicology Program) |
|--|

None of the ingredients is listed.

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· **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.

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. |

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- | | |
|---|-----------------|
| • 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: 9003-27-4	Polyisobutylen	ACTIVE
CAS: 7732-18-5	Water, distilled, conductivity or of similar purity	ACTIVE
CAS: 9005-64-5	Polysorbate 20 Polysorbatum 20	ACTIVE
CAS: 9005-67-8	Sorbitan monostearate, ethoxylated	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.

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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** 01/26/2024

- **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