

Safety Data Sheet

acc. To OSHA HCS

Reviewed on 09/22/2021

Printing date 09/22/2021

Trade Name: Poloxamer 407 NF

1 Identification

1.1 Product identifier

Trade name: Poloxamer 407

Product Code: C6013

Application of the substance / the mixture: Pharma Excipient

1.2 Details of the supplier of the safety data sheet

Manufacturer/Supplier:

SpecializedRx Products, LLC

7237 University Ave. NE

Fridley, MN 55432

www.specializedrx.com

sales@specializedrx.com

Information department:

Tel.: 1-888-512-1209

Fax: 1-612-424-8481

1.3 Emergency telephone number:

Emergency Telephone:

US: 1-888-512-1209

International: 1-888-512-1209

2 Hazard(s) identification

2.1 Classification of the substance or mixture

HCS 2012 (29 CFR 1910.1200)

Combustible dust May form combustible dust concentrations in air.

2.2 Label elements

HCS 2012 (29 CFR 1910.1200)

Signal Word

- Warning

Hazard Statements

- May form combustible dust concentrations in air.

2.3 Other hazards which do not result in classification

- Store in dry, well-ventilated premises at room temperature.

- The molten product can cause serious burns.

3 Composition/information on ingredients

3.1 Chemical Characterization: block copolymer

Description: Ethylene oxide / propylene oxide block co-polymer

Dangerous components: Void

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3.2 Chemical Information:

Chemical Name: Not applicable

Botanical Name: Not applicable

Synonym: Not applicable

Chemical Formula: Not applicable

CAS Number: Not applicable

Alternate CAS Number: Not applicable

Molecular Weight: Not applicable

3.3 Composition:

Chemical Name	CAS Number	% By Weight
Poloxamer 407 NF Grade	9003-11-6	95-100%

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as health hazards and hence require reporting in this section.

4 First-aid measures

4.1 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: Flush with plenty of water for at least 15 minutes

After eye contact: Immediately rinse opened eye for 15 minutes under running water.

After swallowing: Do not induce vomiting. Rinse out mouth with plenty of water.

4.2 Most important symptoms and effects, both acute and delayed

No further relevant information available.

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

5 Fire-fighting measures

Fire Fighting Instructions:

AS IN ANY FIRE, WEAR A SELF-CONTAINED BREATHING APPARATUS IN PRESSURE-DEMAND, MSHA/NIOSH (APPROVED OR EQUIVALENT), AND FULL PROTECTIVE GEAR. FLAMMABLE LIQUID AND VAPOR.

Flammable Properties and Hazards:

FLAMMABLE IN THE PRESENCE OF A SOURCE OF IGNITION WHEN THE TEMPERATURE IS ABOVE THE FLASH POINT.

Autoignition Pt:

Explosive Limits: LEL: UEL:

Suitable Extinguishing Media:

USE WATER SPRAY, DRY CHEMICAL, OR ALCOHOL-RESISTANT FOAM.

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6 Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures: Not required.

6.2 Environmental precautions:

Dilute with plenty of water.

Do not allow to enter sewers/ surface or ground water.

6.3 Methods and material for containment and cleaning up:

CONTAIN SPILLAGE, AND THEN COLLECT WITH SUITABLE APPLIANCE AND DISPOSE OF.

6.4 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

7.1 Precautions for safe handling:

AVOID CONTACT WITH SKIN AND EYES. KEEP AWAY FROM SOURCES OF IGNITION - NO SMOKING.

WASH THOROUGHLY AFTER HANDLING. REMOVE CONTAMINATED CLOTHING AND WASH BEFORE REUSE. AVOID DUST FORMATION. TAKE PRECAUTIONARY MEASURES AGAINST STATIC DISCHARGES.

Dust explosion class: Dust explosion class 1 (Kst-value >0 up to 200 bar m s-1).

7.2 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 and well-ventilated place. Protect against heat. Storage temperature: <= 30 °C

7.3 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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Respiratory Equipment (Specify Type):

Respiratory protection:

Suitable respiratory protection for lower concentrations or short-term effect: Particle filter with low efficiency for solid particles (e.g. EN 143 or 149, Type P1 or FFP1)

REQUIREMENTS OR EUROPEAN STANDARD EN 149 MUST BE FOLLOWED

WHENEVER WORKPLACE

CONDITIONS WARRANT RESPIRATOR USE.

Eye Protection:

USE EQUIPMENT FOR EYE PROTECTION TESTED AND APPROVED UNDER APPROPRIATE GOVERNMENT STANDARDS SUCH AS NIOSH (US) OR EN 166(EU).

Protective Gloves: WEAR CHEMICAL-RESISTANT GLOVES TO PREVENT SKIN EXPOSURE.

Other Protective Clothing: WEAR APPROPRIATE PROTECTIVE CLOTHING TO PREVENT SKIN EXPOSURE.

Engineering Controls (Ventilation etc.):

FACILITIES STORING OR UTILIZING THIS MATERIAL SHOULD BE EQUIPPED WITH AN EYEWASH FACILITY AND A SAFETY SHOWER.

Work/Hygienic/Maintenance Practices:

HANDLE IN ACCORDANCE WITH GOOD INDUSTRIAL HYGIENE AND SAFETY PRACTICE. ENVIRONMENTAL PREVENT FURTHER LEAKAGE OR SPILLAGE IF SAFE TO DO SO. DO NOT LET PRODUCT ENTER DRAINS.

Eye protection: Goggles recommended during handling.

9 Physical and chemical properties

9.1 Information on basic physical and chemical properties

General Information

Appearance: Powder, waxy type

Form: Powder

Color: White

Odor: Characteristic

pH-value: 6-9

Melting point/Melting range: 53 - 57 °C

Boiling point/Boiling range:

Flash point: >150 °C

Flammability (solid, gaseous): The product is a non-volatile solid.

Ignition temperature:

Decomposition temperature: Not determined.

Auto igniting: Product is not self-igniting.

Danger of explosion: Product does not present an explosion hazard. Product is not explosive, however a dust explosion could result from an air / dust mixture.

Explosion limits:

Lower: Not determined.

Upper: Not determined.

Vapor pressure: Not determined.

Specific gravity: Not determined

Density: approx. 300 kg/m³

Relative density: Not determined.

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Vapor density: Not determined.
Evaporation rate: Not determined.
Solubility in / Miscibility with Water: soluble 176 g/l (23 °C)
Partition coefficient (n-octanol/water): Not determined.
Viscosity: Not determined.
Dynamic: Not determined.
Kinematic: Not determined.

9.2 Other information: No further relevant information available.

10 Stability and reactivity

10.1 Reactivity: No further relevant information available.

10.2 Chemical stability

Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.

10.3 Possibility of hazardous reactions: No dangerous reactions known.

10.4 Conditions to avoid: No further relevant information available.

10.5 Incompatible materials: Substances to avoid: strong bases, strong acids, oxidizing agents

10.6 Hazardous decomposition products: No dangerous decomposition products known.

11 Toxicological information

11.1 Information on toxicological effects

Acute toxicity:

Assessment of acute toxicity:

Virtually nontoxic after a single ingestion. Virtually nontoxic after a single skin contact.

Experimental/calculated data:

LD50 rat (oral): > 5,000 mg/kg (BASF-Test)

The product has not been tested. The statement has been derived from substances/products of a similar structure or composition.

LD50 rabbit (dermal): > 2,000 mg/kg

The product has not been tested. The statement has been derived from substances/products of a similar structure or composition. Literature data.

Irritation

Assessment of irritating effects:

Not irritating to the skin. Not irritating to the eyes.

Experimental/calculated data:

Skin corrosion/irritation rabbit: non-irritant (OECD Guideline 404)

The product has not been tested. The statement has been derived from substances/products of a similar structure or composition.

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Serious eye damage/irritation rabbit: non-irritant (OECD Guideline 405)

The product has not been tested. The statement has been derived from substances/products of a similar structure or composition.

Respiratory/Skin sensitization

Assessment of sensitization:

Skin sensitizing effects were not observed in animal studies.

Germ cell mutagenicity

Assessment of mutagenicity:

No mutagenic effect was found in various tests with bacteria and mammalian cell culture.

Carcinogenicity

Assessment of carcinogenicity:

No data available concerning carcinogenic effects.

Reproductive toxicity

Assessment of reproduction toxicity:

No reliable data are available concerning reproduction toxicity.

Developmental toxicity

Assessment of teratogenicity:

No reliable data was available concerning teratogenicity.

Aspiration hazard

No data available.

12 Ecological information

12.1 Toxicity

Aquatic toxicity: The inhibition of the degradation activity of activated sludge is not anticipated when introduced to

biological treatment plants in appropriate low concentrations. There is a high probability that the product is not acutely harmful to aquatic organisms.

Toxicity to fish:

LC50 (96 h) > 120 mg/l, *Oncorhynchus mykiss* (OECD 203; ISO 7346; 92/69/EEC, C.1, static)

Aquatic invertebrates:

EC50 (48 h) > 100 mg/l, *Daphnia magna* (Directive 79/831/EEC, static)

Nominal concentration.

Analogous: Assessment derived from products with similar chemical character.

Aquatic plants:

EC50 (72 h) > 100 mg/l (biomass), *Scenedesmus subspicatus* (DIN 38412 Part 9, static)

Nominal concentration.

Analogous: Assessment derived from products with similar chemical character.

Microorganisms/Effect on activated sludge:

EC50 (30 min) > 1,000 mg/l, activated sludge, domestic (OECD Guideline 209, aquatic)

Nominal concentration.

12.2 Persistence and degradability: Assessment biodegradation and elimination (H₂O):

Not readily biodegradable (by OECD criteria). Poorly biodegradable.

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Elimination information:

0 - 10 % DOC reduction (28 d) (OECD 301 A (new version)) (aerobic, activated sludge, domestic)
Not readily biodegradable (by OECD criteria).

12.3 Bioaccumulative potential: No further relevant information available.

12.4 Mobility in soil: Assessment transport between environmental compartments:

The substance will not evaporate into the atmosphere from the water surface.
Adsorption to solid soil phase is possible.

Additional ecological information:

General notes:

12.5 Results of PBT and vPvB assessment

According to Annex XIV of Regulation (EC) No.1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH): The product does not contain a substance fulfilling the PBT (persistent/bioaccumulative/toxic) criteria or the vPvB (very persistent/very bioaccumulative) criteria. Self classification

12.6 Other adverse effects: No further relevant information available.

13 Disposal considerations

13.1 Waste treatment methods

Must be disposed of or incinerated in accordance with local regulations.

Contaminated packaging:

Uncontaminated packaging can be re-used.

Packs that cannot be cleaned should be disposed of in the same manner as the contents.

14 Transport information

14.1 UN-Number

DOT, ADR, ADN, IMDG, IATA

Not Regulated

14.2 UN proper shipping name

DOT, ADR, ADN, IMDG, IATA

Void

14.3 Transport hazard class(es)

DOT, ADR, ADN, IMDG, IATA

Class

Not Regulated

14.4 Packing group

DOT, ADR, IMDG, IATA

Void

14.5 Environmental hazards:

Not applicable.

14.6 Special precautions for user

Not applicable.

14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

Not applicable.

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UN "Model Regulation":

Void

15 Regulatory information

15.2 Chemical safety assessment: A Chemical Safety Assessment no required.

If other regulatory information applies that is not already provided elsewhere in this safety data sheet, then it is described in this subsection.

16 Other information

This SDS is intended to provide a brief summary of our knowledge and guidance regarding the use of this material. The information contained here has been compiled from sources considered to be dependable and is accurate to the best of the Company's knowledge. However, the information is provided without any representation or warranty, expressed or implied regarding its accuracy or correctness. The Company cannot assume responsibility for adverse events which may occur in the use and/or misuse of this product and expressly disclaims liability for loss, damage and/or expense arising out of or in any way connected with the handling, storage, use and/or disposal of this product.

Department issuing SDS:

SpecializedRx Products, LLC
Quality Assurance

Contact: sales@specializedrx.com

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Abbreviations and acronyms:

ADR: Accord européen sur le transport 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

GHS: Globally Harmonized System of Classification and Labelling of Chemicals

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)

VOC: Volatile Organic Compounds (USA, EU)

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

OSHA: Occupational Safety & Health

TLV: Threshold Limit Value

PEL: Permissible Exposure Limit

REL: Recommended Exposure Limit