

Safety Data Sheet

acc. To OSHA HCS

Reviewed on 19 NOV 2019

Printing date 19 NOV 2019

Trade Name: PolyBlend Rx™

1 Identification

1.1 Product identifier

Trade name: PolyBlend Rx

Product Code: B0060

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

Classification according to Regulation (EC) No 1272/2008

The product is not classified according to the CLP regulation.

2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008 Void

Hazard pictograms Void

Signal word Void

Hazard statements Void

2.3 Other hazards

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

3 Composition/information on ingredients

3.1 Chemical Characterization: Substances

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Description: Mixture of the substances listed below with nonhazardous additions.

Dangerous components: Void

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
Polyethylene Glycol (PEG)	25322-68-3	Proprietary
Polysorbate 80	9005-65-6	Proprietary

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.

Notes: *Proprietary: Ingredients indicated as hazardous have been assessed under standards for workplace safety. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as trade secret.

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: Generally the product does not irritate the skin.

After eye contact: Rinse opened eye for several minutes under running water.

After swallowing: Rinse out mouth and then drink 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

5.1 Extinguishing media

Suitable extinguishing agents: Use fire-fighting measures that suit the environment. Water spray, powder, foam, carbon dioxide.

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5.2 Special hazards arising from the substance or mixture: formation of toxic gases is possible during heating or in case of fire. Carbon monoxide (CO).

5.3 Advice for firefighters

Wear protective equipment: Respiratory protective devices.

6 Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures: Ensure adequate ventilation

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:

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

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: Prevent formation of dust.

Information about protection against explosions and fires: Keep away from open flames, hot surfaces and sources of ignition.

7.2 Conditions for safe storage, including any incompatibilities

Storage:

Requirements to be met by storerooms and receptacles: Do not store in heat or direct sunlight.

Information about storage in one common storage facility: Not required.

Further information about storage conditions: Store in cool, dry conditions in well sealed receptacles.

7.3 Specific end use(s): No further relevant information available.

8 Exposure controls/personal protection

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Additional information about design of technical systems: No further data; see item 7.

8.1 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.

8.2 Exposure controls

Personal protective equipment:

General protective and hygienic measures:

The usual precautionary measures for handling chemicals should be followed.

Breathing equipment: Fresh air mask. P2 Filter.

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 cannot 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: Goggles recommended during handling.

Body protection: Protective work clothing.

9 Physical and chemical properties

9.1 Information on basic physical and chemical properties

General Information

Appearance: White Opaque Solid Flakes

Form: Solid

Color: White Opaque

Odor: Bland

pH-value: Undetermined

Melting point/Melting range: 50.0 to 60.0 °C

Boiling point/Boiling range: Undetermined

Flash point: Undetermined

Flammability (solid, gaseous): Not applicable.

Ignition temperature: Undetermined

Decomposition temperature: Undetermined

Auto igniting: Undetermined

Danger of explosion: Product does not present an explosion hazard.

Explosion limits:

Lower: Product does not present explosion hazard.

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Upper: Product does not present explosion hazard.
Vapor pressure: Not determined.
Specific Gravity: Approx. 1.177 at 24 °C
Evaporation rate: Not determined.
Solubility in / Miscibility with Water: Miscible
Solubility in / Miscibility with Oils: Insoluble.
Partition coefficient (n-octanol/water): Not determined.
Viscosity: Not determined.
Dynamic: Not determined.
Kinematic: Not determined.
Solvent content:
 Organic solvents: Not determined.
 Water: Not determined.
 VOC content: 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: Stable under normal conditions.

10.3 Possibility of hazardous reactions: No dangerous reactions known.

10.4 Conditions to avoid: Keep away from open flames, hot surfaces and sources of ignition.

10.5 Incompatible materials: No further relevant information available.

10.6 Hazardous decomposition products: Thermal decomposition leads to formation of carbon monoxide, carbon dioxide, smoke, fumes.

11 Toxicological information

11.1 Information on toxicological effects

Acute toxicity: No evidence of acute toxicity.

Primary irritant effect:

on the skin: Based on available data, the classification criteria are not met.

on the eye: Based on available data, the classification criteria are not met.

Sensitization: Based on available data, the classification criteria are not met.

Additional toxicological information:

Carcinogenic categories

IARC (International Agency for Research on Cancer): None of the ingredients is listed.

NTP (National Toxicology Program): None of the ingredients is listed.

OSHA-Ca (Occupational Safety & Health Administration): None of the ingredients is listed.

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12 Ecological information

12.1 Toxicity

Aquatic toxicity:

EC50 (48h) > 100 mg/l (Daphnia)

EC50(72h) > 100 mg/l (Algen)

LC50 (96h) > 100 mg/l (Fish)

No further relevant information available.

12.2 Persistence and degradability: biodegradable

12.3 Bioaccumulative potential: No further relevant information available. Accumulation in organisms not expected.

12.4 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. Readily biodegradable.

12.5 Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

12.6 Other adverse effects: No further relevant information available.

13 Disposal considerations

13.1 Waste treatment methods

Recommendation: Smaller quantities can be disposed of with household waste. Large quantities incinerator.

Uncleaned packaging:

Recommendation: Disposal must be made according to official regulations.

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

14 Transport information

14.1 UN-Number

DOT, ADR, ADN, IMDG, IATA

Void

14.2 UN proper shipping name

DOT, ADR, ADN, IMDG, IATA

Void

14.3 Transport hazard class(es)

DOT, ADR, ADN, IMDG, IATA

Class

Void

14.4 Packing group

DOT, ADR, IMDG, IATA

Void

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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.
UN "Model Regulation":	Void

15 Regulatory information

15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

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