

# SAFETY DATA SHEET

## POLYSORBATE 80 (USP/NF GRADE)

### 1. PRODUCT INFORMATION AND COMPANY IDENTIFICATION

Product Name: Polysorbate 80 (USP/NF grade)

Company: Natural Bulk Supplies, 318 Half Day Rd, # 348,  
Buffalo Grove, IL 60089 Phone: 847-489-7180

Emergency Contact: Infotrac: 800-535-5053(North America) +1-352-323-3500 (International)

### 2. HAZARD IDENTIFICATION

#### Classification

Skin corrosion/irritation, Category 3

Serious eye damage/eye irritation, Category 2B

#### Label Elements

#### Hazard Pictograms

Not applicable.

#### Signal Word

WARNING

#### Hazard Statements

H316 Causes mild skin irritation.

H320 Causes eye irritation.

#### Precautionary Statements

P264 Wash thoroughly after handling.

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P332+P313 If skin irritation occurs: Get medical advice/attention.

P337+P313 If eye irritation persists: Get medical advice/attention.

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

INCI NAME	Product Type	CAS NO.	Synonyms
Ethoxylated Sorbitan Monooleate	Substance.	9005-65-6	Ethoxylated sorbitan monooleate 20 EO; Polyoxyethylene sorbitan (20)

			monooleate; Sorbitan monooleate polyoxyethylene (20); Monooleate sorbitan (20) PEG; Polysorbate 80; Polysorbate 80 (INCI Name).
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**Impurities which contribute to the classification of the substance**

There are no impurities which contribute to the classification of the substance.

**4. FIRST AID MEASURES**

**Procedure in Case of:**

**Ingestion**

Seek prompt medical attention.

Do not induce vomiting.

Vomiting should only be induced by medical personnel.

If vomiting occurs, keep the head lower than chest to avoid aspiration into the lungs.

Never give anything by mouth to an unconscious or convulsing person.

**Inhalation**

Seek prompt medical attention.

Remove victim to fresh air.

If breathing is difficult, give oxygen.

If not breathing, give artificial respiration.

**Skin contact**

Remove contaminated clothing and shoes. Wash affected areas with plenty of running water, preferably under a shower.

Seek prompt medical attention.

**Eye contact**

Immediately flush with plenty of running water for at least 15 minutes, keeping eyelids open.

Remove contact lenses if easy to do. Seek prompt medical attention.

**Most important symptoms/effects, acute and delayed**

Ingestion - Large doses may cause abdominal spasms and diarrhea. Aspiration could cause chemical pneumonitis.

Inhalation - May cause respiratory tract irritation.

Skin - It is considered to be nonirritating to human skin.

Eyes - Causes mild irritation.

**Information for doctor**

There is not known any specific antidote.

Direct the treatment in accordance with the symptoms and clinical conditions of the patient.

## 5. FIRE FIGHTING MEASURES

### Extinguishing Media

In case of fire, use:

Alcohol resistant foam. Water spray.

Carbon dioxide (CO<sub>2</sub>).

Dry chemical powder.

### Specific Hazards

Product is not flammable.

In case of combustion it may generate carbon monoxide, besides CO<sub>2</sub>.

### Protective measures for fire-fighters

Water jets should not be used directly on igniting products because it may disperse the material and intensify the fire.

Self-contained breathing apparatus and protective clothing are required. Cool the intact fire-exposed containers with water spray and remove them.

### NFPA Rating

Health

0

Flammability

1

Instability

0

Special

## 6. ACCIDENTAL RELEASE MEASURES

### Personal precautions, protective equipment and emergency procedures

Isolate and signalize area.

Keep heat and/or ignition sources away.

Use personal protection equipment as indicated in Section 8, in order to avoid contact with spilled product.

### Environmental Precautions

Prevent product from entering into soil and waterways.

Notify the competent authorities if the product has run into drainage systems or watercourse or has contaminated the ground or vegetation.

### Methods and materials for containment and cleaning up

Stop if possible.

Contain and dike spilled product with earth or sand. Eliminate ignition or heat sources.

Transfer to proper container.

Collect remnants with an appropriate absorbent material.

Wash the contaminated surface with water, which should be collected for disposal.

## 7. HANDLING AND STORAGE

### Precautions for safe handling

Use in a well-ventilated area.

Avoid inhalation and contact with eyes, skin or clothing through proper protection.

If occurs accidental contact, exposed area should be washed immediately.

Emergency eyewashes and showers shall be located in accessible locations.

Wash hands and face thoroughly after handling. Wash contaminated clothing before reuse.

### Conditions for safe storage

Store in a covered and well-ventilated area, away from sunlight and sources of heat or open flames.

Ensure that the storage location has adequate moisture, pressure and temperature.

Keep containers tightly closed when not in use.

### Incompatibilities

Avoid contact with: Strong oxidizing agents.

### Packaging Material

Recommended: Stainless steel. Carbon steel.

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### Control parameters

#### TLV-TWA (ACGIH)

1,4-Dioxane: 20 ppm; 72 mg/m<sup>3</sup> [Skin][A3].

Ethylene oxide: 1 ppm; 1.8 mg/m<sup>3</sup> [A2].

Skin - Danger of cutaneous absorption.

A2 - Suspected Human Carcinogen

A3 - Confirmed animal carcinogen with unknown relevance to humans.

#### PEL-TWA (OSHA)

1,4-Dioxane: 100 ppm; 360 mg/m<sup>3</sup> [Skin].

Ethylene oxide: 1 ppm.

Skin - Danger of cutaneous absorption.

#### TLV-STEL (ACGIH)

Not established.

#### LT(NR15)

Ethylene oxide: 39 ppm; 70 mg/m<sup>3</sup>.

**Odor Threshold**

Not available.

**IDLH**

1,4-Dioxane: 500 ppm.

Ethylene oxide: 800 ppm.

**Biological Exposure Indices (ACGIH)**

Not established.

**Engineering Control Measures**

In closed environments, this product should be handled keeping proper exhaust (general diluter or local exhauster).

**Individual Protection Measures**

**Eye Protection**

Side shields or wide vision safety goggles.

**Skin Protection**

PVC apron.

It is recommended to adopt safety boots/shoes.

**Hand Protection**

Gloves made of: Rubber.

PVC (Polyvinyl chloride).

**Breathing equipment**

In case of emergency or contact with high concentrations of the product, wear an air supplied mask or self contained breathing apparatus.

It is recommended to wear face mask with organic vapors cartridge in case of exposure to vapors/aerosols.

**9. PHYSICAL AND CHEMICAL PROPERTIES**

Appearance	Liquid. Yellowish. Amber.
Odour and Odour threshold.	Not available
pH	6.0 - 7.0 (sol. 5%).
Melting point/Freezing point	> 20 °C.
Initial Boiling Point and Boiling Range	> 100 °C.
Flash point	> 149 °C (open cup).
Evaporation rate	Not

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	available.
Flammability (solid, gas)	Not applicable.
Upper/lower flammability or explosive limits	Not available.
Vapour pressure	0.001 kPa (25 °C).
Vapour density (air = 1)	45.
Relative density (water=1)	1.07 g/cm <sup>3</sup> (25 °C).
Apparent density	Not applicable.
Solubility	Soluble in water (20 ° C for 1 hour / concentration of 0.5%). Soluble in ethanol (25 ° C).
Partition Coefficient n-octanol/water	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	300 - 500 cSt (25 °C).

## 10. STABILITY AND REACTIVITY

### Chemical stability

Stable under normal conditions of use and storage.

### Reactivity

No hazardous reactivity is expected.

### Possibility of Hazardous Reactions

Not polymerize.

### Conditions to avoid

High temperatures, ignition sources and prolonged exposure to the air.

### Incompatible materials

Avoid contact with:  
Strong oxidizing agents.

### Hazardous decomposition products

In case of combustion it may generate carbon monoxide, besides CO<sub>2</sub>.

**Considerations on the use of the product**

Not applicable.

**11. TOXICOLOGICAL INFORMATION**

**Acute Toxicity**

Oral

LD50, rat: 34500 µL/kg.

LD50, mouse: 25000 mg/kg.

Probable lethal dose for humans is above 15 g/kg for 70 kg person (150 lb).

**Inhalation**

Not available.

**Dermal**

Not available.

**Skin corrosion/irritation**

Reported to be nonirritating when applied undiluted to human skin for 48 hours.

Produced inflammation, thickening and necrosis when applied to rabbits for one month.

**Serious eye damage/eye irritation**

Slight irritant (150 mg, rats)

**Respiratory or skin sensitization**

Not a skin sensitizer in guinea-pigs.

**Germ cell mutagenicity**

Negative results with sister chromatid exchange and Ames tests. Positive results with chromosome aberration test (induced rat liver S9).

**Carcinogenicity**

There was no evidence of carcinogenic activity in female rats or in male or female mice which received diets containing 25,000 or 50,000 ppm for 2 years.

**Reproductive toxicity**

Reproductive effects have been reported in animals. 10-20

day old male rat pups whose dams received chronic doses (1.25 mL/L) via drinking water exhibited an enhancement in their exploratory and locomotor activity during the diurnal period of the day.

LOAEL, oral, rat: 500 mg/kg/day (based upon an increase in maternal relative liver weight).

NOAEL, oral, rat: > 5000 mg/kg/day (based on prenatal development).

**Specific target organ toxicity - Single exposure**

Not available.

**Specific target organ toxicity - Repeated exposure**

Daily doses of up to 15 grams given to adult humans produced no adverse effects. Mild to moderate central nervous system depression with ataxia, paralytic activity and reduced rectal temperature was reported after oral administration in laboratory animals. Pheochromocytomas in male rats as well as inflammation, squamous hyperplasia and ulcers of the forestomach of rats and mice have been reported in 2 year feeding studies.

**Aspiration hazard**

Not available.

**12. ECOLOGICAL INFORMATION**

**Ecotoxicity**

The aquatic toxicity is not known.

**Persistence and Degradability**

Not readily biodegradable.  
32% after 28 days.

**Bioaccumulative Potential**

It is not expected to bioaccumulate in the environment.

**Mobility in soil**

It is expected to have high mobility in soil.

**Other Adverse Effects**

Water hazard class 1: Slightly hazardous to water.

**13. DISPOSAL CONSIDERATIONS**

**Recommended methods of disposal**

**Product**

The preferred options for disposal include reuse, recycling, co-processing, finding a use for a byproduct, incineration or other thermal destruction process at licensed facilities. All procedures must follow specific operation standards in order to reduce health, safety and environmental risks.

Perform co-processing, incineration or other thermal destruction process at facilities capable of minimizing or reducing air pollution emissions.

The disposal must comply with federal, state, and local laws and regulations in accordance with the environmental agencies.

**Product Remains**

Same method as indicated for product.

**Packaging**

Do not cut or pierce the packaging, nor do hot work near them. Do not remove labels until the product has been fully removed and the packaging cleaned.

The preferred options for disposal include reuse, recycling or reclamation at licensed facilities. All procedures must follow specific operation standards in order to reduce health, safety and environmental risks.

The disposal must comply with local legislation and in accordance with standards from local environmental agencies.

**14. TRANSPORT INFORMATION**

**Land Transport ANTT**

Product not classified as hazardous in accordance with Resolution 420/2004 - Transport Ministry.

**UN number**

N/A

**Proper Shipping Name**

Not classified.

**Hazard Class**

Not classified.

**Hazard Number**

Not classified.

**Packaging Group**

Not classified.

**Maritime Transport IMDG**

Product not classified as hazardous in accordance with IMDG Code - 2012 Edition - IMO (International Maritime Organization).

**UN number**

N/A

**Proper Shipping Name**

Not classified.

**IMDG Class**

Not classified.

**Packaging Group**

Not classified.

**EmS**

Not classified.

**# Air Transport ICAO-TI and IATA-DGR**

Product not classified as hazardous in accordance with Dangerous Goods Regulations - 56th Edition - IATA (International Air Transport Association).

**UN number**

N/A

**Proper Shipping Name**

Not classified.

**ICAO/IATA Class**

Not classified.

**Label**

Not classified.

**Packaging Group**

Not classified.

**Land Transportation ADR/RID (crossborder)**

Product not classified as hazardous in accordance with Dangerous Goods by Road - Applicable from 1st January 2011 - Unece (United Nations Economic Commission for Europe).

**UN number**

N/A

**Proper Shipping Name**

Not classified.

**ADR/RID class**

Not classified.

**Packaging Group**

Not classified.

**Danger code (Kemler)**

Not classified.

**Restriction Code**

Not classified.

**Land Transportation U.S DOT**

Product not classified as hazardous in accordance with



U.S. DOT (United States Department of Transportation) - 49 CFR 172.101.

**Packaging Type**

Bulk and Non-bulk

**Proper Shipping Name**

Not classified.

**Hazard Class or Division**

Not classified.

**ID Number**

Not classified.

**Packaging Group**

Not classified.

**Remarks**

Not classified.

**15. REGULATORY INFORMATION**

**Applicable standards**

Resolution 420 / 2004 - Transport Ministry.

Dangerous Goods by Road (ADR) - Available from January 1st, 2011 - Unece (United Nations Economic Commission for Europe).

U.S.A Department of Transportation - DOT - 49 CFR 172.101.

IMDG Code - 2012 Edition - IMO (International Maritime Organization).

Dangerous Goods Regulations - 56th Edition - IATA (International Air Transport Association).

**OSHA Hazard Communication Standard**

This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

**SARA Title III - Sections 311 / 312 (40 CFR 370 Subparts B and C)**

Immediate (Acute) Health Hazard: Yes.

Delayed (Chronic) Health Hazard: No.

Fire Hazard: No.

Sudden Release of Pressure Hazard: No.

Reactive Hazard: No.

**SARA Title III - Section 313 (40 CFR 372.65)**

This product does not contain a chemical which is listed in Section 313 at or above de minimis concentrations.

**SARA Title III - Section 302 (40 CFR 355 Appendix A)**

Ethylene oxide (CAS 75-21-8): max. 1 ppm. TPQ: 1000 lbs.

**CERCLA (40 CFR 302.4) / SARA 304**

1,4-Dioxane (CAS 123-91-1): max. 10 ppm. RQ: 100 lbs. Ethylene oxide (CAS 75-21-8): max. 1 ppm. RQ 10 lbs.

Reportable Quantity (RQ) of this product is 10000000 pounds based upon 1,4-Dioxane / Ethylene oxide which yielded the lowest resultant RQ according to the following formula: CERCLA ingredient RQ/ % of that ingredient in the product.

**New Jersey Hazardous Substance List**

1,4-Dioxane: Substance# 0789 (Special Health Hazard Code: CA - Carcinogen; F3 - Flammable 3rd degree).

Ethylene oxide: Substance# 0882 (Special Health Hazard Code: CA - Carcinogen; MU - Mutagen; TE - Teratogen; F4 - Flammable 4th degree; R3 - Reactive 3rd degree).

**California Proposition 65 (Safe Drinking Water and Toxic Enforcement Act)**

WARNING! This product contains a chemical known to the State of California to cause cancer. 1,4-Dioxane.

Ethylene oxide.

WARNING! This product contains a chemical known to the State of California to cause birth defects or other reproductive harm.

Ethylene oxide.

**Pennsylvania Hazardous Substance List**

1,4-Dioxane (CAS 123-91-1) and Ethylene oxide (CAS 75-21-8): Listed also as an environmental hazard and as a special hazardous substance.

**Inventory Status**

United States & Puerto Rico - Toxic Substances Control Act (TSCA) Inventory: Yes

Canada - Domestic Substances List (DSL): Yes Canada - Non-Domestic Substances List (NDSL): No

Europe - European Inventory of Existing Commercial Chemical Substances (EINECS): No

Europe - European List of Notified Chemical Substances (ELINCS): No

Australia - Australian Inventory of Chemical Substances (AICS): Yes

Philippines - Philippine Inventory of Chemicals and Chemical Substances (PICCS): Yes Japan - Inventory of Existing and New Chemical Substances (ENCS): Yes

Korea - Existing Chemicals List (ECL): Yes

Canada - Non-Domestic Substances List (NDSL): Yes New Zealand - New Zealand Inventory: Yes

\*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s).



## 16. OTHER INFORMATION

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