



Safety Data Sheet

Polyglykol 3350 PSB/FIBC USA

SECTION 1: IDENTIFICATION

Identification of the company: GAVIS Pharmaceuticals, LLC
400 Campus Drive
Somerset NJ 08873
908-603-6080
In case of emergency call: 911
US Poison Control Center: 1-800-222-1222

Trade name: Polyglykol 3350 PSB/FIBC USA 1000
Material number: 229274
CAS number: 25322-68-3

Primary product use: Thickening agent for cosmetics.
Primary product use: pharmaceutical active substance
Chemical family: Polyethylene glycol: HO-(CH₂-CH₂-O)_n-H .
(Average molecular weight = 3350)

SECTION 2: HAZARDS IDENTIFICATION

GHS Classification
Combustible dust :

GHS Label element
Signal word : Warning
Hazard statements : May form combustible dust concentrations in air
Precautionary statements : **Prevention:**
P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P243 Take precautionary measures against static discharge.
P233 Keep container tightly closed.

Other hazards
Hazards Not Otherwise Classified:
Particulates of this material may cause mechanical irritation to the skin, eye and/or respiratory tract.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous components

Chemical Name	CAS-No.	Concentration (%)
Polyethylene glycol	25322-68-3	100

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SECTION 4: FIRST AID MEASURES

General advice	: Remove/Take off immediately all contaminated clothing. Get medical advice/ attention if you feel unwell.
If inhaled	: Move the victim to fresh air. Give oxygen or artificial respiration if needed. Get immediate medical advice/ attention. Never give anything by mouth to an unconscious person.
In case of skin contact	: Wash thoroughly with soap and water for 15 minutes. If skin irritation occurs, seek medical attention.
In case of eye contact	: Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Get medical attention immediately if irritation develops and persists.
If swallowed	: IF SWALLOWED: Immediately call a POISON CENTER or doctor/ physician.
Most important symptoms and effects, both acute and delayed	: The possible symptoms known are those derived from the labeling (see section 2). No additional symptoms are known.
Notes to physician	: None known.

SECTION 5: FIRE-FIGHTING MEASURES

Suitable extinguishing media	: Foam Water spray jet
Unsuitable extinguishing media	: High volume water jet Dry powder Carbon dioxide (CO ₂)
Specific hazards during firefighting	: In case of fires, hazardous combustion gases are formed: Carbon monoxide (CO) Carbon dioxide (CO ₂) Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard. Routine housekeeping should be instituted to ensure that dusts do not accumulate on surfaces. Take measures to prevent the build up of electrostatic charge. Ground/bond container and receiving equipment.
Further information	: Exercise caution when fighting any chemical fire. Use NIOSH approved self-contained breathing apparatus and full protective clothing.
Special protective equipment for firefighters	: Self-contained breathing apparatus

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SECTION 6: ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	: Wear suitable protective equipment. Pre-wet material with water to avoid dust formation. Sweep or vacuum and place in sealable container for disposal. Wear protective equipment and wash thoroughly after handling. Flush residue with water.
Environmental precautions	: The product should not be allowed to enter drains, water courses or the soil.
Methods and materials for containment and cleaning up	: Take up mechanically

SECTION 7: HANDLING AND STORAGE

Advice on protection against fire and explosion	: Capable of dust explosion (method: Hartmann tube, spark ignition) Take precautionary measures against build-up of electrostatic charges, e.g earthing during loading and offloading operations. Keep away from sources of ignition – No smoking.
Advice on safe handling	: Wear suitable protective equipment. Keep tightly closed in a dry and cool place. Do not breathe vapours/dust. Do not get in eyes or mouth or on skin. Avoid dust formation. Keep away from sources of ignition. Lead off electrostatic charges.
Technical measures/Precautions	: Keep container closed.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Polyethylene glycol	25322-68-3	TWA (aerosol)	10 mg/m ³	US WEEL

Engineering measures	: Where a closed system is not used, good enclosure and local exhaust ventilation should be provided.
Personal protective equipment	
Respiratory protection	: If airborne concentrations pose a health hazard, become irritating or exceed recommended limits, use a NIOSH approved respirator in accordance with OSHA respiratory protection requirements under 29 CFR 1910.134
Hand protection Remarks	: Butyl Rubber, PVC Or Neoprene.
Eye protection	: Safety glasses or chemical splash goggles.

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Skin and body protection	: Protective clothing to minimize skin contact should be worn. Chemically resistant safety shoes. Wash contaminated clothing with soap and water and dry before reuse. Safety showers and eyewash stations should be provided in all areas where this material is handled.
Protective measures	: Observe the usual precautions for handling chemicals. Do not breathe dust.
Hygiene measures	: Do not breathe dust.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Appearance	: powder
Color	: white
Odor	: characteristic
Odor Threshold	: not tested.
pH	: 5 - 7, Concentration: 100 g/l (20 °C) Method: DIN 19268
Melting point	: 53 - 57 °C Method: European Pharmacopoeia / 2.2.18
Boiling point	: not determined
Flash point	: 260 °C Method: DIN 51376 (open cup)
Evaporation rate	: Not applicable
Upper explosion limit	: Not applicable
Lower explosion limit	: Not applicable
Vapor pressure	: < 0.001 kPa (20 °C)
Relative vapor density	: Not applicable
Density	: 1.2 g/cm ³ Method: DIN 51757
Bulk density	: not tested.
Solubility(ies)	: approx. 500 g/l soluble (20 °C)
Water solubility	: not tested.
Solubility in other solvents	Solvent: fat
Partition coefficient: noctanol/water	: log Pow: < -1 Method: Calculated by Syracuse.

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Auto-ignition temperature	: > 320 °C Method: DIN 51794
Decomposition temperature	: 360 °C
Viscosity	
Viscosity, dynamic	: 85 - 100 mPa.s (20 °C) Method: DIN 53019 50 % aqueous solution
Viscosity, kinematic	: not tested.
Explosive properties	: no data available
Oxidizing properties	: not tested.

SECTION 10: STABILITY AND REACTIVITY

Reactivity	: No dangerous reaction known under conditions of normal use.
Chemical stability	: Stable
Possibility of hazardous reactions	: The product is not a dust explosion risk as supplied; however the build-up of fine dust can lead to a risk of dust explosions.
Conditions to avoid	: Keep away from heat. Keep away from flames and sparks.
Incompatible materials	: not known
Hazardous decomposition products	: When handled and stored appropriately, no dangerous decomposition products are known

SECTION 11: TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Eye contact
Skin contact
Inhalation

Acute toxicity

Product:

Acute oral toxicity : LD50 (Rat): > 15,000 mg/kg
Acute inhalation toxicity : Remarks: not tested.
Acute dermal toxicity : Remarks: not tested.

Skin corrosion/irritation

Product:

Result: No skin irritation

Serious eye damage/eye irritation

Product:

Result: No eye irritation



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Respiratory or skin sensitization

Product:

Result: non-sensitizing

Germ cell mutagenicity

Product:

Germ cell mutagenicity – Assessment : Not mutagenic in Ames Test

Carcinogenicity

Product:

Carcinogenicity – Assessment : No information available.

IARC

Not listed

OSHA

Not listed

NTP

Not listed

Reproductive toxicity

Product:

Reproductive toxicity – Assessment : No information available.

No information available.

STOT - single exposure

Product:

Remarks: not tested.

STOT - repeated exposure

Product:

Remarks: not tested.

Repeated dose toxicity

Product:

Remarks: not tested.

Aspiration toxicity

Product:

no data available

Experience with human exposure

Product:

General Information : The possible symptoms known are those derived from the labeling (see section 2).

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SECTION 12: ECOLOGICAL INFORMATION

Ecotoxicity

Product:

Toxicity to fish : LC50 (Leuciscus idus (Golden orfe)): > 10 mg/l
Exposure time: 48 h
Method: DIN 38412 T.15

Toxicity to daphnia and other aquatic invertebrates :
Remarks: not tested.

Toxicity to algae : Remarks: not tested.

Toxicity to bacteria : EC50: > 1,000 mg/l
Method: OECD Test Guideline 209

Persistence and degradability

Product:

Biodegradability : Result: Not readily biodegradable.
Biodegradation: < 20 %
Method: OECD Test Guideline 302B

Bioaccumulative potential

Product:

Bioaccumulation : Remarks: not tested.

Mobility in soil

Product:

Distribution among environmental compartments : Remarks: not tested.

Other adverse effects

Product:

Environmental fate and pathways : Remarks: no data available

Results of PBT and vPvB assessment : Remarks: no data available

Additional ecological information : no data available

SECTION 13: DISPOSAL CONSIDERATIONS

Disposal methods

RCRA – Resource Conservation and Recovery Authorization Act : No -- Not as sold.

Waste from residues : Must be incinerated in a suitable incineration plant holding a permit delivered by the competent authorities.

Contaminated packaging : Packaging that cannot be cleaned should be disposed of as product waste



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SECTION 14: TRANSPORT INFORMATION

DOT	not restricted
IATA	not restricted
IMDG	not restricted

SECTION 15: REGULATORY INFORMATION

EPCRA - Emergency Planning and Community Right-to-Know Act

CERCLA Reportable Quantity

This material does not contain any components with a CERCLA RQ.

SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

SARA 311/312 Hazards : No SARA Hazards

SARA 302 : No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

SARA 313 : This product does not contain any toxic chemical listed under Section 313 of the Emergency Planning and Community Right-To-Know Act of 1986.

Clean Water Act

Contains no known priority pollutants at concentrations greater than 0.1%.

The components of this product are reported in the following inventories:

TSCA : All components of this product are listed on the TSCA Inventory. However, the primary use of this product is NOT subject to TSCA but rather to FDA and must comply with the FDA regulations.

Inventories

AICS (Australia), DSL (Canada), IECSC (China), REACH (European Union), ENCS (Japan), ISHL (Japan), KECI (Korea), NZIoC (New Zealand), PICCS (Philippines), TSCA (USA)

SECTION 16: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION

Further information

Observe national and local legal requirements

Observe all necessary precautions for handling fine powders to control dust. May present dust explosion hazard.

Reference exposure limit: ACGIH (TLV) for particulate matter – 10 mg/m³ inhalable particulates, 3 mg/m³ respirable particulates. OSHA Permissible Limit (PEL) for particulate matter: total dust: 15 mg/m³; respirable fraction: 5 mg/m³

Revision Date : 04/30/2015

This information is supplied under the OSHA Hazard Communication Standard, 29 CFR 1910.1200, and is offered in good faith based on data available to us that we believe to be true and accurate. The recommended industrial hygiene and safe handling procedures are believed to be generally applicable to the material. However, each user should review these recommendations in the specific context of the intended use and determine whether they are appropriate for that use. No warranty, express or implied, is made regarding the accuracy of this data, the hazards connected with the use of the material, or the results to be obtained from the use thereof. We assume no responsibility for damage or injury from the use of the product described herein. Data provided here are typical and not intended for use as product specifications.

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