

SAFETY DATA SHEET

Issuing Date No data available

Revision Date 28-Jul-2014

Revision Number 1

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

Product identifier

Product Name Ear Wax Remover

Other means of identification

Synonyms None

Recommended use of the chemical and restrictions on use

Recommended Use Cosmetics

Uses advised against No information available

Details of the supplier of the safety data sheet

Supplier Name Sheffield Pharmaceuticals
Supplier Address 170 Broad Street
New London
CT
06320
US
Supplier Phone Number Phone:860-442-4451
Fax:860-442-4451
Contact Phone860-442-4451
Supplier Email ana.deoliveira@sheffield-pharmaceuticals.com
Emergency telephone number

2. HAZARDS IDENTIFICATION

Classification

This chemical is considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Serious eye damage/eye irritation	Category 2A
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GHS Label elements, including precautionary statements

Emergency Overview

Signal word	Warning
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Hazard Statements
Causes serious eye irritation



Appearance Clear**Physical State** Liquid**Odor** Slight sweet**Precautionary Statements - Prevention**

Wash face, hands and any exposed skin thoroughly after handling
Wear protective gloves/protective clothing/eye protection/face protection

Precautionary Statements - Response**Eyes**

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
If eye irritation persists: Get medical advice/attention

Precautionary Statements - Storage

None

Precautionary Statements - Disposal

None

Hazards not otherwise classified (HNOC)

Not applicable

Unknown Toxicity

1.01% of the mixture consists of ingredient(s) of unknown toxicity

Other information

No information available

Interactions with Other Chemicals

No information available.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS No.	Weight-%	Trade Secret
Glycerin	56-81-5	60 - 100	*
Urea peroxide	124-43-6	3 - 7	*
Tartaric acid	87-69-4	1 - 5	*

*The exact percentage (concentration) of composition has been withheld as a trade secret

4. FIRST AID MEASURES**First aid measures****General Advice**

Show this safety data sheet to the doctor in attendance.

Eye Contact

If symptoms persist, call a physician. Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Keep eye wide open while rinsing. Do not rub affected area.

Skin Contact

Wash skin with soap and water. In the case of skin irritation or allergic reactions see a physician.

Inhalation

Remove to fresh air. If symptoms persist, call a physician.

Ingestion Do NOT induce vomiting. Rinse mouth immediately and drink plenty of water. Never give anything by mouth to an unconscious person. Call a physician.

Self-protection of the first aider Avoid contact with skin, eyes or clothing. Wear personal protective clothing (see section 8).

Most important symptoms and effects, both acute and delayed

Most Important Symptoms and Effects Burning sensation.

Indication of any immediate medical attention and special treatment needed

Notes to Physician Treat symptomatically.

5. FIRE-FIGHTING MEASURES

Suitable Extinguishing Media

Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Unsuitable Extinguishing Media

CAUTION: Use of water spray when fighting fire may be inefficient.

Specific Hazards Arising from the Chemical

No information available.

Uniform Fire Code Irritant: Liquid

Hazardous Combustion Products

Carbon oxides.

Explosion Data

Sensitivity to Mechanical Impact No.

Sensitivity to Static Discharge No.

Protective equipment and precautions for firefighters

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Personal Precautions Avoid contact with skin, eyes or clothing. Use personal protective equipment as required.

Other Information Refer to protective measures listed in Sections 7 and 8.

Environmental Precautions

Environmental Precautions Refer to protective measures listed in Sections 7 and 8.

Methods and material for containment and cleaning up

Methods for Containment Prevent further leakage or spillage if safe to do so.

Methods for cleaning up Soak up with inert absorbent material. Pick up and transfer to properly labeled containers.

7. HANDLING AND STORAGE

Precautions for safe handling

Handling Handle in accordance with good industrial hygiene and safety practice. Avoid contact with eyes. Use personal protection equipment.

Conditions for safe storage, including any incompatibilities

Storage Keep containers tightly closed in a dry, cool and well-ventilated place.

Incompatible Products None known based on information supplied.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

Exposure Guidelines

Chemical Name	ACGIH TLV	OSHA PEL	NIOSH IDLH
Glycerin 56-81-5	TWA: 10 mg/m ³ mist	TWA: 15 mg/m ³ mist, total particulate TWA: 5 mg/m ³ mist, respirable fraction (vacated) TWA: 10 mg/m ³ mist, total particulate (vacated) TWA: 5 mg/m ³ mist, respirable fraction	

ACGIH TLV: American Conference of Governmental Industrial Hygienists - Threshold Limit Value OSHA PEL: Occupational Safety and Health Administration - Permissible Exposure Limits NIOSH IDLH Immediately Dangerous to Life or Health

Other Exposure Guidelines Vacated limits revoked by the Court of Appeals decision in AFL-CIO v. OSHA, 965 F.2d 962 (11th Cir., 1992) See section 15 for national exposure control parameters

Appropriate engineering controls

Engineering Measures

Showers
Eyewash stations
Ventilation systems

Individual protection measures, such as personal protective equipment

Eye/Face Protection If splashes are likely to occur. Wear safety glasses with side shields (or goggles). None required for consumer use.

Skin and Body Protection Wear protective gloves and protective clothing.

Respiratory Protection No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.

Hygiene Measures Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes or clothing. Wear suitable gloves and eye/face protection. Do not eat, drink or smoke when using this product.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical and Chemical Properties

Physical State	Liquid	Odor	Slight sweet
Appearance	Clear	Odor Threshold	No information available
Color	No information available		

<u>Property</u>	<u>Values</u>	<u>Remarks/ Method</u>
pH	7	None known
Melting / freezing point	No data available	None known
Boiling point / boiling range	No data available	None known
Flash Point	5001 C / 9034 F	None known
Evaporation Rate	No data available	None known
Flammability (solid, gas)	No data available	None known
Flammability Limit in Air		
Upper flammability limit	No data available	
Lower flammability limit	No data available	
Vapor pressure	No data available	None known
Vapor density	No data available	None known
Specific Gravity	No data available	None known
Water Solubility	Easily soluble	None known
Solubility in other solvents	No data available	None known
Partition coefficient: n-octanol/water	No data available	None known
Autoignition temperature	No data available	None known
Decomposition temperature	No data available	None known
Kinematic viscosity	No data available	None known
Dynamic viscosity	No data available	None known
Explosive properties	No data available	
Oxidizing Properties	No data available	

Other Information

Softening Point	No data available
VOC Content (%)	No data available
Particle Size	No data available
Particle Size Distribution	No data available

10. STABILITY AND REACTIVITY

Reactivity

No data available.

Chemical stability

Stable under recommended storage conditions.

Possibility of Hazardous Reactions

None under normal processing.

Hazardous Polymerization

Hazardous polymerization does not occur.

Conditions to avoid

None known based on information supplied.

Incompatible materials

None known based on information supplied.

Hazardous Decomposition Products

Carbon oxides.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Product Information

Product does not present an acute toxicity hazard based on known or supplied information.

Inhalation

Specific test data for the substance or mixture is not available. May cause irritation of respiratory tract.

Eye Contact

Specific test data for the substance or mixture is not available. Expected to be an irritant based on components. May cause redness, itching, and pain. May cause temporary eye irritation.

Skin Contact

Specific test data for the substance or mixture is not available. May cause irritation. Prolonged contact may cause redness and irritation.

Ingestion

Specific test data for the substance or mixture is not available. Ingestion may cause irritation to mucous membranes. Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhea.

Component Information

Chemical Name	Oral LD50	Dermal LD50	Inhalation LC50
Glycerin 56-81-5	-	> 10 g/kg (Rabbit)	-

Information on toxicological effects

Symptoms

May cause redness and tearing of the eyes.

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Sensitization	No information available.
Mutagenic Effects	No information available.
Carcinogenicity	Contains no ingredient listed as a carcinogen.
Reproductive Toxicity	No information available.
STOT - single exposure	No information available.
STOT - repeated exposure	No information available.
Chronic Toxicity	No known effect based on information supplied.
Target Organ Effects	Eyes. Kidney. Respiratory system. Skin.
Aspiration Hazard	No information available.

Numerical measures of toxicity Product Information

The following values are calculated based on chapter 3.1 of the GHS document
Not applicable

12. ECOLOGICAL INFORMATION**Ecotoxicity**

The environmental impact of this product has not been fully investigated.

Persistence and Degradability

No information available.

Bioaccumulation

Chemical Name	Log Pow
Glycerin 56-81-5	-1.76

Other adverse effects

No information available.

13. DISPOSAL CONSIDERATIONS**Waste treatment methods**

Disposal methods	This material, as supplied, is not a hazardous waste according to Federal regulations (40 CFR 261). This material could become a hazardous waste if it is mixed with or otherwise comes in contact with a hazardous waste, if chemical additions are made to this material, or if the material is processed or otherwise altered. Consult 40 CFR 261 to determine whether the altered material is a hazardous waste. Consult the appropriate state, regional, or local regulations for additional requirements.
Contaminated Packaging	Dispose of contents/containers in accordance with local regulations.

California Hazardous Waste Codes 331

14. TRANSPORT INFORMATION

DOT	NOT REGULATED
Proper Shipping Name	NON REGULATED
Hazard Class	N/A
TDG	Not regulated
MEX	Not regulated
ICAO	Not regulated
IATA	Not regulated
Proper Shipping Name	NON REGULATED
Hazard Class	N/A
IMDG/IMO	Not regulated
Hazard Class	N/A
RID	Not regulated
ADR	Not regulated
ADN	Not regulated

15. REGULATORY INFORMATION

International Inventories

TSCA	Complies
DSL	All components are listed either on the DSL or NDSL.

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

US Federal Regulations

SARA 313

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372

SARA 311/312 Hazard Categories

Acute Health Hazard	Yes
Chronic Health Hazard	No
Fire Hazard	No
Sudden release of pressure hazard	No
Reactive Hazard	No

CWA (Clean Water Act)

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42)

CERCLA

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material

US State Regulations

California Proposition 65

This product does not contain any Proposition 65 chemicals.

U.S. State Right-to-Know Regulations

Chemical Name	New Jersey	Massachusetts	Pennsylvania	Rhode Island	Illinois
Glycerin 56-81-5	X	X	X	X	
Urea peroxide 124-43-6	X				
Propylene Glycol 57-55-6	X		X		

International Regulations**Mexico****National occupational exposure limits**

Component	Carcinogen Status	Exposure Limits
Glycerin 56-81-5 (60 - 100)	-	10mg/m ³ (mist) TWA

Mexico - Occupational Exposure Limits - Carcinogens

Canada**WHMIS Hazard Class**

D2B - Toxic materials

**16. OTHER INFORMATION**

NFPA	Health Hazards 2	Flammability 0	Instability 0	Physical and Chemical Hazards -
HMIS	Health Hazards 2	Flammability 0	Physical Hazard 0	Personal Protection X

Prepared By

Product Stewardship
23 British American Blvd.
Latham, NY 12110
1-800-572-6501

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28-Jul-2014

Revision Note

No information available.

Disclaimer

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

End of Safety Data Sheet