

SAFETY DATA SHEET

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

Product identifier

Product Name Auro Homeopathic Ear Relief Drops

Other means of identification

Synonyms None

Recommended use of the chemical and restrictions on use

Recommended Use Medicinal Liquids (cough medicine, eye drops, ear drops, nasal spray and inhalers)

Uses advised against No information available

Details of the supplier of the safety data sheet

Supplier Name Insight Pharmaceuticals
Supplier Address 900 Northbrook DR
Suite 200
Langhorne
PA
19053
US
Supplier Phone Number Phone:267-852-0505
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Supplier Email Ifreedman@insightpharma.org
Emergency telephone number

2. HAZARDS IDENTIFICATION

Classification

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

Skin sensitization	Category 1
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GHS Label elements, including precautionary statements

Emergency Overview



Signal word	Warning
Hazard Statements May cause an allergic skin reaction	
	
Appearance Water white	Physical State Liquid
	Odor Slight sweet

Precautionary Statements - Prevention

Avoid breathing dust/fume/gas/mist/vapors/spray
Contaminated work clothing should not be allowed out of the workplace
Wear protective gloves

Precautionary Statements - Response

Specific treatment (see supplemental first aid instructions on this label)

Skin

IF ON SKIN: Wash with plenty of soap and water
If skin irritation or rash occurs: Get medical advice/attention
Wash contaminated clothing before reuse

Precautionary Statements - Storage

None

Precautionary Statements - Disposal

Dispose of contents/container to an approved waste disposal plant

Hazards not otherwise classified (HNOC)

Not applicable

Unknown Toxicity

0.0201% of the mixture consists of ingredient(s) of unknown toxicity

Other information

Repeated or prolonged skin contact may cause allergic reactions with susceptible persons

Interactions with Other Chemicals

No information available.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS No	Weight-%	Trade Secret
Glycerin	56-81-5	10 - 30	*
Chamomilla recutita extract	84082-60-0	0.1 - 1	*

*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

Rinse thoroughly with plenty of water, also under the eyelids. If symptoms persist, call a physician.

Skin Contact

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

Inhalation

Remove to fresh air.

Ingestion

Rinse mouth immediately and drink plenty of water. Never give anything by mouth to an unconscious person.

Most important symptoms and effects, both acute and delayed

Most Important Symptoms and Effects Itching. Rashes. Hives.

Indication of any immediate medical attention and special treatment needed

Notes to Physician

May cause sensitization of susceptible persons. 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

Product is or contains a sensitizer. May cause sensitization by skin contact.

Uniform Fire Code

Sensitizer: 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 eyes.

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.

Conditions for safe storage, including any incompatibilities

Storage Keep container tightly closed.

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 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
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Individual protection measures, such as personal protective equipment

Eye/Face Protection	Wear safety glasses with side shields (or goggles).
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. Take off contaminated clothing and wash before reuse.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical and Chemical Properties

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

<u>Property</u>	<u>Values</u>	<u>Remarks</u>	<u>Method</u>
pH	UNKNOWN	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	Soluble in water	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	

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

Inhalation	Specific test data for the substance or mixture is not available.
Eye Contact	Specific test data for the substance or mixture is not available.
Skin Contact	Specific test data for the substance or mixture is not available.
Ingestion	Specific test data for the substance or mixture is not available.

Component Information

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

Information on toxicological effects

Symptoms Itching. Rashes. Hives.

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

Sensitization May cause sensitization of susceptible persons. May cause sensitization by skin contact.

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	Skin. Eyes. Kidney. Respiratory system.
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.

Chemical Name	Toxicity to Algae	Toxicity to Fish	Toxicity to Microorganisms	Daphnia Magna (Water Flea)
Glycerin 56-81-5		96h LC50: 51 - 57 mL/L (Oncorhynchus mykiss)		24h EC50: > 500 mg/L

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.



14. TRANSPORT INFORMATION

<u>DOT</u>	NOT REGULATED
<u>TDG</u>	Not regulated
<u>MEX</u>	Not regulated
<u>ICAO</u>	Not regulated
<u>IATA</u>	Not regulated
<u>IMDG/IMO</u>	Not regulated
<u>RID</u>	Not regulated
<u>ADR</u>	Not regulated
<u>ADN</u>	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	

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

Component	Carcinogen Status	Exposure Limits
Glycerin 56-81-5 (10 - 30)	-	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
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Disclaimer

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End of Safety Data Sheet