



SDS: Lindane Lotion USP, 1%

SAFETY DATA SHEET

1. Identification

Product Identifier: Lindane Lotion USP, 1%

Synonyms: Gamma benzene hexachloride

National Drug Code (NDC): 61748-401-02

Recommended Use: Pharmaceutical.

Company: Akorn, Inc.
1925 West Field Court, Suite 300
Lake Forest, Illinois 60045

Contact Telephone: 1-800-932-5676

E mail: customer.service@akorn.com

Emergency Phone Number: CHEMTREC 1-800-424-9300 (U.S. and Canada)

2. Hazard(s) Identification

Physical Hazards: Not classifiable.

Health Hazards: Not classifiable.

Symbol(s): None.

Signal Word: None.

Hazard Statement(s): None.

Precautionary Statement(s): None.

Hazards Not Otherwise Classified: Not classifiable.

Supplementary Information: While this material is not classifiable as hazardous under the OSHA standard, this SDS contains valuable information critical to safe handling and proper use of the product. This SDS should be retained and available for employees and other users of this product.

3. Composition/Information on Ingredients

Chemical Name	CAS Number	Synonyms	Chemical Formula	Molecular Weight	Percentage
Cyclohexane, 1,2,3,4,5,6-hexachloro-, (1alpha, 2alpha, 3beta, 4alpha, 5alpha, 6beta)-	58-89-9	Gamma benzene hexachloride	C ₆ H ₆ Cl ₆	290.83	1%

*The formula also contains Butyl Paraben, Carrageenan, Cetyl Alcohol, Glyceryl Monostearate, Methylparaben, Perfume Compound, Purified Water, Stearic Acid and Triethanolamine to form a lotion.

4. First Aid Measures

Ingestion:	If a person vomits place them in the recovery position so that vomit will not reenter the mouth and throat. Rinse mouth with water. If swallowed, seek medical advice immediately and show the container or label. Treat symptomatically and supportively. Ensure that medical personnel are aware of the material(s) involved and take precautions to protect themselves.
Eye Contact:	Remove from source of exposure. Flush with copious amounts of water for at least 15 minutes. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.
Skin Contact:	Remove from source of exposure. Remove and isolate contaminated clothing and shoes. Flush with copious amounts of water for at least 20 minutes. Use soap. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.
Inhalation:	Remove from source of exposure. Move individual(s) to fresh air. Give artificial respiration if individual(s) are not breathing and call emergency medical service. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.
Protection of First-Aiders:	Use personal protective equipment (see section 8).
Signs and Symptoms:	May include any of the following: allergic skin irritation, burning itching, redness, muscle cramps, rapid heartbeat, dizziness rash, and discomfort irritability vomiting. Symptoms of overdose may include: convulsion, dizziness, and vomiting.
Medical Conditions Aggravated by Exposure:	No data available.
Notes to Physician:	Treat supportively and symptomatically.

5. Firefighting Measures

Suitable Extinguishing Media:	Use extinguishing media for type of surrounding fire.
Unsuitable Extinguishing Media:	Not determined.

Specific Hazards Arising from the Chemical:

Hazardous Combustion Products: Non-Flammable.

Other Specific Hazards: Closed containers may explode from the heat of fire.

Special Protective Equipment/Precautions for Firefighters: Wear self-contained breathing apparatus and full and protective gear.

6. Accidental Release Measures

Personal Precautions: Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate personal protective equipment and clothing.

Personal Protective Equipment: For personal protection see section 8.

Methods for Cleaning Up: Absorb with inert material. Recover product and place in an appropriate container for disposal in accordance with local, state and federal regulations.

Environmental Precautions: Contain material and prevent release to basements, confined spaces, waterways or soil.

Reference to Other Sections: Refer to Sections 8, 12 and 13 for further information.

7. Handling and Storage

Precautions for Safe Handling: Handle in accordance with product label and/or product insert information. Handle in accordance with good industrial hygiene and safety practices.

Conditions for Safe Storage, Including Any Incompatibilities: Store according to label and/or product insert information.

Specific End Use: Pharmaceuticals.

8. Exposure Controls/Personal Protection

Occupational Exposure Guidelines:

Common or Chemical Name	Employee Exposure Limits
Lindane	OSHA PEL: 0.5 mg/m ³ NIOSH REL: 0.5 mg/m ³ ACGIH TLV TWA: 0.5 mg/m ³

Engineering Controls: Engineering controls should be used as the primary means to control exposures.

Respiratory Protection: Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator

program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).

Eyes Protection:

Safety glasses with side shields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.

Hand Protection:

Chemically compatible gloves are recommended. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic non-latex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy.

Skin Protection:

Wear protective laboratory coat, apron, or disposable garment when working with large quantities.

9. Physical and Chemical Properties

Physical State/Color:	White viscous liquid.
Odor:	Pleasantly scented.
Odor Threshold:	No data available.
pH:	6.5 – 8.5.
Melting Point:	No data available.
Freezing Point:	No data available.
Boiling Point:	No data available.
Flash Point:	No data available.
Evaporation Rate:	Slower than ether.
Flammability (solid, gas):	No data available.
Flammability Limit - Lower:	No data available.
Flammability Limit - Upper:	No data available.
Vapor Pressure:	No data available.
Vapor Density:	Lighter than air.
Relative Density:	No data available.
Solubility(ies):	No data available.
Partition Coefficient (n-octanol/water):	No data available.
Auto-Ignition Temperature:	No data available.
Decomposition Temperature:	No data available.
Viscosity:	No data available.

10. Stability and Reactivity

Reactivity:	No data available.
Chemical Stability:	Stable under recommended storage conditions.
Possibility of Hazardous Reactions:	No data available.
Conditions to Avoid (e.g., static discharge, shock, or vibration):	Excessive Heat.

Incompatible Materials: None.

Hazardous Decomposition Products: No data available.

Hazardous Polymerization: Will not occur.

11. Toxicological Information

Information on the Likely Routes of Exposure:

Inhalation: May cause respiratory tract irritation.

Ingestion: May be harmful if swallowed.

Skin Contact: May cause skin irritation.

Eye Contact: May cause eye irritation.

Symptoms Related to the Physical, Chemical and Toxicological Characteristics:

See Section 4. To the best of our knowledge, the chemical, physical and toxicological properties have not been thoroughly investigated.

Delayed and Immediate Effects of Exposure:

Adverse CNS effects. May be more likely in patients over 60 years of age.

Acute Toxicity:

Compound	Species	Route	Test Type	Dose
Lindane	Rat	Oral	LD ₅₀	76 mg/kg
Lindane	Rat	Inhalation	LC ₅₀	1.56 mg/l
Lindane	Rat	Dermal	LD ₅₀	500 mg/kg
Lindane	Rabbit	Dermal	LD ₅₀	50 mg/kg

Acute Toxicity – Dermal: No data available.

Acute Toxicity – Inhalation: No data available.

Corrosivity: No data available.

Dermal Irritation: No data available.

Eye Irritation: No data available.

Sensitization: No data available.

Toxicokinetics/Metabolism: No data available.

Target Organ Effects: No data available.

Reproductive Effects: No data available.

Pregnancy: Lindane is absorbed through the skin. Advice your doctor if pregnant. Do not use Lindane more than twice during pregnancy. Category B.

Nursing Mothers: Lindane is secreted in human breast milk in low concentrations. If Lindane is used during breast-feeding, do not breast feed for four days.

SDS: Lindane Lotion USP, 1%

Carcinogenicity: No data available.

National Toxicology Program (NTP): Not considered to be a carcinogen.

International Agency for Research on Cancer (IARC): Not considered to be a carcinogen.

Occupational Safety and Health Administration (OSHA): Not considered to be a carcinogen.

Mutagenicity: No data available.

Aspiration Hazard: No data available.

12. Ecological Information

Ecotoxicity

Aquatic:

Compound	Species	Test Type	Dose
Lindane	Water flea (<i>Daphnia carinata</i>)	EC ₅₀	0.1 mg/l, 48 hours
Lindane	Brown trout (<i>Salmo trutta</i>)	LC ₅₀	0.001 – 0.003 mg/l, 96 hours

Terrestrial: No data available.

Persistence and Degradability: No data available.

Bioaccumulative Potential: No data available.

Mobility in Soil: No data available.

Mobility in Environment: No data available.

Other Adverse Effects: No data available.

13. Disposal Considerations

Dispose of all waste in accordance with Federal, State and Local regulations.

14. Transport Information

UN Number: UN2761 (Lindane)

UN Proper Shipping Name: Organochlorine pesticide, solid, toxic (Lindane), MARINE POLLUTANT

Transport Hazard Class(es): 6.1 (Lindane)

Packing Group: III (Lindane)

Department of Transportation: Regulated as a hazardous material. (Lindane)

International Air Transport Association (IATA): Regulated as a dangerous good. (Lindane)

International Maritime Dangerous Good (IMDG): Regulated as a dangerous good. (Lindane)

15. Regulatory Information**US Federal Regulations:****Toxic Substance Control Act (TSCA):**

Lindane is listed.

CERCLA Hazardous Substance and Reportable Quantity:

Not listed.

SARA 313:

Lindane is listed.

SARA 302:

Lindane is listed.

State Regulations**Massachusetts:**

Not listed.

New Jersey:

Not listed.

Pennsylvania:

Not listed.

California Proposition 65:

Lindane contains a chemical known to the State of California to cause cancer.

16. Other Information**Revision Date:** 09/04/2015**Revision Number:** 0

Disclaimer: This document is generated to distribute health, safety and environmental data. It is not a specification sheet and none of the displayed data should be construed as a specification. Information on this SDS sheet was obtained from sources which we believe are reliable, and we believe that the information is complete and accurate. However, the information is provided without any warranty, express or implied, regarding its correctness. Some of the information presented and conclusions drawn are from sources other than direct test data of the substance. The conditions or methods of handling, storage, use and disposal of the product are beyond our control and may also be beyond our knowledge. It is the user's responsibility to determine the suitability of any material for a specific purpose and to adopt such safety precautions as may be necessary. If the product is used as a component in another product, this SDS information may not be applicable. For these reasons, we do not assume any responsibility and expressly disclaim liability for any loss, damage or expense arising out of or in any way connected with the handling, storage, use or disposal of this product.