



IN CASE OF EMERGENCY
Emergency Phone: (614) 276-4000

Material Safety Data Sheet

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION		
Common/Trade Name: Diphenoxylate Hydrochloride and Atropine Sulfate Oral Solution USP C		
Chemical Name: Diphenoxylate HCl: (Ethyl 1-(3-cyano-3,3-diphenylpropyl)-4-phenylisoni-pecotate monohydrochloride Atropine Sulfate: endo-(±)-α-(hydroxymethyl) benzeneacetic acid 8-methyl-8-azabicyclo[3.2.1] oct-3-yl ester sulfate (2:1) (salt) monohydrate		
Synonyms: None		
Molecular Formula: Diphenoxylate HCl: C ₃₀ H ₃₂ N ₂ O ₂ • HCl; Atropine Sulfate: (C ₁₇ H ₂₃ NO ₃) ₂ • H ₂ SO ₄ • H ₂ O		
Molecular Weight: Diphenoxylate HCl: 489.05; Atropine Sulfate: 694.83		
CAS No: 3810-80-8; 55-48-1		
Chemical Family: Antidiarrheal, anticholinergic		
Product Use: Treatment of diarrhea		
Manufacturer's Name: Boehringer Ingelheim Roxane, Inc. Address: 1809 Wilson Road Columbus, Ohio 43228		
2. COMPOSITION / INFORMATION ON INGREDIENTS		
Composition	CAS#	Exposure Limit
Diphenoxylate hydrochloride (active ingredient)	3810-80-8	None established
Atropine sulfate (active ingredient)	55-48-1	None established
Alcohol, ethyl	64-17-5	ACGIH TLV-TWA: 1000 ppm OSHA Z-1 PEL: 1000 ppm
<i>REFER to PHYSICIAN'S DESK REFERENCE for common components present as <1%</i>		
3. HAZARDS IDENTIFICATION		
Emergency Overview	Physical State: Liquid solution administered orally. Clear, orange-colored, cherry-flavored solution with 2.5 mg of Diphenoxylate Hydrochloride and 0.025 mg Atropine Sulfate per 5 mL. Odor: No data available WARNING! May be harmful if swallowed. Accidental ingestion of large amounts may be harmful.	
Primary Route(s) of Entry	Ingestion	
Potential Health Effects:	Inhalation: Not expected to be an inhalation hazard in final pharmaceutical form. Eye Contact: Not expected to be a hazard to the eye. Contact with eye may cause irritation, burning and redness. Skin Contact: Not expected to be a hazard to the skin. Can cause hypersensitive reactions resulting in rash, redness, itching and inflammation. Ingestion: May be harmful if ingested. Ingestion may cause nausea, vomiting, dehydration, dizziness and weakness.	



Toxicity Data:	See Section 11
Effects of Overexposure:	The potential for exposure is reduced in finished pharmaceutical form. Overexposure by ingestion may cause severe respiratory depression and coma, possibly leading to permanent brain damage or death.
Target Organs:	Gastrointestinal Tract
4. FIRST AID MEASURES	
Eye Exposure	Any material that contacts the eye should be washed out immediately with water. If easy to do, remove contact lenses if worn. Get medical attention if symptoms persist.
Skin Exposure	Wash with soap and water. Get medical attention if symptoms occur.
Ingestion	Call a physician or poison control center immediately.
Inhalation	Should not pose a hazard in the final form. If breathing is difficult, move to fresh air. Get medical attention immediately.
5. FIRE AND EXPLOSION HAZARDS	
Flammability	Lower: N/A Upper: N/A
Flash Point	N/A
Extinguishing Media	Use water spray, dry chemical, carbon dioxide, foam or material appropriate for fire in surrounding area
Special Fire Fighting Procedures	Wear full protective clothing and self-contained breathing apparatus. Use water spray to keep fire-exposed containers cool.
Unusual Fire/Explosion Hazards	For significant quantities of product: Vapors may cause a flash fire or ignite explosively. Vapors may travel considerable distance to a source of ignition and flashback. Prevent build-up of vapors or gases to explosive concentrations.
Hazardous Combustion Products	Carbon dioxide, carbon monoxide, oxides of nitrogen, oxides of sulfur, hydrogen chloride
6. ACCIDENTAL RELEASE INFORMATION	
STEPS TO BE TAKEN IF SIGNIFICANT QUANTITIES OF LIQUID IS SPILLED: Use appropriate personal protective equipment (see Section 8). Eliminate ignition sources. Wipe up and containerize spill material in a compatible container. Dispose according to applicable regulations. Incineration of the waste at an approved facility is recommended.	
7. PRECAUTIONS FOR SAFE HANDLING AND USE	
Precautions Handling Significant Quantities of Liquid:	Observe good industrial hygiene practices.
Storage	Store at 20° to 25°C (68° to 77°F). Keep container closed tightly. Protect from light and moisture. Store away from foodstuffs. Discard open bottle after 90 days.
8. CONTROL MEASURES AND PERSONAL PROTECTIVE EQUIPMENT	
Exposure Limits	None
Engineering Controls	Not required when handling liquid or containers. Good ventilation should be used. Ventilation should be matched to conditions.
Respiratory Protection	Not required when handling liquid or containers. NIOSH/MSHA approved respirators for protection should be used if respirators are found to be necessary. Ventilation should be matched to conditions.
Personal Protection	Not required when handling final product. If containers are compromised or exposure is likely wear: Goggles, Lab Coat, Gloves
Recommended Facilities	Eye wash, washing facilities
9. PHYSICAL / CHEMICAL CHARACTERISTICS	



Appearance	Clear, orange-colored liquid solution	Melting point	Not available	Solubility in water	Soluble
Odor	Not available	Boiling point	Not available	Specific Gravity	Not available
Taste	Cherry	Vapor Pressure	Not available	Flashpoint	N/A
pH	Not available	Density	Not available	Flammability Limits	Not available

10. STABILITY AND REACTIVITY DATA

Stability	Stable
Incompatibility	Strong oxidizers
Hazardous Decomposition	Oxides of carbon, oxides of nitrogen, oxides of sulfur, hydrogen chloride
Conditions to Avoid	Excessive heat, light
Hazardous Polymerization	Will not occur.

11. TOXICOLOGICAL INFORMATION

Acute Toxicity:

Diphenoxylate Hydrochloride:
LD50 Oral (rat): 221 mg/kg

Atropine Sulfate:
LD50 Oral (rat): 500 mg/kg
LD50 Oral (mouse): 468 mg/kg

Carcinogenicity: Not listed as a carcinogen by NTP, IARC Monographs or OSHA.

12. ENVIRONMENTAL IMPACT INFORMATION

No information is currently available on the environmental impact of this product.

13. DISPOSAL INFORMATION

Waste Disposal Considerations: Drug Enforcement Administration controlled substances must be destroyed following DEA Guidelines for witnessed destruction of the product beyond reclamation. Disposal by incineration is recommended.

At home: Discard away from children's reach.

14. TRANSPORTATION INFORMATION

DOT: Limited Quantity of liquids and solids containing ethyl alcohol are exempt from provisions of 49CFR by DOT granting of Special Permit DOT-SP-9275

TDG: Not Regulated

IATA: Limited Quantity of liquids and solids containing ethyl alcohol are exempt from provisions of 49CFR by DOT granting of Special Permit DOT-SP-9275

IMDG: Not Regulated

15. REGULATORY INFORMATION

DEA: Diphenoxylate Hydrochloride  and Atropine Sulfate Oral Solution is a controlled substance.

FDA: Diphenoxylate Hydrochloride  and Atropine Sulfate Oral Solution is an approved prescription medication.


Inventory Status: This material is not listed on the US TSCA Inventory. Therefore, it can only be used for TSCA exempt purposes such as R&D or drug use.

This material is not listed on the DSL Inventory but is exempt.

**16. OTHER DATA****ABBREVIATIONS:**

N/A – not applicable

Prepared by: **Boehringer Ingelheim Roxane, Inc.****References:**

1. Diphenoxylate Hydrochloride and Atropine Sulfate Oral Solution , Package Insert, **Boehringer Ingelheim Roxane, Inc.**, Columbus, Ohio
2. RTECS No. NS5300000 - Ethyl 1-(3-cyano-3,3-diphenylpropyl)-4-phenylisonipecotate monohydrochloride
3. RTECS No. CK2450000 - Atropine, sulfate (2:1)
4. Ariel Webinsight. Regulatory and ChemExpert Database.
5. PDR – Physicians Desk Reference

Date: 09/13/2008 - New MSDS

SEE CURRENT PACKAGE INSERT FOR FURTHER INFORMATION

*The information provided is believed to be complete and accurate. If this product is combined with other materials, deteriorates or becomes contaminated, it may pose hazards not mentioned in this MSDS. It is the users' responsibility to use the information according to the application. **Boehringer Ingelheim Roxane, Inc.** assumes no responsibility or liability resulting from the use of this information.*