

SAFETY DATA SHEETS

This SDS packet was issued with item:

078937305

N/A

SAFETY DATA SHEET

1. Identification

Product identifier	Diphenoxylate HCl and Atropine Sulfate Oral Solution USP CV
Other means of identification	None.
Recommended use	Management of diarrhea
Recommended restrictions	None known.

Manufacturer/Importer/Supplier/Distributor information

Company name	Boehringer Ingelheim Roxane Inc.
Address	1809 Wilson Road Columbus, Ohio 43228
Telephone	(614) 276-4000
Emergency phone number	(614) 276-4000

2. Hazard(s) identification

Physical hazards	Not classified.
Health hazards	Not classified.
OSHA defined hazards	Not classified.

Label elements

Hazard symbol	None.
Signal word	Warning
Hazard statement	This is a pharmaceutical product designed to be prescribed by a licensed health care professional. Should any person while using this product observe any adverse health effects, they should seek medical treatment.

Precautionary statement

Prevention	Observe good industrial hygiene practices.
Response	Wash hands after handling.
Storage	Store away from incompatible materials. Store at 20 – 25 °C (68 - 77°F).
Disposal	Incineration of waste at an approved USEPA incinerator is recommended.

Hazard(s) not otherwise classified (HNOC)	None known.
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3. Composition/information on ingredients

Substances

Chemical name	Common name and synonyms	CAS number	%
Alcohol		67-63-0	15%
endo-(±)-α-(hydroxymethyl) benzeneacetic acid 8-methyl-8-azabicyclo[3.2.1] oct-3-yl ester sulfate (2:1) (salt) monohydrate		55-48-1	0.025 mg
ethyl 1-(3-cyano-3,3-diphenylpropyl)-4-phenylisonipecotate monohydrochloride		3810-80-8	2.5 mg

Composition comments	Refer to Physician's Desk Reference for common components present at <1%
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4. First-aid measures

Inhalation	Move to fresh air. Call a physician if symptoms develop or persist.
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Skin contact	Wash off with soap and water. Get medical attention if irritation develops and persists.
Eye contact	Rinse with water. Get medical attention if irritation develops and persists.
Ingestion	Rinse mouth. Get medical attention if symptoms occur. If ingestion of a large amount does occur, call a poison control center immediately.
Most important symptoms/effects, acute and delayed	The following effects are listed in decreasing order of severity, but not of frequency: toxic megacolon, paralytic ileus, pancreatitis, vomiting, nausea, anorexia, abdominal discomfort
Indication of immediate medical attention and special treatment needed	In the event of overdose, induction of vomiting, gastric lavage, establishment of a patent airway, and possibly mechanically assisted respiration are advised.
General information	Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

5. Fire-fighting measures

Suitable extinguishing media	Water fog. Foam. Dry chemical powder. Carbon dioxide (CO ₂).
Unsuitable extinguishing media	Do not use water jet as an extinguisher, as this will spread the fire.
Specific hazards arising from the chemical	During fire, gases hazardous to health may be formed.
Special protective equipment and precautions for firefighters	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
Fire fighting equipment/instructions	Use water spray to cool unopened containers.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.
General fire hazards	No unusual fire or explosion hazards noted.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	Keep unnecessary personnel away. Wear appropriate personal protective equipment (See Section 8).
Methods and materials for containment and cleaning up	Wipe up with absorbent material. Following product recovery, flush area with water. Incineration of waste at an approved USEPA incinerator is recommended. Controlled substances must be destroyed following DEA guidelines for witnessed destruction of the product beyond reclamation.
Environmental precautions	Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling	Avoid contact with eyes, skin, and clothing. Wash hands thoroughly after handling.
Conditions for safe storage, including any incompatibilities	Store away from incompatible materials (see Section 10 of the SDS). Discard opened bottle after 90 days. Store at 20 – 25 °C (68 - 77°F).

8. Exposure controls/personal protection

Occupational exposure limits

US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)

Components	Type	Value
Alcohol (CAS 67-63-0)	PEL	980 mg/m ³ 400 ppm

US. ACGIH Threshold Limit Values

Components	Type	Value
Alcohol (CAS 67-63-0)	STEL	400 ppm
	TWA	200 ppm

US. NIOSH: Pocket Guide to Chemical Hazards

Components	Type	Value
Alcohol (CAS 67-63-0)	STEL	1225 mg/m ³ 500 ppm
	TWA	980 mg/m ³ 400 ppm

Biological limit values

ACGIH Biological Exposure Indices

Components	Value	Determinant	Specimen	Sampling Time
Alcohol (CAS 67-63-0)	40 mg/l	Acetone	Urine	*

* - For sampling details, please see the source document.

Appropriate engineering controls Ventilation should be matched to conditions.

Individual protection measures, such as personal protective equipment

Eye/face protection None required for consumer use. In laboratory, medical or industrial settings, safety glasses with side shields are recommended. The use of goggles or full face protection may be required depending on the industrial exposure setting. Contact a health and safety professional for specific information.

Skin protection

Hand protection For consumer use, no unusual precautions are necessary.

Other None required for consumer use. In laboratory, medical or industrial settings, gloves and lab coats are recommended. The use of additional personal protective equipment such as shoe coverings, gauntlets, hood or head coverings may be necessary. Contact a health and safety professional for specific information.

Respiratory protection None required for consumer use. Respirators may be required for certain laboratory and manufacturing tasks if engineering controls do not maintain airborne concentrations below recommended exposure limits (where applicable) or to an acceptable level (where exposure limits have not been established). Workplace risk assessments should be completed before specifying and implementing respirator usage. All respirators must conform to specifications for efficiency and performance. In the United States of America, if respirators are used, a program should be instituted to assure compliance with OSHA Standard 29 CFR 1910.134. Respirator type: Air-purifying respirator with an appropriate, air-purifying filter, cartridge or canister. Contact a health and safety professional or manufacturer for specific information.

Thermal hazards Wear appropriate thermal protective clothing, when necessary.

General hygiene considerations Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

9. Physical and chemical properties

Appearance Clear orange liquid.

Physical state Liquid.

Form Liquid.

Color Clear colorless.

Odor Not available.

Odor threshold Not available.

pH Not available.

Melting point/freezing point Not available.

Initial boiling point and boiling range Not available.

Flash point Not available.

Evaporation rate Not available.

Flammability (solid, gas) Not available.

Upper/lower flammability or explosive limits

Flammability limit - lower (%) Not available.

Flammability limit - upper (%) Not available.

Explosive limit - lower (%) Not available.

Explosive limit - upper (%) Not available.

Vapor pressure Not available.

Vapor density Not available.

Relative density Not available.

Relative density temperature	estimated
Solubility(ies)	
Solubility (water)	Insoluble
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.

10. Stability and reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	Contact with incompatible materials. Exposure to light.
Incompatible materials	Strong oxidizing agents.
Hazardous decomposition products	No hazardous decomposition products are known.

11. Toxicological information

Information on likely routes of exposure

Inhalation	Not expected to be hazardous in final pharmaceutical form.
Skin contact	Not expected to be hazardous in final pharmaceutical form.
Eye contact	Not expected to be hazardous in final pharmaceutical form. Direct contact with eyes may cause temporary irritation.
Ingestion	Ingestion may cause irritation and malaise.

Symptoms related to the physical, chemical and toxicological characteristics The following effects are listed in decreasing order of severity, but not of frequency: toxic megacolon, paralytic ileus, pancreatitis, vomiting, nausea, anorexia, abdominal discomfort

Information on toxicological effects

Acute toxicity May be harmful if swallowed in large quantities.

Components	Species	Test Results
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Alcohol (CAS 67-63-0)

Acute

Dermal

LD50	Rabbit	12800 mg/kg
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Oral

LD50	Rat	4.7 g/kg
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Skin corrosion/irritation Prolonged skin contact may cause temporary irritation.

Serious eye damage/eye irritation Direct contact with eyes may cause temporary irritation.

Respiratory or skin sensitization

Respiratory sensitization Not a respiratory sensitizer.

Skin sensitization Rash and other skin reactions have been observed.

Germ cell mutagenicity No mutagenicity studies have been conducted

Carcinogenicity No carcinogenicity studies have been conducted

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

Reproductive toxicity Pregnancy Category C: There are no adequate and well-controlled studies in pregnant women.

This product passes into breast milk. Breast-feeding is not advised in mothers being treated.

Specific target organ toxicity - single exposure Not classified.

Specific target organ toxicity - repeated exposure Not classified.
Aspiration hazard Not classified.
Further information See package insert.

12. Ecological information

Ecotoxicity The product is not classified as environmentally hazardous.

Components	Species	Test Results
Alcohol (CAS 67-63-0)		
Aquatic		
Fish	LC50 Bluegill (<i>Lepomis macrochirus</i>)	> 1400 mg/l, 96 hours

* Estimates for product may be based on additional component data not shown.

Persistence and degradability No data is available on the degradability of this product.

Bioaccumulative potential No data available.

Partition coefficient n-octanol / water (log Kow)

Alcohol (CAS 67-63-0) 0.05

Mobility in soil No data available.

Other adverse effects None.

13. Disposal considerations

Disposal instructions Collect and reclaim or dispose in sealed containers at licensed waste disposal site.

Local disposal regulations Dispose in accordance with all applicable regulations.

Hazardous waste code The waste code should be assigned in discussion between the user, the producer and the waste disposal company.

Waste from residues / unused products Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).

Contaminated packaging Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

DOT

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not applicable.

15. Regulatory information

US federal regulations 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.

DEA: Diphenoxylate HCl and Atropine Sulfate Oral Solution CV is a DEA scheduled V controlled substance.

FDA: Diphenoxylate HCl and Atropine Sulfate Oral Solution CV is an approved prescription medication

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories Immediate Hazard - No
Delayed Hazard - No
Fire Hazard - No
Pressure Hazard - No
Reactivity Hazard - No

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical No

SARA 313 (TRI reporting)
Not regulated.

Other federal regulations Drug Enforcement Administration (DEA): Digoxin is not a controlled substance.

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act (SDWA) Not regulated.

Drug Enforcement Administration (DEA): This product is a Schedule V Controlled Substance (21 CFR 1308.14)

US state regulations

US. Massachusetts RTK - Substance List

Alcohol (CAS 67-63-0)

US. New Jersey Worker and Community Right-to-Know Act

Alcohol (CAS 67-63-0)

US. Pennsylvania Worker and Community Right-to-Know Law

Alcohol (CAS 67-63-0)

US. Rhode Island RTK

Alcohol (CAS 67-63-0)

US. California Proposition 65

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	Yes
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	Yes
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	Yes
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates this product complies with the inventory requirements administered by the governing country(s).

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information, including date of preparation or last revision

Issue date 05-December-2014
Revision date -
Version # 01

References

- 1) Diphenoxylate Hydrochloride and Atropine Sulfate Oral Solution USP, Package Insert, Roxane Laboratories, Inc. , Columbus, Ohio
- 2) PDR – Physicians Desk Reference.
- 3) Ariel Websight. Regulatory and ChemExpert Database.

Disclaimer

Boehringer Ingelheim Roxane Inc. cannot anticipate all conditions under which this information and its product, or the products of other manufacturers in combination with its product, may be used. It is the user's responsibility to ensure safe conditions for handling, storage and disposal of the product, and to assume liability for loss, injury, damage or expense due to improper use. The information in the sheet was written based on the best knowledge and experience currently available.