

# SAFETY DATA SHEET

## 1. Identification

1. Identification		
Product identifier	Almotriptan Related Compound B	
Other means of identification		
Catalog number	1013545	
Chemical name	(2-{5-[(pyrrolidin-1-ylsulfonyl)m	ethyl]-1H-indol-3-yl}ethanamine hemifumarate
Recommended use	Specified quality tests and ass	ay use only.
Recommended restrictions	Not for use as a drug. Not for a	dministration to humans or animals.
Manufacturer/Importer/Supplier/	Distributor information	
Company name Address	U. S. Pharmacopeia 12601 Twinbrook Parkway Rockville MD 20852-1790 US	
Telephone	RS Technical Services	301-816-8129
Website	www.usp.org	
E-mail	RSTECH@usp.org CHEMTREC within US &	1-800-424-9300
Emergency phone number	Canada	1-000-424-3300
	CHEMTREC outside US & Canada	+1 703-527-3887
2. Hazard(s) identification		
Note	Information on the chemical, physical, and toxicological properties of this material is not readily available. Individuals working with this chemical should consider it to be potentially hazardous even if its actual hazards may be uncharacterized or unknown.	
Physical hazards	Not classified.	
Health hazards	Not classified.	
OSHA hazard(s)	Not classified.	
Label elements		
Hazard symbol	No symbol.	
Signal word	Not available.	
Hazard statement	Not available.	
Precautionary statement		
Prevention	Not available.	
Posponso	Not available	

ResponseNot available.StorageNot available.DisposalNot available.Hazard(s) not otherwise<br/>classified (HNOC)Not classified.

# 3. Composition/information on ingredients

Substance			
Non-hazardous components Chemical name	Common name and synonyms	CAS number	%
Almotriptan Related Compound B		1246860-65-0	100
4. First-aid measures			
Inhalation	If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. Call a physician if symptoms develop or persist.		
Skin contact Eye contact	Wash off with soap and water. Get medical attention if irritation develops and persists. Flush eyes with water as a precaution. Get medical attention if irritation develops and persists.		

Ingestion	Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately.	
Most important symptoms/effects, acute and delayed	Not available.	
Indication of immediate medical attention and special treatment needed	Treat symptomatically.	
General information	Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is 1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.	
5. Fire-fighting measures		
Suitable extinguishing media	Water spray, dry chemical, carbon dioxide, or foam as appropriate for surrounding fire and materials.	
Unsuitable extinguishing media	None known.	
Specific hazards arising from the chemical	No unusual fire or explosion hazards noted.	
Special protective equipment and precautions for firefighters	Wear suitable protective equipment.	
Fire-fighting equipment/instructions	As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.	
Specific methods	Cool containers exposed to flames with water until well after the fire is out.	
6. Accidental release measures		
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Personal precautions, protective equipment and emergency procedures	Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Avoid inhalation of dust from the spilled material. Ensure adequate ventilation. Wear appropriate personal protective equipment.
Methods and materials for containment and cleaning up	Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid the generation of dusts during clean-up. For waste disposal, see section 13 of the SDS. Wash spill site.
7. Handling and storage	

Precautions for safe handling	As a general rule, when handling USP Reference Standards, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly. Use of a designated area is recommended for handling of potent materials.
Conditions for safe storage, including any incompatibilities	Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.

# 8. Exposure controls/personal protection

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Biological limit values	No biological exposure limits noted for the ingredient(s).
Exposure guidelines	No exposure standards allocated.
Appropriate engineering controls	Airborne exposure should be controlled primarily by engineering controls such as general dilution ventilation, local exhaust ventilation, or process enclosure. Local exhaust ventilation is generally preferred to general exhaust because it can control the contaminant at its source, preventing dispersion into the work area. An industrial hygiene survey involving air monitoring may be used to determine the effectiveness of engineering controls. Effectiveness of engineering controls intended for use with highly potent materials should be assessed by use of nontoxic surrogate materials. Local exhaust ventilation such as a laboratory fume hood or other vented enclosure is recommended, particularly for grinding, crushing, weighing, or other dust-generating procedures.
Individual protection measur	es, such as personal protective equipment
Eye/face protection	Safety glasses with sideshields 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.
Skin protection	
Hand protection	Chemically compatible gloves. 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 nonlatex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy.
Other	For handling of laboratory scale quantities, a cloth lab coat is recommended. Where significant quantities are handled, work clothing may be necessary to prevent take-home contamination.
Material name: Almotriptan Relate	ed Compound B USP SDS US

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).
Thermal hazards	Not available.
General hygiene considerations	Handle in accordance with good industrial hygiene and safety practice.

## 9. Physical and chemical properties

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Appearance	White to off-white powder.
Physical state	Solid.
Form	Powder.
Odor	Not available.
Odor threshold	Not available.
рН	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 applicable.
Upper/lower flammability or exp	losive 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.
Solubility in water	Not available.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Other information	
Molecular formula	C15H21N3O2S . 1/2 C4H4O4
Molecular weight	365.46
10. Stability and reactivity	
Reactivity	No reactivity hazards known.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	None known.

Incompatible materials None known.

NOx. SOx. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

## 11. Toxicological information

Hazardous decomposition

products

#### Information on likely routes of exposure

Ingestion	Due to lack of data the classification is not possible.
Inhalation	Due to lack of data the classification is not possible.
Skin contact	Due to lack of data the classification is not possible.
Eye contact	Due to lack of data the classification is not possible.

Symptoms related to the physical, chemical, and toxicological characteristics	Not available.
Acute toxicity	Due to lack of data the classification is not possible.
Skin corrosion/irritation	Due to lack of data the classification is not possible.
Serious eye damage/eye irritation	Due to lack of data the classification is not possible.
Respiratory sensitization	Due to lack of data the classification is not possible.
Skin sensitization	Due to lack of data the classification is not possible.
Germ cell mutagenicity	Due to lack of data the classification is not possible.
Carcinogenicity	Due to lack of data the classification is not possible. This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.
Reproductive toxicity	Due to lack of data the classification is not possible.
Specific target organ toxicity - single exposure	Due to lack of data the classification is not possible.
Specific target organ toxicity - repeated exposure	Due to lack of data the classification is not possible.
Aspiration hazard	Based on available data, the classification criteria are not met.
12. Ecological information	
Ecotoxicity	No ecotoxicity data noted for the ingredient(s).
Persistence and degradability	No data is available on the degradability of this product.
Bioaccumulative potential	Not available.
Mobility in soil	Not available.
Other adverse effects	Not available.

### 13. Disposal considerations

Disposal instructions	This product, in its present state, when discarded or disposed of, is not a hazardous waste according to Federal regulations (40 CFR 261.4 (b)(4)). Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste. Dispose in accordance with all applicable regulations.
Local disposal regulations	Not available.
Hazardous waste code	Not available.
Waste from residues / unused products	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 a hazardous material by DOT.

#### IATA

Not regulated as a dangerous good.

Transport in bulk according to No information available. Annex II of MARPOL 73/78 and the IBC Code

## 15. Regulatory information

#### 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	No
SARA 311/312 Hazardous chemical	No

Other federal regulations		
Safe Drinking Water Act (SDWA)	Not regulated.	
Food and Drug Administration (FDA)	Not regulated.	
International Inventories		
Country(s) or region	Inventory name On inventory (ye	es/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
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	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No
*A "Yes" indicates that all compor	nents of this product comply with the inventory requirements administered by the governing country(s)	

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

Issue date Version # Further information Disclaimer	12-20-2013 01 Not available. USP Reference Standards are sold for chemical test and assay purposes only, and NOT for human consumption. The information contained herein is applicable solely to the chemical substance when used as a USP Reference Standard and does not necessarily relate to any other use of the substance described, (i.e. at different concentrations, in drug dosage forms, or in bulk quantities). USP Reference Standards are intended for use by persons having technical skill and at their own discretion and risk. This information has been developed by USP staff from sources considered reliable but has not been independently verified by the USP. Therefore, the USP Convention cannot guarantee the accuracy of the information in these sources nor should the statements contained herein be considered an official expression. NO REPRESENTATION OR WARRANTY, EXPRESS OR IMPLIED, INCLUDING THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE is made with respect to the information contained herein.
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