



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

Material Safety Data Sheet

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION		
Common/Trade Name: Balsalazide Disodium Capsules		
Chemical Name: (E)-5-[[[-4-[[[2-carboxyethyl) amino]carbonyl] phenyl]azo]-2-hydroxybenzoic acid, disodium salt, dihydrate		
Synonyms: None		
Molecular Formula: C ₁₇ H ₁₃ N ₃ O ₆ Na ₂ · 2H ₂ O		
Molecular Weight: 437.32		
CAS No: 150399-21-6		
Chemical Family: Aminosalicylate		
Product Use: Treatment of mildly to moderately active ulcerative colitis in adults.		
Manufacturer's Name: Boehringer Ingelheim Roxane Inc.		
Address: 1809 Wilson Road Columbus, Ohio 43228		
2. COMPOSITION / INFORMATION ON INGREDIENTS		
Composition	CAS#	Exposure Limit
Balsalazide Disodium (active ingredient)	150399-21-6	None established
<i>REFER to PHYSICIAN'S DESK REFERENCE for common components present as <1%</i>		
3. HAZARDS IDENTIFICATION		
Emergency Overview	Physical State: Light orange opaque capsules containing 750 mg balsalazide disodium and "54 795" imprinted in black ink on the cap and body. 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 in final pharmaceutical form. 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 adverse hepatic events, alopecia, headache, diarrhea, and arthralgia.	
Toxicity Data:	See Section 11	
Effects of Overexposure:	The potential for exposure is reduced in finished pharmaceutical form. Overexposure by ingestion may cause headache, abdominal pain, diarrhea, nausea, vomiting and respiratory infection.	
Target Organs:	Rectum, colon, kidneys, liver	
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	Not Applicable				
Extinguishing Media	Use water spray, dry chemical, carbon dioxide or material appropriate for fire in surrounding area				
Special Fire Fighting Procedures	Wear full protective clothing and self-contained breathing apparatus.				
Unusual Fire/Explosion Hazards	Not Applicable				
Hazardous Combustion Products	Carbon dioxide, carbon monoxide, oxides of nitrogen, oxides of sodium				
6. ACCIDENTAL RELEASE INFORMATION					
STEPS TO BE TAKEN IF SIGNIFICANT QUANTITIES OF PRODUCT IS SPILLED: Use appropriate personal protective equipment (see Section 8). Sweep 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 Product:	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.				
8. CONTROL MEASURES AND PERSONAL PROTECTIVE EQUIPMENT					
Exposure Limits	None				
Engineering Controls	Not required when handling capsules or containers. Ventilation should be matched to conditions.				
Respiratory Protection	Not required when handling capsules 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 capsules. If containers are compromised or exposure is likely wear: Goggles, Lab Coat, Gloves				
Recommended Facilities	Eye wash, washing facilities				
9. PHYSICAL / CHEMICAL CHARACTERISTICS					
Appearance	Light orange opaque capsules containing a yellow-orange powder	Melting point	Not available	Solubility in water	Complete
Odor	Not available	Boiling point	Not available	Specific Gravity	Not available
Taste	Not available	Vapor Pressure	Not available	Flashpoint	Not available
pH	Not available	Density	Not available	Flammability Limits	Not available
10. STABILITY AND REACTIVITY DATA					

Stability	Stable
Incompatibility	None known
Hazardous Decomposition	Oxides of carbon, oxides of nitrogen, oxides of sodium
Conditions to Avoid	Excessive heat, light
Hazardous Polymerization	Will not occur.
11. TOXICOLOGICAL INFORMATION	
Acute Toxicity:	
Active Ingredient: No data available	
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: Dispose of material according to federal, state and local disposal regulations or company operating procedures. Disposal by incineration is recommended. At home: Discard away from children's reach.	
14. TRANSPORTATION INFORMATION	
This product is not subject to the regulations for the safe transport of hazardous chemicals. DOT: Not regulated TDG: Not regulated IATA: Not regulated IMDG: Not regulated	
15. REGULATORY INFORMATION	
DEA: Balsalazide Disodium is not a controlled substance.	
FDA: Balsalazide Disodium 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. Balsalazide Disodium Capsules, Package Insert, Boehringer Ingelheim Roxane, Inc. , Columbus, Ohio 2. Ariel Webinsight. Regulatory and ChemExpert Database. 3. PDR – Physicians Desk Reference 4. FDA, www.fda.gov	
Date: New MSDS: 09/19/2007	Revised: 9/24/2008
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.