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| IN CASE OF EMERGENCY Emergency Phone: (614) 276-4000 |
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Material Safety Data Sheet

| 1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION | | | |
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| Common/Trade Name: Balsalazide Disodium Capsules USP | | | |
| Chemical Name: (E)-5-[[4-[[[(2-carboxyethyl) amino]carbonyl] phenyl]azo]-2-hydroxybenzoic acid, disodium salt, dihydrate | | | |
| Synonyms: Balsalazide disodium dihydrate | | | |
| 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: Roxane Laboratories Inc. | | | |
| Address: 1809 Wilson Road Columbus, Ohio 43228 | | | |
| 2. COMPOSITION / INFORMATION ON INGREDIENTS | | | |
| Composition | CAS# | Mg | Exposure Limit |
| (E)-5-[[4-[[[(2-carboxyethyl) amino]carbonyl] phenyl]azo]-2-hydroxybenzoic acid, disodium salt, dihydrate | 150399-21-6 | 750 mg | 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, containing a yellow-orange powder. Color: Light orange opaque capsules containing a yellow-orange powder 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, and other systemic effects. | | |
| WARNINGS | Observe patients closely for exacerbations of ulcerative colitis while on treatment. Patients with pyloric stenosis may have prolonged gastric retention of balsalazide capsules. Renal toxicity has been observed in animals and patients given other mesalamine products. Therefore, caution should be exercised when administering balsalazide to patients with known renal dysfunction or a history of renal disease. Hypersensitivity reactions may include, but are not limited to, the following: anaphylaxis, bronchospasm, and skin reactions. The safety and efficacy of Balsalazide Disodium Capsules beyond 12 weeks in adults have not | | |

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| | <p>been established. Pediatric use information is protected by marketing exclusivity.</p> <p>No drug interaction studies have been conducted for balsalazide.</p> |
| Contraindications | Hypersensitivity to salicylates (e.g., aspirin), balsalazide disodium, or any other component of the therapeutic system. |
| Adverse Reactions to Product: | The most common side effects are headache, abdominal pain, diarrhea, nausea, vomiting, respiratory infection, and joint pain. |
| Toxicity Data: | See Section 11 |
| Effects of Overexposure: | The signs of overdosage might be expected to include nausea, vomiting and abdominal pain. Human experience with overdosage of balsalazide disodium is limited. |
| 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. Only induce vomiting at the instruction of medical personnel. Never give anything by mouth to an unconscious person. |
| Inhalation | Should not pose a hazard in the final form. Move to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention immediately. |
| Notes to Physician | If balsalazide overdose should occur, treatment should be supportive, with particular attention to correction of electrolyte abnormalities. In managing overdosage, consider the possibility of multiple drug involvement. |
| 5. FIRE AND EXPLOSION HAZARDS | |
| Flammability | Lower: N/A Upper: N/A |
| Flash Point | Not Applicable |
| Extinguishing Media | Use water spray 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, nitrogen oxides, sodium oxides |
| 6. ACCIDENTAL RELEASE INFORMATION | |
| STEPS TO BE TAKEN IF SIGNIFICANT QUANTITIES OF TABLETS ARE BROKEN: Use appropriate protective equipment (see Section 8). Sweep/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 Broken Tablets: | Avoid contact with eyes, skin and clothing. Wash thoroughly after handling. |
| Storage | Keep container tightly sealed. Store at 20 - 25°C (68 - 77°F) with excursions permitted between 15 - 30°C (59 - 86°F). Protect from light. Store away from foodstuffs. |
| 8. CONTROL MEASURES AND PERSONAL PROTECTIVE EQUIPMENT | |
| Exposure Limits | None |
| Engineering Controls | Not required when handling tablets or containers. Good ventilation (typically 10 air changes per hour) should be used. Ventilation should be matched to conditions. |

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| Respiratory Protection | Not required when handling tablets 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 tablets. 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 applicable |
| pH | Not available | Density | Not available | Flammability Limits | Not applicable |
| 10. STABILITY AND REACTIVITY DATA | | | | | |
| Stability | Stable | | | | |
| Incompatibility | None known | | | | |
| Hazardous Decomposition | Carbon dioxide, carbon monoxide, nitrogen oxides, sodium oxides | | | | |
| Conditions to Avoid | Excessive heat | | | | |
| Hazardous Polymerization | Will not occur. | | | | |
| 11. TOXICOLOGICAL INFORMATION | | | | | |
| <p>Acute Toxicity:</p> <p>A single oral dose of balsalazide disodium at 5 g/kg or 4-aminobenzoyl-β-alanine, a metabolite of balsalazide disodium, at 1 g/kg was non-lethal in mice and rats. No symptoms of acute toxicity were seen at these levels. In animal studies conducted at doses up to 2000 mg/kg (approximately 21 times the recommended 6.75 g/day dose on a mg/kg basis for a 70 kg person), balsalazide disodium demonstrated no nephrotoxic effects in rats or dogs.</p> <p>Product: No case of overdose has occurred with balsalazide.</p> <p>Teratogenicity: Pregnancy Category B: No evidence of teratogenicity or other embryo/fetal toxicity was found when rats and rabbits were treated orally with balsalazide disodium at doses up to 2 g/kg/day (respectively 2.4 times and 4.7 times the recommended human dose).</p> <p>Pregnancy: There are no adequate and well-controlled studies in pregnant women. Balsalazide disodium should be used during pregnancy only if clearly needed.</p> <p>Nursing Mothers: It is not known whether balsalazide disodium is excreted in human milk. In the absence of this information, caution should be exercised when balsalazide is administered to a nursing woman.</p> <p>Carcinogenesis/Mutagenesis: In a 24-month rat (Sprague Dawley) carcinogenicity study, oral (dietary) balsalazide disodium at doses up to 2 g/kg/day (2.4 times the recommended human dose on a mg/m² basis) was not tumorigenic. Balsalazide disodium was not genotoxic in the following <i>in vitro</i> or <i>in vivo</i> tests: Ames test, human lymphocyte chromosomal aberration test, and mouse lymphoma cell (L5178Y/TK+/-) forward mutation test, or mouse micronucleus test. However, it was genotoxic in the <i>in vitro</i> Chinese hamster lung cell (CH V79/HGPRT) forward mutation test.</p> <p>4-aminobenzoyl-β-alanine, a metabolite of balsalazide disodium, was not genotoxic in the Ames test and mouse lymphoma cell (L5178Y/TK+/-) forward mutation test but was positive in the human lymphocyte chromosomal aberration test. N-acetyl-4-aminobenzoyl-β-alanine, a conjugated metabolite of balsalazide disodium, was not</p> | | | | | |

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| <p>genotoxic in the Ames test, mouse lymphoma cell (L5178Y/TK+/-) forward mutation test, or the human lymphocyte chromosomal aberration test</p> <p>Impairment of Fertility: Balsalazide disodium at oral doses up to 2 g/kg/day (2.4 times the recommended human dose on a mg/m² basis) was found to have no effect on fertility and reproductive performance in rats.</p> <p>Carcinogenicity: Not listed as a carcinogen or potential carcinogen by NTP, IARC Monographs or OSHA.</p> |
| <p>12. ENVIRONMENTAL IMPACT INFORMATION</p> <p>No information is currently available on the environmental impact of this product.</p> |
| <p>13. DISPOSAL INFORMATION</p> <p>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.</p> |
| <p>14. TRANSPORTATION INFORMATION</p> <p>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</p> |
| <p>15. REGULATORY INFORMATION</p> <p>See package insert for NDC Numbers</p> <p>DEA: Balsalazide disodium is not a controlled substance.</p> <p>FDA: Balsalazide disodium is an approved anti-inflammatory prescription medication.</p> <p>Canadian Controlled Products Regulations: This product has been classified in according to the hazard criteria of the Canadian Controlled Products Regulations, Section 33, and the MSDS contains all the required information.</p> <p>WHMIS Classification for Product: Not controlled, exempt.</p> <p>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 on the DSL Inventory but is exempt.</p> |
| <p>16. OTHER DATA</p> <p>ABBREVIATIONS: N/A – not applicable</p> <p>Prepared by: Roxane Laboratories, Inc.</p> <p>References:</p> <ol style="list-style-type: none"> 1. Balsalazide Disodium Capsules USP, Package Insert, Roxane Laboratories, Inc., Columbus, Ohio 2. Balsalazide Disodium USP, Ariel WebInsight, Global Regulatory Database. 3. PDR – Physicians Desk Reference 4. FDA, www.fda.gov <p>Date: 10/24/2012- REVISED MSDS</p> <p style="text-align: center;">SEE CURRENT PACKAGE INSERT FOR FURTHER INFORMATION</p> |

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. Roxane Laboratories Inc. assumes no responsibility or liability resulting from the use of this information.