



MATERIAL SAFETY DATA SHEET

While we believe the information provided herein is accurate and current, JHP Pharmaceuticals makes no representation or warranties, either explained or implied, and assume no responsibility for any damage or injuries of any kind, which may result from use or reliance upon this information

SECTION 1 MATERIAL IDENTIFICATION

PRODUCT NAME: Sumatriptan Succinate Injection, 0.6 (base)/ 0.5 ml (2 ml SDV), Pack of 5's **DATE OF ISSUE:** 7/1/2009

FORMULA: Solution **SUPERCEDES:** 5/20/2009 **REVISION:** 3.0

NDC#: 42023-121-05

SYNONYMS: Sumatriptan Succinate

MANUFACTURER: JHP Pharmaceuticals, LLC. **ADDRESS:** 870 Parkdale Road Rochester, MI 48307 **PHONE:** Emergency: 1-800-424-9300 (CHEMTREC) Medical Affairs: 866-923-2547

SECTION 2 INGREDIENT (S)

| Component | CAS No. | EINECS No. |
|-----------------------|-----------|------------|
| Sumatriptan Succinate | 6106-21-4 | 213-568-1 |
| Sodium Chloride | 7647-14-5 | 231-598-3 |

SECTION 3 HAZARD IDENTIFICATION

HMIS: 2-Health, 1-Flammability, 1-Reactivity

EMERGENCY OVERVIEW: Caution – Pharmaceutical agent. This MSDS is written to address potential worker health and safety issues associated with the handling of formulated final product solution, e.g., during the transportation, distribution, and use by medical personnel. For worker health and safety information during the manufacture of Sumatriptan Succinate, please refer to the MSDS on each component. Accidental inhalation of large quantities may cause irritation of the respiratory tract. Accidental contact with eyes, skin or mucous membranes may cause irritation. Overexposure may be harmful to the cardiovascular system. Avoid contact with eyes, skin and clothing. See Section 11 for detailed information.

SECTION 3**HAZARD IDENTIFICATION cont.****POTENTIAL HEALTH EFFECTS:**

INHALATION: Possible irritation of mucous membranes from direct contact with material.

EYE CONTACT: Possible eye irritation from direct contact with material.

SKIN CONTACT: Possible irritation from direct contact with material.

INGESTION: Not expected to be toxic.

SECTION 4**FIRST AID INFORMATION**

INHALATION: Remove the exposed person to fresh air. Give artificial respiration if not breathing. Seek medical aid if necessary.

EYE CONTACT: Flush eyes with copious amounts of water for at least 15 minutes. Seek medical attention.

SKIN CONTACT: Remove any contaminated clothing with appropriate personal protective equipment and wash area thoroughly with soap and water for at least 15 minutes. Get medical attention if irritation occurs, which may be immediate or delayed.

INGESTION: Never give anything by mouth to someone who is unconscious or convulsive. Do not induce vomiting. If person is conscious give plenty of water to drink. Seek medical attention immediately.

SECTION 5**FIRE AND EXPLOSION DATA**

FLASH POINT AND METHOD: Not applicable.

EXTINGUISHING MEDIUM: Water spray, carbon dioxide, dry chemical

HAZARDOUS DECOMPOSITION OR COMBUSTION PRODUCTS: Oxides of Carbon, Carbon Monoxide and Nitrogen Oxides

EXPLOSION HAZARDS: None expected for product.

SPECIAL FIRE PROCEDURES: Move container from fire area if it can be done without risk. Avoid inhalation of material or combustion by-products. Stay upwind and keep out of low areas. Wear a self-contained breathing apparatus and full bunker gear when fighting these fires. All equipment should be thoroughly decontaminated after use. Do not release the material into sewers or waterways

HAZARDOUS DECOMPOSITION OR COMBUSTION PRODUCTS: Fire may produce irritating, corrosive, and/or toxic gases, such as carbon monoxide and nitrogen oxides.

SECTION 6**ACCIDENTAL RELEASE MEASURES**

ACTION TO BE TAKEN IF MATERIAL IS RELEASED OR SPILLED: Immediately notify appropriate emergency response, safety and environmental personnel of any spills or leaks. Cleanup personnel need protection against inhalation and skin contact (see Section 8). Contain the spill and pick up material for recovery or disposal when feasible. Avoid creating a dust cloud of active material, wet down with water spray or use a vacuum equipped with HEPA filters. Do not dispose of the material in any sanitary sewer, storm sewer, sink, toilet, or floor drain. Contact a licensed waste-disposal contractor for detailed disposal recommendations.

SECTION 7**HANDLING AND STORAGE**

HANDLING: No special control measures required for the normal handling of this product. Normal room ventilation is expected to be adequate for routine handling of this product.

STORAGE: No storage requirements necessary for occupational hazards. Follow product information storage instructions to maintain efficacy.

SECTION 8**SPECIAL PROTECTION INFORMATION**

| Composition | | | | | |
|-----------------------|----------------|-----------------|------------------|------------------|---|
| Component | CAS No. | OSHA PEL | ACGIH TLV | NIOSH REL | Other limits |
| Sumatriptan Succinate | 6106-21-4 | NA | NA | NA | 100 mcg/m ³ STEL 50 mcg/m ³ 8 hour TWA* |
| Sodium Chloride | 7647-14-5 | NA | NA | NA | Respirable dust: 5 mg/m ³ TWA |

NA – Not available

*Occupational exposure limit proposed by GlaxoSmithKline

VENTILATION: To maintain airborne levels of components of this product in compliance with airborne concentration limits, use appropriate ventilation and/or enclose the process to control emissions during handling and other dust producing operations.

EYE PROTECTION: Wear safety goggles or safety glasses in compliance with OSHA regulations in 29 CFR 1910.133. Provide an emergency eye wash fountain and quick drench shower in the immediate work area.

CLOTHING: Wear appropriate chemical resistant clothing. Refer to 29 CFR 1910.133.

GLOVES: Standard rubber or polymer gloves that are impermeable to solid powder materials are adequate for prolonged exposure to all the components of this material. Refer to 29 CFR 1910.132.

RESPIRATOR: Under conditions of frequent use or heavy exposure, respiratory protection may be needed. Ensure compliance with airborne concentration limits. Respiratory protection is ranked in order from minimum to maximum. Consider warning properties before use.

Any chemical cartridge respirator with appropriate organic vapor and particulate filter cartridges(s)

Any chemical cartridge respirator with a full face piece and appropriate organic vapor and particulate filter cartridge(s).

Any air-purifying respirator with a full face piece and appropriate organic vapor and particulate filter canister

For Unknown Concentrations or Immediately Dangerous to Life or Health*

Any supplied-air respirator with full face piece and operated in a pressure-demand or other positive –pressure mode in combination with a separate escape supply.

Any self-contained breathing apparatus with a full face piece.

SECTION 9**PHYSICAL AND CHEMICAL DATA**

| | |
|--|---|
| Appearance: | Clear to pale yellow solution (final product) |
| Physical State: | Solution |
| Odor: | Odorless |
| Odor threshold: | Not Available |
| pH: | 4.5 to 5 |
| Boiling or Melting Point: | Not available |
| Vapor Pressure @ 20°C: | Not Available |
| Vapor Density (air = 1): | Not Available |
| Solubility in Water: | Soluble |
| Specific Gravity (water = 1): | Not Available |
| Volatile organic compound (VOC) content: | Not Available |
| Evaporation Rate: | Not Available |
| Octanol/Water Partition Coefficient: | Not Available |
| Flammability: | Not Available |
| Flammability/explosion limits: | Not Available |
| Flashpoint: | Not Available |
| Auto-ignition temperature: | Not Available |
| Decomposition temperature: | Not Available |

SECTION 10**STABILITY AND REACTIVITY**

REACTIVITY: Stable at normal temperature and pressure when properly stored (refer to section 7).

CONDITIONS TO AVOID: None when properly handled.

INCOMPATIBLES: None.

POLYMERIZATION: Hazardous polymerization will not occur.

SECTION 11**TOXICOLOGY**

Note: Refer to packaging insert for additional information. Oral or systemic toxicity and effects data are available for this material as a whole due to its use as a pharmaceutical product. However, some toxic effects described in this section are those that might be expected, based on data for the components of the material. Many of these effects are only associated with very high levels of exposure based on tests in animals or by routes of exposure (e.g., ingestion) that are of minimal relevance for occupational situations. Furthermore, exposure to bulk material could result in health effects that may not be a concern for the formulated material distributed as solution, since exposure to the final product (outside its intended pharmaceutical use) would be limited. Based on this information the material is unlikely to pose a significant hazard to human health if appropriate handling procedures, protective clothing and ventilation practices are followed. .

Toxicity data for the active ingredient, Sumatriptan Succinate: Oral LD50 (rat) > 2939 mg/kg

EYE: Irritation might occur following direct contact with eyes.

SKIN: Irritation might occur following direct contact with skin.

ACUTE INGESTION: Not expected to be toxic following ingestion.

ACUTE INHALATION: Not available.

CHRONIC TOXICITY: Not available.

SECTION 11**TOXICOLOGY cont.**

SUB-CHRONIC TOXICITY: Not available.

TARGET ORGAN SYSTEMS: No specific target organs have been identified.

CARCINOGENICITY:

Negative in laboratory animals. Oral treatment of rats and mice did not result in increases in tumors in either species.

| Chemical | ACGIH | NTP | IARC | EPA | OSHA |
|-----------------------|------------|------------|------------|------------|------------|
| Sumatriptin Succinate | Not listed | Not Listed | Not Listed | Not Listed | Not Listed |
| Sodium Chloride | Not Listed | Not listed | Not Listed | Not Listed | Not Listed |

REPRODUCTION and DEVELOPMENT: Not expected to produce adverse effects on fertility or development under occupational exposure conditions.

GENOTOXICITY: Not expected to be genotoxic under occupational exposure conditions. Not mutagenic in a battery of assays, including Ames gene mutation and mammalian Chinese hamster assays and in vitro system assays for clastogenic effects. In a study of rats subcutaneously dosed with Sumatriptin Succinate prior and throughout pregnancy, there was no evidence of teratogenicity.

SENSITISATION: Not expected to cause sensitization.

SECTION 12**ECOLOGICAL INFORMATION****ECOLOGICAL EFFECTS**

This material contains an active pharmaceutical ingredient that has been tested and which may be harmful if released directly to the environment. Consult the MSDS of the active ingredient for specific information about potential environmental effects. Appropriate precautions should be taken to limit release of this material to the environment. Local regulations and procedures should be consulted prior to environmental release.

SECTION 13**DISPOSAL**

RCRA Hazardous Waste (40 CFR 261): Product is not listed as a hazardous waste. Consult an expert on the management and disposal of recovered material. Do not dispose of the material in any sanitary sewer or storm sewer system, which includes sinks, toilets, and floor drains. Ensure conformity with Federal, state, and local disposal regulations.

SECTION 14**TRANSPORTATION**

The final packaged product is considered to be non-hazardous for transport.

PROPER SHIPPING NAME: Not applicable

ID/UN NUMBER: Not applicable

HAZARD CLASS: Not applicable

PACKAGING GROUP: Not applicable

U.S REGULATIONS:**CERCLA SECTIONS 102a/103 HAZARDOUS SUBSTANCES (40 CFR 302.4):** Not regulated.**SARA TITLE III SECTIONS 302/304 EXTREMELY HAZARDOUS SUBSTANCES:** Not regulated.**SARA TITLE III SECTIONS 311/312 HAZARDOUS CATEGORIES:** Not regulated.**SARA TITLE II SECTION 313:** Not regulated.**STATE REGULATIONS:****California Proposition 65:** Not listed.**NATIONAL INVENTORY STATUS:****U.S. INVENTORY (TSCA):** Exempt**OSHA:** The final product is considered hazardous under the US Hazard Communication Standard.

NA – NOT APPLICABLE**ND – NO DATA FOUND**

The information provided in this Material Safety Data Sheet has been compiled from our experience and the data presented in various technical publications. It is the user's responsibility to determine the suitability of this information for the adoption of safety precautions as may be necessary. We reserve the right to revise the Material Safety Data Sheets from time to time as new information becomes available. The user has the responsibility to contact the company to make sure the sheet is the latest one issued.