



# Material Safety Data Sheet

12601 Twinbrook Parkway,  
Rockville, MD 20852 USA

Phone Calls: 301-816-8129  
8 a.m. to 5 p.m. EST Mon. - Fri.

## ATTENTION !

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.

## SALICYLIC ACID TABLETS (DISSOLUTION CALIBRATOR, NON-DISINTEGRATING)

Catalog Number: 1609501

Revision Date:

August 13, 2009

### SECTION 1 - PRODUCT AND COMPANY IDENTIFICATION

**Common Name:** Salicylic Acid Tablets

**Manufacturer:** U. S. Pharmacopeia

**Responsible Party:** Reference Standards Technical Services

**Mailing Address:** 12601 Twinbrook Parkway, Rockville, MD 20852 USA

**Phone:** 301-816-8129

**Hours:** 8 a.m. to 5 p.m. EST Mon. - Fri.

**Product Use:** USP Reference Standards and Authentic Substances are used for chemical tests and assays in analytical, clinical, pharmaceutical, and research laboratories.

### SECTION 2 - HAZARD INFORMATION

#### EMERGENCY OVERVIEW : Irritant.

**Adverse Effects:** Adverse effects of salicylate ingestion may include stomach pain, heartburn, and nausea. Inhalation of salicylic acid may cause cough and sore throat. Skin contact with salicylic acid may result in irritation, rash, and systemic absorption. Possible allergic reaction to material if inhaled, ingested, or in contact with skin.

**Overdose Effects:** Overdose of salicylates may cause salicylism characterized by nausea, vomiting, stomach discomfort, diarrhea, ringing in ears or hearing loss, headache, dizziness, drowsiness, vision problems, flushing, sweating, thirst, agitation, confusion, and fast or deep breathing. Severe overdose may cause delirium, mental disturbances, lethargy, fever, dehydration, seizures, stupor, coma, respiratory failure, cardiovascular collapse, and death.

**Acute:** Eye, skin, gastrointestinal and/or respiratory tract irritation.

**Chronic:** Possible hypersensitization; salicylism (see Overdose Effects); kidney, liver, or pancreas damage; gastrointestinal bleeding; and death.

**Medical Conditions Aggravated by Exposure:** Hypersensitivity to material; anemia; hemophilia, vitamin K deficiency, or other bleeding problems; ulcers; impaired liver or kidney function; diabetes mellitus; circulatory disorders; and asthma.

**Cross Sensitivity:** Persons sensitive to one salicylate, including methyl salicylate, or to nonsteroidal anti-inflammatory agents or related materials may be sensitive to this material also. Individuals sensitive to aspirin may not necessarily be sensitive to nonacetylated salicylates.

**Target Organs:** n/f

**For additional information on toxicity, see Section 11.**

# SALICYLIC ACID TABLETS (DISSOLUTION CALIBRATOR, NON-DISINTEGRATING)

Catalog Number: 1609501

Revision Date:

August 13, 2009

## SECTION 3 - COMPOSITION/INFORMATION ON INGREDIENTS

**Common Name:** Salicylic Acid Tablets

**Formula:** C<sub>7</sub>H<sub>6</sub>O<sub>3</sub>

**Synonym:** n/f

**Chemical Name:** Benzoic acid, 2-hydroxy-

**CAS:** 69-72-7

**RTECS Number:** VO0525000

**Chemical Family:** Aromatic carboxylic acid (Salicylate)

**Therapeutic Category:** Keratolytic; antifungal

**Composition:** Pure material

## SECTION 4 - FIRST AID MEASURES

**Inhalation:** Causes irritation. Remove to fresh air.

**Eye:** Causes irritation. Flush with copious quantities of water for 15 minutes.

**Skin:** Causes irritation. Material is readily absorbed through the skin, and may be absorbed sufficiently to cause signs of overdose. Flush with copious quantities of soap and water.

**Ingestion:** Causes irritation and toxicity. Flush out mouth with water.

**General First Aid Procedures:** Remove from exposure. Remove contaminated clothing. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen. Obtain medical attention.

### Note to Physicians

**Overdose Treatment:** Treatment of salicylate overdose should be symptomatic and supportive and may include the following:

1. Administer activated charcoal as a slurry. Multiple doses may be beneficial.
2. Perform gastric lavage, unless contraindicated, soon after ingestion. Protect airway and control seizures first.
3. Correct dehydration with 0.9% NaCl until good urine flow is obtained. Do not over hydrate. Add potassium to subsequent fluid. Monitor pulmonary status, urine output, urine pH, and serum potassium.
4. Alkalinize urine with sodium bicarbonate in D5W to achieve a urine pH greater than 7.5. Additional potassium chloride may be required.
5. For acidosis, administer sodium bicarbonate intravenously. Correct pH to 7.4. Monitor ABGs
6. Treat hyperthermia with external cooling.
7. Early treatment with hemodialysis may be useful if blood salicylate levels are high or if symptoms of salicylism persist. Hemodialysis rapidly increases salicylate clearance and corrects acid-base, fluid, and electrolyte disturbances.
8. For seizures, administer a benzodiazepine intravenously. If seizures recur, consider phenobarbital or propofol. Monitor for hypotension, dysrhythmias, respiratory depression, and need for endotracheal intubation. Evaluate for hypoglycemia, electrolyte imbalances, and hypoxia.
9. For active bleeding or coagulation disorders, give blood or blood platelets if needed. Vitamin K may improve prothrombin time. [Poisindex 2009]

## SECTION 5 - FIREFIGHTING MEASURES

**Extinguisher Media:** Water spray, dry chemical, carbon dioxide, or foam as appropriate for surrounding fire and materials.

**Fire and Explosion Hazards:** This material is assumed to be combustible.

**Firefighting Procedures:** As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.

## SECTION 6 - ACCIDENTAL RELEASE MEASURES

# SALICYLIC ACID TABLETS (DISSOLUTION CALIBRATOR, NON-DISINTEGRATING)

Catalog Number: 1609501

Revision Date:

August 13, 2009

**Spill Response:** Wear approved respiratory protection, chemically compatible gloves, and protective clothing. Wipe up spillage or collect spillage using a high-efficiency vacuum cleaner. Avoid breathing dust. Place spillage in appropriately labeled container for disposal. Wash spill site.

## SECTION 7 - HANDLING AND STORAGE

**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. Wash thoroughly after handling.

**Storage:** Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity. Store in a desiccator or in a dry place at room temperature.

## SECTION 8 - EXPOSURE CONTROL / PERSONAL PROTECTION

**Engineering Controls:** Engineering controls such as exhaust ventilation are recommended.

**Respiratory Protection:** Use a NIOSH-approved respirator, if it is determined to be necessary by an industrial hygiene survey involving air monitoring. In the event that a respirator is not required, an approved dust mask should be used.

**Gloves:** Chemically compatible

**Eye Protection:** Safety goggles or glasses

**Protective Clothing:** Protect exposed skin.

**Exposure Limits:** Industry : 3000 micrograms/m<sup>3</sup>

## SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

Properties as indicated on the MSDS are general and not necessarily specific to the USP Reference Standard Lot provided.

**Appearance and Odor:** White tablets; almost odorless.

**Odor Threshold:** n/f

**pH:** 2.4 (saturated aqueous solution)

**Melting Range:** 157 - 161° C; 76° C (sublimes)

**Boiling Point:** 211° C (at 20 mm Hg)

**Flash Point:** 157° C (CC)

**Autoignition Temperature:** 540° C

**Evaporation Rate:** n/f

**Upper Flammability Limit:** n/f

**Lower Flammability Limit:** 1.4%

**Vapor Pressure:** 8.2 x 10<sup>-5</sup> mm Hg (at 25° C)

**Vapor Density:** 4.8 (air = 1)

**Specific Gravity:** 1.443 (at 20° C/4° C)

**Solubility in Water:** Slightly soluble

**Fat Solubility:** n/f

**Other Solubility:** Slightly soluble in benzene; freely soluble in alcohol and in ether; soluble in boiling water; sparingly soluble in chloroform; slightly soluble in toluene.

**Partition Coefficient: n-octanol/water:** 2.26 (at 37° C)

**Percent Volatile:** n/f

**Reactivity in Water:** n/f

---

**SALICYLIC ACID TABLETS (DISSOLUTION CALIBRATOR, NON-DISINTEGRATING)****Catalog Number:** 1609501**Revision Date:**August 13, 2009

---

**Explosive Properties:** n/f**Oxidizing Properties:** n/f**Formula:** C<sub>7</sub>H<sub>6</sub>O<sub>3</sub>**Molecular Weight:** 138.12

# SALICYLIC ACID TABLETS (DISSOLUTION CALIBRATOR, NON-DISINTEGRATING)

Catalog Number: 1609501

Revision Date:

August 13, 2009

## SECTION 10 - STABILITY AND REACTIVITY

**Conditions to Avoid:** Moisture

**Incompatibilities:** Iron salts, spirit nitrous ether, lead acetate, iodine, oxidizing agents, bases.

**Decomposition Products:** When heated to decomposition, material emits acrid smoke and irritating fumes. Emits toxic fumes of phenol under fire conditions.

**Stable?** Yes      **Hazardous Polymerization?** No

## SECTION 11 - TOXICOLOGICAL PROPERTIES

**Oral Rat:** LD50 : 891 mg/kg

**Oral Mouse:** LD50 : 480 mg/kg

**Other Toxicity Data:** Inhalation Rat LC50 : >900 mg/m<sup>3</sup>/1 hr  
Skin Rabbit LD50 : >10 grams/kg  
Skin Rat LD50 : >2 grams  
Oral Rabbit LD50 : 1300 mg/kg  
Oral Cat LD50 : 400 mg/kg

**Irritancy Data:** Skin/Rabbit : mild (Standard Draize; 500 mg; 24 hour)  
Eye/Rabbit : severe (Standard Draize; 100 mg)  
Skin/Human : irritant

**Corrosivity:** n/f

**Sensitization Data:** Mouse ear swelling test : not sensitizing

**Listed as a Carcinogen by:**      **NTP:** No      **IARC:** No      **OSHA:** No

**Other Carcinogenicity Data:** No

**Mutagenicity Data:** Salicylic acid was weakly mutagenic in the Ames test in Salmonella typhimurium strain TA100 with activation, but not mutagenic in other Salmonella typhimurium strains and in E.Coli. It showed DNA-damaging tendencies in the Rec-assay. It tested positive in the reverse gene mutation assay in Saccharomyces cerevisiae. In vivo, it was not genotoxic in the sister chromatid exchange and chromosomal aberration tests in mouse bone marrow.

**Reproductive and Developmental Effects:** Salicylates are associated with increased prenatal and newborn mortality, anemia, prolonged pregnancy, maternal bleeding complications, and prolonged or complicated deliveries when used therapeutically in the third trimester of pregnancy. It has been suggested that maternal ingestion of salicylates may cause premature closure of the fetal ductus arteriosus and lead to pulmonary hypertension in some infants. Pregnant rats gavaged with salicylic acid in doses of 150 mg/kg showed mortality and growth retardation of the fetuses and abnormalities. Doses of 300 mg/kg caused maternal toxicity, fetal mortality, and cranial and skeletal malformations. In pregnant mice, a single oral dose of 500 mg/kg caused muscular and skeletal abnormalities. Salicylic acid caused malformations in rat embryos in vitro.

## SECTION 12 - ECOLOGICAL INFORMATION

**Ecological Information:** Salicylic acid is readily biodegradable according to OECD guidelines.  
Daphnia magna EC50 : 1060 mg/liter (24 hour; freshwater; static; 21° C; pH 7.45)  
BOD : 141% (5 days)

## SECTION 13 - DISPOSAL CONSIDERATIONS

**Disposal:** Dispose of waste in accordance with all applicable Federal, State, and local laws.

## SECTION 14 - TRANSPORT INFORMATION

---

**SALICYLIC ACID TABLETS (DISSOLUTION CALIBRATOR, NON-DISINTEGRATING)****Catalog Number:** 1609501**Revision Date:**August 13, 2009

---

**Shipping Name:** n/f**Class:** n/f**UN Number:** n/f**Packing Group:** n/f**Additional Transport Information:** n/f

<b>SECTION 15 - REGULATORY INFORMATION</b>
--

**U.S. Regulatory Information:** n/f**International Regulatory Information:** EINECS # 200-712-3

<b>SECTION 16 - OTHER INFORMATION</b>
---------------------------------------

**Revision:** 13-Aug-09**Previous Revision Date:** 01-Jun-09