

SAFETY DATA SHEET

1. Identification

Product identifier Bismuth Subsalicylate

Other means of identification

Catalog number 1075553

Chemical name (2-Hydroxybenzoato-O1)-oxobismuth

Recommended use Specified quality tests and assay use only.

Recommended restrictions Not for use as a drug. Not for administration to humans or animals.

Manufacturer/Importer/Supplier/Distributor information

Company name U. S. Pharmacopeia
Address 12601 Twinbrook Parkway

Rockville

MD

20852-1790

US

Telephone RS Technical Services 301-816-8129

Website www.usp.org
E-mail RSTECH@usp.org

Emergency phone number CHEMTREC within US &

Canada

CHEMTREC outside US & +1 703-527-3887

Canada

2. Hazard(s) identification

Physical hazards Not classified.

Health hazards Serious eye damage/eye irritation Category 2A

Reproductive toxicity Category 2

OSHA hazard(s) Not classified.

Label elements



Signal word Warning

Hazard statement Causes serious eye irritation. Suspected of damaging fertility or the unborn child.

Precautionary statement

Prevention Wash thoroughly after handling. Obtain special instructions before use. Do not handle until all

safety precautions have been read and understood. Wear protective gloves/protective

1-800-424-9300

clothing/eye protection/face protection.

Response If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and

easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention. If exposed or

concerned: Get medical advice/attention.

Storage Store locked up.

Disposal Dispose of contents/container in accordance with local/regional/national/international regulations.

Hazard(s) not otherwise

classified (HNOC)

Not classified.

3. Composition/information on ingredients

Substance

Hazardous components

Chemical nameCommon name and synonymsCAS number%Bismuth Subsalicylate14882-18-9100

Material name: Bismuth Subsalicylate

USP SDS US

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 Rinse skin with water/shower. Get medical attention if irritation develops and persists.

Eye contact Rinse with water. 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

Indication of immediate medical attention and special treatment needed

Irritation of eyes and mucous membranes.

Treatment of overdose should be symptomatic and supportive and may include the following: Administer activated charcoal as a slurry. Multiple doses may be beneficial. Perform gastric lavage, unless contraindicated, soon after ingestion. Protect airway and control seizures first. 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. Alkalinize urine with sodium bicarbonate in D5W to achieve a urine pH greater than 7.5. Additional potassium chloride may be required. For acidosis, administer sodium bicarbonate intravenously. Correct pH to 7.4. Monitor ABGs. Treat hyperthermia with external cooling. 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. Chelation with unithiol combined with hemodialysis may increase bismuth elimination. 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. For active bleeding or coagulation disorders, give blood or blood platelets if needed. Vitamin K may improve prothrombin time. [Poisindex 2009]

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 Use fire-extinguishing media appropriate for surrounding materials. Water. Foam. Dry chemical or

CO2. None known.

Unsuitable extinguishing

media

Specific hazards arising from the chemical

Special protective equipment

and precautions for firefighters

Fire-fighting equipment/instructions

Specific methods

Wear suitable protective equipment.

No unusual fire or explosion hazards noted.

Use water spray to cool unopened containers. As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.

Use standard firefighting procedures and consider the hazards of other involved materials.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Methods and materials for containment and cleaning up

Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Avoid inhalation of dust from the spilled material. Wear appropriate personal protective equipment.

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. Clean surface thoroughly to remove residual contamination.

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.

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.

Material name: Bismuth Subsalicylate

8. Exposure controls/personal protection

Exposure limit values

Industrial Use

MaterialTypeValueBismuth Subsalicylate (CASTWA15 mg/m3

14882-18-9)

Biological limit values

Appropriate engineering controls

No biological exposure limits noted for the ingredient(s).

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 measures, 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

Other

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.

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.

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

General hygiene considerations

Handle in accordance with good industrial hygiene and safety practice.

9. Physical and chemical properties

Appearance Fine white to off-white crystalline powder.

Not available.

Physical state Solid.
Form Powder.
Odor Odorless.
Odor threshold Not available.

pH 2.7 - 5 (9 grams in 10 mL water)

Melting point/freezing pointNot available.Initial boiling point and boilingNot available.

range

Flash point Not available.

Evaporation rate Not available.

Flammability (solid, gas) Not applicable.

Upper/lower flammability or explosive limits

Flammability limit - lower

Not available.

(%)

Flammability limit - upper

Not available.

(%)

Explosive limit - lower (%) Not available.

Explosive limit - upper (%) Not available.

Vapor pressure 0.0000008 kPa at 25 °C

Vapor density Not available.

Relative density Not available.

Solubility in water Practically insoluble.

Partition coefficient

Not available.

(n-octanol/water)

Not available. **Auto-ignition temperature Decomposition temperature** Not available. Not available. Viscosity

Other information

C7H5BiO4 Molecular formula 362.09 Molecular weight

Solubility (other) Practically insoluble in alcohol and in ether.

Specific gravity 0.6 (water = 1)

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 Strong oxidizing agents. Alkalis. Mineral acids.

Hazardous decomposition

products

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

11. Toxicological information

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 Causes serious eye irritation.

Symptoms related to the physical, chemical, and toxicological characteristics

Salicylates: Heartburn, Nausea, Vomiting, Stomach pain, Diarrhea, Ringing in ears, Headache, Dizziness. Drowsiness. Visual disturbances. Flushing. Sweating. Thirst. Agitation. Confusion. Fast breathing. Mental status changes. Delirium. Seizures.

Delayed and immediate effects

of exposure

Salicylates: Coma. Respiratory failure. Cardiovascular collapse. Kidney, liver, and pancreas

damage. Gastrointestinal bleeding. Death.

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.

Medical conditions aggravated

by exposure

Salicylates: Anemia. Bleeding disorders. Impaired liver function. Impaired kidney function.

Diabetes. Asthma. Circulatory disorders.

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

Causes serious eye irritation.

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. Data from germ cell mutagenicity tests were

not found.

Mutagenicity

Reproductive toxicity

S. typhimurium Ames assay

Result: Negative.

Carcinogenicity Due to lack of data the classification is not possible. This material is not considered to be a

carcinogen by IARC, NTP, or OSHA.

Suspected of damaging fertility or the unborn child. 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.

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.

Based on available data, the classification criteria are not met. **Aspiration hazard**

Material name: Bismuth Subsalicylate

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 Not available. Other adverse effects

13. Disposal considerations

Disposal instructions Dispose in accordance with all applicable regulations. 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.

Local disposal regulations Not available. Hazardous waste code Not available.

Waste from residues / unused

products

Dispose of in accordance with local regulations. 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

14. Transport information

DOT

Not regulated as a hazardous material by DOT.

IATA

Not regulated as a dangerous good.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

No information available.

15. Regulatory information

US federal regulations CERCLA/SARA Hazardous Substances - Not applicable.

All components are on the U.S. EPA TSCA Inventory List.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories Immediate Hazard - Yes Delayed Hazard - No

Fire Hazard - No Pressure Hazard - No Reactivity Hazard - No

SARA 302 Extremely hazardous substance

SARA 311/312 Hazardous

chemical

No

Other federal regulations

Safe Drinking Water Act

(SDWA)

Japan

Not regulated.

Food and Drug Administration (FDA)

Not regulated.

US state regulations

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

International Inventories

| Country(s) or region | Inventory name | On inventory (yes/no)* |
|----------------------|--|------------------------|
| Australia | Australian Inventory of Chemical Substances (AICS) | Yes |
| Canada | Domestic Substances List (DSL) | Yes |
| 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) | Yes |
| Europe | European List of Notified Chemical Substances (ELINCS) | No |

Material name: Bismuth Subsalicylate USP SDS US

Inventory of Existing and New Chemical Substances (ENCS)

Yes

Country(s) or region Inventory name On inventory (yes/no)*

KoreaExisting Chemicals List (ECL)NoNew ZealandNew Zealand InventoryYes

Philippines Philippine Inventory of Chemicals and Chemical Substances

(PICCS)

United States & Puerto Rico Toxic Substances Control Act (TSCA) Inventory Yes

*A "Yes" indicates that all components 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
 08-13-2009

 Revision date
 03-04-2015

Version # 02

Further information Not available.

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Revision InformationThis document has undergone significant changes and should be reviewed in its entirety.

Material name: Bismuth Subsalicylate usp sps us

No