1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

Product identifier
Chemical Name
Bismuth Subcitrate Potassium

Other means of identification
Product Code
880149-29-1
Synonyms
1,2,3-Propanetricarboxylic acid, 2-hydroxy-, bismuth(3+) potassium salt (2:1:5) Biscalcitrate K

Recommended use of the chemical and restrictions on use
Recommended Use
Antibiotic

This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to medicinal use of the product. In this instance patients should consult prescribing information/package insert/product label or consult their pharmacist or physician. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate safety data sheet for each ingredient.

Details of the supplier of the safety data sheet
Manufacturer
Allergan plc
5 Giralda Farms
Madison, NJ USA 07940
+1-800-272-5525
E-mail address
SDS@Allergan.com

Emergency telephone number
Emergency Telephone
Call CHEMTREC Day or Night
Within USA or Canada: 1-800-424-9300
Outside USA and Canada: +1-703-741-5970 (collect calls accepted)

2. HAZARDS IDENTIFICATION

Classification
OSHA Regulatory Status
This chemical is considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Specific target organ toxicity (repeated exposure) Category 2

Label elements
Warning

Hazard statements
H373 - May cause damage to organs through prolonged or repeated exposure
Precautionary statements

P260 - Do not breathe dust/fume/gas/mist/vapors/spray
P314 - Get medical advice/attention if you feel unwell
P501 - Dispose of contents/ container to an approved waste disposal plant

Other Information

Over the counter drugs in their solid form are considered exempt under the criteria of the Federal OSHA Hazard Communication Standard 20 CFR 1910.1200. However, in an industrial setting where a component's occupational exposure limit may be surpassed, than can be considered hazardous.

3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>CAS No.</th>
<th>EINECS</th>
<th>Weight-%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bismuth Subcitrate Potassium</td>
<td>880149-29-1</td>
<td>N/A</td>
<td>100</td>
</tr>
</tbody>
</table>

*The exact percentage (concentration) of composition has been withheld as a trade secret.

4. FIRST AID MEASURES

First aid measures

General advice
Immediate medical attention is required.

Eye contact
Immediately flush with plenty of water. After initial flushing, remove any contact lenses and continue flushing for at least 15 minutes. Keep eye wide open while rinsing. Call a physician immediately.

Skin Contact
Immediate medical attention is required. Wash off immediately with soap and plenty of water while removing all contaminated clothes and shoes.

Inhalation
Immediate medical attention is required. Remove to fresh air. If not breathing, give artificial respiration. Avoid direct contact with skin. Use barrier to give mouth-to-mouth resuscitation.

Ingestion
Do NOT induce vomiting. Call a physician or poison control center immediately. Never give anything by mouth to an unconscious person. Drink plenty of water.

Note to physicians
BAL has been used for treatment of poisoning by any bismuth compound. Other treatment is symptomatic.

5. FIRE-FIGHTING MEASURES
Suitable extinguishing media
Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Unsuitable extinguishing media
None known.

Specific hazards arising from the chemical
Fire may produce irritating, corrosive and/or toxic gases.

Explosion data
Sensitivity to Mechanical Impact
Not impact sensitive.
Sensitivity to Static Discharge
Fine dust dispersed in air, in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.

Protective equipment and precautions for firefighters
As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions
Use personal protective equipment as required. Keep people away from and upwind of spill/leak.

Environmental precautions
Prevent further leakage or spillage if safe to do so. Prevent product from entering drains. See Section 12 for additional ecological information.

Methods for containment
Prevent further leakage or spillage if safe to do so. Cover powder spill with plastic sheet or tarp to minimize spreading. Dike far ahead of liquid spill for later disposal.

Methods for cleaning up
Use personal protective equipment as required. Cover powder spill with plastic sheet or tarp to minimize spreading and keep powder dry. Take up mechanically, placing in appropriate containers for disposal. Avoid creating dust. Clean contaminated surface thoroughly.

7. HANDLING AND STORAGE

Advice on safe handling
Avoid contact with skin, eyes or clothing. Use personal protective equipment as required. Wash contaminated clothing before reuse. Do not breathe dust/fume/gas/mist/vapors/spray. Do not eat, drink or smoke when using this product.

Storage Conditions
Keep container tightly closed in a dry and well-ventilated place. Keep out of the reach of children.

Incompatible materials
None known based on information supplied.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters
Exposure Guidelines
This product, as supplied, does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.

Appropriate engineering controls
Engineering Controls
The following requirements list high level controls designed to control exposure below the OEL. More specific requirements may apply.

Individual protection measures, such as personal protective equipment
PPE
The following high level PPE requirements assume Engineering Controls that reduce exposure below the limit are not in place. More specific requirements may apply.

Eye/face protection
Tight sealing safety goggles.
Skin and body protection
During medical administration of this product, medical latex or nitrile gloves should be worn to avoid absorption of the product. Use appropriate protective clothing for the task (e.g., lab coat, etc.).

Respiratory protection
Respiratory protection is generally not needed during routine conditions of use of this product. If respiratory protection is needed, use only respiratory protection authorized under appropriate regional regulations.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

<table>
<thead>
<tr>
<th>Property</th>
<th>Values</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical state</td>
<td>Solid</td>
</tr>
<tr>
<td>Color</td>
<td>White</td>
</tr>
<tr>
<td>Odor threshold</td>
<td>No information available</td>
</tr>
<tr>
<td>Appearance</td>
<td>amorphous powder</td>
</tr>
<tr>
<td>Odor</td>
<td>Odorless</td>
</tr>
<tr>
<td>pH</td>
<td>No information available</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No information available</td>
</tr>
<tr>
<td>Boiling point / boiling range</td>
<td>No information available</td>
</tr>
<tr>
<td>Flash point</td>
<td>No information available</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>No information available</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>No information available</td>
</tr>
<tr>
<td>Flammability Limit in Air</td>
<td>No information available</td>
</tr>
<tr>
<td>Upper flammability limit:</td>
<td>No information available</td>
</tr>
<tr>
<td>Lower flammability limit:</td>
<td>No information available</td>
</tr>
<tr>
<td>Vapor pressure</td>
<td>No information available</td>
</tr>
<tr>
<td>Vapor density</td>
<td>No information available</td>
</tr>
<tr>
<td>Specific Gravity</td>
<td>No information available</td>
</tr>
<tr>
<td>Water solubility</td>
<td>Soluble in water</td>
</tr>
<tr>
<td>Solubility in other solvents</td>
<td>No information available</td>
</tr>
<tr>
<td>Partition coefficient</td>
<td>No information available</td>
</tr>
<tr>
<td>Autoignition temperature</td>
<td>No information available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No information available</td>
</tr>
<tr>
<td>Explosive properties</td>
<td>No information available</td>
</tr>
<tr>
<td>Oxidizing properties</td>
<td>No information available</td>
</tr>
<tr>
<td>Molecular weight</td>
<td>834.71</td>
</tr>
<tr>
<td>VOC Content (%)</td>
<td>No information available</td>
</tr>
<tr>
<td>Density</td>
<td>No information available</td>
</tr>
<tr>
<td>Bulk density</td>
<td>No information available</td>
</tr>
</tbody>
</table>

10. STABILITY AND REACTIVITY

Reactivity
Not defined As Reactive substance

Chemical stability
Stable under normal conditions.

Possibility of Hazardous Reactions
None under normal processing.

Conditions to avoid
Aerosol formation.

Incompatible materials
None known based on information supplied.

Hazardous Decomposition Products
None known based on information supplied.
11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Acute toxicity

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Inhalation</th>
<th>Eye contact</th>
<th>Skin Contact</th>
<th>Ingestion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bismuth Subcitrate Potassium</td>
<td>Poorly Absorbed if Inhaled.</td>
<td>Moderately irritating to the eyes, check for and remove contact lenses and flush with copious amounts of water; assure adequate flushing by separating the eyelids with fingers; call a physician.</td>
<td>Poorly Absorbed if ingested.</td>
<td>Prolonged contact may cause redness and irritation.</td>
</tr>
</tbody>
</table>

Delayed and immediate effects as well as chronic effects from short and long-term exposure

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Germ cell mutagenicity</th>
<th>Carcinogenicity</th>
<th>Reproductive toxicity</th>
<th>Effects on or via lactation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bismuth Subcitrate Potassium</td>
<td>No information available.</td>
<td>No information available.</td>
<td>None known.</td>
<td>No information available.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>STOT - single exposure</th>
<th>STOT - repeated exposure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bismuth Subcitrate Potassium</td>
<td>No information available.</td>
<td>kidney.</td>
</tr>
</tbody>
</table>

Chronic toxicity

May cause adverse liver effects.

Target Organ Effects

Gastrointestinal tract (GI), kidney, liver.

Numerical measures of toxicity - Product Information

The following values are calculated based on chapter 3.1 of the GHS document.

ATEmix (oral) 100

12. ECOLOGICAL INFORMATION

Ecotoxicity

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Persistence and degradability</th>
<th>Bioaccumulation</th>
<th>Mobility</th>
<th>Partition coefficient</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bismuth Subcitrate Potassium</td>
<td>No information available.</td>
<td>The hydrolysis of bismuth salts to insoluble basic salts limits bioconcentration in aquatic organisms.</td>
<td>No information available</td>
<td>N/A</td>
</tr>
</tbody>
</table>

Other adverse effects

No information available

13. DISPOSAL CONSIDERATIONS

Waste treatment methods

Disposal of wastes

Disposal should be in accordance with applicable regional, national and local laws and regulations.

Contaminated packaging

Do not reuse container. Dispose of contents/containers in accordance with local regulations.

14. TRANSporte INFORMATION
15. REGULATORY INFORMATION

International Inventories

<table>
<thead>
<tr>
<th>Legend:</th>
<th>Not Listed</th>
</tr>
</thead>
<tbody>
<tr>
<td>TSCA</td>
<td>Not Listed</td>
</tr>
<tr>
<td>DSL/NDSL</td>
<td>Not Listed</td>
</tr>
<tr>
<td>EINECS/ELINCS</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

**US Federal Regulations**

**SARA 313**
Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372

**SARA 311/312 Hazard Categories**

<table>
<thead>
<tr>
<th>Acute health hazard</th>
<th>Yes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chronic Health Hazard</td>
<td>No</td>
</tr>
<tr>
<td>Fire hazard</td>
<td>No</td>
</tr>
<tr>
<td>Sudden release of pressure hazard</td>
<td>No</td>
</tr>
<tr>
<td>Reactive Hazard</td>
<td>No</td>
</tr>
</tbody>
</table>

**CWA (Clean Water Act)**
This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42)

**CERCLA**
This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material

**US State Regulations**

**California Proposition 65**
This product does not contain any Proposition 65 chemicals

**U.S. State Right-to-Know Regulations**

16. OTHER INFORMATION

Revision Date 02-Oct-2018
Revision Note No information available
Disclaimer
The information provided in this Material Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

End of Safety Data Sheet