

## 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**

**Emergency Overview**

**Warning**

**Hazard statements**

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



<b>Appearance</b> amorphous powder	<b>Physical state</b> Solid	<b>Odor</b> Odorless
<b>Chemical Name</b> Bismuth Subcitrate Potassium	<b>Symptoms</b> Diarrhea, nausea, vomiting, headache and dizziness. There have been rare reports of neurotoxicity associated with excessive doses of various bismuth-containing products. Effects have been reversible with discontinuation of therapy. Bismuth subcitrate potassium and other bismuth-containing products may cause a temporary and harmless darkening of the tongue and/or black stool. Stool darkening must not be confused with melena. Decreased appetite, weakness, rheumatic pain, diarrhea, fever, metal line on the gums, foul breath, gingivitis, and dermatitis. Jaundice and conjunctival hemorrhage are rare but have been reported. Bismuth nephropathy with proteinuria may occur.	
<b>Chemical Name</b> Bismuth Subcitrate Potassium	<b>Medical Conditions Aggravated by Exposure</b> Impaired Kidney or liver function.	

**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

Chemical Name	CAS No.	EINECS	Weight-%
Bismuth Subcitrate Potassium	880149-29-1	N/A	100

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

### 4. FIRST AID MEASURES

**First aid measures**

<b>General advice</b>	Immediate medical attention is required.
<b>Eye contact</b>	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.
<b>Skin Contact</b>	Immediate medical attention is required. Wash off immediately with soap and plenty of water while removing all contaminated clothes and shoes.
<b>Inhalation</b>	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.
<b>Ingestion</b>	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.

**Chemical Name**  
Bismuth Subcitrate Potassium

**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

<b>Personal precautions</b>	Use personal protective equipment as required. Keep people away from and upwind of spill/leak.
<b>Environmental precautions</b>	Prevent further leakage or spillage if safe to do so. Prevent product from entering drains. See Section 12 for additional ecological information.
<b>Methods for containment</b>	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.
<b>Methods for cleaning up</b>	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

<b>Advice on safe handling</b>	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.
<b>Storage Conditions</b>	Keep container tightly closed in a dry and well-ventilated place. Keep out of the reach of children.
<b>Incompatible materials</b>	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.

<b>Skin and body protection</b>	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.).
<b>Respiratory protection</b>	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

<b>Physical state</b>	Solid	<b>Appearance</b>	amorphous powder
<b>Color</b>	White	<b>Odor</b>	Odorless
<b>Odor threshold</b>	No information available		

### Property

pH

Melting point/freezing point

Boiling point / boiling range

Flash point

Evaporation rate

Flammability (solid, gas)

Flammability Limit in Air

Upper flammability limit:

Lower flammability limit:

Vapor pressure

Vapor density

Specific Gravity

Water solubility

Solubility in other solvents

Partition coefficient

Autoignition temperature

Decomposition temperature

Explosive properties

Oxidizing properties

### Values

No information available

No information available

No information available

No information available

No information available

No information available

No information available

No information available

No information available

No information available

No information available

No information available

Soluble in water

No information available

No information available

No information available

No information available

No information available

No information available

### Other Information

Molecular weight

834.71

VOC Content (%)

No information available

Density

No information available

Bulk density

No information available

## 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

Chemical Name	Inhalation	Eye contact	Skin Contact	Ingestion
Bismuth Subcitrate Potassium	Poorly Absorbed if Inhaled.	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.	flush with copious amounts of water; remove contaminated clothing and shoes; call a physician, Prolonged contact may cause redness and irritation.	Poorly Absorbed if ingested.

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

Chemical Name	Germ cell mutagenicity	Carcinogenicity	Reproductive toxicity	Effects on or via lactation
Bismuth Subcitrate Potassium	No information available.	No information available.	None known.	No information available

Chemical Name	STOT - single exposure	STOT - repeated exposure
Bismuth Subcitrate Potassium	No information available.	kidney.

**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

Chemical Name	Persistence and degradability	Bioaccumulation	Mobility	Partition coefficient
Bismuth Subcitrate Potassium 880149-29-1	No information available	The hydrolysis of bismuth salts to insoluble basic salts limits bioconcentration in aquatic organisms.	No information available	N/A

**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. TRANSPORT INFORMATION

<u>DOT</u>	Not regulated
<u>TDG</u>	Not regulated
<u>ICAO (air)</u>	Not regulated
<u>IATA</u>	Not regulated
<u>IMDG</u>	Not regulated
<u>ADR</u>	Not regulated
<u>ADN</u>	Not regulated

## 15. REGULATORY INFORMATION

### International Inventories

<b>TSCA</b>	Not Listed
<b>DSL/NDSL</b>	Not Listed
<b>EINECS/ELINCS</b>	Not Listed

### Legend:

**TSCA** - United States Toxic Substances Control Act Section 8(b) Inventory

**DSL/NDSL** - Canadian Domestic Substances List/Non-Domestic Substances List

**EINECS/ELINCS** - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

### 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**

<b>Acute health hazard</b>	Yes
<b>Chronic Health Hazard</b>	No
<b>Fire hazard</b>	No
<b>Sudden release of pressure hazard</b>	No
<b>Reactive Hazard</b>	No

#### **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

<b>Revision Date</b>	02-Oct-2018
<b>Revision Note</b>	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**