

# SAFETY DATA SHEET

Revision date: February 2016

Version: 1

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## 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING

### Product Identifier

**Material Name:** Bio-Cox® 60 G**Trade Name:** BioCox  
**Compound Number:** 400103, 400103 / 400124  
**Chemical Family:** Mixture

### Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

**Intended Use:** Veterinary antibiotic agent  
**Restrictions on Use:** Not for human use

### Manufacturer/Supplier:

**Huvepharma Inc.**  
612 S 28th Street  
Van Buren, AR 72956**Huvepharma, Inc.**  
525 Westpark Drive, Suite 230  
Peachtree City, GA 30269  
Telephone: 1-770-486-7212**Emergency telephone number:** 1-877-994-4883  
**Contact e-mail:** customerservice@huvepharma.us

## 2. HAZARDS IDENTIFICATION

**Appearance:** Light brown solid

### Classification of the Substance or Mixture

#### GHS - Classification

Acute Oral Toxicity: Category 4  
Skin Corrosion/Irritation: Category 2  
Serious Eye Damage/Eye Irritation: Category 2A  
Reproductive Toxicity: Category 1B  
Acute aquatic toxicity: Category 3  
Chronic aquatic toxicity: Category 3

#### US OSHA Specific - Classification

**Physical Hazard:** Combustible Dust

#### EU Classification:

EU Indication of danger: Harmful  
Toxic to reproduction, Category 2EU Symbol: T  
R22 - Harmful if swallowed.  
R61 - May cause harm to the unborn child.  
R52/53 - Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

### Label Elements

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### 2. HAZARDS IDENTIFICATION

**Signal Word:** Danger  
**Hazard Statements:** H360D - May damage the unborn child  
H315 - Causes skin irritation  
H319 - Causes serious eye irritation  
H302 - Harmful if swallowed  
H412 - Harmful to aquatic life with long lasting effects  
May form combustible dust concentrations in air

**Precautionary Statements:** P201 - Obtain special instructions before use  
P202 - Do not handle until all safety precautions have been read and understood  
P210 - Keep away from heat/sparks/open flames/hot surfaces. - No smoking  
P240 - Ground/Bond container and receiving equipment  
P280 - Wear protective gloves/protective clothing/eye protection/face protection  
P264 - Wash hands thoroughly after handling  
P270 - Do not eat, drink or smoke when using this product  
P273 - Avoid release to the environment  
P308 + P313 - IF exposed or concerned: Get medical attention/advice  
P301+ P312 - IF SWALLOWED: Call a POISON CENTRE or doctor/physician if you feel unwell  
P330 - Rinse mouth  
P302+ P352 - IF ON SKIN: Wash with plenty of soap and water  
P332 + P313 - If skin irritation occurs: Get medical advice/attention  
P362 - Take off contaminated clothing and wash before reuse  
P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing  
P337 + P313 - If eye irritation persists: Get medical advice/attention  
P405 - Store locked up  
P501 - Dispose of contents/container in accordance with all local and national regulations



#### Other Hazards

##### Short Term:

Causes eye irritation . Signs and symptoms might include redness, swelling, blurred vision or pain. Can cause skin irritation. Signs and symptoms might include skin rash, itching, redness or swelling. Dust may cause irritation .

##### Long Term:

##### Known Clinical Effects:

may have the potential to produce effects on the developing fetus.  
Symptoms reported after accidental human exposure have included nausea , shortness of breath (dyspnea) , dizziness , muscle weakness , muscle destruction (rhabdomyolysis) .  
Hazardous Substance. Non-Dangerous Goods.

#### Australian Hazard Classification (NOHSC):

#### Note:

This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

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### 3. COMPOSITION/INFORMATION ON INGREDIENTS

**Hazardous**

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Salinomycin sodium	55721-31-8	Not Listed	T;R25 Repr. Cat.2;R61 Xi;R36/38 N;R51/53	Acute Tox. 2 (H300) Repr. Cat. 1B (H360) Skin Irrit. 2 (H315) Eye Irrit. 2A (H319) Aq. Acute 2 (H401) Aq. Chronic 2 (H411)	13

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Calcium carbonate	1317-65-3	215-279-6	Not Listed	Not Listed	65-85

**Additional Information:** Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

**For the full text of the R phrases and CLP/GHS abbreviations mentioned in this Section, see Section 16**

### 4. FIRST AID MEASURES

**Description of First Aid Measures**

- Eye Contact:** Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.
- Skin Contact:** Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
- Ingestion:** Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.
- Inhalation:** Remove to fresh air and keep patient at rest. Seek medical attention immediately.

**Most Important Symptoms and Effects, Both Acute and Delayed**

- Symptoms and Effects of Exposure:** For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.
- Medical Conditions Aggravated by Exposure:** Breathing dust may worsen asthma symptoms.

**Indication of the Immediate Medical Attention and Special Treatment Needed**

- Notes to Physician:** Treat symptomatically.

### 5. FIRE-FIGHTING MEASURES

**Extinguishing Media:** Extinguish fires with CO<sub>2</sub>, extinguishing powder, foam, or water.

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### Special Hazards Arising from the Substance or Mixture

**Hazardous Combustion Products:** Formation of toxic gases is possible during heating or fire.

**Fire / Explosion Hazards:** Dust can form an explosive mixture in air. Fine particles (such as dust and mists) may fuel fires/explosions.

### Advice for Fire-Fighters

During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

## 6. ACCIDENTAL RELEASE MEASURES

### Personal Precautions, Protective Equipment and Emergency Procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure. Avoid dust formation.

### Environmental Precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

### Methods and Material for Containment and Cleaning Up

**Measures for Cleaning / Collecting:** Contain the source of the spill if it is safe to do so. Avoid generating airborne dust. Collect spilled material by a method that controls dust generation. Eliminate possible ignition sources (e.g., heat, sparks, flame, impact, friction, electricity), and follow appropriate grounding procedures. Use non-combustible absorbent material to wipe up spill and place in a sealed container for disposal. Clean contaminated surface thoroughly.

**Additional Consideration for Large Spills:** Eliminate possible ignition sources (e.g., heat, sparks, flame, impact, friction, electricity), and follow appropriate grounding procedures. Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

## 7. HANDLING AND STORAGE

### Precautions for Safe Handling

Eliminate possible ignition sources (e.g., heat, sparks, flame, impact, friction, electricity), and follow appropriate grounding and bonding procedures. Avoid contact with eyes, skin and clothing. Avoid breathing dust. Minimize dust generation and accumulation. Use with adequate ventilation. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

### Conditions for Safe Storage, Including any Incompatibilities

**Storage Conditions:** Store at room temperature in properly labeled containers. Keep away from heat, sparks and flames.

**Specific end use(s):** No data available

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

### Control Parameters

Refer to available public information for specific member state Occupational Exposure Limits.

### Calcium carbonate

Belgium OEL - TWA

10 mg/m<sup>3</sup>

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Bulgaria OEL - TWA	1.0 fiber/cm <sup>3</sup> 10.0 mg/m <sup>3</sup>
Czech Republic OEL - TWA	10.0 mg/m <sup>3</sup>
Estonia OEL - TWA	10 mg/m <sup>3</sup> 5 mg/m <sup>3</sup>
Greece OEL - TWA	10 mg/m <sup>3</sup> 5 mg/m <sup>3</sup>
Hungary OEL - TWA	10 mg/m <sup>3</sup>
Ireland OEL - TWAs	10 mg/m <sup>3</sup> 4 mg/m <sup>3</sup>
OSHA - Final PELs - TWAs:	15 mg/m <sup>3</sup>
Romania OEL - TWA	10 mg/m <sup>3</sup>
Slovakia OEL - TWA	10 mg/m <sup>3</sup>
Switzerland OEL -TWAs	3 mg/m <sup>3</sup>

The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

#### Salinomycin sodium

##### Huvepharma OEB

OEB 1 (control exposure to the range of 1000ug/m<sup>3</sup> to 3000ug/m<sup>3</sup>)

#### Exposure Controls

##### Engineering Controls:

Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep air contamination levels below the exposure limits or within the OEB range listed above in this section.

##### Personal Protective Equipment:

Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

##### Hands:

Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.

##### Eyes:

Wear safety glasses or goggles if eye contact is possible.

##### Skin:

Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

##### Respiratory protection:

If airborne exposures are within or exceed the Occupational Exposure Band (OEB) range, wear an appropriate respirator with a protection factor sufficient to control exposures to the bottom of the OEB range. If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

### 9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Powder	Color:	Light brown
Odor:	None	Odor Threshold:	No data available.
Molecular Formula:	Mixture	Molecular Weight:	Mixture
Solvent Solubility:	No data available		
Water Solubility:	Insoluble		
pH:	No data available.		
Melting/Freezing Point (°C):	No data available		
Boiling Point (°C):	No data available.		

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### 9. PHYSICAL AND CHEMICAL PROPERTIES

**Partition Coefficient: (Method, pH, Endpoint, Value)**

Salinomycin sodium Log P >6.2

**Salinomycin**

Measured Log P >6.2

**Decomposition Temperature (°C):** No data available.

**Evaporation Rate (Gram/s):** No data available

**Vapor Pressure (kPa):** No data available

**Vapor Density (g/ml):** No data available

**Relative Density:** No data available

**Viscosity:** No data available

**Flammability:**

**Autoignition Temperature (Solid) (°C):** No data available

**Flammability (Solids):** No data available

**Flash Point (Liquid) (°C):** No data available

**Upper Explosive Limits (Liquid) (% by Vol.):** No data available

**Lower Explosive Limits (Liquid) (% by Vol.):** No data available

### 10. STABILITY AND REACTIVITY

**Reactivity:** No data available

**Chemical Stability:** Stable under normal conditions of use.

**Possibility of Hazardous Reactions**

**Oxidizing Properties:** No data available

**Conditions to Avoid:** Keep away from heat, spark, flames and all other sources of ignition. Avoid dispersion as a dust cloud. Dust may form explosive mixture in air. Fine particles (such as dust and mists) may fuel fires/explosions.

**Incompatible Materials:** As a precautionary measure, keep away from strong oxidizers

**Hazardous Decomposition Products:** Thermal decomposition products may include carbon monoxide, carbon dioxide and other toxic vapors.

### 11. TOXICOLOGICAL INFORMATION

**Information on Toxicological Effects**

**General Information:**

Toxicological properties of the formulation have not been investigated. The information in this section describes the potential hazards of the individual ingredients and the formulation, and/or of a chemically-related material. The toxicities of the two materials can be expected to be similar. Routes of exposure: eye contact, skin contact, inhalation

**Acute Toxicity: (Species, Route, End Point, Dose)**

**Salinomycin sodium**

Rat Oral LD50 46 mg/kg

Rat Dermal LD50 > 5000 mg/kg

**Salinomycin**

Mouse (F) Oral LD50 50 mg/kg

Mouse (F) Dermal LD50 164.3 mg/kg

Rat (F) Oral LD50 48 mg/kg

Rat Dermal LD50 1030 mg/kg

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### 11. TOXICOLOGICAL INFORMATION

**Inhalation Acute Toxicity** Dust may cause irritation

**Irritation / Sensitization: (Study Type, Species, Severity)**

**Salinomycin sodium**

Skin Irritation Irritant  
Eye Irritation Irritant

**Salinomycin**

Skin Irritation Rabbit Moderate  
Eye Irritation Rabbit Severe  
Skin Sensitization Guinea Pig Negative  
Antigenicity- Delayed skin reaction Guinea Pig Negative

**Irritation / Sensitization Comments:** May cause eye irritation.  
**Skin Irritation / Sensitization** May cause skin irritation.

**Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)**

**Salinomycin**

5 Day(s) Pig Oral 46 mg/kg LOEL Brain, Skeletal muscle

**Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))**

**Salinomycin**

2 Generation Reproductive Toxicity Rat Oral 5 mg/kg/day NOEL  
Embryo / Fetal Development Mouse Oral 4 mg/kg/day NOEL Fetotoxicity, Maternal Toxicity  
Embryo / Fetal Development Rabbit Oral 0.25 mg/kg/day NOEL Not Teratogenic, Maternal Toxicity, Fetotoxicity,

**Reproductive & Development Toxicity Comments:** may have the potential to produce effects on the developing fetus.

**Genetic Toxicity: (Study Type, Cell Type/Organism, Result)**

**Salinomycin**

*In Vitro* Bacterial Mutagenicity (Ames) Not specified Negative  
Mammalian Cell Mutagenicity Mouse Lymphoma Negative  
Sex-Linked Recessive Lethal Test Drosophila Negative

**Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))**

**Salinomycin**

2 Year(s) Rat No route specified 2.5 mg/kg/day Not carcinogenic  
2 Year(s) Mouse Oral < 1.4 mg/kg/day Not carcinogenic

**Carcinogen Status:** None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

**Product Level Toxicity Data**

**Acute (Oral) Toxicity Estimate (ATE) Calculated:** 355 mg/kg

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### 12. ECOLOGICAL INFORMATION

**Environmental Overview:** Environmental properties of the formulation have not been investigated. The following information is available for the individual ingredients. The information in this section includes the potential hazards of a chemically related material. The toxicities of the two materials can be expected to be similar. Releases to the environment should be avoided.

**Toxicity:**

**Aquatic Toxicity: (Species, Method, End Point, Duration, Result)**

**Salinomycin sodium**

*Selenastrum capricornutum* (Green Alga) EC50 72 Hours 1.5 mg/L  
*Oncorhynchus mykiss* (Rainbow Trout) LC50 96 Hours 1.14 mg/L

**Salinomycin**

*Daphnia magna* (Water Flea) OECD EC50 48 Hours 14.4 mg/L  
*Selenastrum capricornutum* (Green Alga) OECD EC50 72 Hours 1.5 mg/L  
*Oncorhynchus mykiss* (Rainbow Trout) OECD LC50 96 Hours 1.14 mg/L

**Persistence and Degradability:**

**Salinomycin**

OECD Soil (various) Ultimate (CO2 Evolution) 81.37-103.63% After 131 Day(s) Not Ready

**Bio-accumulative Potential:**

**Salinomycin sodium** Log P >6.2

**Salinomycin**

Measured Log P >6.2

**Mobility in Soil:**

**Salinomycin**

OECD Soil (various) Adsorption KOC 77-153  
OECD Soil (various) Desorption KOC 77-120

### 13. DISPOSAL CONSIDERATIONS

**Waste Treatment Methods:**

Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

### 14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

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### 15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

#### Canada - WHMIS: Classifications

##### WHMIS hazard class:

Class D, Division 1, Subdivision B

Class D, Division 2, Subdivision A

Class D, Division 2, Subdivision B

This product has been classified in accordance with the hazard criteria of the CPR and the SDS contains all of the information required by the CPR.



#### Salinomycin sodium

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed

#### Calcium carbonate

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	215-279-6

### 16. OTHER INFORMATION

#### Text of R phrases and GHS Classification abbreviations mentioned in Section 3

Acute toxicity, oral-Cat.2; H300 - Fatal if swallowed

Skin corrosion/irritation-Cat.2; H315 - Causes skin irritation

Serious eye damage/eye irritation-Cat.2A; H319 - Causes serious eye irritation

Reproductive toxicity-Cat.1B; H360D - May damage the unborn child

Hazardous to the aquatic environment, acute toxicity-Cat.2; H401 - Toxic to aquatic life

Hazardous to the aquatic environment, chronic toxicity-Cat.2; H411 - Toxic to aquatic life with long lasting effects

T - Toxic

Xi - Irritant

Toxic to Reproduction: Category 2

N - Dangerous for the environment

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R25 - Toxic if swallowed.

R61 - May cause harm to the unborn child.

R36/38 - Irritating to eyes and skin.

R51/53 - Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

**Data Sources:** The data contained in this SDS may have been gathered from confidential internal sources, raw material suppliers, or from the published literature.

**Reasons for Revision:** Updated Section 2 - Hazard Identification. Updated Section 11 - Toxicology Information.  
Updated Section 12 - Ecological Information.

**Prepared by:** Toxicology and Hazard Communication  
Huvepharma Global Risk Management

Huvepharma Inc. believes that the information contained in this Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

**End of Safety Data Sheet**