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Safety data sheet according to 1907/2006/EC

Version Nr: 1



Printing date 03.01.2012

Revision: 02.01.2012

1 Identification of the substance/mixture and of the company/undertaking

- · Product identifier
- · Trade name COXIBAN
- · Article number: 5285470000
- · Relevant identified uses of the substance or mixture and uses advised against
- · Application of the substance / the preparation Pharma Active ingredients
- · Details of the supplier of the safety data sheet
- · Manufacturer/Supplier:

SUPPLIER:

Biesterfeld International GmbH

Ferdinandstr. 41 D-20095 Hamburg

Germany

Informing department:

Dept. QSHE, Mr. P. Tentler, Phone: +49 2224981155; e-mail: sdb @biesterfeld.com

Emergency telephone number:

Giftinformationszentrum - Nord

Zentrum für Pharmakologie und Toxikologie

der Universität Göttingen

Robert-Koch-Straße 40

37075 Göttingen

Germany

EMERGENCY NUMBER: +49 551 19240

2 Hazards identification

- · Classification of the substance or mixture
- Classification according to Regulation (EC) No 1272/2008



GHS07

Acute Tox. 4 H302 Harmful if swallowed.

· Classification according to Directive 67/548/EEC or Directive 1999/45/EC



Xn; Harmful

R22: Harmful if swallowed.

Classification system:

The classification is in line with current EC lists. It is expanded, however, by information from technical literature and by information furnished by supplier companies.

- · Label elements
- · Labelling according to Regulation (EC) No 1272/2008

The product is classified and labelled according to the CLP regulation.

Hazard pictograms



GHS07

- · Signal word Warning
- Hazard-determining components of labelling:

Salinomycin sodium salt

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· Hazard statements

H302 Harmful if swallowed.

· Precautionary statements

P260 Do not breathe dust.

P281 Use personal protective equipment as required.

P264 Wash thoroughly after handling.

P270 Do not eat, drink or smoke when using this product.

P301+P312 IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.

P330 Rinse mouth.

P501 Dispose of contents/container in accordance with local/regional/national/international

regulations.

· Other hazards: Only for industrial use!

Results of PBT and vPvB assessment: Not applicable.

· **PBT:** Not applicable. · **vPvB:** Not applicable.

3 Composition/information on ingredients

- · Chemical characterization: Mixtures
- · Description: Mixture consisting of the following components with harmless additives.

· Dangerous	components:
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· Additional information: For the wording of the listed risk phrases refer to section 16.

4 First aid measures

Description of first aid measures

· General information

Personal protection for the First Aider.

Remove contaminated clothing.

Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident.

· After inhalation

Take affected persons into the open air and position comfortably

Supply fresh air. If required, provide artificial respiration. Keep patient warm. Consult doctor if symptoms persist.

If unconscious, place in recovery position and seek medical advice.

After skin contact

Remove contaminated clothing.

Wash off with plenty of water.

Or better;

Wash with water and soap and rinse thoroughly.

If skin irritation continues, consult a doctor.

· After eye contact

Rinse opened eye for several minutes under running water. If symptoms persist, consult Oculist.

After swallowing

Rinse out mouth and then drink plenty of water.

Do not induce vomiting.

Call for medical help.

Turn a vomiting person on the side if lying on the back.

If vomiting occurs, the head should be kept low.

Information for doctor: The toxicological properties of this material have not been fully investigated.

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· Most important symptoms and effects, both acute and delayed

A description of symptoms is not present at the moment.

Danger

Harmful if swallowed.

Danger of disturbed CNS.

There are at present no indications to further acute dangers for the health.

Further health dangers cannot be excluded however.

Indication of any immediate medical attention and special treatment needed

Elemental assistance.

Decontamination.

Treat symptomatically and supportively.

5 Firefighting measures

- Extinguishing media:
- · Suitable extinguishing agents:

CO2, extinguishing powder or water fog. Fight larger fires with water fog or alcohol-resistant foam.

- For safety reasons unsuitable extinguishing agents: Water with a full water jet.
- · Special hazards arising from the substance or mixture:

Formation of toxic gases is possible during heating or in case of fire.

Can be released in case of fire:

Carbon monoxide and carbon dioxide.

Sodium oxides

Dust explosion hazard!

- · Advice for firefighters:
- · Protective equipment:

Wear self-contained breathing apparatus.

Wear full protective suit.

Additional information: Collect contaminated firefighting water separately. It must not enter drains.

6 Accidental release measures

· Personal precautions, protective equipment and emergency procedures:

Wear protective equipment. Keep unprotected persons away.

Use breathing protection against the effects of fumes/dust/aerosol.

Keep away from sources of ignition.

Avoid causing dust.

Ensure adequate ventilation

Bring persons out of danger.

· Environmental precautions:

Do not allow to enter sewing systems, water bodies, groundwater or soil.

Inform respective authorities in case product reaches water, sewage system or soil.

Methods and material for containment and cleaning up:

Avoid causing dust.

Ensure adequate ventilation.

Collect mechanically.

Clean up affected area.

May be recycled or disposed of in appropriate containers

Dispose of contaminated material as waste according to item 13.

· Reference to other sections:

See Section 7 for information on safe handling

See Section 8 for information on personal protection equipment.

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See Section 13 for information on disposal.

7 Handling and storage

- · Handling
- · Precautions for safe handling
- · Keep containers tightly closed.

Prevent formation of dust.

Ensure good ventilation/exhaustion at the workplace.

· Hygiene measures:

Keep away from foodstuffs, beverages and feed stuff.

Instantly remove any soiled and impregnated garments.

Store protective clothing separately.

Wash hands during breaks and at the end of the work.

Do not inhale dust / smoke / mist.

Avoid contact with the eyes and skin.

Do not eat, drink or smoke while working.

· Information about protection against explosions and fires:

The product is practically non-combustible.

Dust can combine with air to form an explosive mixture.

Firefighting equipment must be available.

Protect from heat.

Avoid deposition of dust.

Keep ignition sources away - Do not smoke.

Protect against electrostatic charges.

- Conditions for safe storage, including any incompatibilities
- Storage
- Requirements to be met by storerooms and containers:

Store in cool location.

Store in original container if possible.

Provide floor trough without outlet.

Prevent any penetration into the ground.

Information about storage in one common storage facility:

Store away from foodstuffs.

Do not store together with materials/products which can form dangerous chemical reactions.

See point 10: stability and reactivity.

Further information about storage conditions:

Store in cool, dry conditions in well closed containers.

Protect from heat and direct sunlight.

Store container in a well-ventilated position.

- Recommended storage temperature: < +25℃</p>
- · Specific end use(s): No further relevant information available.

8 Exposure controls/personal protection

- Additional information about design of technical systems: No further data; see item 7.
- · Control parameters
- Components with critical values that require monitoring at the workplace:

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

· Additional information: The lists that were valid during the compilation were used as basis.

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- · Exposure controls
- · Personal protective equipment
- · General protective measures:

Be sure to clean skin thoroughly after work and before breaks.

The usual precautionary measures should be adhered to in handling the chemicals.

· Breathing equipment:

If used in closed systems or well-ventilated area breathing protection is not necessary. Required when dusts are generated.



In case of brief exposure or low pollution use breathing filter apparatus. In case of intensive or longer exposure use breathing apparatus that is independent of circulating air.

Filter P2.

or

Filter P3.

· Protection of hands:



Chemical-protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation. Check protective gloves prior to each use for their proper condition.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

Preventive skin protection by use of skin-protecting agents is recommended.

Material of gloves

No material can be recommended.

Experience says that polychloroprene, nitrile rubber, butyl rubber, fluoro-caoutchouc, and polyvinyl chloride are suitable as glove materials for protection against undissolved solids.

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material cannot be calculated in advance and has therefore to be checked prior to the application.

ASK THE MANUFACTURER FOR SUITABLE MATERIAL.

· Penetration time of glove material

At the permeation time no data are present.

The penetration of the glove material is impossible with dry and not gassing solids.

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

· Not suitable are gloves made of the following materials:

Strong gloves

Leather gloves

Eye protection:



Safety glasses with side protection.

Body protection:

Wear dust tight protective clothing.

Apron,

Boots

or

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Suitable chemical protection suit.

Protective clothing should be selected specifically for the working place, depending on concentration and quantity of the hazardous substances handled. The resistance of the protective clothing to chemicals should be ascertained with the respective supplier.

9 Physical and chemical proper	ties
· Information on basic physical and cl · General Information	hemical properties
Appearance:	
Form:	Granulate
Colour:	yellowish to brownish
Smell:	No description available.
Odour threshold:	No data available
· pH-value:	No data available
· Change in condition	
Melting point/Melting range:	No data available
Boiling point/Boiling range:	No data available
· Flash point:	625℃
· Ignition temperature:	No data available
Decomposition temperature:	No data available
· Danger of explosion:	Product does not present an explosion hazard. Dust explosion hazard!
· Critical values for explosion:	
Lower:	No data available
Upper:	No data available
· Steam pressure:	No data available
· Vapour Density (air=1):	No data available
Density	No data available
· Settled apparent density	No data available
Vapour density	Not applicable.
· Evaporation rate	Not applicable.
· Solubility in / Miscibility with	
Water:	Readily soluble
· Segregation coefficient (n-octanol/w	vater): No data available
· Viscosity:	
Dynamic:	Not applicable.
Kinematic:	Not applicable.
· Solvent content:	
Organic solvents:	0,0 %
· Other information	No further relevant information available.

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10 Stability and reactivity

- · Reactivity
- · Chemical stability
- · Conditions to be avoided:

No decomposition if used and stored according to specifications.

To avoid thermal decomposition do not overheat.

Flames, sparks, electrostatic charges.

Possibility of hazardous reactions

The product is not capable of dust explosion in the form supplied; enrichment with fine dust causes risk of dust explosion.

No dangerous reactions known.

- · Conditions to avoid No further relevant information available.
- · Incompatible materials: No further relevant information available.
- Hazardous decomposition products:

Can be released in case of fire:

Carbon monoxide (CO) and carbon dioxide (CO2)

Sodium oxide

11 Toxicological information

- Information on toxicological effects
- · Acute toxicity:
- · LD/LC50 values that are relevant for classification:

Quantitative data on the toxicity of this product are not available.

- · Primary irritant effect:
- On the skin: Results from bioassays are not available (irritation possible).
- On the eye: Results from bioassays are not available (irritation possible).
- Sensitization:

Results from bioassays are not available.

No sensitizing effect known.

Sub-acute to chronic toxicity:

No indication to reproduction-endangering effect.

No indication of teratogenic activity.

No indication of mutagenic activity.

No indication of carcinogenic activity.

IARC (International Agency for Research on Cancer)

No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

Additional toxicological information:

The product shows the following dangers according to the calculation method of the General EC Classification Guidelines for Preparations as issued in the latest version:

Harmful if swallowed.

The toxicological properties of this material have not been fully investigated.

Further hazardous properties cannot be excluded.

12 Ecological information

- · Toxicity
- · Aquatic toxicity: No data available
- · Terrestrial toxicity: No data available
- Persistence and degradability No data available
- Behavior in environmental systems:
- · Bio accumulative potential: No data available

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- · Mobility in soil No data available
- · Additional ecological information:
- · AOX-indication: The product does not contribute to the AOX value of the waste water.
- General notes:

Quantitative data on the ecological effect of this product are not available.

Do not allow product to reach ground water, water bodies, sewage system or soil.

- · Results of PBT and vPvB assessment
- · PBT: Not applicable.
- · vPvB: Not applicable.
- Other adverse effects No further relevant information available.

13 Disposal considerations

- · Waste treatment methods
- · Recommendation

Must not be disposed of together with household garbage. Do not allow product to reach sewage system.

Disposal must be made according to official regulations.

· European waste catalogue

A waste code in accordance with the European Waste Catalogue (EWC) may not be assigned to this product since it admits of a classification only when the consumer uses it for some purpose. In agreement with the waste code must be determined regional waste disposal authority or company.

- Uncleansed packaging:
- · Recommendation: Disposal must be made according to official regulations.

UN-Number	
ADR, ADN, IMDG, IATA	Void
UN proper shipping name ADR, ADN, IMDG, IATA	Void
· · · ·	Void
Transport hazard class(es)	
ADR, ADN, IMDG, IATA	
Class	Void
Packing group	
ADR, IMDG, IATA	Void
Special precautions for user	Not applicable.
Transport in bulk according to Annex II of	•
MARPOL73/78 and the IBC Code	Not applicable.
Transport/Additional information:	Not dangerous according to the above specifications.
UN "Model Regulation":	-

15 Regulatory information

· Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

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16 Other information

These statements solely describe the safety demands of the product and base according to the best of our belief on our today's knowledge. They, however, do not represent any assurance towards properties of the product within the sense of liability, resp. guaranty regulations and thus are given without any obligation.

· Relevant phrases

H301 Toxic if swallowed.

R25 Toxic if swallowed.

- · Department issuing data specification sheet: Dept. QSHE
- · Contact: Mr. Dr. Hollitzer, Tel: +49 4032008284; mailto: sdb @biesterfeld.com
- · Abbreviations and acronyms:

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations

Concerning the International Transport of Dangerous Goods by Rail)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

ICAO: International Civil Aviation Organization

GHS: Globally Harmonized System of Classification and Labelling of Chemicals

LC₅₀: Lethal concentration, 50 percent

LD₅₀: Lethal dose, 50 percent

Lit.: Literature

Sources

Information of distributor.

MSDS of different manufacturers.

euSDB - Search Index for Material Safety Data Sheets

http://www.eusdb.de/

Environmental Health and Toxicology National Library of Medicine TOXNET.

http://sis.nlm.nih.gov/enviro.html

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