

## SAFETY DATA SHEET

according to Directive 67/548/EC and Regulation 1907/2906/EC as amended.

### 1. IDENTIFICATION OF THE SUBSTANCE AND OF THE COMPANY

GRAMICIDIN S . 2 HCl      Biotika a.s.  
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Tel. +421 48 4368 111 Fax +421 48 418 70 60  
contract manufacturing for  
Join Stock Company Valenta Pharmaceuticals  
(JSC Valenta Pharm)  
18/2, Generala Dorokhova street,  
Moscow, Russian Federation  
Tel. +7 (495) 933 60 80 Fax +7 (495) 933 60 81

### 2. HAZARDS IDENTIFICATION

Substance is not classified in Annex I of Directive 67/548/EC.

Prolonged or repeated exposure may cause allergic reactions in certain individuals (antibiotic).

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

Gramicidin consists of a family of antimicrobial linear polypeptides, usually obtained by extraction from tyrothricin, the complex isolated from the fermentation broth of *Aneurinibacillus migulanus*. The main component is gramicidin S, together with gramicidins A1, A2, B1, C1 and C2 in particular.

CAS:                            15207-30-4  
EC No:                        Not Available  
EC Index:                    None  
NB:                             Antibiotic.

### 4. FIRST AID MEASURES

Inhalation:                  Remove to fresh air. If breathing becomes difficult, call a physician.  
Skin contact:                Flush with copious amounts of water for at least 15 minutes. Remove contaminated clothing and shoes.  
Eyes contact:                Assure adequate flushing by separating the eyelids with fingers. Flush with copious amounts of water for at least 15 minutes.  
Ingestion:                    Wash out mouth with water provided person is conscious.

*In case of reactions described in hazards identification or other severe, immediate or persisting symptoms seek medical advice and call the nearest poison centre. Show the label and this safety data sheet.*

### 5. FIRE FIGHTING MEASURES

Extinguishing media:      Carbon dioxide, dry chemical powder or appropriate foam. Water spray. This substance may form dust and is sensitive to ignition. Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes. Emits toxic fumes under fire conditions.  
Dangerous combustion products:      CO<sub>x</sub>, NO<sub>x</sub> and other noxious gases or vapours in case of incomplete combustion.

## **6. ACCIDENTAL RELEASE MEASURES**

Wear respirator, chemical safety goggles, rubber boots and heavy rubber gloves. Sweep up, place in a bag and hold for waste disposal. Avoid raising dust. Ventilate area and wash spill site with soap water after material pick up is complete.

## **7. HANDLING AND STORAGE**

Handling: Do not breathe dust. Avoid contact with eyes, skin or clothing. Avoid prolonged or repeated exposure. Wash thoroughly after handling.  
Storage: Keep unopened in the original container.

## **8. EXPOSURE CONTROLS/PERSONAL PROTECTION**

Handle small quantities in fume hood. Safety shower and eye bath required.

Respiratory protection: Protection mask (PI)  
Hand protection: Compatible chemical-resistant gloves  
Eye protection: Chemical safety goggles

## **9. PHYSICAL AND CHEMICALS PROPERTIES**

Appearance: White or almost white, crystalline powder.  
Solubility: Practically insoluble in acetone, sparingly soluble in alcohol (1:15).

## **10. STABILITY AND REACTIVITY**

Incompatibilities: Not known.  
Hazardous combustion or decomposition products: Nature of decomposition products not known.  
Hazardous polymerisation will not occur.

## **11. TOXICOLOGICAL INFORMATION**

LD50 (oral-rat): Information not available.  
LC50 (inhalation-rat): Information not available.  
LC50 (skin-rat): Information not available.  
Prolonged or repeated exposure may cause allergic reactions in certain individuals.  
Carcinogenicity, Mutagenicity, Reproductive toxicity and Sensitisation: None identified.

**12. ECOLOGICAL INFORMATION** Not available.

## **13. DISPOSAL CONSIDERATIONS**

Incinerate in an approved facility.  
*Observe all federal state and local environmental regulations.*

**14. TRANSPORT INFORMATION** Not applicable.