



Creation Date 14-Sep-2010

Revision Date 13-Mar-2014

Revision Number 3

## SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

### 1.1. Product identifier

**Product Description:** Nystatin  
**Cat No. :** 455500000; 455500010; 455500050; 455500250  
**CAS-No** 1400-61-9  
**EC-No.** 215-749-0

### 1.2. Relevant identified uses of the substance or mixture and uses advised against

**Recommended Use** Laboratory chemicals  
**Uses advised against** No Information available

### 1.3. Details of the supplier of the safety data sheet

**Company** Acros Organics BVBA  
Janssen Pharmaceuticaaan 3a  
2440 Geel, Belgium  
**E-mail address** begel.sdsdesk@thermofisher.com

### 1.4. Emergency telephone number

For information **US** call: 001-800-ACROS-01 / **Europe** call: +32 14 57 52 11  
Emergency Number **US**:001-201-796-7100 / **Europe**: +32 14 57 52 99  
**CHEMTREC** Tel. No.**US**:001-800-424-9300 / **Europe**:001-703-527-3887

## SECTION 2: HAZARDS IDENTIFICATION

### 2.1. Classification of the substance or mixture

#### CLP Classification - Regulation (EC) No 1272/2008

##### Physical hazards

Based on available data, the classification criteria are not met

##### Health hazards

Based on available data, the classification criteria are not met

##### Environmental hazards

Based on available data, the classification criteria are not met

#### Classification according to EU Directives 67/548/EEC or 1999/45/EC

**R-phrase(s)** none

For the full text of the R-phrases and H-Statements mentioned in this Section, see Section 16

### 2.2. Label elements

#### Hazard Statements

**Precautionary Statements****2.3. Other hazards**

No information available.

## SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

**3.1. Substances**

Component	CAS-No	EC-No.	Weight %	CLP Classification - Regulation (EC) No 1272/2008	DSD Classification - 67/548/EEC
Nystatin	1400-61-9	EEC No. 215-749-0	>95	-	-

For the full text of the R-phrases and H-Statements mentioned in this Section, see Section 16

## SECTION 4: FIRST AID MEASURES

**4.1. Description of first aid measures**

<b>Eye Contact</b>	Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Obtain medical attention.
<b>Skin Contact</b>	Wash off immediately with plenty of water for at least 15 minutes. Get medical attention immediately if symptoms occur.
<b>Ingestion</b>	Do not induce vomiting. Obtain medical attention.
<b>Inhalation</b>	Move to fresh air. If breathing is difficult, give oxygen. Get medical attention immediately if symptoms occur.
<b>Protection of First-aiders</b>	No special precautions required.

**4.2. Most important symptoms and effects, both acute and delayed**

No information available

**4.3. Indication of any immediate medical attention and special treatment needed**

**Notes to Physician**                      Treat symptomatically

## SECTION 5: FIREFIGHTING MEASURES

**5.1. Extinguishing media****Suitable Extinguishing Media**

Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

**Extinguishing media which must not be used for safety reasons**

No information available.

**5.2. Special hazards arising from the substance or mixture**

Thermal decomposition can lead to release of irritating gases and vapors

**Hazardous Combustion Products**

Carbon monoxide (CO), Carbon dioxide (CO<sub>2</sub>), Nitrogen oxides (NO<sub>x</sub>).

**5.3. Advice for firefighters**

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

## SECTION 6: ACCIDENTAL RELEASE MEASURES

### 6.1. Personal precautions, protective equipment and emergency procedures

Ensure adequate ventilation. Use personal protective equipment. Avoid dust formation.

### 6.2. Environmental precautions

Should not be released into the environment. See Section 12 for additional ecological Information.

### 6.3. Methods and material for containment and cleaning up

Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid dust formation.

### 6.4. Reference to other sections

Refer to protective measures listed in Sections 8 and 13.

## SECTION 7: HANDLING AND STORAGE

### 7.1. Precautions for safe handling

Wear personal protective equipment. Ensure adequate ventilation. Avoid contact with skin, eyes and clothing. Avoid ingestion and inhalation. Avoid dust formation.

### 7.2. Conditions for safe storage, including any incompatibilities

Store in freezer. Keep container tightly closed in a dry and well-ventilated place. Store under an inert atmosphere.

### 7.3. Specific end use(s)

Use in laboratories

## SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

### 8.1. Control parameters

#### Exposure limits

List source(s):

Component	Russia	Slovak Republic	Slovenia	Sweden	Turkey
Nystatin	MAC: 1 mg/m <sup>3</sup>				

#### Biological limit values

This product, as supplied, does not contain any hazardous materials with biological limits established by the region specific regulatory bodies.

#### Monitoring methods

BS EN 14042:2003 Title Identifier: Workplace atmospheres. Guide for the application and use of procedures for the assessment of exposure to chemical and biological agents.

MDHS14/3 General methods for sampling and gravimetric analysis of respirable and inhalable dust

**Derived No Effect Level (DNEL)** No information available.

<u>Route of exposure</u>	<u>Acute effects (local)</u>	<u>Acute effects (systemic)</u>	<u>Chronic effects (local)</u>	<u>Chronic effects (systemic)</u>
Oral Dermal Inhalation				

**Predicted No Effect Concentration (PNEC)** No information available.

### 8.2. Exposure controls

#### Engineering Measures

None under normal use conditions..

#### Personal protective equipment

##### Eye Protection

Safety glasses with side-shields (European standard - EN 166)

##### Hand Protection

Protective gloves

<u>Glove material</u>	<u>Breakthrough time</u>	<u>Glove thickness</u>	<u>EU standard</u>	<u>Glove comments</u>
Natural rubber	See manufacturers recommendations	-	EN 374	(minimum requirement)
Nitrile rubber				
Neoprene				
PVC				

##### Skin and body protection

Wear appropriate protective gloves and clothing to prevent skin exposure

Inspect gloves before use.

Please observe the instructions regarding permeability and breakthrough time which are provided by the supplier of the gloves. (Refer to manufacturer/supplier for information)

Ensure gloves are suitable for the task: Chemical compatability, Dexterity, Operational conditions, User susceptibility, e.g. sensitisation effects, also take into consideration the specific local conditions under which the product is used, such as the danger of cuts, abrasion. Remove gloves with care avoiding skin contamination.

##### Respiratory Protection

No protective equipment is needed under normal use conditions.

##### Large scale/emergency use

Use a NIOSH/MSHA or European Standard EN 136 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced..  
**Recommended Filter type:** Particle filter.

##### Small scale/Laboratory use

Maintain adequate ventilation

#### Hygiene Measures

Handle in accordance with good industrial hygiene and safety practice

#### Environmental exposure controls

No information available.

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

### 9.1. Information on basic physical and chemical properties

#### Appearance

##### Physical State

Solid.

##### Odor

No information available

##### Odor Threshold

No data available

##### pH

No data available

## Nystatin

<b>Melting Point/Range</b>	No data available	
<b>Softening Point</b>	No data available	
<b>Boiling Point/Range</b>	No information available.	
<b>Flash Point</b>	No information available.	<b>Method</b> - No information available.
<b>Evaporation Rate</b>	Not applicable	Solid
<b>Flammability (solid,gas)</b>	No information available.	
<b>Explosion Limits</b>	No data available.	
<b>Vapor Pressure</b>	No data available	
<b>Vapor Density</b>	Not applicable	Solid
<b>Specific Gravity / Density</b>	No data available	
<b>Bulk Density</b>	No data available	
<b>Water Solubility</b>	practically insoluble	
<b>Solubility in other solvents</b>	No information available.	
<b>Partition Coefficient (n-octanol/water)</b>	<b>Component</b> Nystatin	<b>log Pow</b> 7.08
<b>Autoignition Temperature</b>	Not applicable	
<b>Decomposition temperature</b>	No data available	
<b>Viscosity</b>	Not applicable	Solid
<b>Explosive Properties</b>	No information available.	
<b>Oxidizing Properties</b>	No information available.	

9.2. Other information**SECTION 10: STABILITY AND REACTIVITY**10.1. Reactivity

None known, based on information available.

10.2. Chemical stability

Air sensitive. Light sensitive.

10.3. Possibility of hazardous reactions**Hazardous Polymerization  
Hazardous Reactions**Hazardous polymerization does not occur.  
None under normal processing.10.4. Conditions to avoid

Excess heat, Incompatible products, Avoid dust formation.

10.5. Incompatible materials

Strong oxidizing agents.

10.6. Hazardous decomposition productsCarbon monoxide (CO), Carbon dioxide (CO<sub>2</sub>), Nitrogen oxides (NO<sub>x</sub>).**SECTION 11: TOXICOLOGICAL INFORMATION**11.1. Information on toxicological effects**Product Information****(a) acute toxicity;**  
Oral

Based on available data, the classification criteria are not met

Nystatin

**Dermal** No data available  
**Inhalation** No data available

Component	LD50 Oral	LD50 Dermal	LC50 Inhalation
Nystatin	10 g/kg ( Rat )		

**(b) skin corrosion/irritation;** No data available

**(c) serious eye damage/irritation;** No data available

**(d) respiratory or skin sensitization;**  
**Respiratory** No data available  
**Skin** No data available

**(e) germ cell mutagenicity;** No data available

**(f) carcinogenicity;** No data available

There are no known carcinogenic chemicals in this product

**(g) reproductive toxicity;** No data available

**(h) STOT-single exposure;** No data available

**(i) STOT-repeated exposure;** No data available

**Target Organs** None known.

**(j) aspiration hazard;** Not applicable  
Solid

**Other Adverse Effects** The toxicological properties have not been fully investigated.  
**Symptoms / effects,** No information available.  
**both acute and delayed**

## SECTION 12: ECOLOGICAL INFORMATION

### 12.1. Toxicity

**Ecotoxicity effects** Contains no substances known to be hazardous to the environment or that are not degradable in waste water treatment plants

**12.2. Persistence and degradability** No information available

**12.3. Bioaccumulative potential** No information available.

Component	log Pow	Bioconcentration factor (BCF)
Nystatin	7.08	No data available

**12.4. Mobility in soil** No information available.

**12.5. Results of PBT and vPvB assessment** No data available for assessment

### 12.6. Other adverse effects

**Endocrine Disruptor Information** This product does not contain any known or suspected endocrine disruptors  
**Persistent Organic Pollutant** This product does not contain any known or suspected substance  
**Ozone Depletion Potential** This product does not contain any known or suspected substance

### SECTION 13: DISPOSAL CONSIDERATIONS

#### 13.1. Waste treatment methods

##### Waste from Residues / Unused Products

Chemical waste generators must determine whether a discarded chemical is classified as a hazardous waste. Consult local, regional, and national hazardous waste regulations to ensure complete and accurate classification.

##### Contaminated Packaging

Empty remaining contents. Dispose of in accordance with local regulations. Do not re-use empty containers.

##### European Waste Catalogue (EWC)

According to the European Waste Catalogue, Waste Codes are not product specific, but application specific

##### Other Information

Waste codes should be assigned by the user based on the application for which the product was used

### SECTION 14: TRANSPORT INFORMATION

#### IMDG/IMO

Not regulated

##### 14.1. UN number

##### 14.2. UN proper shipping name

##### 14.3. Transport hazard class(es)

##### 14.4. Packing group

#### ADR

Not regulated

##### 14.1. UN number

##### 14.2. UN proper shipping name

##### 14.3. Transport hazard class(es)

##### 14.4. Packing group

#### IATA

Not regulated

##### 14.1. UN number

##### 14.2. UN proper shipping name

##### 14.3. Transport hazard class(es)

##### 14.4. Packing group

##### 14.5. Environmental hazards

No hazards identified

##### 14.6. Special precautions for user

No special precautions required

##### 14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

Not applicable, packaged goods

### SECTION 15: REGULATORY INFORMATION

#### 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

##### International Inventories

X = listed

Component	EINECS	ELINCS	NLP	TSCA	DSL	NDSL	PICCS	ENCS	CHINA	AICS	KECL
Nystatin	215-749-0	-		-	X	-	-	-	-	X	-

##### National Regulations

Take note of Control of Substances Hazardous to Health Regulations (COSHH) 2002 and 2005 Amendment

Take note of Dir 94/33/EC on the protection of young people at work

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work

### 15.2. Chemical safety assessment

A Chemical Safety Assessment/Report (CSA/CSR) has not been conducted

## SECTION 16: OTHER INFORMATION

### Full text of R-phrases referred to under sections 2 and 3

Not applicable

### Legend

**CAS** - Chemical Abstracts Service

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

**PICCS** - Philippines Inventory of Chemicals and Chemical Substances

**IECSC** - China Inventory of Existing Chemical Substances

**KECL** - Existing and Evaluated Chemical Substances

**WEL** - Workplace Exposure Limit

**ACGIH** - American Conference of Industrial Hygiene

**DNEL** - Derived No Effect Level

**RPE** - Respiratory Protective Equipment

**LC50** - Lethal Concentration 50%

**NOEC** - No Observed Effect Concentration

**PBT** - Persistent, Bioaccumulative, Toxic

**ADR** - European Agreement Concerning the International Carriage of Dangerous Goods by Road

**IMO/IMDG** - International Maritime Organization/International Maritime Dangerous Goods Code

**OECD** - Organisation for Economic Co-operation and Development

**BCF** - Bioconcentration factor

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

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

**ENCS** - Japan Existing and New Chemical Substances

**AICS** - Australian Inventory of Chemical Substances

**NZIoC** - New Zealand Inventory of Chemicals

**TWA** - Time Weighted Average

**IARC** - International Agency for Research on Cancer

**PNEC** - Predicted No Effect Concentration

**LD50** - Lethal Dose 50%

**EC50** - Effective Concentration 50%

**POW** - Partition coefficient Octanol:Water

**vPvB** - very Persistent, very Bioaccumulative

**ICAO/IATA** - International Civil Aviation Organization/International Air Transport Association

**MARPOL** - International Convention for the Prevention of Pollution from Ships

**ATE** - Acute Toxicity Estimate

**VOC** - Volatile Organic Compounds

### Key literature references and sources for data

Suppliers safety data sheet,

Chemadvisor - LOLI,

Merck index,

RTECS

### Training Advice

Chemical hazard awareness training, incorporating labelling, Safety Data Sheets (SDS), Personal Protective Equipment (PPE) and hygiene.

**Creation Date** 14-Sep-2010

**Revision Date** 13-Mar-2014

**Revision Summary** Not applicable

**This safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006**

### Disclaimer

The information provided on this 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 guide for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered as 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 material or in any process, unless specified in the text.

**End of Safety Data Sheet**