

Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

EN

FORM-06-14-01 (V00)

Page 1/8

Publication: 16/12/2020

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

1.1 Product identifier

Product name:	Nystatin Nystatinum Nystatine Nystatine Nystatin
N° CAS:	1400-61-9
N° EC:	215-749-0

1.2 Relevant identified uses of the substance/mixture and uses advised against

Identified uses:	Active Pharmaceutical Ingredient or Excipient.
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1.3 Details of the supplier of the safety data sheet

Company:	FAC SECUNDUM ARTEM NV Oostmalsebaan 1c (unit 5) 2960 Sint-Lenaarts Belgium
Telephone:	(+32) (0)3 457 11 76
Email:	info@magis-pharma.be
Web page:	www.magis-pharma.be

1.4 Emergency telephone number

Public utility foundation:	Belgisch Antigifcentrum	Centre Antipoisons Belge
Telephone:	(+32) (0)70 245 245	(Service 24/7)
Web page:	www.antigifcentrum.be	www.centreantipoisons.be

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance/mixture

Classification according to (EC) n° 1272/2008

Not available.

2.2 Label elements

Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):	Not available.
Signal word(s):	Not available.
Hazard statements:	Not available.
Precautionary statements:	Not available.
Additional applicable label elements:	

2.3 Other hazards

Prolonged or repeated exposure may cause allergic reactions. Allergic reactions have been reported very rarely.

Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

EN

FORM-06-14-01 (V00)

Page 2/8

Publication: 16/12/2020

Revision: 16/12/2020

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MAGIS
PHARMA

NYSTATINUM

Since the absorption of nystatin from the gastro-intestinal tract is negligible, accidental ingestion causes no systemic toxicity.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name:	Nystatin
IUPAC name:	1 <i>S</i> ,15 <i>S</i> ,16 <i>R</i> ,17 <i>R</i> ,18 <i>S</i> ,19 <i>E</i> ,21 <i>E</i> ,25 <i>E</i> ,27 <i>E</i> ,29 <i>E</i> ,31 <i>E</i>)-33-[(2 <i>S</i> ,3 <i>S</i> ,4 <i>S</i> ,5 <i>S</i> ,6 <i>R</i>)-4-amino-3,5-dihydroxy-6-methyloxan-2-yl]oxy-1,3,4,7,9,11,17,37-octahydroxy-15,16,18-trimethyl-13-oxo-14,39-dioxabicyclo[33.3.1]nonatriaconta-19,21,25,27,29,31-hexaene-36-carboxylic acid
Synonyms:	Nilstat Stamycin
N° CAS:	1400-61-9
N° EC:	215-749-0
Molecular Formula:	C ₄₇ H ₇₅ NO ₁₇
Content:	Minimum 4400 IU/mg (dried substance) and minimum 5000 IU/mg (dried substance) if intended for oral administration.

3.2 Mixtures

Not applicable.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

After inhalation:	Remove to fresh air. Rest. Get medical advice/attention if you feel unwell.
After skin contact:	Remove contaminated clothing and shoes. Wash the exposed skin with mild soap and tap water. Wash contaminated clothing before reuse.
After eye contact:	Check for and remove any contact lenses. Immediately flush eyes with tap water for several minutes, keeping eyelids open. Do not use an eye ointment. Get medical advice/attention if eye irritation persists.
After ingestion:	Rinse mouth, provided person is conscious. If swallowed, seek medical advice and show this safety data sheet or label.

4.2 Most important symptoms and effects, both acute and delayed

Not available.

4.3 Indication of any immediate medical attention and special treatment needed

In all cases of doubt, or when symptoms persist, seek medical attention.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media:	Carbon dioxide, dry chemical powder, or foam as appropriate for surrounding fire and materials.
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Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

EN

FORM-06-14-01 (V00)

Page 3/8

Publication: 16/12/2020

Revision: 16/12/2020

Version: 00



MAGIS
PHARMA

NYSTATINUM

Unsuitable extinguishing media: Do not use a heavy water stream.

5.2 Special hazards arising from the substance/mixture

Under fire conditions, may produce toxic fumes of carbon monoxide, carbon dioxide and oxides of nitrogen

5.3 Advice for firefighters

Surrounding fires: Not available.

Protection against fire: Observe general rules for preventive fire protection. Do not inhale combustion gases. Do not enter fire area without proper protective equipment for firefighters, including respiratory protection.

Hazardous combustion products: Not available.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Wear suitable personal protective equipment. Avoid dust formation. Minimize direct contact with skin or eyes and prevent inhalation of dust.

For emergency responders

Wear suitable personal protective equipment. Avoid dust formation. Minimize direct contact with skin or eyes and prevent inhalation of dust.

6.2 Environmental precautions

Not available.

6.3 Methods and material for containment and cleaning up

Collect powder using vacuum equipment designed specifically for dust or use appropriate tools to put the material in a suitable waste disposal container. Avoid dust formation. Clean the contaminated surface by water / detergent and dispose according to local and regional authority requirements

6.4 Reference to other sections

Not available.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling: Avoid all unnecessary exposure. Handle in accordance with good industrial hygiene and safety procedures. Avoid generating dusts while handling the product and mixing. Wear suitable protective equipment. Wash hands after handling. Do not eat, drink and smoke in work areas.

Personal protection: Not available.

Technical protective measures: Not available.

Handling: Not available.

7.2 Conditions for safe storage, including any incompatibilities

Storage: For long term storage: Store in the original package, protected from light, at a temperature between 2 and 8 °C.

Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

EN

FORM-06-14-01 (V00)

Page 4/8

Publication: 16/12/2020

Revision: 16/12/2020

Version: 00



NYSTATINUM

Conditions for safe storage, including any incompatibilities:

Storage – away from:

For short term storage (transport purposes), for not more than 30 days from the day when the product left Antibiotice S.A.:

Store in the original package, protected from light, at a temperature below 25 °C.

Strong oxidizing agents

7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Occupational exposure limits: Not required

8.2 Exposure controls

Appropriate engineering control

No special ventilation requirements are normally necessary for this product. However, make sure that the work environment remains clean and that dusts are minimized.

Individual protection measures

Eye/face protection: If dust occurs: chemical goggles or safety glasses.

Skin protection: Wear suitable protective clothing

Hand protection: Protective gloves.

Respiratory protection: No special protective equipment required. If dust occurs: dust mask (class P1).

Thermal hazards: Not determined.

Environmental exposure control

Not available.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance: Solid, Yellow or slightly brownish powder, hygroscopic

Odour: Suggestive of cereals

Odour threshold: Not available.

pH: Between 6.0 and 8.0

Melting/freezing point: Gradually decomposition above 160 °C, without melting by 2500 °C

Initial boiling point: Not available.

Boiling range: Not available.

Flash point: Not available.

Evaporation rate: Not available.

Flammability (solid/gas): Not available.

Upper/lower flammability or explosive limits: Not available.

Vapour pressure: Not available.

Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

EN

FORM-06-14-01 (V00)

Page 5/8

Publication: 16/12/2020

Revision: 16/12/2020

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MAGIS
PHARMA

NYSTATINUM

Vapour density:	Not available.
Relative density:	Not available.
Solubility:	Freely soluble in dimethylformamide and in dimethyl sulphoxide, slightly soluble in methanol, practically insoluble in alcohol.
Solubility in water:	Practically insoluble in water,
Partition coefficient (n-octanol/water):	log P octanol / water: 7.08
Auto-ignition temperature:	Not available.
Decomposition temperature:	Not available.
Viscosity:	Not available.
Explosive properties:	Not available.
Oxidising properties:	Not available.

9.2 Other information

Not available.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

Stable under normal conditions.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

None under normal conditions. Hazardous polymerization: Will not occur.

10.4 Conditions to avoid

Heat. Light. Moisture. Air.

10.5 Incompatible materials

Materials to avoid: Strong oxidizers.

10.6 Hazardous decomposition products

Hazardous combustion products: carbon monoxide, carbon dioxide, nitrogen oxides.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity:	Nystatin is not absorbed from the gastrointestinal tract and following topical administration to intact skin or mucous membranes.
Skin corrosion/irritation:	Not available.
Serious eye damage/irritation:	Not available.
Respiratory/skin sensitisation:	Not available.
Germ cell mutagenicity:	Not available.
Carcinogenicity:	Not available.
Reproductive toxicity:	Not available.

Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

EN

FORM-06-14-01 (V00)

Page 6/8

Publication: 16/12/2020

Revision: 16/12/2020

Version: 00



NYSTATINUM

Summary of evaluation of the CMR properties:	Not available.
STOT-single exposure:	Not available.
STOT-repeated exposure:	Not available.
Aspiration Hazard:	Not available.
Other:	Not available.

11.2 Additional information on potential adverse human health effects and symptoms

Eye contact:	Not available.
Skin contact:	Not available.
Inhalation:	Not available.
Ingestion:	Not available.
Aspiration:	Not available.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Quantitative data on the ecological effect of this product are not available. No ecological damage caused by this product has been reported to date. Observe local environmental regulations.

12.2 Persistence and degradability

Not available.

12.3 Bioaccumulative potential

Log Pow 7.08 at 20°C

12.4 Mobility in soil

Not available.

12.5 Results of PBT and vPvB assessment

Not available.

12.6 Other adverse effects

Not available.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Dispose of this material and its container at special waste collection point. Incinerate in an approved facility. Dispose in a safe manner in accordance with local/national regulations

SECTION 14: TRANSPORT INFORMATION

Transport information according to ADR/RID/IMDG/ICAO/IATA

14.1 UN Number

ADR/ RID(Land),IMDG(Sea),
IATA/ICAO (Air) : No dangerous good in sense of transport regulations.

14.2 UN proper shipping name

Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

EN

FORM-06-14-01 (V00)

Page 7/8

Publication: 16/12/2020

Revision: 16/12/2020

Version: 00



NYSTATINUM

ADR/ RID(Land),IMDG(Sea),
IATA/ICAO (Air) : No dangerous goods.

14.3 Transport hazard class(es)

ADR/ RID(Land),IMDG(Sea),
IATA/ICAO (Air) : No dangerous goods.

14.4 Packing group

ADR/ RID(Land),IMDG(Sea),
IATA/ICAO (Air) : No dangerous goods.

14.5 Environmental hazards

ADR/ RID(Land),IMDG(Sea),
IATA/ICAO (Air) : Other information: No supplementary information available.

14.6 Special precautions for user

Not available.

14.7 Transport in bulk according to annex II of Marpol and the IBC Code

Not available.

14.8 Additional transport information

Not available.

SECTION 15: REGULATORY INFORMATION

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

Hazard symbol: Not available.

Risk phrases: Not available.

Safety phrases: Not available.

15.2 Chemical safety assessment

Not available.

SECTION 16: OTHER INFORMATION

16.1 Changes since the previous version

Not applicable.

16.2 Abbreviations and acronyms used

ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road

CAS: Chemical Abstracts Service (division of the American Chemical Society)

EC (number): European Community (number)

IATA: International Air Transport Association

ICAO: International Civil Aviation Organization

IMDG: International Maritime Code for Dangerous Goods

IUPAC: International Union of Pure and Applied Chemistry

PBT: Persistent, Bioaccumulative and Toxic substance

Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

EN

FORM-06-14-01 (V00)

Page 8/8

Publication: 16/12/2020

Revision: 16/12/2020

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NYSTATINUM

RID:	Regulations Concerning the International Transport of Dangerous Goods by Rail
STOT:	Specific Target Organ Toxicity
UN (number):	United Nations (number)
vPvB:	very Persistent and very Bioaccumulative

16.3 Key literature references/sources for data

European Chemicals Agency.

<https://www.echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database/>

16.4 Method of classification in case of mixture

Not applicable.

16.5 Relevant Hazard statements and/or precautionary statements

For information on hazard and/or precautionary statements refer to section 2 up to and including section 15.

16.6 Training advisement

Not available

16.7 Notice for user(s)

The information provided in this MSDS has been established in accordance with Commission Regulation (EU) 2015/830 of 28 May 2015, amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council, on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing the European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94, as well as Council Directive 76/769/EEC and Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC of the Commission.

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16.8 Department issuing MSDS

Quality Department

FAC SECUNDUM ARTEM NV

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