

# Nystatin

## Safety Data Sheet

according to Regulation (EU) 2015/830

Date of issue: 10/05/2011 Revision date 16/03/2018

Supersedes 05/08/2011

**N0138**

Version: 2.0

### SECTION 1: Identification of the substance/mixture and of the company/undertaking

#### 1.1. Product identifier

Product form : Substance  
 Trade name : Nystatin  
 EC-No. : 215-749-0  
 CAS-No. : 1400-61-9  
 Product code : N0138  
 Formula : C<sub>47</sub>H<sub>75</sub>NO<sub>17</sub>  
 Synonyms : Nystattinum micronisatum  
 Product group : Raw material

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

##### 1.2.1. Relevant identified uses

Main use category : Professional use  
 Industrial/Professional use spec : For professional use only. Duchefa Biochemie B.V. products are intended only for "in vitro laboratory" research purposes.

##### 1.2.2. Uses advised against

No additional information available

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

##### Supplier

Duchefa Biochemie B.V.  
 A. Hofmanweg 71  
 2031 BH Haarlem - The Netherlands  
 T +31(0)23-5319093 - F +31(0)23-5318027  
[info@duchefa.nl](mailto:info@duchefa.nl)

#### 1.4. Emergency telephone number

Emergency number : Supplier contact information:  
 +31(0)23-5319093 (M-F 09:00-17:00)  
 +31(0)6-30109355 (outside office hours)

Organisation/Company	Address	Comment
World Health Organization world directory of poison centres	<a href="http://apps.who.int/poisoncentres/">http://apps.who.int/poisoncentres/</a>	Consult website for a local poison centre

### SECTION 2: Hazards identification

#### 2.1. Classification of the substance or mixture

##### Classification according to Regulation (EC) No. 1272/2008 [CLP]

Not classified

##### Adverse physicochemical, human health and environmental effects

No additional information available

## 2.2. Label elements

### Labelling according to Regulation (EC) No. 1272/2008 [CLP]

No labelling applicable

## 2.3. Other hazards

No additional information available

## SECTION 3: Composition/information on ingredients

### 3.1. Substances

Comments : Content: > 5000 IU/mg

Name	Product identifier	%
Nystatin	(CAS-No.) 1400-61-9 (EC-No.) 215-749-0	100

Full text of H-statements: see section 16

### 3.2. Mixtures

Not applicable

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

First-aid measures general : Seek medical attention if ill effect or irritation develops.  
First-aid measures after inhalation : Assure fresh air breathing  
Allow the victim to rest.  
First-aid measures after skin contact : Wash skin with mild soap and water.  
First-aid measures after eye contact : Rinse with water.  
First-aid measures after ingestion : Rinse mouth  
Seek medical attention if ill effect or irritation develops.

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

Symptoms/effects : Not expected to present a significant hazard under anticipated conditions of normal use.

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

No additional information available

## SECTION 5: Firefighting measures

### 5.1. Extinguishing media

Suitable extinguishing media : Foam  
Dry powder  
Water spray.  
Unsuitable extinguishing media : Do not use a heavy water stream.

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

Hazardous decomposition products in case of fire : When exposed to heat, may decompose liberating hazardous gases  
- COx  
- NOx.

### 5.3. Advice for firefighters

- Firefighting instructions : Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Prevent fire fighting water from entering the environment.
- Protection during firefighting : Do not enter fire area without proper protective equipment, including respiratory protection.

## SECTION 6: Accidental release measures

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

#### 6.1.1. For non-emergency personnel

No additional information available

#### 6.1.2. For emergency responders

- Protective equipment : Equip cleanup crew with proper protection. In case of inadequate ventilation wear respiratory protection.

### 6.2. Environmental precautions

Prevent entry to sewers and public waters.

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

- Methods for cleaning up : On land, sweep or shovel into suitable containers. Minimize generation of dust.

### 6.4. Reference to other sections

Reference to other sections (8, 13).

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

- Precautions for safe handling : Handle in accordance with good industrial hygiene and safety procedures.

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

- Storage conditions : Keep only in the original container in a cool, well-ventilated place  
Keep container closed when not in use  
Store in a dry place.  
Store at room temperature.

- Storage temperature : 15 - 25 °C

### 7.3. Specific end use(s)

For professional use only. Duchefa Biochemie B.V. products are intended only for "in vitro laboratory" research purposes.

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

No additional information available

### 8.2. Exposure controls

#### Personal protective equipment:

Avoid all unnecessary exposure.

#### Hand protection:

Type	Material	Permeation	Thickness (mm)	Standard
Gloves	Nitrile rubber (NBR)	6 (> 480 minutes)	0,11	EN 374

**Eye protection:**

Chemical goggles or safety glasses

**Skin and body protection:**

Wear suitable protective clothing

**Respiratory protection:**

Wear appropriate mask. Dust production: dust mask with filter type P1

## SECTION 9: Physical and chemical properties

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

Physical state	: Solid
Appearance	: Powder.
Molecular mass	: 926,1 g/mol
Colour	: Yellow-brown.
Odour	: odourless.
Odour threshold	: No data available
pH	: No data available
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: > 160 °C
Freezing point	: No data available
Boiling point	: No data available
Flash point	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Flammability (solid, gas)	: No data available
Vapour pressure	: No data available
Relative vapour density at 20 °C	: No data available
Relative density	: No data available
Solubility	: Poorly soluble in water Soluble in : DMSO.
Log Pow	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: No data available
Oxidising properties	: No data available
Explosive limits	: No data available

### 9.2. Other information

No additional information available

### SECTION 10: Stability and reactivity

#### 10.1. Reactivity

Stable under normal conditions of storage, handling and use.

#### 10.2. Chemical stability

Stable under normal conditions.

#### 10.3. Possibility of hazardous reactions

No additional information available

#### 10.4. Conditions to avoid

Direct sunlight

Extremely high or low temperatures.

#### 10.5. Incompatible materials

Strong oxidizers.

#### 10.6. Hazardous decomposition products

When heated to decomposition, emits dangerous fumes:

- COx

- NOx.

### SECTION 11: Toxicological information

#### 11.1. Information on toxicological effects

Acute toxicity : Not classified

Nystatin (1400-61-9)	
LD50 oral rat	10000 mg/kg
LD50 oral	8000 mg/kg (mouse)

Skin corrosion/irritation : Not classified

Additional information : Based on available data, the classification criteria are not met

Serious eye damage/irritation : Not classified

Additional information : Based on available data, the classification criteria are not met

Respiratory or skin sensitisation : Not classified

Additional information : Based on available data, the classification criteria are not met

Germ cell mutagenicity : Not classified

Based on available data, the classification criteria are not met

Carcinogenicity : Not classified

Additional information : Based on available data, the classification criteria are not met

Reproductive toxicity : Not classified

Additional information : Based on available data, the classification criteria are not met

STOT-single exposure : Not classified

Additional information : Based on available data, the classification criteria are not met

STOT-repeated exposure : Not classified

Additional information : Based on available data, the classification criteria are not met

Aspiration hazard : Not classified

Additional information : Based on available data, the classification criteria are not met

Other information : See actual entry in RTECS for complete information: RF5950000.

## SECTION 12: Ecological information

### 12.1. Toxicity

No additional information available

### 12.2. Persistence and degradability

Nystatin (1400-61-9)	
Persistence and degradability	Not established.

### 12.3. Bioaccumulative potential

Nystatin (1400-61-9)	
Bioaccumulative potential	Not established.

### 12.4. Mobility in soil

No additional information available

### 12.5. Results of PBT and vPvB assessment

No additional information available

### 12.6. Other adverse effects

Additional information : Avoid release to the environment.

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

Product/Packaging disposal recommendations : Dispose in a safe manner in accordance with local/national regulations.

Ecology - waste materials : Avoid release to the environment.

## SECTION 14: Transport information

In accordance with ADR / IATA / IMDG

ADR	IMDG	IATA
<b>14.1. UN number</b>		
Not regulated	Not regulated	Not regulated
<b>14.2. UN proper shipping name</b>		
Not regulated	Not regulated	Not regulated
Not regulated	Not regulated	Not regulated
<b>14.3. Transport hazard class(es)</b>		
Not regulated	Not regulated	Not regulated
Not regulated	Not regulated	Not regulated
<b>14.4. Packing group</b>		
Not regulated	Not regulated	Not regulated
<b>14.5. Environmental hazards</b>		
Not regulated	Not regulated	Not regulated
No supplementary information available		

**14.6. Special precautions for user****Overland transport**

Not regulated

**- Transport by sea**

Not regulated

**- Air transport**

Not regulated

**14.7. Transport in bulk according to Annex II of Marpol and the IBC Code**

Not applicable

**SECTION 15: Regulatory information****15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture****15.1.1. EU-Regulations**

No REACH Annex XVII restrictions

Nystatin is not on the REACH Candidate List

Nystatin is not on the REACH Annex XIV List

**15.1.2. National regulations**

Ensure all national/local regulations are observed.

**Germany**

Reference to AwSV

: Water hazard class (WGK) 1, low hazard to waters

12th Ordinance Implementing the Federal Immission Control Act - 12.BImSchV

: Is not subject of the 12. BImSchV (Hazardous Incident Ordinance)

**Netherlands**

SZW-lijst van kankerverwekkende stoffen

: The substance is not listed

SZW-lijst van mutagene stoffen

: The substance is not listed

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Borstvoeding

: The substance is not listed

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Vruchtbaarheid

: The substance is not listed

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Ontwikkeling

: The substance is not listed

**15.2. Chemical safety assessment**

No chemical safety assessment has been carried out

**SECTION 16: Other information**

Indication of changes:

1.1	EC-No.	Added	
1.4	Emergency telephone	Modified	Added additional information
8.2	Hand protection	Modified	Specified material, thickness, et cetera of gloves

Abbreviations and acronyms:

ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
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# Nystatin

## Safety Data Sheet

**N0138**

according to Regulation (EU) 2015/830

ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
BCF	Bioconcentration factor
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008
EC50	Median effective concentration
IARC	International Agency for Research on Cancer
IATA	International Air Transport Association
IMDG	International Maritime Dangerous Goods
LC50	Median lethal concentration
LD50	Median lethal dose
LOAEL	Lowest Observed Adverse Effect Level
NOAEC	No-Observed Adverse Effect Concentration
NOAEL	No-Observed Adverse Effect Level
NOEC	No-Observed Effect Concentration
OECD	Organisation for Economic Co-operation and Development
PBT	Persistent Bioaccumulative Toxic
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
SDS	Safety Data Sheet

Data sources : REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Other information : REACH Disclaimer:  
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