

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

Product name: C*Pharm Mannidex 16700 / Mannitol

Version	Update date	MSDS No:	Date of last issue: -
1.0	31.08.2021	300000017001	First release date: 31.08.2021

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

1.1 Product identifier:

Trade name: C*PharmMannidex16700
Identifier: 69-65-8
Bar code: 713053
Composition for the label / Other names: Mannitol

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

Use of the Substance/Mixture: Chemical substance

1.3 Details of the supplier of the safety data sheet

Company : CCEU Sp. z o.o.
ul. Ostatnia 45
PL 60-102 Poznan

Telephone : +48 888-666-474

Email address to the person responsible for MSDS : reach@cristalchem.com

Emergency telephone number:
Clinical Department of Toxicology : +48 12 411 99 99

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SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

General risk

The product is not classified as hazardous in accordance with the applicable regulations

Health hazards

Not applicable

Physical threats

Not applicable

Environmental hazards

Not applicable

2.2 Label elements

Hazard indication pitogram (s):

Signal word:

The signal word is not required

2.3 Other dangers

Dusts can form explosive mixtures with air.

The substance does not meet the PBT or vPvB criteria in accordance with Annex XIII of the Regulation (EC) No. 1907/2006.

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SECTION 3: COMPOSITION / INFORMATION ON INGREDIENTS

3.1 Substances

Substance	CAS	WE	Index number
Mannitol	69-65-8	200-711-8	Not applicable

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

Inhalation

Take the injured person to fresh air. If disturbing symptoms occur, ensure medical assistance.

Skin contact

Wash off with soap and water. Seek medical attention immediately in the event of disturbing symptoms.

Contact with eyes

Wash off immediately with plenty of water. Remove contact lenses. Seek medical attention immediately in the event of disturbing symptoms

Consumption

Provide medical assistance.

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4.2 The most important acute and delayed symptoms and effects of exposure

Effects and Symptoms:

Dusts may cause mechanical irritation, eye irritation, irritation of the respiratory tract.

4.3 Indication of any immediate medical aid and special treatment of the sufferer

Symptomatic treatment.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Extinguishing media

Water, water mist, foam, dry powder, carbon dioxide (CO₂)

5.2 Special hazards related to the substance or mixture

Dusts can form explosive mixtures with air.

Avoid generating dust.

5.3 Information for fire brigades

Use self-contained breathing apparatus and full protective clothing.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Use personal protective equipment. Avoid generating dust. Dusts can form explosive mixtures with air. Prevent unauthorized persons from entering the danger zone.

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6.2 Environmental precautions

Prevent from spreading to or entering drains, water drains, soil.

6.3 Methods and materials preventing the spread of contamination and used for removing contamination

Collect the spilled product mechanically to a closed container. Forward for removal / liquidation.

6.4 Reference to other sections

Information on suitable personal protective equipment is given in section 8.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Avoid dust formation. Use in accordance with the principles of occupational health and safety. Take precautionary measures to prevent the formation of static electricity. Use proper grounding procedures. Wash hands before each break and after finishing work. Do not eat, drink or smoke in the application area. Remove and wash contaminated clothing before re-use.

7.2 Conditions for safe storage, including any reciprocal information

Incompatibilities

Store in tightly closed containers. Store in a dry place.

Store in a dry place. Store away from oxidants..

7.3 Specific end use (s)

No data available.

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SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1 Control parameters

Value DNEL

Comment

DNEL values have not been determined for this product

Value PNEC

Comment

PNEC values have not been determined for this product

The highest permissible concentrations

Comment

NDS value has not been determined for this product

NDS in accordance with the MRPIPS Regulation of June 12, 2018, Journal of Laws No. 2018, item 1286 as amended.

Biological limit values

Comment

No data available

Recommended monitoring procedures

Regulation of the Minister of Health of February 2, 2011 on tests and measurements of factors harmful to health in the work environment (Journal of Laws 2011, No. 33, item 166)

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8.2 Exposure controls

Technical control measures

Provide adequate ventilation.

Individual protection measures

Other protective equipment:

Workwear

Legislative references

Personal protective equipment should meet the requirements of the Regulation of the Minister of Economy of December 21, 2005 on the essential requirements for personal protective equipment (Journal of Laws No. 259, item 2173).

General recommendations

Do not inhale the dust. Do not eat, drink or smoke while using the product. Wash hands before meals and at the end of work. Remove and wash contaminated clothing before re-use.

Environmental exposure controls

Avoid release to the environment.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

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9.1 Information on basic physical and chemical properties

State of aggregation	Powder		
Appearance	White	Crystalline	
Odor Threshold:			
Smell:	No smell	Not applicable	
Melting point / freezing point:	166°C		
Boiling point or initial Boiling point and range Boiling point:	Not applicable		

Flammability of materials:	No data available		
Lower and upper explosion limits:	No data available		
Flash-point:	Not applicable		
Temperature of self-ignition:	No data available		
Decomposition temperature:	No data available		
pH:	5 - 7		
Kinematic viscosity:	No data available		
Solubility:	Water	220 g/l	20°C
Partition coefficient: n-octanol / water	No data available		
Vapor pressure:	Not applicable		
Relative vapor density:	Not applicable		

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9.2 Other informations

Information on the physical hazard classes:	No data available
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SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

No data available

10.2 Chemical stability

Stable under normal conditions

10.3 Possibility of hazardous reactions

Dust can form an explosive mixture with air. There is no hazardous polymerization.

10.4 Conditions to Avoid

Avoid dust formation.

10.5 Incompatible materials

Strong oxidizers.

10.6 Hazardous decomposition products

There are no known hazardous decomposition products.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on the hazard classes defined in Regulation (EC) No 1272/2008

Acute toxicity by oral route

No data available.

Acute dermal toxicity : No data available.

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Acute inhalation toxicity

No data available.

Toxicity by other routes of administration

No data available.

Corrosive / irritating effect on the skin

Dusts can cause mechanical irritation.

Serious eye damage / eye irritation

Dusts can cause mechanical irritation.

Skin sensitization

There is no known sensitizing effect.

Mutagenic effect on reproductive cells

Summary

No data available

Carcinogenic effect

Summary

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

No component of this product present at levels greater than or equal to 0.1% is identified as a potential carcinogen ACGIH

No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP

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No component of this product present at levels greater than or equal to 0.1% has identified OSHA as a potential carcinogen

Harmful effect on reproduction

Summary

No data available

Toxic effect on target organs - single exposure

Summary

No data available

Toxic effect on target organs - repeated exposure

Summary

No data available

Aspiration hazard

No data available

Information on likely routes of exposure

Contact with eyes.

Symptoms related to the physical, chemical and toxicological characteristics

No data available

Delay, immediate and chronic effects from short and long-term exposure

Dusts can cause mechanical irritation.

Irritation of the respiratory tract.

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11.2 Information about other threats

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Summary

No data available

12.2 Persistence and degradability

Summary

Biodegradable

12.3 Bioaccumulative potential

Summary

Biodegradable

12.4 Mobility in soil

Summary

No data available

12.5 Results of PBT and vPvB assessment

The substance does not meet the PBT or vPvB criteria according to Annex XIII of the Regulation (EC) No. 1907/2006.

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12.6 Endocrine disrupting properties

12.7 Other harmful effects

SECTION 13: HANDLING OF WASTES

13.1 Waste neutralization methods

Comply with the following regulations:

The Act of 14 December 2012 on waste (Journal of Laws of 2013, item 21), as amended.

Act of 13 June 2013 on the management of packaging and packaging waste (Journal of Laws 2013, item 888).

Destroy in accordance with applicable waste disposal regulations.

SECTION 14: TRANSPORT INFORMATION

14.1 UN number or ID identification number

Transport type	UN No
ADR	N/A
RID	N/A
IMDG	N/A
ICAO	N/A
ADN	N/A

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14.2 UN proper shipping name

Transport type	UN proper shipping name
ADR	It is not subject to transport regulations
RID	It is not subject to transport regulations
IMDG	It is not subject to transport regulations
ICAO	It is not subject to transport regulations
ADN	It is not subject to transport regulations

14.3 Transport hazard class (es)

Transport type:	Transport hazard class:	Classification code:	Hazard identification number:	Tunnel restriction code:	Warning sticker number:
ADR	Not applicable	Not applicable	Not applicable	-	Not applicable
RID	Not applicable	Not applicable	Not applicable	-	Not applicable
IMDG	Not applicable				Not applicable
ICAO	Not applicable				Not applicable
ADN	Not applicable				Not applicable

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14.4 Packing group

Transport type:	Packing group:
ADR	Not applicable
RID	Not applicable
IMDG	Not applicable
ICAO	Not applicable
ADN	Not applicable

14.5 Environmental hazards

The product does not pose a threat to the environment in accordance with the criteria of the UN Model Regulations.

14.6 Special precautions for users

No data available

14.7 Sea transport in bulk in accordance with IMO instruments

No data available

SECTION 15: REGULATORY INFORMATION

15.1 It prescribes safety, health and environmental protection laws specific to a substance or mixture

Regulation (EC) No. 1907/2006 of the European Parliament and of the Council of 18 December 2006 on REACH as amended

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Regulation of the European Parliament (EC) No. 1272/2008 of December 16, 2008. on classification, labeling and packaging of substances and mixtures, amending Directives 67/548 / EEC and 1999/45 / EC and amending Regulation (EC) No 1907/2006 as amended

Act of January 17, 2018 on chemical substances and their mixtures (Journal of Laws 2018, item 143)

15.2 Chemical safety assessment

Not applicable

SECTION 16: OTHER INFORMATION

Changes compared to the previous version

Not applicable

Explanation of abbreviations and acronyms used in the safety data sheet

STOT RE – Specific target organ toxicity - repeated exposure, Category 1

Asp. Tox. – Aspiration hazard

Aquatic Acute – Hazardous to the aquatic environment, acute hazard

Aquatic Chronic – Hazardous to the aquatic environment, chronic hazard

Ozone – Hazardous for the ozone layer

Lact. – Effects on or via lactation

NDS The highest acceptable concentration

NDSch Maximum permissible instantaneous concentration

NDSP Maximum permissible ceiling concentration

vPvB (substancja) Very persistent and very bioaccumulative

PBT (substancja) Persistent, bioaccumulative and toxic

PNEC Predicted No Effect Concentration

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DNEL Derived no effect concentration level

LD50 Lethal concentration at which 50% of the tested animals die

LC50 Lethal concentration at which 50% of the tested animals die

LOEC The lowest concentration producing an observable effect

NEOL The highest level at which no effects are observed

NOEC The highest concentration at which no effects are observed

ECX Effective concentration where X% change is observed, eg reduction in growth or speed growth

ADR European agreement on the international carriage of goods by road dangerous

ADN European agreement concerning the international carriage of goods by road

Dangerous inland waterways

RID Regulations for the international carriage of dangerous goods by rail

IMDG International Maritime Code for Dangerous Goods

ICAO / IATA International Air Transport Association

UVCB Substances of unknown or variable composition, complex reaction products or materials

Biological

Expl. Explosive

Flam. Gas. Flammable gas

Flam. Aerosol Flammable aerosol

Ox. Gas Oxidising gas

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Press. Gas Gas under pressure

Flam. Liq. Flammable liquid

Flam. Salt. Pyrophoric solid

Self-react. Self-reactive substance or mixture

Pyr. Liq. Liquid pyrophoric substance

Pyr. Salt. Pyrophoric solid

Self-heat A self-heating substance or mixture

Water-react. Substance or mixture which in contact with water liberates a flammable gas

Ox. Liq. Oxidising liquid

Ox. Salt. Oxidising solid

Org. Perox. Organic peroxide, type A

Underworld. Corr. Substance or mixture corrosive to metals

Acute Tox. Acute toxicity

Skin Corr Corrosive to skin

Skin Irrit. Irritating effect on the skin

Resp. Meaning. Respiratory sensitization

Skin Sens. Skin sensitization

Muta. Mutagenic effect on reproductive cells, category 1A

Carc. Carcinogenicity

Repr. Reproductive toxicity, category 1A

STOT SE Toxic effect on target organs

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References to key literature and data sources

This safety data sheet has been prepared on the basis of the provided safety data sheet
By the manufacturer and / or online databases and applicable regulations.

Recommendations for any indicated employee training

People involved in the marketing of the product should be trained in the field
proceedings,
Safety and hygiene.

List of hazard statements and conditions of safe use

Not applicable

The product is not classified as hazardous in accordance with the applicable regulations
regulations

Other informations

The product is exempt from registration under Reach (Regulation (EC)
1907/2006

Based on Annex IV or V. The information contained in the safety data sheet applies to
the product as it is delivered.

The data contained in the safety data sheet are based on our current knowledge and experience and
they describe

Product in terms of safety requirements.

These data can in no case be considered as a description of the quality of the goods (product
specification).



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