

SAFETY DATA SHEET

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**SAFETY DATA SHEET**

Revision Date: 24.04.2019

Print Date: 18.06.2020

SDS Number: 000000298494

Version: 1.0

Conforms to EU Regulation 1907/2006/EC as amended. - SDSGHS_DE

SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1 Product identifier**

Trade name : Benecel™ ME 233 P, Art.-Nr. 2440 600

Substance name : BENECEL ME 233 P PHARM

Substance No.

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

Recommended use : Pharmaceutical

1.3 Details of the supplier of the safety data sheet

Deffner & Johann GmbH
 P.O. Box 8619
 DE-97520 Röthlein
 Netherlands

info@deffner-johann.de

1.4 Emergency telephone number

+49-9723-9350-0, (Mo-Fr 08:00-15:00), or contact
 your local emergency telephone number at 112

SECTION 2: Hazards identification**2.1 Classification of the substance or mixture****Classification (REGULATION (EC) No 1272/2008)**

Not a hazardous substance or mixture.

2.2 Label elements**Labelling (REGULATION (EC) No 1272/2008)**

Not a hazardous substance or mixture.

Precautionary statements : **Prevention:**



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Keep dust/air mixtures away from ignition sources.

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Additional advice

No information available.

SECTION 3: Composition/information on ingredients

3.1 Substances

Chemical nature : organic

Hazardous components

No hazardous ingredients

SECTION 4: First aid measures

4.1 Description of first aid measures

- General advice : No hazards which require special first aid measures.
- If inhaled : If breathed in, move person into fresh air.
If unconscious, place in recovery position and seek medical advice.
If symptoms persist, call a physician.
- In case of skin contact : First aid is not normally required. However, it is recommended that exposed areas be cleaned by washing with soap and water.
- In case of eye contact : Remove contact lenses.
Protect unharmed eye.
- If swallowed : Do not give milk or alcoholic beverages.
Never give anything by mouth to an unconscious person.
If symptoms persist, call a physician.



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4.2 Most important symptoms and effects, both acute and delayed

Symptoms : Signs and symptoms of exposure to this material through breathing, swallowing, and/or passage of the material through the skin may include:
stomach or intestinal upset (nausea, vomiting, diarrhea)
irritation (nose, throat, airways)

4.3 Indication of any immediate medical attention and special treatment needed

Treatment : No hazards which require special first aid measures.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Water spray
Foam

5.2 Special hazards arising from the substance or mixture

Hazardous combustion products : Carbon dioxide (CO₂)
Carbon monoxide
Chlorine compounds
Sodium oxides
Hydrogen chloride gas

5.3 Advice for firefighters

Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.

Specific extinguishing methods : Product is compatible with standard fire-fighting agents.

Further information : Standard procedure for chemical fires.

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SECTION 6: Accidental release measures**6.1 Personal precautions, protective equipment and emergency procedures**

Personal precautions : Avoid dust formation.
 Avoid breathing dust.
 Material can create slippery conditions.
 Persons not wearing protective equipment should be excluded from area of spill until clean-up has been completed.
 Comply with all applicable federal, state, and local regulations.

6.2 Environmental precautions

Environmental precautions : Prevent further leakage or spillage if safe to do so.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Pick up and arrange disposal without creating dust.
 Keep in suitable, closed containers for disposal.

6.4 Reference to other sections**SECTION 7: Handling and storage****7.1 Precautions for safe handling**

Advice on safe handling : Avoid dust formation.
 Ensure all equipment is electrically grounded and bonded before beginning transfer operations.
 The material can accumulate static charge and can therefore cause electrical ignition of flammable atmospheres.
 Smoking, eating and drinking should be prohibited in the application area.
 For personal protection see section 8.
 Maintain good housekeeping. Do not permit dust layers to accumulate, for example, on floors, ledges, and equipment, in order to avoid any potential for dust explosion hazards.

Advice on protection against fire and explosion : Take measures to prevent the build up of electrostatic charge.
 Provide appropriate exhaust ventilation at places where dust is formed.

Hygiene measures : Avoid breathing dust.



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7.2 Conditions for safe storage, including any incompatibilities

- Requirements for storage areas and containers : No smoking.
- Advice on common storage : No materials to be especially mentioned.
- Storage class (TRGS 510) : 11, Combustible Solids
- Other data : Keep in a dry place. No decomposition if stored and applied as directed.

7.3 Specific end use(s)

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Contains no substances with occupational exposure limit values.

8.2 Exposure controls

Engineering measures

Provide appropriate exhaust ventilation at places where dust is formed. General room ventilation should be adequate for normal conditions of use. However, if unusual operating conditions exist, provide sufficient mechanical (general and/or local exhaust) ventilation to maintain exposure below exposure guidelines (if applicable) or below levels that cause known, suspected or apparent adverse effects.

Personal protective equipment

Eye protection : Safety glasses
Use eye protection according to EN 166.

Hand protection
Material : butyl-rubber
Break through time : 480 min
Glove thickness : > 0,5 mm

Remarks : The exact break through time can be obtained from the protective glove producer and this has to be observed. Gloves should be discarded and replaced if there is any indication of degradation or chemical breakthrough.

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The selected protective gloves have to satisfy the specifications of Regulation (EU) 2016/425 and the standard EN 374 derived from it.

Skin and body protection : Wear as appropriate:
Safety shoes

Protective clothing complying with EN 13688.
Safety shoes complying with EN ISO 20345.

Respiratory protection : In the case of dust or aerosol formation use respirator with an approved filter within the capabilities of the respirator/filter combination.

Where concentrations are above recommended limits or are unknown, or a cartridge type respirator is not adequate, wear a positive-pressure supplied-air respirator.

Respiratory protection complying with EN 136.
Respiratory protection complying with EN 140.
Respiratory protection complying with EN 14387.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance : granules, powder

Colour : off-white

Odour : odourless

Odour Threshold : No data available

pH : 5,0 - 8,5
Concentration: 2 %
(as aqueous solution)

Melting point/freezing point : No data available

Boiling point/boiling range : No data available

Flash point : Not applicable

Evaporation rate : No data available

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Flammability (solid, gas) : No data available
 Upper explosion limit : No data available
 Lower explosion limit : 30 g/m³
 Vapour pressure : No data available
 Relative vapour density : No data available
 Relative density : No data available
 Density : 0,25 g/cm³
 Bulk density : 200 - 500 kg/m³
 Solubility(ies)
 Water solubility : soluble, Limited by viscosity
 Solubility in other solvents : No data available
 Partition coefficient: n-octanol/water : No data available
 Auto-ignition temperature : 380 °C
 Decomposition temperature : No data available
 Viscosity
 Viscosity, dynamic : No data available
 Viscosity, kinematic : No data available
 Oxidizing properties : No data available

9.2 Other information

Dust deflagration index (Kst) : < 300 m.b./s
 Minimum ignition energy : > 10 mJ



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SECTION 10: Stability and reactivity

10.1 Reactivity

No decomposition if stored and applied as directed.

10.2 Chemical stability

Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions : Dust may form explosive mixture in air.

10.4 Conditions to avoid

Conditions to avoid : UV light.
Exposure to sunlight.

Keep away from heat, flame, sparks and other ignition sources.

10.5 Incompatible materials

Materials to avoid : Acids
Bases
Oxidizing agents

10.6 Hazardous decomposition products

Hazardous decomposition products : Carbon monoxide
Carbon dioxide (CO₂)
Hydrogen chloride gas

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Information on likely routes of exposure : Inhalation
Skin contact
Eye Contact
Ingestion

Acute toxicity

Not classified based on available information.

Skin corrosion/irritation

Not classified based on available information.



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Serious eye damage/eye irritation

Not classified based on available information.

Product:

Remarks: Unlikely to cause eye irritation or injury., Product dust may be irritating to eyes, skin and respiratory system.

Respiratory or skin sensitisation

Skin sensitisation: Not classified based on available information.

Respiratory sensitisation: Not classified based on available information.

Germ cell mutagenicity

Not classified based on available information.

Carcinogenicity

Not classified based on available information.

Reproductive toxicity

Not classified based on available information.

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

Not classified based on available information.

Aspiration toxicity

Not classified based on available information.

Further information**Product:**

Remarks: No data available

SECTION 12: Ecological information
12.1 Toxicity

No data available

12.2 Persistence and degradability

No data available

12.3 Bioaccumulative potential

No data available

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment**Product:**

Assessment : This substance/mixture contains no components considered

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to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher..

12.6 Other adverse effects**Product:**

Additional ecological information : No data available

SECTION 13: Disposal considerations**13.1 Waste treatment methods**

Contaminated packaging : Empty remaining contents.

SECTION 14: Transport information**SECTION 14: Transport information****14.1 UN number**

ADN: Not dangerous goods

ADR: Not dangerous goods

INTERNATIONAL AIR TRANSPORT ASSOCIATION - CARGO: Not dangerous goods

INTERNATIONAL AIR TRANSPORT ASSOCIATION - PASSENGER: Not dangerous goods

INTERNATIONAL MARITIME DANGEROUS GOODS: Not dangerous goods

RID: Not dangerous goods

14.2 UN proper shipping name

ADN: Not dangerous goods

ADR: Not dangerous goods

INTERNATIONAL AIR TRANSPORT ASSOCIATION - CARGO: Not dangerous goods

INTERNATIONAL AIR TRANSPORT ASSOCIATION - PASSENGER: Not dangerous goods

INTERNATIONAL MARITIME DANGEROUS GOODS: Not dangerous goods

RID: Not dangerous goods

14.3 Transport hazard class(es)

ADN: Not dangerous goods



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ADR: Not dangerous goods

INTERNATIONAL AIR TRANSPORT ASSOCIATION - CARGO: Not dangerous goods

INTERNATIONAL AIR TRANSPORT ASSOCIATION - PASSENGER: Not dangerous goods

INTERNATIONAL MARITIME DANGEROUS GOODS: Not dangerous goods

RID: Not dangerous goods

14.4 Packing group

ADN: Not dangerous goods

ADR: Not dangerous goods

INTERNATIONAL AIR TRANSPORT ASSOCIATION - CARGO: Not dangerous goods

INTERNATIONAL AIR TRANSPORT ASSOCIATION - PASSENGER: Not dangerous goods

INTERNATIONAL MARITIME DANGEROUS GOODS: Not dangerous goods

RID: Not dangerous goods

14.5 Environmental hazards

ADN: Not applicable

ADR: Not applicable

INTERNATIONAL AIR TRANSPORT ASSOCIATION - CARGO: Not applicable

INTERNATIONAL AIR TRANSPORT ASSOCIATION - PASSENGER: Not applicable

INTERNATIONAL MARITIME DANGEROUS GOODS: Not applicable

RID: Not applicable

14.6 Special precautions for user

Not applicable

14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Ship Type: Not applicable

Hazard code(s): Not applicable

Pollutant Category: Not applicable

Dangerous goods descriptions (if indicated above) may not reflect quantity, end-use or region-specific exceptions that can be applied. Consult shipping documents for descriptions that are specific to the shipment.

SECTION 15: Regulatory information

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

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59) : Not applicable

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REACH - List of substances subject to authorisation (Annex XIV) : Not applicable

Regulation (EC) No 1005/2009 on substances that deplete the ozone layer : Not applicable

Regulation (EC) No 850/2004 on persistent organic pollutants : Not applicable

Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals : Not applicable

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII) : Not applicable

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.
Not applicable

Water contaminating class (Germany) : WGK 1 slightly hazardous to water

TA Luft List (Germany) : Total dust, Not applicable

: Inorganic substances in powdered form, Not applicable

: Inorganic substances in vapour or gaseous form, Not applicable

: Organic Substances, Not applicable

: Carcinogenic substances, Not applicable

: Mutagenic, Not applicable

: Toxic to reproduction, Not applicable

The components of this product are reported in the following inventories:

DSL : All components of this product are on the Canadian DSL

AICS On the inventory, or in compliance with the inventory



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ENCS	On the inventory, or in compliance with the inventory
KECI	On the inventory, or in compliance with the inventory
PICCS	On the inventory, or in compliance with the inventory
IECSC	On the inventory, or in compliance with the inventory
TCSI	On the inventory, or in compliance with the inventory
TSCA	On TSCA Inventory

Inventories

AICS (Australia), DSL (Canada), IECSC (China), REACH (European Union), ENCS (Japan), ISHL (Japan), KECI (Korea), NZIoC (New Zealand), PICCS (Philippines), TCSI (Taiwan), TSCA (USA)

Substance name BENECEL ME 233 P PHARM

15.2 Chemical safety assessment

No data available

SECTION 16: Other information

Further information

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Full text of H-Statements

Other information : The information accumulated herein is believed to be accurate but is not warranted to be whether originating with the company or not. Recipients are advised to confirm in advance of need that the information is current, applicable, and suitable to their circumstances. This SDS has been prepared by Ashland's Environmental Health and Safety Department (+31

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10 497 5000).

Sources of key data used to compile the Safety Data Sheet

Ashland internal data including own and sponsored test reports

The UNECE administers regional agreements implementing harmonised classification for labelling (GHS) and transport.

List of abbreviations and acronyms that could be, but not necessarily are, used in this safety data sheet :

ACGIH : American Conference of Industrial Hygienists

BEI : Biological Exposure Index

CAS : Chemical Abstracts Service (Division of the American Chemical Society).

CMR : Carcinogenic, Mutagenic or Toxic for Reproduction

FG : Food grade

GHS : Globally Harmonized System of Classification and Labeling of Chemicals.

H-statement : Hazard Statement

IATA : International Air Transport Association.

IATA-DGR : Dangerous Goods Regulation by the "International Air Transport Association" (IATA).

ICAO : International Civil Aviation Organization

ICAO-TI (ICAO) : Technical Instructions by the "International Civil Aviation Organization"

IMDG : International Maritime Code for Dangerous Goods

ISO : International Organization for Standardization

logPow : octanol-water partition coefficient

LCxx : Lethal Concentration, for xx percent of test population

LDxx : Lethal Dose, for xx percent of test population.

ICxx : Inhibitory Concentration for xx of a substance

Ecxx : Effective Concentration of xx

N.O.S.: Not Otherwise Specified

OECD : Organization for Economic Co-operation and Development

OEL : Occupational Exposure Limit

P-Statement : Precautionary Statement

PBT : Persistent , Bioaccumulative and Toxic

PPE : Personal Protective Equipment

STEL : Short-term exposure limit

STOT : Specific Target Organ Toxicity

TLV : Threshold Limit Value

TWA : Time-weighted average

vPvB : Very Persistent and Very Bioaccumulative

WEL : Workplace Exposure Level

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GAM : Water Hazard Class for the Netherlands

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

ADNR: Regulation for the Carriage of Dangerous Substances on the Rhine

CLP : Classification, Labelling and Packaging

CSA : Chemical Safety Assessment

CSR : Chemical Safety Report

DNEL : Derived No Effect Level.

EINECS : European Inventory of Existing Commercial Chemical Substances.

ELINCS : European List of Notified Chemical Substances

GV: Exposure limits (DK)

PEC : Predicted Effect Concentration

PEL : Permissible Exposure Limits

PNEC : Predicted No Effect Concentration

REACH : Registration, Evaluation, Authorisation and Restriction of Chemicals

RID : Regulation Concerning the International Transport of Dangerous Goods by Rail

WGK : German Water Hazard Class