

Cellulose microcryst

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830
Date of issue: 15/09/2013 Revision date: 15/03/2017

248584

Version: 2.0

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

1.1. Product identifier

Product form : Substance
Substance name : Cellulose microcryst
Product code : 248584

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

1.2.1. Relevant identified uses

Main use category : Pharmaceutical
Industrial/Professional use spec : Industrial
For professional use only

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Supplier

Duchefa Farma BV
A. Hofmanweg 71
2031BH Haarlem - The Netherlands
T +31(0)23-5319093
farma@ducheffa.nl - www.duchefa-farma.com

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)

| Country | Organisation/Company | Address | Emergency number | Comment |
|----------------|--|---------------------------------|------------------|---------|
| United Kingdom | Guy's & St Thomas' Poisons Unit Medical Toxicology Unit, Centre Hospitalier Universitaire de Constantine | Avonley Road SE14 5ER London | 0870 243 2241 | |

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

Name : Cellulose microcryst

| Name | Product identifier | % | Classification according to Regulation (EC) No. 1272/2008 [CLP] |
|-------------------|---|----|---|
| Cellulose | (CAS-No.) 9004-34-6 (EC-No.) 232-674-9 | 87 | Not classified |
| Carmellose sodium | (CAS-No.) 9004-32-4 (EC-No.) polymeer | 13 | Not classified |

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 | : Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible). |
| First-aid measures after inhalation | : Assure fresh air breathing. Allow the victim to rest. Call a POISON CENTER or doctor/physician if you feel unwell. |
| First-aid measures after skin contact | : Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse. |
| First-aid measures after eye contact | : Rinse immediately with plenty of water. Obtain medical attention if pain, blinking or redness persists. |
| First-aid measures after ingestion | : Rinse mouth. Do NOT induce vomiting. Call a POISON CENTER or doctor/physician if you feel unwell. Drink plenty of water. |

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

Symptomatically (decontamination, vital function), no specific antidote known.

SECTION 5: Fire-fighting measures

5.1. Extinguishing media

| | |
|------------------------------|--|
| Suitable extinguishing media | : Dry powder. Carbon dioxide. Water spray. For large fire: Alcohol resistant foam. |
|------------------------------|--|

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

5.2. Special hazards arising from the substance or mixture

Explosion hazard : Risk of dust explosion.

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

General measures : Potential dust explosion hazard from airborne release. Product forms slippery surface when combined with water. Remove ignition sources. Avoid raising dust.

6.1.1. For non-emergency personnel

Emergency procedures : Evacuate unnecessary personnel.

6.1.2. For emergency responders

Protective equipment : Equip cleanup crew with proper protection.

Emergency procedures : Ventilate area.

6.2. Environmental precautions

Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or 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. Store away from other materials.

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 : Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Provide good ventilation in process area to prevent formation of vapour.

7.2. Conditions for safe storage, including any incompatibilities

Technical measures : Proper grounding procedures to avoid static electricity should be followed.

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

Incompatible products : Strong bases. Strong acids.

Incompatible materials : Sources of ignition. Direct sunlight.

Storage area : Keep away from: humid air. Water. Hygroscopic.

7.3. Specific end use(s)

Pharmaceutical industry.

SECTION 8: Exposure controls/personal protection**8.1. Control parameters**

| | | |
|--------------------------------------|-----------------|--------------------|
| Carmellose sodium (9004-32-4) | | |
| United Kingdom | Remark (WEL) | OES (GB) 10 mg/cbm |
| Cellulose (9004-34-6) | | |
| United Kingdom | WEL TWA (mg/m³) | 5 mg/m³ |

Additional information : TWA (mg/m³). 5 mg/ 8h

8.2. Exposure controls**Appropriate engineering controls:**

Avoid inhalation of the product.

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:

Safety glasses (to European standard EN 166 or equivalent)

Respiratory protection:

Approved dust respirator. Dust production: dust mask with filter type P1

Other information:

Do not eat, drink or smoke during use.

SECTION 9: Physical and chemical properties**9.1. Information on basic physical and chemical properties**

| | |
|--|-----------------------|
| Physical state | : Solid |
| Appearance | : Crystalline powder. |
| Colour | : almost white. |
| Odour | : odourless. |
| Odour threshold | : No data available |
| pH | : 6 - 8 |
| pH solution | : 20 g/l |
| Relative evaporation rate (butylacetate=1) | : No data available |
| Melting point | : No data available |
| Freezing point | : No data available |
| Boiling point | : No data available |
| Flash point | : No data available |
| Auto-ignition temperature | : 420 °C |
| Decomposition temperature | : No data available |
| Flammability (solid, gas) | : Non flammable |
| Vapour pressure | : No data available |
| Relative vapour density at 20 °C | : No data available |

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| | |
|----------------------|---|
| Relative density | : No data available |
| Density | : 600 kg/m ³ |
| Solubility | : dispersible in water, forms colloidal solutions. |
| Log Pow | : No data available |
| Viscosity, kinematic | : No data available |
| Viscosity, dynamic | : No data available |
| Explosive properties | : Dust may form explosive mixture in air. dust explosion class I. |
| 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**

No additional information available

10.2. Chemical stability

Not established.

10.3. Possibility of hazardous reactions

Not established.

10.4. Conditions to avoid

Direct sunlight. Extremely high or low temperatures.

10.5. Incompatible materials

Strong acids. Strong bases.

10.6. Hazardous decomposition products

release of harmful/irritant gases/vapours. Carbon monoxide. Carbon dioxide.

SECTION 11: Toxicological information**11.1. Information on toxicological effects**

Acute toxicity : Not classified

| Cellulose microcryst | |
|----------------------|--------------|
| LD50 oral rat | > 5000 mg/kg |
| LD50 dermal rabbit | > 2000 mg/kg |
| LC50 inhalation rat | 5.12 mg/l/4h |

| Carmellose sodium (9004-32-4) | |
|-------------------------------|--------------|
| LD50 oral rat | > 2000 mg/kg |

| | |
|-------------------------------|-------------------------------|
| Skin corrosion/irritation | : Not classified pH: 6 - 8 |
| Additional information | : Not irritating to skin |
| Serious eye damage/irritation | : Not classified pH: 6 - 8 |
| Additional information | : Not irritating to eyes |

| | |
|---|---|
| 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 |
| Potential adverse human health effects and symptoms | : Based on available data, the classification criteria are not met. |

SECTION 12: Ecological information

12.1. Toxicity

No additional information available

12.2. Persistence and degradability

| | |
|--------------------------------------|------------------------|
| Cellulose microcryst | |
| Persistence and degradability | Biodegradable. |
| Carmellose sodium (9004-32-4) | |
| Persistence and degradability | Readily biodegradable. |

12.3. Bioaccumulative potential

| | |
|--------------------------------------|------------------|
| Cellulose microcryst | |
| Bioaccumulative potential | Not established. |
| Carmellose sodium (9004-32-4) | |
| 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

| | |
|--------------------------------|---|
| Regional legislation (waste) | : Disposal must be done according to official regulations. |
| Waste treatment methods | : wastes from the MFSU of pharmaceuticals. |
| Waste 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 / RID / IMDG / IATA / ADN

| ADR | IATA |
|---|------------------------------------|
| 14.1. UN number | |
| Not applicable | Not applicable |
| 14.2. UN proper shipping name | |
| Not applicable | Not applicable |
| 14.3. Transport hazard class(es) | |
| Not applicable | Not applicable |
| Not applicable | Not applicable |
| 14.4. Packing group | |
| Not applicable | Not applicable |
| 14.5. Environmental hazards | |
| Dangerous for the environment : No | Dangerous for the environment : No |
| No supplementary information available | |

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

No data available

- Air transport

No data available

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

Cellulose microcryst is not on the REACH Candidate List

Cellulose microcryst is not on the REACH Annex XIV List

15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Indication of changes:

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

| | | | |
|-----|---------------------|----------|-----------------------------------|
| 1.4 | Emergency telephone | Modified | Added additional information |
| 8.2 | Hand protection | Modified | Specified material, thickness, et |

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Abbreviations and acronyms:

| | |
|-------|---|
| SDS | Safety Data Sheet |
| RID | Regulations concerning the International Carriage of Dangerous Goods by Rail |
| REACH | Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006 |
| IMDG | International Maritime Dangerous Goods |
| IATA | International Air Transport Association |
| ADR | European Agreement concerning the International Carriage of Dangerous Goods by Road |
| ADN | European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways |
| CLP | Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008 |

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:
This information is based on current knowledge. Consistency of data in the SDS with CSR is considered, as far as the information is available at the time of compilation (cfr Revision date and Version number). DISCLAIMER OF LIABILITY The information in this SDS was obtained from sources which we believe are reliable. However, the information is provided without any warranty, express or implied, regarding its correctness.

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