# Trade Name: Microcrystalline Cellulose, NF/Ph. Eur. (101)

# **1 Identification**

### **1.1 Product identifier**

**Product name:** Microcrystalline Cellulose, NF/Ph. Eur. (101) Product Code: C6030 Application of the substance / the mixture: Pharma Excipient

**1.2 Details of the supplier of the safety data sheet Manufacturer/Supplier:** SpecializedRx Products, LLC 7237 University Ave. NE Fridley, MN 55432 www.specializedrx.com sales@specializedrx.com

Information department: Tel.: 1-888-512-1209 Fax: 1-612-424-8481

### 1.3 Emergency telephone number:

Emergency Telephone: US: 1-888-512-1209 International: 1-888-512-1209

# 2 Hazard(s) identification

## 2.1 Classification of the substance or mixture

Not a hazardous substance or mixture.

2.2 Label elements Hazard pictograms N/A Signal word None Hazard statements N/A

Precautionary statements (GHS US) : N/A

**2.3 Other hazards Results of PBT and vPvB assessment** PBT: Not applicable. vPvB: Not applicable.

## **3 Composition/information on ingredients**

**3.1 Chemical Characterization**: **Description:** Polysaccharide derived from wood pulp



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CAS No. 9004-34-6

Common Name: Microcrystalline cellulose (MCC)

Impurities and/or Stabilizing Additives: No data available.

### 4 First-aid measures

### 4.1 Description of first aid measures

General information: No special measures required.

After inhalation: Remove from exposure. Get medical aid if cough or other symptoms appear. After skin contact: Wash skin with soap and water.

After eye contact: Rinse opened eye for several minutes under running water. If irritation persists obtain medical attention.

**After swallowing:** Wash mouth out thoroughly with water; no anticipated hazards associated with ingestion incidental to industrial exposure. In severe cases, obtain medical attention.

4.2 Most important symptoms and effects, both acute and delayed

No further relevant information available.

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

## **5 Fire-fighting measures**

### 5.1 Extinguishing media

Suitable extinguishing agents: alcohol-resistant foam, dry chemical, water spray, sand. Use fire-fighting measures that suit the environment.

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

Avoid dust formation, as fine dust dispersed in the air in the presence of an ignition source may result in explosion. Static electricity may be sufficient to ignite dust clouds; ignition possibility is dependent upon minimum ignition energy (MIE), which is outside the scope of this SDS.

### 5.3 Advice for firefighters

Protective equipment: In the event of fire, wear self-contained breathing apparatus.

### 6 Accidental release measures

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

Avoid dispersing dust into air, (i.e. avoid use of compressed air to clean surfaces). Avoid breathing dust; powder may become slippery when wet.

### 6.2 Environmental precautions:

Non-hazardous.

6.3 Methods and material for containment and cleaning up:



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Sweep, vacuum or shovel into suitable containers for disposal; use non-sparking (e.g. plastic) tools and avoid the use of water, as the powder may become slippery when wet.

### 6.4 Reference to other sections

See Section 7 for information on safe handling. See Section 8 for information on personal protection equipment. See Section 13 for disposal information.

# 7 Handling and storage

### 7.1 Precautions for safe handling:

Wear dust mask, gloves, goggles and (c)overalls while working with powder. Minimize dust creation during clean-up.

# 7.2 Conditions for safe storage, including any incompatibilities Storage:

Material is slightly hygroscopic; store in tightly sealed containers to prevent moisture ingress and potential contamination.

7.3 Specific end use(s): No further relevant information available.

### 8 Exposure controls/personal protection

Additional information about design of technical systems: No further data; see item 7.

### 8.1 Control parameters

Components with limit values that require monitoring at the workplace:

Microcrystalline cellulose (9004-34-6) ACGIH TLV TWA: 10 mg/m3 OSHA PEL TWA: 15 mg/m3 TWA: 5 mg/m3 NIOSH TWA: 10 mg/m3 TWA: 5 mg/m3 **Mexico**: TWA 10 mg/m3 Mexico: STEL 20 mg/m3 Microcrystalline cellulose (9004-34-6) **British Columbia** TWA: 10 mg/m3 TWA: 3 mg/m3 **Quebec** TWA: 10 mg/m3 TWA: 5 mg/m3 **Ontario** TWAEV TWA: 10 mg/m3 **Alberta** TWA: 10 mg/m3 TWA: 5 mg/m3

### 8.2 Exposure controls

Engineering measures: use local ventilation; dusting may occur

### Personal protective equipment:

**Breathing equipment:** If irritation is experienced or exposure limits are exceeded, NIOSH approved protection should be worn.

**Protection of skin:** Minimize skin contact by wearing gloves/appropriate outerwear to limit skin exposure.

**Eye protection:** Goggles recommended during handling.

## 9 Physical and chemical properties

9.1 Information on basic physical and chemical properties
General Information
Appearance:
Form: dry free-flowing powder
Color: white or practically white powder



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Odor: Odorless **pH-value:** 5.5 – 7.0 (11% solids dispersion in solution) Melting/Freezing point: (260-270) °C, (500-518) °F (decomposes) Boiling point/Boiling range: Not applicable Flash point: Not applicable Flammability (solid, gaseous): Not applicable. Ignition temperature: Not determined Decomposition temperature: (260-270)°C; (500-518)°F Auto igniting: 232°C; 449.6°F Danger of explosion: Not determined Explosion limits: Lower: Not determined Upper: Not determined Vapor pressure: Not determined **Density:** at 20°C 0.25 – 0.37 g/cm<sup>3</sup> Relative density: Not determined. Vapor density: Not determined. Evaporation rate: Not determined. Solubility in / Miscibility with Water: Insoluble, but dispersible in water Partition coefficient (n-octanol/water): Not determined. Viscosity: **Dvnamic:** Not determined Kinematic: Not determined. Solvent content: Organic solvents: 0.0 % Water: 0.0 % VOC content: 0.0 %

9.2 Other information: No further relevant information available.

### **10 Stability and reactivity**

10.1 Reactivity: No data available.

10.2 Chemical stability: Stable under normal conditions.

**10.3 Possibility of hazardous reactions:** None under normal processing.

**10.4 Conditions to avoid:** Avoid dust formation.

**10.5 Incompatible materials:** Reacts with oxidants and strong acids.

**10.6 Hazardous decomposition products:** Burning produces obnoxious and toxic fumes: sulfur oxides.

11 Toxicological inform	ation		
11.1 Information on toxicolo Acute toxicity:	gical effects		
LD/LC50 values that are rel	evant for classification:		
Oral	LD50	500 mg/kg (rat)	
Dermal	LD50	>2000 mg/kg (rabbit)	
Inhalation	LC50	>5800 mg/kg (rat) 4h	



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Primary irritant effect:
on the skin: Irritating to affected tissue.
on the eye: May cause scratching to eye surfaces.
Sensitization: Not a known sensitizer/no known sensitizing effects known.
Additional toxicological information:
Aspiration hazard: aspiration may cause chemical pneumonitis; excessive inhalation of dust can mechanically impede respiration.
Carcinogenic categories
IARC (International Agency for Research on Cancer): Substance not listed.
NTP (National Toxicology Program): Substance is not listed.

OSHA-Ca (Occupational Safety & Health Administration): Substance is not listed.

### **12 Ecological information**

12.1 Toxicity

Aquatic toxicity: No further relevant information available. 12.2 Persistence and degradability: No further relevant information available.

**12.3 Bioaccumulative potential:** No further relevant information available.

**12.4 Mobility in soil**: No further relevant information available.

Additional ecological information:

**General notes:** 

No further relevant information available.

12.5 Results of PBT and vPvB assessment

**PBT:** Not applicable.

vPvB: Not applicable.

12.6 Other adverse effects: No further relevant information available.

## **13 Disposal considerations**

13.1 Waste treatment methods

**Recommendation:** Disposal must be done according to local regulations. **Uncleaned packaging:** Disposal must be made according to local regulations. **Recommendation:** Disposal must be made according to official regulations. **Recommended cleansing agent:** Not determined.

14 Transport information		
14.1 UN-Number		
DOT, ADR, ADN, IMDG, IATA	Void	
14.2 UN proper shipping name		
DOT, ADR, ADN, IMDG, IATA	Void	
14.3 Transport hazard class(es)		
DOT, ADR, ADN, IMDG, IATA		
Class	Void	
14.4 Packing group		
DOT, ADR, IMDG, IATA	Void	



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14.5 Environmental hazards:	Not applicable.
14.6 Special precautions for user	Not applicable.
14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	Not applicable.
UN "Model Regulation":	Void

## **15 Regulatory information**

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

- · Sara Section 355 (extremely hazardous substances): Substance is not listed.
- Sara Section 313 (Specific toxic chemical listings): Substance is listed.
- · TSCA (Toxic Substances Control Act): ACTIVE
- · Hazardous Air Pollutants Substance is not listed.
- · Proposition 65
- Chemicals known to cause cancer: Substance is not listed.
- · Chemicals known to cause reproductive toxicity for females: Substance is not listed.
- · Chemicals known to cause reproductive toxicity for males: Substance is not listed

## **16 Other information**

This SDS is intended to provide a brief summary of our knowledge and guidance regarding the use of this material. The information contained here has been compiled from sources considered to be dependable and is accurate to the best of the Company's knowledge. However, the information is provided without any representation or warranty, expressed or implied regarding its accuracy or correctness. The Company cannot assume responsibility for adverse events which may occur in the use and/or misuse of this product and expressly disclaims liability for loss, damage and/or expense arising out of or in any way connected with the handling, storage, use and/or disposal of this product.

### Department issuing SDS:

SpecializedRx Products, LLC Quality Assurance **Contact:** sales@specializedrx.com **Date of preparation / last revision:** 01 Mar 2022

### Abbreviations and acronyms:

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road) IMDG: International Maritime Code for Dangerous Goods DOT: US Department of Transportation IATA: International Air Transport Association GHS: Globally Harmonized System of Classification and Labelling of Chemicals EINECS: European Inventory of Existing Commercial Chemical Substances ELINCS: European List of Notified Chemical Substances CAS: Chemical Abstracts Service (division of the American Chemical Society) VOC: Volatile Organic Compounds (USA, EU) PBT: Persistent, Bioaccumulative and Toxic



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vPvB: very Persistent and very Bioaccumulative

OSHA: Occupational Safety & Health

TLV: Threshold Limit Value

PEL: Permissible Exposure Limit REL: Recommended Exposure Limit

