## **Safety Data Sheet**

according to WHS Regulations

Printing date 06.06.2023 Revision: 06.06.2023 Version number 1.0

#### 1 Identification

· Product identifier

· Trade name: Croscarmellose Sodium

· Article number: 100005

· CAS Number: 74811-65-7 · EC number: 629-739-2

- · Relevant identified uses of the substance or mixture and uses advised against No further relevant information available.
- · Application of the substance / the mixture Pharmaceutical intermediate
- · Details of the supplier of the safety data sheet
- · Manufacturer/Supplier:

Fagron Services B.V.

Molenwerk 13, UITGEEST, 1911DB

Netherlands

Phone: +31251361400

Supplier Azelis Australia Suite 217 117 Old Pittwater Road Brookvale NSW 2100

Australia Phone: +61 0299392188

Fax: +61 0299392799 e-mail: info@azelis.com.au

- · Further information obtainable from: info@fagron.com.au
- · Emergency telephone number:

In case of emergency, please call your local poisons:

Emergency Australia: 13 11 26

Emergency NZ: 0800 764 766 (0800 POISON)

1800 127 406 (24 h, Australia) | +64 4 917 9888 (24 h, Worldwide) CareChem 24x7 : EUROPE: +44 1235 239670 | USA: +1 202 464 2554 | CANADA - +1 800 579 7421 (Toll Free)| ASIA - +65 3158 1074 | MOROCCO - +44 1235 239671 | REST OF THE WORLD - +44 1865 407333 (English only )

## 2 Hazard(s) Identification

· Classification of the substance or mixture

The substance is not classified, according to the Globally Harmonised System (GHS).

- · Label elements
- · GHS label elements Void
- · Hazard pictograms Void
- · Signal word Void
- · Hazard statements Void

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

## 3 Composition and Information on Ingredients

- · Chemical characterisation: Substances
- · CAS No. Description

CAS: 74811-65-7 Croscarmellose Sodium

- · Identification number(s)
- · EC number: 629-739-2

#### **4 First Aid Measures**

- · Description of first aid measures
- · General information: No special measures required.
- · After inhalation: Supply fresh air; consult doctor in case of complaints.
- · After skin contact:

Immediately rinse with water.

If skin irritation continues, consult a doctor.

· After eye contact:

Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.

· After swallowing:

Rinse out mouth and then drink plenty of water.

Seek immediate medical advice.

- · Information for doctor:
- · Most important symptoms and effects, both acute and delayed

No further relevant information available.

· Indication of any immediate medical attention and special treatment needed

No further relevant information available.

## **5 Fire Fighting Measures**

- · Extinguishing media
- Suitable extinguishing agents:

Use fire extinguishing methods suitable to surrounding conditions.

Water

Foam

Carbon dioxide

Fire-extinguishing powder

- · Special hazards arising from the substance or mixture No further relevant information available.
- Advice for firefighters
- · Protective equipment:

Wear self-contained respiratory protective device.

Wear fully protective suit.

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#### **6 Accidental Release Measures**

· Personal precautions, protective equipment and emergency procedures

Avoid formation of dust.

Wear protective equipment. Keep unprotected persons away.

- · Environmental precautions: Do not allow to enter sewers/ surface or ground water.
- Methods and material for containment and cleaning up:

Pick up mechanically.

Dispose of the material collected according to regulations.

Dispose contaminated material as waste according to item 13.

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

- · Handling:
- · Precautions for safe handling

Keep away from heat and direct sunlight.

Prevent formation of dust.

· Information about fire - and explosion protection:

Keep ignition sources away - Do not smoke.

Dust can combine with air to form an explosive mixture.

Protect against electrostatic charges.

- · Conditions for safe storage, including any incompatibilities
- · Storage:
- Requirements to be met by storerooms and receptacles: No special requirements.
- · Information about storage in one common storage facility: Not required.
- · Further information about storage conditions:

Keep container tightly sealed.

Store in dry conditions.

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

## 8 Exposure controls and personal protection

- · Additional information about design of technical facilities: No further data; see item 7.
- · Control parameters
- · Ingredients with limit values that require monitoring at the workplace: Not required.
- · Additional information: The lists valid during the making were used as basis.
- · Exposure controls
- · Personal protective equipment:
- · General protective and hygienic measures:

The usual precautionary measures are to be adhered to when handling chemicals.

• Respiratory protection: Use suitable respiratory protective device in case of insufficient ventilation.

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#### · Protection of hands:

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.



#### Protective gloves

Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

#### · Material of gloves

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer.

Nitrile rubber, NBR

#### · Penetration time of glove material

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

- · Eye protection: Safety glasses
- · Body protection: Protective work clothing

### 9 Physical and Chemical Properties

| · Information on basic physical and cher<br>· General Information  | nical properties                              |
|--|---|
| · Appearance: Form: Colour: · Odour: · Odour threshold:  | Powder White Odourless Not determined.        |
| · pH-value:  | 5–7   |
| <ul> <li>Change in condition</li> <li>Melting point/freezing point:</li> <li>Initial boiling point and boiling range:</li> </ul> | Undetermined.<br>: Undetermined.              |
| · Flash point:   | Not applicable.                               |
| · Flammability (solid, gas):   | Product is not flammable.                     |
| · Decomposition temperature:   | Not determined.                               |
| · Auto-ignition temperature:   | Not determined.                               |
| · Explosive properties:  | Product does not present an explosion hazard. |
| · Explosion limits:<br>Lower:<br>Upper:  | Not determined.<br>Not determined.            |
| · Vapour pressure:   | Not applicable.                               |
| · Density:   | Not determined.                               |

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| Relative density                        | Not determined.                            |           |
| · Vapour density                        | Not applicable.                            |           |
| · Evaporation rate                      | Not applicable.                            |           |
| Solubility in / Miscibility with        |  |           |
| water at 20°C:                          | 30 g/l                                     |           |
| Partition coefficient: n-octanol/water: | Not determined.                            |           |
| Viscosity:                              |  |           |
| Dynamic:                                | Not applicable.                            |           |
| Kinematic:                              | Not applicable.                            |           |
| Other information                       | No further relevant information available. |           |

## 10 Stability and Reactivity

- · Reactivity No further relevant information available.
- · Chemical stability
- · Thermal decomposition / conditions to be avoided:

No decomposition if used according to specifications.

· Possibility of hazardous reactions

Risk of dust explosion if enriched with fine dust in the presence of air.

Reacts with strong oxidising agents.

- · Conditions to avoid No further relevant information available.
- · Incompatible materials: No further relevant information available.
- · Hazardous decomposition products: No dangerous decomposition products known.

## 11 Toxicological Information

- · Information on toxicological effects
- · Additional toxicological information:

When used and handled according to specifications, the product does not have any harmful effects to our experience and the information provided to us.

The substance is not subject to classification according to the latest version of the EU lists.

## 12 Ecological Information

- Toxicity
- · Aquatic toxicity: No further relevant information available.
- · Persistence and degradability No further relevant information available.
- · Behaviour in environmental systems:
- · Bioaccumulative potential No further relevant information available.
- · Mobility in soil No further relevant information available.
- · Additional ecological information:
- · General notes:

Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

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- · Results of PBT and vPvB assessment
- · **PBT:** Not applicable.
- · vPvB: Not applicable.
- · Other adverse effects No further relevant information available.

### 13 Disposal considerations

- · Waste treatment methods
- · Recommendation Smaller quantities can be disposed of with household waste.
- · Uncleaned packaging:
- · Recommendation: Disposal must be made according to official regulations.

### 14 Transport information

| · UN-Number<br>· ADG, IMDG, IATA                            | not regulated            |
|---|--------------------------|
| · UN proper shipping name<br>· ADG, IMDG, IATA              | not regulated            |
| · Transport hazard class(es)                                |                          |
| · ADG, ADN, IMDG, IATA<br>· Class                           | not regulated            |
| · Packing group<br>· ADG, IMDG, IATA                        | not regulated            |
| · Environmental hazards:                                    | Not applicable.          |
| · Special precautions for user                              | Not applicable.          |
| Transport in bulk according to Anno Marpol and the IBC Code | ex II of Not applicable. |
| · UN "Model Regulation":                                    | not regulated            |

## 15 Regulatory information

- · Safety, health and environmental regulations/legislation specific for the substance or mixture
- · Australian Inventory of Industrial Chemicals Substance is listed.
- · Standard for the Uniform Scheduling of Medicines and Poisons Substance is not listed.
- · Australia: Priority Existing Chemicals Substance is not listed.
- · Directive 2012/18/EU
- · Named dangerous substances ANNEX I Substance is not listed.
- · National regulations:
- Other regulations, limitations and prohibitive regulations
  Therapeutic goods are listed on the Australian Register of Therapeutic Goods(ARTG)

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· Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

#### 16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

- · Department issuing SDS: Product Safety Department
- Contact:
- · Abbreviations and acronyms:

ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

EINECS: European Inventory of Existing Commercial Chemical Substances CAS: Chemical Abstracts Service (division of the American Chemical Society)

PBT: Persistent, Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative

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