according to 1907/2006/EC, Article 31

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

· 1.1 Product identifier

· Trade name: Croscarmellose Sodium

· Article number: 100005

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

• 1.2 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

· 1.3 Details of the supplier of the safety data sheet

Fagron UK Ltd 4B Coquet St Newcastle upon Tyne England NE1 2QB Tel. 0845 6522525

· Further information obtainable from:

Emergency response telephone number:

+44 (0) 845 652 2525

· 1.4 Emergency telephone number:

Emergency response telephone number:

+44 (0) 845 652 2525

### SECTION 2: Hazards identification

- · 2.1 Classification of the substance or mixture
- Classification according to Regulation (EC) No 1272/2008
   The substance is not classified, according to the GB CLP regulation.

The substance is not classified, according to the QD Oct Tegulation

- · 2.2 Label elements
- · Labelling according to Regulation (EC) No 1272/2008 Void
- · Hazard pictograms Void
- · Signal word Void
- · Hazard statements Void
- · 2.3 Other hazards
- · Results of PBT and vPvB assessment
- PBT: Not applicable.vPvB: Not applicable.

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

- · 3.1 Substances
- · CAS No. Description

CAS: 74811-65-7 Croscarmellose Sodium

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

#### **SECTION 4: First aid measures**

- · 4.1 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 eve 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.

· 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.

### **SECTION 5: Firefighting measures**

- · 5.1 Extinguishing media
- Suitable extinguishing agents:

Use fire extinguishing methods suitable to surrounding conditions.

Water

Foam

Carbon dioxide

Fire-extinguishing powder

5.2 Special hazards arising from the substance or mixture

No further relevant information available.

- · 5.3 Advice for firefighters
- · Protective equipment:

Wear self-contained respiratory protective device.

Wear fully protective suit.

#### **SECTION 6: Accidental release measures**

· 6.1 Personal precautions, protective equipment and emergency procedures

Avoid formation of dust.

Wear protective equipment. Keep unprotected persons away.

- · 6.2 Environmental precautions: Do not allow to enter sewers/ surface or ground water.
- · 6.3 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.

· 6.4 Reference to other sections

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

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See Section 13 for disposal information.

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### SECTION 7: Handling and storage

#### · 7.1 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.

- · 7.2 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.

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

### **SECTION 8: Exposure controls/personal protection**

- · 8.1 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.
- · 8.2 Exposure controls
- Appropriate engineering controls No further data; see item 7.
- Individual protection measures, such as 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.
- · Hand protection

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.

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· Eye/face protection Safety glasses

· Body protection: Protective work clothing

### **SECTION 9: Physical and chemical properties**

· 9.1 Information on basic physical and chemical properties

· General Information

Physical state
Colour:
Odour:
Odourless
Odour threshold:
Melting point/freezing point:

Solid
White
Odourless
Not determined.
Undetermined.

· Boiling point or initial boiling point and boiling

range Undetermined.

• Flammability Product is not flammable.

· Lower and upper explosion limit

Lower: Not determined.
Upper: Not determined.
Flash point: Not applicable.
Decomposition temperature: Not determined.

• **pH** 5–7

· Viscosity:

Kinematic viscosityDynamic:Not applicable.Not applicable.

· Solubility

• water at 20°C: 30 g/l

· Partition coefficient n-octanol/water (log

value) Not determined.

• Vapour pressure: Not applicable.

· Density and/or relative density

Density: Not determined.
 Relative density Not determined.
 Vapour density Not applicable.

· 9.2 Other information

· Appearance:

· Form: Powder

· Important information on protection of health

and environment, and on safety.

· Auto-ignition temperature: Not determined.

• Explosive properties: Product does not present an explosion hazard.

· Change in condition

• Evaporation rate Not applicable.

· Information with regard to physical hazard

classes

Explosives Void
Flammable gases Void
Aerosols Void
Oxidising gases Void

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· Gases under pressure	Void	
Flammable liquids	Void	
· Flammable solids	Void	
· Self-reactive substances and mixtures	Void	
· Pyrophoric liquids	Void	
· Pyrophoric solids	Void	
Self-heating substances and mixtures	Void	
· Substances and mixtures, which emit		
flammable gases in contact with water	Void	
· Oxidising liquids	Void	
· Oxidising solids	Void	
· Organic peroxides	Void	
· Corrosive to metals	Void	
· Desensitised explosives	Void	

### **SECTION 10: Stability and reactivity**

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

No decomposition if used according to specifications.

· 10.3 Possibility of hazardous reactions

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

Reacts with strong oxidising agents.

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

### **SECTION 11: Toxicological information**

- · 11.2 Information on other hazards
- · Endocrine disrupting properties Substance is not listed.

## **SECTION 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.
- 12.5 Results of PBT and vPvB assessment
- · PBT: Not applicable.
- · **vPvB**: Not applicable.
- · 12.6 Endocrine disrupting properties

The product does not contain substances with endocrine disrupting properties.

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- · 12.7 Other adverse effects
- · 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.

### **SECTION 13: Disposal considerations**

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

### **SECTION 14: Transport information**

· 14.1 UN number or ID number · ADR, IMDG, IATA	not regulated
· 14.2 UN proper shipping name · ADR, IMDG, IATA	not regulated
· 14.3 Transport hazard class(es)	
· ADR, ADN, IMDG, IATA · Class	not regulated
· 14.4 Packing group · ADR, IMDG, IATA	not regulated
· 14.5 Environmental hazards:	Not applicable.
· 14.6 Special precautions for user	Not applicable.
· 14.7 Maritime transport in bulk according to IMO instruments  Not applicable.	
· UN "Model Regulation":	not regulated

### **SECTION 15: Regulatory information**

- · 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
- · Directive 2012/18/EU
- · Named dangerous substances ANNEX I Substance is not listed.
- · 15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

#### SECTION 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.

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#### Department issuing SDS:

Fagron UK

Quality Assurance

- · Contact: quality@fagron.co.uk
- · 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
GHS: Globally Harmonised System of Classification and Labelling of Chemicals 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