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

1.1 Product identifier:

Substance name: **Croscarmellose Sodium**
CAS No.: 74811-65-7
Product code: **TekLeu®CSS**
REACH Registration No.: Irrelevant as pharmaceutical excipient

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

Relevant identified uses: pharmaceutical excipient
Uses advised against: Not identified
Reason why uses advised against: Not identified

1.3. Details of the Supplier of the safety data sheet**1.3.1 Details of the supplier of the safety data sheet:**

Manufacturer/Supplier: Libertia Performance Chemicals Co., Ltd
Address: Creative Campus | Alfred-Nobel-Strasse 10 | 40789 Monheim am Rhein | Germany
Telephone number: 0086 138 18547689

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture**2.1.1 Classification according to Regulation (EC) No 1272/2008 (CLP)**

Not Classified

Additional information: For full text of Hazard- and EU Hazard-statements: see SECTION 16.

2.2: Label elements

Labelling according to Regulation (EC) No
Hazard pictograms
Signal word: N/A
Hazard statements: Not Classified
Supplemental Hazard information (EU)54: Not applicable.

2.3 Other hazards

Not Classified

3: Composition/information on ingredients

Product identifier type in accordance with Article 18(2) of Regulation (EC) No 1272/2008	Identification number	Substance name	name Weight % content (or range)	EC Number	CL/ M-factor/ATE
Index number in CLP Annex VI	74811-65-7	Croscarmellos	99.70 – 100.0	618-378-6	n/a

4: First aid measures

General information

	Get medical advice/attention if you feel unwell.
Inhalation	Remove person to fresh air and keep comfortable for breathing. If breathing stops, provide artificial respiration. When breathing is difficult, properly trained personnel may assist affected person by administering oxygen. Get medical attention if symptoms are severe or persist.
Ingestion:	Do not induce vomiting. Never give anything by mouth to an unconscious person. Rinse mouth thoroughly with water. Give plenty of water to drink. Get medical attention if symptoms are severe or persist.
Skin contact	Remove contaminated clothing. Rinse with water. Continue to rinse for at least 15 minutes. Wash contaminated clothing before reuse. Get medical attention if symptoms are severe or persist. Rinse immediately with plenty of water. Continue to rinse for at least 15 minutes, Get medical attention if symptoms are severe or persist.
Eye contact:	
4.2. Most important symptoms and effects, both acute and delayed	General information See Section 11 for additional information on health hazards.
4.3. Indication of any immediate medical attention and special treatment needed	Notes for the doctor Treat symptomatically.
5.3 Advice for firefighters	Special protective equipment: Wear positive pressure self-contained breathing apparatus (SCBA) and appropriate protective for firefighters clothing. Firefighter's clothing conforming to European standard EN469 (including helmets, protective boots and gloves) will provide a basic level of protection for chemical incidents. Use protective equipment appropriate for surrounding materials.

6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

	Personal precautions Wear protective clothing as described in Section 8 of this safety data sheet. No action shall be taken without appropriate training or involving any personal risk. Do not touch or walk into spilled material. Avoid inhalation of dust and vapours. Provide adequate ventilation. Keep unnecessary and unprotected personnel away from the spillage.
6.2 Environmental precautions	Avoid discharge into drains or watercourses or onto the ground.
6.3 Methods and material for containment and cleaning up	Wear protective clothing as described in Section 8 of this safety data sheet. Collect powder using special dust vacuum cleaner with particle filter or carefully sweep into suitable waste disposal containers and seal securely. Clear up spills immediately and dispose of waste safely. Flush contaminated area with plenty of water. Wash thoroughly after dealing with a spillage. For waste disposal, see Section 13.
6.4 Reference to other sections	Reference to other sections For personal protection, see Section 8. See Section 11 for additional information on health hazards. See Section 12 for additional information on ecological hazards. For waste disposal, see Section 13.

7: Handling and storage

7.1 Precautions for safe handling	Usage precautions Wear protective clothing as described in Section 8 of this safety data sheet. Wash hands thoroughly after handling. Provide adequate ventilation. Avoid generation and spreading of dust. Avoid contact with skin and eyes. Avoid inhalation of dust and vapours.
7.2 Conditions for safe storage, including any incompatibilities	Store in well-closed container at room temperature. Whether in the wet granulation process or the direct tableting process, if there are other hygroscopic excipients in the prescription, the disintegration effect can be slightly reduced. Combining with methyl cellulose will prolong the disintegration time, and corn starch will inhibit the disintegration effect. Incompatible with soluble salts of strong acids, iron, or other metals (such as aluminum, mercury, zinc).
7.3 Specific end use(s)	The identified uses for this product are detailed in Section 1.2.

8: Exposure controls/personal protection

8.1 Control parameters	No exposure limits known for ingredient(s).
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8.2 Exposure controls

Appropriate engineering controls	Provide adequate ventilation. Observe any occupational exposure limits for the product or ingredients
Eye/face protection	Unless the assessment indicates a higher degree of protection is required, the following protection should be worn: Tight-fitting safety glasses. Personal protective equipment for eye and face protection should comply with European Standard EN166.
Hand protection	Wear protective gloves. To protect hands from chemicals, gloves should comply with European Standard EN374.
Other skin and body protection	Wear appropriate clothing to prevent repeated or prolonged skin contact.
Respiratory protection	Respiratory protection complying with an approved standard should be worn if a risk assessment indicates inhalation of contaminants is possible. Ensure all respiratory protective equipment is suitable for its intended use and is 'CE'-marked. Particulate filters should comply with European Standard EN143. Full face mask respirators with replaceable filter cartridges should comply with European Standard EN136. Half mask and quarter mask respirators with replaceable filter cartridges should comply with European Standard EN140.
Environmental exposure controls	Keep container tightly sealed when not in use.

9: Physical and chemical properties

9.1 Information on basic physical and chemical properties	
Colour	White.
Odour	Odourless.
Odour threshold	No data available.
pH	pH (concentrated solution): 5 to 7 at 20 °C, 10 g/L
Melting point	>205°C
Initial boiling point and range	No data available.
Flash point	No data available.
Evaporation rate	No data available.
Flammability (solid, gas)	No data available.
Upper/lower flammability or explosive limits	Lower flammable/explosive limit: 200 g/m ³
Vapour pressure	No data available.
Vapour density	No data available.
Relative density	No data available.
Solubility(ies)	30 g/l water @ 20°C
Partition coefficient	No data available.
Auto-ignition temperature	No data available.
Decomposition Temperature	No data available.
Viscosity	No data available.
Explosive properties	No data available.
Oxidising properties	No data available.
9.2 Other information	
	Molecular weight 982.44

10: Stability and Reactivity

10.1 Reactivity	No data available.
10.2 Chemical stability	Stable under the prescribed storage conditions.
10.3 Possibility of hazardous reactions	No data available.
10.4 Conditions to avoid	No data available.
10.5 Incompatible materials	Strong oxidising agents.
10.6 Hazardous decomposition products	Oxides of carbon. Metal oxide(s).

11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008	
Toxicological effects	Not regarded as a health hazard under current legislation.
Acute toxicity - oral (oral LD ₅₀)	Based on available data the classification criteria are not met.
Acute toxicity - dermal (dermal LD ₅₀)	Based on available data the classification criteria are not met.
Acute toxicity - inhalation (inhalation LC ₅₀)	Based on available data the classification criteria are not met.
Skin corrosion/irritation Animal data	Based on available data the classification criteria are not met.
Respiratory sensitisation	Based on available data the classification criteria are not met.
Skin sensitisation	Based on available data the classification criteria are not met.
Germ cell mutagenicity	
Genotoxicity - in vitro	Based on available data the classification criteria are not met.
Carcinogenicity	Based on available data the classification criteria are not met.
IARC carcinogenicity	None of the ingredients are listed or exempt.
Reproductive toxicity - fertility	Based on available data the classification criteria are not met.
Reproductive toxicity-Specific target organ toxicity	Based on available data the classification criteria are not met.
Aspiration hazard	Not relevant. Solid.
General information	No specific health hazards known. Dust may irritate the eyes and the respiratory system. The severity of the symptoms described will vary dependent on the concentration and the length of exposure.
Inhalation	Dust may irritate the respiratory system. Frequent inhalation of dust over a long period of time
Ingestion	No specific symptoms known. May cause discomfort if swallowed.

Skin contact	Prolonged contact may cause dryness of the skin.
Eye contact	Dust may cause slight irritation.
Route of exposure	Ingestion Inhalation Skin and/or eye contact

12: Ecological information

12.1 Toxicity	Based on available data the classification criteria are not met.
12.2 Persistence and degradability	The degradability of the product is not known.
12.4 Mobility in soil	No data available.
12.5 Results of PBT and vPvB assessment	No data available.
12.6 Endocrine disrupting properties	None known
12.7 Other adverse effects	None known

13: Disposal considerations

13.1 Waste treatment methods	Dispose of waste to licensed waste disposal site in accordance with the requirements of the local Waste Disposal Authority. This material and its container must be disposed of in a safe way. When handling waste, the safety precautions applying to handling of the product should be considered.
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14: Transport Information

The product is not covered by international regulations on the transport of dangerous goods (IMDG, IATA, ADR/RID).

14.1. UN number	Not applicable.
14.2. UN proper shipping name	Not applicable.
14.3. Transport hazard class(es)	Not applicable.
14.4. Packing group	Not applicable.
14.5. Environmental hazards	Not applicable.
14.6. Special precautions for user	Not applicable.
14.7. Transport in bulk according to Annex II of MARPOL and the IBC	Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

15: Regulatory information

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

National regulations Health and Safety at Work etc. Act 1974 (as amended). The Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2009 (SI 2009 No. 1348) (as amended) ["CDG 2009"].
EH40/2005 Workplace exposure limits.
EU legislation Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (as amended).
Commission Regulation (EU) No 2015/830 of 28 May 2015.
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 (as amended).

16: Other information

Disclaimer:

Our company provides this MSDS sheet in good faith but makes no representation as to its comprehensiveness or accuracy. This SDS sheet is intended only as a guide to the appropriate precautionary handling of the material by a properly trained person using this product. The above information has been compiled from various sources and has the possibility of discrepancy and being out-dated information. Individuals receiving the information must exercise their independent judgment and do further search in determining its appropriateness for a particular purpose. In no case shall our company be liable to loss or damages by the product user.