Safety Information

Product group:	Superdisintegrants
Brand name:	Primellose®
Article code:	743737
Product description:	Croscarmellose Sodium
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1. Product and Company Identification

- Product Name: Primellose® (Croscarmellose Sodium)
- Manufacturer/Supplier: DFE Pharma
- Address: A Kleverstrasse 187, 47568 Goch, Germany
- Phone: +49 2823 9288770
- Fax: +49 2823 92887799
- Website: www.dfepharma.com
- Emergency Contact: +49 2823 9288770
- Recommended Use: Pharmaceutical excipient

2. Hazards identification

- Classification: Not classified as hazardous under Regulation (EC) No. 1272/2008 (CLP) or OSHA 29 CFR 1910.1200.
- Label Elements: None
- Signal Word: None
- Hazard Statements: May form combustible dust concentrations in air.
- Precautionary Statements: Avoid dust formation. Ensure proper ventilation.

3. Composition/Information on Ingredients

- Substance: Croscarmellose Sodium
- CAS Number: 74811-65-7
- EC Number: Not assigned
- Concentration: 100%

4. First aid measures

- Inhalation: Move to fresh air.
- Skin Contact: Wash with water.
- Eye Contact: Rinse thoroughly with water.
- Ingestion: Rinse mouth and drink water.

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5. Firefighting measures

- Suitable Extinguishing Media: Water spray, foam, dry chemical, CO_2.
- Hazards: Emits CO and CO_2 on combustion.
- Explosion hazard: ST1 dust explosion class

6. Accidental release measures

- Avoid dust formation.
- Sweep up and place in suitable container.
- Ventilate area.

7. Handling and storage

- Store in tightly closed containers in a dry, cool, and well-ventilated place.
- Avoid dust generation.

8. Exposure controls/personal protection

- Engineering Controls: Use local exhaust ventilation to minimize dust.
- Personal Protective Equipment:
    a. Eye Protection: Safety glasses with side shields (EN 166)
    b. Respiratory Protection: Dust mask (e.g., N95 or FFP2)
    c. Hand Protection: Protective gloves (EN 374)
    d. Skin Protection: Protective clothing
- Occupational Exposure Limits: No established limits for Croscarmellose Sodium.

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9. Physical and chemical properties

- Appearance: White to off-white powder
- Odor: Slight odor
- pH: 5.0–7.0
- Explosion Class: ST1
- Lower Explosion Limit: ~125 g/m³
- Kst: ~53 bar·m/s
- Max Pressure: ~7.2 bar
- Min Ignition Energy: >8700 mJ
- Min Ignition Temp: ~360°C

10. Stability and reactivity

- Stable under normal conditions.
- Avoid: Heat, sparks, open flames.
- Hazardous decomposition: CO, CO_2.

11. Toxicological information

- Acute Toxicity: No data available.
- Skin Corrosion/Irritation: No data available.
- Serious Eye Damage/Irritation: No data available.
- Respiratory or Skin Sensitization: No data available.
- Carcinogenicity: Not classified.
- Reproductive Toxicity: No data available.
- STOT – Single Exposure: No data available.
- STOT – Repeated Exposure: No data available.
- Aspiration Hazard: Not applicable.

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12. Ecological information

- Toxicity: No data available.
- Persistence and Degradability: No data available.
- Bioaccumulative Potential: No data available.
- Mobility in Soil: No data available.
- Other Adverse Effects: Not expected to pose significant ecological risks.

13. Disposal considerations

- Waste Treatment Methods: Dispose of in accordance with local, regional, national, and international regulations.
- Waste Code: Not classified as hazardous waste under applicable regulations.

14. Transport information

- Not classified as dangerous goods under ADR, IMDG, or IATA.

15. Regulatory information

- Safety, health and environmental regulations/legislation specific for the substance or mixture
    a. Not subject to REACH registration.
    b. No known regulatory restrictions.

16. Other information

- Date of Preparation: 24-06-2025
- Version: 10.0
- References: SDS prepared in accordance with Regulation (EC) No. 1907/2006 and OSHA 29 CFR 1910.1200.

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