Safety Information

Product group:	Superdisintegrants
Brand name:	Primojel®
Article code:	743736
Product description:	Sodium Starch Glycolate
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1. Identification of the substance/mixture and of the company/undertaking

- Product Name: Primojel®® (Sodium Starch Glycolate)
- Recommended Use: Pharmaceutical excipient
- Manufacturer/Supplier: DFE Pharma
- Address: A Kleverstrasse 187, 47568 Goch, Germany
- T: +49 2823 9288770, F +49 2823 92887799
- W: www.dfepharma.com
- Emergency Contact: : +49 2823 9288770

2. Hazards identification

- Classification: Not classified as hazardous under Regulation (EC) No. 1272/2008 (CLP) or OSHA HCS.
- Hazards: May form combustible dust concentrations in air.
- Label Elements:
- Signal Word: Warning
- Hazard Statement: May form combustible dust concentrations in air.
- Precautionary Statements: Avoid dust formation. Ensure proper ventilation. Ground/bond container and receiving equipment.
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3. Composition/information on ingredients

- Substance: Sodium Starch Glycolate
- CAS Number: 9063-38-1
- EC Number: Not assigned
- Impurities: Ethanol (<6%), CAS No. 64-17-5

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4. First aid measures

- Inhalation: Move to fresh air. Seek medical attention if symptoms persist.
- Skin Contact: Wash with soap and water.
- Eye Contact: Rinse cautiously with water for several minutes.
- Ingestion: Rinse mouth. Drink water. Seek medical attention if large amounts are ingested.

5. Firefighting measures

- Suitable Extinguishing Media: Water spray, foam, dry chemical, carbon dioxide.
- Hazards: Combustion may produce CO and CO_2.
- Protective Equipment: Wear self-contained breathing apparatus and full protective gear.

6. Accidental release measures

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

7. Handling and storage

- Handling: Avoid dust formation. Ground equipment. Use explosion-proof equipment.
- Storage: Store in tightly closed containers in a dry, cool, and well-ventilated place.

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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

9. Physical and chemical properties

- Appearance: White powder
- Odor: Slight odor (not truly odorless)
- pH: 5.5–7.5 (1% solution)
- Explosion Class: ST1
- Lower Explosion Limit: 125 g/m³
- Kst: 56 bar·m/s
- Maximum Explosion Pressure: 7.2 bar
- Minimum Ignition Energy: >8700 mJ
- Minimum Ignition Temperature: 360°C
- Smoulder Temperature: 310–320°C
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10. Stability and reactivity

- Reactivity: Not reactive under normal conditions.
- Chemical Stability: Stable under recommended storage conditions.
- Possibility of Hazardous Reactions: None known.
- Conditions to Avoid: Heat, sparks, open flames, dust accumulation.
- Incompatible Materials: Strong oxidizing agents.
- Hazardous Decomposition Products: CO and CO_2.

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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.

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.

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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: 9.0
- References: SDS prepared in accordance with Regulation (EC) No. 1907/2006 and OSHA 29 CFR 1910.1200.

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