

SAFETY DATA SHEET
GLYCOLYS® MAIZE

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

1.1 Product identifier:

Product name: GLYCOLYS® MAIZE

Chemical name: Starch, carboxymethyl ether, sodium salt

CAS-No.: 9063-38-1

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

Identified uses:	Uses advised against:
Pharmaceuticals., Dissolution accelerator, Disintegrant,	No data available.

1.3 Details of the supplier of the safety data sheet:

Supplier:

ITACEL FARMOQUIMICA LTDA.
R. DR JOSÉ ALEXANDRE CROSGNAC, 645
06680-035 - ITAPEVI - SP - BRAZIL

Telephone: +55 11 4144-9400

E-mail: rbr.contacto@roquette.com

1.4 Emergency telephone number:

National Capital Poison Center: 1 800 222 1222 (24/24)

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture:

This product is not hazardous according to OSHA 29CFR 1910.1200.

2.2 Label elements: Not applicable

2.3 Other hazards: Dust may form an explosive mixture in the atmosphere.

SECTION 3: Composition/information on ingredients

3.1 Substance:

Chemical name	Concentration	CAS-No.
Starch, carboxymethyl ether, sodium salt	>=96%	9063-38-1

SECTION 4: First aid measures

4.1 Description of first aid measures:

Inhalation: Move the exposed person to fresh air at once. Get medical attention if any discomfort continues.

Eye contact: Flush thoroughly with water for at least 15 minutes. Get medical assistance.

Skin contact: Wash with soap and water.

Ingestion: Get medical attention if symptoms occur.

4.2 Most important symptoms and effects, both acute and delayed: Dust may irritate the eyes and the respiratory system. May cause eye irritation. May cause skin irritation/eczema

4.3 Indication of any immediate medical attention and special treatment needed:

Treatment: Treat symptomatically.

SECTION 5: Firefighting measures

5.1 Extinguishing media:

Suitable extinguishing media: Water spray.

Unsuitable extinguishing media: Dry chemicals or foams.

5.2 Special hazards arising from the substance or mixture: Fire or excessive heat may produce hazardous decomposition products. Dust may form an explosive mixture in the atmosphere. See Section 10.

5.3 Advice for firefighters:

Special Fire Fighting Procedures: Prevent dust cloud.

Special protective equipment for fire-fighters: Firefighters must use standard protective equipment including flame retardant coat, helmet with face shield, gloves, rubber boots, and in enclosed spaces, SCBA.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures: See Section 8 of the SDS for Personal Protective Equipment.

6.2 Environmental precautions: Avoid release to the environment.

6.3 Methods and material for containment and cleaning up: Remove material, as much as possible, using mechanical equipment. Prevent dust cloud. Collect and dispose of spillage as indicated in section 13 of the SDS.

6.4 Reference to other sections: For waste disposal, see section 13 of the SDS.

SECTION 7: Handling and storage

7.1 Precautions for safe handling: Avoid generation and spreading of dust. See Section 8 of the SDS for Personal Protective Equipment.

7.2 Conditions for safe storage, including any incompatibilities:

Keep containers tightly closed. Store in original container.

7.3 Specific end use(s):

Pharmaceuticals.,

SECTION 8: Exposure controls/personal protection

8.1 Control parameters:

Occupational exposure limits:

This product does not contain any components >1% with specific occupational exposure limits.

Chemical name	Type	Exposure Limit Values	Source
Dust - Inhalable particles.	TWA	10 mg/m3	US. ACGIH Threshold Limit Values (01 2010)
Dust - Respirable particles.	TWA	3 mg/m3	US. ACGIH Threshold Limit Values (01 2010)
Dust - Respirable fraction.	PEL	5 mg/m3	US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000) (02 2006)
Dust - Total dust.	PEL	15 mg/m3	US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000) (02 2006)
Dust - Total dust.	TWA	15 mg/m3	US. OSHA Table Z-3 (29 CFR 1910.1000) (2000)
Dust - Respirable fraction.	TWA	5 mg/m3	US. OSHA Table Z-3 (29 CFR 1910.1000) (2000)

8.2 Exposure controls:

Appropriate engineering controls:

Ventilate as needed to control airborne dust. Use explosion-proof ventilation equipment if airborne dust levels are high.

Individual protection measures, such as personal protective equipment:

Eye/face protection:

Wear dust-resistant safety goggles where there is danger of eye contact.

Skin protection:

Hand Protection:

Gloves are recommended for prolonged use.

Other:

Wear appropriate clothing to prevent any possibility of skin contact.

Respiratory Protection:

In case of inadequate ventilation or risk of inhalation of dust, use suitable respiratory equipment with particle filter (type P1).

Hygiene measures:

Handle the product in accordance with the good hygiene practices and safety instructions.

Environmental exposure controls:

Avoid release to the environment.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties:

Physical State:	solid
Form:	Powder
Water, moisture:	< 10 %
Color:	White
Odor:	Odorless

pH:	5.5 - 7.5 at 3.3 %
Melting Point:	No data available.
Boiling Point:	Not Applicable
Flash Point:	Not Applicable
Vapor pressure:	Not Applicable
Vapor density (air=1):	Not Applicable
Relative density:	Not determined.
Solubility in Water:	Miscible with water.
Explosive properties: - INERIS -Data from similar product.	
Ignition Temperature:	~ 380 °C (Godbert-Greenwald) MIT in Cloud. ~ 251 °C product in deposit.
MIE (Minimum Ignition Energy):	> 1,200 mJ (Hartmann)
dP/dtmax (Maximum Rate of explosion Pressure rise):	~ 220 bar/s (EN 14034-2)
Pmax (Maximum Explosion OverPressure) ±10%:	~ 7.2 bar (EN 14034-1)
Kst value (±20%):	~ 59 barm/s (EN 14034-2)
Dust Explosion Class:	st 1 (VDI 3673)
Volume resistivity:	> 10 ⁹ Ω.m (IEC 61241-2-2 / Group IIIB non-conductive dust.)
Moisture:	~ 3.85 % (ISO 589)
Mv (Median value):	~ 48.24 µm (NFX 11-666)

9.2 Other information:

SECTION 10: Stability and reactivity

10.1 Reactivity:	Oxidizing agents.
10.2 Chemical stability:	Material is stable under normal conditions.
10.3 Possibility of hazardous reactions:	No hazardous reactions under ordinary conditions of use and storage.
10.4 Conditions to avoid:	Prevent dust cloud. Dust clouds may be explosive under certain conditions. Avoid dust close to ignition sources.
10.5 Incompatible materials:	Strong oxidizing substances.
10.6 Hazardous decomposition products:	Carbon Dioxide. Carbon Monoxide.

SECTION 11: Toxicological information

11.1 Information on toxicological effects:

Acute toxicity :

Test / Substance	Species	Type / Result	Exposure	Remarks
Carboxymethyl starch	Rat	LD50 - Oral : >2000 mg/kg Not classified		- Literature Reference -

Skin irritation. : No data available.

Serious eye irritation : No data available.

Sensitization :	No data available.
Repeated dose toxicity :	No data available.
Mutagenesis:	No data available.
Carcinogenicity:	No data available.
Reproductive toxicity:	No data available.
Remarks:	No data on possible toxicity effects have been found. The ingredients of this product are not classified as carcinogenic by the ACGIH, the CIRC, the OSHA or the NTP.

SECTION 12: Ecological information

12.1 Toxicity:	No data available.
12.2 Persistence and degradability:	No data available.
12.3 Bioaccumulative potential:	No data available.
12.4 Mobility in soil:	No data available.
12.5 Results of PBT and vPvB assessment:	No data available.
12.6 Other adverse effects:	None known.

SECTION 13: Disposal considerations

13.1 Waste treatment methods:

Product:	Dispose of waste in an appropriate authorised treatment facility in accordance with regulations in force and product characteristics at time of disposal.
Packaging material:	Single use packaging. Collect for salvage or disposal.

SECTION 14: Transport information

This material is not subject to transport regulations (DOT, IMDG, IATA).'

SECTION 15: Regulatory information

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

SARA Title III (Superfund Amendments and Reauthorization Act) :

Section: 302 Not Applicable

Section: 311 Not listed

US. NFPA 325 - Guide to Fire Hazard Properties of Flammable Liquids, Gases, and Volatile Solids. :

NFPA Health Rating: 1

NFPA Flammability Rating: 1

NFPA Instability Rating: 0

NFPA Special Hazard: No

US. HMIS Chemical Ratings (Hazardous Materials Information System, Chemical Ratings Guide) :

Health hazard: 1

Flammability hazard: 1

Physical hazard: 0

Personal Protection: E

US. California Safe Drinking Water & Toxic Enforcement Act (Proposition 65) :

Not listed

International Inventories :

Australia. Inventory of Chemical Substances (AICS):	Listed.
Canada. Canadian Environmental Protection Act (CEPA). Domestic Substances List (DSL):	Listed.
China. Inventory of Existing Chemical Substances (IECSC):	Listed.
EU. European Inventory of Existing Commercial Chemical Substances (EINECS):	Exempted
Japan. Inventory of Existing & New Chemical Substances (ENCS):	Listed.
Japan. Industrial Safety & Health Law (ISHL):	Listed.
Mexico. National Inventory of Chemical Substances (INSQ):	Listed.
Korea. Existing Chemicals Inventory (KECI):	Listed.
New Zealand. Inventory of Chemicals (NZIoC):	Listed.
Philippines. Inventory of Chemicals and Chemical Substances (PICCS):	Listed.
Taiwan. Existing Chemicals Inventory (TCSI):	Listed.
US. Toxic Substances Control Act (TSCA):	Listed.
Vietnam. National Chemical Inventory:	Listed.

This Safety Data Sheet is in conformity with appendix D of the OSHA Hazard Communication Standard 29CFR 1910.1200.

SECTION 16: Other information

Revision Information: Not relevant.

Key literature references and sources for data: No data available.

Abbreviations and acronyms used in the SDS.:

LD50: lethal dose 50%

CAS: Chemical Abstracts Service (division of the American Chemical Society)

Disclaimer:

The information provided in this Safety Data Sheet (SDS) relates only to the specific product designated and may not be applicable when such product is used in combination with other materials or in any process. It is the responsibility of the user to be aware of and to follow the regulations applying to our product for its possession, handling and use.

The information given is designed only as a guidance and is not to be considered a warranty or quality specification.

All information and instructions provided in this SDS are based on the current state of our knowledge at the latest revision date indicated.