



SAFETY DATA SHEET GLYCOLYS® LOW PH

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

1.1 Product identifier:

Product name: GLYCOLYS® LOW PH - SODIUM STARCH GLYCOLATE

Synonyms: Sodium salt of a cross-linked partly O-carboxymethylated potato starch.

INCI Name: SODIUM CARBOXYMETHYL STARCH

UFI Number: Not applicable.

Chemical name: Starch, carboxymethyl ether, sodium salt

DUIN Number : exempted (Article 2.9 Polymer)

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.	No data available.

1.3 Details of the supplier of the safety data sheet:

Supplier:

ROQUETTE FRERES
1 Rue de la Haute Loge
62136 LESTREM - France

Telephone: +33 3 21 63 36 00

Fax: +33 3 21 63 38 50

E-mail: sds@roquette.com

1.4 Emergency telephone number:

NPIS (24/24) : 844 892 0111

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture:

The product has not been classified as dangerous according to the legislation in force : CLP Regulation (EC) No 1272/2008.

2.2 Label elements: Not applicable

2.3 Other hazards: May form explosible dust-air mixture if dispersed in the air
Not fulfilling PBT (persistent/bioaccumulative/toxic) criteria
Not fulfilling vPvB (very persistent/very bioaccumulative) criteria

SECTION 3: Composition/information on ingredients

3.1 Substance:

Chemical name	Concentration	CAS-No.	EC No.	DUIN Number :
Starch, carboxymethyl ether, sodium salt	>80%	9063-38-1	Polymer	exempted (Article 2.9 Polymer)

Impurities contributing to the hazard

Chemical name	Concentration	CAS-No.	EC No.	Classification according to Regulation (EC) No 1272/2008 (CLP)	Specific concentration limit, M-Factor, Estimated acute toxicity:
ethanol; ethyl alcohol	<10%	64-17-5	200-578-6	Flam. Liq. 2 H225 Eye Irrit. 2 H319	
sodium salt of chloroacetic acid; sodium chloroacetate	<=0.3%	3926-62-3	223-498-3	Acute Tox. 3 H301 Skin Irrit. 2 H315 Aquatic Acute 1 H400	

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. Straight Streams of Water

- 5.2 Special hazards arising from the substance or mixture:** Fire or excessive heat may produce hazardous decomposition products. See Section 10. Combustible dusts : may form an explosible mixture in the air.

5.3 Advice for firefighters:

- Special Fire Fighting Procedures:** Prevent dust cloud. Do not use water jet as an extinguisher, as this will spread the fire.
- 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:** Preserve in well-closed original packing, preferably protected from large temperature and humidity variations, which may cause caking.
- 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 dust.	TWA	10 mg/m ³	UK. EH40 Workplace Exposure Limits (WELs) (2018)
Dust - Respirable dust.	TWA	4 mg/m ³	UK. EH40 Workplace Exposure Limits (WELs) (2018)

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-proof safety goggles where there is a risk of eyes contact. (EN 166)

Skin protection:

Hand Protection: Wear 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). (EN 143)
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
Color:	White
Odor:	Odorless
Odor Threshold:	No data available.
Melting Point:	Not Applicable
Boiling Point:	Not Applicable
Flash Point:	Not Applicable
Decomposition Temperature:	No data available.
pH:	~ 4.4 at 3 % w/w in water
Flammability (solid, gas):	NC: Not Classified
Solubility in Water:	~ 50 g/l at 20 °C
Partition coefficient (n-octanol/water):	No data available.
Vapor pressure:	Not Applicable
Relative density:	~ 0.55
Vapor density (air=1):	Not Applicable

9.2 Other information:

9.2.1 Information with regard to physical hazard classes:

No data available.

9.2.2 Other safety characteristics:

Formation of explosible dust/air mixtures:	- INERIS - Data from similar product.
MIT (Minimum ignition temperature):	MITc (cloud) : ~ 380 °C (EN 50281-2-1 / ASTM E1491) TDA (Differential Thermal Analysis), Δt : ~ 251 °C (EN 50281-2-1 / ASTM E1491)
MIE (Minimum Ignition Energy):	1,200 mJ (Hartmann) Very insensitive to the risk of inflammation by an electrostatic discharge.
(dP/dt)max (Maximum Rate of explosion Pressure rise):	~ 220 bar/s (EN 14034-2 / ASTM E1226)
Pmax (Maximum Explosion OverPressure) $\pm 10\%$:	~ 7.2 bar (EN 14034-1 / ASTM E1226)
Kst value ($\pm 20\%$):	~ 59 barm/s (EN 14034-2 / ASTM E1226)
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 μ m (ISO 13320)
Other Data:	MEC (Minimum Explosible Concentration) : 30-60 g/m ³ (EN 14034-3 / ASTM E1515)
Oxidizing properties	NC: Not Classified

Evaporation Rate: Not Applicable

The data reported in this section does not take the place of specifications.

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 hazard classes as defined in Regulation EC 1272/2008:

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.

11.2 Information on other hazards:

Remarks: No data available. 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:	Exempted
12.6 Endocrine disrupting properties:	No data available.
12.7 Other adverse effects:	None known.

SECTION 13: Disposal considerations

13.1 Waste treatment methods:

Product:	Dispose of waste in an appropriate authorized 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

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 regulated.
14.6 Special precautions for user:	No special precautions.
14.7 Maritime transport in bulk according to IMO instruments:	Not applicable.

SECTION 15: Regulatory information

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

EU.REACH Article 59, candidate List of Substances of Very High Concern (SVHC).
Not listed

Regulation (EC) No. 1907/2006 Annex XVII Substances subject to restriction on marketing and use
Not Applicable

Regulation (EC) No. 1907/2006, REACH Annex XIV Substances subject to authorisation, as amended
Not Applicable

REGULATION (EU) 2017/542 (CLP Annex VIII) :harmonised information relating to emergency health response and preventative measures.
UFI Number: Not Applicable

REGULATION (EU) 2019/1148 on the marketing and use of explosives precursors.
Not Applicable

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 conforms to annex II of regulation (EC) 1907/2006 (REACH) and its amendments.

This Safety Data Sheet conforms to SCHEDULE 3 / Part 1 / annex II of regulation (GB)2019 n°758.

15.2 Chemical safety assessment:

Exempted

SECTION 16: Other information

Revision Information: 10/25/2021

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

Other information: Updated version of this document is available at :<https://www.roquette.com/site-search#documents>

Abbreviations and acronyms used in the SDS.:

LD50: lethal dose 50%
CAS: Chemical Abstracts Service (division of the American Chemical Society)
CLP : Classification, Labelling and Packaging (Reg. EC 1272/2008).
OECD : Organisation for Economic Cooperation and Development
PBT: Persistent, Bioaccumulative and Toxic
REACH : Registration, Evaluation, Authorisation and Restriction of Chemicals.
vPvB: very persistent and very bioaccumulative substance.

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.