

SAFETY DATA SHEET
SOLUTAB® A

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

1.1 Product identifier:

Product name: SOLUTAB® A - SODIUM CROSCARMELOSE

Synonyms: Cross-linked carboxymethylcellulose sodium; cross-linked cellulose gum; E 468

UFI Number: Not applicable.

Chemical name: Carboxymethylcellulose Sodium

DUIN Number : Exempted (Article 2).

CAS-No.: 74811-65-7

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

Identified uses:	Uses advised against:
Pharmaceuticals. Food additive. Disintegrant , Dissolution accelerator	None Reported

1.3 Details of the supplier of the safety data sheet:

Supplier:

ITACEL FARMOQUIMÍCA 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:

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

SECTION 3: Composition/information on ingredients

3.1 Substance:

Chemical name	Concentration	CAS-No.	EC No.	DUIN Number :
Carboxymethylcellulose Sodium	>=93 - <=98.5%	74811-65-7	-	Exempted (Article 2).

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:	Promptly wash eyes with plenty of water while lifting the eye lids. Get medical attention if irritation persists after washing.
Skin contact:	Wash with soap and water.
Ingestion:	Drink plenty of water. Never give liquid to an unconscious person. 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.

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. Combustible dusts : may form an explosible mixture in the air. 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:	No special precautions. Do not discharge into drains, water courses or onto the ground.

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. Avoid contact with eyes, skin, and clothing. Avoid heat, sparks, open flames and other ignition sources. Provide good ventilation.

7.2 Conditions for safe storage, including any incompatibilities:

Store in original container. Keep containers tightly closed. Keep container in a well-ventilated place. Store in a dry place. Avoid exposure to high temperatures or direct sunlight.

7.3 Specific end use(s):

Pharmaceuticals., Food additive., Disintegrant, Dissolution accelerator,

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:

Provide adequate ventilation. Observe Occupational Exposure Limits and minimize the risk of inhalation of dust.

Individual protection measures, such as personal protective equipment:

Eye/face protection:

Wear dust-proof safety goggles where there is a risk of eyes contact.

Skin protection:

Hand Protection:

Wear suitable gloves.

Other:

Wear suitable protective clothing.

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:

Do not allow runoff to sewer, waterway or ground.

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
Odor Threshold:	No data available.
Melting Point:	Not Applicable
Boiling Point:	Not Applicable
Flash Point:	Not Applicable
pH:	5 - 7 at 10 g/l
Flammability (solid, gas):	NC: Not Classified
Solubility in Water:	The product is partly soluble in water. 1 - 10 % (w/w)
Partition coefficient (n-octanol/water):	No data available.
Vapor pressure:	Not Applicable
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:	- CHILWORTH - Data from similar product.
MIT (Minimum ignition temperature):	MITc (cloud) : ~ 460 °C (EN 50281-2-1 / ASTM E1491) MITL (5mm Layer) : ~ 340 °C (EN 50281-2-1 / ASTM E2021)
MIE (Minimum Ignition Energy):	> 1,000 mJ (EN 13821 / ASTM E2019, Without Inductance, <63 µm) Very insensitive to the risk of inflammation by an electrostatic discharge.
(dP/dt)_{max} (Maximum Rate of explosion Pressure rise):	~ 269 bar/s (EN 14034-2 / ASTM E1226)
P_{max} (Maximum Explosion OverPressure) ±10%:	~ 8.3 bar (EN 14034-1 / ASTM E1226)
K_{st} value (±20%):	~ 73 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:	~ 6.13 % (ISO 589)
M_v (Median value):	~ 68.44 µm (ISO 13320)
Other Data:	MEC (Minimum Explosible Concentration) : 30-60 g/m ³ (EN 14034-3 / ASTM E1515) Particle size (D10%) : 20,38 µm (ISO 13320) Particle size (D90%) : 245 µm (ISO 13320)
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
Cellulose, carboxymethyl ether, sodium salt	Guinea Pig	LD50 - Oral : 16 g/kg		- Literature Reference -
Cellulose, carboxymethyl ether, sodium salt	Rat	LD50 - Oral : 27 g/kg		- Literature Reference -

Skin irritation. :

Test / Substance	Species	Result	Exposure	Remarks
Hydroxyethylcellulose	Rabbit	Not Irritating	48 h	- Literature Reference -

Serious eye irritation :

Test / Substance	Species	Result	Exposure	Remarks
Hydroxyethylcellulose	Rabbit	Not Irritating		- Literature Reference -

Sensitization :

Test / Substance	Type	Species	Result	Remarks
Hydroxypropylmethylcellulose		Guinea Pig	Non-Sensitising	- Literature Reference -

Repeated dose toxicity :

Test / Substance	Species	Result	Exposure	Remarks
OECD 408 Cellulose, carboxymethyl ether, sodium salt	Rat	No treatment related effects.	90 day(s)	- Literature Reference -

Mutagenesis :

Test / Substance	Type	Species	Result	Remarks
Ames Cellulose, carboxymethyl ether, sodium salt		S. typhimurium	Negative	- Literature Reference -

Carcinogenicity :

Test / Substance	Species	Route of Exposure / Exposure	Result	Remarks
Scientific evaluation. Methylcellulose	Rat	Subcutaneous	Negative	- Literature Reference -
Scientific evaluation. Cellulose, carboxymethyl ether, sodium salt	Rat	Oral 103 Week(s).	Negative	- Literature Reference -

Reproductive toxicity :

Test / Substance	Species	Route of Exposure / Exposure	Result	Remarks
Scientific evaluation. Hydroxypropylmethylcellulose	Rat	Oral 28 day(s)	No treatment related effects.	- Literature Reference -
Scientific evaluation. Methylcellulose	Rat	Oral	No treatment related effects.	- Literature Reference -

11.2 Information on other hazards: No data available.
Remarks: 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:

Acute toxicity:

Test / Substance	Species	Type/Result	Exposure	Remarks
Cellulose, carboxymethyl ether, sodium salt	Ceriodaphnia	EC50 : > 100 mg/l	48 h	- Literature Reference -
Cellulose, carboxymethyl ether, sodium salt	Rainbow Trout	LC50 : >20000 mg/l	96 h	- Literature Reference -

Chronic Toxicity: No data available.

12.2 Persistence and degradability:

Test / Substance	Result	Remarks
Cellulose	> 70 % Inherently biodegradable	- Literature Reference -

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. (for example, energy recovery).

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.
China. Inventory of Existing Chemical Substances (IECSC):	Listed.
Japan. Pharmacopoeia Listing:	Listed.
Mexico. National Inventory of Chemical Substances (INSQ):	Listed.
Philippines. Inventory of Chemicals and Chemical Substances (PICCS):	Listed.
New Zealand. Inventory of Chemicals (NZIoC):	Listed.
Taiwan. Existing Chemicals Inventory (TCSI):	Listed.
Vietnam. National Chemical Inventory:	Listed.

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: 10/26/2021

Key literature references and sources for data: JECFA : Joint FAO/WHO Expert Committee on Food Additives.
ToxNet Database.
COSMETICS INGREDIENT REVIEW (PERSONAL CARE PRODUCTS COUNCIL)

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

Abbreviations and acronyms used in the SDS.:

CAS: Chemical Abstracts Service (division of the American Chemical Society)
CLP : Classification, Labelling and Packaging (Reg. EC 1272/2008).
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.