

## SAFETY DATA SHEET LYCATAB® CT

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

#### 1.1 Product identifier:

**Product name:** LYCATAB® CT

**Synonyms:** Pregelatinised starch - EP / USP  
**UFI Number:** Not applicable.  
**Chemical name:** Starch  
**DUIN Number :** Exempted (Annex IV).  
**CAS-No.:** 9005-25-8  
**EC No.:** 232-679-6

#### 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:**

Crest Cellulose Private Limited.  
Plot no: 12 & 13, Block-B, APIIC Industrial Park.  
Menakur Village, Naidupet Mandal, SPS Nellore  
District Nellore, Andhra Pradesh - 524421 - INDIA

**Telephone:** +91 98 4874 5566

**E-mail:** sagar.suravashi@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 :
Starch	>=86%	9005-25-8	232-679-6	Exempted (Annex IV).

## SECTION 4: First aid measures

### 4.1 Description of first aid measures:

<b>Inhalation:</b>	Move the exposed person to fresh air at once. Get medical attention if any discomfort continues.
<b>Eye contact:</b>	Flush thoroughly with water. If irritation occurs, get medical assistance.
<b>Skin contact:</b>	Wash with soap and water.
<b>Ingestion:</b>	Get medical attention if symptoms occur.

<b>4.2 Most important symptoms and effects, both acute and delayed:</b>	Dust may irritate the eyes and the respiratory system.
---	--

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

<b>Treatment:</b>	Treat symptomatically.
-------------------	------------------------

## SECTION 5: Firefighting measures

### 5.1 Extinguishing media:

<b>Suitable extinguishing media:</b>	Water spray.
<b>Unsuitable extinguishing media:</b>	Dry chemicals or foams.

<b>5.2 Special hazards arising from the substance or mixture:</b>	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:

<b>Special Fire Fighting Procedures:</b>	Prevent dust cloud.
<b>Special protective equipment for fire-fighters:</b>	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

<b>6.1 Personal precautions, protective equipment and emergency procedures:</b>	See Section 8 of the SDS for Personal Protective Equipment.
<b>6.2 Environmental precautions:</b>	Avoid discharge to the aquatic environment.
<b>6.3 Methods and material for containment and cleaning up:</b>	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.

**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 dust.	TWA	10 mg/m <sup>3</sup>	UK. EH40 Workplace Exposure Limits (WELs) (2018)
Dust - Respirable dust.	TWA	4 mg/m <sup>3</sup>	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.

**Skin protection:**

**Hand Protection:**

No special precautions.

**Other:**

No special precautions.

**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 discharge to the aquatic environment.

## SECTION 9: Physical and chemical properties

**9.1 Information on basic physical and chemical properties:**

**Physical State:**

solid

**Form:**

Powder

<b>Water, moisture:</b>	< 14 %
<b>Color:</b>	White
<b>Odor:</b>	Odorless
<b>Odor Threshold:</b>	No data available.
<b>Melting Point:</b>	Not applicable
<b>Boiling Point:</b>	Not Applicable
<b>Flash Point:</b>	Not Applicable
<b>Decomposition Temperature:</b>	No data available.
<b>pH:</b>	~ 5.4 at 3 % w/w in water
<b>Flammability (solid, gas):</b>	NC: Not Classified
<b>Solubility in Water:</b>	Completely soluble in water at 90 °C
<b>Partition coefficient (n-octanol/water):</b>	< -2 - ECHA Database - Similar substance
<b>Vapor pressure:</b>	Not Applicable
<b>Relative density:</b>	~ 0.6
<b>Vapor density (air=1):</b>	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:

<b>Formation of explosible dust/air mixtures:</b>	- INERIS - Data from similar product.
<b>MIT (Minimum ignition temperature):</b>	MITc (cloud) : ~ 480 °C (EN 50281-2-1 / ASTM E1491)
<b>MIE (Minimum Ignition Energy):</b>	~ 225 mJ (EN 13821 / ASTM E2019, Without Inductance) Sensitive to the risk of inflammation by an electrostatic discharge.
<b>(dP/dt)max (Maximum Rate of explosion Pressure rise):</b>	~ 460 bar/s (EN 14034-2 / ASTM E1226)
<b>Pmax (Maximum Explosion OverPressure) ±10%:</b>	~ 8.5 bar (EN 14034-1 / ASTM E1226)
<b>Kst value (±20%):</b>	~ 124 barm/s (EN 14034-2 / ASTM E1226)
<b>Dust Explosion Class:</b>	st 1 (VDI 3673)
<b>Volume resistivity:</b>	7,5x10 <sup>13</sup> Ω.cm (IEC 61241-2-2 / Group IIIB non-conductive dust.)
<b>Moisture:</b>	~ 12.38 % (ISO 589)
<b>Mv (Median value):</b>	~ 18 µm (ISO 13320)
<b>Other Data:</b>	MEC (Minimum Explosible Concentration) : 30-60 g/m <sup>3</sup> (EN 14034-3 / ASTM E1515) BZ (Combustion class) : 3 (VDI 2263-1)
<b>Oxidizing properties</b>	NC: Not Classified
<b>Evaporation Rate:</b>	Not Applicable

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

## SECTION 10: Stability and reactivity

<b>10.1 Reactivity:</b>	Oxidizing agents.
<b>10.2 Chemical stability:</b>	Material is stable under normal conditions.
<b>10.3 Possibility of hazardous reactions:</b>	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
Test not published. Starch	Rat	LD50 : > 50,000 mg/kg		- Literature Reference -

**Skin irritation. :** No data available.

**Serious eye irritation :** No data available.

**Sensitization :** No data available.

#### Repeated dose toxicity :

Test / Substance	Species	Result	Exposure	Remarks
Starch	Rat	NOAEL : > 5000 mg/kg		- Literature Reference -

**Mutagenesis:** No data available.

**Carcinogenicity:** No data available.

**Reproductive toxicity:** No data available.

### 11.2 Information on other hazards:

**Remarks:** No data available.  
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
OECD 203 Glucose syrups wheat hydrolysed	Common Carp	LC50 : > 100 mg/l Not classified	96 h	- REACH data - Data from similar product.
OECD 202 Glucose syrups wheat hydrolysed	Daphnia magna	LC50 : > 100 mg/l Not classified	48 h	- REACH data - Data from similar product.
OECD 201 Glucose syrups wheat hydrolysed	Pseudokirchneriella subcapitata	LC50 : > 100 mg/l Not classified	72 h	- REACH data - Data from similar product.

**Chronic Toxicity:** No data available.

## 12.2 Persistence and degradability:

Test / Substance	Result	Remarks
OECD 301b Glucose syrups wheat hydrolysed	> 73 % / 28 d The product is readily biodegradable.	- REACH data - Data from similar product.

## 12.3 Bioaccumulative potential:

Test / Substance	Log Pow (n-Octanol/Water Partition Coefficient)	Bioconcentration Factor (BCF) / Bioaccumulation	Remarks
Starch	< -2	3.16	Potential to bioaccumulate is low. - ECHA Database -

## 12.4 Mobility in soil:

This material is readily biodegraded and is not likely to bioconcentrate.

## 12.5 Results of PBT and vPvB assessment:

Exempted

## 12.6 Endocrine disrupting properties:

No data available.

## 12.7 Other adverse effects:

[http://ec.europa.eu/environment/chemicals/reach/pdf/6b\\_appendix\\_2.pdf](http://ec.europa.eu/environment/chemicals/reach/pdf/6b_appendix_2.pdf) (P26 / Starch)

# 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

**Turkey. KKDİK Regulation (Turkey REACH)**  
Exempted ANNEX IV

**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):	Listed.
Japan. Inventory of Existing & New Chemical Substances (ENCS):	Listed.
Japan. Industrial Safety & Health Law (ISHL):	Listed.
Japan. Pharmacopoeia Listing:	Listed.
Korea. Existing Chemicals Inventory (KECI):	Listed.
Mexico. National Inventory of Chemical Substances (INSQ):	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 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:** [http://ec.europa.eu/environment/chemicals/reach/pdf/6b\\_appendix\\_2.pdf](http://ec.europa.eu/environment/chemicals/reach/pdf/6b_appendix_2.pdf) (P26 / Starch)

**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.

