

SAFETY DATA SHEET



**STARCH 1500 PARTIALLY
PREGELATINIZED MAIZE
STARCH 2001**

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

1.1 Product identifier

Product name : STARCH 1500 PARTIALLY PREGELATINIZED MAIZE STARCH
Product code : 2001

1.2 Use of the substance/mixture

Manufacture of pharmaceutical products and/or Manufacture of food products

1.3 Details of the supplier of the safety data sheet

Supplier : Colorcon Asia Pvt. Limited
Plot Nos. M14 - M18
Verna Industrial Estate
Verna, Goa 403 722 India
www.colorcon.com
E-mail: safety@colorcon.com
Phone: +91-832-6727373
Fax: +91-832-6625870

1.4 Emergency telephone number

Emergency telephone number : +1 760 476 3960

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Product definition : Mono-constituent substance

Classification according to Regulation (EC) No. 1272/2008 [CLP/GHS]

The product is not classified as hazardous according to Regulation (EC) 1272/2008 as amended.

2.2 Label elements

Signal word : Warning
Hazard statements : Causes mild skin irritation.
Precautionary statements
General : Not applicable.
Prevention : Not applicable.
Response : skin irritation occurs: Get medical advice or attention.
Storage : Not applicable.
Disposal : Not applicable.

2.3 Other hazards

**STARCH 1500 PARTIALLY
PREGELATINIZED MAIZE
STARCH 2001**

SECTION 2: Hazards identification

Product meets the criteria for PBT or vPvB according to Regulation (EC) No. 1907/2006, Annex XIII

PBT	P	B	T	vPvB	vP	vB
No	N/A	N/A	No	N/A	N/A	N/A

Other hazards which do not result in classification

: Fine dust clouds may form explosive mixtures with air. Handling and/or processing of this material may generate a dust which can cause mechanical irritation of the eyes, skin, nose and throat.
None identified.

See Section 11 for more detailed information on health effects and symptoms.

SECTION 3: Composition/information on ingredients

Substance/mixture : Mono-constituent substance

Product/ingredient name	Identifiers	%	Classification	Specific Conc. Limits, M-factors and ATEs	Type
Europe STARCH 1500 PARTIALLY PREGELATINIZED MAIZE STARCH	REACH #: Annex IV EC: 232-679-6 CAS: 9005-25-8	70 - 100	Not classified.	-	[1]

Occupational exposure limits, if available, are listed in Section 8.

Type

☒ Constituent

SECTION 4: First aid measures

4.1 Description of first aid measures

- A. Eye contact** : Affected individual should remove contact lens, if present. In case of contact with eyes, rinse immediately with plenty of water. or saline solution. Get medical attention if irritation occurs.
- B. Skin contact** : Wash contaminated skin with soap and water. Get medical attention if irritation develops.
- C. Inhalation** : If inhaled, remove to fresh air. Get medical attention if symptoms appear. If exposed person is not breathing, give artificial respiration or oxygen applied by trained personnel.
- D. Ingestion** : Wash out mouth with water. Do not induce vomiting unless directed to do so by medical personnel. Get medical attention if symptoms occur. Never give anything by mouth to an unconscious person.

See Section 11 for more detailed information on health effects and symptoms.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media : ☒ Recommended: alcohol-resistant foam, CO₂, powders, water spray.

Unsuitable extinguishing media : ☒ Do not use water jet.

SECTION 5: Firefighting measures

5.2 Special hazards arising from the substance or mixture

- Specific hazards arising from the chemical** : Fire will produce dense black smoke. Exposure to decomposition products may cause a health hazard.
May be explosive or flammable if dispersed in air and in the presence of ignition sources.
- Hazardous thermal decomposition products** : Decomposition products may include the following materials: carbon monoxide, carbon dioxide, smoke, oxides of nitrogen.

5.3 Advice for firefighters

- Special protective equipment for fire-fighters** : Appropriate breathing apparatus may be required.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

- Personal precautions, protective equipment and emergency procedures** : Keep unnecessary personnel away. Avoid breathing dust. Provide adequate ventilation. Use suitable protective equipment (section 8).

6.2 Environmental precautions

- : Avoid breathing vapor or mist. Refer to protective measures listed in sections 7 and 8.
If emergency personnel are unavailable, carefully scoop up spilled materials and use a non-sparking or explosion-proof means to transfer material to an appropriate container for disposal by incineration. Use spark-proof tools and explosion-proof equipment. Avoid creating dusty conditions and prevent wind dispersal.

6.3 Methods for cleaning up

- : Use spark-proof tools and explosion-proof equipment.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Handling

- : Fine dust clouds may form explosive mixtures with air. Handling and/or processing of this material may generate a dust which can cause mechanical irritation of the eyes, skin, nose and throat.
Avoid breathing dust. Good housekeeping is essential for prevention of explosion hazards. Prevent dust accumulation. Control ignition sources. Dust accumulations or layers may ignite if exposed to elevated temperatures. If ignition sources are present, use methods that do not generate dust clouds. Dust can be ignited by electrostatic discharge. Additional precautions are required if a flammable vapor is present. For general guidance and system design considerations, refer to the following National Fire Protection Association (NFPA) standards or their country-specific equivalents for information on prevention of fire and dust explosions: NFPA 77 (Recommended Practice on Static Electricity) and NFPA 654 (Standard for the Prevention of Fire and Dust Explosions from the Manufacturing, Processing, and Handling of Combustible Particulate Solids) as well as standards referenced therein. (In Europe this is the EU Directive 99/92/EC, also known as 'ATEX 137' Directive). Empty containers or liners may retain some product residues. Residual dust in container may ignite if exposed to an ignition source of sufficient energy. Contact Colorcon if more specific dust safety data is needed.

7.2 Conditions for safe storage

- : Keep container tightly closed. Store in a dry, cool and well-ventilated area. Eliminate all ignition sources. Store in accordance with local regulations.

SECTION 7: Handling and storage

See Finished Product Label for specific storage conditions.

SECTION 8: Exposure controls/personal protection

The information in this section contains generic advice and guidance. Information is provided based on typical anticipated uses of the product. Additional measures might be required for bulk handling or other uses that could significantly increase worker exposure or environmental releases.

8.1 Control parameters

Occupational exposure limits

Product/ingredient name	Exposure limit values
STARCH 1500 PARTIALLY PREGELATINIZED MAIZE STARCH	EH40/2005 WELs (United Kingdom (UK), 1/2020). TWA: 4 mg/m ³ 8 hours. Form: respirable TWA: 10 mg/m ³ 8 hours. Form: total inhalable

Recommended monitoring procedures : If this product contains ingredients with exposure limits, personal, workplace atmosphere or biological monitoring may be required to determine the effectiveness of the ventilation or other control measures and/or the necessity to use respiratory protective equipment. Reference should be made to monitoring standards, such as the following: European Standard EN 689 (Workplace atmospheres - Guidance for the assessment of exposure by inhalation to chemical agents for comparison with limit values and measurement strategy) Reference to national guidance documents for methods for the determination of hazardous substances will also be required.

DNELs/DMELs

No DNELs/DMELs available.

PNECs

No PNECs available.

8.2 Exposure controls

Appropriate engineering controls : Provide adequate ventilation. Where reasonably practicable, this should be achieved by the use of local exhaust ventilation and good general extraction.

Individual protection measures

Hygiene measures : Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.

Eye/face protection : Use safety eyewear designed to protect against splash of liquids.

Skin protection

Hand protection : There is no one glove material or combination of materials that will give unlimited resistance to any individual or combination of chemicals. The breakthrough time must be greater than the end use time of the product. The instructions and information provided by the glove manufacturer on use, storage, maintenance and replacement must be followed. Gloves should be replaced regularly and if there is any sign of damage to the glove material. Always ensure that gloves are free from defects and that they are stored and used correctly. The performance or effectiveness of the glove may be reduced by physical/chemical damage and poor maintenance. Barrier creams may help to protect the exposed areas of the skin but should not be applied once exposure has occurred.

SECTION 8: Exposure controls/personal protection

- Body protection** : ☒ Not applicable.
- Other skin protection** : Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.
- Respiratory protection** : ☒ Not applicable.
- Environmental exposure controls** : ☒ Do not allow to enter drains or watercourses.

SECTION 9: Physical and chemical properties

Values provided should not be construed as specifications. See product specification for additional information.

9.1 Information on basic physical and chemical properties

- Physical state** : Solid. [Powder.]
- Appearance** : White Powder
- Odor** : Odorless.
- Odor threshold** : Not available.
- pH** : Not available.
- Melting point/freezing point** : Not available.
- Evaporation rate** : Not available.
- Flammability (solid, gas)** : Not applicable.
- Upper/lower flammability or explosive limits** : Not applicable.
- Vapor pressure** : Not available.
- Vapor density** : Not available.
- Relative density** : Not available.
- Solubility(ies)** : Not available.
- Partition coefficient: n-octanol/water** : Not available.
- Auto-ignition temperature** : Not applicable.
- Decomposition temperature** : Not available.
- Viscosity** : Not available.
- Explosive properties** : May be explosive or flammable if dispersed in air and in the presence of ignition sources.
- Oxidizing properties** : Not available.

SECTION 10: Stability and reactivity

- 10.1 Reactivity** : ☒ No specific test data related to reactivity available for this product or its ingredients.
- 10.2 Chemical stability** : ☒ Stable under recommended storage and handling conditions (see Section 7).
- 10.3 Possibility of hazardous reactions** : ☒ Under normal conditions of storage and use, hazardous reactions will not occur.
- 10.4 Conditions to avoid** : ☒ When exposed to high temperatures may produce hazardous decomposition products.

SECTION 10: Stability and reactivity

10.5 Incompatible materials : Keep away from the following materials to prevent strong exothermic reactions: oxidizing agents, strong alkalis, strong acids.

10.6 Hazardous decomposition products : Decomposition products may include the following materials: carbon monoxide, carbon dioxide, smoke, oxides of nitrogen.

SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

There are no data available on the mixture itself. The product is not classified as hazardous according to Regulation (EC) 1272/2008 as amended.

If splashed in the eyes, the liquid may cause irritation and reversible damage.

This takes into account, where known, delayed and immediate effects and also chronic effects of components from short-term and long-term exposure by oral, inhalation and dermal routes of exposure and eye contact.

Potential acute health effects

- Inhalation** : Fine dust clouds may form explosive mixtures with air. Handling and/or processing of this material may generate a dust which can cause mechanical irritation of the eyes, skin, nose and throat.
Exposure to airborne concentrations above statutory or recommended exposure limits may cause irritation of the nose, throat and lungs.
- Ingestion** : No known significant effects or critical hazards.
- Skin contact** : No known significant effects or critical hazards.
- Eye contact** : This product may irritate eyes upon contact.

Acute toxicity

<u>Inгредиент name</u>	<u>CAS #</u>	<u>Result</u>	<u>Species</u>	<u>Dose</u>	<u>Exposure</u>
STARCH 1500 PARTIALLY PREGELATINIZED MAIZE STARCH	9005-25-8	LD50 Intraperitoneal	Mouse	6600 mg/kg	-

Irritation/Corrosion

<u>Product/ingredient name</u>	<u>Result</u>	<u>Species</u>	<u>Score</u>	<u>Exposure</u>	<u>Observation</u>
STARCH 1500 PARTIALLY PREGELATINIZED MAIZE STARCH	Skin - Mild irritant	Human	-	72 hours 300 ug l	-

Chronic effects

<u>Inгредиент name</u>	<u>ACGIH</u>	<u>IARC</u>	<u>EPA</u>	<u>NIOSH</u>	<u>NTP</u>	<u>OSHA</u>
PREGELATINIZED CORN STARCH	A4	-	-	-	-	-

Additional information :

Not available.

Other toxic effects on humans

Fine dust clouds may form explosive mixtures with air. Handling and/or processing of this material may generate a dust which can cause mechanical irritation of the eyes, skin, nose and throat.

Specific effects on humans

Mutagenicity / Teratogenicity / Reproductive toxicity : Not available.

Over-exposure signs/symptoms

SECTION 11: Toxicological information

- Inhalation** : Adverse symptoms may include the following:
respiratory tract irritation
coughing
- Ingestion** : No specific data.
- Skin contact** : No specific data.
- Eye contact** : Adverse symptoms may include the following:
irritation
redness

SECTION 12: Ecological information

12.1 Toxicity

: Not available.

12.2 Persistence and degradability

Conclusion/Summary : Not available.

12.3 Bioaccumulative potential

Not available.

12.5 Results of PBT and vPvB assessment

Product/ingredient name	PBT	P	B	T	vPvB	vP	vB
Starch	No	N/A	N/A	No	N/A	N/A	N/A

12.6 Other adverse effects : No known significant effects or critical hazards.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product

Methods of disposal : The generation of waste should be avoided or minimized wherever possible. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements.

Hazardous waste : Within the present knowledge of the supplier, this product is not regarded as hazardous waste, as defined by EU Directive 2008/98/EC.

SECTION 14: Transport information

Tunnel code : (-)

This product is not regulated for carriage according to ADR/RID, ADN, IMDG, ICAO/IATA.

SECTION 15: Regulatory information

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

EU Regulation (EC) No. 1907/2006 (REACH)

Annex XIV - List of substances subject to authorization

Annex XIV

None of the components are listed.

Substances of very high concern

None of the components are listed.

NACE : Not available.

UC62 : Not available.

France

Reinforced medical surveillance : Decree n ° 2012-135 of January 30, 2012 relating to the organization of occupational medicine: not applicable

Germany

Storage class (TRGS 510) : 1

Hazard class for water : pwg

Technical instruction on air quality control : TA-Luft Number 5.2.1

Italy

D.Lgs. 152/06 : Not determined.

Netherlands

Water Discharge Policy (ABM) : A(4) Low hazard for aquatic organisms, may have long-term hazardous effects in aquatic environment. Decontamination effort: A

Sweden

Switzerland

VOC content : Exempt.

15.2 Chemical Safety Assessment : No Chemical Safety Assessment has been carried out.

SECTION 16: Other information

CEPE code : 7

Abbreviations and acronyms :

- ATE = Acute Toxicity Estimate
- CLP = Classification, Labelling and Packaging Regulation [Regulation (EC) No. 1272/2008]
- DMEL = Derived Minimal Effect Level
- DNEL = Derived No Effect Level
- EUH statement = CLP-specific Hazard statement
- PBT = Persistent, Bioaccumulative and Toxic
- PNEC = Predicted No Effect Concentration
- RRN = REACH Registration Number
- vPvB = Very Persistent and Very Bioaccumulative

Procedure used to derive the classification according to Regulation (EC) No. 1272/2008 [CLP/GHS]

Classification	Justification
Not classified.	

Precautionary statements

SECTION 16: Other information

Not applicable.

Indicates information that has changed from previously issued version.

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Version : 1.02

Notice to reader

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