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MATERIAL SAFETY DATA SHEET

Starch, pregelatinized starch According to the European Directive 1907/2006/ EC

SECTION 1: PRODUCT AND COMPANY IDENTIFICATION

Product Name : Partly pregelatinized starch, Pregelatinized starch Synonym(s) : Starch, pregelatinized starch General Use : Excipient for pharmaceuticals Additive for foods and cosmetics Product Description : Powder of carbohydrate MSDS Type: US

Manufacturer: Maple Biotech Pvt. Ltd.

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SECTION 2. COMPOSITION / INFORMATION ON INGREDIENTS

Chemical Name : Starch, pregelatinized starch CAS Registry Number : 9005-25-8 Chemical Formula : $(C_6H_{10}O_5)_x$ Ingredients (Impurities) & Composition Starch : 90.0 % or more

SECTION 3. HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW: Combustible powder material. May form flammable / explosive dust-air mixture.

POTENTIAL HEALTH EFFECTS:

Inhalation: Very low hazard in normal use. Dust may be slightly irritating. Eye: Very low hazard in normal use. Dust may cause mechanical irritation. Skin: Very low hazard in normal use. May cause skin irritation to hypersensitive persons. Ingestion: Very low hazard in normal use. Large doses may results in abnormal symptoms.

> POTENTIAL ENVIRONMENTAL EFFECTS: Inherently biodegradable



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SECTION 4. FIRST AID MEASURES

INHALATION:

Remove to fresh air. If breathing is difficult, give oxygen or get medical attention.

EYE:

Flush eyes with water for at least 15 minutes. Get medical attention, if irritation persists.

SKIN:

Wash with soap and water. Get medical attention, if irritation persists.

INGESTION:

Starch, which has been used for food from ancient times, is very safe to eat.

However, if ingestion of large quantities results in abnormal symptoms, get medical attention.

PROTECTION TO FIRST-AIDERS:

Not specifically.

SECTION 5. FIRE FIGHTING MEASURES

FLAMMABLE PROPERTIES:

Combustible at elevated temperatures. Contact with strong oxidizers may cause fire. Dusts at sufficient concentrations can form explosive mixtures with air.

Auto-ignition temperature: 390°C.

Lower explosion limit: 40 g/m³

EXTINGUISHING MEDIA:

Generally use extinguishing media such as water, carbon dioxide, dry chemical powder, and foam.

FIRE FIGHTING INSTRUCTIONS:

Evacuate area and fight fire from a safe distance. Wear full fire-fighting turn-out gear (full bunker gear) and respiratory protection (self-contained breathing apparatus) as in an ordinary type of fire.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Wear appropriate personal protection. (See Section 8.)

LAND SPILL:

Sweep up material and place in a disposal container. Reduce airborne dust and prevent scattering by moistening with water.

WATER SPILL:

Pick up spill for recovery or disposal and place in a closed container

SECTION 7. HANDLING AND STORAGE

HANDLING:

Handle without making air-suspended dust. May form flammable dust-air mixture. Be careful to prevent quality deterioration due to exposure to light, heat, or moisture.

STORAGE:

Store in a cool, dry, well-ventilated indoor location. Protect from direct sunlight, high temperature, and moisture. Place in a polyethylene bag or equivalent for protection from moisture, after opening the container.



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SECTION 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

EXPOSURE LIMIT VALUES: Starch

OSHA Permissible Exposure Limit (PEL):

total dust: 15 mg/m³ TWA, respirable fraction: 5 mg/m³ TWA. ACGIH Threshold Limit Value (TLV):

 $10 \text{ mg/m}^3 \text{TWA}$

10 mg/m TW.

EXPOSURE CONTROLS

Occupational Exposure Controls

Engineering controls:

Provide local exhaust ventilation, or other engineering controls to control airborne levels below recommended exposure limits. Make available in the work area emergency shower and eye wash, and clarify their locations.

Personal Protection

Respiratory Protection: If airborne concentrations are expected to exceed exposure limits, an air purifying respirator may be worn.

Eye Protection : Wear safety glasses or safety goggles, if necessary.

Skin Protection : Wear protective gloves, if necessary.

Environmental Exposure Controls

Not specifically

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : White to light yellow, free flowing powder Odor : Odorless pH : 4.0 - 7.5 as an 2% solid dispersion Melting Point/Melting Range : Not applicable Decomposition Temperature : Not available Flash Point : Not applicable Auto Ignition Temperature: 390°C Flammability : Flammable Lower explosion limit: 40 g/m³

Relative Density : Approximately 0.5 g/cm³ (Bulk density) Solubility : Substantially insoluble in water and in most of organic solvent. Partly soluble in hot water

SECTION 10. STABILITY AND REACTIVITY

CONDITIONS TO AVOID:

Direct sunlight High temperatures

STABILITY:

Chemically stable when used under normal conditions.

MATERIALS TO AVOID:

Moisture

Oxidizing materials

HAZARDOUS REACTIONS/DECOMPOSITION PRODUCTS

Carbon monoxide and carbon dioxide may form when heated to decomposition.



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SECTION 11. TOXICOLOGICAL INFORMATION

Acute Toxicity: LD₅₀ > 6,600 mg/kg (mouse, intraperitoneal admin.) Eye Irritation: Not available Skin Irritation: No irritation to human skin. (300μg/ 3 days, intermittent) Chronic Toxicity; Starch is regarded as GRAS (generally recognized as safe) by FDA. Mutagenicity: not available. Carcinogenicity:

IARC: Not listed NTP: Not listed ACGIH: Not listed

SECTION 12. ECOLOGICAL INFORMATION

ECOTOXICITY Not available PERSISTENCE AND BIODEGRADABILITY Inherently biodegradable. BIOACCUMULATIVE POTENTIAL Not available.

SECTION 13. DISPOSAL CONSIDERATIONS

Comply with all federal, state and local regulations. Do not dump this product into sewers, on the ground or into any body of water.

SECTION 14. TRANSPORT INFORMATION

NOTE:

Avoid exposure to direct sunlight, high temperature, and moisture. Be careful not to allow moisture absorption and contamination.

ADR, RID, IMDG, ICAO/IATA UN Class UN Number Not applicable

Not applicable Not applicable

SECTION 15. REGULATORY INFORMATION

No labeling requirements under Directives 1999/45/EC and 67/548/EEC. Additional Regulatory Information: PCS meets the standards set forth in the European Pharmacopeia, pregelatinized starch.

Please refer to any other EU, national and local regulations.

SECTION 16.



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OTHER INFORMATION

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