

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

Product Names: Jack Bean Urease Control Tablets; CLOtest Reagent Urease Type 2 Tablets, 230 units

Product Number: 60407

Date Prepared:	4/28/16 Revision No: 2
Manufacturer: Sharp Clinical Services	300 Kimberton Rd Phoenixville, PA. 19460 United States of America 610-422-3224
Telephone: MEDICAL EMERGENCY TRANSPORTATION EMERGENCY INFORMATION	1-877-561-6587 Chemtrec 1-800-424-9300 1-888-346-4652

Product Use: Medical diagnostic.

2. HAZARDS IDENTIFICATION

White to off-white tablet.

Emergency Overview: May cause eye/skin irritation. Inhalation of dust may cause mucous membrane and respiratory irritation.

EU Classification (1999/45/EC): Not classified as a dangerous substance or preparation.

US OSHA Classification (29CFR1910.1200): Not Hazardous

Canadian WHMIS Classification: Not a controlled product.

3. COMPOSITION/INFORMATION ON INGREDIENTS

<i>Chemical Name</i>	<i>CAS-No./ EINECS-No</i>	<i>%</i>	<i>EU Classification (67/548/EEC):</i>
Mannitol	69-65-8 / 200-711-8	60 - 80%	Not applicable
Urease	9002-13-5 / 232-656-0	20-40%	Not applicable
Non-Hazardous Polymers	Mixture	1 - 5%	Not applicable

4. FIRST AID MEASURES

Inhalation: Move to fresh air. Seek medical advice if cough, shortness of breath or other respiratory problems occur.

Skin contact: Wash thoroughly with soap and water after handling. Seek medical advice if redness, swelling, itching or burning occurs.

Eye contact: Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Obtain medical attention if irritation persists.

Ingestion: If victim is conscious, rinse mouth with a small amount of water. Never give anything by mouth to a person who is unconscious or drowsy. Obtain immediate medical attention.

5. FIRE-FIGHTING MEASURES

Suitable Extinguishing Media: Water, water fog, foam, carbon dioxide, dry chemical.

Special Fire Fighting Procedures: In the event of fire, wear self contained breathing apparatus.

Unusual Fire and Explosion Hazards: If tablets are damaged, high concentrations of airborne dusts may present a fire or explosion hazard.

6. ACCIDENTAL RELEASE MEASURES

Wear appropriate protective clothing and equipment. Remove all sources of ignition. Spills should be cleaned up immediately using methods that minimize the generation of airborne dust.

7. HANDLING AND STORAGE

Avoid contact with skin and eyes. Avoid breathing dust. Minimize the generation and accumulation of dust. Follow good housekeeping practices to keep surfaces, including areas overhead such as piping, drop ceilings, ductwork, etc. free from settled dust.

Store in refrigerated conditions. Store at 2°C - 8°C. Protect from light.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure limit(s)

Mannitol	None established
Urease	None established
Non-Hazardous Polymers	15 mg/m ³ PEL-TWA (total dust), 5 mg/m ³ PEL-TWA (respirable dust)

Ventilation: Local exhaust ventilation recommended at points of emission to reduce exposure to dust during processing and to reduce the accumulation of dust in the work area.

Respiratory Protection: None required for normal use. If the exposure limit is exceeded or for symptoms of overexposure, wear an appropriate NIOSH (or local authority) certified respirator.

Protective Gloves: Impervious gloves recommended as good industrial hygiene practice.

Eye Protection: Safety glasses or goggles if needed to prevent eye contact.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance and Odor	White to off-white tablet.
Boiling point/range	Not applicable
Melting point/range	Not available
Specific Gravity (water=1)	Not available
Vapor pressure	Not applicable
Vapor density (air=1)	Not applicable
Solubility	Complete
pH	Not available
Partition coefficient (n-octanol/water):	Not available
Evaporation Rate (Butyl acetate=1)	Not applicable
Percent Volatile by Volume (%)	<1%
Volatile Organic Carbon Compounds (VOC) (g/L)	0%
Flashpoint:	Not applicable
Flammable Limits in Air % by Volume:	LEL (Lower):Not applicable UEL (Upper):Not applicable

10. STABILITY AND REACTIVITY

Stability: Stable

Conditions to Avoid: Excessive heating.

Materials to avoid: Strong oxidizing agents.

Hazardous Decomposition Products: Carbon monoxide, carbon dioxide.

Hazardous Polymerization: Does not occur.

11. TOXICOLOGICAL INFORMATION

Symptoms/Effects of Overexposure:

Inhalation: Inhalation of dust may cause mucous membrane and respiratory irritation. Prolonged or repeated overexposure may result in allergic reaction with asthma-like symptoms in certain individuals.

Skin contact: May cause skin irritation and/or dermatitis.

Eye contact: Contact with eyes may cause irritation.

Ingestion: May be harmful if swallowed. May cause mucous membrane and gastrointestinal irritation and other adverse effects.

Chronic toxicity: None expected.

Medical Conditions Aggravated by Exposure: None expected.

Carcinogenicity Data: None of the components of this product is listed as a carcinogen by IARC, NTP, US OSHA or the European Directive (67/548/EEC).

Reproductive Toxicity: None currently known.

Acute Toxicity Values: Mannitol: LD50 oral rat 13,500 mg/kg

Urease: No data available

12. ECOLOGICAL INFORMATION

No data is currently available.

13. DISPOSAL CONSIDERATIONS

Dispose in accordance with all state, local and federal regulations.

14. TRANSPORT INFORMATION

US DOT Shipping Description: Not regulated

IATA Shipping Description (Air): Not regulated

IMDG Shipping Description (Vessel): Not regulated

15. REGULATORY INFORMATION

US Regulations

EPA Toxic Substances Control Act (TSCA): All of the components of this product are listed on the TSCA Inventory or exempted from TSCA.

SARA 302 Listed Chemicals: None.

SARA 311/312 Hazard Categories: None.

SARA 313 This Product Contains the Following Chemicals Subject to Annual Release Reporting Requirements Under the SARA Section 313 (40 CFR 372): None.

California Proposition 65: This product does not contain chemicals listed per the Safe Drinking Water and Toxic Enforcement Act of 1986.

International Regulations

Canadian WHMIS Classification: Not a controlled product.

This product has been classified in accordance with the hazard criteria of the CPR and the MSDS contains all the information required by the CPR.

EU Labeling: Not required.

16. OTHER INFORMATION

EU Classes and Risk Phrases for Reference (See Sections 2 and 3):

None.

HMIS Rating: Health 1 Fire 1 Physical Hazard 0

0 = Minimal Hazard, 1 = Slight Hazard, 2 = Moderate Hazard, 3 = Serious Hazard, 4 = Severe Hazard

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