

SAFETY DATA SHEET

SECTION 1) IDENTIFICATION

Product ID: 450-2, 450-A OSHA **Product Name:** Bile Acid Reagent B

Revision Date: Jan 15, 2019 Date Printed: Apr 24, 2019

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Manufacturer's Name: Trinity Biotech Plc Distributor's Name: Trinity Biotech USA

Address: IDA Business Park Address: 2823 Girts Road Jamestown, NY, USA, 14701

Southern Cross Road Bray, Co. Wicklow,

IRL

Emergency Phone: Contact your local Emergency Health Distributor's Phone:

Care Provider. USA-Technical Support

Group: 1-800-325-3424

Information Phone Number: +353 1 276 9800 Distributor's Emergency: Contact your local Emergency Health Care

Provider. Ireland-Technical Support Group 00353-1-

276-9800

+1 800-325-3424

Fax: +353 1 276 9888

SECTION 2) HAZARDS IDENTIFICATION

Classification of the substance or mixture

Not a hazardous substance or mixture according to United States Occupational Safety and Health Administration (OSHA) Hazard Communication Standard (29 CFR 1910.1200) and the Canadian Workplace Hazardous Materials Information System (WHMIS).

Classification

Not classified

Pictograms

None

Signal Word

No signal word available.

Precautionary Statements - General

No precautionary statement available.

Precautionary Statements - Prevention

No precautionary statement available.

Precautionary Statements - Response

No precautionary statement available.

Precautionary Statements - Storage

No precautionary statement available.

Precautionary Statements - Disposal

No precautionary statement available.

Hazards Not Otherwise Classified (HNOC)

CAUTION: Handle all controls and all biological samples as though capable of transmitting infectious agents.

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SECTION 3) COMPOSITION/INFORMATION ON INGREDIENTS

CAS	Chemical Name	% By Weight
0000069-65-8	D-Mannitol	74.51%
0009048-46-8	Albumins, blood serum	24.84%
0007758-11-4	DIPOTASSIUM PHOSPHATE	< 1%
0009028-56-2	3α-HSDH	< 1%
0007778-77-0	POTASSIUM DIHYDROGEN PHOSPHATE	< 1%

SECTION 4) FIRST-AID MEASURES

Inhalation

Remove source of exposure or move person to fresh air and keep comfortable for breathing. If unwell, or exposed and concerned: Get medical advice/attention.

If exposed or concerned: Get medical advice/attention.

Eye Contact

Immediately call a POISON CENTER/doctor.

Rinse eyes cautiously with lukewarm, gently flowing water for several minutes, while holding the eyelids open. Remove contact lenses, if present and easy to do. Continue rinsing for a flushing duration of 15-20 minutes. Take care not to rinse contaminated water into the unaffected eye or onto the face. If eye irritation persists: Get medical advice/attention.

Skin Contact

Take off contaminated clothing, shoes and leather goods (e.g. watchbands, belts). Wash with plenty of lukewarm, gently flowing water for a duration of 15-20 minutes. If skin irritation or rash occurs: Get medical advice/attention. Store clothing under water and wash clothing before re-use or discard. If exposed or concerned: Get medical advice/attention.

Ingestion

Rinse mouth. Do NOT induce vomiting. If vomiting occurs naturally, lie on your side, in the recovery position. If exposed or concerned: Get medical advice/attention.

Most Important Symptoms and Effects, Both Acute and Delayed

No Data Available

Indication of Any Immediate Medical Attention and Special Treatment Needed

No Data Available

SECTION 5) FIRE-FIGHTING MEASURES

Suitable Extinguishing Media

Small Fire: Dry chemical, foam, carbon dioxide, water-spray or alcohol-resistant foam. Carbon dioxide can displace oxygen. Use caution when applying carbon dioxide in confined spaces. Large Fire: Water spray, fog or alcohol-resistant foam.

Unsuitable Extinguishing Media

No Data Available

Carbon dioxide can displace oxygen. Use caution when applying carbon dioxide in confined spaces.

Specific Hazards in Case of Fire

Burning can produce irritating, toxic and obnoxious fumes.

Fire-Fighting Procedures

Isolate immediate hazard area and keep unauthorized personnel out. Stop spill/release if it can be done safely. Move undamaged containers from immediate hazard area if it can be done safely. Cool containers with flooding quantities of water until well after fire is out. Caution should be exercised when using water or foam as frothing may occur, especially if sprayed into containers of hot, burning liquid. Dispose of fire debris and contaminated extinguishing water in accordance with official regulations.

Special Protective Actions

Wear protective pressure self-contained breathing apparatus (SCBA) and full turnout gear.

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SECTION 6) ACCIDENTAL RELEASE MEASURES

Emergency Procedure

If spilled material is cleaned up using a regulated solvent, the resulting waste mixture may be regulated.

Recommended Equipment

Wear liquid tight chemical protective clothing in combination with positive pressure self-contained breathing apparatus (SCBA).

Personal Precautions

DO NOT get on skin, eyes or clothing. Do not touch damaged containers or spilled materials unless wearing appropriate protective clothing.

Environmental Precautions

Prevent spilled material from entering sewers, storm drains, other unauthorized drainage systems and natural waterways by using sand, earth, or other appropriate barriers.

Stop spill/release if it can be done safely.

Methods and Materials for Containment and Cleaning Up

Absorb liquids in vermiculite, dry sand, earth, or similar inert material and deposit in sealed containers for disposal. Contaminated absorbent material may pose the same hazard as the spilled product.

SECTION 7) HANDLING AND STORAGE

General

Wash hands after use. Do not get in eyes, on skin or on clothing. Do not breathe vapors or mists. Use good personal hygiene practices. Eating, drinking and smoking in work areas is prohibited. Remove contaminated clothing and protective equipment before entering eating areas. Eyewash stations and showers should be available in areas where this material is used and stored. Use Good Laboratory Procedures (GLP) during handling.

Ventilation Requirements

Use only with adequate ventilation to control air contaminants to their exposure limits. The use of local ventilation is recommended to control emissions near the source.

Storage Room Requirements

Store in cool, dry, well-ventilated areas away from heat, direct sunlight and strong oxidizers. Store in approved containers and protect against physical damage. Keep container(s) tightly closed and properly labeled.

SECTION 8) EXPOSURE CONTROLS/PERSONAL PROTECTION

Eye Protection

Wear eye protection with side shields or goggles. Wear indirect-vent, impact and splash resistant goggles when working with liquids. If additional protection is needed for entire face, use in combination with a face shield.

Skin Protection

Use of gloves approved to relevant standards made from the following materials may provide suitable chemical protection: PVC, neoprene or nitrile rubber gloves. Suitability and durability of a glove is dependent on usage, e.g. frequency and duration of contact, chemical resistance of glove material, glove thickness, dexterity. Always seek advice from glove suppliers. Contaminated gloves should be replaced. The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace. Launder soiled clothes or properly disposed of contaminated material, which cannot be decontaminated.

Respiratory Protection

If engineering controls do not maintain airborne concentrations to a level which is adequate to protect worker, a respiratory protection program should be followed. Check with respiratory protective equipment suppliers.

Appropriate Engineering Controls

Provide exhaust ventilation or other engineering controls to keep the airborne concentrations of vapors below their respective threshold limit value.

Chemical Name	OSHA STEL (ppm)	OSHA STEL (mg/m3)	OSHA TWA (ppm)	OSHA TWA (mg/m3)	OSHA Carcinogen	OSHA Carcinogen	OSHA Skin designation	OSHA Skin designation

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Chemical Name	OSHA Tables (Z1, Z2, Z3)	NIOSH STEL (ppm)	NIOSH STEL (mg/m3)	NIOSH TWA (ppm)	NIOSH TWA (mg/m3)	NIOSH Carcinogen	NIOSH Carcinogen	ACGIH STEL (ppm)
No applicable chemical	-	-	-	-	-	-	-	-

Chemical Name	ACGIH TWA (ppm)	ACGIH STEL (mg/m3)	ACGIH TWA (mg/m3)	ACGIH TLV Basis	ACGIH Carcinogen	ACGIH Carcinogen	ACGIH Notations
No applicable chemical	-	-	-	-	-	-	-

8.33963 lb/gal

SECTION 9) PHYSICAL AND CHEMICAL PROPERTIES

Physical and Chemical Properties

Density

Specific Gravity	0.99931
Appearance	N/A
Odor Description	N/A
Odor Threshold	N/A
рН	2
Water Solubility	N/A
Flammability	N/A
Flash Point	15 °C
Viscosity	N/A
Lower Explosion Level	N/A
Upper Explosion Level	N/A
Vapor Pressure	N/A
Vapor Density	N/A
Freezing Point	N/A
Melting Point	N/A
Low Boiling Point	30 °C
High Boiling Point	N/A
Auto Ignition Temp	N/A
Decomposition Pt	N/A
Evaporation Rate	N/A
Coefficient Water/Oil	N/A

SECTION 10) STABILITY AND REACTIVITY

Stability

Stable under normal storage and handling conditions.

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Conditions to Avoid

Avoid heat, sparks, flame, high temperature, freezing and contact with incompatible materials.

Hazardous Reactions/Polymerization

Hazardous polymerization will not occur.

Incompatible Materials

Strong bases, acids, oxidizing and reducing agents.

Hazardous Decomposition Products

No Data Available

SECTION 11) TOXICOLOGICAL INFORMATION

Likely Routes of Exposure

Inhalation, ingestion, skin absorption.

Aspiration Hazard

No Data Available

Carcinogenicity

No Data Available

Germ Cell Mutagenicity

No Data Available

Reproductive Toxicity

No Data Available

Respiratory/Skin Sensitization

No Data Available

Serious Eye Damage/Irritation

No Data Available

Skin Corrosion/Irritation

No Data Available

Specific Target Organ Toxicity - Repeated Exposure

No Data Available

Specific Target Organ Toxicity - Single Exposure

No Data Available

Acute Toxicity

No Data Available

SECTION 12) ECOLOGICAL INFORMATION

Toxicity

No Data Available

Mobility in Soil

No Data Available

Bio-accumulative Potential

No Data Available

Persistence and Degradability

No Data Available

Other Adverse Effects

No Data Available

SECTION 13) DISPOSAL CONSIDERATIONS

Waste Disposal

Under RCRA it is the responsibility of the user of the product to determine at the time of disposal whether the product meets RCRA criteria for hazardous waste. Waste management should be in full compliance with federal, state and local laws. Empty Containers retain product residue which may exhibit hazards of material, therefore do not pressurize, cut, glaze, weld or use for any other purposes.

SECTION 14) TRANSPORT INFORMATION

US DOT/IMDG/IATA Information

UN number: Not Regulated UN proper shipping name: N/A Transport hazard class(es): Not Applicable Packing group: Not Applicable Marine Pollutant: No data available

SECTION 15) REGULATORY INFORMATION

CAS	Chemical Name	% By Weight	Regulation List
0000069-65-8	D-Mannitol	74.51%	SARA312,TSCA
0009048-46-8	Albumins, blood serum	24.84%	SARA312,TSCA
0007758-11-4	DIPOTASSIUM PHOSPHATE	< 1%	SARA312,TSCA
0009028-56-2	3α-HSDH	< 1%	SARA312
0007778-77-0	POTASSIUM DIHYDROGEN PHOSPHATE	< 1%	SARA312,TSCA

SECTION 16) OTHER INFORMATION

Glossary

ACGIH- American Conference of Governmental Industrial Hygienists; ANSI- American National Standards Institute; Canadian TDGCanadian Transportation of Dangerous Goods; CAS- Chemical Abstract Service; Chemtrec- Chemical Transportation Emergency Center(US); CHIP- Chemical Hazard Information and Packaging; DSL- Domestic Substances List; EC- Equivalent Concentration; EH40 (UK)- HSE Guidance Note EH40 Occupational Exposure Limits; EPCRA- Emergency Planning and Community Right-To-Know Act; ESL Effects screening levels; HMIS- Hazardous Material Information Service; LC- Lethal Concentration; LD- Lethal Dose; NFPA- National Fire Protection Association; OEL- Occupational Exposure Limits; OSHA- Occupational Safety and Health Administration, US Department of Labor; PEL- Permissible Exposure Limit; SARA (Title III)- Superfund Amendments and Reauthorization Act; SARA 313- Superfund Amendments and Reauthorization Act, Section 313; SCBA- Self Contained Breathing Apparatus; STEL-Short Term Exposure Limit; TCEQ

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Texas Commission on Environmental Quality; TLV- Threshold Limit Value; TSCA- Toxic Substances Control Act Public Law 94-469; TWA Time Weighted Value; US DOT- US Department of Transportation; WHMIS- Workplace Hazardous Materials Information System.

Version 1.0:

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