

SECTION 1) IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product Identifier:

Product ID: ACE Calibrator 305-50 (CLP) **Revision Date:** Jun 17, 2019

Product Name: Angiotensin Converting Enzyme Calibrator 305-50 **Version:** 1.0

1.2 Relevant Identified Uses of the Substance or Mixture: **Date Printed:** Jun 17, 2019

Medical Diagnostics **Supersedes Date:** N.A.

1.3 Details of the Supplier of the Safety Data Sheet:

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

Address: 2823 Girts Road Jamestown, NY, USA, 14701 **Address:** IDA Business Park Southern Cross Road Bray, Co. Wicklow, IRL

Information Phone Number: +1 800-325-3424 **Information Phone Number:** +353 1 276 9800

Fax: +1 716-487-1419 **Fax:** +353 1 276 9888

1.4 Emergency Information:

Emergency Phone: Contact your local Emergency Health Care Provider. USA-Technical Support Group: 1-800-325-3424 **Emergency Phone:** Contact your local Emergency Health Care Provider. Ireland-Technical Support Group 00353-1-276-9800

SECTION 2) HAZARDS IDENTIFICATION

2.1 Classification

Not a hazardous substance or mixture according to Council Directives 1907/2006 (REACH) and 1272/2008 (CLP) on classification, labelling and packaging of substances and mixtures and their subsequent amendments.

2.2 Label Elements

None

2.3 Other hazards

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

Acute toxicity of 100% of the mixture is unknown

SECTION 3) COMPOSITION/INFORMATION ON INGREDIENTS

3.2 Mixtures

CAS	Chemical Name	GHS Classifications	% By Weight	EC No
NA_TRINITY	Human Serum	N.A.	60% - 75%	-

Specific chemical identity and/or exact percentage (concentration) of the composition has been withheld to protect confidentiality.

SECTION 4) FIRST-AID MEASURES

4.1 Description of 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.

Eye Contact

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.

4.2 Most important symptoms and effects, both acute and delayed

No data available.

4.3 Indication of any immediate medical attention and special treatment needed

No data available.

SECTION 5) FIRE-FIGHTING MEASURES

5.1 Extinguishing media

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.

5.2 Special hazards arising from the substance or mixture

Burning can produce irritating, toxic and obnoxious fumes.

5.3 Advice for firefighters

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.

SECTION 6) ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Emergency Procedure

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

Recommended Equipment

Gloves and safety glasses.

Personal Precautions

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

6.2 Environmental precautions

Stop spill/release if it can be done safely. Prevent spilled material from entering sewers, storm drains, other unauthorized drainage systems and natural waterways by using sand, earth, or other appropriate barriers.

6.3 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

7.1 Precautions for safe handling

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. Handle as if capable of transmitting a disease.

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.

7.2 Conditions for safe storage, including incompatibilities

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

7.3 Specific end use(s)

Medical Diagnostics

SECTION 8) EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Chemical Name	IOELV STEL (ppm)	IOELV STEL (mg/m ³)	IOELV TWA (ppm)	IOELV TWA (mg/m ³)	IOELV Notations	IOELV Directive	NIOSH STEL (ppm)	NIOSH STEL (mg/m ³)
No applicable chemical	-	-	-	-	-	-	-	-

Chemical Name	NIOSH TWA (ppm)	NIOSH TWA (mg/m ³)	NIOSH Carcinogen	NIOSH Carcinogen	ACGIH STEL (ppm)	ACGIH STEL (mg/m ³)	ACGIH TWA (ppm)	ACGIH TWA (mg/m ³)
No applicable chemical	-	-	-	-	-	-	-	-

Chemical Name	ACGIH TLV Basis	ACGIH Carcinogen	ACGIH Carcinogen	ACGIH Notations
No applicable chemical	-	-	-	-

8.2 Exposure controls

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.

Environmental exposure controls

No data available.

SECTION 9) PHYSICAL AND CHEMICAL PROPERTIES

9.1 Physical and Chemical Properties

Density	8.52949 lb/gal
Specific Gravity	1.02206
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Appearance	Off-white lyophilized solid
Odor Description	N/A
Odor Threshold	N/A
pH	N/A
Water Solubility	N/A
Flammability	N/A
Flash Point	N/A
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	N/A
High Boiling Point	N/A
Auto Ignition Temp	N/A
Decomposition Pt	N/A
Evaporation Rate	N/A
Coefficient Water/Oil	N/A

9.2 Other Information

No data available.

SECTION 10) STABILITY AND REACTIVITY

10.1 Reactivity

No data available.

10.2 Chemical stability

Stable under normal storage and handling conditions.

10.3 Possibility of hazardous reactions

Hazardous polymerization will not occur.

10.4 Conditions to avoid

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

10.5 Incompatible materials

Strong bases, acids, oxidizing and reducing agents.

10.6 Hazardous Decomposition Products

No data available.

SECTION 11) TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

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

12.1 Toxicity

No data available.

12.2 Persistence and degradability

No data available.

12.3 Bio-accumulative Potential

No data available.

12.4 Mobility in Soil

No data available.

12.5 Results of the PBT and vPvB assessment

No data available.

12.6 Other Adverse Effects

No data available.

SECTION 13) DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

It is the responsibility of the user of the product to determine at the time of disposal whether the product meets local criteria for hazardous waste. Waste management should be in full compliance with federal, state and local laws.

SECTION 14) TRANSPORT INFORMATION

ADR/IMDG/IATA Information

- 14.1 UN number: Not Regulated
- 14.2 UN proper shipping name: N/A
- 14.3 Transport hazard class(es): Not Applicable
- 14.4 Packing group: Not Applicable
- 14.5 Environmental hazards: No Data Available
- 14.6 Special precautions for user: No Data Available
- 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code: No Data Available

SECTION 15) REGULATORY INFORMATION

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

This Safety Data Sheet was prepared in accordance with Council Directives 1907/2006 (REACH), 1272/2008 (CLP) and their subsequent amendments.

CAS	Chemical Name	% By Weight	Regulation List
No applicable CAS	No applicable chemical	-	-

15.2 Chemical Safety Assessment

No data available.

SECTION 16) OTHER INFORMATION

Glossary

ACGIH- American Conference of Governmental Industrial Hygienists; ANSI- American National Standards Institute; Canadian TDG Canadian 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 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.

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