

2 WEST PARK ROAD
HAVERTOWN, PA 19083

1-800-247-6665
610-853-1130

SAFETY DATA SHEET

1. Identification of the substance / mixture and of the company /undertaking

1.1 Product identifier.

Product name: Epinephrine
Product number: 393
Brand : CHRONO-PAR®

1.2. Relevant identified uses of the substances or mixtures and uses advised against.

Relevant Identified uses: Epinephrine is a platelet aggregation agonist and is used to diagnose platelet dysfunction, or normal platelet activity in human platelet rich plasma or whole blood.

1.3. Details of the supplier of the safety data sheet:

Company : Chrono-log Corp
2 West Park Road
Havertown, PA 19083
USA
Telephone : 610-853-1130
Email: chronolog@chronolog.com

1.4 Emergency telephone number

Emergency Phone # : 610-853-1130

2. HAZARDS IDENTIFICATION

2.1 Classification of the substance/mixture:

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

Classification for finished Product (lyophilised vial):

H300 Acute toxicity category 1.

Classification for in-use product (Reconstituted 5.0ml liquid):

H300 Acute toxicity category 1

Additional information:

For the full text of H statements mentioned, see SECTION 16.

2.2 Label elements:

Labelling according Regulation (EC) No 1272/2008 [CLP]

Hazard pictogram:

Health Hazard Pictogram Acute Toxicity



Signal word: Danger

Hazard statement(s):

H300 Fatal if swallowed.

Precautionary statements:

P301 + P330 + P331 + P310 IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. immediately contact a POISON CENTRE or doctor/physician.

Supplement Hazard Information: Not applicable
Intended to be used by professional users of IVD reagents

2.3. Other hazards: None

3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances:

Not applicable, this product is regulated as a mixture.

3.2 Mixtures:

Description of the mixture: Comprises of Epinephrine bitartrate salt (Epinephrine Hydrogen tartrate), water buffer and sodium chloride. Epinephrine bitartrate salt is classifiable as hazardous in the mixture as concentration >0.1%.

Hazardous Ingredients:

FORMAT	CAS No	EC No	REACH No	% Weight	Name	Classification (EC) No 1272/2008
Lyophilised vial	51-42-3	200-097-1	None available	1.7	Epinephrine bitartrate salt	Acute Toxicity Cat 1 H300
Reconstituted 5.0ml liquid	51-42-3	200-097-1	None available	0.3	Epinephrine bitartrate salt	Acute Toxicity Cat 1 H300

4. FIRST AID MEASURES

4.1. Description of first aid measures:

General advice:

Consult a physician. Show this SDS to the doctor in attendance.

After Inhalation:

If inhaled, remove person to fresh air. If breathing becomes difficult obtain immediate medical attention, give artificial respiration. Consult a physician.

After Skin Contact:

Immediately remove all contaminated clothing & shoes. Immediately wash skin with soap and copious amounts of water. Consult a physician.

After Eye Contact:

Irrigate with copious amounts of clean fresh water for at least 15 minutes and consult a physician.

After Ingestion:

Do NOT induce vomiting. Wash out mouth with water, provided person is conscious. Never give anything by mouth to an unconscious person. Consult a doctor/physician or poison centre.

Self-protection for first aider:

Personal protective equipment for first aid responder is recommended.

4.2 Most important symptoms and effects both acute and delayed

The most important known symptoms and effects are described in section 2.2.

4.3 Indication of any immediate medical attention and special treatment needed

Follow guidance described in section 2.2.

5. FIREFIGHTING MEASURES

5.1. Extinguishing media:

Suitable extinguishing media: Water, alcohol resistant foam, CO₂, Dry Chemical Extinguisher

5.2 Special hazards arising from the substance or mixture:

Carbon oxides, nitrogen oxides (NOx), Hydrogen cyanide (hydrocyanic acid).

5.3 Advice for firefighters

Wear suitable protective clothing/equipment. Wear self-contained breathing apparatus for firefighting if necessary.

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures.

For non-emergency personnel

Protective Equipment: Exercise appropriate precautions to minimise direct contact with skin or eyes and prevent inhalation of vapours – Wear personal protective equipment (PPE) such as gloves, safety glasses.

Emergency Procedures: Wear respiratory protection, avoid dust formation and avoid breathing vapours, dust, mist or gas. Ensure adequate ventilation and evacuate personnel to safe areas.

For emergency responders

Personal protective equipment for first aid responder(s) is/are recommended.

6.2. Environmental precautions:

Prevent further leakage or spillage if safe to do so and do not let product enter drains.

6.3. Methods and material for containment and cleaning up:

For containment: Spillages should be contained using absorbent material to prevent contamination of drains and watercourses.

For cleaning up: Pick up and arrange disposal without additional leaking of material. Use adsorbent materials and wash spill site for decontamination after material pickup. Waste material from spillages should be disposed of in accordance with local regulations.

Other information: Spilled material may cause surfaces to become slippery, clear spills immediately.

6.4 Reference to other sections

Refer to section 8 for exposure controls and personal protection and sections 13 for disposal considerations.

7: HANDLING & STORAGE

7.1. Precautions for safe handling

Recommendations: Wear appropriate PPE. Avoid contact with eyes, skin and clothing. For IVD use only. Not for medicinal use. DO NOT INGEST. Reduce the release of substance to the environment by avoiding spillages. For precautions see section 2.2.

General occupational hygiene: Do not eat, drink or smoke in work areas. Wash hands after use. Remove protective equipment before entering eating areas.

7.2. Conditions for safe storage including any incompatibilities:

Store securely in the original labelled container. Storage conditions according to product label (2-8°C). For post reconstitution storage conditions refer to product instructions for use. Product is sensitive to light.

7.3. Specific end use(s):

Use in accordance with product instructions for use provided in kit. For In vitro diagnostic use only in platelet aggregation testing.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control Parameters

Components with workplace control parameters: Contains no substances with occupational exposure limit values.

8.2 Exposure controls

Appropriate engineering controls:

Follow good clinical hygiene practices adopting suitable individual protective measures. Avoid contact with skin, eyes and clothing. Do not eat or smoke while handling the product. Wash hands before breaks and immediately after handling the product.

Individual protection measures, such as personal protective equipment:

Eye/face Protection:

Wear safety glasses or goggles. Use equipment for eye protection tested and approved under appropriate government standards such as EN 166(EU).

Skin Protection:

Handle with gloves. Gloves must be inspected prior to use to ensure good condition. Use proper glove removal technique (without touching gloves outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with good laboratory practice and applicable laws. Wash hands and dry.

This recommendation applies only to the product stated in the safety data sheet supplied by us and for the designated use. When dissolving in or mixing with other substances and under conditions deviating from those stated in EN374, please contact the supplier of CE-approved gloves (e.g. KCL GmbH, D-36124 Eichenzell, Internet: www.kcl.de).

Full contact

Material: Nitrile rubber
Minimum layer thickness: 0.11 mm
Break through time: 480 min
Material tested: KCL 740 Dermatril®

Splash contact

Material: Nitrile rubber
Minimum layer thickness: 0.11 mm
Break through time: 480 min
Material tested: KCL 740 Dermatril®

Body Protection

Wear laboratory coat/work coat or apron in line with protective equipment at the specific work place.

Respiratory Protection

Wear simple mask to prevent inhalation of dust / vapour.

Thermal Hazards

List PPE applicable

Environmental Exposure Controls

Prevent further leakage or spillage if safe to do so as described in section 6.3. Do not let product enter drains.

9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Physical State: - Lyophilised: White compact lyophilised cake present at base of vial. Housed in an amber 6ml glass vial with white freeze dry stopper and wadless screw seal cap.

Once reconstituted – clear colourless solution.

Colour:	Colourless
Odour:	Odourless
pH:	7.4
Melting point/freezing point:	Melting point/range: No data available
Initial boiling point and boiling range:	No data available
Flash Point:	No data available
Flammability (solid, gas):	No data available
Upper/lower explosive limits:	No data available
Vapour Pressure:	No data available
Relative Vapour Density:	No data available
Particle characteristics	No data available
Density and/or relative density	No data available
Solubility:	No data available
Partition Coefficient: n-octanol/water (log value):	No data available
Auto-ignition temperature	No data available
Decomposition temperature	No data available
Kinetic Viscosity	No data available

9.2 Other information

Information with Regard to Physical Hazard Classes

Not applicable

Other Safety Characteristics

Water soluble

10. STABILITY AND REACTIVITY

- 10.1 Reactivity:** No data available
- 10.2 Chemical stability:** This product is stable in normal conditions of use and storage.
- 10.3 Possibility of hazardous reactions:** No data available
- 10.4 Conditions to avoid:** No data available
- 10.5 Incompatible materials:** Bases, oxidising agents, iron and irons salts, copper.
- 10.6 Hazardous decomposition products:** No known hazardous decomposition products

11. TOXICOLOGICAL INFORMATION

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

Acute Toxicity:	LD50 Oral - Mouse - 4 mg/kg
Skin corrosion/irritation:	No data available
Serious Eye damage/irritation:	No data available
Respiratory or skin sensitisation:	No data available
Germ cell mutagenicity:	No data available
Carcinogenicity: IARC:	No data available
Reproductive Toxicity:	No data available
Summary of evaluation of the CMR properties:	No data available
STOT-single exposure:	No data available
STOT-repeated exposure:	No data available
Aspiration hazard:	No data available
Additional Information:	No data available

Symptoms of Exposure:

In case of Ingestion:	No data available
In case of skin contact:	No data available
In case of inhalation	No data available
In case of eye contact	No data available

11.2 Other Information:

Endocrine disrupting properties: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher. RTECS: DO3500000

Other information: No data available

12. ECOLOGICAL INFORMATION

12.1 Toxicity:

Toxicity to fish	No data available
Toxicity to daphnia	No data available
Toxicity to Algae	No data available
Toxicity to bacteria	No data available

12.2 Persistence and degradability: No data available

12.3 Bioaccumulative potential: No data available

12.4 Mobility in soil: No data available

12.5 Results of PBT and vPvB assessment: No data available

12.6 Endocrine disrupting properties: No data available

12.7 Other adverse effects: No data available

Use according to good clinical hygiene practices; avoid dispersion of the product in the environment.

13. DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product: Disposal of waste must always comply with existing EEC, national and local regulations. Registered waste carriers and licensed disposal sites must be used.

Contaminated packaging: Dispose of as unused product.

14. TRANSPORT INFORMATION

14.1 UN number: No number available/ not required for mixture

14.2 UN Proper Shipping name: Not required

14.3 Transport Hazard Classes: Not required

14.4 Packaging Group: Not required

14.5 Environmental Hazards: Not required

14.6 Special precautions for user: Not required

14.7 Maritime transport in bulk according to IMO instruments: It is not intended that this product is transported as bulk and therefore the shipping/transport regulations for bulk hazardous material do not apply.

15: REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture: No data available

15.2 Chemical Safety Assessment: No chemical safety assessment has been carried out for this substance/mixture by the supplier.

16: OTHER INFORMATION

Full text of H-Statements referred to under sections 2 and 3

H300

Fatal if swallowed

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:

Lyophilised Vial:

- Acute Toxicity 1 Calculation Method

Reconstituted 5ml Liquid:

- Acute Toxicity 1 Calculation Method

Further information

The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. Chrono-log Corp. shall not be held liable for any damage resulting from handling or from contact with the above product.