CHRONO-LOG CORPORATION

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SAFETY DATA SHEET

1. PRODUCT AND COMPANY IDENTIFICATION

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:

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

Classification for finished Product (lyophilised vial):

H300	Acute toxicity category 2.
H315	Skin Irritation category 2.
H319	Eye Irritation category 2.
H335	Specific Target organ toxicity – single exposure category 3

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

H300	Acute toxicity category 2

2.1.2 Classification according to Directive 67/548/EEC

T+ Very toxic R28,R36/37/38

2.1.3 Additional information:

For the full text of R-phrases mentioned, see SECTION 16.

2.2 Label elements:

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

Hazard pictogram:

Signal word: Danger

Hazard statement(s):

H300	Fatal if swallowed.
H315	Causes skin irritation.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.

Precautionary statements:

P261	Avoid breathing dust.
P264	Wash hands thoroughly after handling.
P301 + P310	IF SWALLOWED immediately contact a POISON CENTRE or doctor/physician.
P305 +P351 + P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do so. Continue rinsing.

Supplement Hazard Information (EU): Not applicable

2.3. Other hazards: None

3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Mixtures:

Description of the mixture: Comprises of Epinephrine bitartrate salt (Epinephrine Hydrogen tartrate)

Hazardous Ingredients:

FORMAT	CAS No	EC No	REACH No	% Weight	Name	Classification 67/548/EEC	Classification (EC) No 1272/2008
Lyophilised vial	51-42-3	200-097-1	None available	1.7	Epinephrine bitartrate salt	T+ R28 – R36/37/38	Acute Toxicity Cat 2 H300 Skin Irritation Cat 2 H315. Eye Irritation Cat 2 H319. Specific Target organ toxicity Cat 3 H335
Reconstituted 5.0ml liquid	51-42-3	200-097-1	None available	0.3	Epinephrine bitartrate salt	T+ R28 – R36/37/38	Acute Toxicity Cat 2 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 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. If irritation persists seek medical attention.

After Ingestion: Wash out mouth with water provided person is conscious. Urgently seek immediate medical attention. Consult a doctor/physician or poison centre.

Self-protection for first aider: Personal protective equipment for first aid responder is recommended.

5. FIREFIGHTING MEASURES

5.1. Extinguishing media:

Suitable extinguishing media: Water, alcohol resistant foam, CO_2, Dry Chemical Extinguisher

5.2 Special hazards arising from the substance or mixture:

Carbon oxides, nitrogen oxides (NOx)

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.

6.1.1 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.

6.1.2 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:

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

6.3.2 For cleaning up: Pick up and arrange disposal without creating dust. 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.

6.3.3 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

7.1.1. Recommendations: Avoid inhalation. 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.

7.1.2. 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:

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

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

8.2 Exposure controls

8.2.1 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.

8.2.2 Personal Protection Equipment:

8.2.2.1 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).

8.2.2.2 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.
The selected protective gloves have to satisfy the specifications of EU directive 89/686/EEC and the standard EN 374 Derived from it.

Full contact example from raw material chemical supplier:
Material: Nitrile Rubber
Minimum layer thickness: 0.11mm
Break through time 480 min.

Splash contact from raw material chemical supplier:
Material: Nitrile Rubber
Minimum layer thickness: 0.11mm
Break through time 480 min.

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

8.2.2.3 Respiratory Protection

Wear simple mask to prevent inhalation of dust / vapour.

8.2.3 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

a) **Appearance:** - 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.

b) **Odour:** Odourless

c) **Odour threshold:** no data available

d) **pH:** 7.4

e) **Melting point/freezing point:** Melting point/range:155^{o}C

f) **Initial boiling point and boiling range:** No data available

g) **Flash Point:** No data available

h) **Evaporation Weight** No data available

i) **Flammability (solid,gas):** No data available

j) **Upper/lower flammability or explosive limits:** No data available

k) **Vapour Pressure:** No data available

l) **Vapour Density:** No data available

m) **Relative Density** No data available

n) **Water Solubility** No data available

o) **Partition Coefficient:n-octanol/water** No data available

p) **Auto-ignition temperature** No data available

q) **Decomposition temperature** No data available

r) **Viscosity** No data available

s) **Explosive properties** No data available

t) **Oxidising Properties** No data available

9.2 Other safety information

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 toxicological effects:

Acute Toxicity: No data available

Skin corrosion/irritation: No data available

Serious Eye damage/irritation: No data available

Respiratory or skin sensitisation: No data available

Germ cell mutagenicity: mouse, other cell types, DNA inhibition

Carcinogenicity: IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

Reproductive Toxicity: Laboratory experiments have shown teratogenic effects.

Reproductive toxicity – mouse – subcutaneous

Paternal Effects: Spermatogenesis (including generic material, sperm morphology, motility and count).

Summary of evaluation of the CMR properties: No data available
STOT-single exposure: Inhalation – May cause respiratory irritation
STOT-repeated exposure: No data available
Aspiration hazard: No data available
Additional Information: RTECS:DO3500000

Laboratory experiments in animals have shown fetotoxic results; palpitations, tremors, weakness and headache.

12. ECOLOGICAL INFORMATION

12.1 Toxicity: 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: PBT/vPvB assessment not availaible as chemical safety assessment not required/not conducted
12.6 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 Transport in bulk according to Annex II MARPOL73/78 and the IBC Code: 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:
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

Acute Tox.	**Acute Toxicity**
Eye Irrit.	**Eye Irritation**
H300	**Fatal if swallowed**
H315	**Causes skin irritation**
H319	**Causes serious eye irritation**

H335	**May cause respiratory irritation**
Skin Irrit.	**Skin Irritation**

Full text of R-phrases referred to under sections 2 and 3

T+	**Very toxic**
R28	**Very toxic if swallowed**
R36/37/38	**Irritating to eyes, respiratory system and skin**

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

- Acute Toxicity 2 Calculation Method
- Skin Irritation 2 Calculation Method
- Eye Irritation 2 Calculation Method
- Specific target organ toxicity 3 Calculation Method

Reconstituted 5ml Liquid:

- Acute Toxicity 2 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.