


**SECTION 1: PRODUCT IDENTIFICATION**

<b>PRODUCT NAME</b>	<b>EDETATE DISODIUM, USP</b>
<b>PRODUCT CODE</b>	<b>0545</b>
<b>SUPPLIER</b>	<b>MEDISCA Inc.</b> Tel.: 1.800.932.1039   Fax.: 1.855.850.5855 661 Route 3, Unit C, Plattsburgh, NY, 12901 3955 W. Mesa Vista Ave., Unit A-10, Las Vegas, NV, 89118 6641 N. Belt Line Road, Suite 130, Irving, TX, 75063 <b>MEDISCA Pharmaceutique Inc.</b> Tel.: 1.800.665.6334   Fax.: 514.338.1693 4509 Rue Dobrin, St. Laurent, QC, H4R 2L8 21300 Gordon Way, Unit 153/158, Richmond, BC V6W 1M2 <b>MEDISCA Australia PTY LTD</b> Tel.: 1.300.786.392   Fax.: 61.2.9700.9047 Unit 7, Heritage Business Park 5-9 Ricketty Street, Mascot, NSW 2020
<b>EMERGENCY PHONE</b>	CHEMTREC Day or Night Within USA and Canada: 1-800-424-9300 NSW Poisons Information Centre: 131 126
<b>USES</b>	Chelating agent

**SECTION 2: HAZARDS IDENTIFICATION**

<b>GHS CLASSIFICATION</b>	Acute Toxicity - Inhalation (Category 4) Acute Toxicity - Oral (Category 4) Skin Irritation (Category 2) Eye Irritation (Category 2A)
<b>PICTOGRAM</b>	
<b>SIGNAL WORD</b>	Warning
<b>HAZARD STATEMENT(S)</b>	May be harmful if swallowed. Harmful if inhaled. Causes skin irritation. Causes serious eye irritation.
<b>AUSTRALIA-ONLY HAZARDS</b>	Repeated exposure may cause skin dryness or cracking.
<b>PRECAUTIONARY STATEMENT(S)</b>	<p><b>Prevention</b></p> Wash thoroughly after handling Do not eat, drink or smoke when using this product Avoid breathing dust/fume/gas/mist/ vapors/spray Use only outdoors or in a well-ventilated area Wear protective gloves, eye and face protection.
	<p><b>Response</b></p> IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a poison center or medical professional. IF SWALLOWED: Immediately call a poison center or medical professional; Rinse mouth. IF ON SKIN (HAIR): Wash with plenty of water. If skin irritation occurs: Get medical advice/attention. Take off contaminated clothing and wash it before reuse. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.
	<p><b>Storage</b></p> Not applicable

HMIS CLASSIFICATION	<b>Disposal</b>	Not applicable	
	<b>Health Hazard</b>	1	<b>Flammability</b> 0
	<b>Reactivity</b>	0	<b>Personal Protection</b> G

### SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

<b>CHEMICAL NAME</b>	Dihydrogenethylenediaminetetraacetic acid disodium salt, dihydrate
<b>BOTANICAL NAME</b>	Not applicable
<b>SYNONYM</b>	Disodium EDTA dihydrate; Disodium Ethylenediamine Tetraacetate Dihydrate
<b>CHEMICAL FORMULA</b>	C <sub>10</sub> H <sub>14</sub> N <sub>2</sub> Na <sub>2</sub> O <sub>8</sub> · 2H <sub>2</sub> O
<b>CAS NUMBER</b>	6381-92-6 (Dihydrate)
<b>ALTERNATE CAS NUMBER</b>	139-33-3 (General)
<b>MOLECULAR WEIGHT</b>	372.2

CHEMICAL NAME	CAS NUMBER	% BY WEIGHT
EDETATE DISODIUM (Dihydrate)	6381-92-6	100

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as health hazards and hence require reporting in this section.

<b>NOTES</b>	Chemical family: Diamine.
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### SECTION 4: FIRST-AID MEASURES

<b>IN CASE OF EYE CONTACT</b>	Flush with copious amounts of water for 15 minutes, separating eyelids with fingers. If irritation persists seek medical aid.
<b>IN CASE OF SKIN CONTACT</b>	Wash with soap & water for 15 minutes. If irritation persists seek medical aid.
<b>IF SWALLOWED</b>	Call a physician. Wash out mouth with water. Do not induce vomiting without medical advice.
<b>IF INHALED</b>	Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Call a physician
<b>SYMPTOMS AND EFFECTS</b>	Not expected to present a significant hazard under anticipated conditions of normal use.

### SECTION 5: FIREFIGHTING MEASURES

<b>SPECIFIC HAZARDS ARISING FROM THE CHEMICAL</b>	Not applicable
<b>FLAMMABLE PROPERTIES</b>	May be combustible at high temperature
<b>HAZARDOUS COMBUSTION PRODUCTS</b>	Under fire conditions, hazardous fumes will be present.
<b>EXTINGUISHING MEDIA</b>	<b>Small fire:</b> dry chemical, CO <sub>2</sub> or water spray. <b>Large fire:</b> dry chemical, CO <sub>2</sub> , alcohol resistant foam or water spray. Do not get water inside containers.
<b>PROTECTIVE EQUIPMENT AND PRECAUTIONS FOR FIREFIGHTERS</b>	Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.

### SECTION 6: ACCIDENTAL RELEASE MEASURES

**PERSONAL PRECAUTIONS**

Wear respiratory protection. Avoid dust formation. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust.

**METHODS & MATERIAL FOR CONTAINMENT**

On land, sweep or shovel into suitable containers. Minimize generation of dust.

**CLEANUP PROCEDURE**

Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Wear respirator, chemical safety goggles, rubber boots and heavy rubber gloves. Stop leak if you can do it without risk. Prevent entry into waterways, sewers, basements or confined areas. Shut off all sources of ignition. Evacuate the area. If necessary, employ water fog to disperse the vapors. Absorb the matter with compatible vermiculite or other absorbing material. Place in a suitable container and retain for disposal. Ventilate and clean the affected area. Do not flush into sewerage system or to drains.

**SECTION 7: HANDLING AND STORAGE**
**PRECAUTIONS FOR SAFE HANDLING**

Do not inhale. Avoid contact with eyes, skin and clothing. Avoid prolonged or repeated exposure. Wash thoroughly after handling. Store away from incompatible materials, in a well-ventilated area. Eliminate all sources of ignition. Store in accordance with local regulations. Do not store in unlabelled containers. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Use appropriate containment to avoid environmental contamination.

**STORAGE CONDITIONS**

Store in original container, tightly sealed, protected from direct sunlight and moisture. Avoid metal and galvanized containers. Storage temperature range: -6 to 49°C. Preserve in well-closed containers. Protect from light.

**SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION**

Chemical Name: EDETATE DISODIUM (Dihydrate) CAS #: 6381-92-6

	TWA	Ceiling	STEL	REL	IDLH	Remarks
OSHA PEL	N/L	N/L	-	-	-	-
ACGIH TLV	N/L	N/L	N/L	-	-	-
NIOSH	N/L	N/L	N/L	N/L	N/L	-
AIHA WEEL	N/L	N/L	N/L	-	-	-
Safe Work Australia HSIS	N/L	N/L	N/L	-	-	-
HSE	N/L	N/L	N/L	-	-	-

N/L = Not Listed

**EXPOSURE GUIDELINES**

Consult local authorities for provincial or state exposure limits. Particulates not otherwise regulated, respirable fraction: 5 mg/m<sup>3</sup>

**PERSONAL PROTECTIVE EQUIPMENT**

**Eyes:** Wear appropriate protective eyeglasses or chemical safety goggles as described by WHMIS or OSHA's eye and face protection regulations in 29 CFR 1910.133 or European Standard EN166. **Skin:** Wear appropriate gloves to prevent skin exposure. **Clothing:** Wear appropriate protective clothing to minimize contact with skin. **Respirators:** Follow WHMIS or OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149. Use a NIOSH/MSHA or European Standard EN 149 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced.

**SPECIFIC ENGINEERING CONTROLS**

Adequate mechanical ventilation. Fumehood, eye wash station, and safety shower.

**SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES**
**PHYSICAL STATE**

Solid

**DESCRIPTION**

White or almost white, crystalline powder. Slightly hygroscopic.

<b>SOLUBILITY</b>	Soluble in water, practically insoluble in ethanol (96%).				
<b>ODOR</b>	Odorless or characteristic odor				
<b>FLAMMABILITY</b>	May be combustible at high temperature				
<b>ODOR THRESHOLD</b>	Not available	<b>pH</b>	4.0 - 6.0 (5%)	<b>MELTING POINT</b>	252°C, 485.6°F (decomposes)
<b>BOILING POINT</b>	Not available	<b>FREEZING POINT</b>	252°C, 485.6°F	<b>FLASH POINT</b>	>100°C, >212°F
<b>SPECIFIC GRAVITY</b>	Not available	<b>EVAPORATION RATE</b>	Not available	<b>EXPLOSIVE LIMIT</b>	Not available
<b>UPPER FLAMMABLE/EXPLOSIVE LIMIT(S)</b>	Not available	<b>LOWER FLAMMABLE/EXPLOSIVE LIMIT(S)</b>	Not available	<b>VAPOR PRESSURE</b>	< 0.01 mm Hg
<b>VAPOR DENSITY (AIR = 1)</b>	Not available	<b>RELATIVE DENSITY (WATER = 1)</b>	Not available	<b>log P (OCTANOL-WATER)</b>	-11.7 (20°C)
<b>AUTO-IGNITION TEMPERATURE</b>	Not available	<b>DECOMPOSITION TEMPERATURE</b>	252°C, 485.6°F	<b>VISCOSITY</b>	Not available

**NOTES** The physical data presented above are typical values and should not be construed as a specification.

## SECTION 10: STABILITY AND REACTIVITY

<b>REACTIVITY</b>	Not established
<b>STABILITY</b>	Stable under recommended storage conditions
<b>MATERIALS TO AVOID</b>	Strong oxidants. Strong acids. Strong bases. Aluminium. Moisture. Metals. Galvanized containers.
<b>HAZARDOUS DECOMPOSITION PRODUCTS</b>	Toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides and other gases may occur.
<b>HAZARDOUS POLYMERIZATION</b>	Will not occur
<b>POSSIBILITY OF HAZARDOUS REACTION</b>	Flammable hydrogen may be generated from contact with metals such as aluminum.
<b>CONDITIONS TO AVOID</b>	Moisture, sunlight and extreme temperatures

## SECTION 11: TOXICOLOGICAL INFORMATION

<b>ACUTE TOXICITY</b>	Oral: Rat: LD50: (mg/kg): 2000 - 2200 Dermal: Rabbit LD50: (mg/kg): Not available Inhalation: Rat: LD50: (mg/L/4hr): > 2.27 (estimated)
<b>SKIN CORROSION/IRRITATION</b>	pH: 4.0 - 6.0: Causes skin irritation.
<b>SERIOUS EYE DAMAGE/EYE IRRITATION</b>	pH: 4.0 - 6.0: Causes serious eye irritation.
<b>RESPIRATORY OR SKIN SENSITIZATION</b>	Respiratory sensitization Due to lack of data the classification is not possible. Skin sensitization Based on available data, the classification criteria are not met. Guinea pig sensitization test; Result: Negative.

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<b>GERM CELL MUTAGENICITY</b>	Due to lack of data the classification is not possible.
<b>CARCINOGENICITY</b>	<p><b>OSHA</b> EDETATE DISODIUM is not listed.</p> <p><b>NTP</b> EDETATE DISODIUM is not listed.</p> <p><b>IARC</b> EDETATE DISODIUM was not evaluated.</p> <p><b>California Proposition 65</b> This product does not contain any chemicals known to the State of California to cause cancer, birth defects, or any other reproductive harm.</p>
<b>ADDITIONAL CARCINOGENICITY INFORMATION</b>	Due to lack of data the classification is not possible.
<b>REPRODUCTIVE TOXICITY</b>	Based on available data, the classification criteria are not met. Studies in rats have shown that edetate disodium causes impaired reproduction and fetal malformations. It is believed that zinc deficiency may be the cause, since these effects were prevented by simultaneous supplementation of dietary zinc.
<b>SPECIFIC TARGET ORGAN TOXICITY - SINGLE EXPOSURE</b>	Based on available data, the classification criteria are not met.
<b>SPECIFIC TARGET ORGAN TOXICITY - REPEATED EXPOSURE</b>	Based on available data, the classification criteria are not met.
<b>ASPIRATION HAZARDS</b>	Based on available data, the classification criteria are not met.
<b>SIGNS AND SYMPTOMS OF EXPOSURE</b>	<p>Not expected to present a significant hazard under anticipated conditions of normal use.</p> <p>Symptoms related to the physical, chemical, and toxicological characteristics Nausea. Vomiting. Diarrhea. Abdominal pain. Cramps. Loss of appetite. Thirst. Numbness, tingling, or burning sensations. Headache. Tiredness. Dizziness. Convulsions. Muscle spasms. Fever. Chills. Skin rash. Difficulty breathing. Painful or difficult urination.</p> <p>Delayed and immediate effects of exposure Hypocalcemia. Hypokalemia. Hypomagnesemia. Irregular heartbeat. Heart failure. Cardiac arrest. Drop in blood pressure. Kidney impairment.</p> <p>Medical conditions aggravated by exposure Anuria. Liver impairment. Kidney impairment. Seizure disorders. Cardiac arrhythmias. Heart disease. Hypocalcemia. Hypokalemia. Diabetes mellitus. Tuberculosis</p>
<b>POTENTIAL HEALTH EFFECTS</b>	<p><b>Inhalation</b> Harmful if inhaled. May cause respiratory tract irritation.</p> <p><b>Ingestion</b> Harmful if swallowed.</p> <p><b>Skin</b> May be harmful if absorbed through skin. Causes skin irritation.</p> <p><b>Eyes</b> Causes serious eye irritation.</p>

## SECTION 12: ECOLOGICAL INFORMATION

<b>TOXICITY</b>	<p>EC50: 48 Hr: Crustacea: Daphnia magna: (mg/L): &gt;100</p> <p>LC50: 96 Hr: Fish: Lepomis macrochirus: (mg/L): 159</p> <p>LC50: 96 Hr: Fish: Poecilia reticulata: (mg/L): 320</p> <p>IC50: 72 Hr: Algae: (mg/L): &gt;100</p>
<b>PERSISTENCE AND DEGRADABILITY</b>	Potentially biodegradable.
<b>BIOACCUMULATIVE POTENTIAL</b>	Low: LogPow: -11.7 (20°C)
<b>MOBILITY IN SOIL</b>	Soluble in water: 10.8g/100mL; 5-7 wt% (25°C)
<b>OTHER ADVERSE EFFECTS</b>	<p>Not available</p> <p>This product is not intended to be released into the environment</p>

**SECTION 13: DISPOSAL CONSIDERATIONS**
**WASTE DISPOSAL**

Dispose of in accordance with federal / local laws and regulations. Avoid release into the environment.

**SECTION 14: TRANSPORT INFORMATION**
**UNITED STATES & CANADA**
**UN PROPER SHIPPING NAME**

Not dangerous good

**UN NUMBER**

Not applicable

**CLASS**

Not applicable

**PACKING GROUP**

Not applicable

**AUSTRALIA**
**UN PROPER SHIPPING NAME**

Not dangerous good

**UN NUMBER**

Not applicable

**CLASS**

Not applicable

**PACKING GROUP**

Not applicable

**HAZCHEM**

Not applicable

**ENVIRONMENTAL HAZARDS**

Not available

**SPECIAL SHIPPING INFORMATION**

Not applicable

**SECTION 15: REGULATORY INFORMATION**

Chemical Name & CAS	CERCLA 40 CFR Part 302.4	SARA (Title III) 40 CFR Part 372.65	EPA 40 CFR Part 355		Pennsylvania	Right-to-know		California Prop 65
			Appendix A	Appendix B		New Jersey	Massachusetts	
EDETATE DISODIUM (Dihydrate) 6381-92-6	N/L	N/L	N/L	N/L	N/L	N/L	N/L	N/L

N/L = Not Listed; X = Listed

**AUSTRALIAN REGULATIONS**

Chemical Name & CAS	Poisons and Therapeutic Goods Regulation	Therapeutic Goods Act	Code of Practices - Illicit Drug Precursors
EDETATE DISODIUM (Dihydrate) 6381-92-6	N/L	N/L	N/L

**SECTION 16: OTHER INFORMATION**
**REFERENCES**

Available upon request

**ABBREVIATIONS AND ACRONYMS**

**CAS** – Chemical Abstract Service; **GHS** – Global Harmonized System; **OSHA PEL** – Occupational Safety & Health Administration Permissible Exposure Limits; **TWA** – Time Weighted Average; **HSIS** – Hazardous Substances Information System; **STEL** – Short Term Exposure Limit; **AIHA WEEL** – American Industrial Hygiene Association Workplace Environment Exposure Levels; **LD50** – Lethal Dose, 50%; **IARC** – International Agency for Research on Cancer; **NTP** – National Toxicology Program; **WHMIS** – Workplace Hazardous Materials Information System; **SARA** – Superfund Amendments and Reauthorization Act; **EPA** – Environmental Protection Agency; **CERCLA** – Comprehensive Environmental Response, Compensation, and Liability Act; **HMIS** – Hazardous Materials Information System; **NIOSH** – National Institute for Occupational Safety and Health; **MSHA** - Mine Safety and Health Administration; **ACGIH** - American Conference of Governmental Industrial Hygienists; **IDHL** - Immediately Dangerous to Health or Life; **TLV** – Threshold Limit Value; **HSE** – Health and Safety Executive; **REL** - Recommended Exposure Limit

**LAST REVISION**

03/2018

**SUPERSEDES**

12/2015

**DISCLAIMER**

This document was created in accordance with OSHA, Safe Work Australia and WHMIS regulations. 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. MEDISCA® shall not be held liable for any damage resulting from handling or from contact with the above product. Recipients of the product must take responsibility for observing existing laws and regulations.