


SECTION 1: PRODUCT IDENTIFICATION

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|----------------------------|--|
| PRODUCT NAME | EDETATE DISODIUM, USP |
| PRODUCT CODE | 0545 |
| SUPPLIER | MEDISCA Inc. Tel.: 1.800.932.1039 Fax.: 1.855.850.5855 661 Route 3, Unit C, Plattsburgh, NY, 12901 6641 N. Belt Line Road, Suite 130, Irving, TX, 75063 MEDISCA Pharmaceutique Inc. 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 MEDISCA Australia PTY LTD Tel.: 1.300.786.392 Fax.: 61.2.9700.9047 Unit 7, Heritage Business Park 5-9 Ricketty Street, Mascot, NSW 2020 |
| EMERGENCY PHONE | CHEMTREC Day or Night Within USA and Canada: 1-800-424-9300 NSW Poisons Information Centre: 131 126 National Chemical Emergency Centre 44(0)1235239670 |
| RECOMMENDED USES | Manufacturing and Compounding |
| RESTRICTIONS ON USE | Not applicable |

SECTION 2: HAZARDS IDENTIFICATION

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| GHS CLASSIFICATION | Acute Toxicity - Inhalation (Category 4) Acute Toxicity - Oral (Category 4) Skin Irritation (Category 2) Eye Irritation (Category 2A) |
| PICTOGRAM |  |
| SIGNAL WORD | Warning |
| HAZARD STATEMENT(S) | May be harmful if swallowed. Harmful if inhaled. Causes skin irritation. Causes serious eye irritation. |
| ADVERSE PHYSIOCHEMICAL, HUMAN HEALTH AND ENVIRONMENTAL EFFECTS | Repeated exposure may cause skin dryness or cracking. |

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|-----------------------------------|----------------------|---|----------------------------|---|
| PRECAUTIONARY STATEMENT(S) | Prevention | Wash hands thoroughly after handling. Do not touch eyes. 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. | | |
| | Response | IF INHALED: Remove person to fresh air and keep comfortable for breathing. Get medical help. IF SWALLOWED: Immediately call a poison center. Get medical help. 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 help. | | |
| | Storage | Not applicable | | |
| | Disposal | Not applicable | | |
| HMIS CLASSIFICATION | Health Hazard | 1 | Flammability | 0 |
| | Reactivity | 0 | Personal Protection | G |

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

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

| CHEMICAL NAME | CAS NUMBER | EC NUMBER | % BY WEIGHT |
|------------------------------|------------|-----------|-------------|
| EDETATE DISODIUM (Dihydrate) | 6381-92-6 | 613-386-6 | 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.

SECTION 4: FIRST-AID MEASURES

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

SECTION 5: FIREFIGHTING MEASURES

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

SECTION 6: ACCIDENTAL RELEASE MEASURES

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| 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. |
| REFERENCE TO OTHER SECTIONS | See Section 7 for information on safe handling. See Section 8 for information on personal protection equipment. See Section 13 for disposal information. |

SECTION 7: HANDLING AND STORAGE

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| 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 unlabeled containers. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Use appropriate containment to avoid environmental contamination. |
| CONDITIONS FOR SAFE STORAGE | 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 unlabeled 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. Store at controlled room temperature. Controlled room temperature indicates a temperature 20° to 25°C (68° to 77°F); that results in a mean kinetic temperature calculated to be not more than 25°C; and that allows for excursions between 15° and 30°C (59° and 86°F) that are experienced in pharmacies, hospitals, and warehouses. Provided the mean kinetic temperature remains in the allowed range, transient spikes up to 40°C (104°F) are permitted as long as they do not exceed 24 hours. |

SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION
Chemical Name: EDETATE DISODIUM (Dihydrate) CAS #: 6381-92-6

| | Country | Limit value-8 hours | | Limit value-Short Term | | IDLH | REL | Advisory | Notes |
|---------------|-------------|---------------------|-------------------|------------------------|-------------------|------|-----|----------|-------|
| | | ppm | mg/m ³ | ppm | mg/m ³ | | | | |
| OSHA | USA | N/L | N/L | N/L | N/L | N/L | N/L | N/A | N/A |
| ACGIH | USA | N/L | N/L | N/L | N/L | N/L | N/L | N/A | N/A |
| NIOSH | USA | N/L | N/L | N/L | N/L | N/L | N/L | N/A | N/A |
| WEEL | USA | N/L | N/L | N/L | N/L | N/L | N/L | N/A | N/A |
| HSIS | Australia | N/L | N/L | N/L | N/L | N/L | N/L | N/A | N/A |
| HSE | UK | N/L | N/L | N/L | N/L | N/L | N/L | N/A | N/A |
| GESTIS | Add Country | N/L | N/L | N/L | N/L | N/L | N/L | N/A | N/A |

N/L = Not listed ; N/A = Not Available

PELs are 8-hour TWAs = Limit value - Eight hours

Ceiling or Short-Term TWA = STEL = Limit value - Short term

EXPOSURE GUIDELINES

 Consult local authorities for provincial or state exposure limits. Particulates not otherwise regulated, respirable fraction: 5 mg/m³
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. **Thermal Hazards:** For products representing a thermal hazard, appropriate Personal Protective Equipment should be used.

SPECIFIC ENGINEERING CONTROLS

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

BIOLOGICAL MONITORING

Not available

CONTROL BANDING

Not available

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES
PHYSICAL STATE

Solid

DESCRIPTION

White or almost white, crystalline powder. Slightly hygroscopic.

SOLUBILITY

Soluble in water, practically insoluble in ethanol (96%).

ODOR

Odorless or characteristic odor

FLAMMABILITY

May be combustible at high temperature

AUTO-IGNITION TEMPERATURE

Not available

BOILING POINT

Not available

DECOMPOSITION TEMPERATURE

252°C, 485.6°F

EVAPORATION RATE

Not available

EXPLOSIVE LIMIT

Not available

FLASH POINT

>100°C, >212°F

| | | | | | |
|---|---------------|--|----------------------------|--|--------------------------------|
| log P (OCTANOL-WATER) | -11.7 (20°C) | LOWER FLAMMABLE/ EXPLOSIVE LIMIT(S) | Not available | MELTING/FREEZING POINT | 252°C, 485.6°F (decomposes) |
| PARTICLE CHARACTERISTICS | Not available | OXIDIZING PROPERTY | Not available | pH | 4.0 - 6.0 (5%) |
| RELATIVE DENSITY (WATER = 1) | Not available | SPECIFIC GRAVITY | Not available | UPPER FLAMMABLE/ EXPLOSIVE LIMIT(S) | Not available |
| VAPOR DENSITY (AIR = 1) | Not available | VAPOR PRESSURE | < 0.0000001 hPa (25 °C) | VISCOSITY | Not available |

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

SECTION 10: STABILITY AND REACTIVITY

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

SECTION 11: TOXICOLOGICAL INFORMATION

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|--|---|
| ACUTE TOXICITY | Oral: Rat: LD50: (mg/kg): 2000 - 2200 Dermal: Rabbit LD50: (mg/kg): Not available Inhalation: Rat: LC50: (mg/L/4hr): > 2.27 (estimated) |
| SKIN CORROSION/IRRITATION | pH: 4.0 - 6.0: Causes skin irritation. |
| SERIOUS EYE DAMAGE/EYE IRRITATION | pH: 4.0 - 6.0: Causes serious eye irritation. |
| RESPIRATORY SENSITIZATION | Due to lack of data the classification is not possible. |
| SKIN SENSITIZATION | Based on available data, the classification criteria are not met. |
| GERM CELL MUTAGENICITY | Due to lack of data the classification is not possible. |
| CARCINOGENICITY | OSHA EDETATE DISODIUM is not listed. NTP EDETATE DISODIUM is not listed. IARC EDETATE DISODIUM was not evaluated. California Proposition 65 This product does not contain any chemicals known to the State of California to cause cancer, birth defects, or any other reproductive harm. |

ADDITIONAL CARCINOGENICITY INFORMATION

Due to lack of data the classification is not possible.

REPRODUCTIVE TOXICITY

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.

Suspected toxic for reproduction: The Toolbox profiler 'DART scheme v.1.0' gives an alert for toxicity to reproduction; Developmental/Reproductive Toxicity library (PG) in VEGA (Q)SAR platform predicts that the chemical is Toxicant (moderate reliability)

SPECIFIC TARGET ORGAN TOXICITY - SINGLE EXPOSURE

Due to lack of data the classification is not possible.

SPECIFIC TARGET ORGAN TOXICITY - REPEATED EXPOSURE

Due to lack of data the classification is not possible.

ASPIRATION HAZARDS

Based on available data, the classification criteria are not met.

SIGNS AND SYMPTOMS OF EXPOSURE
ROUTES OF EXPOSURE:

Oral, Dermal, Inhalation, Eye contact

EARLY ONSET SYMPTOMS RELATED TO EXPOSURE:

Not available

DELAYED HEALTH EFFECT FROM EXPOSURE:

Hypocalcemia. Hypokalemia. Hypomagnesemia. Irregular heartbeat. Heart failure. Cardiac arrest. Drop in blood pressure. Kidney impairment.

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.

Medical conditions aggravated by exposure:

Anuria. Liver impairment. Kidney impairment. Seizure disorders. Cardiac arrhythmias. Heart disease. Hypocalcemia. Hypokalemia. Diabetes mellitus. Tuberculosis.

POTENTIAL HEALTH EFFECTS

Inhalation Harmful if inhaled. May cause respiratory tract irritation.

Ingestion Harmful if swallowed.

Skin May be harmful if absorbed through skin. Causes skin irritation.

Eyes Causes serious eye irritation.

NOTES

Pharmacologically active material. Occupational exposure may cause physiological effects.

SECTION 12: ECOLOGICAL INFORMATION
ECOTOXICITY

EC50: 48 Hr: Crustacea: Daphnia magna: (mg/L): >100

LC50: 96 Hr: Fish: Lepomis macrochirus: (mg/L): 159

LC50: 96 Hr: Fish: Poecilia reticulata: (mg/L): 320

EC50: 72 Hr: Algae: (mg/L): >100

PERSISTENCE AND DEGRADABILITY

Potentially biodegradable.

BIOACCUMULATIVE POTENTIAL

Low: LogPow: -11.7 (20°C)

MOBILITY IN SOIL

Soluble in water: 10.8g/100mL; 5-7 wt% (25°C)

OTHER ADVERSE EFFECTS

Not available

This product is not intended to be released into the environment

SECTION 13: DISPOSAL CONSIDERATIONS
DISPOSAL METHODS

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

SECTION 14: TRANSPORT INFORMATION
UN PROPER SHIPPING NAME

Not dangerous good

UN NUMBER

Not applicable

CLASS

Not applicable

PACKING GROUP

Not applicable

AUSTRALIA
HAZCHEM

Not applicable

EU
TRANSPORT IN BULK ACCORDING TO ANNEX II OF MARPOL 73/78 AND THE IBC CODE

Not Listed

ENVIRONMENTAL HAZARDS

Not available

SPECIAL SHIPPING INFORMATION

Not applicable

SECTION 15: REGULATORY INFORMATION
UNITED STATES REGULATIONS

| 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 | Therapeutic Goods Act | Code of Practices - Illicit Drug Precursors | Poisons Standard | Work Health and Safety Regulations | Inventory of Industrial Chemicals |
|--|-------------------------------|-----------------------|---|------------------|------------------------------------|-----------------------------------|
| EDETATE DISODIUM (Dihydrate) 6381-92-6 | N/L | N/L | N/L | N/L | N/L | N/L |

N/L = Not Listed

EU REGULATIONS

| Chemical Name & CAS | REACH ANNEX XVII | REACH ANNEX XIV | EC 1005/2009 | EC 850/2004 | EC 1107/2009 | PIC - Prior Informed Consent Regulation | EC 2012/18 |
|--|------------------|-----------------|--------------|-------------|--------------|---|------------|
| EDETATE DISODIUM (Dihydrate) 6381-92-6 | N/L | N/L | N/L | N/L | N/L | N/L | N/L |

N/L = Not Listed; X = Listed

Any EU regulation not listed above is not applicable to this product.

SUBJECT TO INTERNATIONAL AGREEMENT Not applicable

SECTION 16: OTHER INFORMATION

REFERENCES

Available upon request

ABBREVIATIONS AND ACRONYMS

ACGIH - American Conference of Governmental Industrial Hygienists; **AIHA WEEL** - American Industrial Hygiene Association Workplace Environment Exposure Levels; **CAESAR** - Computer Assisted Evaluation of industrial chemical Substances According to Regulations; **CAS** - Chemical Abstract Service; **CERCLA** - Comprehensive Environmental Response, Compensation, and Liability Act; **EC50** - Effective Concentration, 50%; **EPA** - Environmental Protection Agency; **GHS** - Global Harmonized System; **HMIS** - Hazardous Materials Information System; **HSE** - Health and Safety Executive; **HSIS** - Hazardous Substances Information System; **IARC** - International Agency for Research on Cancer; **IDLH** - Immediately Dangerous to Life or Health; **IRFMN** - Ready Biodegradability Model; **ISS** - Istituto Superiore Sanità; **LC50** - Lethal Concentration, 50%; **LD50** - Lethal Dose, 50%; **MSHA** - Mine Safety and Health Administration; **NIOSH** - National Institute for Occupational Safety and Health; **NTP** - National Toxicology Program; **OSHA PEL** - Occupational Safety & Health Administration Permissible Exposure Limits; **QSAR** - Quantitative Structure-activity relationship; **REL** - Recommended Exposure Limit; **SARA** - Superfund Amendments and Reauthorization Act; **STEL** - Short Term Exposure Limit; **TLV** - Threshold Limit Value; **TWA** - Time Weighted Average; **WHMIS** - Workplace Hazardous Materials Information System

LAST REVISION

02/2023

SUPERSEDES

09/2021

For a list of changes to the SDS since the last version, please communicate with MEDISCA at www.medisca.com

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.

SUPPLEMENTARY INFORMATION

For all country specific requirements not outlined on this Safety Data Sheet, please request Supplementary Page to this Safety Data Sheet.