

**SECTION 1: PRODUCT IDENTIFICATION**

|                        |  |
|------------------------|--|
| <b>PRODUCT NAME</b>    | <b>EDETATE CALCIUM DISODIUM, USP</b>   |
| <b>PRODUCT CODE</b>    | <b>2459</b>  |
| <b>SUPPLIER</b>        | <b>MEDISCA Inc.</b><br>Tel.: 1.800.932.1039   Fax.: 1.855.850.5855<br>661 Route 3, Unit C, Plattsburgh, NY, 12901<br>3955 W. Mesa Vista Ave., Unit A-10, Las Vegas, NV, 89118<br>6641 N. Belt Line Road, Suite 130, Irving, TX, 75063<br><b>MEDISCA Pharmaceutique Inc.</b><br>Tel.: 1.800.665.6334   Fax.: 514.338.1693<br>4509 Rue Dobrin, St. Laurent, QC, H4R 2L8<br>21300 Gordon Way, Unit 153/158, Richmond, BC V6W 1M2<br><b>MEDISCA Australia PTY LTD</b><br>Tel.: 1.300.786.392   Fax.: 61.2.9700.9047<br>Unit 7, Heritage Business Park<br>5-9 Ricketty Street, Mascot, NSW 2020 |
| <b>EMERGENCY PHONE</b> | CHEMTREC Day or Night Within USA and Canada: 1-800-424-9300<br>NSW Poisons Information Centre: 131 126   |
| <b>USES</b>            | Pharmaceutic Aid (Chelating agent)   |

**SECTION 2: HAZARDS IDENTIFICATION**

|                                   |   |                |                            |   |
|-----------------------------------|---|----------------|----------------------------|---|
| <b>GHS CLASSIFICATION</b>         | Based on available data, the classification criteria are not met. |                |                            |   |
| <b>PICTOGRAM</b>                  | Not Applicable  |                |                            |   |
| <b>SIGNAL WORD</b>                | Not applicable  |                |                            |   |
| <b>HAZARD STATEMENT(S)</b>        | Not applicable  |                |                            |   |
| <b>AUSTRALIA-ONLY HAZARDS</b>     | Not Applicable.   |                |                            |   |
| <b>PRECAUTIONARY STATEMENT(S)</b> | <b>Prevention</b>   | Not applicable |                            |   |
|                                   | <b>Response</b>   | Not applicable |                            |   |
|                                   | <b>Storage</b>  | Not applicable |                            |   |
|                                   | <b>Disposal</b>   | Not applicable |                            |   |
| <b>HMS CLASSIFICATION</b>         | <b>Health Hazard</b>  | 1              | <b>Flammability</b>        | 1 |
|                                   | <b>Reactivity</b>   | 0              | <b>Personal Protection</b> | E |

**SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS**

|                             |   |
|-----------------------------|---|
| <b>CHEMICAL NAME</b>        | Calciate (2-), ((ethylenedinitrilo) tetraacetato)-, disodium, hydrate |
| <b>BOTANICAL NAME</b>       | Not applicable  |
| <b>SYNONYM</b>              | EDTA Calcium Disodium Salt  |
| <b>CHEMICAL FORMULA</b>     | $C_{10}H_{12}CaN_2Na_2O_8 \cdot xH_2O$                                |
| <b>CAS NUMBER</b>           | 23411-34-9  |
| <b>ALTERNATE CAS NUMBER</b> | 62-33-9   |

|                         |  |                   |                    |
|-------------------------|--|-------------------|--------------------|
| <b>MOLECULAR WEIGHT</b> | 374.27 (Anhydrous)   |                   |                    |
| <b>COMPOSITION</b>      | <b>CHEMICAL NAME</b>   | <b>CAS NUMBER</b> | <b>% BY WEIGHT</b> |
|                         | EDETATE CALCIUM DISODIUM   | 23411-34-9        | 100                |
| <b>NOTES</b>            | 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.<br>Chemical family: Diamine (symmetrical). |                   |                    |

## 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

|   |  |
|---|--|
| <b>PERSONAL PRECAUTIONS</b>                   | Wear respiratory protection. Avoid dust formation. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust.  |
| <b>METHODS &amp; MATERIAL FOR CONTAINMENT</b> | On land, sweep or shovel into suitable containers. Minimize generation of dust.  |
| <b>CLEANUP PROCEDURE</b>                      | 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. Preserve in airtight container, protected from light.

**SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION**
**Chemical Name: EDETATE CALCIUM DISODIUM CAS #: 23411-34-9**

|                          | TWA                  | Ceiling | STEL | REL | IDLH | Remarks    |
|--------------------------|----------------------|---------|------|-----|------|------------|
| OSHA PEL                 | 15 mg/m <sup>3</sup> | N/L     | -    | -   | -    | total dust |
| ACGIH TLV                | N/L                  | N/L     | N/L  | -   | -    | -          |
| NIOSH                    | 15 mg/m <sup>3</sup> | 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, crystalline granules or white, crystalline powder. Is odorless, is slightly hygroscopic.

**SOLUBILITY**

Freely soluble in water.

**ODOR**

Odorless

**FLAMMABILITY**

May be combustible at high temperature

**ODOR THRESHOLD**

Not available

**pH**

6.5 - 7.5 (1%)

**MELTING POINT**

 >252°C,  
>485.6°F  
(decomposes)

**BOILING POINT**

Not available

**FREEZING POINT**

 >252°C,  
>485.6°F

**FLASH POINT**

Not available

**SPECIFIC GRAVITY**

Not available

**EVAPORATION RATE**

Not available

**EXPLOSIVE LIMIT**

Not available

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|  |                  |  |                     |                                  |               |
|--|------------------|--|---------------------|----------------------------------|---------------|
| <b>UPPER FLAMMABLE/<br/>EXPLOSIVE LIMIT(S)</b> | Not available    | <b>LOWER FLAMMABLE/<br/>EXPLOSIVE LIMIT(S)</b> | Not available       | <b>VAPOR PRESSURE</b>            | < 0.1 mm Hg   |
| <b>VAPOR DENSITY<br/>(AIR = 1)</b>             | Not available    | <b>RELATIVE DENSITY<br/>(WATER = 1)</b>        | Not available       | <b>log P<br/>(OCTANOL-WATER)</b> | -10.42 (20°C) |
| <b>AUTO-IGNITION<br/>TEMPERATURE</b>           | >200 °C, >392 °F | <b>DECOMPOSITION<br/>TEMPERATURE</b>           | >252°C,<br>>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 oxidizing agents, strong bases, and polyvalent metal ions such as copper, nickel, and copper alloy. |
| <b>HAZARDOUS DECOMPOSITION<br/>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<br/>REACTION</b> | Not established  |
| <b>CONDITIONS TO AVOID</b>                   | Moisture, sunlight and extreme temperatures  |

## SECTION 11: TOXICOLOGICAL INFORMATION

|   |   |
|---|---|
| <b>ACUTE TOXICITY</b>                             | Oral: Rat: LD50: (mg/kg): 10 000<br>Dermal: Rabbit LD50: (mg/kg): Not available<br>Inhalation: Rat: LD50: (mg/L/4hr): Not available   |
| <b>SKIN CORROSION/IRRITATION</b>                  | Based on available data, the classification criteria are not met.<br>It is not considered to be irritating to skin based on tests with structurally related products.<br>pH 6.5 - 7.5 (1%)                            |
| <b>SERIOUS EYE DAMAGE/EYE<br/>IRRITATION</b>      | Based on available data, the classification criteria are not met.<br>This product may be minimally irritating to eyes based on tests with similar products.<br>May cause serious eye irritation.<br>pH 6.5 - 7.5 (1%) |
| <b>RESPIRATORY OR SKIN<br/>SENSITIZATION</b>      | Due to lack of data the classification is not possible.   |
| <b>GERM CELL MUTAGENICITY<br/>CARCINOGENICITY</b> | Due to lack of data the classification is not possible.   |
|   | <b>OSHA</b> EDETATE CALCIUM DISODIUM is not listed.   |
|   | <b>NTP</b> EDETATE CALCIUM DISODIUM is not listed.  |
|   | <b>IARC</b> EDETATE CALCIUM DISODIUM is not listed.   |
|   | <b>California<br/>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.                                     |
| <b>ADDITIONAL CARCINOGENICITY<br/>INFORMATION</b> | Due to lack of data the classification is not possible.   |

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|---|---|-------------------|---|------------------|------------------------------|-------------|--|-------------|-----------------------------------|
| <b>REPRODUCTIVE TOXICITY</b>                              | Based on available data, the classification criteria are not met.<br>1340 mg/kg Reproductivity test: Result: No birth defects observed.: Species: Rat<br>< 250 mg/kg Reproductivity test: Result: No adverse effects over four generations.: Species: Rat   |                   |   |                  |                              |             |  |             |                                   |
| <b>SPECIFIC TARGET ORGAN TOXICITY - SINGLE EXPOSURE</b>   | Due to lack of data the classification is not possible.   |                   |   |                  |                              |             |  |             |                                   |
| <b>SPECIFIC TARGET ORGAN TOXICITY - REPEATED EXPOSURE</b> | Due to lack of data the classification is not possible.   |                   |   |                  |                              |             |  |             |                                   |
| <b>ASPIRATION HAZARDS</b>                                 | Based on available data, the classification criteria are not met.   |                   |   |                  |                              |             |  |             |                                   |
| <b>SIGNS AND SYMPTOMS OF EXPOSURE</b>                     | Symptoms related to the physical, chemical, and toxicological characteristics:<br>Chills. Fever. Tiredness. Weakness. Headache. Muscle pain. Joint pain. Thirst. Loss of appetite. Sneezing. Stuffy nose. Watery eyes. Dizziness. Lightheadedness. Fainting. Nausea. Vomiting. Cloudy urine. Bleeding or bruising. Sore throat. Drowsiness. Dry mouth. Dry skin.<br><br>Delayed and immediate effects of exposure:<br>Kidney damage. Zinc deficiency.<br><br>Medical conditions aggravated by exposure:<br>Impaired kidney function. Anuria. Oliguria. Dehydration. Hepatitis.<br><br>May cause renal tubular necrosis, nausea, diarrhoea, and abdominal cramp, thrombophlebitis, fever, malaise, headache, myalgia, sneezing, nasal congestion, lacrymation, skin eruptions, transient hypotension, and ECG abnormalities. |                   |   |                  |                              |             |  |             |                                   |
| <b>POTENTIAL HEALTH EFFECTS</b>                           | <table border="0"> <tr> <td style="vertical-align: top;"><b>Inhalation</b></td> <td>May be harmful if inhaled. May cause respiratory tract irritation. Inhalation of dust may cause discomfort and/or irritation of the respiratory system.</td> </tr> <tr> <td style="vertical-align: top;"><b>Ingestion</b></td> <td>May be harmful if swallowed.</td> </tr> <tr> <td style="vertical-align: top;"><b>Skin</b></td> <td>May be harmful if absorbed through skin. May cause skin irritation</td> </tr> <tr> <td style="vertical-align: top;"><b>Eyes</b></td> <td>May cause serious eye irritation.</td> </tr> </table>  | <b>Inhalation</b> | May be harmful if inhaled. May cause respiratory tract irritation. Inhalation of dust may cause discomfort and/or irritation of the respiratory system. | <b>Ingestion</b> | May be harmful if swallowed. | <b>Skin</b> | May be harmful if absorbed through skin. May cause skin irritation | <b>Eyes</b> | May cause serious eye irritation. |
| <b>Inhalation</b>   | May be harmful if inhaled. May cause respiratory tract irritation. Inhalation of dust may cause discomfort and/or irritation of the respiratory system.   |                   |   |                  |                              |             |  |             |                                   |
| <b>Ingestion</b>  | May be harmful if swallowed.  |                   |   |                  |                              |             |  |             |                                   |
| <b>Skin</b>   | May be harmful if absorbed through skin. May cause skin irritation  |                   |   |                  |                              |             |  |             |                                   |
| <b>Eyes</b>   | May cause serious eye irritation.   |                   |   |                  |                              |             |  |             |                                   |

## SECTION 12: ECOLOGICAL INFORMATION

|                                      |   |
|--------------------------------------|---|
| <b>TOXICITY</b>                      | EC50: 48 Hr: Crustacea: (mg/L): Not available<br>LC50: 96 Hr: Fish: (mg/L): Not available<br>IC50: 72 Hr: Algae: (mg/L): Not available  |
| <b>PERSISTENCE AND DEGRADABILITY</b> | EDTA (acid form) and its salts are not readily biodegradable. Under special conditions like adaptation or slightly alkaline pH, which is realistic under environmental surface water conditions, the biodegradability of EDTA is considered enhanced and, as such, EDTA is considered ultimately biodegradable. |
| <b>BIOACCUMULATIVE POTENTIAL</b>     | Bioaccumulation is not expected due to the substance's high water solubility.   |
| <b>MOBILITY IN SOIL</b>              | Ionic structure under environmental relevant pH conditions. No adsorption onto the organic fraction of soil or sediments is expected.   |
| <b>OTHER ADVERSE EFFECTS</b>         | Not available<br><br>This product is not intended to be released into the environment   |

## SECTION 13: DISPOSAL CONSIDERATIONS

|                       |   |
|-----------------------|---|
| <b>WASTE DISPOSAL</b> | 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<br>40 CFR<br>Part 302.4 | SARA (Title III)<br>40 CFR<br>Part 372.65 | EPA 40 CFR Part 355 |            | Pennsylvania | Right-to-know |               | California<br>Prop 65 |
|--|--------------------------------|---|---------------------|------------|--------------|---------------|---------------|-----------------------|
|  |                                |   | Appendix A          | Appendix B |              | New Jersey    | Massachusetts |                       |
| EDETATE CALCIUM<br>DISODIUM 23411-34-9 | 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 CALCIUM<br>DISODIUM 23411-34-9 | 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**

02/2018

**SUPERSEDES**

02/2015

**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<sup>®</sup> 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.