

SAFETY DATA SHEET

Date: 01/10/2020

Generic Name: Ethacrynic acid Tablets, USP 25 mg

Brand Equivalent: Edecrin[®]

| SECTION 1: IDENTIFICATION | |
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| Product Name | Ethacrynic acid Tablets, USP 25 mg |
| Active substance | Ethacrynic acid |
| Synonyms | N/A |
| Formula | C ₁₃ H ₁₂ C ₁₂ O ₄ |
| Therapeutic Category: | For short term diuresis |
| Chemical Name | 1-(4-fluorophenyl)-3(R)-[3-(4-fluorophenyl)-3(S) hydroxypropyl]-4(S)-(4-hydroxyphenyl)-2-azetidinone. |
| How Supplied | 25mg -Tablets white, capsule shaped, scored tablets, coded MSD 65 on one side and EDECRIN on the other |
| Manufacturer Name & Address | ScieGen Pharmaceuticals, Inc. 89 Arkay drive, Hauppauge, NY 11788. |
| Telephone No. | 631-434-2723 |

2. HAZARDS IDENTIFICATION:

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| Appearance: | Tablets |
| Signal Word: | WARNING |
| Statement of Hazard: | Harmful if swallowed. |
| Additional Hazard Information: Long Term: | Repeat-dose studies in animals have shown a potential to cause adverse effects on liver (based on components) |
| Known Clinical Effects | The most common adverse effects seen during clinical use of this drug include loss of appetite (anorexia), abdominal pain, changes in electrolytes, inability to swallow (dysphagia), nausea, vomiting, thirst, diarrhea. Clinical use has resulted in liver effects. Symptoms may include jaundice, liver function test abnormalities, and hepatitis. May cause adverse effects on the kidney. Other less common effects include allergic reaction, effects on hearing, vision. Drowsiness, fatigue, or headache are also possible. |
| EU Indication of danger: | Harmful |
| EU Risk Phrases: | R22 - Harmful if swallowed. |
| Australian Hazard Classification (NOHSC): | Hazardous Substance. Non-Dangerous Goods |
| Note: | This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace. |

| 3. Composition/Information on ingredients | | |
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| Components | CAS-No | Concentration (%w/w) |
| Ethacrynic acid | [58-54-8] | 18.52 |
| Lactose Monohydrate, NF (80M) | 64044-51-5 | * |
| Pregelatinized Starch, NF (Starch 1500) | 9005-25-8 | * |
| Colloidal Silicon Dioxide, NF (Aerosil 200 Pharma) | 112945-52-5 | * |
| Talc, USP (140) | 14807-96-6 | * |
| Calcium Stearate, NF (Ligamed CPR-2-K) | 1592230 | * |

* Proprietary, In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

| 4. FIRST AID MEASURES | |
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| Eye contact | Flush eye(s) immediately with plenty of water. If irritation occurs or persists, get medical attention. |
| Skin contact | Wash exposed area with soap and water, remove contaminated clothing and obtain medical assistance if irritation occurs. This material may not be completely removed by conventional laundering. Consult professional laundry service. Do not home launder |
| Inhalation | Remove to fresh air and keep patient at rest. Seek medical attention immediately |
| Ingestion | Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately. |

| 5. FIRE-FIGHTING MEASURES | |
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| Suitable extinguishing media | Use carbon dioxide, dry chemical, or water spray. |
| Hazardous Combustion Products | May emit toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, hydrogen chloride, and other chlorine-containing compounds. |
| Fire Fighting Procedures | During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus |
| Fire / Explosion Hazards: | Not applicable |

| 6. ACCIDENTAL RELEASE MEASURES | |
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| Health and Safety Precautions: | Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure. |

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| Measures for Cleaning / Collecting | Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly. |
| Measures for Environmental Protections: | Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release. |
| Additional Consideration for Large Spills: | Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel |

| 7. HANDLING AND STORAGE | |
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| General Handling: | Avoid generating airborne dust. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes |
| Storage Conditions: | Store as directed by product packaging. |

| 8. Exposure controls/Personal protection | |
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| Exposure Limits/Control Parameters: Ventillation And Engineering Controls | Use with adequate ventilation. Follow standard operating procedures and requirements for handling this product. Ensure eyewash stations and deluge showers are available and accessible in areas where this product is used. |
| Workplace Exposure Limits/Control Parameters | There are no occupational exposure limits for this product. |
| Respiratory Protection | None needed for normal handling of this product. For large spill response or tasks involving generation of aerosols, use the appropriate Self-Contained Breathing Apparatus (SCBA) pressure-demand or other positive-pressure mode. |
| Eye/face protection | Wear splash goggles or safety glasses as appropriate for the task. |
| Skin protection | Use appropriate protective clothing for the task (e.g., lab coat, etc.). |
| Hand protection | Wear nitrile or other appropriate gloves to avoid contact and/or absorption of the product. Use double gloves for spill response. |

| 9. PHYSICAL AND CHEMICAL PROPERTIES | |
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| General Information | |
| Physical State: | Tablets |
| Color: | Not applicable |
| Molecular Formula: | Mixture |
| Molecular weight: | Mixture |

| 10. Stability and Reactivity | |
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| Reactivity | Not water reactive |
| Chemical Stability | Stable under normal conditions |
| Possibility of hazardous reactions | Hazardous polymerization does not occur. |
| Conditions to avoid | None known. |
| Incompatible materials | Incompatible with acids |

| 11. Toxicological Information | |
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| Symptoms Of Exposure By Route Of Exposure | The main expected routes of occupational exposure to this product are via inhalation of dusts, eye and skin contact. Exposure may cause allergic reaction. Exposure may also cause effects described under 'Other Potential Health Effects'. |
| Inhalation | Dusts may irritate the nose and upper respiratory system. Symptoms may include sneezing, coughing, and nasal congestion. |
| Contact With Skin or Eyes | Mild irritation possible. Symptoms may include itching and redness and swelling |
| Skin Absorbtion | No information available. |
| Ingestion | May be harmful or toxic. May irritate the mouth, throat, and gastrointestinal system |
| Injection | Not a likely route of exposure. |
| Aspiration hazard | No aspiration toxicity classification |
| Carcinogenicity | Due to lack of data the classification is not possible. This material is not considered to be a carcinogen by IARC, NTP, or OSHA |
| Reproductive Toxicity | Due to lack of data the classification is not possible |
| Developmental Toxicity | Due to lack of data the classification is not possible |
| Pharmacokinetics/Toxicokinetics | Due to lack of data the classification is not possible |
| Other Toxicity Information | Due to lack of data the classification is not possible |

| 12. Ecological Information | |
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| Environmental Overview: | Environmental properties have not been investigated. Releases to the environment should be avoided. |

| 13. Disposal considerations | |
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| Disposal instructions | Dispose of contents/container in accordance with local/regional/national/international regulations. |
| Precautions to be followed during waste handling | Wear proper protective equipment when handling waste materials |

| 14. Transport Information | |
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| U.S. Department of Transportation | This product is NOT classified as dangerous goods, per U.S. DOT regulations, under 49 CFR 172.101 |
| Transport Canada Transportation of Dangerous Goods Regulations | This material does not meet the criteria of classification of Dangerous Goods, per regulations of Transport Canada |
| International Air Transport Association (IATA): | This product does not meet the criteria as Dangerous Goods, per rules of IATA |
| International Maritime Organization Designation (IMO) | This product is NOT classified as Dangerous Goods by the International Maritime Organization. |
| European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR) | Does not meet the criteria as Dangerous Goods of the United Nations Economic Commission for Europe. |
| Transport in Bulk according to the IBC CODE | Not applicable. |
| Environmental hazards | This product does not meet the criteria of environmentally hazardous according to the criteria of the UN Model Regulations (as reflected in the IMDG Code, ADR, RID, and ADN) and no component is not specifically listed in Annex III under MARPOL 73/78 |

| 15. Regulatory Information | |
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| U.S. Sara Reporting Requirements | The components of this product are not subject to the reporting requirements of Sections 302, 304, and 313 of Title III of the Superfund Amendments and Reauthorization Act. |
| U.S. SARA Threshold Planning Quantity | There are no specific Threshold Planning Quantities for components of this product. The default Federal SDS submission and inventory requirement filing threshold of 10,000 lb (4,540 kg) may apply, per 40 CFR 370.20. |
| U.S. SARA Hazard Categories (Section 311/312, 40 CFR 370-21): | ACUTE: Yes; CHRONIC: Yes; FIRE: No; REACTIVE: No; SUDDEN RELEASE: No |
| U.S. CERCLA Reportable Quantity (RQ): | Not applicable. |
| U.S. TSCA Inventory status | This product is regulated under Food and Drug Administration standards; this product is not subject to requirements under TSCA. |
| OTHER U.S. Federal Regulations | Under the Hazard Communication Standard (HCS), Section (b)(5)(ii) drugs are subject to labeling requirements by the FDA under the Federal Food, Drug and Cosmetic Act and are exempt from labeling provisions of the HCS; this section of the HCS exempts only labeling requirements and not requirements for a Safety Data Sheet for drugs. |
| California Safe Drinking water and Toxic Enforcement Act (PROPOSITION 65) | No component of this product is listed on the California Proposition 65 Lists |

| 16. Other information | |
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| Recommended Restrictions for Use: | Not available |
| Prepared on | 01/10/2020 |
| Revision | 00 |
| Disclaimer | The above information is believed to be correct but should only be used as a guide. ScieGen Pharmaceuticals, Inc. disclaims any express or implied warranty as to the accuracy of the above information and shall not be held liable for any direct, incidental or consequential damages resulting from reliance on the above information. |