

SAFETY DATA SHEET

1. Identification

| In addition of the second second | | |
|--|---|--|
| Product identifier | Anagrelide Hydrochloride | |
| Other means of identification | | |
| Catalog number | 1034738 | |
| CAS number | 823178-43-4 | |
| Chemical name | 6-7,Dichloro-1,5-dihydroimidazo[2,1-b]quinazolin-2(3H)-one hydrochloride, monohydrate | |
| Recommended use | Specified quality tests and assay use only. | |
| Recommended restrictions | Not for use as a drug. Not for administration to humans or animals. | |
| Manufacturer/Importer/Supplier/ | Distributor information | |
| Manufacturer | | |
| Company name Address | U. S. Pharmacopeia 12601 Twinbrook Parkway Rockville MD 20852-1790 United States | |
| Telephone | RS Technical Services 301-816-8129 | |
| Website | www.usp.org | |
| E-mail | RSTECH@usp.org | |
| Emergency phone number | CHEMTREC within US & 1-800-424-9300 | |
| | Canada CHEMTREC outside US & +1 703-527-3887 Canada | |
| 2. Hazard(s) identification | | |
| Physical hazards | Not classified. | |
| Health hazards | Specific target organ toxicity, repeated Category 2 (blood) exposure | |
| Environmental hazards | Not classified. | |
| OSHA defined hazards | Not classified. | |
| Label elements | | |
| | | |
| Signal word | Warning | |
| Hazard statement | May cause damage to organs (blood) through prolonged or repeated exposure. | |
| Precautionary statement | | |
| Prevention | Do not breathe dust/fume/gas/mist/vapors/spray. | |
| Response | Get medical advice/attention if you feel unwell. | |
| Storage | Not available. | |
| Disposal | Dispose of contents/container in accordance with local/regional/national/international regulations. | |
| Hazard(s) not otherwise classified (HNOC) | None known. | |
| Supplemental information | Potent pharmacologically active material. | |
| 3. Composition/informatio | n on ingredients | |

3. Composition/information on ingredients

Substance

| Chemical name | Common name and synonyms | CAS number | % |
|--|---|---|--|
| Anagrelide Hydrochloride | | 823178-43-4 | 100 |
| 4. First-aid measures | | | |
| nhalation | Move to fresh air. Call a physician if symptoms | s develop or persist. | |
| Skin contact | Wash off with soap and water. Get medical att | ention if irritation develops and | persists. |
| Eye contact | Rinse with water. Get medical attention if irrita | tion develops and persists. | |
| ngestion | Rinse mouth. Get medical attention if sympton | ns occur. | |
| Most important symptoms/effects, acute and delayed | Blood disorders. Potent pharmacologically act amounts may cause physiological effects. | ive material. Occupational expo | osure to small |
| Indication of immediate medical attention and special treatment needed | Provide general supportive measures and trea | it symptomatically. | |
| General information | Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is 1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention. | | |
| 5. Fire-fighting measures | | | |
| Suitable extinguishing media | Water. Foam. Dry chemical or CO2. Use fire-e materials. | extinguishing media appropriate | for surrounding |
| Unsuitable extinguishing media | None known. | | |
| Specific hazards arising from the chemical | No unusual fire or explosion hazards noted. | | |
| Special protective equipment and precautions for firefighters | Wear suitable protective equipment. | | |
| Fire fighting equipment/instructions | Use water spray to cool unopened containers. Firefighters should use self-contained breathin | | |
| Specific methods | Use standard firefighting procedures and cons | ider the hazards of other involv | ed materials. |
| General fire hazards | No unusual fire or explosion hazards noted. | | |
| 6. Accidental release meas | sures | | |
| Personal precautions, protective equipment and emergency procedures | Keep unnecessary personnel away. Wear app inhalation of dust from the spilled material. Do unless wearing appropriate protective clothing protection, see section 8 of the SDS. | not touch damaged containers | or spilled material |
| Methods and materials for containment and cleaning up | Avoid the generation of dusts during clean-up. suitable container for disposal. Clean surface waste disposal, see section 13 of the SDS. | | |
| Environmental precautions | Avoid discharge into drains, water courses or | onto the ground. | |
| 7. Handling and storage | | | |
| Precautions for safe handling | As a general rule, when handling USP Referent dust, mists, and/or vapors associated with the suitable detergent or solvent after use. After re- thoroughly. Select and use containment device risk assessment of material potency and expo | material. Clean equipment and emoving gloves, wash hands ar es and personal protective equi | work surfaces with d other exposed sk |
| Conditions for safe storage, including any incompatibilities | Store in tight container as defined in the USP- label instructions to ensure product integrity. | NF. This material should be ha | ndled and stored pe |
| 8. Exposure controls/pers | onal protection | | |
| Occupational exposure limits | No exposure limits noted for ingredient(s). | | |
| · · | 2 () | | |

Biological limit values No biological exposure limits noted for the ingredient(s).

| Appropriate engineering controls | No open handling. For laboratory operations, use approved ventilation or containment system (biological safety cabinet, ventilated balance enclosure, glovebox). Control exposures to below the occupational exposure level (if available). Select and use containment devices and personal protective equipment based on a risk assessment of exposure potential. Cover all containers for solutions and slurries while being transferred. |
|-----------------------------------|---|
| Individual protection measures, | such as personal protective equipment |
| Eye/face protection | Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Base the choice of protection on the job activity and potential for contact with eyes or face. An emergency eye wash station should be available. |
| Skin protection | |
| Hand protection | Consider double gloves. Wear nitrile or other impervious gloves if skin contact is possible. When the material is dissolved or suspended in an organic solvent, wear gloves that provide protection against the solvent. |
| Other | Train employees in proper gowning and degowning practices. Wear disposable lab coat, disposable sleeve covers and two pair of gloves as appropriate for the task. Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use. Do not wear protective garments in common areas (e.g., cafeterias) or out-of-doors. |
| Respiratory protection | Use a powered air-purifying respirator (PAPR) with HEPA filters, disposable outerware and head cover for spill cleanup. Choose respiratory protection appropriate to the task and the level of existing engineering controls. |
| Thermal hazards | Wear appropriate thermal protective clothing, when necessary. |
| General hygiene considerations | Pharmacological effects may be seen with occupational exposure. Handling practices in this SDS are recommendations for laboratory use of reference standards. Procedures for any other uses or quantities should be determined after an appropriate assessment. |

9. Physical and chemical properties

| Appearance | Appearance descriptions are general information and not specific to any USP lot. |
|---|--|
| Physical state | Solid. |
| Form | Powder. |
| Color | Off-white. White. |
| Odor | Not available. |
| Odor threshold | Not available. |
| рН | Not available. |
| Melting point/freezing point | 536 °F (280 °C) (decomposes) |
| Initial boiling point and boiling range | Not available. |
| Flash point | Not available. |
| Evaporation rate | Not available. |
| Flammability (solid, gas) | Not available. |
| Upper/lower flammability or exp | losive limits |
| Flammability limit - lower (%) | Not available. |
| Flammability limit - upper (%) | Not available. |
| Explosive limit - lower (%) | Not available. |
| Explosive limit - upper (%) | Not available. |
| Vapor pressure | Not available. |
| Vapor density | Not available. |
| Relative density | Not available. |
| Solubility(ies) | |
| Solubility (water) | Very slightly soluble. |
| Solubility (other) | Dimethylformamide: Sparingly soluble. DMSO: Sparingly soluble. |
| Auto-ignition temperature | Not available. |
| Decomposition temperature | Not available. |
| Viscosity | Not available. |

| Other information | |
|-------------------|--------------------------------|
| Chemical family | Imidazoquinazoline derivative. |
| Molecular formula | C10H7Cl2N3O . HCl . H2O |
| Molecular weight | 310.56 |

10. Stability and reactivity

| Reactivity | The product is stable and non-reactive under normal conditions of use, storage and transport. |
|---------------------------------------|---|
| Chemical stability | Material is stable under normal conditions. |
| Possibility of hazardous reactions | No dangerous reaction known under conditions of normal use. |
| Conditions to avoid | Contact with incompatible materials. |
| Incompatible materials | Strong oxidizing agents. Strong acids. Strong bases. |
| Hazardous decomposition products | Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions. CI NOx. |

11. Toxicological information

Information on likely routes of exposure

| Inhalation | Knowledge about health hazard is incomplete. |
|--|--|
| Skin contact | Knowledge about health hazard is incomplete. |
| Eye contact | Knowledge about health hazard is incomplete. |
| Ingestion | Based on information from therapeutic use, this material may cause: Platelet inhibition. |
| Symptoms related to the physical, chemical, and toxicological characteristics | Phosphodiesterase (PDE) 3 inhibitors: Change in blood pressure, heart rhythm, or heart rate. Headache. Chest pain. Gastrointestinal disturbances. |

Information on toxicological effects

Acute toxicity

| Product | Species | Test Results |
|---|---|--------------|
| Anagrelide Hydrochloride (CAS | 823178-43-4) | |
| Oral | | |
| LD50 | Monkey | > 200 mg/kg |
| | Mouse | > 2500 mg/kg |
| | Rat | > 1500 mg/kg |
| Skin corrosion/irritation | Knowledge about health hazard is incomplete. | |
| Serious eye damage/eye irritation | Knowledge about health hazard is incomplete. | |
| Respiratory or skin sensitizati | on | |
| Respiratory sensitization | Knowledge about health hazard is incomplete. | |
| Skin sensitization | Knowledge about health hazard is incomplete. | |
| Germ cell mutagenicity | Knowledge about mutagenicity is incomplete. | |
| | Knowledge about carcinogenicity is incomplete. year carcinogenicity study, Increased enocarcinomas in females. Benign and ors observed in males. | |
| IARC Monographs. Overal | II Evaluation of Carcinogenicity | |
| Not listed. OSHA Specifically Regula | ted Substances (29 CFR 1910.1001-1052) | |
| Not regulated. | | |
| US. National Toxicology P | Program (NTP) Report on Carcinogens | |
| Not listed. | | |
| Reproductive toxicity | Knowledge about health hazard is incomplete. | |

| effects observed in m implantation disruptio observed in females. Species: Rat < 200 mg/kg/day Ter- fertility or harm to the Species: Rabbit | atogenicity, No evidence of impaired |
|--|---|
| Specific target organ toxicity - single exposure | Knowledge about health hazard is incomplete. |
| Specific target organ toxicity - repeated exposure | May cause damage to organs (blood) through prolonged or repeated exposure. |
| Aspiration hazard | Based on available data, the classification criteria are not met. |
| Further information | Potent pharmacologically active material. Occupational exposure to small amounts may cause physiological effects. |

12. Ecological information

| Ecotoxicity | The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment. |
|-------------------------------|--|
| Persistence and degradability | No data is available on the degradability of this substance. |
| Bioaccumulative potential | No data available. |
| Mobility in soil | No data available. |
| Other adverse effects | No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component. |

13. Disposal considerations

| Disposal instructions | Dispose in accordance with all applicable regulations. Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste. |
|--|--|
| Local disposal regulations | Dispose in accordance with all applicable regulations. |
| Hazardous waste code | The waste code should be assigned in discussion between the user, the producer and the waste disposal company. |
| Waste from residues / unused products | Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions). |
| Contaminated packaging | Since emptied containers may retain product residue, follow label warnings even after container is emptied. |

14. Transport information

DOT

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

| Transport in bulk according to | Not applicable. |
|--------------------------------|-----------------|
| Annex II of MARPOL 73/78 and | |
| the IBC Code | |

the IBC Code General information

It is the shipper's responsibility to determine the correct transport classification at the time of shipment.

15. Regulatory information

| US federal regulations | This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200. |
|------------------------|--|
| | |

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1052)

Not regulated.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous Yes

chemical

Classified hazard Specific target organ toxicity (single or repeated exposure) categories

SARA 313 (TRI reporting)

Not regulated.

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

| Clean Air Act (CAA) Section | 112(r) Accidental Release Prevention (40 CFR 68.130) |
|-----------------------------|--|
| Not regulated. | |
| Safe Drinking Water Act | Not regulated. |
| (SDWA) | |

US state regulations

California Proposition 65

California Safe Drinking Water and Toxic Enforcement Act of 2016 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins. For more information go to www.P65Warnings.ca.gov.

International Inventories

| Country(s) or region | Inventory name On inve | ntory (yes/no)* |
|------------------------------------|---|-----------------|
| Australia | Australian Inventory of Chemical Substances (AICS) | No |
| Canada | Domestic Substances List (DSL) | No |
| Canada | Non-Domestic Substances List (NDSL) | No |
| China | Inventory of Existing Chemical Substances in China (IECSC) | No |
| Europe | European Inventory of Existing Commercial Chemical Substances (EINECS) | No |
| Europe | European List of Notified Chemical Substances (ELINCS) | No |
| Japan | Inventory of Existing and New Chemical Substances (ENCS) | No |
| Korea | Existing Chemicals List (ECL) | No |
| New Zealand | New Zealand Inventory | No |
| Philippines | Philippine Inventory of Chemicals and Chemical Substances (PICCS) | No |
| Taiwan | Taiwan Chemical Substance Inventory (TCSI) | No |
| United States & Puerto Rico | Toxic Substances Control Act (TSCA) Inventory | No |
| *A "Vee" in diseases that all some | | - t () |

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s) A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information, including date of preparation or last revision

| Issue date | 08-31-2011 |
|---------------|------------|
| Revision date | 01-07-2020 |
| Version # | 03 |

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