

SAFETY DATA SHEET

1. Identification

| Product identifier | Bupropion Hydrobromide | |
|--|---|--|
| Other means of identification | | |
| Catalog number | 1078846 | |
| CAS number | 905818-69-1 | |
| Synonyms | 2-(tert-butylamino)-3'-chloro | propiophenone hydrobromide |
| Chemical name | 1-Propanone, 1-(3-chloroph hydrobromide (1:1) | enyl)-2-[(1,1-dimethylethyl)amino]-, |
| Recommended use | Specified quality tests and a | issay use only. |
| Recommended restrictions | Not for use as a drug. Not for | or administration to humans or animals. |
| Manufacturer/Importer/Supplier/I Manufacturer | Distributor information | |
| 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 & Canada | 1-800-424-9300 |
| | CHEMTREC outside US & Canada | +1 703-527-3887 |
| 2. Hazard(s) identification | | |
| Physical hazards | Not classified. | |
| Health hazards | Acute toxicity, oral | Category 4 |
| Environmental hazards | Not classified. | |
| OSHA defined hazards | Not classified. | |
| Label elements | <u>(!)</u> | |
| Signal word | Warning | |
| Hazard statement | Harmful if swallowed. | |
| Precautionary statement | | |
| Prevention | Wash thoroughly after hand | lling. |
| Response | If swallowed: Call a poison of | center/doctor if you feel unwell. Rinse mouth. |
| Storage | Not available. | |
| Disposal | Dispose of contents/contain | er in accordance with local/regional/national/international regulations. |
| Hazard(s) not otherwise classified (HNOC) | None known. | |
| | | |

Supplemental information

Pharmacologically active material. 3. Composition/information on ingredients

Substance

| Chemical name | Common name and synonyms | CAS number | % |
|--|---|--|--|
| Bupropion Hydrobromide | 2-(tert-butylamino)-3'-chloropropiophenon e hydrobromide | 905818-69-1 | 100 |
| 4. First-aid measures | | | |
| Inhalation | If breathing is difficult, remove to fresh air and keep Call a physician if symptoms develop or persist. | p at rest in a position comfo | ortable for breathing. |
| Skin contact | Rinse skin with water/shower. Get medical attentio | n if irritation develops and | persists. |
| Eye contact | Rinse with water. Get medical attention if irritation | develops and persists. | |
| Ingestion | Rinse mouth. Do not induce vomiting without advic keep head low so that stomach content doesn't ge does occur, call a poison control center immediate | t into the lungs. If ingestion | |
| Most important symptoms/effects, acute and delayed | Pharmacologically active material. Occupational ex | xposure may cause physiol | ogical effects. |
| Indication of immediate medical attention and special treatment needed | Provide general supportive measures and treat syn | nptomatically. | |
| General information | Remove from exposure. Remove contaminated clo an occupational health physician or other licensed chemical exposures. In the United States, the natio 1-800-222-1222. If person is not breathing, give ar oxygen if available. Persons developing serious hy receive immediate medical attention. | health-care provider familia onal poison control center p tificial respiration. If breathi | ar with workplace phone number is ing is difficult, give |
| 5. Fire-fighting measures | | | |
| Suitable extinguishing media | Water. Foam. Dry chemical or CO2. Use fire-exting materials. | guishing 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. As a Firefighters should use self-contained breathing ec | | |
| Specific methods | Cool containers exposed to flames with water until | well after the fire is out. | |
| 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 appropr inhalation of dust from the spilled material. Do not unless wearing appropriate protective clothing. En- protection, see section 8 of the SDS. | touch damaged containers | or spilled material |
| Methods and materials for containment and cleaning up | Avoid the generation of dusts during clean-up. Swe suitable container for disposal. Clean surface thoro 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 Reference s dust, mists, and/or vapors associated with the mate suitable detergent or solvent after use. After remove thoroughly. Select and use containment devices and risk assessment of material potency and exposure | erial. Clean equipment and ring gloves, wash hands ar nd personal protective equi | work surfaces with wher exposed skir |
| Conditions for safe storage, including any incompatibilities | Store in tight container as defined in the USP-NF. label instructions to ensure product integrity. | This material should be ha | ndled and stored per |
| 8. Exposure controls/perse | onal protection | | |
| Occupational exposure limits | No exposure limits noted for ingredient(s). | | |
| Dielegieel limit velvee | No biological exposure limits noted for the ingradie | | |

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

| Appropriate engineering controls | For laboratory operations, use local exhaust ventilation or a ventilated enclosure for high energy operations such as particle sizing. 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 | 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 lab coat. 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 | Respirators are generally not required for laboratory operations. Use a tight-fitting full-face respirator with HEPA filters 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 | Handle in accordance with good industrial hygiene and safety practice. 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 | White. Off-white. |
| Odor | Not available. |
| Odor threshold | Not available. |
| рН | Not available. |
| Melting point/freezing point | 441.5 - 450.5 °F (227.5 - 232.5 °C) |
| 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) | Freely soluble. |
| Auto-ignition temperature | Not available. |
| Decomposition temperature | Not available. |
| Viscosity | Not available. |
| Other information | |
| Chemical family | Aminoketone. |
| Molecular formula | C13H18CINO.HBr |
| | |

Molecular weight 320.65

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. |
| Hazardous decomposition products | NOx, HBr, Cl Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions. |

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 | Harmful if swallowed. |
| Symptoms related to the physical, chemical, and toxicological characteristics | Gastrointestinal disturbances. Nausea. Dry mouth. Sore throat. Sweating. Salivation. Skin rash. Headache. Dizziness. Drowsiness. Agitation. Hallucinations. Tremor. Insomnia. Fast heartbeat. Irregular heartbeat. |

Information on toxicological effects

| Acute toxicity | Harmful if swallowed. | |
|--|--|--|
| Product | Species | Test Results |
| Bupropion Hydrobromide (CAS 90 | 05818-69-1) | |
| Oral | | |
| LD50 | Rat | 482 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 sensitizatio | n | |
| Respiratory sensitization | Knowledge about sensitization hazard is incomplete. | |
| Skin sensitization | Knowledge about sensitization hazard is incomplete. | |
| Germ cell mutagenicity | Knowledge about mutagenicity is incomplete. | |
| Mutagenicity Ames test Result: Negative | | |
| Carcinogenicity | Knowledge about carcinogenicity is incomplete. | |
| IARC Monographs. Overall | Evaluation of Carcinogenicity | |
| Not listed. | | |
| | ed Substances (29 CFR 1910.1001-1052) | |
| Not regulated. | ogram (NTP) Report on Carcinogens | |
| Not listed. | ogram (NTP) Report on Carcinogens | |
| Reproductive toxicity | Knowledge about health hazard is incomplete. | |
| Specific target organ toxicity - single exposure | Knowledge about health hazard is incomplete. | |
| Specific target organ toxicity - repeated exposure | Knowledge about health hazard is incomplete. | |
| Aspiration hazard | Based on available data, the classification criteria and | e not met. |
| Further information | Pharmacologically active material. Occupational exp | osure 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 product. |
| 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 of contents/container in accordance with local/regional/national/international 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 | Dispose of in accordance with local regulations. 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 | Empty containers should be taken to an approved waste handling site for recycling or disposal. 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 Annex II of MARPOL 73/78 and the IBC Code | Not applicable. |
|--|---|
| 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
chemicalYesClassified hazard
categoriesAcute toxicity (any route of exposure)

SARA 313 (TRI reporting)

Not regulated.

Other federal regulations

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

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 inventory (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 "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 | 01-07-2013 |
|---------------|---|
| Revision date | 10-09-2019 |
| Version # | 02 |
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