

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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