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Hikal

Jigani, Bangalore


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SOP Ref. No.: ES04011

Reference No.: HJ/SDS/P0033-04

SAFETY DATA SHEET

SECTION I: MATERIAL IDENTIFICATION AND USE	
Material Name	Butorphanol (+)-tartrate salt
Trade Name	No data available
Synonyms	L-N-Cyclobutylmethyl-3,14-dihydroxymorphinan(+)-tartrate salt, Stadol, Torate, Torbutrol
Manufacturer's Name	Hikal Limited
Contact No	+91-080-6177 1100
Address	Jigani, Bengaluru
Postal Code	560 105
Emergency Telephone No	+91-080-6177 1100
Intended Use	Pharmaceutical active

SECTION II: HAZARDS IDENTIFICATION	
Pictogram	
Signal word	Warning
Hazard statement(s)	H302 Harmful if swallowed. H361 Suspected of damaging fertility or the unborn child.
Precautionary statement(s)	P281 Use personal protective equipment as required.

SECTION III: COMPOSITION / INFORMATION ON INGREDIENTS	
Formula	$C_{21}H_{29}NO_2 \cdot C_4H_6O_6$
Molecular weight	477.55 g/mol
CAS Number	58786-99-5
Ingredients	17 (Cyclobutylmethyl) morphinan-3,14-diyl [S(R*,R*)] -2,3-dihydroxysuccinate
Concentration	<= 100 %

SECTION IV: FIRST AID MEASURES	
General advice	Consult a physician. Show this safety data sheet to the doctor in attendance.
If inhaled	If breathed in, move person into fresh air. If not breathing, give artificial respiration. Consult a physician.
In case of skin contact	Wash off with soap and plenty of water. Consult a physician.
In case of eye contact	Flush eyes with water as a precaution.
If swallowed	Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.

SECTION V: FIREFIGHTING MEASURES	
Flammability of the Product	May be combustible at high temperature
Suitable extinguishing media	Use water spray, alcohol-resistant foam, DCP or CO ₂ .
Special hazards arising from the substance or mixture	Carbon oxides, Nitrogen oxides (NO _x)
Advice for fire fighters	Wear self-contained breathing apparatus for firefighting if necessary.
Fire Hazards in Presence of Various Substances	Slightly flammable to flammable in presence of heat. Non-flammable in presence of shocks.
Explosion Hazards in Presence of Various Substances	Slightly explosive in presence of open flames and sparks. Non-explosive in presence of shocks.

SECTION VI: ACCIDENTAL RELEASE MEASURES	
Personal precautions, protective equipment and emergency procedures	Use personal protective equipment. Avoid dust formation. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust.
Environmental precautions	Prevent further leakage or spillage if safe to do so. Do not let product enter drains.
Methods and materials for containment and cleaning up	Pick up and arrange disposal without creating dust. Sweep up and shovel. Keep in suitable, closed containers for disposal.

SECTION VII: HANDLING AND STORAGE	
Precautions for safe handling	Avoid contact with skin and eyes. Avoid formation of dust and aerosols. Provide appropriate exhaust ventilation at places where dust is formed. Normal measures for preventive fire protection.
Conditions for safe storage, including any incompatibilities	Preserve in tight containers. Store at 25°C, excursions permitted between 15°C and 30°C.

SECTION VIII: EXPOSURE CONTROLS / PERSONNEL PROTECTION	
Occupational Exposure Limits	OEL: 8 µg/m ³ (8 Hr – TWA) Occupational Exposure Category: 4 Occupational Exposure Band (OEB Class): Class-D Ref.: Occupational Health Categorization Report from M/s. Vanguard Industrial Hygiene Laboratory, Pune, India, developed in-house.
Appropriate engineering controls	Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.
Eye/face protection	Safety glasses with side-shields. Use equipment for eye protection tested and approved under appropriate government standards.
Skin protection	Handle with gloves. Gloves must be inspected prior to use. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash, dry hands.
Body Protection	Complete suit protecting against chemicals, The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

SECTION VIII: EXPOSURE CONTROLS / PERSONNEL PROTECTION

Respiratory protection	Use respirator cartridges as a backup to engineering controls. Use respirators and components tested and approved under appropriate government standards.
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SECTION IX: PHYSICAL AND CHEMICAL PROPERTIES

Appearance	Form	Crystals solid, Crystalline powder
	Color	White, Off-white
Odour		Odorless to almost odorless
pH		Not available.
Melting point/freezing point		217°C (422.6°F) - 219 °C
Initial boiling point		Not available
Relative density		Not available
Water solubility		Very slightly soluble in cold water.
Other safety information		Not available

SECTION X: STABILITY AND REACTIVITY

Reactivity	No data available
Chemical stability	Stable under recommended storage conditions.
Possibility of hazardous reactions	No data available
Conditions to avoid	Excess heat, dust generation
Incompatible materials	Strong oxidizing agents
Hazardous decomposition products.	Carbon oxides, Nitrogen oxides (NOx)

SECTION XI: TOXICOLOGICAL INFORMATION

Acute toxicity	LD ₅₀ Oral - Rat - 315 mg/kg Remarks: Behavioral: Somnolence (general depressed activity). Behavioral: Convulsions or effect on seizure threshold. Lungs, Thorax, or Respiration: Dyspnea.
Skin corrosion / irritation	No data available
Serious eye damage / eye irritation	No data available
Respiratory or skin sensitization	No data available
Germ cell mutagenicity	No data available
Carcinogenicity	IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.
Reproductive toxicity	Possible risk of congenital malformation in the fetus. Suspected human reproductive toxicant
Additional Information	RTECS: QC7795000 Exposure to and/or consumption of alcohol may increase toxic effects., Nausea, Dizziness, Headache, Drowsiness, To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated

SECTION XII: ECOLOGICAL INFORMATION	
EcoToxicity	No data available
Persistence and degradability	No data available
Bio accumulative potential	No data available
Mobility in soil	No data available
Results of PBT and vPvB assessment	This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

SECTION XIII: DISPOSAL CONSIDERATIONS	
Product	Offer surplus and non-recyclable solutions to a licensed disposal company. Contact a licensed professional waste disposal service to dispose of this material. Dissolve or mix the material with a combustible solvent and burn in a chemical scrubber.
Contaminated packaging	Dispose of as unused product.

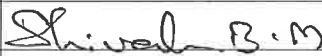

SECTION XIV: TRANSPORT INFORMATION	
UN number	Not dangerous goods
UN proper shipping name	Not dangerous goods
Transport hazard class(es)	Not dangerous goods
Transport hazard class(es) label	Not dangerous goods
Packaging group	Not dangerous goods
Environmental hazards	Do not let product enter drains. Discharge into the environment must be avoided.
Special precautions for user	Transport in accordance with local, state, and federal regulations.

SECTION XV: REGULATORY INFORMATION	
SHE regulations / legislation specific for the substance	No data available
Chemical Safety Assessment	No data available

SECTION XVI: OTHER INFORMATION	
References	In-house data and information from the internet.
Other Special Considerations	No data available

DISCLAIMER:

While this information and recommendations set forth are believed to be accurate as of the date hereof; Hikal Limited, makes no warranty with respect here to and disclaims all liability from reliance thereon.

Prepared By	Signature	Approved By	Signature
Shivakumar B M		Prakash Bhavikatti	
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