

MASTER COPY  
EHS DEPT.


CONTROL COPY  
No: 11

**HIKAL**  
Jigani, Bangalore

Format No.: ES/RPF/SAF/018-02  
SOP Ref. No.: ES04011  
Reference No.: HJ/SDS/P0009-02

SAFETY DATA SHEET

SECTION I: MATERIAL IDENTIFICATION AND USE	
Material Name	Gabapentin
Trade Name	Not available
Synonyms	Neurontin; 1-(Aminomethyl)-cyclohexaneacetic acid;
Chemical Family	Not available
Manufacturer's Name	Hikal Limited
Contact No	+91-080 – 39861100
Address	Bangalore
Postal Code	560 105
Emergency Telephone No	+91-080 – 39861100
Intended Use	Pharmaceutical active

SECTION II: HAZARDOUS IDENTIFICATION	
Pictogram	
Signal word	Danger
Hazard statement(s)	H315: Harmful in contact with skin. H319: Causes serious eye irritation. H335: May cause respiratory irritation. H360: May damage fertility or the unborn child.
Precautionary statement(s)	P201: Obtain special instructions before use. P202: Do not handle until all safety precautions have been read and understood. P261: Avoid breathing {dust/fume/gas/mist/vapors/spray}. P264: Wash {hands} thoroughly after handling. P280: Wear {protective gloves/protective clothing/eye protection /face protection}. P302+352: IF ON SKIN: Wash with plenty of soap and water. P304+340: IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. P305+351+338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P308+313: IF exposed or concerned: Get medical attention/advice. P312: Call a POISON CENTER or doctor/physician if you feel unwell. P332+313: If skin irritation occurs, get medical advice/attention. P337+313: If eye irritation persists, get medical advice/attention. P362+364: Take off contaminated clothing and wash it before reuse.

SECTION III: COMPOSITION/INFORMATION ON INGREDIENTS	
Formula	C <sub>9</sub> H <sub>17</sub> NO <sub>2</sub>
Molecular weight	171.2 g/mol
CAS-No.	60142-96-3

Concentration	<=100%
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**SECTION IV: EMERGENCY / FIRST AID MEASURES**

If inhaled	If breathed in, move person into fresh air and give artificial respiration. Consult a physician.
In case of skin contact	Wash off the contact area with soap and plenty of water. Consult a physician.
In case of eye contact	Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician
If swallowed	Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.

**SECTION V: FIRE FIGHTING MEASURES**

Extinguishing media	Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.
Special hazards arising from the substance	Carbon oxides, nitrogen oxides (NOx)
Advice for fire fighters	Wear self-contained breathing apparatus for firefighting if necessary.

**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 & 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. Avoid exposure - obtain special instructions before use. Provide appropriate exhaust ventilation at places where dust is formed. Normal measures for preventive fire protection
Conditions for safe storage, including any incompatibilities	Store in well closed air tight containers at less than 30°C.

**SECTION VIII: EXPOSURE CONTROL/PERSONNEL PROTECTION**

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	Use safety glasses. 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 and dry hands.
Body Protection	Impervious clothing, The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.
Respiratory protection	Use respirator cartridges as a backup to engineering controls. Use respirators and components tested and approved under appropriate government standards

SECTION IX: PHYSICAL AND CHEMICAL DATA FOR MATERIAL	
Appearance	Form: Crystalline Solid Colour: White / Off-white
Odour	Odourless
pH	No data available
Melting point/freezing point	160-168°C
Initial boiling point and Boiling range	No data available
Flammability (solid, gas)	No data available
Water solubility	Easily soluble in water
Other safety information	No data available

SECTION X: STABILITY AND REACTIVITY DATA	
Reactivity	No data available
Chemical stability	Stable under recommended storage conditions.
Possibility of hazardous reactions	No data available
Conditions to avoid	Excess heat, incompatible materials
Incompatible materials	Strong oxidising agents.
Hazardous decomposition products.	Carbon oxides, Nitrogen oxides (NOx)

SECTION XI: TOXICOLOGICAL PROPERTIES OF MATERIAL	
Acute toxicity	Oral LD (rat): >8 gm/kg; Oral LD (mouse): >8053 mg/kg; Intraperitoneal TDLO (rat): 30 mg/kg; Subcutaneous TDLO (mouse): 30 mg/kg;
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	May cause congenital malformation in the fetus. Presumed human reproductive toxicant
Specific target organ toxicity - single exposure	Inhalation - May cause respiratory irritation.
Additional Information	RTECS: GU6496000

SECTION XII: ECOLOGICAL INFORMATION	
Eco Toxicity	Avoid release into the environment. Runoff from fire control or dilution water may cause pollution.
Persistence and degradability	No data available
Bio accumulative potential	No data available
Mobility in soil	No data available
Results of PBT and vPvB assessment	PBT/vPvB assessment not available as chemical safety assessment not required/not conducted

SECTION XIII: DISPOSAL CONSIDERATION	
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 chem scrubber.
Contaminated packaging	Dispose of as unused product.

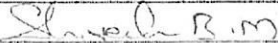
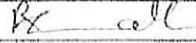
SECTION XIV: TRANSPORT INFORMATION	
UN number	ADR/RID: - Not dangerous goods IMDG: - Not dangerous goods IATA: - Not dangerous goods
UN proper shipping name	ADR/RID: - Not dangerous goods IMDG: - Not dangerous goods IATA: - Not dangerous goods
Transport hazard class (es)	ADR/RID: - Not dangerous goods IMDG: - Not dangerous goods IATA: - Not dangerous goods
Packaging group	ADR/RID: - Not dangerous goods IMDG: - Not dangerous goods IATA: - Not dangerous goods
Environmental hazards	ADR/RID: - No IMDG: - No IATA: - No
Additional Transport Information	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	Not 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
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