



## Safety Data Sheet

**HIKAL**

SECTION I: MATERIAL IDENTIFICATION AND USE	
<b>Material Name</b>	Gabapentin
<b>Trade Name</b>	Not applicable
<b>Compound Number</b>	Not applicable
<b>Synonyms</b>	Neurontin 1-(Aminomethyl)-cyclohexaneacetic acid
<b>Chemical Family</b>	Not determined
<b>Manufacturer's Name</b>	M/s. Hikal ltd
<b>Contact No</b>	+91-080 – 39861100
<b>Address</b>	Bangalore
<b>Postal Code</b>	562 105
<b>Emergency Telephone No</b>	+91-080 – 39861100
<b>Intended Use</b>	Pharmaceutical active

SECTION II: HAZARDOUS IDENTIFICATION	
<b>Classification of the substance or mixture</b>	
<b>Classification according to Regulation (EC) No</b>	1272/2008[EU-GHS/CLP] Skin irritation (Category 2) Eye irritation (Category 2) Reproductive toxicity (Category 1B) Specific target organ toxicity - single exposure (Category 3)
<b>Classification according to EU Directives</b>	67/548/EEC or 1999/45/EC T Toxic R61, R36/37/38
<b>Label elements</b>	Labelling according Regulation (EC) No 1272/2008 [CLP]
<b>Pictogram</b>	
<b>Signal word</b>	Danger
<b>Hazard statement(s)</b>	H315 Causes skin irritation. H319 Causes serious eye irritation. H335 May cause respiratory irritation. H360 May damage fertility or the unborn child.
<b>Precautionary statement(s)</b>	P201 Obtain special instructions before use. P261 Avoid breathing dust/ fume/ gas/ mist/ vapours/ spray. P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P308 + P313 IF exposed or concerned: Get medical advice/ attention.
<b>Supplemental Hazard Statements</b>	None
<b>According to European Directive 67/548/EEC as amended.</b>	none
<b>Hazard symbol(s)</b>	
<b>R-phrase(s)</b>	R61,R36/37/38
<b>S-phrase(s)</b>	Not a hazardous substance
<b>Other hazards</b>	None

SECTION III: HAZARDOUS INGREDIENTS OF MATERIAL			
Ingredients	CAS Number	Formula	%
Neurontin 1-(Aminomethyl)-cyclohexaneacetic acid	60142-96-3	C9H17NO2	100



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SECTION IV: EMERGENCY / FIRST AID MEASURES	
<b>General advice</b>	Consult a physician. Show this safety data sheet to the doctor in attendance.
<b>If inhaled</b>	If breathed in, move person into fresh air and give artificial respiration. Consult a physician.
<b>In case of skin contact</b>	Wash off the contact area with soap and plenty of water.
<b>In case of eye contact</b>	Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician
<b>If swallowed</b>	Never give anything by mouth to an unconscious person. Rinse mouth with water.
<b>Most important symptoms and effects, both acute and delayed</b>	No data available
<b>Indication of any immediate medical attention and special treatment needed</b>	No data available
SECTION V: FIRE FIGHTING MEASURES	
<b>Extinguishing media : Suitable extinguishing media</b>	Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.
<b>Special hazards arising from the substance or mixture</b>	Carbon oxides, nitrogen oxides (NOx)
<b>Advice for fire fighters</b>	Wear self contained breathing apparatus for fire fighting if necessary.
SECTION VI: ACCIDENTAL RELEASE MEASURES	
<b>Personal precautions, protective equipment and emergency procedures</b>	Use personal protective equipment. Avoid dust formation. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust.
<b>Environmental precautions</b>	Prevent further leakage or spillage if safe to do so. Do not let product enter drains.
<b>Methods and materials for containment and cleaning up</b>	Pick up and arrange disposal without creating dust. Sweep up and shovel. Keep in suitable, closed containers for disposal.
<b>Reference to other sections</b>	For disposal see section 13.
SECTION VII: HANDLING AND STORAGE	
<b>Precautions for safe handling</b>	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
<b>Conditions for safe storage, including any incompatibilities</b>	Preserve in well-closed air tight containers at less than 30°C
<b>Specific end uses</b>	No data available
SECTION VIII: EXPOSURE CONTROL/PERSONNEL PROTECTION	
<b>Control parameters</b>	Components with workplace control parameters.
<b>Exposure controls Appropriate engineering controls</b>	General industrial hygiene practice
<b>Personal protective equipment Eye/face protection</b>	Use equipment for eye protection tested and approved under appropriate government standards.
<b>Skin protection</b>	Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique to avoid skin contact with this product.
<b>Body Protection</b>	Choose body protection in relation to its type, to the concentration and to the specific work-place.



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<b>Respiratory protection</b>	Respiratory protection is not required. Where protection from nuisance levels of dusts are desired, use type N95 (US) or type P1 (EN 143) dust masks. Use respirators and components tested and Approved under appropriate government standards such as NIOSH (US) or CEN (EU).
<b>SECTION IX: PHYSICAL AND CHEMICAL DATA FOR MATERIAL</b>	
<b>Information on basic physical and chemical properties</b>	
<b>Appearance</b>	Form: solid Colour: white powder
<b>Odour</b>	Faint organic odour
<b>Odour Threshold</b>	no data available
<b>pH</b>	neutral
<b>Melting point/freezing point</b>	166-167°C
<b>Initial boiling point and Boiling range</b>	no data available 297°C
<b>Flash point</b>	no data available
<b>Evaporation rate</b>	no data available
<b>Flammability (solid, gas)</b>	Minimum ignition energy: 3mJ<ME>10mJ
<b>Upper/lower flammability or Explosive limits</b>	no data available
<b>Vapour pressure</b>	No data available
<b>Vapour density</b>	no data available
<b>Relative density</b>	no data available
<b>Water solubility</b>	>100g/l (20°C)
<b>Partition coefficient: Noctanol/water</b>	No data available
<b>Auto ignition temperature</b>	no data available
<b>Decomposition Temperature</b>	no data available
<b>Viscosity</b>	no data available
<b>Explosive properties</b>	no data available
<b>Oxidizing properties</b>	Non oxidising
<b>Other safety information</b>	no data available
<b>SECTION X: STABILITY AND REACTIVITY DATA</b>	
<b>Reactivity</b>	no data available
<b>Chemical stability</b>	no data available
<b>Possibility of hazardous reactions</b>	no data available
<b>Conditions to avoid</b>	no data available
<b>Incompatible materials</b>	Strong oxidising agents.
<b>Hazardous decomposition products.</b>	Other decomposition products-no data available
<b>SECTION XI: TOXICOLOGICAL PROPERTIES OF MATERIAL</b>	
<b>Information on toxicological effects</b>	
<b>Acute toxicity</b>	no data available
<b>Skin corrosion/irritation</b>	no data available
<b>Serious eye damage/eye irritation</b>	no data available
<b>Respiratory or skin sensitization</b>	May be harmful if absorbed through skin
<b>Germ cell mutagenicity</b>	no data available
<b>Carcinogenicity</b>	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.
<b>Reproductive toxicity</b>	May cause congenital malformation in the fetus. Presumed human reproductive toxicant
<b>Specific target organ toxicity - single exposure</b>	Inhalation - May cause respiratory irritation.
<b>Specific target organ toxicity - repeated exposure</b>	No data available.



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<b>Aspiration hazard</b>	no data available
<b>Potential health effects</b>	May cause respiratory irritation.
<b>Inhalation</b>	
<b>Ingestion</b>	no data available
<b>Skin</b>	no data available
<b>Eyes</b>	no data available
<b>Signs and Symptoms of Exposure</b>	no data available
<b>Additional Information</b>	Chronic toxicity                      Subacute 28-day oral toxicity, rat NOEL=200mg/Kg/Day NOAEL=1000mg/kg/day
<b>SECTION XII: ECOLOGICAL INFORMATION</b>	
<b>Eco Toxicity</b>	No data available
<b>Persistence and degradability</b>	No data available
<b>Bio accumulative potential</b>	no data available
<b>Mobility in soil</b>	no data available
<b>Results of PBT and vPvB assessment</b>	no data available
<b>Other adverse effects</b>	no data available
<b>SECTION XIII: DISPOSAL CONSIDERATION</b>	
<b>Waste treatment methods</b>	
<b>Product</b>	Offer surplus and non-recyclable solutions to a licensed disposal company.
<b>Contaminated packaging</b>	Dispose of as unused product.
<b>SECTION XIV: TRANSPORT INFORMATION</b>	
<b>UN number</b>	ADR/RID: - Not dangerous goods IMDG : - Not dangerous goods IATA : - Not dangerous goods
<b>UN proper shipping name</b>	Not dangerous goods
<b>Transport hazard class (es)</b>	ADR/RID: - Not dangerous goods IMDG : - Not dangerous goods IATA : -Not dangerous goods
<b>Packaging group</b>	ADR/RID: - Not dangerous goods IMDG : -Not dangerous goods IATA : -Not dangerous goods
<b>Environmental hazards</b>	ADR/RID: Not dangerous goods IMDG Marine pollutant: Not dangerous goods IATA: Not dangerous goods
<b>Special precautions for user</b>	No data available
<b>SECTION XV: REGULATORY INFORMATION</b>	
<b>Safety, health and environmental regulations/ legislation specific for the substance or mixture</b>	no data available
<b>Chemical Safety Assessment</b>	no data available
<b>SECTION XVI: OTHER INFORMATION</b>	
<b>References:</b>	Not available.
<b>Other Special Considerations:</b>	Not available

**DISCLAIMER**

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

Prepared by : Head EHS, Jigani  
Revision. 01

Approved by: Corporate head EHS  
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