

## SECTION 1: Identification of the substance/mixture and of the company/undertaking

- **Trade name:** Nicotine dihydrogen ditartrate
- **CAS Number:**  
65-31-6
- **EC number:**  
200-607-2
- **Index number:** 614-002-00-X
- **Registration number** 17-2119382437-31-0000 (pre-registration no.)
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**  
No further relevant information available.
- **Application of the substance / the preparation**
  - Used for laboratory tests and assays.
  - Active ingredient used in antismoking therapy products such as lozenges, aerosols or disintegrable oral films.
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**  
M/s. BGP Healthcare Pvt. Ltd.  
Plot No-3707, GIDC,  
Ankleshwar (Gujarat)  
State: Gujarat,  
INDIA-393002
- **Further information obtainable from:**  
Telephone number: +91-2646-651287/ +91-98250-73320  
Fax number : +91-2646-227375  
e-mail : jbpatel@bgpgroup.biz
- **1.4 Emergency telephone number:**  
Contact details of European importer  
Emergency telephone number:  
Telephone number of EU importer:  
Opening hours:  
Other Comments (e.g. language(s) of the phone service): English

## SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**



GHS06 skull and crossbones

Acute Tox. 2      H300 Fatal if swallowed.  
Acute Tox. 1      H310 Fatal in contact with skin.  
Acute Tox. 2      H330 Fatal if inhaled.



GHS09 environment

Aquatic Chronic 2 H411 Toxic to aquatic life with long lasting effects.

- **Classification according to Directive 67/548/EEC or Directive 1999/45/EC**



T+; Very toxic

R26/27/28: Very toxic by inhalation, in contact with skin and if swallowed.



N; Dangerous for the environment

R51/53: Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

- **Information concerning particular hazards for human and environment:** Not applicable.

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**Trade name: Nicotine dihydrogen ditartrate**

· **2.2 Label elements**

· **Labelling according to Regulation (EC) No 1272/2008**

The substance is classified and labelled according to the CLP regulation.

· **Hazard pictograms**



GHS06 GHS09

· **Signal word** *Danger*

· **Hazard statements**

H300 Fatal if swallowed.

H310 Fatal in contact with skin.

H330 Fatal if inhaled.

H411 Toxic to aquatic life with long lasting effects.

· **Precautionary statements**

P301+P310 **IF SWALLOWED:** Immediately call a POISON CENTER or doctor/physician.

P310 Immediately call a POISON CENTER or doctor/physician.

P320 Specific treatment is urgent (see on this label).

P361 Remove/Take off immediately all contaminated clothing.

P405 Store locked up.

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

· **2.3 Other hazards**

· **Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

### SECTION 3: Composition/information on ingredients

· **3.1 Chemical characterization: Substances**

· **CAS No. Description**

65-31-6 nicotine dihydrogen ditartrate

· **Identification number(s)**

· **EC number:** 200-607-2

· **Additional information:**

Chemical Formula : C10H14N2.2C4H6O6

Molecular weight : 462.2AMU

### SECTION 4: First aid measures

· **4.1 Description of first aid measures**

· **General information:**

Immediately remove any clothing soiled by the product.

Remove breathing equipment only after contaminated clothing have been completely removed.

In case of irregular breathing or respiratory arrest provide artificial respiration.

· **After inhalation:**

Supply fresh air or oxygen; call for doctor.

In case of unconsciousness place patient stably in side position for transportation.

· **After skin contact:** Immediately wash with water and soap and rinse thoroughly.

· **After eye contact:** Rinse opened eye for several minutes under running water. Then consult a doctor.

· **After swallowing:** Do not induce vomiting; call for medical help immediately.

· **4.2 Most important symptoms and effects, both acute and delayed**

Inhalation: Choking, drowsiness, respiratory disorders

Eye contact: Irritation, redness.

Body contact: irritation, itching, redness.

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- Ingestion* : Nausea, abdominal pain
- **Information for doctor:** Treat symptomatically and supportively.
  - **4.3 Indication of any immediate medical attention and special treatment needed**  
No further relevant information available.

### SECTION 5: Firefighting measures

- **5.1 Extinguishing media**
- **Suitable extinguishing agents:**  
CO<sub>2</sub>, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **5.2 Special hazards arising from the substance or mixture** May emit toxic fumes under fire condition.
- **5.3 Advice for firefighters**
- **Protective equipment:**  
Wear self contained breathing apparatus and protective clothing to prevent contact with skin.

### SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures**  
Wear protective equipment. Keep unprotected persons away.  
Ensure adequate ventilation
- **6.2 Environmental precautions:**  
Inform respective authorities in case of seepage into water course or sewage system.
- **6.3 Methods and material for containment and cleaning up:**  
Sweep or scoop up the spilled material into a container for disposal. Close the container tightly. Clean by water.  
Dispose contaminated material as waste according to item 13.
- **6.4 Reference to other sections**  
See Section 7 for information on safe handling.  
See Section 8 for information on personal protection equipment.

### SECTION 7: Handling and storage

- **7.1 Precautions for safe handling**  
Ensure good ventilation/exhaustion at the workplace.  
Open and handle receptacle with care.
- **Information about fire - and explosion protection:** Keep respiratory protective device available.
- **7.2 Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:**  
Store in a cool, dry, well-ventilated area away from incompatible substances.
- **Information about storage in one common storage facility:** Store away from oxidizing agents.
- **Further information about storage conditions:** Keep container tightly sealed.
- **7.3 Specific end use(s)**
  - Used for laboratory tests and assays.
  - Active ingredient used in antismoking therapy products such as lozenges, aerosols or disintegrable oral films.

### SECTION 8: Exposure controls/personal protection

- **Additional information about design of technical facilities:** No further data; see item 7.
- **8.1 Control parameters**
- **Ingredients with limit values that require monitoring at the workplace:** Not required.

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- **8.2 Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**  
*Keep away from foodstuffs, beverages and feed.  
 Immediately remove all soiled and contaminated clothing  
 Wash hands before breaks and at the end of work. Store protective clothing separately.  
 Avoid contact with the eyes and skin.*
- **Respiratory protection:**  
*In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.*
- **Protection of hands:**



Protective gloves

- The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.  
 Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.  
 Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation*
- **Material of gloves**  
*The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer.*
  - **Penetration time of glove material**  
*The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.*
  - **Eye protection:**



Tightly sealed goggles

## SECTION 9: Physical and chemical properties

### · 9.1 Information on basic physical and chemical properties

#### · General Information

##### · Appearance:

**Form:** Crystalline powder

**Colour:** White

· **Odour:** Characteristic

· **Odour threshold:** Not determined.

· **pH-value:** 3-3.4 (10% aq. solution)

##### · Change in condition

**Melting point/Melting range:** 98 °C

**Boiling point/Boiling range:** 751.6 °C (760 mmHg)

· **Flash point:** 408.3 °C

· **Flammability (solid, gaseous):** May be combustible at high temperature

· **Ignition temperature:** 244 °C

· **Self-igniting:** Product is not selfigniting.

· **Danger of explosion:** Product does not present an explosion hazard.

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· <b>Vapour pressure at 25 °C:</b>	9.89 x 10 <sup>-24</sup> mmHg
· <b>Density:</b>	Not determined.
· <b>Solubility in / Miscibility with water:</b>	Soluble.
· <b>Partition coefficient (n-octanol/water):</b>	Not determined.
· <b>9.2 Other information</b>	No further relevant information available.

### SECTION 10: Stability and reactivity

- **10.1 Reactivity**
- **10.2 Chemical stability**
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **10.3 Possibility of hazardous reactions**  
Reacts instantaneously with strong oxidizing agents, heat and humidity
- **10.4 Conditions to avoid** Avoid contact with air, humidity, light, heat, and ignition
- **10.5 Incompatible materials:** Avoid contact with strong oxidizing agents.
- **10.6 Hazardous decomposition products:** May produce oxides of carbon and nitrogen.

### SECTION 11: Toxicological information

- **11.1 Information on toxicological effects**
- **Acute toxicity:**

- **LD/LC50 values relevant for classification:**

Oral	LD50	65 mg/kg (rat)
Dermal	LD50	50 mg/kg (nicotine) (rabbit)

- **Primary irritant effect:**
- **on the skin:** No irritant effect.
- **on the eye:** No irritating effect.
- **Sensitization:** No sensitizing effects known.
- **Subacute to chronic toxicity:**

**EFFECTS OF SHORT-TERM EXPOSURE:**

The substance irritates the eyes and the skin. The substance may cause effects on the central nervous system, resulting in convulsions and respiratory failure. Exposure at high concentrations may result in death. The effects may be delayed.

**EFFECTS OF LONG-TERM OR REPEATED EXPOSURE:**

Absorption into the body leads to the formation of methemoglobin which in sufficient concentration causes cyanosis. Onset may be delayed 2 to 4 hours or longer. Animal tests show that this substance possibly causes toxic effects upon human reproduction

- **Additional toxicological information:** Danger through skin adsorption.

### SECTION 12: Ecological information

- **12.1 Toxicity**

- **Aquatic toxicity:**

EC50 (48h)	0.24 mg/l (Daphnia magna)
LC50 (96h)	4 mg/l (Fish)

- **12.2 Persistence and degradability**

**Products of Biodegradation:**

Possibly hazardous short term degradation products are not likely. However, long term degradation products may arise.

**Toxicity of the Products of Biodegradation:**

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- The products of degradation are less toxic than the product itself*
- **12.3 Bioaccumulative potential** Log Pow: 1.17. (Risk of redistribution into fats is low)
- **12.4 Mobility in soil** No further relevant information available.
- **Ecotoxicological effects:**
- **Remark:** Toxic for fish
- **Additional ecological information:**
- **General notes:**  
Also poisonous for fish and plankton in water bodies.  
Toxic for aquatic organisms
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Other adverse effects** No further relevant information available.

### SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**
- **Recommendation**  
Dissolve or mix the material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber.
- **Uncleaned packaging:**
- **Recommendation:**  
Dispose of as unused product.  
Disposal must be made according to official regulations.

### SECTION 14: Transport information

· <b>14.1 UN-Number</b> · <b>ADR, IMDG, IATA</b>	UN1659
· <b>14.2 UN proper shipping name</b> · <b>ADR</b> · <b>IMDG</b> · <b>IATA</b>	1659 NICOTINE TARTRATE, ENVIRONMENTALLY HAZARDOUS NICOTINE TARTRATE, MARINE POLLUTANT NICOTINE TARTRATE
· <b>14.3 Transport hazard class(es)</b> · <b>ADR, IMDG</b>	
	
· <b>Class</b> · <b>Label</b>	6.1 Toxic substances. 6.1
· <b>IATA</b>	
	
· <b>Class</b> · <b>Label</b>	6.1 Toxic substances. 6.1
· <b>14.4 Packing group</b> · <b>ADR, IMDG, IATA</b>	II

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· <b>14.5 Environmental hazards:</b>	
· <b>Marine pollutant:</b>	Yes (P) Symbol (fish and tree)
· <b>Special marking (ADR):</b>	Symbol (fish and tree)
· <b>14.6 Special precautions for user</b>	Warning: Toxic substances.
· <b>Danger code (Kemler):</b>	66
· <b>EMS Number:</b>	F-A,S-A
· <b>14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</b>	Not applicable.
· <b>Transport/Additional information:</b>	
· <b>ADR</b>	
· <b>Limited quantities (LQ)</b>	500 g
· <b>Transport category</b>	1
· <b>Tunnel restriction code</b>	C/E
· <b>UN "Model Regulation":</b>	UN1659, NICOTINE TARTRATE, ENVIRONMENTALLY HAZARDOUS, 6.1, II

### SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Labelling according to Regulation (EC) No 1272/2008**
- **Hazard pictograms** Please refer section 2
- **Signal word** Danger
- **Hazard statements** Please refer section 2
- **Precautionary statements** Please refer section 2
- **15.2 Chemical safety assessment:**  
A Chemical Safety Assessment has not been carried out and shall be available at the time of REACH registration.

### SECTION 16: Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

- **Department issuing MSDS:** Product safety department.
- **Contact:**  
Telephone number: +91-2646-651287/ +91-98250-73320  
Fax number: +91-2646-227375  
e-mail: jbpatel@bgpgroup.biz
- **Abbreviations and acronyms:**  
ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)  
IMDG: International Maritime Code for Dangerous Goods  
IATA: International Air Transport Association  
P: Marine Pollutant  
GHS: Globally Harmonized System of Classification and Labelling of Chemicals  
EINECS: European Inventory of Existing Commercial Chemical Substances  
CAS: Chemical Abstracts Service (division of the American Chemical Society)
- **Sources**
  - REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006
  - SDS of European Directorate for quality of Medicines and Healthcare, France (<http://crs.edqm.eu/db/4DCGI/db/4DCGI/MSDS?MSDS=Y0001023>)
  - MSDS of Fisher Scientific, NJ.

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*(<https://fscimage.fishersci.com/msds/91396.htm>)*

• *MSDS of Nicobrand, Ireland ([http://www.nicobrand.com/files/Nicotine\\_Bitartrate\\_Dihydrate\\_Data\\_Sheet.pdf](http://www.nicobrand.com/files/Nicotine_Bitartrate_Dihydrate_Data_Sheet.pdf))*

• *SDS of International Safety Cards*

*(<http://actrav.itcilo.org/actrav-english/telearn/osh/ic/65316.htm>)*

• *SDS of Nicobrand Ltd. ([http://www.nicobrand.com/files/Nicotine\\_Bitartrate\\_Dihydrate\\_MSDS.pdf](http://www.nicobrand.com/files/Nicotine_Bitartrate_Dihydrate_MSDS.pdf))*

• *MSDS of Sciencelab.com, Inc. (<http://sciencelab.com/msds.php?msdsId=9926223>)*

• *Chemspider database (<http://www.chemspider.com/Chemical-Structure.4642648.html>)*

• ***\* Data compared to the previous version altered.***

• *Section 2 : Hazard Identification – Changes in classification and Labelling*

• *Section 4 : First-aid measures*

• *Section 5 : Fire-fighting measures*

• *Section 6 : Accidental Release Measures*

• *Section 7 : Handling and Storage*

• *Section 8 : Exposure Controls / Personal Protection*

• *Section 9 : Physical and Chemical Properties*

• *Section 10 : Stability and Reactivity*

• *Section 11 : Toxicological Information*

• *Section 12 : Ecological Information*

• *Section 13 : Disposal Considerations*