

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

- **Trade name:** Nicotine Polacrilex USP/Nicotine Resinate EP (Contains 20% Nicotine)
- **CAS Number:**
96055-45-7
- **Registration number** 17-2119382435-35-0000 (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**
Active ingredient used in antismoking therapy related products.
- **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 / 98250-73320
Fax number: 91-2646-227375
e-mail : jbpatel@bgpgroup.biz
- **1.4 Emergency telephone number:**
Emergency telephone number: 91-2646-651287 / 98250-73320
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. 3 H301 Toxic if swallowed.
Acute Tox. 1 H310 Fatal in contact with skin.



GHS09 environment

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



GHS07

Eye Irrit. 2 H319 Causes serious eye irritation.

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



T+; Very toxic

R27: Very toxic in contact with skin.



T; Toxic

R25: Toxic if swallowed.



Xi; Irritant

R36: Irritating to eyes.



N; Dangerous for the environment

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

(Contd. on page 2)

Trade name: Nicotine Polacrilex

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

· **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**

H301 Toxic if swallowed.

H310 Fatal in contact with skin.

H319 Causes serious eye irritation.

H411 Toxic to aquatic life with long lasting effects.

· **Precautionary statements**

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

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P310 Immediately call a POISON CENTER or doctor/physician.

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**

96055-45-7 Nicotine Polacrilex

· **Identification number(s) -**

· **Additional information:**

Chemical Formula: (C₁₀H₁₄N₂)_x (C₁₀H₁₀C₄H₆O₂)_y

Molecular weight: not applicable

% concentration: 80% polacrilex resin and 20% nicotine

SECTION 4: First aid measures

· **4.1 Description of first aid measures**

· **General information:** *Seek immediate medical attention.*

· **After inhalation:** *Seek immediate medical attention. Remove patient to fresh air. Keep warm and at rest.*

· **After skin contact:** *Seek immediate medical attention. Remove contaminated clothing.*

· **After eye contact:**

Immediately wash with plenty of water for atleast for 15mins. Flush eyes thoroughly whilst lifting eyelids.

· **After swallowing:**

Seek immediate medical attention. Do not induce vomiting. Rinse mouth with water (do not swallow).

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

(Contd. on page 3)

Trade name: Nicotine Polacrilex

Skin contact- irritation, redness

Eye contact- watery eyes, disturbed vision.

Inhalation- dizziness

Ingestion- nausea, vomiting, increased salivation, diarrhea, and abdominal pain.

· 4.3 Indication of any immediate medical attention and special treatment needed

Notes for the doctor: In particular the respiratory system and cardiovascular system. Ventilation & inotropic support may be necessary in the short term until the nicotine is absorbed.

SECTION 5: Firefighting measures

· 5.1 Extinguishing media

· Suitable extinguishing agents:

Carbon dioxide, dry chemical and water spray should be used to extinguish fire.

· 5.2 Special hazards arising from the substance or mixture *May evolve toxic fumes in fire.*

· 5.3 Advice for firefighters

· Protective equipment:

Wear self-contained breathing apparatus (pressure- demand Equipment MSHA / NIOSH approved or equivalent) and full protective gear.

SECTION 6: Accidental release measures

· 6.1 Personal precautions, protective equipment and emergency procedures

Ensure adequate ventilation

Avoid formation of dust.

Wear proper protective clothing. Avoid contact with eyes and skin.

Use water spray to reduce fire.

· 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.

See Section 13 for disposal information.

SECTION 7: Handling and storage

· 7.1 Precautions for safe handling *Avoid contact with skin and eyes. Wear proper protective equipment.*

· Information about fire - and explosion protection: *Keep ignition sources away - Do not smoke.*

· 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) *Active ingredient used in antismoking therapy related products.*

SECTION 8: Exposure controls/personal protection

· Additional information about design of technical facilities: *No further data; see item 7.*

(Contd. on page 4)

Trade name: Nicotine Polacrilex

- **8.1 Control parameters**
- **Ingredients with limit values that require monitoring at the workplace:** Not required.
- **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:** Suitable respiratory protective device recommended.
- **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

- **Body protection:** Wear apron or other light protective clothing.

SECTION 9: Physical and chemical properties

· 9.1 Information on basic physical and chemical properties

· General Information

· Appearance:

Form:	Powder
Colour:	fine white to off-white
Odour:	Characteristic

· **pH-value:** Not determined.

· Change in condition

Melting point/Melting range:	Undetermined.
Boiling point/Boiling range:	Undetermined.

· **Flash point:** Not applicable.

· **Flammability (solid, gaseous):** Not applicable.

· **Danger of explosion:** Product does not present an explosion hazard.
 Dusts at sufficient concentrations can form explosive mixtures with air

(Contd. on page 5)

Trade name: Nicotine Polacrilex

- | | |
|---|--|
| · Density:
Relative density at 20 °C | 1.0-1.3 g/cm ³ |
| · Solubility in / Miscibility with water: | Practically insoluble |
| · 9.2 Other information | No further relevant information available. |

SECTION 10: Stability and reactivity

- **10.1 Reactivity**
- **10.2 Chemical stability** Stable under normal storage conditions
- **10.3 Possibility of hazardous reactions**
Exposure to strong oxidising agents leads to decomposition and the release of Nicotine.
Reacts with alkalis and other cations to release Nicotine.
- **10.4 Conditions to avoid** Extreme heat
- **10.5 Incompatible materials:** Alkalis and oxidizing substances.
- **10.6 Hazardous decomposition products:** When decomposed nicotine is released.

SECTION 11: Toxicological information

- **11.1 Information on toxicological effects**
- **Acute toxicity:**
- **Primary irritant effect:**
- **on the skin:** No irritant effect.
- **on the eye:** Irritating effect.
- **Sensitization:** No sensitizing effects known.
- **Additional toxicological information:**
Danger through skin adsorption.
Early symptoms of overdose may include nausea, vomiting, increased salivation, watery eyes, abdominal pain, diarrhoea, headache, high blood pressure, dizziness, disturbed hearing and vision, confusion and weakness.
Late symptoms of overdose include fainting, drop in blood pressure, difficult breathing, weak, rapid or irregular pulse, lethargy, convulsion and coma. Death may occur from paralysis of respiratory muscles

SECTION 12: Ecological information

- **12.1 Toxicity**
- **Aquatic toxicity:** Quantitative data on the ecological effect of this product are not available.
- **12.2 Persistence and degradability**
Under certain conditions free base Nicotine can be liberated from this product and the following environmental effects of nicotine are known.
It is readily biodegradable in the presence of air or contact with soil.
- **12.3 Bioaccumulative potential** No further relevant information available.
- **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** To be provided after the REACH registration.
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

(Contd. on page 6)

Trade name: Nicotine Polacrilex

· 12.6 Other adverse effects No further relevant information available.

SECTION 13: Disposal considerations

· 13.1 Waste treatment methods

· Recommendation

Material can be burned in a licensed incinerator under regulated conditions. Material can be treated with alkali to release free base Nicotine for recovery. The inert resin can then be disposed of at an approved land-fill site

Do not allow to enter public sewers and watercourses. If contamination of drainage system or water courses is unavoidable, immediately inform appropriate authorities.

· Uncleaned packaging:

· Recommendation: Disposal must be made according to official regulations.

SECTION 14: Transport information

· 14.1 UN-Number

· ADR, IMDG, IATA UN1655

· 14.2 UN proper shipping name

· ADR 1655 NICOTINE COMPOUND, SOLID, N.O.S. (Nicotine Polacrilex), ENVIRONMENTALLY HAZARDOUS
 · IMDG NICOTINE COMPOUND, SOLID, N.O.S. (Nicotine Polacrilex), MARINE POLLUTANT
 · IATA NICOTINE COMPOUND, SOLID, N.O.S. (Nicotine Polacrilex)

· 14.3 Transport hazard class(es)

· ADR, IMDG



· Class 6.1 Toxic substances.
 · Label 6.1

· IATA



· Class 6.1 Toxic substances.
 · Label 6.1

· 14.4 Packing group

· ADR, IMDG, IATA III

· 14.5 Environmental hazards:

· Marine pollutant: Yes (P)
 Symbol (fish and tree)
 · Special marking (ADR): Symbol (fish and tree)

· 14.6 Special precautions for user

Warning: Toxic substances.
 · Danger code (Kemler): 66
 · EMS Number: F-A,S-A

(Contd. on page 7)

Trade name: Nicotine Polacrilex

· 14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	<i>Not applicable.</i>
· Transport/Additional information:	
· ADR	
· Limited quantities (LQ)	5 kg
· Transport category	1
· Tunnel restriction code	C/E
· UN "Model Regulation":	UN1655, NICOTINE COMPOUND, SOLID, N.O.S. (Nicotine Polacrilex), ENVIRONMENTALLY HAZARDOUS, 6.1, III

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
- **National regulations:**
- **Other regulations, limitations and prohibitive regulations**
- **Substances of very high concern (SVHC) according to REACH, Article 57**
The substance is not listed as SVHC.
- **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 / 98250-73320
Fax number: 91-2646-227375
e-mail: jbpatel@bgpgroup.biz
- **Abbreviations and acronyms:**
RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)
ICAO: International Civil Aviation Organization
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
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
- *** Data compared to the previous version altered.**
Section 2: Hazard Identification
Section 3: composition/information of ingredients
Section 4: First-aid measures.

(Contd. on page 8)

Trade name: Nicotine Polacrilex

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 consideration.

Section 14: Transport Information

Section 15: Regulatory Information.