

MATERIAL SAFETY DATA SHEET

BGP HEALTHCARE PRIVATE LIMITED., ANKLESHWAR



Material Safety Data Sheet (MSDS) as per the requirements of the REACH regulation (EC) No 1907/2006

SDS No: 06

Revision date: 19.08.2010

Date of issue of the SDS: 10.09.2010

Sr. No.	Title of the section	Information required in this section
1.	Identification of the substance /preparation & of the company/ undertaking	
1.1	Identification of the substance or preparation	1.1.1 Substance name: Nicotine Polacrilex 1.1.2 EC No.: Not listed 1.1.3 REACH Registration No.: 17-2119382435-35-0000 (pre-registration no.) 1.1.4 CAS No.: 96055-45-7 1.1.5 Index No. : Not classified
1.2	Use of the substance/ preparation	1.2.1 Relevant identified uses: Active ingredient used in anti-smoking therapy related products.
1.3	Company/ under - taking identification	Contact Person : Mr. Jayesh Patel Manufacturing site address: M/s. BGP Healthcare Pvt. Ltd. Plot No-3707, GIDC, Ankleshwar (Gujarat) State: Gujarat, INDIA-393002. Telephone number: +91-2646-651287 / +91-98250-73320 Fax number : +91-2646-227375 e-mail : jbpatel@bgpgroup.biz
1.4	Emergency telephone	Emergency telephone number : +91-9825073320 Other comments (e.g. language(s) of the phone service): English
2.	Hazard Identification	<u>2.1 Classification of the substance</u> 2.1.1 Classification according to Regulation (EC) No 1272/2008 [CLP/GHS] <ul style="list-style-type: none"> • Acute Tox. 1 Dermal • Acute Tox. 3 * Oral • Aquatic Chronic 2 • Eye Irritation cat. 2 2.1.2. Classification according to Directive 67/548/EEC <ul style="list-style-type: none"> • Xi, R25-27-51/53 • S1/2-36/37-45-61

		<p><u>2.2: Label elements : Labelling according to Regulation (EC) No 1272/2008 [CLP/GHS]</u></p> <p>2.2.1 Hazard pictograms</p> <div style="display: flex; justify-content: space-around; align-items: center;"> <div style="text-align: center;">  <p>GHS06</p> </div> <div style="text-align: center;">  <p>GHS09</p> </div> </div> <p>2.2.2 Signal word – Danger</p> <p>2.2.3 Hazard statements</p> <ul style="list-style-type: none"> • H310: Fatal in contact with skin • H301: Toxic if swallowed • H411: Toxic to aquatic life with long lasting effects • H319: Causes serious eye irritation <p>2.2.4 Precautionary statements</p> <ul style="list-style-type: none"> • P273- Avoid release to the environment. • P301 + P310- IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician. • P302 + P350- IF ON SKIN: Gently wash with plenty of soap and water. • P305 + P351 + P338- IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. • P280- Wear protective gloves/protective clothing/eye protection/ face protection. • P501- Dispose of contents/container in accordance with local/regional/ national/international regulation (to be specified by the company) <p>Additional information (Only 6 statements need to appear on the label)</p> <ul style="list-style-type: none"> • P262- Do not get in eyes, on skin, or on clothing. • P264- Wash ... thoroughly after handling. (Manufacturer/supplier to specify parts of the body to be washed after handling.) • P270- Do not eat, drink or smoke when using this product. • P310- Immediately call a POISON CENTER or doctor/physician. • P322- Specific measures (see ... on this label). (... Reference to supplemental first aid instruction. — if immediate measures such as specific cleansing agent is advised.) • P361- Remove/Take off immediately all contaminated clothing. • P363- Wash contaminated clothing before reuse. • P405- Store locked up. • P321- Specific treatment (see ... on this label). (... Reference to supplemental first aid instruction. — if immediate administration of antidote is required.) • P330- Rinse mouth. • P391- Collect spillage. • P337 + P313- If eye irritation persists: Get medical advice/attention.
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3.	Composition /Information on Ingredients	
3.1	Composition	Chemical Formula : (C ₁₀ H ₁₄ N ₂) x (C ₁₀ H ₁₀ C ₄ H ₆ O ₂) y Molecular weight : not applicable Chemical name : Nicotine Polacrilex CAS no. : 96055-45-7 EC. No. : Not listed % concentration : 61 % polacrilex resin, 24 % Glycerol and 15 % nicotine
3.2	Classification as per the DSD directive	Classification : Xi, R25-27-51/53 S1/2-36/37-45-61 Symbol Letter : Xi R phrase : R25; R27; R51/53
3.3		Name of the substance : Nicotine Polacrilex Registration number as in DSD directive: Not available
4.	First Aid Measures	
4.1	Description of first measures	<ul style="list-style-type: none"> - General notes: Seek immediate medical attention. - Inhalation: Remove patient to fresh air. Keep warm and at rest. - Skin contact: Remove contaminated clothing - Eye contact: Immediately wash with plenty of water for at least for 15mins. Flush eyes thoroughly whilst lifting eyelids. - Ingestion: Do not induce vomiting. Rinse mouth with water (do not swallow).
4.2	Important symptoms & effects	Skin contact- irritation, redness Eye contact- watery eyes, disturbed vision. Inhalation- dizziness Ingestion- nausea, vomiting, increased salivation, diarrhea, and abdominal pain.
4.3	Immediate medical attention	Notes for the doctor: Treatment should be symptomatic and supportive, in particular the respiratory system and cardiovascular system. Ventilation & inotropic support may be necessary in the short term until the nicotine is absorbed.
5.	Fire Fighting Measures	
5.1	suitable extinguishing media	Carbon dioxide, dry chemical and water spray should be used to extinguish fire.
	unsuitable extinguishing media	Extinguishing media should not contain oxidizing substances
5.2	Special hazard arising from the substance	May evolve toxic fumes in fire.

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5.3	Advice for firefighters	Wear self contained breathing apparatus (pressure- demand Equipment MSHA / NIOSH approved or equivalent) and full protective gear.
6. Accidental Release Measures		
6.1	Personal precautions, protective equipment and emergency procedures	<p>For non-emergency personnel</p> <ul style="list-style-type: none"> ➤ <u>Protective equipment:</u> Wear proper protective clothing. Avoid contact with eyes and skin. ➤ <u>Emergency procedures:</u> Use water spray to reduce fire ➤ <u>Removal of ignition sources:</u> Switch off electrical equipment and any other sources of ignition. ➤ <u>provision of sufficient ventilation:</u> Use adequate ventilation ➤ <u>Control of dust:</u> Avoid inhaling and raising dust.
6.2	Environmental precautions	Avoid runoff into storm sewers
6.3	Methods and material for containment and cleaning up	<p><u>6.3.1 Containment technique:</u></p> <p>(a) Bunding, covering of drains: The drains should be properly covered to avoid the entry of the spills into the sewers.</p> <p>(b) Capping procedures: Keep the containers tightly capped.</p> <p><u>6.3.2 Cleaning up:</u></p> <p>(a) Cleaning techniques: sweep or showel-up spillage and remove to safe place.</p> <p>(b) equipment required for containment/clean-up: use water spray, shovel to clean</p>
6.4	Reference to other section	Refer to section 8 and 13 for further information about personal protection equipment and disposal considerations.
7. Handling and Storage		
7.1.	Precautions for safe handling	<p><u>7.1.1. Recommendations shall be specified to:</u></p> <p>(a) Allow safe handling of the substance: Avoid contact with skin and eyes. Wear proper protective equipment.</p> <p>(b) Prevent handling of incompatible substances: Keep away from alkalis, oxidisable substances.</p> <p>(c) Reduce the release of the substance to the environment: Do not allow to enter public sewers and watercourses.</p> <p><u>7.1.2. Advice on general occupational hygiene shall be provided:</u></p> <ul style="list-style-type: none"> • Do not breathe dust. • When using the product do not eat, drink or smoke. • Wash hands thoroughly after using this substance.

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7.2	Conditions for safe storage, including any incompatibilities	<p>(a) How to manage risks associated with:</p> <p><u>(i) incompatible substances or mixtures:</u> Avoid contact with alkalis and oxidisable substances</p> <p><u>(ii) potential ignition sources:</u> Keep away from ignition sources</p> <p><u>(iii) Evaporative conditions:</u> Always keep the working place properly ventilated.</p> <p><u>(iv) Explosive atmospheres:</u> Avoid formation and accumulation of dusts as it can form explosive mixtures with air</p> <p>(b) How to control the effects of:</p> <p><u>(i) Weather conditions:</u> Keep in cool, dry place.</p> <p><u>(ii) Temperature:</u> Keep the surrounding cool where the substance is stored.</p> <p><u>(iii) Sunlight:</u> Keep protected from heat or sunlight.</p> <p><u>(iv) Humidity:</u> Keep away from moisture, air and humid environment.</p> <p>(c) How to maintain the integrity of the substance or mixture by the use of:</p> <p><u>(i) stabilisers:</u> not available</p> <p><u>(ii) antioxidants:</u> not available</p> <p>(d) Other advice including:</p> <p>(i) Ventilation requirements: provide proper ventilation.</p> <p>(ii) specific designs for storage rooms or vessels: Use local or exhaust ventilation to keep dust formation low</p> <p>(iii) quantity limits under storage conditions: Not relevant</p> <p>(iv) Packaging compatibilities: Store in tightly closed containers</p>
7.3	Specific uses	Industrial sector specific solutions: Active ingredient used in antismoking therapy related products.
8.	Exposure Controls / Personal Protection	
8.1.	Control parameters	Exposure limit values are to be provided as per the member states
8.2.	Exposure controls	<p>Exposure scenario: The Chemical Safety Report of this substance will be available after Registration.</p> <p>Substance registered as an isolated intermediate (on-site or transported): This substance qualifies as transported isolated intermediate.</p>
8.2.1.	Appropriate engineering controls	Engineering control should be provided which maintain airborne concentration as low as practicable.
8.2.2.	Individual protection measures	<p>(a) Eye / face protection: wear goggles giving complete eye protection.</p> <p>(b) Skin protection:</p> <p><u>(i) Hand protection:</u> wear plastic or rubber gloves.</p> <p><u>(ii) Other:</u> wear boots, apron or other light protective clothing.</p> <p>(c) Respiratory protection: wear suitable respiratory protection.</p>
8.2.3.	Environmental exposure controls	<p>Commitments under Community environmental protection legislation:</p> <p>The Chemical Safety Report of this substance will be available after Registration.</p>

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9.	Physical & Chemical Properties	
9.1.	Information on basic physical and chemical properties	<p>(a) Appearance: fine white to off-white powder</p> <p>(b) Odour: not available</p> <p>(c) Odour threshold: not available</p> <p>(d) pH: not available</p> <p>(e) Melting point/freezing point: not available</p> <p>(f) Initial boiling point and boiling range: not applicable</p> <p>(g) Flash point: not available</p> <p>(h) Evaporation rate: not available</p> <p>(i) Flammability (solid, gas): not available</p> <p>(j) Upper/lower flammability or explosive limits: not available</p> <p>(k) Vapour pressure : not available</p> <p>(l) Vapour density : not available</p> <p>(m) Relative density:1.0-1.3</p> <p>(n) Solubility(ies): practically insoluble</p> <p>(o) Partition coefficient: n-octanol/water: not available</p> <p>(p) Auto-ignition temperature: not available</p> <p>(q) Decomposition temperature: not available</p> <p>(r) Viscosity: not available</p> <p>(s) Explosive properties: Dusts at sufficient concentrations can form explosive mixtures with air</p> <p>(t) Oxidizing properties: not available</p>
10.	Stability and Reactivity	<p>10.1 Reactivity: Reacts with alkalis and other cations to release Nicotine.</p> <p>10.2 Chemical stability: Stable under recommended conditions of use.</p> <p>10.3 Possibility of hazardous reactions: Exposure to strong oxidizing agents leads to decomposition and the release of Nicotine.</p> <p>10.4 Conditions to avoid: Excessive heat.</p> <p>10.5 Incompatible materials: Alkalis and oxidizing substances.</p> <p>10.6 Hazardous decomposition products: When decomposed nicotine is released.</p>
11.	Toxico-logical Information	
11.1	Information on toxicological effects	<p><u>11.1.1. Substances</u></p> <p>(a) Acute toxicity: Acute Tox. 1 Dermal Acute Tox. 3 * Oral</p> <p>(b) skin corrosion/irritation: not determined</p> <p>(c) Serious eye damage/irritation: Eye Irritation cat. 2</p> <p>(d) respiratory or skin sensitisation: not determined</p> <p>(e) germ cell mutagenicity: not determined</p>

		<p>(f) carcinogenicity: No evidence of carcinogenic properties (g) reproductive toxicity: not determined (h) STOT-single exposure: not determined (i) STOT-repeated exposure: not determined (j) aspiration hazard : not determined</p> <p><u>11.1.2. Relevant toxicological properties:</u> Not available</p> <p><u>11.1.3. Summarise results of the critical studies:</u> Not relevant</p> <p><u>11.1.4. Classification criteria for a particular hazard class not met :</u> Not relevant</p> <p><u>11.1.5. Information on likely routes of exposure</u></p> <p>Skin contact- may cause irritation Eye contact- Irritating to eyes Inhalation: Can cause damage to the mucous membranes, causes dizziness Ingestion: Toxic if swallowed, may cause nausea/vomiting. May cause diarrhoea</p> <p><u>11.1.6. Symptoms related to the physical, chemical and toxicological characteristics</u></p> <ul style="list-style-type: none"> • It may cause dizziness along with damage to mucous membrane. • Diarrhoea can result due to ingestion. • Over dose can lead to watery eyes, abdominal pain, headache, high blood pressure, disturbed hearing and vision, <p><u>11.1.7. Delayed and immediate effects as well as chronic effects from short and long-term exposure</u></p> <p>Effects of short term exposure: It may cause irritation to eyes and skin. Damage to mucous membrane can also occur. Ingestion can lead to nausea and vomiting.</p> <p>Effects of long term exposure:</p> <ul style="list-style-type: none"> • 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 <p><u>11.1.8 Interactive effects</u> Not relevant</p>
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		<p><u>11.1.9 Absence of specific data</u></p> <p>(a) Acute toxicity: This data will be available after registration if provided by the Lead registrant.</p> <p>(b) Serious eye damage/irritation: This data will be available after registration if provided by the Lead registrant.</p>
12.	Ecological Information	
12.1.	Toxicity	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	not available
12.4.	Mobility in soil	not available
12.5.	Results of PBT and vPvB assessment	TO BE PROVIDED IN THE REGISTRATION DOSSIER
13.	Disposal Considerations	
13.1	Waste treatment methods	<p>(a) Waste treatment containers and methods: 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.</p> <p>(b) Physical/chemical properties: Exposure to strong oxidizing agents leads to decomposition and the release of Nicotine.</p> <p>(c) Sewage disposal: Do not allow to enter public sewers and watercourses. If Contamination of drainage system or water courses is unavoidable, immediately inform appropriate authorities</p>
13.2	Additional information:	If contamination of drainage system or water courses is unavoidable, immediately inform appropriate authorities
14.	Transport Information (Information includes RID, ADR, AND, ICAO, IMDG, IATA-DGR)	<p>14.1. UN number : 1655</p> <p>14.2. UN proper shipping name: Nicotine Preparation, Solid, N.O.S.</p> <p>14.3. Transport hazard class(es): 6.1</p> <p>14.4. Packing group : III</p> <p>14.5. Environmental hazards: This substance is toxic to aquatic life with long lasting effects.</p> <p>14.6. Special precautions for user: Handle material with safety. Avoid contact with oxidizing substances.</p> <p>14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code : Not available</p>

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<p align="center">15.</p>	<p align="center">Regulatory Information</p>	<p>15.1 Safety, health and environmental regulations/legislation specific EU regulations</p> <ul style="list-style-type: none"> • Authorizations: The substance is not listed for Authorization • Restrictions on use: Not applicable • Other EU regulations: REGULATION (EC) No1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on classification, labeling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 • Information according 1999/13/EC about limitation of emissions of volatile organic compounds (VOC39 guideline) : Not available • National regulations 1 (Germany): Not available • Restrictions of occupation: Not applicable • Other regulations, restrictions and prohibition regulations: Not available <p>15.2 Chemical Safety Assessment: The Chemical Safety Report of this substance will be available after Registration</p>
<p align="center">16.</p>	<p align="center">Other Information</p>	<p>16.1 Indication of changes:</p> <ul style="list-style-type: none"> • 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 <p>16.2 Abbreviations and acronyms:</p> <ul style="list-style-type: none"> • EC: European Commission • CLP: Classification Labelling and Packaging • GHS: Globally harmonized system on classification and labelling • DSD: Dangerous Substance directive • DCP: NOT AVAILABLE • EWC: European Waste Catalogue • AVV: Waste codes according to the waste catalogue ordinance • PVC: NOT AVAILABLE • ADR: European agreement concerning the International Carriage of Dangerous Goods by Road • RID: European agreement concerning the International Carriage of Dangerous Goods by Rail

		<p>16.3 Key literature references and sources for data:</p> <ul style="list-style-type: none">• 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 <p>16.4 Relevant R- and H-phrases (number and full text):</p> <ul style="list-style-type: none">• R25- Toxic if swallowed.• R27- Very toxic in contact with skin.• R51/53- Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.• H310- Fatal in contact with skin• H301- Toxic if swallowed• H411- Toxic to aquatic life with long lasting effects• H319- Causes serious eye irritation
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