MATERIAL SAFETY DATA SHEET

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

Material Name: NICOTROL Nasal Spray

Trade Name: NICOTROL
Chemical Family: Mixture
Intended Use: Pharmaceutical product used for nicotine addiction

2. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS List</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Citric acid</td>
<td>77-92-9</td>
<td>201-069-1</td>
<td>*</td>
</tr>
<tr>
<td>NICOTINE</td>
<td>54-11-5</td>
<td>200-193-3</td>
<td>1</td>
</tr>
<tr>
<td>Sodium chloride</td>
<td>7647-14-5</td>
<td>231-598-3</td>
<td>*</td>
</tr>
<tr>
<td>Water, purified</td>
<td>7732-18-5</td>
<td>231-791-2</td>
<td>*</td>
</tr>
<tr>
<td>2% polysorbate 80</td>
<td>Proprietary</td>
<td>Not listed</td>
<td>*</td>
</tr>
<tr>
<td>Methylparaben</td>
<td>99-76-3</td>
<td>202-785-7</td>
<td>*</td>
</tr>
<tr>
<td>Propylparaben</td>
<td>94-13-3</td>
<td>202-307-7</td>
<td>*</td>
</tr>
<tr>
<td>Sodium dihydrogen phosphate dihydrate</td>
<td>13472-35-0</td>
<td>Not listed</td>
<td>*</td>
</tr>
<tr>
<td>Fragrance</td>
<td>NOT ASSIGNED</td>
<td>Not listed</td>
<td>*</td>
</tr>
<tr>
<td>Edetate disodium</td>
<td>139-33-3</td>
<td>205-358-3</td>
<td>*</td>
</tr>
</tbody>
</table>

Additional Information: * Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

3. HAZARDS IDENTIFICATION

Appearance: Clear liquid
Signal Word: WARNING

Statement of Hazard: Harmful in contact with skin.
Harmful if swallowed.

Additional Hazard Information:
Short Term: May cause nervous system and cardiovascular system effects. May be absorbed through the skin and cause systemic effects.

Known Clinical Effects: Clinical use of this drug has caused headache, gastrointestinal disturbances nausea, vomiting, nose bleed, changes in heart rate.
EU Indication of danger: Toxic

EU Hazard Symbols: 

Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

4. FIRST AID MEASURES

Eye Contact: Flush eyes with water for at least 15 minutes. If irritation occurs or persists, get medical attention.

Skin Contact: Wash exposed area with soap and water, remove contaminated clothing and obtain medical assistance if irritation or unusual symptoms occur even if they are delayed.

Ingestion: Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

Inhalation: Due to the nature of this material first aid is not normally required. If discomfort occurs, get medical attention.

5. FIRE FIGHTING MEASURES

Extinguishing Media: Use carbon dioxide, dry chemical, or water spray.

Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire.

Fire Fighting Procedures: During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

Fire / Explosion Hazards: Not applicable

6. ACCIDENTAL RELEASE MEASURES

Health and Safety Precautions: Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

Measures for Environmental Protections: Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Additional Consideration for Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.
7. HANDLING AND STORAGE

General Handling: Avoid contact with eyes, skin and clothing. Wash thoroughly after handling.

Storage Conditions: Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

NICOTINE

OSHA - Final PELS - TWAs: $= 0.5 \text{ mg/m}^3 \text{ TWA}$

OSHA - Final PELs - Skin Notations: prevent or reduce skin absorption

ACGIH Threshold Limit Value (TWA) $= 0.5 \text{ mg/m}^3 \text{ TWA}$

ACGIH - Skin Absorption Designation Skin - potential significant contribution to overall exposure by the cutaneous route

Australia TWA $= 0.5 \text{ mg/m}^3 \text{ TWA}$

The exposure limit(s) listed for solid components are only relevant if dust or mist may be generated.


Engineering Controls: Engineering controls should be used as the primary means to control exposures.

Personal Protective Equipment:

Hands: Not required for the normal use of this product. Wear impervious gloves if skin contact is possible.

Eyes: Not required under normal conditions of use. Wear safety glasses or goggles if eye contact is possible.

Skin: Not required for the normal use of this product. Wear protective clothing when working with large quantities.

Respiratory protection: Not required for the normal use of this product. If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

9. PHYSICAL AND CHEMICAL PROPERTIES:

Physical State: Liquid

Molecular Formula: Mixture

Color: Colorless

Molecular Weight: Mixture

10. STABILITY AND REACTIVITY

Stability: Stable under normal conditions of use.

Conditions to Avoid: None known

Incompatible Materials: None known

11. TOXICOLOGICAL INFORMATION

General Information: The information included in this section describes the potential hazards of the individual ingredients.

Acute Toxicity: (Species, Route, End Point, Dose)
MATERIAL SAFETY DATA SHEET

Material Name: NICOTROL Nasal Spray
Revision date: 21-Feb-2007
Version: 1.1

NICOTINE
Rat Oral LD 50 50 mg/kg
Rat Dermal LD 50 140 mg/kg
Mouse Oral LD 50 3340 ug/kg
Mouse Intravenous LD 50 300 ug/kg

Citric acid
Rat Oral LD50 3000 mg/kg

Sodium chloride
Rat Oral LD50 3000 mg/kg
Mouse Oral LD 50 4000 mg/kg

2% polysorbate 80
Rat Intravenous LD 50 1790 mg/kg
Mouse Oral LD 50 25 g/kg

Methylparaben
Mouse Oral LD50 > 8000 mg/kg
Rat Oral LD50 2280 mg/kg

Propylparaben
Mouse Oral LD 50 6332 mg/kg
Mouse Intraperitoneal LD 50 200 mg/kg

Irritation / Sensitization: (Study Type, Species, Severity)

Citric acid
Eye Irritation Rabbit Severe
Skin Irritation Rabbit Mild

Sodium chloride
Eye Irritation Rabbit Moderate
Skin Irritation Rabbit Mild

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Sodium chloride
10 Day(s) Rat Oral 12500 mg/kg LOAEL Kidney, Ureter, Bladder

Propylparaben
3 Week(s) Rat Oral 27.1 g/kg LOAEL Endocrine system
4 Week(s) Rat Oral 347.2 mg/kg LOAEL Male reproductive system

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

NICOTINE
Embryo / Fetal Development Rat 25 mg/kg LOAEL Teratogenic

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

NICOTINE
Bacterial Mutagenicity (Ames) Salmonella Negative

Carcinogen Status:
None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.
12. ECOLOGICAL INFORMATION

Environmental Overview: Releases to the environment should be avoided. This formulation has not been tested as a whole, the following apply to component substance(s):

Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

NICOTINE
Activated sludge (com.) EC-50 48 Hours 0.24 mg/L
Onchorhynchus mykiss LC-50 96 Hours 4 mg/L

13. DISPOSAL CONSIDERATIONS

Disposal Procedures: Dispose of waste in accordance with all applicable laws and regulations.

NICOTINE
RCRA - P Series Wastes waste number P075

14. TRANSPORT INFORMATION

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

15. REGULATORY INFORMATION

EU Symbol: T
EU Indication of danger: Toxic
EU Risk Phrases: R24 - Toxic in contact with skin.
EU Safety Phrases: S 2 - Keep out of the reach of children.
S36/37 - Wear suitable protective clothing and gloves.
S45 - In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

OSHA Label:
WARNING
Harmful in contact with skin.
Harmful if swallowed.
Canada - WHMIS: Classifications

WHMIS hazard class:
None required
This product has been classified in accordance with the hazard criteria of the CPR and the MSDS contains all of the information required by the CPR.

Sodium chloride

- **Inventory - United States TSCA - Sect. 8(b)**: Present
- **Australia (AICS)**: Present
- **EU EINECS List**: 231-598-3

Citric acid

- **Inventory - United States TSCA - Sect. 8(b)**: Present
- **Australia (AICS)**: Present
- **EU EINECS List**: 201-069-1

Water, purified

- **Inventory - United States TSCA - Sect. 8(b)**: Present
- **Australia (AICS)**: Present
- **EU EINECS List**: 231-791-2

**NICOTINE**

- **CERCLA/SARA 313 Emission reporting**: = 1.0 % de minimis concentration
- **CERCLA/SARA Hazardous Substances and their Reportable Quantities:**
  - = 100 lb final RQ
  - = 45.4 kg final RQ
- **CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs**: = 100 lb EPCRA RQ
- **California Proposition 65**: developmental toxicity, initial date 4/1/90
- **Inventory - United States TSCA - Sect. 8(b)**: Present
- **Australia (AICS)**: Present
- **Standard for the Uniform Scheduling for Drugs and Poisons:**
  - Schedule 2
  - Schedule 4
  - Schedule 6
  - Schedule 7
- **EU EINECS List**: 200-193-3

2% polysorbate 80

- **Inventory - United States TSCA - Sect. 8(b)**: XU
- **Australia (AICS)**: Present

**Methylparaben**

- **Inventory - United States TSCA - Sect. 8(b)**: Present
- **Australia (AICS)**: Present
- **EU EINECS List**: 202-785-7

**Propylparaben**
End of Safety Data Sheet