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

Product Identifier

Material Name: NICOTROL Nasal Spray

Trade Name: NICOTROL

Chemical Family: Mixture

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Pharmaceutical product used as an aid to smoking cessation for the relief of nicotine withdrawal symptoms

Details of the Supplier of the Safety Data Sheet

Pfizer Inc
Pfizer Pharmaceuticals Group
235 East 42nd Street
New York, New York 10017
1-800-879-3477

Pfizer Ltd
Ramsgate Road
Sandwich, Kent
CT13 9NJ
United Kingdom
+00 44 (0)1304 616161

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail: pfizer-MSDS@pfizer.com

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification Not classified as hazardous

Label Elements

Signal Word: Not Classified
Hazard Statements: Not classified in accordance with international standards for workplace safety.

Other Hazards

Note: No data available

This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

3. COMPOSITION / INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>GHS Classification</th>
<th>%</th>
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</tr>
</thead>
<tbody>
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<td>Sodium dihydrogen phosphate dihydrate</td>
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<td>9005-65-6</td>
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<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Fragrance</td>
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<td>Not Listed</td>
<td>Not Listed</td>
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<td>202-785-7</td>
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<td>Water, purified</td>
<td>7732-18-5</td>
<td>231-791-2</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>

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

For the full text of the CLP/GHS abbreviations mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Description of First Aid Measures

Eye Contact: Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

Skin Contact: Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

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: Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Most Important Symptoms and Effects, Both Acute and Delayed

Symptoms and Effects of Exposure: For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

Medical Conditions Aggravated by Exposure: None known

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

5. FIRE FIGHTING MEASURES

Extinguishing Media: Extinguish fires with CO2, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture

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

Fire / Explosion Hazards: Fine particles (such as mists) may fuel fires/explosions.
SAFETY DATA SHEET

Material Name: NICOTROL Nasal Spray
Revision date: 07-Mar-2016

Advice for Fire-Fighters
During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures
Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

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

Methods and Material for Containment and Cleaning Up

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.

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

Precautions for Safe Handling
Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Refer to Section 12 - Ecological Information, for information on potential effects on the environment. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Conditions for Safe Storage, Including any Incompatibilities
Storage Conditions:
Store as directed by product packaging.
Specific end use(s):
Pharmaceutical product used as an aid to smoking cessation for the relief of nicotine withdrawal symptoms

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters
Refer to available public information for specific member state Occupational Exposure Limits.

NICOTINE

ACGIH Threshold Limit Value (TWA) 0.5 mg/m³
ACGIH - Skin Absorption Designation Skin - potential significant contribution to overall exposure by the cutaneous route

Australia TWA 0.5 mg/m³
Austria OEL - MAKs 0.07 ppm

Belgium OEL - TWA 0.5 mg/m³
Bulgaria OEL - TWA 0.5 mg/m³
Cyprus OEL - TWA 0.5 mg/m³
Czech Republic OEL - TWA 0.5 mg/m³

Denmark OEL - TWA 0.5 mg/m³
Estonia OEL - TWA 0.5 mg/m³
Finland OEL - TWA 0.5 mg/m³
France OEL - TWA 0.5 mg/m³

Germany - TRGS 900 - TWAs 0.05 mg/m³
Greece OEL - TWA 0.5 mg/m³
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure Controls
- Engineering Controls: Engineering controls should be used as the primary means to control exposures.
- Personal Protective Equipment: Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

Hands:
- Wear impervious gloves if skin contact is possible.

Eyes:
- Wear safety glasses as minimum protection.

Skin:
- Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas.

Respiratory protection:
- 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

Color:
- Colorless

Odor:
- No data available.

Odor Threshold:
- No data available.

Molecular Formula:
- Mixture

Molecular Weight:
- Mixture

Solvent Solubility:
- No data available

Water Solubility:
- No data available

pH:
- No data available.

Melting/Freezing Point (°C):
- No data available

Boiling Point (°C):
- No data available.

Partition Coefficient: (Method, pH, Endpoint, Value)

Sodium dihydrogen phosphate dihydrate
- No data available

Sodium chloride
- No data available
9. PHYSICAL AND CHEMICAL PROPERTIES

No data available

**Fragrance**
No data available

**Methylparaben**
No data available

**Propylparaben**
No data available

**Edetate disodium**
No data available

**Water, purified**
No data available

**NICOTINE**
No data available

**Citric acid**
No data available

**Polysorbate 80**
No data available

Decomposition Temperature (°C): No data available.

Evaporation Rate (Gram/s): No data available

Vapor Pressure (kPa): No data available

Vapor Density (g/ml): No data available

Relative Density: No data available

Viscosity: No data available

**Flammability:**

- Autoignition Temperature (Solid) (°C): No data available
- Flammability (Solids): No data available
- Flash Point (Liquid) (°C): No data available
- Upper Explosive Limits (Liquid) (% by Vol.): No data available
- Lower Explosive Limits (Liquid) (% by Vol.): No data available

10. STABILITY AND REACTIVITY

**Reactivity:** No data available

**Chemical Stability:** Stable under normal conditions of use.

**Possibility of Hazardous Reactions**

- **Oxidizing Properties:** No data available
- **Conditions to Avoid:** Fine particles (such as mists) may fuel fires/explosions. As a precautionary measure, keep away from heat sources and electrostatic discharge.
- **Incompatible Materials:** As a precautionary measure, keep away from strong oxidizers
- **Hazardous Decomposition Products:** No data available

11. TOXICOLOGICAL INFORMATION

**Information on Toxicological Effects**

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

**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.
11. TOXICOLOGICAL INFORMATION

Acute Toxicity: (Species, Route, End Point, Dose)

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

Propylparaben
Mouse Oral  LD 50  6332 mg/kg
Mouse Sub-tenon injection (eye) LD 50  200 mg/kg

Edetate disodium
Rat  Oral  LD50  2000-2200 mg/kg

NICOTINE
Rat  Oral  LD 50  50 - 300 mg/kg
Rat  Dermal LD50  < 50mg/kg
Mouse Oral  LD 50  3.34 mg/kg
Mouse Intravenous LD 50  300ug/kg

Citric acid
Rat  Oral  LD50  3000 mg/kg

Polysorbate 80
Rat  Intravenous LD 50  1790 mg/kg
Mouse Oral  LD 50  25 g/kg

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

Sodium chloride
Eye Irritation Rabbit Moderate
Skin Irritation Rabbit Mild

Citric acid
Eye Irritation Rabbit Severe
Skin Irritation Rabbit Mild

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

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
11. TOXICOLOGICAL INFORMATION

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):

Toxicity:

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

NICOTINE
Daphnia magna (Water Flea)  EC50  48 Hours  0.24 mg/L
Oncorhynchus mykiss (Rainbow Trout)  LC50  96 Hours  4 mg/L

Persistence and Degradability: No data available
Bio-accumulative Potential: No data available
Mobility in Soil: No data available

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods: Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

NICOTINE
RCRA - P Series Wastes  Listed

14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

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

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

NICOTINE
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- Australia (AICS): Present
- EU EINECS/ELINCS List: Not Listed

CERCLA/SARA Hazardous Substances and their Reportable Quantities:
- 100 lb
- 45.4 kg
- 100 lb
- 100 lb

California Proposition 65: developmental toxicity initial date 4/1/90
Inventory - United States TSCA - Sect. 8(b): Schedule 4
Australia (AICS): Schedule 6
EU EINECS/ELINCS List: Schedule 7
200-193-3

Sodium dihydrogen phosphate dihydrate
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- Australia (AICS): Present
- EU EINECS/ELINCS List: Not Listed

Citric acid
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- Inventory - United States TSCA - Sect. 8(b): Present
- Australia (AICS): Present
- EU EINECS/ELINCS List: 201-069-1

Sodium chloride
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- Inventory - United States TSCA - Sect. 8(b): Present
- Australia (AICS): Present
- EU EINECS/ELINCS List: 231-598-3

Polysorbate 80
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- Inventory - United States TSCA - Sect. 8(b): Present
- Australia (AICS): Present
- EU EINECS/ELINCS List: Not Listed

Fragrance

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16. OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in Section 3

Acute toxicity, oral-Cat.3; H301 - Toxic if swallowed
Acute toxicity, dermal-Cat.1; H310 - Fatal in contact with skin
Hazardous to the aquatic environment, chronic toxicity-Cat.2; H411 - Toxic to aquatic life with long lasting effects
Serious eye damage/eye irritation-Cat.2A; H319 - Causes serious eye irritation

Data Sources: Pfizer proprietary drug development information. Publicly available toxicity information.

Reasons for Revision: Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 11 - Toxicology Information. Updated Section 16 - Other Information.

Revision date: 07-Mar-2016
Pfizer Inc believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

End of Safety Data Sheet