



# SAFETY DATA SHEET

Revision date: 07-Mar-2016

Version: 2.0

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## 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

**Emergency telephone number:**  
**International CHEMTREC (24 hours):** +1-703-527-3887

## 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

No data available

**Note:** 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

### Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%

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### 3. COMPOSITION / INFORMATION ON INGREDIENTS

NICOTINE	54-11-5	200-193-3	Acute Tox. 3 (H301) Acute Tox.1 (H310) Aquatic Chronic 2 (H411)	<2
Citric acid	77-92-9	201-069-1	Eye Irrit. 2A (H319)	<1

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Sodium dihydrogen phosphate dihydrate	13472-35-0	Not Listed	Not Listed	*
Sodium chloride	7647-14-5	231-598-3	Not Listed	*
Polysorbate 80	9005-65-6	Not Listed	Not Listed	*
Fragrance	NOT ASSIGNED	Not Listed	Not Listed	*
Methylparaben	99-76-3	202-785-7	Not Listed	*
Propylparaben	94-13-3	202-307-7	Not Listed	*
Edetate disodium	139-33-3	205-358-3	Not Listed	*
Water, purified	7732-18-5	231-791-2	Not Listed	*

**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.

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### 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/m <sup>3</sup>
ACGIH - Skin Absorption Designation	Skin - potential significant contribution to overall exposure by the cutaneous route
Australia TWA	0.5 mg/m <sup>3</sup>
Austria OEL - MAKs	0.07 ppm
	0.5 mg/m <sup>3</sup>
Belgium OEL - TWA	0.5 mg/m <sup>3</sup>
Bulgaria OEL - TWA	0.5 mg/m <sup>3</sup>
Cyprus OEL - TWA	0.5 mg/m <sup>3</sup>
Czech Republic OEL - TWA	0.5 mg/m <sup>3</sup>
Denmark OEL - TWA	0.5 mg/m <sup>3</sup>
Estonia OEL - TWA	0.5 mg/m <sup>3</sup>
Finland OEL - TWA	0.5 mg/m <sup>3</sup>
France OEL - TWA	0.5 mg/m <sup>3</sup>
Germany - TRGS 900 - TWAs	0.05 mg/m <sup>3</sup>
Greece OEL - TWA	0.5 mg/m <sup>3</sup>

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Hungary OEL - TWA	0.5 mg/m <sup>3</sup>
Ireland OEL - TWAs	0.5 mg/m <sup>3</sup>
Italy OEL - TWA	0.5 mg/m <sup>3</sup>
Latvia OEL - TWA	0.5 mg/m <sup>3</sup>
Lithuania OEL - TWA	0.5 mg/m <sup>3</sup>
Luxembourg OEL - TWA	0.5 mg/m <sup>3</sup>
Malta OEL - TWA	0.5 mg/m <sup>3</sup>
Netherlands OEL - TWA	0.5 mg/m <sup>3</sup>
OSHA - Final PELs - TWAs:	0.5 mg/m <sup>3</sup>
OSHA - Final PELs - Skin Notations:	prevent or reduce skin absorption
Poland OEL - TWA	0.5 mg/m <sup>3</sup>
Portugal OEL - TWA	0.5 mg/m <sup>3</sup>
Romania OEL - TWA	0.5 mg/m <sup>3</sup>
Slovakia OEL - TWA	0.5 mg/m <sup>3</sup>
Slovenia OEL - TWA	0.5 mg/m <sup>3</sup>
Spain OEL - TWA	0.5 mg/m <sup>3</sup>
Sweden OEL - TWAs	0.1 mg/m <sup>3</sup>
Switzerland OEL - TWAs	0.07 ppm
	0.5 mg/m <sup>3</sup>
Vietnam OEL - TWAs	0.5 mg/m <sup>3</sup>

#### Sodium chloride

Latvia OEL - TWA	5 mg/m <sup>3</sup>
Lithuania OEL - TWA	5 mg/m <sup>3</sup>

#### Exposure Controls

<b>Engineering Controls:</b>	Engineering controls should be used as the primary means to control exposures.
<b>Personal Protective Equipment:</b>	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).
<b>Hands:</b>	Wear impervious gloves if skin contact is possible.
<b>Eyes:</b>	Wear safety glasses as minimum protection.
<b>Skin:</b>	Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas.
<b>Respiratory protection:</b>	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

<b>Physical State:</b>	Liquid	<b>Color:</b>	Colorless
<b>Odor:</b>	No data available.	<b>Odor Threshold:</b>	No data available.
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	Mixture
<b>Solvent Solubility:</b>	No data available		
<b>Water Solubility:</b>	No data available		
<b>pH:</b>	No data available.		
<b>Melting/Freezing Point (°C):</b>	No data available		
<b>Boiling Point (°C):</b>	No data available.		
<b>Partition Coefficient: (Method, pH, Endpoint, Value)</b>			
<b>Sodium dihydrogen phosphate dihydrate</b>			
No data available			
<b>Sodium chloride</b>			

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### 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.

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### 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 LD 50 < 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

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### 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.

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### 15. REGULATORY INFORMATION

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

##### NICOTINE

CERCLA/SARA 313 Emission reporting	1.0 %
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	100 lb
CERCLA/SARA - Section 302 Extremely Hazardous TPQs	45.4 kg
CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs	100 lb
California Proposition 65	100 lb
Inventory - United States TSCA - Sect. 8(b)	developmental toxicity initial date 4/1/90
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Present
	Schedule 4
	Schedule 6
	Schedule 7
EU EINECS/ELINCS List	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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### 15. REGULATORY INFORMATION

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed

**Methylparaben**

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	202-785-7

**Propylparaben**

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	202-307-7

**Edetate disodium**

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	205-358-3

**Water, purified**

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	231-791-2

### 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.

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**Prepared by:** Product Stewardship Hazard Communication  
Pfizer Global Environment, Health, and Safety Operations

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**