



MATERIAL SAFETY DATA SHEET

Revision date: 21-Feb-2007

Version: 1.1

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

Pfizer Inc
Pfizer Pharmaceuticals Group
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New York, New York 10017
1-212-573-2222

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

Emergency telephone number:
ChemSafe (24 hours): +44 (0)208 762 8322

Material Name: NICOTROL Inhaler

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

2. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS List	%
NICOTINE	54-11-5	200-193-3	10 mg #####

Ingredient	CAS Number	EU EINECS List	%
L-Menthol	2216-51-5	218-690-9	*

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

3. HAZARDS IDENTIFICATION

Appearance: Porous plug laden with active ingredient
Signal Word: DANGER

Statement of Hazard: Fatal if swallowed.
Fatal in contact with skin.
Toxic to aquatic life with long lasting effects.

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, sore throat, sore mouth, changes in heart rate.

EU Indication of danger: Very toxic
Toxic
Dangerous for the Environment

EU Hazard Symbols:

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EU Risk Phrases:

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.

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: Due to the nature of this material first aid is not normally required.

Skin Contact: Due to the nature of this material first aid is not normally required.

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: Collect spilled material by a method that controls dust generation.

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.

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7. HANDLING AND STORAGE

General Handling: Avoid contact with eyes . Wash thoroughly after handling.
Storage Conditions: Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

NICOTINE

OSHA - Final PELs - TWAs:	= 0.5 mg/m ³ TWA
OSHA - Final PELs - Skin Notations:	prevent or reduce skin absorption
ACGIH Threshold Limit Value (TWA)	= 0.5 mg/m ³ TWA
ACGIH - Skin Absorption Designation	Skin - potential significant contribution to overall exposure by the cutaneous route
Australia TWA	= 0.5 mg/m ³ TWA

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

Analytical Method: Analytical method available for Nicotine. Contact Pfizer Inc for further information.

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:	Solid	Color:	No data available.
Molecular Formula:	Mixture	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)

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L-Menthol

Rat Oral LD50 3300 mg/kg

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

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

L-Menthol

Eye Irritation Rabbit Severe

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): Toxic to aquatic organisms. See Aquatic toxicity data of the active ingredient, below:

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

L-Menthol

Fathead minnow LC50 96 Hours 18.9 mg/L

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

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14. TRANSPORT INFORMATION

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

15. REGULATORY INFORMATION

EU Symbol: T+ , N
EU Indication of danger: Very toxic
Toxic
Dangerous for the Environment

EU Risk Phrases:
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.

EU Safety Phrases:
S 2 - Keep out of the reach of children.
S24 - Avoid contact with skin.
S45 - In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

OSHA Label:
DANGER
Fatal if swallowed.
Fatal in contact with skin.
Toxic to aquatic life with long lasting effects.

Canada - WHMIS: Classifications

WHMIS hazard class:
Class D, Division 1, Subdivision A



NICOTINE

CERCLA/SARA 313 Emission reporting	= 1.0 % de minimis concentration
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	= 100 lb final RQ
CERCLA/SARA - Section 302 Extremely Hazardous TPQs	= 45.4 kg final RQ
CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs	= 100 lb TPQ
California Proposition 65 Inventory - United States TSCA - Sect. 8(b)	= 100 lb EPCRA RQ
	developmental toxicity, initial date 4/1/90
	Present

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Australia (AICS): Standard for the Uniform Scheduling for Drugs and Poisons:	Present Schedule 2 Schedule 4 Schedule 6 Schedule 7
EU EINECS List	200-193-3

L-Menthol	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	218-690-9

16. OTHER INFORMATION

Reasons for Revision: Updated Section 14 - Transport Information.

Prepared by: Toxicology and Hazard Communication
Pfizer Global Environment, Health, and Safety

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.

End of Safety Data Sheet