MATERIAL SAFETY DATA SHEET

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: Nafarelin Acetate Nasal Solution

Trade Name: Synarel; Nasanyl; Synrelina; Synarela
Chemical Family: Mixture
Intended Use: Pharmaceutical product for the treatment of Central Precocious Puberty endometriosis

2. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS List	%
Nafarelin Acetate	86220-42-0	Not listed	2
Acetic acid USP - glacial	64-19-7	200-580-7	*
Hydrochloric Acid	7647-01-0	231-595-7	**
Benzalkonium Chloride	61789-71-7	263-080-8	*
Sodium hydroxide	1310-73-2	215-185-5	**

Ingredient	CAS Number	EU EINECS List	%
Sorbitol solution	50-70-4	200-061-5	*
Water	7732-18-5	231-791-2	*

Additional Information:
* Proprietary
** to adjust pH

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

3. HAZARDS IDENTIFICATION

Appearance: Clear, colorless to slightly yellow solution
Signal Word: WARNING

Statement of Hazard:
May cause reproductive system effects
May cause harm to the unborn child.
Possible carcinogen

Short Term: May cause eye and skin irritation, Not a skin sensitizer , Not acutely toxic (based on components) .

Long Term: Repeat-dose studies in animals have shown a potential to cause adverse effects on liver, blood.

Known Clinical Effects: Adverse effects most commonly reported in clinical use include headache, hot flashes, changes in libido, vaginal dryness, acne, emotional lability, myalgia, decreased breast size and irritation of the nasal mucosa. Hypersensitivity reactions may also occur in susceptible individuals.

EU Indication of danger: Toxic to reproduction, Category 2
Carcinogenic: Category 3

EU Hazard Symbols:

EU Risk Phrases:

R40 - Limited evidence of a carcinogenic effect
R60 - May impair fertility.
R61 - May cause harm to the unborn child.

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: Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. If irritation occurs or persists, get medical attention.

Skin Contact: Remove contaminated clothing. Wash skin with soap and water. If irritation occurs or persists, get medical attention.

Ingestion: Call a physician immediately.

Inhalation: Remove to fresh air. Consult a physician

5. FIRE FIGHTING MEASURES

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

Hazardous Combustion Products: May include oxides of nitrogen.

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 open handling. Minimize generation of mists. Use local exhaust or perform work under hood/fume cupboard. Avoid inhalation and contact with skin, eyes, and clothing. When handling, use appropriate personal protective equipment (see Section 8).

Storage Conditions: Store at room temperature in properly labeled containers. Keep away from heat, sparks and flames. Protect from light.

Storage Temperature: 25°C (77°F)

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Nafarelin Acetate

Pfizer OEL TWA-8 Hr:	15 ng/m^3

Acetic acid USP - glacial

OSHA - Final PELS - TWAs:	= 10 ppm TWA = 25 mg/m^3 TWA
ACGIH Threshold Limit Value (TWA)	= 10 ppm TWA
ACGIH Threshold Limit Value (STEL)	= 15 ppm STEL
Australia STEL	= 15 ppm STEL = 37 mg/m^3 STEL
Australia TWA	= 10 ppm TWA = 25 mg/m^3 TWA

Hydrochloric Acid

ACGIH Ceiling Threshold Limit:	= 2 ppm Ceiling
Australia PEAK	= 5 ppm Peak = 7.5 mg/m^3 Peak

Sodium hydroxide

OSHA - Final PELS - TWAs:	2 mg/m^3
ACGIH Ceiling Threshold Limit:	= 2 mg/m^3 Ceiling
Australia PEAK	= 2 mg/m^3 Peak

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

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

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

Personal Protective Equipment:

Hands:	Chemical protective gloves
Eyes:	Safety glasses or goggles
Skin:	Wear protective clothing with long sleeves to avoid skin contact. Wash hands and arms thoroughly after handling this product.
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 solution	**Color:**	Colorless to slightly yellow
Molecular Formula:	Mixture	**Molecular Weight:**	Mixture

10. STABILITY AND REACTIVITY

Stability: Stable under normal conditions of use.
Conditions to Avoid: Exposure to light .
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)

Nafarelin Acetate
Rat Oral LD 50 >50 mg/kg
Rat Subcutaneous LD 50 0.5 ug/kg
Rat Intraperitoneal LD 50 0.5 ug/kg
Mouse Oral LD 50 >100 mg/kg
Mouse Subcutaneous LD 50 >0.5 mg/kg

Sodium hydroxide
Mouse IP LD50 40 mg/kg

Sorbitol solution
Rat Oral LD50 15,900 mg/kg
Mouse Oral LD50 17,800 mg/kg

Acute Toxicity Comments: A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

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

Nafarelin Acetate
Eye Irritation Rabbit No effect
Skin Irritation Rabbit No effect
Skin Sensitization Guinea Pig Negative

Sodium hydroxide
Eye Irritation Rabbit Severe
Skin Irritation Rabbit Severe

Hydrochloric Acid
Skin Irritation Severe
Eye Irritation Severe

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

Nafarelin Acetate
28 Day(s) Rat Subcutaneous 2 µg/kg/day LOAEL Reproductive system
6 Month(s) Rat Intramuscular 2 µg/kg/day LOAEL Reproductive system
6 Month(s) Monkey Intramuscular 2 µg/kg/day LOAEL Reproductive system

18 Month(s) Dog Subcutaneous 32 µg/kg/day LOAEL Female reproductive system
1 Year(s) Rat Intramuscular 10 ug/kg/day LOAEL Reproductive system, Liver, Blood

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

Nafarelin Acetate
Reproductive & Fertility Rat Intramuscular 0.04 ug/kg/day LOAEL Reproductive toxicity
Reproductive & Fertility Rat Intramuscular 0.1 ug/kg/day LOAEL Reproductive toxicity, Neonatal mortality
Reproductive & Fertility Rabbit Intramuscular 0.18 ug/kg/day LOAEL Fetotoxicity
Reproductive & Fertility Rat Intramuscular 0.4 ug/kg/day LOAEL Maternal Toxicity, Fetotoxicity
Reproductive & Fertility Mouse Intramuscular 600 ug/kg/day NOAEL Negative

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

Nafarelin Acetate
Bacterial Mutagenicity (Ames) *Salmonella* , *E. coli* Negative
Chromosome Aberration Chinese Hamster Ovary (CHO) cells Negative
Mitotic Gene Conversion Fungi Negative
In Vivo Micronucleus Mouse Negative

Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Nafarelin Acetate
18 Month(s) Mouse Intramuscular 500 ug/kg/day LOAEL Benign tumors
2 Year(s) Rat Intramuscular 10 ug/kg/day LOAEL Benign tumors

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

Hydrochloric Acid
IARC: Group 3

12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties of the formulation have not been thoroughly investigated. Releases to the environment should be avoided.

13. DISPOSAL CONSIDERATIONS

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

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 to reproduction, Category 2
Carcinogenic: Category 3

EU Risk Phrases:

R40 - Limited evidence of a carcinogenic effect
R60 - May impair fertility.
R61 - May cause harm to the unborn child.

EU Safety Phrases:

S36/37 - Wear suitable protective clothing and gloves.
S53 - Avoid exposure - obtain special instructions before use.

OSHA Label:
WARNING
May cause reproductive system effects
May cause harm to the unborn child.
Possible carcinogen

Canada - WHMIS: Classifications

WHMIS hazard class:
Class D, Division 2, Subdivision A

Nafarelin Acetate

California Proposition 65	developmental toxicity, initial date 4/1/90

Acetic acid USP - glacial

CERCLA/SARA Hazardous Substances and their Reportable Quantities:	= 2270 kg final RQ = 5000 lb final RQ
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 2 Schedule 5 Schedule 6
EU EINECS List	200-580-7

Hydrochloric Acid

CERCLA/SARA 313 Emission reporting	= 1.0 % de minimis concentration acid aerosols including mists, vapors, gas, fog, and other airborne forms of any particle size
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	= 2270 kg final RQ = 5000 lb final RQ
CERCLA/SARA - Section 302 Extremely Hazardous TPQs	= 500 lb TPQ gas only
CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs	= 5000 lb EPCRA RQ gas only
Inventory - United States TSCA - Sect. 8(b)	T
Australia (AICS):	Present

Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 5 Schedule 6
EU EINECS List	231-595-7

Benzalkonium Chloride

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	263-080-8

Sorbitol solution

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	200-061-5

Sodium hydroxide

CERCLA/SARA Hazardous Substances and their Reportable Quantities:	= 1000 lb final RQ = 454 kg final RQ
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 5 Schedule 6
EU EINECS List	215-185-5

Water

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

16. OTHER INFORMATION

Reasons for Revision: Updated Section 3 - Hazard Identification. Updated Section 6 - Accidental Release Measures. Updated Section 8 - Exposure Controls / Personal Protection.

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

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End of Safety Data Sheet