



# SAFETY DATA SHEET

Revision date: 13-Dec-2017

Version: 2.1

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

### Product Identifier

**Material Name:** Nafarelin Acetate Nasal Solution

**Trade Name:** Synarel; Nasanyl; Synrelina; Synarela

**Chemical Family:** Mixture

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

**Intended Use:** Pharmaceutical product for the treatment of Central Precocious Puberty endometriosis

### 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**  
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**+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

Skin Corrosion/Irritation: Category 2

Reproductive Toxicity: Category 1B

Carcinogenicity: Category 2

### Label Elements

**Signal Word:** Danger

**Hazard Statements:**  
H315 - Causes skin irritation  
H360FD - May damage fertility. May damage the unborn child.  
H351 - Suspected of causing cancer

**Precautionary Statements:**  
P201 - Obtain special instructions before use  
P281 - Use personal protective equipment as required  
P302+ P352 - IF ON SKIN: Wash with plenty of soap and water  
P308 + P313 - IF exposed or concerned: Get medical attention/advice  
P362 - Take off contaminated clothing and wash before reuse  
P405 - Store locked up

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**Other Hazards**

An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

**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	%
Acetic acid USP - glacial	64-19-7	200-580-7	Skin Corr.1A (H314) Flam. Liq.3 (H226)	1-5
HYDROCHLORIC ACID	7647-01-0	231-595-7	Skin Corr.1B (H314) STOT SE 3 (H335)	**
Nafarelin Acetate	86220-42-0	Not Listed	Repr.1B (H360FD) Carc.2 (H351)	1-5
Sodium hydroxide	1310-73-2	215-185-5	Skin Corr.1A (H314)	**

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Benzalkonium chloride	8001-54-5	Not Listed	Not Listed	*
Sorbitol solution	50-70-4	200-061-5	Not Listed	*
Water	7732-18-5	231-791-2	Not Listed	*

**Additional Information:**

\* Proprietary  
\*\* to adjust pH  
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

**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.

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**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 CO<sub>2</sub>, 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 dust and mists) may fuel fires/explosions.

### Advice for Fire-Fighters

During all firefighting 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. Cleanup operations should only be undertaken by trained personnel.

## 7. HANDLING AND STORAGE

### Precautions for Safe Handling

Restrict access to work area. Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. 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 drug product

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

#### Control Parameters

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

#### Acetic acid USP - glacial

ACGIH Threshold Limit Value (TWA)	10 ppm
ACGIH Threshold Limit Value (STEL)	15 ppm
Australia STEL	15 ppm
	37 mg/m <sup>3</sup>
Australia TWA	10 ppm
	25 mg/m <sup>3</sup>
Austria OEL - MAKs	10 ppm
	25 mg/m <sup>3</sup>
Belgium OEL - TWA	10 ppm
	25 mg/m <sup>3</sup>
Bulgaria OEL - TWA	25.0 mg/m <sup>3</sup>
Cyprus OEL - TWA	10 ppm
	25 mg/m <sup>3</sup>
Czech Republic OEL - TWA	25 mg/m <sup>3</sup>
Denmark OEL - TWA	10 ppm
	25 mg/m <sup>3</sup>
Estonia OEL - TWA	10 ppm
	25 mg/m <sup>3</sup>
Finland OEL - TWA	5 ppm
	13 mg/m <sup>3</sup>
Germany - TRGS 900 - TWAs	10 ppm
	25 mg/m <sup>3</sup>
Germany (DFG) - MAK	10 ppm
	25 mg/m <sup>3</sup>
Greece OEL - TWA	10 ppm
	25 mg/m <sup>3</sup>
Hungary OEL - TWA	25 mg/m <sup>3</sup>
Ireland OEL - TWAs	10 ppm
	25 mg/m <sup>3</sup>
Latvia OEL - TWA	10 ppm
	25 mg/m <sup>3</sup>
Lithuania OEL - TWA	10 ppm
	25 mg/m <sup>3</sup>
Luxembourg OEL - TWA	10 ppm
	25 mg/m <sup>3</sup>
Malta OEL - TWA	10 ppm
	25 mg/m <sup>3</sup>
Netherlands OEL - TWA	25 mg/m <sup>3</sup>
OSHA - Final PELs - TWAs:	10 ppm
	25 mg/m <sup>3</sup>
Poland OEL - TWA	25 mg/m <sup>3</sup>
Portugal OEL - TWA	10 ppm
	25 mg/m <sup>3</sup>
Romania OEL - TWA	10 ppm
	25 mg/m <sup>3</sup>
Slovakia OEL - TWA	10 ppm
	25 mg/m <sup>3</sup>
Slovenia OEL - TWA	10 ppm
	25 mg/m <sup>3</sup>

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Spain OEL - TWA	10 ppm 25 mg/m <sup>3</sup>
Sweden OEL - TWAs	5 ppm 13 mg/m <sup>3</sup>
Switzerland OEL - TWAs	10 ppm 25 mg/m <sup>3</sup>
Vietnam OEL - TWAs	25 mg/m <sup>3</sup>

#### HYDROCHLORIC ACID

ACGIH Ceiling Threshold Limit:	2 ppm
Australia PEAK	5 ppm 7.5 mg/m <sup>3</sup>
Austria OEL - MAKs	5 ppm 8 mg/m <sup>3</sup>
Belgium OEL - TWA	5 ppm 8 mg/m <sup>3</sup>
Bulgaria OEL - TWA	5 ppm 8.0 mg/m <sup>3</sup>
Cyprus OEL - TWA	5 ppm 8 mg/m <sup>3</sup>
Czech Republic OEL - TWA	8 mg/m <sup>3</sup>
Estonia OEL - TWA	5 ppm 8 mg/m <sup>3</sup>
Germany - TRGS 900 - TWAs	2 ppm 3 mg/m <sup>3</sup>
Germany (DFG) - MAK	2 ppm 3.0 mg/m <sup>3</sup>
Greece OEL - TWA	5 ppm 7 mg/m <sup>3</sup>
Hungary OEL - TWA	8 mg/m <sup>3</sup>
Ireland OEL - TWAs	5 ppm 8 mg/m <sup>3</sup>
Italy OEL - TWA	5 ppm 8 mg/m <sup>3</sup>
Japan - OELs - Ceilings	2 ppm 3.0 mg/m <sup>3</sup>
Latvia OEL - TWA	5 ppm 8 mg/m <sup>3</sup>
Lithuania OEL - TWA	5 ppm 8 mg/m <sup>3</sup>
Luxembourg OEL - TWA	5 ppm 8 mg/m <sup>3</sup>
Malta OEL - TWA	5 ppm 8 mg/m <sup>3</sup>
Netherlands OEL - TWA	8 mg/m <sup>3</sup>
Poland OEL - TWA	5 mg/m <sup>3</sup>
Portugal OEL - TWA	5 ppm 8 mg/m <sup>3</sup>
Romania OEL - TWA	5 ppm 8 mg/m <sup>3</sup>
Slovakia OEL - TWA	5 ppm 8.0 mg/m <sup>3</sup>
Slovenia OEL - TWA	5 ppm 8 mg/m <sup>3</sup>

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Spain OEL - TWA	5 ppm 7.6 mg/m <sup>3</sup>
Switzerland OEL -TWAs	2 ppm 3.0 mg/m <sup>3</sup>
Vietnam OEL - TWAs	5 mg/m <sup>3</sup>
<b>Nafarelin Acetate</b>	
Pfizer OEL TWA-8 Hr:	0.015 µg/m <sup>3</sup>
<b>Sodium hydroxide</b>	
ACGIH Ceiling Threshold Limit:	2 mg/m <sup>3</sup>
Australia PEAK	2 mg/m <sup>3</sup>
Austria OEL - MAKs	2 mg/m <sup>3</sup>
Bulgaria OEL - TWA	2.0 mg/m <sup>3</sup>
Czech Republic OEL - TWA	1 mg/m <sup>3</sup>
Estonia OEL - TWA	1 mg/m <sup>3</sup>
France OEL - TWA	2 mg/m <sup>3</sup>
Greece OEL - TWA	2 mg/m <sup>3</sup>
Hungary OEL - TWA	2 mg/m <sup>3</sup>
Japan - OELs - Ceilings	2 mg/m <sup>3</sup>
Latvia OEL - TWA	0.5 mg/m <sup>3</sup>
OSHA - Final PELs - TWAs:	2 mg/m <sup>3</sup>
Poland OEL - TWA	0.5 mg/m <sup>3</sup>
Slovakia OEL - TWA	2 mg/m <sup>3</sup>
Slovenia OEL - TWA	2 mg/m <sup>3</sup>
Sweden OEL - TWAs	1 mg/m <sup>3</sup>
Switzerland OEL -TWAs	2 mg/m <sup>3</sup>

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

#### Benzalkonium chloride

**Pfizer Occupational Exposure Band (OEB):** OEB 2 - Sensitizer (control exposure to the range of 100µg/m<sup>3</sup> to < 1000µg/m<sup>3</sup>, provide additional precautions to protect from skin contact)

#### Exposure Controls

**Engineering Controls:** Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section. It is recommended that all operations be fully enclosed and no air recirculated.

**Personal Protective Equipment:** Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

**Hands:** Impervious disposable gloves (e.g. Nitrile, etc.) (double recommended) if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.)

**Eyes:** Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)

**Skin:** Impervious disposable protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.)

**Respiratory protection:** Under normal conditions of use, 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 (e.g. particulate respirator with a full mask, P3 filter). (Respirators must meet the standards in accordance with EN136, EN143, ASTM F2704-10 or international equivalent.)

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### 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Physical State:</b>	Liquid solution	<b>Color:</b>	Colorless to slightly yellow
<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>Water</b>			
No data available			
<b>Nafarelin Acetate</b>			
No data available			
<b>Sorbitol solution</b>			
No data available			
<b>Benzalkonium chloride</b>			
No data available			
<b>Acetic acid USP - glacial</b>			
No data available			
<b>Sodium hydroxide</b>			
No data available			
<b>Decomposition Temperature (°C):</b>	No data available.		
<b>Evaporation Rate (Gram/s):</b>	No data available		
<b>Vapor Pressure (kPa):</b>	No data available		
<b>Vapor Density (g/ml):</b>	No data available		
<b>Relative Density:</b>	No data available		
<b>Viscosity:</b>	No data available		
<b>Flammability:</b>			
<b>Autoignition Temperature (Solid) (°C):</b>		No data available	
<b>Flammability (Solids):</b>		No data available	
<b>Flash Point (Liquid) (°C):</b>		No data available	
<b>Upper Explosive Limits (Liquid) (% by Vol.):</b>		No data available	
<b>Lower Explosive Limits (Liquid) (% by Vol.):</b>		No data available	

### 10. STABILITY AND REACTIVITY

<b>Reactivity:</b>	No data available
<b>Chemical Stability:</b>	Stable under normal conditions of use.
<b>Possibility of Hazardous Reactions</b>	
<b>Oxidizing Properties:</b>	No data available
<b>Conditions to Avoid:</b>	Exposure to light As a precautionary measure, keep away from heat sources and electrostatic discharge. Fine particles (such as dust and mists) may fuel fires/explosions.
<b>Incompatible Materials:</b>	As a precautionary measure, keep away from strong oxidizers
<b>Hazardous Decomposition Products:</b>	No data available

### 11. TOXICOLOGICAL INFORMATION

#### Information on Toxicological Effects

NAFARELIN ACETATE SOLUTION

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### 11. TOXICOLOGICAL INFORMATION

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

**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.

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

##### **Nafarelin Acetate**

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

##### **Sorbitol solution**

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

##### **Benzalkonium chloride**

Rat Oral LD50 240 mg/kg

##### **Sodium hydroxide**

Mouse IP LD50 40 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

##### **Benzalkonium chloride**

Skin Irritation Rabbit Moderate  
Eye Irritation Rabbit Severe

##### **Sodium hydroxide**

Eye Irritation Rabbit Severe  
Skin Irritation Rabbit 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



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### 11. TOXICOLOGICAL INFORMATION

#### 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)	<i>Salmonella</i> , <i>E. coli</i>	Negative
Chromosome Aberration	Chinese Hamster Ovary (CHO) cells	Negative
Mitotic Gene Conversion	Fungi	Negative
<i>In Vivo</i> 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:** See below

### 12. ECOLOGICAL INFORMATION

<b>Environmental Overview:</b>	Environmental properties of the formulation have not been thoroughly investigated. Releases to the environment should be avoided.
<b>Toxicity:</b>	No data available
<b>Persistence and Degradability:</b>	No data available
<b>Bio-accumulative Potential:</b>	No data available
<b>Mobility in Soil:</b>	No data available

### 13. DISPOSAL CONSIDERATIONS

<b>Waste Treatment Methods:</b>	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.
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### 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

#### Acetic acid USP - glacial

CERCLA/SARA 313 Emission reporting	Not Listed
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	5000 lb 2270 kg
California Proposition 65	Not Listed
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/ELINCS List	200-580-7

#### Benzalkonium chloride

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 5 Schedule 6
EU EINECS/ELINCS List	Not Listed

#### HYDROCHLORIC ACID

CERCLA/SARA 313 Emission reporting	1.0 %
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	5000 lb 2270 kg
CERCLA/SARA - Section 302 Extremely Hazardous TPQs	500 lb
CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs	5000 lb
California Proposition 65	Not Listed
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/ELINCS List	231-595-7

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### 15. REGULATORY INFORMATION

#### Nafarelin Acetate

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	developmental toxicity 4/1/1990
EU EINECS/ELINCS List	Not Listed

#### Sodium hydroxide

CERCLA/SARA 313 Emission reporting	Not Listed
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	1000 lb 454 kg
California Proposition 65	Not Listed
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/ELINCS List	215-185-5

#### Sorbitol solution

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	200-061-5

#### Water

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

Reproductive toxicity-Cat.1B; H360FD - May damage fertility. May damage the unborn child.  
Carcinogenicity-Cat.2; H351 - Suspected of causing cancer  
Skin corrosion/irritation-Cat.1A; Skin corrosion/irritation-Cat.1B; H314 - Causes severe skin burns and eye damage  
Acute toxicity, inhalation-Cat.3; H331 - Toxic if inhaled  
Flammable liquids-Cat.3; H226 - Flammable liquid and vapor  
Specific target organ toxicity, single exposure; Respiratory tract irritation-Cat.3; H335 - May cause respiratory 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 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 16 - Other Information.

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Product Stewardship Hazard Communication  
**Prepared by:** 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**