



SAFETY DATA SHEET

Revision date: 04-Apr-2015

Version: 1.3

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

Product Identifier

Material Name: Tramadol Hydrochloride Modified Release Tablets

Trade Name: Nobligan Retard

Chemical Family: Mixture

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

Intended Use: Pharmaceutical product used as analgesic

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
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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

Acute Oral Toxicity: Category 4

EU Classification:

EU Indication of danger: Harmful

EU Risk Phrases:

R22 - Harmful if swallowed.

Label Elements

Signal Word: Warning

Hazard Statements: H302 - Harmful if swallowed

Precautionary Statements:

P264 - Wash hands thoroughly after handling
P270 - Do not eat, drink or smoke when using this product
P301+ P312 - IF SWALLOWED: Call a POISON CENTRE or doctor/physician if you feel unwell
P301+ P330 + P331 - IF SWALLOWED: Rinse mouth. Do NOT induce vomiting
P501 - Dispose of contents/container in accordance with all local and national regulations

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Other Hazards

No data available

Australian Hazard Classification (NOHSC):

Hazardous Substance. Non-Dangerous Goods.

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 | EU Classification | GHS Classification | % |
|----------------------------|------------|-----------------------|-------------------|--------------------|---------------|
| Tramadol Hydrochloride | 73806-49-2 | Not Listed | Xn; R22 | Acute Tox.3 (H301) | 100-200 mg*** |
| Microcrystalline cellulose | 9004-34-6 | 232-674-9 | Not Listed | Not Listed | * |
| Magnesium stearate | 557-04-0 | 209-150-3 | Not Listed | Not Listed | * |
| Colloidal silicon dioxide | 7631-86-9 | 231-545-4 | Not Listed | Not Listed | * |
| Propylene glycol | 57-55-6 | 200-338-0 | Not Listed | Not Listed | * |
| Titanium dioxide | 13463-67-7 | 236-675-5 | Not Listed | Not Listed | * |
| Talc (non-asbestiform) | 14807-96-6 | 238-877-9 | Not Listed | Not Listed | * |

| Ingredient | CAS Number | EU EINECS/ELINCS List | EU Classification | GHS Classification | % |
|-------------------------------|--------------|-----------------------|-------------------|--------------------|---|
| Hydroxypropyl methylcellulose | 9004-65-3 | Not Listed | Not Listed | Not Listed | * |
| Lactose NF, monohydrate | 64044-51-5 | Not Listed | Not Listed | Not Listed | * |
| Macrogol 6000 | Not assigned | Not Listed | Not Listed | Not Listed | * |
| Red iron oxide | Not assigned | Not Listed | Not Listed | Not Listed | * |
| Brown iron oxide | Not assigned | Not Listed | Not Listed | Not Listed | * |
| Quinoline yellow lake (E104) | Not assigned | Not Listed | Not Listed | Not Listed | * |

Additional Information:

* Proprietary

*** per tablet/capsule/lozenge/suppository

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 R phrases and CLP/GHS abbreviations mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Description of First Aid Measures

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4. FIRST AID MEASURES

- Eye Contact:** Immediately flush eyes with water for at least 15 minutes. If irritation occurs or persists, get medical attention.
- Skin Contact:** Wash skin with soap and water. If irritation occurs or persists, get 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:** Not applicable

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 spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. 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

Minimize dust generation and accumulation. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. When handling, use appropriate personal protective equipment (see Section 8).

Conditions for Safe Storage, Including any Incompatibilities

- Storage Conditions:** Store as directed by product packaging.

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Specific end use(s): Pharmaceutical drug product

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

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

Microcrystalline cellulose

| | |
|-----------------------------------|----------------------|
| ACGIH Threshold Limit Value (TWA) | 10 mg/m ³ |
| Australia TWA | 10 mg/m ³ |
| Belgium OEL - TWA | 10 mg/m ³ |
| Estonia OEL - TWA | 10 mg/m ³ |
| France OEL - TWA | 10 mg/m ³ |
| Ireland OEL - TWAs | 10 mg/m ³ |
| | 4 mg/m ³ |
| Latvia OEL - TWA | 2 mg/m ³ |
| OSHA - Final PELs - TWAs: | 15 mg/m ³ |
| Portugal OEL - TWA | 10 mg/m ³ |
| Romania OEL - TWA | 10 mg/m ³ |
| Russia OEL - TWA | 6 mg/m ³ |
| Spain OEL - TWA | 10 mg/m ³ |
| Switzerland OEL - TWAs | 3 mg/m ³ |
| Vietnam OEL - TWAs | 10 mg/m ³ |
| | 5 mg/m ³ |

Magnesium stearate

| | |
|-----------------------------------|----------------------|
| ACGIH Threshold Limit Value (TWA) | 10 mg/m ³ |
| Lithuania OEL - TWA | 5 mg/m ³ |
| Sweden OEL - TWAs | 5 mg/m ³ |

Colloidal silicon dioxide

| | |
|--|-----------------------|
| Australia TWA | 2 mg/m ³ |
| Austria OEL - MAKs | 4 mg/m ³ |
| | 0.3 mg/m ³ |
| Czech Republic OEL - TWA | 0.1 mg/m ³ |
| | 4.0 mg/m ³ |
| Estonia OEL - TWA | 2 mg/m ³ |
| Finland OEL - TWA | 5 mg/m ³ |
| Germany - TRGS 900 - TWAs | 4 mg/m ³ |
| Germany (DFG) - MAK | 4 mg/m ³ |
| Ireland OEL - TWAs | 6 mg/m ³ |
| | 2.4 mg/m ³ |
| Latvia OEL - TWA | 1 mg/m ³ |
| OSHA - Final PELs - Table Z-3 Mineral D: | 20 mppcf |
| | Listed |
| Slovakia OEL - TWA | 4.0 mg/m ³ |
| Switzerland OEL - TWAs | 4 mg/m ³ |
| | 0.3 mg/m ³ |

Propylene glycol

| | |
|---------------|-----------------------|
| Australia TWA | 150 ppm |
| | 474 mg/m ³ |
| | 10 mg/m ³ |

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

| | |
|---------------------|--|
| Ireland OEL - TWAs | 150 ppm 470 mg/m ³ 10 mg/m ³ |
| Latvia OEL - TWA | 7 mg/m ³ |
| Lithuania OEL - TWA | 7 mg/m ³ |

Titanium dioxide

| | |
|---|---|
| ACGIH Threshold Limit Value (TWA) | 10 mg/m ³ |
| ACGIH OELs - Notice of Intended Changes | Listed |
| Australia TWA | 10 mg/m ³ |
| Austria OEL - MAKs | 5 mg/m ³ |
| Belgium OEL - TWA | 10 mg/m ³ |
| Bulgaria OEL - TWA | 10.0 mg/m ³ |
| Denmark OEL - TWA | 6 mg/m ³ |
| Estonia OEL - TWA | 5 mg/m ³ |
| France OEL - TWA | 10 mg/m ³ |
| Greece OEL - TWA | 10 mg/m ³ 5 mg/m ³ |
| Ireland OEL - TWAs | 10 mg/m ³ 4 mg/m ³ |
| Latvia OEL - TWA | 10 mg/m ³ |
| Lithuania OEL - TWA | 5 mg/m ³ |
| OSHA - Final PELs - TWAs: | 15 mg/m ³ |
| Poland OEL - TWA | 10.0 mg/m ³ |
| Portugal OEL - TWA | 10 mg/m ³ |
| Romania OEL - TWA | 10 mg/m ³ |
| Russia OEL - TWA | 10 mg/m ³ |
| Spain OEL - TWA | 10 mg/m ³ |
| Sweden OEL - TWAs | 5 mg/m ³ |
| Switzerland OEL - TWAs | 3 mg/m ³ |
| Vietnam OEL - TWAs | 6 mg/m ³ 5 mg/m ³ |

Talc (non-asbestiform)

| | |
|-----------------------------------|---|
| ACGIH Threshold Limit Value (TWA) | 2 mg/m ³ |
| Australia TWA | 2.5 mg/m ³ |
| Austria OEL - MAKs | 2 mg/m ³ |
| Belgium OEL - TWA | 2 mg/m ³ |
| Bulgaria OEL - TWA | 1.0 fiber/cm ³ 6.0 mg/m ³ 3.0 mg/m ³ |
| Czech Republic OEL - TWA | 2.0 mg/m ³ |
| Denmark OEL - TWA | 0.3 fiber/cm ³ |
| Finland OEL - TWA | 0.5 fiber/cm ³ |
| Greece OEL - TWA | 10 mg/m ³ 2 mg/m ³ |
| Hungary OEL - TWA | 2 mg/m ³ |
| Ireland OEL - TWAs | 10 mg/m ³ 0.8 mg/m ³ |
| Lithuania OEL - TWA | 2 mg/m ³ 1 mg/m ³ |
| Netherlands OEL - TWA | 0.25 mg/m ³ |

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

| | |
|--|-----------------------|
| OSHA - Final PELs - Table Z-3 Mineral D: | 20 mppcf |
| Poland OEL - TWA | 4.0 mg/m ³ |
| | 1.0 mg/m ³ |
| Portugal OEL - TWA | 2 mg/m ³ |
| Romania OEL - TWA | 2 mg/m ³ |
| Slovakia OEL - TWA | 2 mg/m ³ |
| | 10 mg/m ³ |
| Slovenia OEL - TWA | 2 mg/m ³ |
| Spain OEL - TWA | 2 mg/m ³ |
| Sweden OEL - TWAs | 2 mg/m ³ |
| | 1 mg/m ³ |
| Switzerland OEL -TWAs | 2 mg/m ³ |

The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

Tramadol Hydrochloride

Pfizer Occupational Exposure Band (OEB): OEB 2 (control exposure to the range of 100ug/m³ to < 1000ug/m³)

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 air contamination levels below the exposure limits or within the OEB range listed above in this section.

Personal Protective Equipment:

Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

Hands:

Not required for the normal use of this product. Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.

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. Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

Respiratory protection:

Not required for the normal use of this product. Whenever excessive air contamination (dust, mist, vapor) is generated, respiratory protection, with appropriate protection factors, should be used to minimize exposure.

9. PHYSICAL AND CHEMICAL PROPERTIES

| | | | |
|---|--------------------|--------------------------|--------------------|
| Physical State: | Tablets | Color: | No data available. |
| 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) | | | |

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9. PHYSICAL AND CHEMICAL PROPERTIES

Hydroxypropyl methylcellulose

No data available

Microcrystalline cellulose

No data available

Magnesium stearate

No data available

Lactose NF, monohydrate

No data available

Macrogol 6000

No data available

Talc (non-asbestiform)

No data available

Titanium dioxide

No data available

Tramadol Hydrochloride

Predicted 7 Log P 1.34

Propylene glycol

No data available

Colloidal silicon dioxide

No data available

Red iron oxide

No data available

Brown iron oxide

No data available

Quinoline yellow lake (E104)

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: None known

Incompatible Materials: As a precautionary measure, keep away from strong oxidizers

Hazardous Decomposition Products: No data available

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11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

General Information:

There are no data for this formulation. The information included in this section describes the potential hazards of the individual ingredients.

Short Term:

Active ingredient is not a skin irritant ; Not an eye irritant ; Harmful if swallowed (based on animal data) .

Long Term:

Use of this drug is habit forming. Addiction may occur.

Known Clinical Effects:

Ingestion of this material may cause effects similar to those seen in clinical use including dry mouth, drowsiness, headache, dizziness, nausea, vomiting, weakness, anxiety, and dilated pupils. Cases of severe overdose may lead to respiratory depression, hypotension, coma, convulsions, cardiac arrhythmia, and tachycardia.

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

Hydroxypropyl methylcellulose

Rat Oral LD50 > 10,000 mg/kg

Microcrystalline cellulose

Rat Oral LD50 > 5000 mg/kg

Rabbit Dermal LD50 > 2000 mg/kg

Magnesium stearate

Rat Oral LD50 > 2000 mg/kg

Rat Inhalation LC50 > 2000 mg/m³

Talc (non-asbestiform)

Rat Oral LD50 > 1600 mg/kg

Titanium dioxide

Rat Oral LD50 > 7500 mg/kg

Rat Subcutaneous LD50 50 mg/kg

Tramadol Hydrochloride

Rat Oral LD50 228 mg/kg

Rat Para-periosteal LD50 57.6mg/kg

Rat Subcutaneous LD50 286mg/kg

Mouse Oral LD50 270mg/kg

Mouse Intravenous LD50 60.4mg/kg

Propylene glycol

Rat Oral LD 50 22,000 mg/kg

Mouse Oral LD 50 24,900mg/kg

Rabbit Dermal LD 50 20,800mg/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)

Microcrystalline cellulose

Skin Irritation Rabbit Non-irritating

Eye Irritation Rabbit Non-irritating

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11. TOXICOLOGICAL INFORMATION

Propylene glycol

Skin Irritation Rabbit Mild
Eye Irritation Rabbit Mild

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

Tramadol Hydrochloride

6 Week(s) Rat Oral 20 mg/kg/day NOAEL
26 Week(s) Dog Oral 10 mg/kg/day NOAEL

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

Tramadol Hydrochloride

Reproductive & Fertility Rat Oral 50-75 mg/kg NOAEL Fertility
Embryo / Fetal Development Rat Oral 25 mg/kg LOAEL Maternal Toxicity, Fetotoxicity
Embryo / Fetal Development Rabbit Oral 75 mg/kg LOAEL Maternal Toxicity, Fetotoxicity
Embryo / Fetal Development Mouse Oral 120 mg/kg LOAEL Maternal Toxicity, Fetotoxicity
Peri-/Postnatal Development Rat Oral 50 mg/kg LOAEL Maternal Toxicity, Fetotoxicity

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

Tramadol Hydrochloride

Bacterial Mutagenicity (Ames) *Salmonella*, *E. coli* Negative
In Vivo Chromosome Aberration Chinese Hamster Ovary (CHO) cells Negative
In Vivo Micronucleus Mouse Bone Marrow Negative
In Vitro Micronucleus Rat Positive
In Vitro Mammalian Cell Mutagenicity Mouse Lymphoma Positive

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

Tramadol Hydrochloride

2 Year(s) Mouse Oral 30 mg/kg/day NOEL Not carcinogenic
2 Year(s) Rat Oral 30 mg/kg/day NOAEL Not carcinogenic

Carcinogen Status: See below

Talc (non-asbestiform)

IARC: Group 3 (Not Classifiable)

Titanium dioxide

IARC: Group 2B (Possibly Carcinogenic to Humans)

Colloidal silicon dioxide

IARC: Group 3 (Not Classifiable)

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12. ECOLOGICAL INFORMATION

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

Toxicity: No data available

Persistence and Degradability: No data available

Bio-accumulative Potential:
Partition Coefficient: (Method, pH, Endpoint, Value)
Tramadol Hydrochloride
Predicted 7 Log P 1.34

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.

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

Canada - WHMIS: Classifications

WHMIS hazard class:

Class D, Division 1, Subdivision B



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15. REGULATORY INFORMATION

Tramadol Hydrochloride

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

Hydroxypropyl methylcellulose

| | |
|---|------------|
| CERCLA/SARA 313 Emission reporting | Not Listed |
| 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 4 |
| EU EINECS/ELINCS List | Not Listed |

Microcrystalline cellulose

| | |
|---|---------------------------------------|
| 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 XVII - Restrictions on Certain Dangerous Substances: | Use restricted. See item 9[f]. powder |
| EU EINECS/ELINCS List | 232-674-9 |

Magnesium stearate

| | |
|---|------------|
| 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 | 209-150-3 |

Colloidal silicon dioxide

| | |
|---|------------|
| 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 | 231-545-4 |

Lactose NF, monohydrate

| | |
|--|------------|
| CERCLA/SARA 313 Emission reporting | Not Listed |
| California Proposition 65 | Not Listed |
| Australia (AICS): | Present |
| REACH - Annex IV - Exemptions from the obligations of Register: | Present |
| EU EINECS/ELINCS List | Not Listed |

Macrogol 6000

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

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15. REGULATORY INFORMATION

Propylene glycol

| | |
|---|------------|
| 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 | 200-338-0 |

Titanium dioxide

| | |
|---|---|
| CERCLA/SARA 313 Emission reporting | Not Listed |
| California Proposition 65 | carcinogen initial date 9/2/11 airborne, unbound particles of respirable size |
| Inventory - United States TSCA - Sect. 8(b) | Present |
| Australia (AICS): | Present |
| EU EINECS/ELINCS List | 236-675-5 |

Red iron oxide

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

Brown iron oxide

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

Quinoline yellow lake (E104)

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

Talc (non-asbestiform)

| | |
|---|------------|
| 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 | 238-877-9 |

16. OTHER INFORMATION

Text of R phrases and GHS Classification abbreviations mentioned in Section 3

Acute toxicity, oral-Cat.3; H301 - Toxic if swallowed

Xn - Harmful

R22 - Harmful if swallowed.

Data Sources:

Pfizer proprietary drug development information. Publicly available toxicity information.

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Reasons for Revision: Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 4 - First Aid Measures. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 11 - Toxicology Information.

Revision date: 04-Apr-2015

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