



# SAFETY DATA SHEET

Revision date: 22-Aug-2014

Version: 4.0

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

### Product Identifier

**Material Name:** Sertraline Hydrochloride Oral Concentrate - 20 mg/mL

**Trade Name:** ZOLOFT; TATIG; LUSTRAL; BESITRAN

**Chemical Family:** Mixture

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

**Intended Use:** Pharmaceutical product used as antidepressant

### 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

Flammable liquids- Category 3

#### EU Classification:

EU Risk Phrases:

R10 - Flammable.

### Label Elements

**Signal Word:** Warning

**Hazard Statements:** H226 - Flammable liquid and vapor

#### Precautionary Statements:

P210 - Keep away from heat/sparks/open flames/hot surfaces. - No smoking  
P233 - Keep container tightly closed  
P240 - Ground/Bond container and receiving equipment  
P241 - Use explosion-proof electrical/ventilating/lighting/equipment  
P242 - Use only non-sparking tools  
P243 - Take precautionary measures against static discharge  
P280 - Wear protective gloves/protective clothing/eye protection/face protection  
P303 + P361 + P353 - IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower  
P370 + P378 - In case of fire: Use .? for extinction  
P403 + P235 - Store in a well-ventilated place. Keep cool  
P501 - Dispose of contents/container in accordance with all local and national regulations

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**Other Hazards**  
**Australian Hazard Classification**  
**(NOHSC):**

No data available  
Hazardous Substance. 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	%
Ethyl alcohol (ethanol)	64-17-5	200-578-6	F; R11	Flam. Liq. 2 (H225)	12.0
Sertraline hydrochloride	79559-97-0	Not Listed	N;R50 Xn;R22	Acute Tox.4 (H302) STOT RE.2 (H373) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)	2.0
Glycerin, USP	56-81-5	200-289-5	Not Listed	Not Listed	*
Butylated hydroxytoluene	128-37-0	204-881-4	Not Listed	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Menthol, USP	89-78-1	201-939-0	Not Listed	Not Listed	*

**Additional Information:** \* Proprietary  
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**  
**Eye Contact:**

Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

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**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 CO<sub>2</sub>, extinguishing powder, foam, or water.

### Special Hazards Arising from the Substance or Mixture

**Hazardous Combustion Products:** May emit toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, hydrogen chloride and other chlorine-containing compounds.

**Fire / Explosion Hazards:** Flammable liquid.

### Advice for Fire-Fighters

Wear approved positive pressure, self-contained breathing apparatus and full protective turn out gear. Use caution in approaching fire.

## 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. Eliminate all sources of ignition and ventilate area using explosion-proof equipment.

### 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

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### 7. HANDLING AND STORAGE

Keep away from heat. Use adequate ventilation. Eliminate possible ignition sources (e.g., heat, sparks, flame, impact, friction, electricity), and follow appropriate grounding and bonding procedures. Minimize generating airborne mists and vapors. 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. Refer to Section 12 - Ecological Information, for information on potential effects on the environment.

#### Conditions for Safe Storage, Including any Incompatibilities

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

#### Ethyl alcohol (ethanol)

ACGIH Threshold Limit Value (STEL)	1000 ppm
Australia TWA	1000 ppm 1880 mg/m <sup>3</sup>
Austria OEL - MAKs	1000 ppm 1900 mg/m <sup>3</sup>
Belgium OEL - TWA	1000 ppm 1907 mg/m <sup>3</sup>
Bulgaria OEL - TWA	1000.0 mg/m <sup>3</sup>
Czech Republic OEL - TWA	1000 mg/m <sup>3</sup>
Denmark OEL - TWA	1000 ppm 1900 mg/m <sup>3</sup>
Estonia OEL - TWA	500 ppm 1000 mg/m <sup>3</sup>
Finland OEL - TWA	1000 ppm 1900 mg/m <sup>3</sup>
France OEL - TWA	1000 ppm 1900 mg/m <sup>3</sup>
Germany - TRGS 900 - TWAs	500 ppm 960 mg/m <sup>3</sup>
Germany (DFG) - MAK	500 ppm 960 mg/m <sup>3</sup>
Greece OEL - TWA	1000 ppm 1900 mg/m <sup>3</sup>
Hungary OEL - TWA	1900 mg/m <sup>3</sup>
Latvia OEL - TWA	1000 mg/m <sup>3</sup>
Lithuania OEL - TWA	500 ppm 1000 mg/m <sup>3</sup>
Netherlands OEL - TWA	260 mg/m <sup>3</sup>
OSHA - Final PELs - TWAs:	1000 ppm 1900 mg/m <sup>3</sup>
Poland OEL - TWA	1900 mg/m <sup>3</sup>
Portugal OEL - TWA	1000 ppm
Romania OEL - TWA	1000 ppm 1900 mg/m <sup>3</sup>

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Russia OEL - TWA	1000 mg/m <sup>3</sup>
Slovakia OEL - TWA	500 ppm
	960 mg/m <sup>3</sup>
Slovenia OEL - TWA	1000 ppm
	1900 mg/m <sup>3</sup>
Spain OEL - TWA	1000 ppm
	1910 mg/m <sup>3</sup>
Sweden OEL - TWAs	500 ppm
	1000 mg/m <sup>3</sup>
Switzerland OEL -TWAs	500 ppm
	960 mg/m <sup>3</sup>
Vietnam OEL - TWAs	1000 mg/m <sup>3</sup>
Sertraline hydrochloride	
Pfizer OEL TWA-8 Hr:	500µg/m <sup>3</sup>
Glycerin, USP	
Australia TWA	10 mg/m <sup>3</sup>
Belgium OEL - TWA	10 mg/m <sup>3</sup>
Czech Republic OEL - TWA	10 mg/m <sup>3</sup>
Estonia OEL - TWA	10 mg/m <sup>3</sup>
Finland OEL - TWA	20 mg/m <sup>3</sup>
France OEL - TWA	10 mg/m <sup>3</sup>
Germany (DFG) - MAK	50 mg/m <sup>3</sup>
Greece OEL - TWA	10 mg/m <sup>3</sup>
Ireland OEL - TWAs	10 mg/m <sup>3</sup>
OSHA - Final PELs - TWAs:	15 mg/m <sup>3</sup>
Poland OEL - TWA	10 mg/m <sup>3</sup>
Portugal OEL - TWA	10 mg/m <sup>3</sup>
Spain OEL - TWA	10 mg/m <sup>3</sup>
Switzerland OEL -TWAs	50 mg/m <sup>3</sup>
Butylated hydroxytoluene	
ACGIH Threshold Limit Value (TWA)	2 mg/m <sup>3</sup>
Australia TWA	10 mg/m <sup>3</sup>
Austria OEL - MAKs	10 mg/m <sup>3</sup>
Belgium OEL - TWA	2 mg/m <sup>3</sup>
Bulgaria OEL - TWA	10.0 mg/m <sup>3</sup>
Denmark OEL - TWA	10 mg/m <sup>3</sup>
Finland OEL - TWA	10 mg/m <sup>3</sup>
France OEL - TWA	10 mg/m <sup>3</sup>
Germany - TRGS 900 - TWAs	10 mg/m <sup>3</sup>
Germany (DFG) - MAK	10 mg/m <sup>3</sup>
Greece OEL - TWA	10 mg/m <sup>3</sup>
Ireland OEL - TWAs	10 mg/m <sup>3</sup>
Portugal OEL - TWA	2 mg/m <sup>3</sup>
Slovenia OEL - TWA	10 mg/m <sup>3</sup>
Switzerland OEL -TWAs	10 mg/m <sup>3</sup>

#### Exposure Controls

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<b>Engineering Controls:</b>	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.
<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>	Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.
<b>Eyes:</b>	Wear safety glasses or goggles if eye contact is possible.
<b>Skin:</b>	Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.
<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>	Clear, 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.

#### Partition Coefficient: (Method, pH, Endpoint, Value)

Sertraline hydrochloride  
Predicted 7.0 Log D 2.39

**Menthol, USP**  
No data available

**Glycerin, USP**  
No data available

**Ethyl alcohol (ethanol)**  
No data available

**Butylated hydroxytoluene**  
No data available

**Decomposition Temperature (°C):** 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

#### Flammability:

<b>Autoignition Temperature (Solid) (°C):</b>	No data available
<b>Flammability (Solids):</b>	No data available
<b>Flash Point (Liquid) (°C):</b>	27
<b>Upper Explosive Limits (Liquid) (% by Vol.):</b>	No data available
<b>Lower Explosive Limits (Liquid) (% by Vol.):</b>	No data available

**Partition Coefficient (n-octanol/water - Log P):** 2.9 (pH 7) (Sertraline HCl)

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### 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:** Direct sunlight, excessive heat, sparks or open flame  
**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 be harmful if swallowed. May cause irritation (based on components) .  
**Long Term:** Repeat-dose studies in animals have shown a potential to cause adverse effects on : liver.  
**Known Clinical Effects:** Ingestion of this material may cause effects similar to those seen in clinical use including nausea, diarrhea, insomnia, and headache. Signs and symptoms associated with non-fatal overdose were drowsiness, vomiting, rapid heart rate, nausea, dizziness, agitation, and tremor.

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

##### Sertraline hydrochloride

Mouse Oral LD50 419 - 548 mg/kg  
Rat Oral LD50 1327 - 1591mg/kg

##### Glycerin, USP

Mouse Oral LD50 4090 mg/kg  
Rat Oral LD50 12.6 g/kg  
Rabbit Dermal LD50 > 10 g/kg  
Rat Inhalation LC50 1hr > 570 mg/m<sup>3</sup>  
Rat Dermal LD 50 > 21.9 g/kg

##### Ethyl alcohol (ethanol)

Mouse Oral LD50 3450 mg/kg  
Rat Oral LD50 7060mg/kg  
Rat Inhalation LC50 10h 20,000ppm

##### Butylated hydroxytoluene

Rat Oral LD50 1700 mg/kg  
Mouse Oral LD50 650 mg/kg  
Rat Oral LD50 890 mg/kg  
Mouse Intraperitoneal LD 50 138 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)

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### 11. TOXICOLOGICAL INFORMATION

#### Glycerin, USP

Eye Irritation Rabbit Mild

#### Ethyl alcohol (ethanol)

Eye Irritation Rabbit Severe  
Skin Irritation Rabbit Mild

#### Butylated hydroxytoluene

Eye Irritation Rabbit Moderate  
Skin Irritation Rabbit Moderate

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

##### Sertraline hydrochloride

3 Month(s)	Rat	Oral	80 mg/kg/day	LOAEL	Liver
3 Month(s)	Dog	Oral	80 mg/kg/day	LOAEL	Liver
1 Year(s)	Dog	Oral	30 mg/kg/day	LOAEL	Central Nervous System
2 Year(s)	Rat	Oral	40 mg/kg/day	LOAEL	Liver

##### Butylated hydroxytoluene

4 Week(s)	Rat	Oral	5185 mg/kg	LOAEL	Liver
4 Day(s)	Mouse	Oral	2000 mg/kg	LOAEL	Liver, Kidney, Ureter, Bladder

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

##### Sertraline hydrochloride

Peri-/Postnatal Development	Rat	Oral	20 mg/kg/day	LOAEL	Early embryonic development, Developmental toxicity
Reproductive & Fertility	Rat	Oral	80 mg/kg/day	LOAEL	Fertility
Reproductive & Fertility	Rat	Oral	10 mg/kg/day	LOAEL	Developmental toxicity
Embryo / Fetal Development	Rabbit	Oral	40 mg/kg/day	NOAEL	Not Teratogenic
Embryo / Fetal Development	Rat	Oral	80 mg/kg/day	NOAEL	Not Teratogenic

##### Butylated hydroxytoluene

Embryo / Fetal Development	Rat	Oral	6 g/kg	LOEL	Teratogenic
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#### Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

##### Sertraline hydrochloride

Bacterial Mutagenicity (Ames)	<i>Salmonella</i> , <i>E. coli</i>	Negative
Mammalian Cell Mutagenicity	Mouse Lymphoma	Negative
<i>In Vitro</i> Chromosome Aberration	Human Lymphocytes	Negative
Bone Marrow Metaphase Analysis	Mouse	Negative
<i>In Vitro</i> Cytogenetics	Mouse Bone Marrow	Negative

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

##### Sertraline hydrochloride

2 Year(s)	Rat	Oral	40 mg/kg/day	NOAEL	Not carcinogenic
2 Year(s)	Mouse	Oral	40 mg/kg/day	LOAEL	Benign tumors, Liver, Lungs

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**Carcinogen Status:** Carcinogenicity of the mixture has not been determined. Consumption of alcoholic beverages is considered carcinogenic to humans (Group 1) by IARC, though ethanol itself has not been classified by this agency. No other components are listed as carcinogens by IARC, US OSHA or NTP.

#### Ethyl alcohol (ethanol)

IARC: Group 1 (Carcinogenic to Humans)  
OSHA: Listed

#### Butylated hydroxytoluene

IARC: Group 3 (Not Classifiable)

### 12. ECOLOGICAL INFORMATION

**Environmental Overview:** In the environment, the active ingredient in this formulation is expected to remain in water or migrate through the soil to groundwater. Harmful effects to aquatic organisms could occur. Releases to the environment should be avoided.

#### Toxicity:

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

##### Sertraline hydrochloride

*Daphnia magna* (Water Flea) EC50 1.25 Hours 2.14 mg/L  
*Pimephales promelas* (Fathead Minnow) TAD LC50 96 Hours 0.30 mg/L  
*Pseudokirchneriella subcapitata* (Green Alga) NPDES EC50 96 Hours 0.03 mg/L  
*Skeletonema costatum* (Marine Diatom) NPDES EC50 96 Hours 0.03 mg/L  
*Pseudokirchneriella subcapitata* (Green Alga) TAD NOEC 12 Days 0.033 mg/L

##### Glycerin, USP

*Oncorhynchus mykiss* (Rainbow Trout) LD50 96 Hours 50 mg/L  
*Daphnia magna* (Water Flea) EC50 24 Hours >500 mg/L

#### Ethyl alcohol (ethanol)

*Oncorhynchus mykiss* (Rainbow Trout) LC50/96h 12,900-15,300 mg/L

**Aquatic Toxicity Comments:** A greater than symbol (>) indicates that aquatic toxicity was not observed at the maximum dose tested.

**Persistence and Degradability:** No data available

#### Bio-accumulative Potential:

#### Partition Coefficient: (Method, pH, Endpoint, Value)

##### Sertraline hydrochloride

Predicted 7.0 Log D 2.39

**Mobility in Soil:** No data available

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### 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.

This material is regulated for transport under DOT, ADR, IMDG, and IATA regulations.

**UN number:** UN 1170  
**UN proper shipping name:** Ethyl alcohol solution  
**Transport hazard class(es):** 3  
**Packing group:** III  
**Flash Point (°C):** 27

**Flash Point (°C):** 27

### 15. REGULATORY INFORMATION

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

#### Canada - WHMIS: Classifications

**WHMIS hazard class:**

D2b toxic materials



#### Menthol, USP

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	201-939-0

#### Ethyl alcohol (ethanol)

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	carcinogen initial date 4/29/11 in alcoholic beverages developmental toxicity initial date 10/1/87 in alcoholic beverages

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### 15. REGULATORY INFORMATION

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	200-578-6
<b>Sertraline hydrochloride</b>	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed
<b>Glycerin, USP</b>	
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 V - Exemptions from the obligations of Register:	Present if not chemically modified, except they meet the criteria for classification as dangerous according to Directive 67/548/EEC, except those only classified as flammable [R10], as a skin irritant [R38] or as an eye irritant [R36], except they are persistent, bioaccumulative, and toxic or very persistent and very bioaccumulative in accordance with the criteria set out in Annex XIII, except they were identified in accordance with Article 59[1] at least two years previously as substances giving rise to an equivalent level of concern
EU EINECS/ELINCS List	200-289-5
<b>Butylated hydroxytoluene</b>	
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	204-881-4

### 16. OTHER INFORMATION

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

Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed  
 Flammable liquids-Cat.3; H226 - Flammable liquid and vapor  
 Specific target organ toxicity, repeated exposure-Cat.2; H373 - May cause damage to organs through prolonged or repeated exposure  
 Hazardous to the aquatic environment, acute toxicity-Cat.1; H400 - Very toxic to aquatic life  
 Hazardous to the aquatic environment, chronic toxicity-Cat.1; H410 - Very toxic to aquatic life with long lasting effects

F - Highly flammable  
 Xn - Harmful  
 N - Dangerous for the environment

R50 - Very toxic to aquatic organisms.  
 R11 - Highly flammable.  
 R22 - Harmful if swallowed.

**Data Sources:** Pfizer proprietary drug development information. Safety data sheets for individual ingredients.

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**Reasons for Revision:**

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 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 11 - Toxicology Information.

**Revision date:**

22-Aug-2014

**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**