



# MATERIAL SAFETY DATA SHEET

Revision date: 15-Aug-2013

Version: 3.0

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

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**Pfizer Pharmaceuticals Group**  
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**Material Name: Doxycycline calcium oral suspension syrup**

<b>Trade Name:</b>	Vibramycin
<b>Chemical Family:</b>	Mixture
<b>Intended Use:</b>	Pharmaceutical product used as antibiotic agent

## 2. HAZARDS IDENTIFICATION

**Appearance:** Raspberry-apple flavored syrup  
**Signal Word:** DANGER

**Statement of Hazard:** May damage the unborn child.

**Additional Hazard Information:**  
**Short Term:** May cause allergic reactions in susceptible individuals. Accidental ingestion may cause effects similar to those seen in clinical use.

**Known Clinical Effects:** May cause permanent discoloration of teeth if used during tooth development. May cause effects similar to those generally seen in clinical use of tetracyclines including gastrointestinal irritation, nausea, vomiting, and diarrhea. Photosensitivity has been reported in some individuals taking tetracyclines.

**EU Indication of danger:** Toxic to reproduction: Category 1

**EU Hazard Symbols:**



**EU Risk Phrases:**

**Australian Hazard Classification (NOHSC):**

R61 - May cause harm to the unborn child.  
Hazardous Substance. Non-Dangerous Goods.

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### 2. HAZARDS IDENTIFICATION

**Note:** This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients 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.

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

#### Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Calcium chloride USP	10035-04-8	Not Listed	Not Listed	*
Doxycycline calcium	94088-85-4	302-088-9	Repr.Cat.1;R61	1
Glycerin, USP	56-81-5	200-289-5	Not Listed	*
Hydrogen chloride	7647-01-0	231-595-7	T; R23 C; R35	**
Magnesium aluminum silicate	1327-43-1	215-478-8	Not Listed	*
Sodium hydroxide	1310-73-2	215-185-5	C; R35	**
Sodium metabisulfite USP	7681-57-4	231-673-0	Xn; R22 R31 Xi; R41	<1.0

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Apple flavor, artificial	NOT ASSIGNED	Not Listed	Not Listed	*
Butylparaben	94-26-8	202-318-7	Not Listed	*
Carmine	1328-60-5	215-527-3	Not Listed	*
Povidone	9003-39-8	Not Listed	Not Listed	*
Propylene glycol	57-55-6	200-338-0	Not Listed	*
Propylparaben	94-13-3	202-307-7	Not Listed	*
Raspberry flavor	NOT ASSIGNED	Not Listed	Not Listed	*
Simethicone emulsion	67762-90-7	Not Listed	Not Listed	*
Sorbitol	6706-59-8	Not Listed	Not Listed	*
Water, purified	7732-18-5	231-791-2	Not Listed	*

#### Additional Information:

\*\* to adjust pH

\* Proprietary

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

For the full text of the R phrases mentioned in this Section, see Section 16

### 4. 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.

#### 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.

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**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.

### 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:** Fine particles (such as dust and mists) may fuel fires/explosions.

### 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:** Minimize generating airborne mists and vapors. Avoid breathing vapor or mist. 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.

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

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Doxycycline calcium  
Pfizer OEL TWA-8 Hr: 0.25 mg/m<sup>3</sup>

Glycerin, USP

ACGIH Threshold Limit Value (TWA)	10 mg/m <sup>3</sup>
ACGIH OELs - Notice of Intended Changes	Listed
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>

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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>

#### Hydrogen chloride

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	8.0 mg/m <sup>3</sup>
	5 ppm
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	5 ppm
	7.5 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>
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>
Propylene glycol	
Australia TWA	150 ppm 474 mg/m <sup>3</sup> 10 mg/m <sup>3</sup>
Ireland OEL - TWAs	150 ppm 470 mg/m <sup>3</sup> 10 mg/m <sup>3</sup>
Latvia OEL - TWA	7 mg/m <sup>3</sup>
Lithuania OEL - TWA	7 mg/m <sup>3</sup>
Sodium hydroxide	
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>
Sodium metabisulfite USP	
ACGIH Threshold Limit Value (TWA)	5 mg/m <sup>3</sup>
Australia TWA	5 mg/m <sup>3</sup>
Belgium OEL - TWA	5 mg/m <sup>3</sup>
Denmark OEL - TWA	5 mg/m <sup>3</sup>
France OEL - TWA	5 mg/m <sup>3</sup>
Greece OEL - TWA	5 mg/m <sup>3</sup>
Ireland OEL - TWAs	5 mg/m <sup>3</sup>
Portugal OEL - TWA	5 mg/m <sup>3</sup>
Spain OEL - TWA	5 mg/m <sup>3</sup>

<b>Analytical Method:</b>	Analytical method available for Doxycycline. Contact Pfizer Inc for further information.
<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>Environmental Exposure Controls:</b>	Refer to specific Member State legislation for requirements under Community environmental legislation.
<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.

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

**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

<b>Physical State:</b>	Syrup	<b>Color:</b>	Red
<b>Odor:</b>	Light raspberry	<b>Molecular Formula:</b>	Mixture
<b>Molecular Weight:</b>	Mixture		

**Polymerization:** Will not occur

### 10. STABILITY AND REACTIVITY

**Chemical Stability:** Stable under normal conditions of use.

**Conditions to Avoid:** Fine particles (such as dust and mists) may fuel fires/explosions.

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

### 11. TOXICOLOGICAL INFORMATION

**General Information:** The information in this section describes the hazards of various forms of the active ingredient. The remaining information describes the potential hazards of the individual ingredients.

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

##### **Doxycycline calcium**

Mouse Oral LD50 1900 mg/kg (hydrochloride)  
Rat Oral LD50 > 2000 mg/kg (hydrochloride)

##### **Propylparaben**

Mouse Oral LD 50 6332 mg/kg  
Mouse Sub-tenon injection (eye) LD 50 200 mg/kg

##### **Calcium chloride USP**

Rat Oral LD50 1000 mg/kg  
Mouse Oral LD50 1940 mg/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

##### **Povidone**

Rat Oral LD50 100 g/kg

##### **Propylene glycol**

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### 11. TOXICOLOGICAL INFORMATION

Mouse Oral LD50 22,000 mg/kg  
Rat Oral LD50 20,000 mg/kg  
Rabbit Dermal LD50 20,800 mg/kg

#### Hydrogen chloride

Rat Sub-tenon injection (eye) LC50 1H 3,124 ppm  
Mouse Inhalation LC50 1H 1,108 ppm  
Mouse Oral LD50 900 mg/kg

#### Sodium hydroxide

Mouse IP LD50 40 mg/kg

#### Doxycycline hydrochloride

Rat Oral LD50 1700 mg/kg  
Mouse Oral LD50 1890 mg/kg  
Dog Oral LD50 > 500 mg/kg  
Rat IV LD50 137 mg/kg  
Rat Subcutaneous LD50 700 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)

##### Glycerin, USP

Eye Irritation Rabbit Mild

##### Propylene glycol

Skin Irritation Rabbit Mild  
Eye Irritation Rabbit Mild

##### Sodium hydroxide

Eye Irritation Rabbit Severe  
Skin Irritation Rabbit Severe

##### Skin Irritation / Sensitization

Photosensitivity manifested by an exaggerated sunburn reaction has been observed in some individuals taking tetracyclines.

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

##### Propylparaben

3 Week(s) Rat Oral 27.1 g/kg LOAEL Endocrine system  
4 Week(s) Rat Oral 347.2 mg/kg LOAEL Male reproductive system

##### Doxycycline monohydrate

30 Day(s) Rat Oral 500 mg/kg/day NOEL No effects at maximum dose  
18 Month(s) Rat Oral 500 mg/kg/day NOAEL None identified  
1 Year(s) Dog Oral 100 mg/kg/day LOEL Liver

#### Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))

##### Doxycycline monohydrate

Reproductive & Fertility Rat Oral 250 mg/kg/day NOAEL No effects at maximum dose  
Embryo / Fetal Development Monkey Oral 50 mg/kg/day NOAEL Not Teratogenic

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### 11. TOXICOLOGICAL INFORMATION

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

**Povidone**

**IARC:** Group 3 (Not Classifiable)

**Hydrogen chloride**

**IARC:** Group 3 (Not Classifiable)

**Sodium metabisulfite USP**

**IARC:** Group 3 (Not Classifiable)

### 12. ECOLOGICAL INFORMATION

**Environmental Overview:** The environmental characteristics of this material have not been fully evaluated. Releases to the environment should be avoided.

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

**Glycerin, USP**

*Oncorhynchus mykiss* (Rainbow Trout) LD50 96 Hours 50 mg/L

*Daphnia magna* (Water Flea) EC50 24 Hours >500 mg/L

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

### 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

**EU Symbol:**

T

**EU Indication of danger:**

Toxic to reproduction: Category 1

**EU Risk Phrases:**

R61 - May cause harm to the unborn child.

**EU Safety Phrases:**



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### 15. REGULATORY INFORMATION

S53 - Avoid exposure - obtain special instructions before use.

#### OSHA Label:

DANGER

May damage the unborn child.

#### Canada - WHMIS: Classifications

##### WHMIS hazard class:

Class D, Division 2, Subdivision A



#### Apple flavor, artificial

California Proposition 65

Not Listed

#### Butylparaben

California Proposition 65

Not Listed

Inventory - United States TSCA - Sect. 8(b)

Present

Australia (AICS):

Present

EU EINECS/ELINCS List

202-318-7

#### Calcium chloride USP

California Proposition 65

Not Listed

Australia (AICS):

Present

#### Carmines

California Proposition 65

Not Listed

Inventory - United States TSCA - Sect. 8(b)

Present

EU EINECS/ELINCS List

215-527-3

#### Doxycycline calcium

California Proposition 65

developmental toxicity initial date 1/1/92 internal use

EU EINECS/ELINCS List

302-088-9

#### Glycerin, USP

California Proposition 65

Not Listed

Inventory - United States TSCA - Sect. 8(b)

Present

Australia (AICS):

Present

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## 15. REGULATORY INFORMATION

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

### Hydrogen chloride

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

### Magnesium aluminum silicate

California Proposition 65

Not Listed

Inventory - United States TSCA - Sect. 8(b)

Present

Australia (AICS):

Present

EU EINECS/ELINCS List

215-478-8

### Povidone

California Proposition 65

Not Listed

Inventory - United States TSCA - Sect. 8(b)

Present

Australia (AICS):

Present

### Propylene glycol

California Proposition 65

Not Listed

Inventory - United States TSCA - Sect. 8(b)

Present

Australia (AICS):

Present

EU EINECS/ELINCS List

200-338-0

### Propylparaben

California Proposition 65

Not Listed

Inventory - United States TSCA - Sect. 8(b)

Present

Australia (AICS):

Present

EU EINECS/ELINCS List

202-307-7

### Raspberry flavor

California Proposition 65

Not Listed

### Simethicone emulsion

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### 15. REGULATORY INFORMATION

California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present

#### Sodium hydroxide

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

#### Sodium metabisulfite USP

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
EU EINECS/ELINCS List	231-673-0

#### Sorbitol

California Proposition 65	Not Listed
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#### Water, purified

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 R phrases mentioned in Section 3

R61 - May cause harm to the unborn child.  
R22 - Harmful if swallowed.  
R23 - Toxic by inhalation.  
R35 - Causes severe burns.  
R31 - Contact with acids liberates toxic gas.  
R41 - Risk of serious damage to eyes.

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

#### Reasons for Revision:

Updated Section 2 - Hazard Identification. Updated Section 6 - Accidental Release Measures. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 11 - Toxicology Information. Updated Section 13 - Disposal Considerations. Updated Section 15 - Regulatory Information. Updated Section 3 - Composition / Information on Ingredients. Updated Section 4 - First Aid Measures. Updated Section 5 - Fire Fighting Measures. Updated Section 7 - Handling and Storage. Updated Section 10 - Stability and Reactivity.

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**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**