



SAFETY DATA SHEET

Revision date: 06-May-2019

Version: 2.0

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

Product Identifier

Material Name: Tafamidis Capsules, 61 mg

Trade Name: VYNDAMAX
Chemical Family: Not determined

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

Intended Use: Pharmaceutical product

Details of the Supplier of the Safety Data Sheet

Pfizer Inc
235 East 42nd Street
New York, New York 10017
1-800-879-3477

Pfizer Ltd
Ramsgate Road
Sandwich, Kent
CT13 9NJ
United Kingdom
+00 44 (0)1304 616161
Emergency telephone number:
International Chemtrec (24 hours): +1-703-527-3887

Emergency telephone number:
Chemtrec (24 hours): 1-800-424-9300
Contact E-Mail: pfizer-MSDS@pfizer.com

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification

Reproductive Toxicity: Category 1B

Label Elements

Signal Word: Danger
Hazard Statements: H360D - May damage the unborn child

Precautionary Statements: P201 - Obtain special instructions before use
P202 - Do not handle until all safety precautions have been read and understood
P281 - Use personal protective equipment as required
P308 + P313 - IF exposed or concerned: Get medical attention/advice
P405 - Store locked up
P501 - Dispose of contents/container in accordance with all local and national regulations



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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	%
Ammonium hydroxide	1336-21-6	215-647-6	Skin Corr. 1B (H314) Aquatic Acute 1 (H400)	<1.0
Butylated hydroxytoluene	128-37-0	204-881-4	Not Listed	*
ETHYL ALCOHOL	64-17-5	200-578-6	Flam. Liq. 2 (H225)	*
Iron oxide	1309-37-1	215-168-2	Not Listed	*
Isopropyl alcohol	67-63-0	200-661-7	STOT SE 3 (H336) Flam. Liq. 2 (H225) Eye Irrit. 2A (H319)	<1.0
Polyethylene glycol 400	25322-68-3	Not Listed	Not Listed	*
Tafamidis	594839-88-0	Not Listed	Repr.1B (H360D)	5-10
Titanium dioxide	13463-67-7	236-675-5	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Gelatin	9000-70-8	232-554-6	Not Listed	*
Glycerin, USP	56-81-5	200-289-5	Not Listed	*
Polysorbate 20	9005-64-5	Not Listed	Not Listed	*
Polyvinyl Acetate Phthalate	Not Assigned	Not Listed	Not Listed	*
Povidone	9003-39-8	Not Listed	Not Listed	*
Propylene glycol	57-55-6	200-338-0	Not Listed	*
Purified water	7732-18-5	231-791-2	Not Listed	*
Sorbitol	6706-59-8	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 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 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: 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 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. Cleanup 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). 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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Control Parameters

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

Butylated hydroxytoluene

ACGIH Threshold Limit Value (TWA)	2 mg/m ³
Australia TWA	10 mg/m ³
Austria OEL - MAKs	10 mg/m ³
Belgium OEL - TWA	2 mg/m ³
Bulgaria OEL - TWA	10 mg/m ³
Denmark OEL - TWA	10 mg/m ³
Finland OEL - TWA	10 mg/m ³
France OEL - TWA	10 mg/m ³
Germany - TRGS 900 - TWAs	10 mg/m ³
Germany (DFG) - MAK	10 mg/m ³ can occur as vapor and aerosol at the same time
Greece OEL - TWA	10 mg/m ³
Ireland OEL - TWAs	10 mg/m ³
Portugal OEL - TWA	2 mg/m ³
Slovenia OEL - TWA	10 mg/m ³
Spain OEL - TWA	10 mg/m ³
Switzerland OEL - TWAs	10 mg/m ³

ETHYL ALCOHOL

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

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Poland OEL - TWA	1900 mg/m ³
Portugal OEL - TWA	1000 ppm
Romania OEL - TWA	1000 ppm
	1900 mg/m ³
Russia OEL - TWA	1000 mg/m ³
Slovakia OEL - TWA	500 ppm
	960 mg/m ³
Slovenia OEL - TWA	1000 ppm
	1900 mg/m ³
Sweden OEL - TWAs	500 ppm
	1000 mg/m ³
Switzerland OEL -TWAs	500 ppm
	960 mg/m ³
Vietnam OEL - TWAs	1000 mg/m ³
Glycerin, USP	
Australia TWA	10 mg/m ³
Belgium OEL - TWA	10 mg/m ³
Czech Republic OEL - TWA	10 mg/m ³
Estonia OEL - TWA	10 mg/m ³
Finland OEL - TWA	20 mg/m ³
France OEL - TWA	10 mg/m ³
Germany (DFG) - MAK	200 mg/m ³
Greece OEL - TWA	10 mg/m ³
Ireland OEL - TWAs	10 mg/m ³
OSHA - Final PELs - TWAs:	15 mg/m ³
Poland OEL - TWA	10 mg/m ³
Portugal OEL - TWA	10 mg/m ³
Spain OEL - TWA	10 mg/m ³
Switzerland OEL -TWAs	50 mg/m ³
Iron oxide	
ACGIH Threshold Limit Value (TWA)	5 mg/m ³
Australia TWA	5 mg/m ³
	10 mg/m ³
Austria OEL - MAKs	5 mg/m ³
	10 mg/m ³
Belgium OEL - TWA	5 mg/m ³
Bulgaria OEL - TWA	5.0 mg/m ³
Denmark OEL - TWA	3.5 mg/m ³
Estonia OEL - TWA	3.5 mg/m ³
Finland OEL - TWA	5 mg/m ³
France OEL - TWA	5 mg/m ³
Greece OEL - TWA	10 mg/m ³
Hungary OEL - TWA	6 mg/m ³
Ireland OEL - TWAs	5 mg/m ³
	10 mg/m ³
	4 mg/m ³
Lithuania OEL - TWA	3.5 mg/m ³
OSHA - Final PELs - TWAs:	10 mg/m ³
	15 mg/m ³
Poland OEL - TWA	5 mg/m ³
Portugal OEL - TWA	5 mg/m ³

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Romania OEL - TWA	5 mg/m ³
Russia OEL - TWA	6 mg/m ³
Slovakia OEL - TWA	1.5 mg/m ³
Spain OEL - TWA	5 mg/m ³
Sweden OEL - TWAs	3.5 mg/m ³
Switzerland OEL - TWAs	3 mg/m ³
Vietnam OEL - TWAs	5 mg/m ³

Isopropyl alcohol

ACGIH Threshold Limit Value (TWA)	200 ppm
ACGIH Threshold Limit Value (STEL)	400 ppm
ACGIH - Biological Exposure Limit:	40 mg/L
Australia STEL	500 ppm
	1230 mg/m ³
Australia TWA	400 ppm
	983 mg/m ³
Austria OEL - MAKs	200 ppm
	500 mg/m ³
Belgium OEL - TWA	200 ppm
	500 mg/m ³
Bulgaria OEL - TWA	980.0 mg/m ³
Czech Republic OEL - TWA	500 mg/m ³
Denmark OEL - TWA	200 ppm
	490 mg/m ³
Estonia OEL - TWA	150 ppm
	350 mg/m ³
Finland OEL - TWA	200 ppm
	500 mg/m ³
Germany - TRGS 900 - TWAs	200 ppm
	500 mg/m ³
Germany (DFG) - MAK	200 ppm
	500 mg/m ³
Germany - Biological Exposure Limit:	25 mg/L
Greece OEL - TWA	400 ppm
	980 mg/m ³
Hungary OEL - TWA	500 mg/m ³
Ireland OEL - TWAs	200 ppm
Japan - OELs - Ceilings	400 ppm
	980 mg/m ³
Latvia OEL - TWA	350 mg/m ³
Lithuania OEL - TWA	150 ppm
	350 mg/m ³
OSHA - Final PELs - TWAs:	400 ppm
	980 mg/m ³
Poland OEL - TWA	900 mg/m ³
Portugal OEL - TWA	200 ppm
Romania OEL - TWA	81 ppm
	200 mg/m ³
Romania - Biological Exposure Limit:	50 mg/L
Russia OEL - TWA	10 mg/m ³
Slovakia OEL - TWA	200 ppm
	500 mg/m ³

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Slovenia OEL - TWA	200 ppm 500 mg/m ³
Spain OEL - TWA	200 ppm 500 mg/m ³
Spain - Biological Exposure Limit:	40 mg/L
Sweden OEL - TWAs	150 ppm 350 mg/m ³
Switzerland OEL -TWAs	200 ppm 500 mg/m ³
Polyethylene glycol 400	
Austria OEL - MAKs	1000 mg/m ³
Germany - TRGS 900 - TWAs	1000 mg/m ³
Germany (DFG) - MAK	1000 mg/m ³ average molecular weight 200-600
Slovakia OEL - TWA	1000 mg/m ³
Slovenia OEL - TWA	1000 mg/m ³
Switzerland OEL -TWAs	1000 mg/m ³
Propylene glycol	
Australia TWA	150 ppm 474 mg/m ³ 10 mg/m ³
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
Tafamidis	
Pfizer OEL TWA-8 Hr:	20 µg/m ³
Titanium dioxide	
ACGIH Threshold Limit Value (TWA)	10 mg/m ³
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

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Switzerland OEL - TWAs	3 mg/m ³
Vietnam OEL - TWAs	6 mg/m ³
	5 mg/m ³

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.

Personal Protective Equipment:

Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.

Hands:

Impervious gloves (e.g. Nitrile, etc.) are 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 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 half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent.)

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State: Soft gelatin capsule
Odor: No data available.
Molecular Formula: Mixture

Color: Reddish brown
Odor Threshold: No data available.
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)

Tafamidis

Predicted 7.4 Log D -0.644

Gelatin

No data available

Polyethylene glycol 400

No data available

Polysorbate 20

No data available

Povidone

No data available

Butylated hydroxytoluene

No data available

Iron oxide

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9. PHYSICAL AND CHEMICAL PROPERTIES

No data available

Purified water

No data available

d-glucitol, 1-deoxy-1-(methylamino)-, 2-(3,5-dichlorophenyl)-6-benzoxazolecarboxylate

No data available

ETHYL ALCOHOL

No data available

Glycerin, USP

No data available

Polyvinyl Acetate Phthalate

No data available

Propylene glycol

No data available

Titanium dioxide

No data available

Sorbitol

No data available

Ammonium hydroxide

No data available

Isopropyl alcohol

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: Fine particles (such as dust and mists) may fuel fires/explosions. As a precautionary measure, keep away from heat sources and electrostatic discharge.

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 various forms of the active ingredient and the individual ingredients.

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11. TOXICOLOGICAL INFORMATION

Known Clinical Effects: Adverse effects most commonly reported in clinical use include headache, sleepiness (somnolence), infection, gastrointestinal disturbances, insomnia, muscle pain.

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

Tafamidis

Dog Oral Maximally Tolerated Dose > 600 mg/kg

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

ETHYL ALCOHOL

Rat Oral LD 50 7060 mg/kg

Rat IV LD 50 1440mg/kg

Rat Inhalation LC 50 124700mg/m³

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/m³

Rat Dermal LD 50 > 21.9 g/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

Titanium dioxide

Rat Oral LD50 > 7500 mg/kg

Rat Subcutaneous LD50 50 mg/kg

Ammonium hydroxide

Rat Oral LD50 350 mg/kg

Isopropyl alcohol

Rat Oral LD50 > 2000 mg/kg

Mouse Oral LD50 3600 mg/kg

Rat Inhalation LC50-8h 16,000 ppm

Rabbit Dermal LD50 12800 mg/kg

Rat Inhalation LC50 30mg/L

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)

Tafamidis

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Skin Corrosivity (*In vitro*, RHE) Not applicable Negative
Eye Irritation (*In vitro*, BCOP) Not applicable Negative
Skin Sensitization - LLNA Mouse Negative
Skin Irritation Rabbit Negative
Eye Irritation Rabbit Minimal

Polyethylene glycol 400

Eye Irritation Rabbit Mild
Skin Irritation Rabbit Mild

Butylated hydroxytoluene

Eye Irritation Rabbit Moderate
Skin Irritation Rabbit Moderate

d-glucitol, 1-deoxy-1-(methylamino)-, 2-(3,5-dichlorophenyl)-6-benzoxazolecarboxylate

Eye Irritation (*In vitro*, BCOP) Not applicable Mild
Skin Corrosivity (*In vitro*, RHE) Not applicable Negative
Eye Irritation Rabbit Minimal
Skin Irritation Rabbit Negative
Skin Sensitization - LLNA Mouse Negative

Glycerin, USP

Eye Irritation Rabbit Mild

Propylene glycol

Skin Irritation Rabbit Mild
Eye Irritation Rabbit Mild

Ammonium hydroxide

Eye Irritation Rabbit Severe

Isopropyl alcohol

Eye Irritation Rabbit Severe
Skin Irritation Rabbit Mild

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

Tafamidis

10 Day(s)	Rat	Oral	100 mg/kg/day	NOAEL	None identified
7 Day(s)	Dog	Oral	300 mg/kg/day	NOAEL	None identified

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

d-glucitol, 1-deoxy-1-(methylamino)-, 2-(3,5-dichlorophenyl)-6-benzoxazolecarboxylate

28 Day(s)	Mouse	Oral	10 mg/kg/day	NOAEL	Liver
28 Day(s)	Rat	Oral	30 mg/kg/day	NOAEL	Thymus, Gastrointestinal system
13 Week(s)	Rat	Oral	30 mg/kg/day	NOAEL	None identified

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28 Day(s)	Dog	Oral	10 mg/kg/day	NOAEL	Gastrointestinal system, Liver
39 Week(s)	Dog	Oral	45 mg/kg/day	NOAEL	None identified
26 Week(s)	Rat	Oral	30 mg/kg/day	NOAEL	No effects at maximum dose
28 Day(s)	Mouse	Oral	120 mg/kg/day	LOAEL	Liver Lymphoid tissue

Isopropyl alcohol

20 Week(s)	Rat	Inhalation	4000 ppm	NOAEL	Liver, Central nervous system
104 Week(s)	Rat	Inhalation	5000 ppm	Kidney	

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

Butylated hydroxytoluene

Embryo / Fetal Development	Rat	Oral	6 g/kg	LOEL	Teratogenic,
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d-glucitol, 1-deoxy-1-(methylamino)-, 2-(3,5-dichlorophenyl)-6-benzoxazolecarboxylate

Reproductive & Fertility	Rat	Oral	30 mg/kg/day	NOEL	Paternal toxicity, Reproductive toxicity
Reproductive & Fertility	Rat	Oral	(F) 30 mg/kg/day	LOAEL	Maternal Toxicity
Embryo / Fetal Development	Rat	Oral	45 mg/kg/day	LOAEL	Maternal Toxicity
Embryo / Fetal Development	Rat	Oral	30 mg/kg/day	LOAEL	Fetotoxicity
Embryo / Fetal Development	Rabbit	Oral	2 mg/kg/day	LOAEL	Maternal Toxicity
Embryo / Fetal Development	Rabbit	Oral	0.5 mg/kg/day	LOAEL	Fetotoxicity
Prenatal & Postnatal Development	Rat	Oral	15 mg/kg/day	LOAEL	Fetotoxicity

Isopropyl alcohol

Prenatal & Postnatal Development	Rat	Inhalation	7,000 ppm	LOAEL	Maternal toxicity, Fetotoxicity, Embryotoxicity
2 Generation Reproductive Toxicity	Rat	Oral	1000 mg/kg/day	LOAEL	Maternal Toxicity, Fetal mortality
Prenatal & Postnatal Development	Rat	Oral	1200 mg/kg/day	NOAEL	No effects at maximum dose,

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

d-glucitol, 1-deoxy-1-(methylamino)-, 2-(3,5-dichlorophenyl)-6-benzoxazolecarboxylate

Bacterial Mutagenicity (Ames)	<i>Salmonella</i> , <i>E. coli</i>	Negative
Chromosome Aberration	Human Lymphocytes	Negative
<i>In Vivo</i> Micronucleus	Rat Bone Marrow	Negative

Isopropyl alcohol

Bacterial Mutagenicity (Ames)	<i>Salmonella</i>	Negative
Mammalian Cell Mutagenicity	HGPRT Chinese Hamster Ovary (CHO) cells	Negative
<i>In Vitro</i> Sister Chromatid Exchange		Negative

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

d-glucitol, 1-deoxy-1-(methylamino)-, 2-(3,5-dichlorophenyl)-6-benzoxazolecarboxylate

26 Week(s)	Mouse	Oral	90 mg/kg/week	NOAEL	None identified
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Carcinogen Status: See below

Povidone

IARC: Group 3 (Not Classifiable)

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11. TOXICOLOGICAL INFORMATION

Butylated hydroxytoluene

IARC: Group 3 (Not Classifiable)

Iron oxide

IARC: Group 3 (Not Classifiable)

ETHYL ALCOHOL

IARC: Group 1 (Carcinogenic to Humans)

Titanium dioxide

IARC: Group 2B (Possibly Carcinogenic to Humans)

Isopropyl alcohol

IARC: Group 3 (Not Classifiable)

12. ECOLOGICAL INFORMATION

Environmental Overview:

Environmental properties of the formulation have not been investigated. Releases to the environment should be avoided. The following information is available for the individual ingredients.

Toxicity:

ETHYL ALCOHOL

Brachydanio rerio (Zebra fish) OECD NOEC 42 Hours 500 mg/L

Glycerin, USP

Oncorhynchus mykiss (Rainbow Trout) LC50 96 Hours 50 mg/L

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

Ammonium hydroxide

Daphnia magna (Water Flea) LC50 48 Hours 0.66 mg/L

Lepomis macrochirus (Bluegill Sunfish) LC50 48 Hours 0.024 mg/L

Pimephales promelas (Fathead Minnow) LC50 96 Hours 8.2 mg/L

Persistence and Degradability:

No data available

Bio-accumulative Potential:

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

Tafamidis

Predicted 7.4 Log D -0.644

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.

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

Ammonium hydroxide

CERCLA/SARA 313 Emission reporting	Not Listed
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	1000 lb
California Proposition 65	454 kg
Inventory - United States TSCA - Sect. 8(b)	Not Listed
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Present
EU EINECS/ELINCS List	Schedule 5
	Schedule 6
	215-647-6

Butylated hydroxytoluene

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

ETHYL ALCOHOL

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	carcinogen 4/29/2011 in alcoholic beverages
	developmental toxicity 10/1/1987 in alcoholic beverages
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	200-578-6

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15. REGULATORY INFORMATION

Gelatin

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	232-554-6

Glycerin, USP

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, bio accumulative, and toxic or very persistent and very bio accumulative 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

Iron oxide

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	215-168-2

Isopropyl alcohol

CERCLA/SARA 313 Emission reporting	1.0 %
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	200-661-7

Polyethylene glycol 400

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 2 Schedule 3
EU EINECS/ELINCS List	Not Listed

Polysorbate 20

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	Not Listed

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15. REGULATORY INFORMATION

Polyvinyl Acetate Phthalate

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

Povidone

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	Not Listed

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

Purified 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

Sorbitol

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

Tafamidis

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

Titanium dioxide

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	carcinogen 9/2/2011 airborne, unbound particles of respirable size
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	236-675-5

16. OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in Section 3

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Reproductive toxicity-Cat.1B; H360D - May damage the unborn child
Skin corrosion/irritation-Cat.1B; H314 - Causes severe skin burns and eye damage
Flammable gases-Cat.2; H225 - Highly flammable liquid and vapor
Specific target organ toxicity, single exposure; Narcotic effects-Cat.3; H336 - May cause drowsiness and dizziness
Serious eye damage/eye irritation-Cat.2A; H319 - Causes serious eye irritation
Hazardous to the aquatic environment, acute toxicity-Cat.1; H400 - Very toxic to aquatic life

Data Sources: Pfizer proprietary drug development information. Publicly available toxicity information. Safety data sheets for individual ingredients.

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 8 - Exposure Controls / Personal Protection. Updated Section 12 - Ecological Information. Updated Section 11 - Toxicology Information. Updated Section 16 - Other Information.

Revision date: 06-May-2019

Product Stewardship Hazard Communication

Prepared by: Pfizer Global Environment, Health, and Safety Operations

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End of Safety Data Sheet