



SAFETY DATA SHEET

Revision date: 10-Oct-2018

Version: 2.0

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

Product Identifier

Material Name: Talazoparib Capsules

Trade Name: TALZENNA
Compound Number: MDV3800; BMN 673
Chemical Family: Dihydropyridophthalazinone

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

Intended Use: Pharmaceutical product used as Antineoplastic

Details of the Supplier of the Safety Data Sheet

Pfizer Inc
Pfizer Pharmaceuticals Group
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2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification

Germ Cell Mutagenicity: Category 2
Reproductive Toxicity: Category 1B
Specific target organ systemic toxicity (repeated exposure): Category 1

Label Elements

Signal Word: Danger
Hazard Statements: H341 - Suspected of causing genetic defects
H360D - May damage the unborn child
H372 - Causes damage to organs through prolonged or repeated exposure reproductive system blood and blood forming organs bone marrow

Precautionary Statements: P201 - Obtain special instructions before use
P202 - Do not handle until all safety precautions have been read and understood
P260 - Do not breathe dust/fume/gas/mist/vapors/spray
P270 - Do not eat, drink or smoke when using this product
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	%
Talazoparib tosylate	1373431-65-2	Not Listed	Muta 2 (H341) Repr 1B (H360D) STOT RE 1 (H372)	<2.0
Microcrystalline cellulose	9004-34-6	232-674-9	Not Listed	*
Titanium dioxide	13463-67-7	236-675-5	Not Listed	*
Ammonium hydroxide	1336-21-6	215-647-6	Skin Corr. 1B (H314) Aquatic Acute 1 (H400)	<1.0
Ferric oxide red	1309-37-1	215-168-2	Not Listed	*
Potassium hydroxide	1310-58-3	215-181-3	Acute Tox. 4 (H302) Skin Corr. 1A (H314)	<1.0
Silica colloidal, Ph. Eur.	112945-52-5	Not Listed	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Black Iron Oxide	1317-61-9	215-277-5	Not Listed	*
Hydroxypropyl methylcellulose	9004-65-3	Not Listed	Not Listed	*
Propylene glycol	57-55-6	200-338-0	Not Listed	*
Shellac	9000-59-3	232-549-9	Not Listed	*
Ferric oxide yellow	51274-00-1	257-098-5	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.

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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 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. May include oxides of carbon and nitrogen and products of sulfur and fluorine.

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 the spill if it is safe to do so. Collect spilled material by a method that controls dust generation. Avoid use of a filtered vacuum 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

Restrict access to work area. 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

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Storage Conditions: Store as directed by product packaging.
Specific end use(s): Pharmaceutical product used as Antineoplastic

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

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

Talazoparib tosylate

Pfizer OEL TWA-8 Hr: 0.02 µg/m³

Microcrystalline cellulose

ACGIH Threshold Limit Value (TWA) 10 mg/m³
Australia TWA 10 mg/m³
Belgium OEL - TWA 10 mg/m³
Estonia OEL - TWA 10 mg/m³
France OEL - TWA 10 mg/m³
Ireland OEL - TWAs 10 mg/m³
4 mg/m³
Latvia OEL - TWA 2 mg/m³
OSHA - Final PELs - TWAs: 15 mg/m³
Portugal OEL - TWA 10 mg/m³
Romania OEL - TWA 10 mg/m³
Russia OEL - TWA 6 mg/m³
Spain OEL - TWA 10 mg/m³
Switzerland OEL - TWAs 3 mg/m³
Vietnam OEL - TWAs 10 mg/m³
5 mg/m³

Titanium dioxide

ACGIH Threshold Limit Value (TWA) 10 mg/m³
Australia TWA 10 mg/m³
Austria OEL - MAKs 5 mg/m³
Belgium OEL - TWA 10 mg/m³
Bulgaria OEL - TWA 10.0 mg/m³
Denmark OEL - TWA 6 mg/m³
Estonia OEL - TWA 5 mg/m³
France OEL - TWA 10 mg/m³
Greece OEL - TWA 10 mg/m³
5 mg/m³
Ireland OEL - TWAs 10 mg/m³
4 mg/m³
Latvia OEL - TWA 10 mg/m³
Lithuania OEL - TWA 5 mg/m³
OSHA - Final PELs - TWAs: 15 mg/m³
Poland OEL - TWA 10.0 mg/m³
Portugal OEL - TWA 10 mg/m³
Romania OEL - TWA 10 mg/m³
Russia OEL - TWA 10 mg/m³
Spain OEL - TWA 10 mg/m³
Sweden OEL - TWAs 5 mg/m³
Switzerland OEL - TWAs 3 mg/m³
Vietnam OEL - TWAs 6 mg/m³
5 mg/m³

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Ferric oxide red

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
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

Potassium hydroxide

ACGIH Ceiling Threshold Limit:	2 mg/m ³
Australia PEAK	2 mg/m ³
Austria OEL - MAKs	2 mg/m ³
Bulgaria OEL - TWA	2.0 mg/m ³
Czech Republic OEL - TWA	1 mg/m ³
Estonia OEL - TWA	2 mg/m ³
Greece OEL - TWA	2 mg/m ³
Hungary OEL - TWA	2 mg/m ³
Japan - OELs - Ceilings	2 mg/m ³
Poland OEL - TWA	0.5 mg/m ³
Sweden OEL - TWAs	1 mg/m ³
Switzerland OEL - TWAs	2 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

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Lithuania OEL - TWA 7 mg/m³

Silica colloidal, Ph. Eur.

Austria OEL - MAKs 4 mg/m³

Germany (DFG) - MAK 4 mg/m³

Switzerland OEL -TWAs 4 mg/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 airborne contamination levels below the exposure limits listed above in this section. It is recommended that all operations be fully enclosed and no air recirculated.

Personal Protective Equipment:

Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). 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 disposable gloves (e.g. Nitrile, etc.) (double recommended) if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.)

Eyes:

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

Skin:

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

Respiratory protection:

Under normal conditions of use, if the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL (e.g. particulate respirator with a full mask, P3 filter). (Respirators must meet the standards in accordance with EN136, EN143, ASTM F2704-10 or international equivalent.)

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Capsule	Color:	White, Beige, or Ivory
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)	

Talazoparib tosylate

No data available

Microcrystalline cellulose

No data available

Titanium dioxide

No data available

Silica colloidal, Ph. Eur.

No data available

Hydroxypropyl methylcellulose

No data available

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9. PHYSICAL AND CHEMICAL PROPERTIES

Ferric oxide red

No data available

Shellac

No data available

Propylene glycol

No data available

Ferric oxide yellow

No data available

Black Iron Oxide

No data available

Potassium hydroxide

No data available

Ammonium hydroxide

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

Known Clinical Effects: Based on clinical trials in humans, possible adverse effects following exposure to this compound may include: decreased red blood cell count (anemia), thrombocytopenia, neutropenia, nausea, diarrhea, vomiting, and fatigue.

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

Microcrystalline cellulose

Rat Oral LD50 > 5000 mg/kg

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Rabbit Dermal LD50 > 2000 mg/kg

Titanium dioxide

Rat Oral LD50 > 7500 mg/kg
Rat Subcutaneous LD50 50 mg/kg

Hydroxypropyl methylcellulose

Rat Oral LD50 > 10,000 mg/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

Black Iron Oxide

Rat Oral LD50 >1000 mg/kg

Potassium hydroxide

Rat Oral LD50 273 mg/kg

Ammonium hydroxide

Rat Oral LD50 350 mg/kg

Safety Pharmacology:

Talazoparib tosylate: *In vitro* Cardiovascular, *In vivo* Cardiovascular, Central nervous system, and Respiratory: not significant.

Irritation / Sensitization: (Study Type, Species, Severity)

Microcrystalline cellulose

Skin Irritation Rabbit Non-irritating
Eye Irritation Rabbit Non-irritating

Propylene glycol

Skin Irritation Rabbit Mild
Eye Irritation Rabbit Mild

Potassium hydroxide

Skin Irritation Rabbit Severe
Skin Irritation Guinea Pig Severe
Eye Irritation Rabbit Moderate

Ammonium hydroxide

Eye Irritation Rabbit Severe

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

Talazoparib tosylate

28 Day(s) Rat Oral 0.05 mg/kg/day NOAEL Bone marrow, Reproductive system, Gastrointestinal System
13 Week(s) Rat Oral 0.015 mg/kg/day NOAEL Lymphatic system, Bone Marrow, Thymus, Reproductive system,
Blood forming organs, Blood

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11. TOXICOLOGICAL INFORMATION

28 Day(s) Dog Oral 0.01 mg/kg/day NOAEL Lymphatic system, Spleen, Blood, Bone Marrow
13 Week(s) Dog Oral 0.01 mg/kg/day NOAEL Blood, Reproductive system, Blood forming organs

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

Talazoparib tosylate

Embryo / Fetal Development Rat Oral 0.015 mg/kg/day LOAEL Maternal toxicity, Developmental toxicity

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

Talazoparib tosylate

Bacterial Mutagenicity (Ames) *Salmonella*, *E. coli* Negative
In Vitro Chromosome Aberration Human Lymphocytes Negative
In Vivo Micronucleus Rat Bone Marrow Positive

Carcinogen Status: See below

Titanium dioxide

IARC: Group 2B (Possibly Carcinogenic to Humans)

Silica colloidal, Ph. Eur.

IARC: Group 3 (Not Classifiable)

Ferric oxide red

IARC: Group 3 (Not Classifiable)

12. ECOLOGICAL INFORMATION

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

Toxicity: No data available

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: No data available

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

Talazoparib tosylate

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
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
EU EINECS/ELINCS List	232-674-9

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

Black 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

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EU EINECS/ELINCS List	215-277-5
Ammonium hydroxide	
CERCLA/SARA 313 Emission reporting	Not Listed
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	1000 lb 454 kg
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 5 Schedule 6
EU EINECS/ELINCS List	215-647-6
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
Ferric oxide red	
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
Potassium hydroxide	
CERCLA/SARA 313 Emission reporting	Not Listed
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	1000 lb 454 kg
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 5 Schedule 6
EU EINECS/ELINCS List	215-181-3
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
Shellac	
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	232-549-9

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15. REGULATORY INFORMATION

Silica colloidal, Ph. Eur.

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Australia (AICS):	Present
EU EINECS/ELINCS List	Not Listed

Ferric oxide yellow

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	257-098-5

16. OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in Section 3

Germ cell mutagenicity-Cat.2; H341 - Suspected of causing genetic defects
Reproductive toxicity-Cat.1B; H360D - May damage the unborn child
Specific target organ toxicity, repeated exposure-Cat.1; H372 - Causes damage to organs through prolonged or repeated exposure
Skin corrosion/irritation-Cat.1A; Skin corrosion/irritation-Cat.1B; H314 - Causes severe skin burns and eye damage
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.

Reasons for Revision: Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 3 - Composition / Information on Ingredients. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 11 - Toxicology Information. Updated Section 16 - Other Information.

Revision date: 10-Oct-2018
Product Stewardship Hazard Communication

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

Pfizer Inc believes that the information contained in this 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