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Section 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

Product Name Metronidazole Injection (Hospira, Inc.)

Product Code(s) PZ03211
Trade Name: FLAGYL
Chemical Family: Mixture

1.2. Relevant identified uses of the substance or mixture and uses advised against

Recommended Use Pharmaceutical product used as antiprotozoal agent

1.3. Details of the supplier of the safety data sheet

Hospira, A Pfizer Company Pfizer Ireland Pharmaceuticals

275 North Field Drive OSG Building

Lake Forest, Illinois 60045 Ringaskiddy, Co. Cork.

1-800-879-3477 Ireland

+353 21 4378701

E-mail address pfizer-MSDS@pfizer.com

1.4. Emergency telephone number

Emergency Telephone Chemtrec 1-800-424-9300 International Chemtrec (24 hours):+1-703-527-3887

Section 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

GHS - Classification: Regulated according to Regulation (EC) 1272/2008 and/or other applicable regulations.

Germ cell mutagenicityCategory 1B - (H340)CarcinogenicityCategory 1B - (H350)Reproductive toxicityCategory 2 - (H361d)

OSHA Classification

Hazards not otherwise classified (HNOC)

Not applicable

Hazards classified under paragraph (d)(1)(ii) of 1910.1200

Not applicable

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2.2. Label elements



Signal word

Hazard statements

Danger

H350 - May cause cancer

H340 - May cause genetic defects

H361d - Suspected of damaging the unborn child OSHA - May form combustible dust concentrations in air

1272/2008)

Precautionary Statements - EU (§28, 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 advice/attention

P405 - Store locked up

P501 - Dispose of contents/container in accordance with local, regional, national, and

international regulations as applicable

2.3. Other hazards

Other hazards

An Occupational Exposure Value has been established for one or more of the ingredients

(see Section 8).

PBT & vPvB The product does not contain any substance(s) classified as PBT or vPvB.

This product does not contain any known or suspected endocrine disruptors. **Endocrine Disruptor Information**

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.

Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Substances Not applicable

3.2 Mixtures

Hazardous

Chemical name	Weight-%	REACH	EC No (EU	Classification	Specific	M-Factor	M-Factor
		registration	Index No)	according to	concentration		(long-term)
		number	,	Regulation	limit (SCL)		
				(EC) No.			
				1272/2008			
				[CLP]			
Metronidazole	0.5		207-136-1	Carc. 1 (H350)	Not classified	No data	No data
(CAS #: 443-48-1)				Repr. 2		available	available
,				(H361d)			

				Muta.1B			
				(H340)			
Citric acid	< 0.1		201-069-1	Eye Irrit. 2A	Not classified	No data	No data
(CAS #: 77-92-9)			(607-750-00-3)	(H319)SE 3		available	available
				(H335)			
NonHazardous							
Chemical name	Weight-%	REACH	EC No (EU	Classification	Specific	M-Factor	M-Factor
		registration	Index No)	according to	concentration		(long-term)
		number		Regulation	limit (SCL)		
				(EC) No.			
				1272/2008			
				[CLP]			
Water	*	-	231-791-2	Not classified	Not classified	No data	No data
(CAS #: 7732-18-5)						available	available
SODIUM CHLORIDE	*	-	231-598-3	Not classified	Not classified	No data	No data
(CAS #: 7647-14-5)						available	available
Sodium phosphate,	*		231-448-7	Not classified	Not classified	No data	No data
dibasic						available	available
(CAS #: 7558-79-4)							

Full text of H- and EUH-phrases: see section 16

Acute Toxicity Estimate

Chemical name	Oral LD50 mg/kg		Inhalation LC50 - 4 hour - dust/mist - mg/L	Inhalation LC50 - 4 hour - vapor - mg/L	Inhalation LC50 - 4 hour - gas - ppm
Water 7732-18-5	89838.9	No data available	_	No data available	No data available
SODIUM CHLORIDE 7647-14-5	3550	10000	No data available	No data available	No data available
Sodium phosphate, dibasic 7558-79-4	17000	No data available	No data available	No data available	No data available
Metronidazole 443-48-1	3000	No data available	No data available	No data available	No data available
Citric acid 77-92-9	5400	>2000	No data available	No data available	No data available

This product does not contain candidate substances of very high concern at a concentration >=0.1% (Regulation (EC) No. 1907/2006 (REACH), Article 59).

Additional information

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.

Section 4: FIRST AID MEASURES

4.1. Description of first aid measures

Inhalation Remove to fresh air. Seek immediate medical attention/advice.

Eye contact Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids.

Consult a physician.

^{*} Proprietary

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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.

4.2. Most important symptoms and effects, both acute and delayed

Most important symptoms and

effects

For information on potential signs and symptoms of exposure, See Section 2 - Hazards

Identification and/or Section 11 - Toxicological Information.

4.3. Indication of any immediate medical attention and special treatment needed

Note to physicians None.

Section 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing media

Suitable Extinguishing MediaDry chemical, CO2, alcohol-resistant foam or water spray.

5.2. Special hazards arising from the substance or mixture

Specific hazards arising from the

chemical

Not applicable.

Hazardous combustion products

Formation of toxic gases is possible during heating or fire.

Explosion data

Sensitivity to mechanical impact No information available. **Sensitivity to static discharge** No information available.

5.3. Advice for firefighters

Special protective equipment and precautions for fire-fighters

Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear.

Use personal protection equipment.

Section 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions Personnel involved in clean-up should wear appropriate personal protective equipment (see

Section 8). Minimize exposure.

6.2. Environmental precautions

Environmental precautions Place waste in an appropriately labeled, sealed container for disposal. Care should be

taken to avoid environmental release.

6.3. Methods and material for containment and cleaning up

Methods for containment Prevent further leakage or spillage if safe to do so.

Methods for cleaning up Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean

spill area thoroughly.

Prevention of secondary hazards Clean contaminated objects and areas thoroughly observing environmental regulations.

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6.4. Reference to other sections

See section 8 for more information. See section 13 for more information. Reference to other sections

Section 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

Advice on safe handling

Avoid breathing dust/fume/gas/mist/vapors/spray. Avoid contact with skin, eyes or clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. 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.

General hygiene considerations

Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Storage Conditions Store as directed by product packaging.

7.3. Specific end use(s)

Pharmaceutical drug product. Specific use(s)

Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

Exposure Limits

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

Metronidazole

Pfizer OEL TWA-8 Hr: 700 µg/m³

SODIUM CHLORIDE

TWA: 5 mg/m³; Latvia Russia MAC: 5 mg/m³

Sodium phosphate, dibasic

MAC: 10 mg/m³ Russia

Metronidazole

Germany TRGS DS

Netherlands TWA: 0.00012 mg/m³: Russia MAC: 1 mg/m³

Citric acid

Czech Republic 4 mg/m³

Germany DFG TWA-MAK: 2 mg/m3; I(2);inhalable fraction

Peak: 4 mg/m³; respirable fraction

Germany TRGS TWA-AGW; 2 mg/m³ (exposure factor 2); inhalable fraction

Russia MAC: 1 mg/m³

Switzerland TWA-MAK: 2 mg/m3; inhalable dust STEL-KZGW: 4 mg/m3; inhalable dust

Pfizer Occupational Exposure Band

(OEB) Statement:

The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based Product Name Metronidazole Injection (Hospira, Inc.) Page 6/14 Version 4

upon an analysis of all currently available data; as such, this value may be subject to

revision when new information becomes available.

SODIUM CHLORIDE

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Pfizer Occupational Exposure Band (OEB):

OEB 1 (control exposure to the range of 1000ug/m³ to 3000ug/m³)

8.2. Exposure controls

General room ventilation is adequate unless the process generates dust, mist or fumes. **Engineering controls**

Engineering controls should be used as the primary means to control exposures. Keep airborne contamination levels below the exposure limits listed above in this section.

Refer to applicable national standards and regulations in the selection and use of personal Personal protective equipment

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.

Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the Eye/face protection

standards in accordance with EN166, ANSI Z87.1 or international equivalent.).

Hand protection 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.).

Skin and body protection 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.).

Under normal conditions of use, if the applicable Occupational Exposure Limit (OEL) is Respiratory protection

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.).

Thermal hazards No information available.

No information available. **Environmental exposure controls**

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Physical state

Color No information available Odor No information available. **Odor threshold** No information available

Property Values

Melting point / freezing point No data available Boiling point or initial boiling point and boiling range No data available

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Flammability (solid, gas) No data available

Lower and upper explosion limit/flammability limit

Lower explosion limit No data available No data available **Upper explosion limit** Flash point No data available **Autoignition temperature** No data available

Decomposition temperature No data available SADT (°C)

4.5-7.0

pH (as aqueous solution) No data available Kinematic viscosity No data available Dynamic viscosity No data available Solubility No data available No data available Vapor pressure Density and/or relative density No data available **Bulk density** No data available **Liquid Density** No data available Vapor density No data available

Particle characteristics

Particle Size No information available **Particle Size Distribution** No information available

9.2. Other information

Mixture Molecular formula Molecular weight Mixture

9.2.1. Information with regard to physical hazard classes

No information available

9.2.2. Other safety characteristics

No information available

Section 10: STABILITY AND REACTIVITY

10.1. Reactivity

Reactivity No information available.

10.2. Chemical stability

Stable up to .?°C. Stability

Explosion data

Sensitivity to mechanical impact No information available. Sensitivity to static discharge No information available.

10.3. Possibility of hazardous reactions

Possibility of hazardous reactions No information available.

10.4. Conditions to avoid

Conditions to avoid Fine particles (such as mists) may fuel fires/explosions.

10.5. Incompatible materials

Incompatible materials As a precautionary measure, keep away from strong oxidizers.

10.6. Hazardous decomposition products

Hazardous decomposition products No data available.

Section 11: TOXICOLOGICAL INFORMATION

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

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General Information: The information included in this section describes the potential hazards of the individual

ingredients

Short term Ingestion of large amounts may cause central nervous system effects.

Long Term: Animal studies have shown a potential to cause adverse effects on the fetus. Suspected of

causing cancer

Clinical use of this drug has caused peripheral neuropathy, associated with numbness and **Known Clinical Effects:**

tingling of the extremities, pain, and motor weakness. Effects on blood and blood-forming

organs have also occurred.

Acute toxicity Based on available data, the classification criteria are not met. Based on available data, the classification criteria are not met.

Serious eye damage/eye irritation

Skin corrosion/irritation Respiratory or skin sensitization

STOT - single exposure STOT - repeated exposure Reproductive toxicity

Based on available data, the classification criteria are not met. Based on available data, the classification criteria are not met. Based on available data, the classification criteria are not met.

Based on available data, the classification criteria are not met.

Suspected of damaging the unborn child. Classification is based on mixture calculation

methods based on component data.

Germ cell mutagenicity May cause genetic defects. Classification is based on mixture calculation methods based on

component data.

May cause cancer. Classification is based on mixture calculation methods based on Carcinogenicity

component data.

Based on available data, the classification criteria are not met. **Aspiration hazard**

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

SODIUM CHLORIDE

Rat Sub-tenon injection (eye) LC50/1hr > 42 g/m³

Rat Oral LD 50 3 g/kg Mouse Oral LD 50 4 g/kg Rabbit Dermal LD 50 > 10 g/kg

Metronidazole

Rat Oral LD 50 5000 g/kg

Mouse Oral LD 50 4350 mg/kg

Mouse Intraperitoneal LD 50 3650 mg/kg

Citric acid

Mouse Oral LD50 5400 mg/kg

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Water	> 90 mL/kg (Rat)	-	-
SODIUM CHLORIDE	= 3550 mg/kg (Rat)	> 10000 mg/kg (Rabbit)	> 42 mg/L (Rat)1 h
Sodium phosphate, dibasic	= 17 g/kg (Rat)	-	-
Metronidazole	= 3 g/kg (Rat)	-	-
Citric acid	= 3 g/kg (Rat)	> 2000 mg/kg (Rat)	-

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)

SODIUM CHLORIDE

Skin irritation Rabbit Mild Eye irritation Rabbit Mild

Metronidazole

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Eye Irritation Rabbit No effect

Citric acid

Eye Irritation Rabbit Severe Skin Irritation Rabbit Mild

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

Metronidazole

4 Week(s) Rat Oral 50 mg/kg/day NOAEL None identified

4 Week(s) Dog Oral 50 mg/kg/day NOAEL None identified

4 Week(s) Rat Intravenous 30 mg/kg/day LOAEL Thyroid

4 Week(s) Dog Intravenous 37.5 mg/kg/day LOAEL Thyroid

13 Week(s) Rat Oral 75 mg/kg/day LOAEL Male reproductive system

14 Week(s) Monkey Oral 45 mg/kg/day LOAEL Liver

17 Week(s) Dog Oral 75 mg/kg/day LOAEL Central Nervous System

6 Month(s) Dog Oral 75 mg/kg/day LOAEL Central Nervous System

Repeated Dose Toxicity Comments: Metronidazole produced tumors in mice and rats.

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

Reproductive & Fertility Rat Oral 400 mg/kg LOAEL Fertility

Reproductive & Fertility Rabbit Oral 200 mg/kg NOAEL Fertility, Developmental toxicity, Fetotoxicity

Embryo / Fetal Development Mouse Intraperitoneal 15 mg/kg/day LOAEL Embryotoxicity

Embryo / Fetal Development Rat Oral 200 mg/kg/day NOAEL Not Teratogenic

Embryo / Fetal Development Rabbit Oral 150 mg/kg/day NOAEL No effects at maximum dose

Embryo / Fetal Development Rat Intravenous 30 mg/kg/day NOAEL Embryotoxicity

Embryo / Fetal Development Rabbit Intravenous 15 mg/kg/day LOAEL Embryotoxicity

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

Metronidazole

Bacterial Mutagenicity (Ames) Salmonella, E. coli Positive

In Vivo Micronucleus Mouse Positive

In Vivo Unscheduled DNA Synthesis Rabbit Human / Rat Hepatocyte Positive

Dominant Lethal Assay Rat Negative

In Vivo Comet DNA Damage Human Lymphocytes Positive

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

78 Week(s) Mouse Oral, in feed 150 mg/kg/day NOAEL Tumors

80 Week(s) Rat Oral 150 mg/kg/day NOAEL Tumors

92 Week(s) Mouse Oral, in feed 150 mg/kg/day NOAEL Tumors Not specified Rat Oral, in feed 150 mg/kg/day NOAEL Tumors

Carcinogenicity See below

<u>Metronidazole</u>

IARC Group 2B

NTP Reasonably Anticipated

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Endocrine disrupting properties Based on available data, the classification criteria are not met.

11.2.2. Other information

Other adverse effects No information available.

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Section 12: ECOLOGICAL INFORMATION

Environmental Overview:

Environmental properties of the formulation have not been thoroughly investigated.

12.1. Toxicity

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

Metronidazole

Mysidopsis bahia (Mysid Shrimp) OECD LC50 96 hours > 180 mg/L

Cyprinodon variegatus (Sheepshead Minnow) OECD LC-50 96 hours > 1060 mg/L

Pseudokirchneriella subcapitata (Green Alga) ISO EC50 72 hours 39.1 mg/L

Chlorella spp Green Alga ISO EC50 72 hours 12.5 mg/L Brachydanio rerio (Zebra fish) ISO NOEC 96 hours 500 mg/L

Aquatic Toxicity Comments: A greater than (>) symbol indicates that acute ecotoxicity was not observed at the maximum

solubility. Since the substance is insoluble in aqueous solutions above this concentration,

an acute ecotoxicity value (i.e. LC/EC50) is not achievable.

Metronidazole

Activated sludge OECD EC50 100 mg/L

Metronidazole

Daphnia magna (Water Flea) N/A 21 Day(s) NOEC 250 mg/L Reproduction

12.2. Persistence and degradability

Persistence and degradability No information available.

12.3. Bioaccumulative potential

Bioaccumulation No information available.

12.4. Mobility in soil

Mobility in soil No information available.

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment

Chemical name	PBT and vPvB assessment	
SODIUM CHLORIDE	Not PBT/vPvB PBT assessment does not apply	
Sodium phosphate, dibasic	PBT assessment does not apply	
Citric acid	Not PBT/vPvB	

12.6. Endocrine disrupting properties

Endocrine disrupting properties Based on available data, the classification criteria are not met.

12.7. Other adverse effects

Other adverse effects No information available.

PMT or vPvM properties Based on available data, the classification criteria are not met.

Section 13: DISPOSAL CONSIDERATIONS

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13.1. Waste treatment methods

Waste from residues/unused products

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 wastewater 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.

Section 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.

UN number:
UN proper shipping name:
Transport hazard class(es):
Packing group:
Not applicable
Not applicable
Not applicable
Not applicable
Not applicable

Section 15: REGULATORY INFORMATION

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

Water

CERCLA/SARA Section 313 de minimus % Not Listed
California Proposition 65 Not Listed
TSCA Present
EINECS 231-791-2
AICS Present

SODIUM CHLORIDE

CERCLA/SARA Section 313 de minimus % Not Listed
California Proposition 65 Not Listed
TSCA Present
EINECS 231-598-3
AICS Present

Sodium phosphate, dibasic

CERCLA/SARA Section 313 de minimus % Not Listed **Hazardous Substances RQs** 5000 lb California Proposition 65 Not Listed Present **TSCA EINECS** 231-448-7 **AICS** Present Standard for Uniform Scheduling of Medicines and Schedule 5 Schedule 6 Poisons (SUSMP)

Metronidazole

CERCLA/SARA Section 313 de minimus % Not Listed California Proposition 65 Carcinogen

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207-136-1 **EINECS** Standard for Uniform Scheduling of Medicines and Schedule 4

Poisons (SUSMP)

Citric acid

CERCLA/SARA Section 313 de minimus % Not Listed **California Proposition 65** Not Listed **TSCA** Present 201-069-1 **EINECS** Present **AICS**

National regulations

France

Occupational Illnesses (R-463-3, France)

Chemical name	French RG number
SODIUM CHLORIDE	RG 78
7647-14-5	

Germany

Chemical Prohibition Ordinance (ChemVerbotsV)

Not applicable

TRGS 905 Not applicable

Chemical name	Netherlands - List of Carcinogens	Netherlands - List of Mutagens	Netherlands - List of Reproductive Toxins
Metronidazole 443-48-1	Present	-	-

<u>Switzerland</u>

Ordinance on the Incentive Tax on Volatile Organic Compounds (OVOC) SR 814.018 Not applicable Storage of Hazardous Material Not applicable WPO (GSchV) SR 814.201; WPA (GSchG) SR 814.20 Not applicable Major Accidents Ordinance SR 814.012 Not applicable

European Union

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work.

Authorizations and/or restrictions on use:

This product contains one or more substance(s) subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

Chemical name	Restricted substance per REACH Annex XVII	Substance subject to authorization per REACH Annex XIV
	VIIIIQY VAII	INLACTI ATTIEX ATV
Citric acid	75	-
77-92-9		

Persistent Organic Pollutants

Not applicable

Ozone-depleting substances (ODS) Regulation (EU) 2024/590 Not applicable.

EU - Plant Protection Products (1107/2009/EC)

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Chemical name	EU - Plant Protection Products (1107/2009/EC)
SODIUM CHLORIDE	Plant protection agent
7647-14-5	·

Chemical name	Biocidal Products Regulation (EU) No 528/2012 (BPR)
SODIUM CHLORIDE	Product-type 1: Human hygiene
7647-14-5	
Citric acid	Product-type 2: Disinfectants and algaecides not intended
77-92-9	for direct application to humans or animals Product-type 6:
	Preservatives for products during storage

Explosives Precursors Marketing and Use (2019/1148)

Not applicable

Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

ENCS - Japan Existing and New Chemical Substances

IECSC - China Inventory of Existing Chemical Substances

KECL - Korean Existing Chemicals Inventory

PICCS - Philippines Inventory of Chemicals and Chemical Substances

AICS - Australian Inventory of Chemical Substances

NZIoC - New Zealand Inventory of Chemicals

TCSI - Taiwan Chemical Substance Inventory

15.2. Chemical safety assessment

Chemical Safety Report No information available

Section 16: OTHER INFORMATION

Key or legend to abbreviations and acronyms used in the safety data sheet

Full text of any hazard and/or precautionary statements referred to under Sections 2-15

H350 - May cause cancer. H361d - Suspected of damaging the unborn child. H319 - Causes serious eye irritation. H340 - May cause genetic defects.

Data Sources: Pfizer proprietary drug development information. Publicly available toxicity information.

Reason 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 15 - Regulatory Information.

Updated Section 16 - Other Information.

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Prepared By Pfizer Global Environment, Health, and Safety

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

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is no known information at this time.