



# SAFETY DATA SHEET

Revision date 06-May-2024

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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  
275 North Field Drive  
Lake Forest, Illinois 60045  
1-800-879-3477

Pfizer Ireland Pharmaceuticals  
OSG Building  
Ringaskiddy, Co. Cork.  
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 mutagenicity** Category 1B - (H340)  
**Carcinogenicity** Category 1B - (H350)  
**Reproductive toxicity** Category 2 - (H361d)

### 2.2. Label elements

**Signal word** Danger

**Hazard statements** H350 - May cause cancer  
H340 - May cause genetic defects

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

## 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



## 2.3. 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 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 Registration Number	EC No	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Metronidazole (CAS #: 443-48-1)	0.5		207-136-1	Carc. 1 (H350) Repr. 2 (H361d) Muta. 1B (H340)	Not Listed	No data available	No data available
Citric acid (CAS #: 77-92-9)	< 0.1		201-069-1	Eye Irrit. 2A (H319)SE 3 (H335)	Not Listed	No data available	No data available

#### NonHazardous

Chemical name	Weight-%	REACH Registration Number	EC No	Classification according to Regulation (EC) No. 1272/2008	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
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				[CLP]			
Water (CAS #: 7732-18-5)	*	-	231-791-2	Not classified as hazardous	Not Listed	No data available	No data available
SODIUM CHLORIDE (CAS #: 7647-14-5)	*	-	231-598-3	Not classified as hazardous	Not Listed	No data available	No data available
Sodium phosphate, dibasic (CAS #: 7558-79-4)	*		231-448-7	Not classified as hazardous	Not Listed	No data available	No data available

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

## Acute Toxicity Estimate

Chemical name	Oral LD50	Dermal LD50	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	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

## 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.

## Section 4: FIRST AID MEASURES

### 4.1. Description of first aid measures

<b>Inhalation</b>	Remove to fresh air. Seek immediate medical attention/advice.
<b>Eye contact</b>	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.
<b>Skin contact</b>	Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
<b>Ingestion</b>	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.

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## 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 Media** Dry 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.

### 5.3. Advice for firefighters

**Special protective equipment 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.

**For emergency responders** Use personal protection recommended in Section 8.

### 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.

### 6.4. Reference to other sections

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

## **Section 7: HANDLING AND STORAGE**

### 7.1. Precautions for safe handling

#### **Advice on safe handling**

Avoid breathing vapor or mist. Avoid contact with eyes, skin and 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.

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## 7.2. Conditions for safe storage, including any incompatibilities

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

## 7.3. Specific end use(s)

**Specific use(s)** Pharmaceutical drug product.

## 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/m<sup>3</sup>

#### SODIUM CHLORIDE

Latvia 5 mg/m<sup>3</sup>  
Russia MAC: 5 mg/m<sup>3</sup>

#### Sodium phosphate, dibasic

Russia MAC: 10 mg/m<sup>3</sup>

#### Metronidazole

Netherlands 0.00012 mg/m<sup>3</sup>  
Russia MAC: 1 mg/m<sup>3</sup>

#### Citric acid

Czech Republic 4 mg/m<sup>3</sup>  
Germany 2 mg/m<sup>3</sup>  
Ceiling / Peak: 4 mg/m<sup>3</sup>  
Germany 2 mg/m<sup>3</sup>  
Russia MAC: 1 mg/m<sup>3</sup>  
Switzerland 2 mg/m<sup>3</sup>  
STEL: 4 mg/m<sup>3</sup>

#### 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 upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

#### SODIUM CHLORIDE

Pfizer Occupational Exposure Band (OEB): OEB 1 (control exposure to the range of 1000ug/m<sup>3</sup> to 3000ug/m<sup>3</sup>)

### 8.2. Exposure controls

#### Engineering controls

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

#### Environmental exposure controls

No information available.

#### 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.

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<b>Eye/face protection</b>	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.).
<b>Hand protection</b>	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.).
<b>Skin and body protection</b>	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.).
<b>Respiratory protection</b>	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.).
<b>General hygiene considerations</b>	Handle in accordance with good industrial hygiene and safety practice.

## Section 9: PHYSICAL AND CHEMICAL PROPERTIES

### 9.1. Information on basic physical and chemical properties

<b>Physical state</b>	Liquid
<b>Color</b>	No information available
<b>Odor</b>	No information available.
<b>Odor threshold</b>	No information available
<b>Molecular formula</b>	Mixture
<b>Molecular weight</b>	Mixture
<b>Property</b>	<b>Values</b>
<b>pH</b>	4.5-7.0
<b>Melting point / freezing point</b>	No data available
<b>Boiling point / boiling range</b>	
<b>Flash point</b>	No information available
<b>Evaporation rate</b>	No data available
<b>Flammability (solid, gas)</b>	No data available
<b>Flammability Limit in Air</b>	
<b>Upper flammability limit:</b>	No data available
<b>Lower flammability limit:</b>	No data available
<b>Vapor pressure</b>	No data available
<b>Vapor density</b>	No data available
<b>Relative density</b>	No data available
<b>Water solubility</b>	No data available
<b>Solubility(ies)</b>	No data available
<b>Partition coefficient</b>	No data available
<b>Autoignition temperature</b>	No data available
<b>Decomposition temperature</b>	No data available
<b>Kinematic viscosity</b>	No data available
<b>Dynamic viscosity</b>	No data available
<b>Particle characteristics</b>	
<b>Particle Size</b>	No information available
<b>Particle Size Distribution</b>	No information available
<b>Explosive properties</b>	No information available

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## 9.2. Other information

No information available

### 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 data available.

### 10.2. Chemical stability

Stability Stable under normal conditions of use.

### Explosion data

Sensitivity to Mechanical Impact No data available.

Sensitivity to Static Discharge No data 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

<b>General Information:</b>	The information included in this section describes the potential hazards of the individual ingredients
<b>Short term</b>	Ingestion of large amounts may cause central nervous system effects.
<b>Long Term:</b>	Animal studies have shown a potential to cause adverse effects on the fetus. Suspected of causing cancer
<b>Known Clinical Effects:</b>	Clinical use of this drug has caused peripheral neuropathy, associated with numbness and tingling of the extremities, pain, and motor weakness. Effects on blood and blood-forming organs have also occurred.
<b>Acute toxicity</b>	Based on available data, the classification criteria are not met.
<b>Serious eye damage/eye irritation</b>	Based on available data, the classification criteria are not met.
<b>Skin corrosion/irritation</b>	Based on available data, the classification criteria are not met.
<b>Respiratory or skin sensitization</b>	Based on available data, the classification criteria are not met.
<b>STOT - single exposure</b>	Based on available data, the classification criteria are not met.
<b>STOT - repeated exposure</b>	Based on available data, the classification criteria are not met.
<b>Reproductive toxicity</b>	Suspected of damaging the unborn child. Classification is based on mixture calculation methods based on component data.
<b>Germ cell mutagenicity</b>	May cause genetic defects. Classification is based on mixture calculation methods based on component data.
<b>Carcinogenicity</b>	May cause cancer. Classification is based on mixture calculation methods based on component data.
<b>Aspiration hazard</b>	Based on available data, the classification criteria are not met.

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

### SODIUM CHLORIDE

Rat Sub-tenon injection (eye) LC50/1hr > 42 g/m<sup>3</sup>

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

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



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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

### Metronidazole

IARC Group 2B (Possibly Carcinogenic to Humans)  
NTP Reasonably Anticipated To Be A Human Carcinogen

## 11.2. Information on other hazards

### 11.2.1. Endocrine disrupting properties

**Endocrine disrupting properties** No information available.

### 11.2.2. Other information

**Other adverse effects** No information available.

## 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.

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## 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	The substance is not PBT / vPvB PBT assessment does not apply
Sodium phosphate, dibasic	PBT assessment does not apply
Citric acid	The substance is not PBT / vPvB

## 12.6. Endocrine disrupting properties

**Endocrine disrupting properties** No information available.

## 12.7. Other adverse effects

No information available.

## **Section 13: DISPOSAL CONSIDERATIONS**

### 13.1. 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 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:** Not applicable  
**UN proper shipping name:** Not applicable  
**Transport hazard class(es):** Not applicable  
**Packing group:** Not applicable  
**Environmental Hazard(s):** Not applicable

**Special precautions for user:** Not applicable

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## 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
TSCA	Present
EINECS	231-448-7
AICS	Present
Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)	Schedule 5 Schedule 6

Metronidazole

CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	carcinogen 1/1/1988
EINECS	207-136-1
Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)	Schedule 4

Citric acid

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

**France**

#### Occupational Illnesses (R-463-3, France)

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

**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
Citric acid - 77-92-9	Use restricted. See item 75.	

**Persistent Organic Pollutants**

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Not applicable

## Ozone-depleting substances (ODS) regulation (EC) 1005/2009

Not applicable

## Plant protection products directive (91/414/EEC)

Chemical name	Plant protection products directive (91/414/EEC)
SODIUM CHLORIDE - 7647-14-5	Plant protection agent

### Legend:

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

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

**AICS** - Australian Inventory of Chemical Substances

## 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 H-Statements referred to under section 3

Carcinogenicity-Cat.1A; H350 - May cause cancer. Reproductive toxicity-Cat.2; H361d - Suspected of damaging the unborn child. Serious eye damage/eye irritation-Cat.2A; H319 - Causes serious eye irritation. Germ cell mutagenicity-Cat.1B; 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.

**Revision date** 06-May-2024

**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 is no known information at this time.**