



SAFETY DATA SHEET

Revision date 18-Jun-2025

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

1.1. Product identifier

Product Name Mitoxantrone Injection (Hospira, Inc.)
Product Code(s) PZ03224
Trade Name:
Chemical Family: Mixture

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

Recommended Use Pharmaceutical product used as Antineoplastic 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 1B - (H360D)

OSHA Classification

Hazards not otherwise classified (HNOC)

Not applicable

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

Not applicable

2.2. Label elements



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Signal word Danger
Hazard statements H340 - May cause genetic defects
H350 - May cause cancer
H360D - May damage the unborn child

Precautionary Statements - EU (§28, 1272/2008) P201 - Obtain special instructions before use
P202 - Do not handle until all safety precautions have been read and understood
P280 - Wear protective gloves and protective clothing
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.

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

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 (EU Index No) | Classification according to Regulation (EC) No. 1272/2008 [CLP] | Specific concentration limit (SCL) | M-Factor | M-Factor (long-term) |
|--|----------|---------------------------|---------------------|--|------------------------------------|-------------------|----------------------|
| SODIUM CHLORIDE (CAS #: 7647-14-5) | * | - | 231-598-3 | Not classified | Not classified | No data available | No data available |
| Mitoxantrone Hydrochloride (CAS #: 70476-82-3) | 0.2 | | 274-619-1 | Acute Tox. 4 (H312) Acute Tox. 4 (H302) Repr. 1B (H360D) Muta. 1B (H340) Carc. 1B (H350) | Not classified | No data available | No data available |
| + ACETIC ACID | ** | | 200-580-7 | Flam. Liq. 3 | Eye Irrit. 2 :: | No data | No data |

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| | | | | | | | |
|------------------|--|--|----------------|-----------------------------------|--|-----------|-----------|
| (CAS #: 64-19-7) | | | (607-002-00-6) | (H226) Skin Corr. 1A (H314) | 10%≤C<25% Skin Corr. 1A :: C≥90% Skin Corr. 1B :: 25%≤C<90% Skin Irrit. 2 :: 10%≤C<25% | available | available |
|------------------|--|--|----------------|-----------------------------------|--|-----------|-----------|

NonHazardous

| Chemical name | Weight-% | REACH registration number | EC No (EU Index No) | Classification according to Regulation (EC) No. 1272/2008 [CLP] | Specific concentration limit (SCL) | M-Factor | M-Factor (long-term) |
|-------------------------------------|----------|---------------------------------|------------------------|--|--|----------------------|-------------------------|
| Water (CAS #: 7732-18-5) | * | - | 231-791-2 | Not classified | Not classified | No data available | No data available |
| Sodium Acetate (CAS #: 127-09-3) | * | | 204-823-8 | Not classified | Not classified | No data available | No data available |

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

Acute Toxicity Estimate No information available

| Chemical name | Oral LD50 mg/kg | Dermal 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 | No data available |
| SODIUM CHLORIDE 7647-14-5 | 3550 | 10000 | No data available | No data available | No data available |
| Sodium Acetate 127-09-3 | 3530 | 10000 | 5.6 | No data available | No data available |
| Mitoxantrone Hydrochloride 70476-82-3 | 682 | 125 | No data available | No data available | No data available |
| + ACETIC ACID 64-19-7 | 3310 | 1060 | 11.4 | 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

* Proprietary

** to adjust pH

+ Substance with a Union workplace exposure limit

as required

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. Non-hazardous ingredients provided for completeness.

Section 4: FIRST AID MEASURES

4.1. Description of first aid measures

Inhalation

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

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

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. |
| 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 the spill if it is safe to do so. Absorb spills with non-combustible |

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Prevention of secondary hazards absorbent material and transfer into a labeled container for disposal. Clean contaminated surface thoroughly.
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

Restrict access to work area. 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 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.

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)

Specific use(s)

Pharmaceutical drug product. Antineoplastic.

Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

Exposure Limits

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

Mitoxantrone Hydrochloride

Pfizer OEL TWA-8 Hr: 0.3 µg/m³, Skin

SODIUM CHLORIDE

Latvia

TWA: 5 mg/m³;

Russia

MAC: 5 mg/m³

Sodium Acetate

Russia

MAC: 10 mg/m³

+ ACETIC ACID

ACGIH TLV

TWA: 10 ppm

STEL: 15 ppm

Austria

TWA-TMW: 10 ppm;

TWA-TMW: 25 mg/m³;

STEL-KZGW: 20 ppm (8 X 5 min);

STEL-KZGW: 50 mg/m³ (8 X 5 min);

Bulgaria

TWA: 25 mg/m³;

TWA: 10 ppm;

STEL: 50 mg/m³;

STEL: 20 ppm;

Czech Republic

25 mg/m³

Ceiling: 50 mg/m³

Denmark

TWA: 10 ppm;

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| | |
|----------------|--|
| Estonia | TWA: 25 mg/m ³ ; STEL: 50 mg/m ³ ; STEL: 20 ppm; TWA: 10 ppm; TWA: 25 mg/m ³ ; STEL: 10 ppm; STEL: 25 mg/m ³ ; |
| European Union | TWA: 25 mg/m ³ ; TWA: 10 ppm; STEL: 50 mg/m ³ ; STEL: 20 ppm; |
| Finland | TWA: 5 ppm; TWA: 13 mg/m ³ ; STEL: 10 ppm; STEL: 25 mg/m ³ ; |
| France | 25 mg/m ³ |
| Germany DFG | TWA-MAK: 10 ppm; I(2); TWA-MAK: 25 mg/m ³ ; I(2); Peak: 20 ppm; Peak: 50 mg/m ³ ; |
| Germany TRGS | TWA-AGW; 10 ppm (exposure factor 2); TWA-AGW; 25 mg/m ³ (exposure factor 2); |
| Hungary | TWA-AK: 10 ppm; TWA-AK: 25 mg/m ³ ; STEL-CK: 20 ppm; STEL-CK: 50 mg/m ³ ; |
| Ireland | TWA: 10 ppm; TWA: 25 mg/m ³ ; STEL: 20 ppm; STEL: 50 mg/m ³ ; |
| Italy MDLPS | TWA: 25 ppm; TWA: 10 mg/m ³ ; STEL: 50 mg/m ³ ; STEL: 20 ppm; |
| Latvia | TWA: 10 ppm; TWA: 25 mg/m ³ ; STEL: 50 mg/m ³ ; STEL: 20 ppm; |
| Netherlands | TWA: 10 ppm; TWA: 25 mg/m ³ ; STEL: 20 ppm; STEL: 50 mg/m ³ ; |
| Poland | TWA-NDS: 25 mg/m ³ ; STEL-NDSch: 50 mg/m ³ ; |
| Romania | TWA: 10 ppm; TWA: 25 mg/m ³ ; STEL: 20 ppm; STEL: 50 mg/m ³ ; |
| Russia | MAC: 5 mg/m ³ |
| Slovakia | Skin TWA: 10 ppm; TWA: 25 mg/m ³ ; Ceiling: 50 mg/m ³ ; |
| Spain | TWA-(VLA-ED): 10 ppm; TWA-(VLA-ED): 25 mg/m ³ ; STEL (VLA-EC): 20 ppm; STEL (VLA-EC): 50 mg/m ³ ; |
| Switzerland | TWA-MAK: 10 ppm; |

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OSHA PEL

TWA-MAK: 25 mg/m³;
STEL-KZGW: 20 ppm;
STEL-KZGW: 50 mg/m³;

United Kingdom

TWA: 10 ppm
TWA: 25 mg/m³
(vacated) TWA: 10 ppm
(vacated) TWA: 25 mg/m³
TWA: 10 ppm;
TWA: 25 mg/m³;
STEL: 20 ppm;
STEL: 50 mg/m³;

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.

8.2. 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.

Eye/face protection

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.).

Hand protection

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.).

Skin and body protection

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.).

Thermal hazards

No information available.

Environmental exposure controls

No information available.

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Section 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

| | |
|----------------|---------------------------|
| Appearance | Sterile solution |
| Physical state | Liquid |
| Color | Dark blue |
| 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 |
| Flammability (solid, gas) | No data available |
| Lower and upper explosion limit/flammability limit | |
| Lower explosion limit | No data available |
| Upper explosion limit | No data available |
| Flash point | No data available |
| Autoignition temperature | No data available |
| Decomposition temperature | |
| SADT (°C) | No data available |
| pH | 3.0-4.5 |
| pH (as aqueous solution) | No data available |
| Kinematic viscosity | No data available |
| Dynamic viscosity | No data available |
| Solubility | No data available |
| Vapor pressure | No data available |
| 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

| | |
|-------------------|---------|
| Molecular formula | Mixture |
| 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

Stability Stable under normal conditions.

Explosion data

Sensitivity to mechanical impact No information available.

Sensitivity to static discharge No information available.

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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 dust and 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

| | |
|--|---|
| General Information: | The information included in this section describes the potential hazards of the individual ingredients |
| Short term | May cause skin irritation, May cause eye irritation (based on components). |
| Long Term: | Animal studies indicate that this material may cause adverse effects on the the developing fetus. |
| Known Clinical Effects: | Adverse effects most commonly reported in clinical use include hematological effects, kidney effects, gastrointestinal disturbances, effects on cardiovascular system, liver effects and skin reaction. |
| Acute toxicity | Based on available data, the classification criteria are not met. |
| Serious eye damage/eye irritation | Based on available data, the classification criteria are not met. |
| Skin corrosion/irritation | Based on available data, the classification criteria are not met. |
| Respiratory or skin sensitization | Based on available data, the classification criteria are not met. |
| STOT - single exposure | Based on available data, the classification criteria are not met. |
| STOT - repeated exposure | Based on available data, the classification criteria are not met. |
| Reproductive toxicity | Classification is based on mixture calculation methods based on component data. |
| Germ cell mutagenicity | Classification is based on mixture calculation methods based on component data. |
| Carcinogenicity | Classification is based on mixture calculation methods based on component data. |
| Aspiration hazard | Based on available data, the classification criteria are not met. |

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

Sodium Acetate

Rat Oral LD 50 3500 mg/kg

Mouse Oral LD 50 4960 mg/kg

Mitoxantrone Hydrochloride

Rat Oral LD50 682 mg/kg

Mouse Oral LD50 502 mg/kg

Rat Dermal LD50 1640 mg/kg

Rabbit Dermal LD50 125 mg/kg

Rat Intravenous LD50 4.8 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 Acetate | = 3530 mg/kg (Rat) | > 10 g/kg (Rabbit) | > 5.6 mg/L (Rat) 4 h |

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|----------------------------|----------------------|-------------------------|-------------------------|
| Mitoxantrone Hydrochloride | = 682 mg/kg (Rat) | = 125 mg/kg (Rabbit) | - |
| + ACETIC ACID | = 3310 mg/kg (Rat) | = 1060 mg/kg (Rabbit) | = 11.4 mg/L (Rat) 4 h |

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

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

Mitoxantrone Hydrochloride

Reproductive & Fertility Rat No route specified 0.25 mg/kg LOAEL Fetotoxicity

Reproductive & Fertility Rabbit Intravenous 0.5 mg/kg NOAEL Negative

Embryo / Fetal Development Rabbit No route specified 0.2 mg/kg/day NOAEL Teratogenic

Embryo / Fetal Development Rat No route specified 6 mg/kg/day NOAEL No effects at maximum dose

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

Mitoxantrone Hydrochloride

In Vivo Cytogenetics Rat Positive

Unscheduled DNA Synthesis Rat Hepatocyte Positive

Sister Chromatid Exchange Chinese Hamster Ovary (CHO) cells Positive

In Vitro Chromosome Aberration Hamster Positive

Somatic Mutation & Recombination Test (SMART) Drosophila Positive

Carcinogenicity See below

Mitoxantrone Hydrochloride

IARC

Group 2B

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.

Section 12: ECOLOGICAL INFORMATION

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

12.1. Toxicity

12.2. Persistence and degradability

Persistence and degradability No information available.

12.3. Bioaccumulative potential

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

| Chemical name | PBT and vPvB assessment |
|-----------------|--|
| SODIUM CHLORIDE | Not PBT/vPvB PBT assessment does not apply |
| Sodium Acetate | Not PBT/vPvB PBT assessment does not apply |

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

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: Not applicable
UN proper shipping name: Not applicable
Transport hazard class(es): Not applicable
Packing group: Not applicable
Environmental Hazard(s): 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 Acetate

| | |
|---|------------|
| CERCLA/SARA Section 313 de minimus % | Not Listed |
| California Proposition 65 | Not Listed |
| TSCA | Present |
| EINECS | 204-823-8 |
| AICS | Present |

Mitoxantrone Hydrochloride

| | |
|---|---------------|
| CERCLA/SARA Section 313 de minimus % | Not Listed |
| California Proposition 65 | Carcinogen |
| EINECS | Developmental |
| | 274-619-1 |

+ ACETIC ACID

| | |
|---|------------|
| CERCLA/SARA Section 313 de minimus % | Not Listed |
| Hazardous Substances RQs | 5000 lb |
| California Proposition 65 | Not Listed |
| TSCA | Present |
| EINECS | 200-580-7 |
| AICS | Present |
| Standard for Uniform Scheduling of Medicines and Poisons (SUSMP) | Schedule 5 |
| | Schedule 6 |
| | Schedule 2 |

National regulations

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

Germany

Chemical Prohibition Ordinance (ChemVerbotsV)

Not applicable

| Chemical name | Number | Class |
|--------------------------|--------|----------|
| + ACETIC ACID 64-19-7 | 5.2.5 | Class II |

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TRGS 905

Not applicable

Switzerland

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 does not contain substances subject to authorization (Regulation (EC) No. 1907/2006 (REACH), Annex XIV) This product does not contain substances 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 |
|--------------------------|---|--|
| + ACETIC ACID 64-19-7 | 75 | - |

Persistent Organic Pollutants

Not applicable

Ozone-depleting substances (ODS) Regulation (EU) 2024/590

Not applicable.

| Chemical name | EU - Plant Protection Products (1107/2009/EC) |
|------------------------------|---|
| SODIUM CHLORIDE 7647-14-5 | Plant protection agent |
| + ACETIC ACID 64-19-7 | Plant protection agent |

| Chemical name | Biocidal Products Regulation (EU) No 528/2012 (BPR) |
|------------------------------|---|
| SODIUM CHLORIDE 7647-14-5 | Product-type 1: Human hygiene |
| Sodium Acetate 127-09-3 | Simplified procedure - Category 1 |
| + ACETIC ACID 64-19-7 | Product-type 2: Disinfectants and algaecides not intended for direct application to humans or animals Simplified procedure - Category 1 |

Explosives Precursors Marketing and Use (2019/1148)

Not applicable

Legend:

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

DSL/NDL - 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

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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

H302 - Harmful if swallowed H312 - Harmful in contact with skin H340 - May cause genetic defects H360D - May damage the unborn child H350 - May cause cancer H314 - Causes severe skin burns and eye damage H226 - Flammable liquid and vapor

Data Sources: Publicly available toxicity information. Safety data sheets for individual ingredients.

Reason for revision Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 5 - Fire Fighting Measures. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 11 - Toxicology Information. Updated Section 12 - Ecological Information.

Revision date 18-Jun-2025

Prepared By Pfizer Global Environment, Health, and Safety

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