

Revision date 19-Dec-2022 Version 2 Page 1/13

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

#### 1.1. Product identifier

Product Name Metoclopramide Injection (Hospira, Inc.)

Product Code(s) PZ03279

Synonyms Metoclopramidum
Trade Name: Not applicable
Chemical Family: Mixture

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

Recommended Use Pharmaceutical product used for nausea and vomiting (antiemetic)

#### 1.3. Details of the supplier of the safety data sheet

Hospira, A Pfizer Company Hospira UK Limited

275 North Field Drive Horizon
Lake Forest, Illinois 60045 Honey Lane
1-800-879-3477 Hurley

Maidenhead, SL6 6RJ United Kingdom

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: Not classified as hazardous according to Regulation (EC) 1272/2008 and/or other applicable regulations.

2.2. Label elements

Signal word Not Classified

Hazard statements Not classified in accordance with international standards for workplace safety.

2.3. Other hazards

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.

Page 2/13

available

available

Version 2

Product Name Metoclopramide Injection (Hospira, Inc.) Revision date 19-Dec-2022

### Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Not applicable **Substances** 

#### 3.2 Mixtures

| Hazardous | Н | la | Z | а | rc | lo | u | s |
|-----------|---|----|---|---|----|----|---|---|
|-----------|---|----|---|---|----|----|---|---|

| Chemical name                       | Weight-% | REACH<br>Registration | EC No     | Classification according to | Specific concentration        | M-Factor             | M-Factor (long-term) |
|-------------------------------------|----------|-----------------------|-----------|-----------------------------|-------------------------------|----------------------|----------------------|
|                                     |          | Number                |           | Regulation                  | limit (SCL)                   |                      |                      |
|                                     |          |                       |           | (EC) No.                    |                               |                      |                      |
|                                     |          |                       |           | 1272/2008                   |                               |                      |                      |
| Motoplopromido                      | 0.5      |                       | 206-662-9 | [CLP]<br>Acute Tox 4        | Not Listed                    | No data              | No data              |
| Metoclopramide<br>(CAS #: 364-62-5) | 0.5      |                       | 200-002-9 | (H302)                      | Not Listed                    | available            | available            |
| Sodium hydroxide                    | **       | _                     | 215-185-5 | Skin Corr.1A                | Eye Irrit. 2 ::               | No data              | No data              |
| (CAS #: 1310-73-2)                  |          | _                     | 210-100-0 | (H314)                      | 0.5%<=C<2%                    | available            | available            |
| (0/10 //. 1010 / 0 2)               |          |                       |           | (1.01.1)                    | Skin Corr. 1A                 | available            | available            |
|                                     |          |                       |           |                             | :: C>=5%                      |                      |                      |
|                                     |          |                       |           |                             | Skin Corr. 1B                 |                      |                      |
|                                     |          |                       |           |                             | :: 2%<=C<5%                   |                      |                      |
|                                     |          |                       |           |                             | Skin Irrit. 2 ::              |                      |                      |
|                                     |          |                       |           |                             | 0.5%<=C<2%                    |                      |                      |
| + Hydrochloric Acid                 | **       | -                     | 231-595-7 | Acute Tox. 3                | Eye Irrit. 2 ::               | No data              | No data              |
| (CAS #: 7647-01-0)                  |          |                       |           | (H331)                      | 10%<=C<25%                    | available            | available            |
|                                     |          |                       |           | Skin Corr. 1A               | Skin Corr. 1B                 |                      |                      |
|                                     |          |                       |           | (H314)<br>Press. Gas        | :: C>=25%<br>Skin Irrit. 2 :: |                      |                      |
|                                     |          |                       |           | Fiess. Gas                  | 10%<=C<25%                    |                      |                      |
|                                     |          |                       |           |                             | STOT SE 3 ::                  |                      |                      |
|                                     |          |                       |           |                             | C>=10%                        |                      |                      |
| NonHazardous                        |          | •                     |           |                             |                               |                      |                      |
| Chemical name                       | Weight-% | REACH                 | EC No     | Classification              | Specific                      | M-Factor             | M-Factor             |
|                                     |          | Registration          |           | according to                | concentration                 |                      | (long-term)          |
|                                     |          | Number                |           | Regulation                  | limit (SCL)                   |                      |                      |
|                                     |          |                       |           | (EC) No.                    |                               |                      |                      |
|                                     |          |                       |           | 1272/2008                   |                               |                      |                      |
| 10/-4                               | *        |                       | 004 704 0 | [CLP]                       | Not listed                    | NII-4-               | NII-4-               |
| Water                               | •        | -                     | 231-791-2 | Not classified              | Not Listed                    | No data              | No data              |
| (CAS #: 7732-18-5)                  | *        |                       | 231-598-3 | as hazardous Not classified | Not Listed                    | available<br>No data | available<br>No data |
| SODIUM CHLORIDE                     |          | _                     | ∠31-096-3 | I NOT Classified            | NOLLISIED                     | พบ นลเล              | ino data             |

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

**Acute Toxicity Estimate** No information available

(CAS #: 7647-14-5)

|   | Chemical name   | Oral LD50 | Dermal LD50       | Inhalation LC50 - 4<br>hour - dust/mist -<br>mg/L | Inhalation LC50 - 4<br>hour - vapor - mg/L |                   |
|---|-----------------|-----------|-------------------|---|--|-------------------|
| Ī | Water           | 89838.9   | No data available | No data available                                 | No data available                          | No data available |
| - | 7732-18-5       |           |                   |   |  |                   |
| Ī | SODIUM CHLORIDE | 3000      | 10000             | No data available                                 | No data available                          | No data available |
| - | 7647-14-5       |           |                   |   |  |                   |

as hazardous

Product Name Metoclopramide Injection (Hospira, Inc.) Revision date 19-Dec-2022

| Chemical name                    | Oral LD50 | Dermal LD50       |                   | Inhalation LC50 - 4<br>hour - vapor - mg/L |                   |
|----------------------------------|-----------|-------------------|-------------------|--|-------------------|
| Metoclopramide<br>364-62-5       | 750       | No data available | No data available | No data available                          | No data available |
| Sodium hydroxide<br>1310-73-2    | 325       | 1350              | No data available | No data available                          | No data available |
| + Hydrochloric Acid<br>7647-01-0 | 238       | 5010              | No data available | No data available                          | 563.3022          |

Additional information \* Proprietary

\*\* to adjust pH

+ Substance with a Union workplace exposure limit

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

Page 3/13

Version 2

completeness.

### Section 4: FIRST AID MEASURES

#### 4.1. Description of first aid measures

**Inhalation** Due to the nature of this material first aid is not normally required.

Eye contact If irritation occurs or persists, get medical attention. Rinse thoroughly with plenty of water,

also under the eyelids.

**Skin contact** Wash exposed area with soap and water, remove contaminated clothing and obtain medical

assistance if irritation occurs.

**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 As for primary cause of fire.

#### 5.2. Special hazards arising from the substance or mixture

Specific hazards arising from the

chemical

Not applicable.

Hazardous combustion products

May emit toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, hydrogen chloride and other chlorine-containing compounds.

### 5.3. Advice for firefighters

PZ03279

Product Name Metoclopramide Injection (Hospira, Inc.) Revision date 19-Dec-2022

Revision date 19-Dec-2022 Version 2

Special protective equipment for

fire-fighters

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

Page 4/13

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.

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 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 product used for nausea and vomiting (antiemetic).

#### Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

### 8.1. Control parameters

#### **Exposure Limits**

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

Metoclopramide

Pfizer OEL TWA-8 Hr: 40 µg/m<sup>3</sup>

**SODIUM CHLORIDE** 

Latvia 5 mg/m<sup>3</sup>

| evision date 19-Dec-2022 |  | version |
|--------------------------|--|---------|
| Russia                   | MAC: 5 mg/m <sup>3</sup>               |         |
| odium hydroxide          | Witte. 5 mg/m                          |         |
| ACGIH OEL (Ceiling)      | 2 mg/m³                                |         |
| ACGIH TLV                | Ceiling: 2 mg/m <sup>3</sup>           |         |
| Austria                  | 2 mg/m³                                |         |
| Austria                  | STEL 4 mg/m <sup>3</sup>               |         |
| Bulgaria                 | 2.0 mg/m <sup>3</sup>                  |         |
| Czech Republic           | 1 mg/m³                                |         |
| Czech Republic           | Ceiling: 2 mg/m <sup>3</sup>           |         |
| Danmark                  |  |         |
| Denmark                  | Ceiling: 2 mg/m <sup>3</sup>           |         |
| Estonia                  | 1 mg/m <sup>3</sup>                    |         |
| F: 1                     | STEL: 2 mg/m³                          |         |
| Finland                  | Ceiling: 2 mg/m <sup>3</sup>           |         |
| France                   | 2 mg/m <sup>3</sup>                    |         |
| Hungary                  | 1 mg/m³                                |         |
|                          | STEL: 2 mg/m <sup>3</sup>              |         |
| Ireland                  | STEL: 2 mg/m <sup>3</sup>              |         |
| Ceiling Limit Value      | 2 mg/m³                                |         |
| Latvia                   | 0.5 mg/m <sup>3</sup>                  |         |
| Poland                   | STEL: 1 mg/m <sup>3</sup>              |         |
|                          | 0.5 mg/m <sup>3</sup>                  |         |
| Romania                  | 1 mg/m <sup>3</sup>                    |         |
|                          | STEL: 3 mg/m <sup>3</sup>              |         |
| Slovakia                 | 2 mg/m <sup>3</sup>                    |         |
| Spain                    | STEL: 2 mg/m <sup>3</sup>              |         |
| Switzerland              | 2 mg/m <sup>3</sup>                    |         |
| Owitzeriana              | STEL: 2 mg/m <sup>3</sup>              |         |
| OSHA PEL                 | 2 mg/m³                                |         |
| OSHAFEL                  |  |         |
| United Kinadom           | (vacated) Ceiling: 2 mg/m <sup>3</sup> |         |
| United Kingdom           | STEL: 2 mg/m <sup>3</sup>              |         |
| Hydrochloric Acid        |  |         |
| ACGIH OEL (Ceiling)      | 2 ppm                                  |         |
| ACGIH TLV                | Ceiling: 2 ppm                         |         |
| Austria                  | 5 ppm                                  |         |
|                          | 8 mg/m³                                |         |
|                          | STEL 10 ppm                            |         |
|                          | STEL 15 mg/m <sup>3</sup>              |         |
| Bulgaria                 | STEL: 10 ppm                           |         |
|                          | STEL: 15.0 mg/m <sup>3</sup>           |         |
|                          | 5 ppm                                  |         |
|                          | 8.0 mg/m <sup>3</sup>                  |         |
| Czech Republic           | 8 mg/m³                                |         |
| •                        | Ceiling: 15 mg/m <sup>3</sup>          |         |
| Denmark                  | Ceiling: 5 ppm                         |         |
| 20                       | Ceiling: 8 mg/m <sup>3</sup>           |         |
| Estonia                  | 5 ppm                                  |         |
| Estoriid                 | 8 mg/m³                                |         |
|                          | STEL: 10 ppm                           |         |
|                          |  |         |
|                          | STEL: 15 mg/m <sup>3</sup>             |         |
| European Union           | TWA: 5 ppm                             |         |
|                          | TWA: 8 mg/m <sup>3</sup>               |         |
|                          | STEL: 10 ppm                           |         |
|                          | STEL: 15 mg/m <sup>3</sup>             |         |
| Finland                  | STEL: 5 ppm                            |         |
|                          | STEL: 7.6 mg/m <sup>3</sup>            |         |
| Germany                  | 2 ppm                                  |         |
|                          | 3.0 mg/m <sup>3</sup>                  |         |
|                          | Ceiling / Peak: 4 ppm                  |         |
|                          | Ceiling / Peak: 6 mg/m <sup>3</sup>    |         |
| Germany                  | 2 ppm                                  |         |
| y                        | - FL                                   |         |
|                          |  |         |

Product Name Metoclopramide Injection (Hospira, Inc.) Revision date 19-Dec-2022

evision date 19-Dec-2022 Version 2

3 mg/m³ Hungary 8 mg/m³

STEL: 16 mg/m<sup>3</sup>
Ireland 8 mg/m<sup>3</sup>

5 ppm STEL: 10 ppm STEL: 15 mg/m³

Italy 5 ppm 8 mg/m<sup>3</sup>

STEL: 10 ppm STEL: 15 mg/m<sup>3</sup> Page 6/13

Ceiling Limit Value 2 ppm 3.0 mg/m³

Latvia 5 ppm 8 mg/m³ CT5L 140 ppm

STEL: 10 ppm STEL: 15 mg/m³ Netherlands 8 mg/m³

STEL: 15 mg/m³

Poland STEL: 10 mg/m<sup>3</sup>

5 mg/m<sup>3</sup>
Romania 5 ppm

5 ppm 8 mg/m³ STEL: 10 ppm STEL: 15 mg/m³ MAC: 5 mg/m³ 5 ppm

 Slovakia
 5 ppm

 8.0 mg/m³

 Spain
 5 ppm

 7.6 mg/m³

STEL: 10 ppm STEL: 15 mg/m<sup>3</sup>

STEL: 15 mg/m Switzerland 2 ppm

3 mg/m<sup>3</sup> STEL: 4 ppm STEL: 6 mg/m<sup>3</sup>

U.S. - OSHA - Final PELs - Ceiling Limits 5 ppm 7 mg/m³

OSHA PEL (vacated) Ceiling: 5 ppm

(vacated) Ceiling: 7 mg/m<sup>3</sup> Ceiling: 5 ppm

Ceiling: 7 mg/m<sup>3</sup>
TWA: 1 ppm
TWA: 2 mg/m<sup>3</sup>

STEL: 5 ppm STEL: 8 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** 

Band (OEB):

United Kingdom

Russia

Pfizer Occupational Exposure OEB 1 (control expos

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

8.2. Exposure controls

**Engineering controls** Engineering controls should be used as the primary means to control exposures. General

Revision date 19-Dec-2022 Version 2

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.

Page 7/13

**Environmental exposure controls** No information available.

Product Name Metoclopramide Injection (Hospira, Inc.)

Personal protective equipment 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. Refer to applicable national standards and regulations in the

selection and use of personal protective equipment (PPE).

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 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.).

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

exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL (e.g. particulate respirator with a half mask, P3 filter).

(Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10

or international equivalent.).

General hygiene considerations 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

Physical state Liquid solution
Color Clear, colorless

Odor No information available.
Odor threshold No information available

Molecular formula Mixture
Molecular weight Mixture

<u>Property</u> <u>Values</u>

pH No data available
Melting point / freezing point No data available

Boiling point / boiling range

Flash point

Evaporation rate

Flammability (solid, gas)

No information available
No data available
No data available

Flammability Limit in Air

Upper flammability limit: No data available

Lower flammability limit: No data available

Vapor pressureNo data availableVapor densityNo data availableRelative densityNo data availableWater solubilityNo data availableSolubility(ies)No data availablePartition coefficientNo data available

Page 8/13

Revision date 19-Dec-2022 Version 2

Autoignition temperatureNo data availableDecomposition temperatureNo data availableKinematic viscosityNo data availableDynamic viscosityNo data availableParticle characteristics

Particle SizeNo information availableParticle Size DistributionNo information availableExplosive propertiesNo information available

#### 9.2. Other information

No information available

#### 9.2.1. Information with regard to physical hazard classes

Product Name Metoclopramide Injection (Hospira, Inc.)

No information available

Oxidizing properties None

#### 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.

**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 None known.

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** Accidental ingestion may cause effects similar to those seen in clinical use.

Known Clinical Effects: Therapeutic use of this substance has resulted in weakness, dizziness, drowsiness, ataxia,

confusion, tremors, headache, and gastrointestinal disturbances. As with all antipsychotic agents, tardive dyskinesia may appear. This syndrome is characterized by rhythmical involuntary movements of the tongue, face, mouth, or jaw. Hypersensitivity reactions may

also occur in susceptible individuals.

**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.

**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.

Product Name Metoclopramide Injection (Hospira, Inc.)
Revision date 19-Dec-2022

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.
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.

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

<u>Metoclopramide</u>

Rat Oral LD 50 750 mg/kg Mouse Oral LD 50 270 mg/kg

Rat Intraperitoneal LD 50 114 mg/kg

Sodium hydroxide

Mouse IP LD50 40 mg/kg

| Chemical name       | Oral LD50             | Dermal LD50              | Inhalation LC50      |
|---------------------|-----------------------|--------------------------|----------------------|
| Water               | > 90 mL/kg (Rat)      | -                        | -                    |
| SODIUM CHLORIDE     | = 3 g/kg (Rat)        | > 10000 mg/kg ( Rabbit ) | > 42 mg/L (Rat)1 h   |
| Metoclopramide      | = 750 mg/kg (Rat)     | -                        | -                    |
| Sodium hydroxide    | = 325 mg/kg (Rat)     | = 1350 mg/kg ( Rabbit )  | -                    |
| + Hydrochloric Acid | 238 - 277 mg/kg (Rat) | > 5010 mg/kg (Rabbit)    | = 1.68 mg/L (Rat)1 h |

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

SODIUM CHLORIDE

Skin irritation Rabbit Mild Eye irritation Rabbit Mild

+ Hydrochloric Acid

Skin irritation Severe Eye irritation Severe

Sodium hydroxide

Eye Irritation Rabbit Severe Skin Irritation Rabbit Severe

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

Metoclopramide

Embryo / Fetal Development Rat Oral 10 mg/kg/day NOEL Not teratogenic Embryo / Fetal Development Rabbit Oral 10 mg/kg/day NOEL Not Teratogenic Embryo / Fetal Development Mouse Oral 10 mg/kg/day NOEL Not Teratogenic

Embryo / Fetal Development Rabbit Intravenous 10 mg/kg NOEL Not Teratogenic

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

+ Hydrochloric Acid

Bacterial Mutagenicity (Ames) Salmonella Negative

In Vivo Micronucleus Rat Negative

Carcinogenicity None of the components of this formulation are listed as a carcinogen by IARC, NTP or

OSHA

+ Hydrochloric Acid

IARC Group 3 (Not Classifiable)

PZ03279

Page 9/13 Version 2

Page 10 / 13

Product Name Metoclopramide Injection (Hospira, Inc.) Revision date 19-Dec-2022

Revision date 19-Dec-2022 Version 2

#### 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 have not been investigated. Releases to the environment should

be avoided.

12.1. Toxicity

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 No information available.

| Chemical name       | PBT and vPvB assessment                             |
|---------------------|---|
| SODIUM CHLORIDE     | The substance is not PBT / vPvB PBT assessment does |
|                     | not apply   |
| Sodium hydroxide    | The substance is not PBT / vPvB PBT assessment does |
|                     | not apply   |
| + Hydrochloric Acid | The substance is not PBT / vPvB PBT assessment does |
|                     | not apply   |

#### 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

PZ03279

Product Name Metoclopramide Injection (Hospira, Inc.) Revision date 19-Dec-2022

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.

Not applicable **UN number:** UN proper shipping name: Not applicable Not applicable Transport hazard class(es): Not applicable Packing group: Not applicable **Environmental Hazard(s):** Not applicable Special precautions for user:

### 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                                  | NI-4 I Satard         |
| CERCLA/SARA Section 313 de minimus %             | Not Listed            |
| California Proposition 65                        | Not Listed<br>Present |
| TSCA<br>EINECS                                   | 231-598-3             |
| AICS   | Present               |
| Metoclopramide                                   | 1 1030III             |
| CERCLA/SARA Section 313 de minimus %             | Not Listed            |
| California Proposition 65                        | Not Listed            |
| EINECS   | 206-662-9             |
| Standard for Uniform Scheduling of Medicines and | Schedule 3            |
| Poisons (SUSMP)                                  | Schedule 4            |
| Sodium hydroxide                                 |                       |
| CERCLA/SARA Section 313 de minimus %             | Not Listed            |
| Hazardous Substances RQs                         | 1000 lb               |
| California Proposition 65 TSCA                   | Not Listed<br>Present |
| EINECS   | 215-185-5             |
| AICS   | Present               |
| Standard for Uniform Scheduling of Medicines and | Schedule 5            |
| Poisons (SUSMP)                                  | Schedule 6            |
| + Hydrochloric Acid                              | 222                   |
| CERCLA/SARA Section 313 de minimus %             | 1.0 %                 |
| Hazardous Substances RQs                         | 5000 lb               |
| California Proposition 65                        | Not Listed            |

Present

PZ03279

**TSCA** 

Page 11 / 13

Version 2

Product Name Metoclopramide Injection (Hospira, Inc.) Revision date 19-Dec-2022

**EINECS** 231-595-7 **AICS** Present Standard for Uniform Scheduling of Medicines and Schedule 5 Poisons (SUSMP) Schedule 6

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

#### **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)

|                                 |                                | <u> </u>                               |
|---------------------------------|--------------------------------|--|
| Chemical name                   | Restricted substance per REACH | Substance subject to authorization per |
|                                 | Annex XVII                     | REACH Annex XIV                        |
| Sodium hydroxide - 1310-73-2    | Use restricted. See item 75.   |  |
| + Hydrochloric Acid - 7647-01-0 | Use restricted. See item 75.   |  |

#### **Persistent Organic Pollutants**

Not applicable

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

Not applicable

| Chemical name                   | Lower-tier requirements (tons) | Upper-tier requirements (tons) |
|---------------------------------|--------------------------------|--------------------------------|
| + Hydrochloric Acid - 7647-01-0 | 25                             | 250                            |

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

| Chemical name                   | EU - Biocides   |
|---------------------------------|---|
| + Hydrochloric Acid - 7647-01-0 | Product-type 2: Disinfectants and algaecides not intended |
| , i                             | for direct application to humans or animals               |

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

No information available **Chemical Safety Report** 

#### 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

Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed Skin corrosion/irritation-Cat.1A; Skin corrosion/irritation-Cat.1B; H314 -Causes severe skin burns and eye damage Acute toxicity, inhalation-Cat.3; H331 - Toxic if inhaled

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

PZ03279

Page 12 / 13

Version 2

Product Name Metoclopramide Injection (Hospira, Inc.)
Revision date 19-Dec-2022

Revision date 19-Dec-2022 Version 2

Reason for revision Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information

on Ingredients. Updated Section 5 - Fire Fighting Measures. Updated Section 11 -

Page 13 / 13

Toxicology Information. Updated Section 12 - Ecological Information.

Revision date 19-Dec-2022

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.