



SAFETY DATA SHEET

Revision date 10-Feb-2022

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

1.1. Product identifier

Product Name	Lidocaine Hydrochloride Injection (Hospira, Inc.)
Product Code(s)	PZ03337
Synonyms	Lidocaine
Trade Name:	Lignocaine Injection
Chemical Family:	Not determined

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

Recommended Use	Pharmaceutical product anesthetic agent
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1.3. Details of the supplier of the safety data sheet

Quantung, Lda. RUA PADRE VINCENTE MARIA DA ROCHA +351 9621 63100	384J 3840-453 VAGOS, PORTUGAL +351 91910 8800
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1.4. Emergency telephone number

Emergency Telephone	(24 hours):+351 91910 8800
E-mail address	info@quantung.com

Section 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

GHS - Classification: Not classified as hazardous

2.2. Label elements

Signal word	Not Classified
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Hazard statements	Not classified in accordance with international standards for workplace safety.
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2.3. Other hazards

Other hazards	An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).
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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)
Lidocaine Hydrochloride 73-78-9	1-2		200-803-8	Acute Tox.4 (H302)	Not Listed	No data available	No data available
Sodium hydroxide 1310-73-2	**		215-185-5	Skin Corr.1A (H314)	Eye Irrit. 2 :: 0.5%<=C<2% Skin Corr. 1A :: C>=5% Skin Corr. 1B :: 2%<=C<5% Skin Irrit. 2 :: 0.5%<=C<2%	No data available	No data available
+ Hydrochloric Acid 7647-01-0	**		231-595-7	Acute Tox. 3 (H331) Skin Corr. 1A (H314) Press. Gas	Eye Irrit. 2 :: 10%<=C<25% Skin Corr. 1B :: C>=25% Skin Irrit. 2 :: 10%<=C<25% STOT SE 3 :: C>=10%	No data available	No data available

NonHazardous

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)
Water 7732-18-5	*		231-791-2	No data available	Not Listed	No data available	No data available
SODIUM CHLORIDE 7647-14-5	*		231-598-3	No data available	Not Listed	No data available	No data available

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

Acute Toxicity Estimate

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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
Lidocaine Hydrochloride 73-78-9	317	No data available	No data available	No data available	No data available
Sodium hydroxide 1310-73-2	325	1350	No data available	No data available	No data available
SODIUM CHLORIDE 7647-14-5	3000	10000	No data available	No data available	No data available
+ Hydrochloric Acid 7647-01-0	238	5010	No data available	No data available	563.3022

Additional information

+ Substance with a Union workplace exposure limit

* Proprietary

** to adjust pH

Non-hazardous ingredients provided for completeness. Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

Section 4: FIRST AID MEASURES

4.1. Description of first aid measures

Inhalation	Remove to fresh air. Seek immediate medical attention/advice.
Eye contact	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.
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

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Specific hazards arising from the chemical Fine particles (such as dust and mists) may fuel fires/explosions.

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 Contain the source of the spill or leak if it is safe to do so. Collect spill with a non-combustible absorbent material and transfer to labeled container for disposal.

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 drug product.

Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

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Exposure Limits

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

Lidocaine Hydrochloride

Pfizer OEL TWA-8 Hr: 300 STEL 2500 $\mu\text{g}/\text{m}^3$, Skin

Sodium hydroxide

ACGIH OEL (Ceiling)	2 mg/m^3
ACGIH TLV	Ceiling: 2 mg/m^3
Austria	2 mg/m^3 STEL 4 mg/m^3
Bulgaria	2.0 mg/m^3
Czech Republic	1 mg/m^3 Ceiling: 2 mg/m^3
Denmark	Ceiling: 2 mg/m^3
Estonia	1 mg/m^3 STEL: 2 mg/m^3
Finland	Ceiling: 2 mg/m^3
France	2 mg/m^3
Hungary	1 mg/m^3 STEL: 2 mg/m^3
Ireland	STEL: 2 mg/m^3
Ceiling Limit Value	2 mg/m^3
Latvia	0.5 mg/m^3
Poland	STEL: 1 mg/m^3 0.5 mg/m^3
Romania	1 mg/m^3 STEL: 3 mg/m^3
Slovakia	2 mg/m^3
Spain	STEL: 2 mg/m^3
Switzerland	2 mg/m^3 STEL: 2 mg/m^3
OSHA PEL	2 mg/m^3 (vacated) Ceiling: 2 mg/m^3
United Kingdom	STEL: 2 mg/m^3

SODIUM CHLORIDE

Latvia	5 mg/m^3
Russia	MAC: 5 mg/m^3

+ Hydrochloric Acid

ACGIH OEL (Ceiling)	2 ppm
ACGIH TLV	Ceiling: 2 ppm
Austria	5 ppm 8 mg/m^3 STEL 10 ppm STEL 15 mg/m^3
Bulgaria	STEL: 10 ppm STEL: 15.0 mg/m^3 5 ppm 8.0 mg/m^3
Czech Republic	8 mg/m^3 Ceiling: 15 mg/m^3
Denmark	Ceiling: 5 ppm Ceiling: 8 mg/m^3
Estonia	5 ppm 8 mg/m^3 STEL: 10 ppm STEL: 15 mg/m^3
European Union	TWA: 5 ppm TWA: 8 mg/m^3 STEL: 10 ppm STEL: 15 mg/m^3

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Finland	STEL: 5 ppm STEL: 7.6 mg/m ³
Germany	2 ppm 3.0 mg/m ³ Ceiling / Peak: 4 ppm Ceiling / Peak: 6 mg/m ³
Germany	2 ppm 3 mg/m ³
Hungary	8 mg/m ³ STEL: 16 mg/m ³
Ireland	8 mg/m ³ 5 ppm STEL: 10 ppm STEL: 15 mg/m ³
Italy	5 ppm 8 mg/m ³ STEL: 10 ppm STEL: 15 mg/m ³
Ceiling Limit Value	2 ppm 3.0 mg/m ³
Latvia	5 ppm 8 mg/m ³ STEL: 10 ppm STEL: 15 mg/m ³
Netherlands	8 mg/m ³ STEL: 15 mg/m ³
Poland	STEL: 10 mg/m ³ 5 mg/m ³
Romania	5 ppm 8 mg/m ³ STEL: 10 ppm STEL: 15 mg/m ³
Russia	MAC: 5 mg/m ³
Slovakia	5 ppm 8.0 mg/m ³
Spain	5 ppm 7.6 mg/m ³ STEL: 10 ppm STEL: 15 mg/m ³
Switzerland	2 ppm 3 mg/m ³ STEL: 4 ppm STEL: 6 mg/m ³
U.S. - OSHA - Final PELs - Ceiling Limits	5 ppm 7 mg/m ³
OSHA PEL	(vacated) Ceiling: 5 ppm (vacated) Ceiling: 7 mg/m ³ Ceiling: 5 ppm Ceiling: 7 mg/m ³
United Kingdom	TWA: 1 ppm TWA: 2 mg/m ³ STEL: 5 ppm STEL: 8 mg/m ³

SODIUM CHLORIDE

Pfizer Occupational Exposure
Band (OEB):

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

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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.

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.
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	Solution
Color	Clear, colorless
Odor	No information available.
Odor threshold	No information available
Molecular formula	Mixture
Molecular weight	Mixture
Property	Values
pH	5-7
Melting point / freezing point	No data available
Boiling point / boiling range	
Flash point	No information available
Evaporation rate	No data available
Flammability (solid, gas)	No data available
Flammability Limit in Air	
Upper flammability limit:	No data available
Lower flammability limit:	No data available
Vapor pressure	No data available
Vapor density	No data available
Relative density	No data available
Water solubility	No data available
Solubility(ies)	No data available
Partition coefficient	No data available

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Autoignition temperature	No data available
Decomposition temperature	No data available
Kinematic viscosity	No data available
Dynamic viscosity	No data available
Particle characteristics	
Particle Size	No information available
Particle Size Distribution	No information available
Explosive properties	No information available

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.

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 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:

There are no data for this formulation. The information included in this section describes the potential hazards of the individual ingredients

Short term

Harmful if swallowed May cause mild eye irritation. May cause slight skin irritation. (based on components) Drugs of this class have been associated with rare, but potentially serious cardiac events. These events have not been observed from occupational exposures, however, those with preexisting cardiovascular illnesses may be at increased risk from exposure.

Known Clinical Effects:

Adverse effects associated with therapeutic use include dizziness, nervousness, agitation, drowsiness, apprehension, euphoria, blurred/double vision, slurred speech, tremors, convulsions, and seizure. Respiratory depression and arrest may follow. Other, more serious effects seen with IV use of this drug, particularly when it is administered rapidly, are cardiovascular collapse, central nervous system depression, and/or hypotension.

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

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Lidocaine Hydrochloride

Rat Oral LD50 317 mg/kg
Rat Para-periosteal LD50 25 mg/kg
Rat Intraperitoneal LD50 133 mg/kg
Mouse Oral LD50 292 mg/kg
Mouse Intravenous LD50 19.5 mg/kg

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 hydroxide

Mouse IP LD50 40 mg/kg

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

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

Lidocaine Hydrochloride

Eye Irritation Rabbit Mild
Skin Irritation Rabbit Mild

+ Hydrochloric Acid

Skin irritation Severe
Eye irritation Severe

SODIUM CHLORIDE

Skin irritation Rabbit Mild
Eye irritation Rabbit Mild

Sodium hydroxide

Eye Irritation Rabbit Severe
Skin Irritation Rabbit Severe

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

Lidocaine Hydrochloride

Embryo / Fetal Development Rat Subcutaneous 30 mg/kg NOAEL Not teratogenic
Embryo / Fetal Development Rat Intraperitoneal 56 mg/kg NOAEL Not Teratogenic
Embryo / Fetal Development Rat Intraperitoneal 72 mg/kg/day NOAEL Not Teratogenic
Embryo / Fetal Development Rat Intravenous 500 mg/kg/day LOAEL Fetotoxicity
Embryo / Fetal Development Rat Intraperitoneal 6 mg/kg LOAEL Developmental toxicity

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

Lidocaine Hydrochloride

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

+ 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)

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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 thoroughly investigated. Releases to the environment should be avoided.

12.1. Toxicity

No information available

12.2. Persistence and degradability

Persistence and degradability No information available.

12.3. Bioaccumulative potential

Bioaccumulation No information available.

12.4. Mobility in soil

Mobility in soil No information available.

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment

Chemical name	PBT and vPvB assessment
Sodium hydroxide	The substance is not PBT / vPvB PBT assessment does not apply
SODIUM CHLORIDE	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

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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.

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

Lidocaine Hydrochloride

CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
TSCA	Present
EINECS	200-803-8

Sodium hydroxide

CERCLA/SARA Section 313 de minimus %	Not Listed
Hazardous Substances RQs	1000 lb
California Proposition 65	Not Listed
TSCA	Present
EINECS	215-185-5
AICS	Present
Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)	Schedule 5 Schedule 6

SODIUM CHLORIDE

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

+ Hydrochloric Acid

CERCLA/SARA Section 313 de minimus %	1.0 %
Hazardous Substances RQs	5000 lb
California Proposition 65	Not Listed
TSCA	Present
EINECS	231-595-7
AICS	Present
Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)	Schedule 5 Schedule 6

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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
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

Named dangerous substances per Seveso Directive (2012/18/EU)

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

Plant protection products directive (91/414/EEC)

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

EU - Biocides

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

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

Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed Skin corrosion/irritation-Cat.1A; H314 - Causes severe skin burns and eye damage Specific target organ toxicity, single exposure; Respiratory tract irritation-Cat.3; H335 - May cause respiratory irritation

Data Sources:

Publicly available toxicity information. Pfizer proprietary drug development information. Safety data sheets for individual ingredients.

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Reason for revision Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 3 - Composition / Information on Ingredients. Updated Section 11 - Toxicology Information. Updated Section 12 - Ecological Information. Updated Section 15 - Regulatory Information. Updated Section 16 - Other Information.

Revision date 10-Feb-2022

Prepared By Quantung Pharma Environment, Health, and Safety

Quantung, Lda., 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 thereis no known information at this time.