

HDL-C DIRETO 1160XXX

FDS0202ENG-REV02 Revision date: 10/2023

Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade Name: HDL-C Direto Reagent R1

Article n°: 1160XXX MS: 80115310267

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

General use: Reagent for in-vitro diagnostics in human samples

For professional use only.

1.3 Details of the supplier of the safety data sheet

Kovalent do Brasil Ltda.

Rua Cristóvão Sardinha, 110 – Jd. Bom Retiro – São Gonçalo – RJ – Brasil.

Tel: +(55 21) 2623-1367

e-mail: kovalent@kovalent.com.br

1.4 Emergency telephone number

Tel: +(55 21) 2623-1367 - Costumer service 8AM to 5PM.

0800 015 1414

In case of emergency

24 hours service

0800-722-6001 - RENACIAT (Rede Nacional de Centros de Informação e Assistência Toxicológica)

2 Hazards Identification

2.1 Classification of the substance or mixture

Classification according to ABNT NBR 14725.

Skin Sens. 1; H317 May cause an allergic skin reaction.

2.2 Label elements

Labelling (GHS)



Pictogram:

Signal word: Warning

Hazard statements: H317 May cause an allergic skin reaction.

Precautionary statements: P280 Wear protective gloves/protective clothing/eye protection.

P302+P352 IF ON SKIN: Wash with plenty of water/soap.

Special labelling

Text for labelling: Contains Mixture of 5-chlorine-2-methyl-2H-isothiazol-3-on and 2-methylen-2H-isothiazol-3-on (3:1)

2.3 Other hazards

Special danger of slipping by leaking/spilling product.

Endocrine disrupting properties, Results of PBT and vPvB assessment:

No data available

3 Composition/information on ingredients

3.1 Substances

Not applicable

3.2 Mixtures

Chemical characterization: Aqueous solution.

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Hazardous ingredients:

Identifiers	Designation Classification	Content
list no. 611-341-5 CAS 55965-84-9	Mixture of 5-chlorine-2-methyl-2H-isothiazol-3-on and 2-methylen-2H-isothiazol-3-on (3:1) Acute Tox. 3; H301. Acute Tox. 2; H310. Acute Tox. 2; H330. Skin Corr. 1C; H314. Eye Dam. 1; H318. Skin Sens. 1A; H317. Aquatic Acute 1; H400. Aquatic Chronic 1; H410. (EUH071). Specific concentration limits (SCL): Skin Corr. 1C; H314: C ≥ 0,6 % / Skin Irrit. 2; H315: 0,06 % ≤ C < 0,6 % / Eye Dam. 1; H318: C ≥ 0,6 % / Eye Irrit. 2; H319: 0,06 ≤ C < 0,6 % Skin Sens. 1A; H317: C ≥ 0,0015 % M-factors: Aquatic Acute 1: M = 100. Aquatic Chronic 1: M = 100.	0,0015 - 0,0025 %

Full text of H- and EUH-statements: see section 16.

4 First aid measures

4.1 Description of first aid measures

General information: If medical advice is needed, have product container or label at hand.

In case of inhalation: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for

breathing. Seek medical attention if problems persist.

Following skin contact: Take off contaminated clothing and wash it before reuse. After contact with skin, wash

immediately with plenty of water. In case of skin reactions, consult a physician.

After eye contact: Immediately flush eyes with plenty of flowing water for 10 to 15 minutes holding eyelids apart.

Remove contact lenses, if present and easy to do. Continue rinsing. Subsequently consult an

ophthalmologist.

After swallowing: Rinse mouth immediately and drink plenty of water. Never give anything by mouth to an

unconscious person. Seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

May cause an allergic skin reaction.

4.3 Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

5 Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media: Product is non-combustible. Extinguishing materials should therefore be

selected according to surroundings.

Extinguishing media which must not be used for safety reasons:

Full water jet

5.2 Special hazards arising from the substance or mixture

Fires in the immediate vicinity may cause the development of dangerous vapours.

In the event of a fire, the following may be produced when the water evaporates: sulphur oxides, nitrogen oxides (NOx), carbon monoxide and carbon dioxide.

5.3 Advice for firefighters

Special protective equipment for firefighters: Wear self-contained breathing apparatus.

Additional information: Do not allow water used to extinguish fire to enter drains, ground or

waterways.

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6 Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Provide adequate ventilation. Do not breathe vapours. Avoid contact with skin and eyes. Wear appropriate protective equipment. Take off contaminated clothing and wash it before reuse. If possible, eliminate leakage. Keep unprotected people away.

6.2 Environmental precautions

Do not allow to penetrate into soil, waterbodies or drains.

6.3 Methods and material for containment and cleaning up

Soak up with absorbent materials such as sand, siliceous earth, acid- or universal binder. Store in special closed containers and dispose of according to ordinance. Final cleaning.

Additional information: Special danger of slipping by leaking/spilling product.

6.4 Reference to other sections

Refer additionally to section 8 and 13.

Handling and storage

7.1 Precautions for safe handling

Advices on safe handling: Provide adequate ventilation, and local exhaust as needed. Avoid contact

with skin and eyes. Wear appropriate protective equipment. Do not breathe

vapors.

Have eye wash bottle or eye rinse ready at workplace. Take off contaminated clothing and wash it before reuse. When using do not eat or drink. Wash hands before breaks and after work. Keep all containers,

equipment and working place clean.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storerooms and containers: Keep containers tightly closed and at a temperature between 2°C and 8°C.

Protect from direct sunlight. Keep sterile.

Hints on joint storage: Do not store together with strong acids and alkalis.

Keep away from food, drink and animal feeding stuffs.

Storage class: 12 = Non-combustible liquids

7.3 Specific end use(s)

No information available.

8 Exposure controls/personal protection

8.1 Control parameters

Additional information: Contains no substances with occupational exposure limit values.

8.2 Exposure controls

Provide good ventilation and/or an exhaust system in the work area.

Personal protection equipment Occupational exposure controls

Respiratory protection: If vapors form, use respiratory protection.

Use combination filter type A/P according to EN 14387.

Hand protection: Protective gloves according to EN 374.

Glove material: Nitrile rubber-Breakthrough time: >480 min.

Observe glove manufacturer's instructions concerning penetrability and breakthrough time.

Eye protection: Tightly sealed goggles according to EN 166.

Body protection: Wear suitable protective clothing.

General protection and hygiene measures:

Do not breathe vapors. Take off contaminated clothing and wash it before reuse. Avoid contact with skin and eyes. Wash hands before breaks and after work. When using do not eat or drink.

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Have eye wash bottle or eye rinse ready at workplace.

Environmental exposure controls

Do not penetrate into soil, waterbodies or drains.

9 Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state at 20 °C and 101.3 kPa Liquid

Colour: Clear, colourless up to slightly pink

Odour: No characteristic odour

Odour threshold: No data available

Melting point/freezing point:

No data available

Initial boiling point and boiling range: No data available

Flammability: No data available

Upper/lower flammability or explosive limits: No data available

Flash point/flash point range: Not combustible

Decomposition temperature: No data available

pH: at 25 °C: approx. 6.90

Viscosity, kinematic: No data available

Water solubility: at 20 °C: completely miscible

Partition coefficient: n-octanol/water: No data available

Vapor pressure: No data available

Density: at 20 °C: 1.0057 g/mL

Vapor density: No data available

Particle characteristics: Not applicable

9.2 Other information

Explosive properties: No data available

Oxidizing characteristics: No data available

Auto-ignition temperature: No data available

Evaporation rate: No data available

Additional information: No data available

10 Stability and reactivity

10.1 Reactivity

Refer to subsection "Possibility of hazardous reactions".

10.2 Chemical stability

Stable under recommended storage conditions.

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10.3 Possibility of hazardous reactions

No hazardous reactions know.

10.4 Conditions to avoid

Protect from frost, heat and sunlight.

10.5 Incompatible materials

Strong acids and alkalis.

10.6 Hazardous decomposition products

No decomposition when used properly.

No data available Thermal decomposition:

Toxicological information

Toxicological effects: The statements are derived from the properties of the single components. No

toxicological data is available for the product as such.

Acute toxicity (oral): Lack of data. Acute toxicity (dermal): Lack of data. Acute toxicity (inhalative): Lack of data. Skin corrosion/irritation: Lack of data. Serious eye damage/irritation: Lack of data. Sensitisation to the respiratory tract: Lack of data.

Skin sensitisation: Skin Sens. 1; H317 = May cause an allergic skin reaction.

Lack of data.

Germ cell mutagenicity/Genotoxicity: Lack of data. Carcinogenicity: Lack of data. Reproductive toxicity: Lack of data. Effects on or via lactation: Lack of data. Specific target organ toxicity: Lack of data.

(single exposure)

Aspiration hazard:

Specific target organ toxicity: Lack of data.

(repeated exposure)

No data available Endocrine disrupting properties:

Other information: No data available

Ecological information

12.1 Toxicity

Aquatic toxicity: Information about Mixture of 5-chloro-2-methyl-2H-isothiazolin-3-one and

2-methyl-2H-isothiazol-3-one (3:1):

Very toxic to aquatic life with long lasting effects. Daphnia toxicity: EC50 Daphnia: 0,16 mg/L/48 h. Fish toxicity: LC50 trout: 0,19 - 0,28 mg/L/96 h.

Water Hazard Class: 1 = slightly hazardous to water

12.2 Persistence and degradability

Further details: No data available

12.3 Bioaccumulative potential

Partition coefficient: n-octanol/water: No data available

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

No data available

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12.6 Endocrine disrupting properties

No data available

12.7 Other adverse effects

General information: Do not allow to enter into ground-water, surface water or drains.

13 Disposal considerations

13.1 Waste treatment methods

Product: Dispose of waste according to applicable legislation.

Package: Dispose of waste according to applicable legislation.

Additional information: Do not reuse empty containers.

14 Transport information

14.1 UN number or ID number

ADR/RID, ADN, IMDG, IATA-DGR Not applicable

14.2 UN proper shipping name

ADR/RID, ADN, IMDG, IATA-DGR Not restricted

14.3 Transport hazard class(es)

ADR/RID, ADN, IMDG, IATA-DGR Not applicable

14.4 Risk Number

-

14.5 Packing group

ADR/RID, ADN, IMDG, IATA-DGR Not applicable

14.6 Environmental hazards

Dangerous for the environment: Substance/mixture is not environmentally hazardous according to the criteria of the

UN model regulations.

Marine pollutant – IMDG:

14.7 Special precautions for user

No dangerous good in sense of these transport regulations.

15 Regulatory information

- Product produced in accordance with the requirements established by RDC 665 of 30/03/2022 and with labeling information in accordance with RDC 206 of 17/11/2006.
- For more details on product disposal refer to RDC 222 of 28/03/2018 and NBR 10004.
- This safety data sheet was prepared in accordance with ABNT/NBR 14725:23.

16 Other information

Wording of the H-phrases under paragraph 2 and 3:

H301 = Toxic if swallowed.

H310 = Fatal in contact with skin.

H314 = Causes severe skin burns and eye damage.

H317 = May cause an allergic skin reaction.

H318 = Causes serious eye damage.

H330 = Fatal if inhaled.

H400 = Very toxic to aquatic life.

H410 = Very toxic to aquatic life with long lasting effects.

EUH071 = Corrosive to the respiratory tract.

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In article XXX: The three X are for the volume.

Abbreviations and acronyms:

Acute Tox.: Acute toxicity

ABNT: Associação Brasileira de Normas Técnicas

ADN: European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways

ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road

Aquatic Acute: Hazardous to the aquatic environment - acute Aquatic Chronic: Hazardous to the aquatic environment - chronic

AS/NZS: Australian Standards/New Zealand Standards

CAS: Chemical Abstracts Service CE: Conformite Europeenne CFR: Code of Federal Regulations

CLP: Classification, Labelling and Packaging

DMEL: Derived minimal effect level DNEL: Derived no-effect level EC: European Community

EC50: Effective Concentration 50%

EN: European Standard EQ: Excepted quantities EU: European Union Eye Dam.: Eye damage

GHS: Globally Harmonized System

IATA: International Air Transport Association

IATA-DGR: International Air Transport Association – Dangerous Goods Regulations

IBC Code: International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk

IMDG Code: International Maritime Dangerous Goods Code

LC50: Median lethal concentration

MARPOL: Maritime Pollution: The International Convention for the Prevention of Pollution from Ships

M-factor: Multiplication factor MS: Ministério da Saúde NBR: Norma Brasileira

OSHA: Occupational Safety and Health Administration

PBT: Persistent, bioaccumulative and toxic PNEC: Predicted no-effect concentration

REACH: Registration, Evaluation, Authorization and Restriction of Chemicals RENACIAT: Rede Nacional de Centros de Informação e Assistência Toxicológica

RDC: Resolução da Diretoria Colegiada

RID: Regulations Concerning the International Carriage of Dangerous Goods by Rail

Skin Corr.: Skin corrosion Skin Sens.: Skin sensitization

TRGS: Technical Rules for Hazardous Substances vPvB: Very persistent and very bioaccumulative

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1 Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade Name: HDL-C Direto Reagent R2

Article n°: 1160XXX MS: 80115310267

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

General use: Reagent for in-vitro diagnostics in human samples

For professional use only.

1.3 Details of the supplier of the safety data sheet

Kovalent do Brasil Ltda.

Rua Cristóvão Sardinha, 110 – Jd. Bom Retiro – São Gonçalo – RJ – Brasil.

Tel: +(55 21) 2623-1367

e-mail: kovalent@kovalent.com.br

1.4 Emergency telephone number

Tel: +(55 21) 2623-1367 - Costumer service 8AM to 5PM.

0800 015 1414

In case of emergency

24 hours service

0800-722-6001 - RENACIAT (Rede Nacional de Centros de Informação e Assistência Toxicológica)

2 Hazards Identification

2.1 Classification of the substance or mixture

Classification according to ABNT NBR 14725.

This mixture is classified as not hazardous.

2.2 Label elements

Labelling (GHS)

Hazard statements: Not applicable

Precautionary statements: Not applicable

Special labelling

EUH210: Safety data sheet available on request.

2.3 Other hazards

No risks worthy of mention.

Endocrine disrupting properties, Results of PBT and vPvB assessment:

No data available

3 Composition/information on ingredients

3.1 Substances

Not applicable

3.2 Mixtures

Chemical characterization: Aqueous solution.

Additional information: Contains Sodium azide (0.95 q/L) as preservative.

Contains Sucrose The maximum workplace exposure limits are, where necessary, listed in

section 8.

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4 First aid measures

4.1 Description of first aid measures

In case of inhalation: Provide fresh air. Seek medical treatment in case of troubles.

Following skin contact: Remove residues with water. Take off contaminated clothing and wash it before reuse. In case

of skin reactions, consult a physician.

After eye contact: Immediately flush eyes with plenty of flowing water for 10 to 15 minutes holding eyelids apart.

Remove contact lenses, if present and easy to do. Continue rinsing. In case of troubles or

persistent symptoms, consult an ophthalmologist.

After swallowing: Rinse mouth thoroughly with water. Never give anything by mouth to an unconscious person.

Seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

No data available.

4.3 Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

5 Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media: Product is non-combustible. Extinguishing materials should therefore be

selected according to surroundings.

5.2 Special hazards arising from the substance or mixture

Fires in the immediate vicinity may cause the development of dangerous vapours.

In the event of a fire, the following may be produced when the water evaporates: Nitrogen oxides (NOx), carbon monoxide and carbon dioxide.

5.3 Advice for firefighters

Special protective equipment for firefighters: Wear self-contained breathing apparatus.

Additional information: Do not allow fire water to penetrate into surface or ground water.

6 Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Avoid contact with skin and eyes. Avoid breathing vapors. Wear appropriate protective equipment.

In enclosed areas: Provide fresh air.

6.2 Environmental precautions

Do not allow to penetrate into soil, waterbodies or drains.

6.3 Methods and material for containment and cleaning up

Soak up with absorbent materials such as sand, siliceous earth, acid- or universal binder.

Store in special closed containers and dispose of according to ordinance. Wash spill area with plenty of water.

6.4 Reference to other sections

Refer additionally to section 8 and 13.

7 Handling and storage

7.1 Precautions for safe handling

Advices on safe handling:

Provide adequate ventilation, and local exhaust as needed. Avoid contact with skin and eyes. Take off contaminated clothing and wash it before reuse. Avoid breathing vapors. Wear appropriate protective equipment. Keep all containers, equipment and working place clean.

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7.2 Conditions for safe storage, including any incompatibilities

Requirements for storerooms and containers: Keep containers tightly closed and at a temperature between 2°C and 8°C.

Protect from direct sunlight. Keep sterile.

Hints on joint storage: Keep away from food, drink and animal feeding stuffs.

Do not store together with strong acids or alkalis.

Storage class: 12 = Non-combustible liquids

7.3 Specific end use(s)

No information available.

8 Exposure controls/personal protection

8.1 Control parameters

Additional information: Contains no substances with occupational exposure limit values.

8.2 Exposure controls

Provide good ventilation and/or an exhaust system in the work area.

Personal protection equipment Occupational exposure controls

Respiratory protection: Respiratory protection must be worn whenever the WEL levels have been exceeded. When

aerosols and vapours form: Use combination filter type A/P according to EN 14387.

Hand protection: Protective gloves according to EN 374.

Glove material: Nitrile rubber Breakthrough time: >480 min.

Observe glove manufacturer's instructions concerning penetrability and breakthrough time.

Eye protection: Tightly sealed goggles according to EN 166.

Body protection: Wear suitable protective clothing.

General protection and hygiene measures:

Avoid contact with skin and eyes. Avoid breathing vapours. Take off contaminated clothing and wash it before reuse. Do not eat, drink or smoke when using this product. Wash hands

before breaks and after work.

Environmental exposure controls

Refer to "6.2 Environmental precautions"

9 Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state at 20 °C and 101.3 kPa Liquid

Colour: Clear, yellowish

Odour: No characteristic odour

Odour threshold: No data available

Melting point/freezing point:

No data available

Initial boiling point and boiling range: No data available

Flammability: No data available

Upper/lower flammability or explosive limits: No data available

Flash point/flash point range: Not combustible

Decomposition temperature: No data available

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pH: at 25 °C: approx. 8.15

Viscosity, kinematic: No data available

Water solubility: Completely miscible

Partition coefficient: n-octanol/water: No data available

Vapor pressure: No data available

Density: at 20 °C: 1.0655 g/mL

Vapor density: No data available

Particle characteristics: Not applicable

9.2 Other information

Explosive properties: No data available

Oxidizing characteristics: No data available

Auto-ignition temperature: No data available

Evaporation rate: No data available

Additional information: No data available

10 Stability and reactivity

10.1 Reactivity

Refer to subsection "Possibility of hazardous reactions".

10.2 Chemical stability

Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions

No hazardous reactions know.

10.4 Conditions to avoid

Protect from frost, heat and sunlight.

10.5 Incompatible materials

Strong acids, alkalis.

10.6 Hazardous decomposition products

No decomposition when used properly.

Thermal decomposition: No data available

11 Toxicological information

Toxicological effects:

Acute toxicity (oral): Lack of data. Acute toxicity (dermal): Lack of data. Acute toxicity (inhalative): Lack of data. Skin corrosion/irritation: Lack of data. Serious eye damage/irritation: Lack of data. Sensitisation to the respiratory tract: Lack of data. Skin sensitisation: Lack of data. Germ cell mutagenicity/Genotoxicity: Lack of data. Carcinogenicity: Lack of data. Reproductive toxicity: Lack of data.

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Effects on or via lactation:
Specific target organ toxicity:

(single exposure)

Specific target organ toxicity:

(repeated exposure)

Aspiration hazard:

Lack of data.

Lack of data.

Lack of data.

Lack of data.

Endocrine disrupting properties: No data available

Other information: Contains Sodium azide (0.95 g/L):

After resorption: headache, dizziness, nausea, cough, vomiting, spasms, breathing

paralysis, CNS disorders, low blood pressure, cardiovascular failure,

unconsciousness, collapse.

12 Ecological information

12.1 Toxicity

Water Hazard Class: 2 = obviously hazardous to water

12.2 Persistence and degradability

Further details: No data available

12.3 Bioaccumulative potential

Partition coefficient: n-octanol/water: No data available

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

No data available

12.6 Endocrine disrupting properties

No data available

12.7 Other adverse effects

General information: Do not allow to enter into ground-water, surface water or drains.

13 Disposal considerations

13.1 Waste treatment methods

Product: Dispose of waste according to applicable legislation.

Package: Dispose of waste according to applicable legislation.

Additional information: Do not reuse empty containers.

14 Transport information

14.1 UN number or ID number

ADR/RID, ADN, IMDG, IATA-DGR Not applicable

14.2 UN proper shipping name

ADR/RID, ADN, IMDG, IATA-DGR Not restricted

14.3 Transport hazard class(es)

ADR/RID, ADN, IMDG, IATA-DGR Not applicable

14.4 Risk Number

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14.5 Packing group

ADR/RID, ADN, IMDG, IATA-DGR Not applicable

14.6 Environmental hazards

Dangerous for the environment: Substance/mixture is not environmentally hazardous according to the criteria of the

UN model regulations.

Marine pollutant - IMDG: No

14.7 Special precautions for user

No dangerous good in sense of these transport regulations.

15 Regulatory information

- Product produced in accordance with the requirements established by RDC 665 of 30/03/2022 and with labeling information in accordance with RDC 206 of 17/11/2006.
- For more details on product disposal refer to RDC 222 of 28/03/2018 and NBR 10004.
- This safety data sheet was prepared in accordance with ABNT/NBR 14725:23.

16 Other information

The above information is considered correct but is not intended to be complete and should be used only as a guide. Kovalent is not responsible for any damage resulting from handling or use.

In article XXX: The three X are for the volume.

Abbreviations and acronyms:

ABNT: Associação Brasileira de Normas Técnicas

ADN: European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways

ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road

AS/NZS: Australian Standards/New Zealand Standards

CAS: Chemical Abstracts Service CE: Conformite Europeenne CFR: Code of Federal Regulations

CLP: Classification, Labelling and Packaging

CNS: Central Nervous System
DMEL: Derived minimal effect level
DNEL: Derived no-effect level
EC: European Community
EN: European Standard
EQ: Excepted quantities

EU: European Union

GHS: Globally Harmonized System

IATA: International Air Transport Association

IATA-DGR: International Air Transport Association – Dangerous Goods Regulations

IBC Code: International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk

IMDG Code: International Maritime Dangerous Goods Code

MARPOL: Maritime Pollution: The International Convention for the Prevention of Pollution from Ships

MS: Ministério da Saúde NBR: Norma Brasileira

OEL: Occupational Exposure Limit Value

OSHA: Occupational Safety and Health Administration

PBT: Persistent, bioaccumulative and toxic PNEC: Predicted no-effect concentration RDC: Resolução da Diretoria Colegiada

RID: Regulations Concerning the International Carriage of Dangerous Goods by Rail

TLV: Threshold Limit Value

TRGS: Technical Rules for Hazardous Substances vPvB: Very persistent and very bioaccumulative

WEL: Workplace Exposure Limit

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