

The Safety Date Sheet is usable for:**KIPB3492****Ferritin IRMA**

Refer to the instructions for the full list of product components

Single components with dangerous ingredients    :

REF	Name	Symbol	Version
B33074	¹²⁵ I-labeled monoclonal anti-ferritin antibody	   [Ab ¹²⁵ I]	1.0
B33174	Control 1	 [CONTROL 1]	1.0
B33174	Control 2	 [CONTROL 2]	1.0
B33175	Calibrator 0	 [CAL 0]	1.0
B33175	Calibrator 1	 [CAL 1]	1.0
B33175	Calibrator 2	 [CAL 2]	1.0
B33175	Calibrator 3	 [CAL 3]	1.0
B33175	Calibrator 4	 [CAL 4]	1.0
B33175	Calibrator 5	 [CAL 5]	1.0
B33176	Wash Solution (20X)	 [WASH SOLN CONC]	1.0

Read the MSDS for the component on the following pages.

Single components for single use  :

REF	Name	Symbol
33173	Coated tubes	

Not listed single components contain no hazardous substances in concentrations to be declared, a labelling is not required.

1 Identification of substance/mixture and company

1.1 Product identifier

Product form : Mixture
Product name : 125I-labeled monoclonal anti-ferritin antibody Ab^{125I}
Catalog # : B33074 REF

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

1.2.1 Relevant identified uses

Use of the substance/mixture : Laboratory reagent, Immunoassays
Use by professionals

1.2.2 Uses advised against

No additional information available

1.3 Details of the supplier of the safety data sheet

Supplier/Manufacturer

DIAsource ImmunoAssays S.A.

Rue du Bosquet, 2

B-1348 Louvain-la-Neuve

Belgium

Tel. Nr. +32 (0)10/84.99.11

E-mail: products.support@diasource.be

1.4 Emergency telephone number

DIAsource (only office hours) : +32 (0)10/84.99.23
Centre Anti-Poisons (BE) : 070 245 245

Please refer to your local Anti-Poison Center!

2 Hazards identification

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) N° 1272/2008 (CLP)

Skin sensitization, Category 1 H317 May cause an allergic skin reaction.

Aquatic Hazard Long term, Category 3 H412 Harmful to aquatic life with long lasting effects.

(Full test of H-statements: see section16)

Adverse physicochemical, human health and environmental effects

Causes severe skin burns and eye damage

2.2 Label element

Labelling according to Regulation (EC) N° 1272/2008 (CLP)

Hazard symbol (CLP) :



Signal word (CLP)

: Warning

Hazard statement (CLP)

: H317 May cause an allergic skin reaction

H412 Harmful to aquatic life with long lasting effects

Precaution statement (CLP)

: P261 Avoid breathing vapours

P272 Contaminated work clothing should not be allowed out of the workplace

P273 Avoid release to the environment

P280 Wear protective gloves, protective clothing, eye protection, face protection

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

P333+P313 If skin irritation or rash occurs: Get medical advice/attention

P362+P364 Take off contaminated clothing and wash it before use

P501 Dispose of contents/container in accordance with local/national regulations

2.3 Other hazards

Radioactive material  : This mixture contains Iodine-125, the activity of the mixture is indicated on the product label. Iodine-125 is a gamma-rays (35.5 keV) and X-rays (28 keV) emitter. Radiation can be protected by 1mm of lead. Half-life: 59.4 days.

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The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605.

3 Composition/information on ingredients

3.1 Substances

Not applicable

3.2 Mixtures

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one (3:1)	(CAS N°) 55965-84-9 (EC N°) - (EC Index N°) 613-167-00-5	≤ 0,05	Acute Tox. Dermal 2, H310 Acute Tox. Inhal. 2, H330 Acute Tox. Oral 3, H301 Aquatic Acute 1, H400 Aquatic Longterm 1, H410 Eye Dam. 1, H318 Skin Corr. 1C, H314 Skin Sens. 1A, H317

Name	Product identifier	Specific concentration limits according to Regulation (EC) No. 1272/2008 [CLP]
reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one (3:1)	(CAS N°) 55965-84-9 (EC N°) - (EC Index N°) 613-167-00-5	(C ≥ 0,6) Skin Corr. 1B, H314 (0,06 ≤ C < 0,6) Skin Irrit. 2, H315 (0,06 ≤ C < 0,6) Eye Irrit. 2, H319 (C ≥ 0,0015) Skin Sens. 1, H317

Full text of H-statements: see section16

4 First aid measures

4.1 Description of first aid measures

First-aid measures general

: Get medical advice/attention if you feel unwell. If possible show him this sheet. Failing this, show him the packaging or label. Never give anything by mouth to an unconscious person. Place the affected person in the recovery position.

First-aid measures after inhalation

: If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration by trained personnel and obtain medical attention immediately.

First-aid measures after skin contact

: In case of skin contact, rinse with water as a precaution.

First-aid measures after eye contact

: If product enters eyes, rinse eyes gently with water as a precaution.

First-aid measures after ingestion

: If product is ingested, rinse mouth with water. If irritation or discomfort occurs, obtain medical attention immediately.

4.2 Most important symptom and effects, both acute and delayed

Symptoms/effects

: May cause an allergic skin reaction.
See Section 11 Toxicological Information for more detailed health information.

4.3 Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

5 Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media

: In case of fire use carbon dioxide (CO₂), dry chemical, water spray or foam.
For large fires use extinguishing media suitable for surrounding fire.

Unsuitable extinguishing media

: Do not use a heavy water stream.

5.2 Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire : No combustion products posing significant hazards are expected from this product.

5.3 Advice for firefighters

Firefighting instructions

: Prevent firefighting water from entering the environment. Use water spray or fog for cooling exposed containers.

Protection during firefighting

: Use a self-contained breathing apparatus and also a protective suit.

6 Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

General measures

: Ensure adequate air ventilation. Avoid contact with skin and eyes. Do not breathe vapours/spray.

6.1.1 For non-emergency personnel

Emergency procedures

: Evacuate unnecessary personnel.

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6.1.2 For emergency responders

Protective equipment

: Use personal protective equipment as required. In case of inadequate ventilation wear respiratory protection.

6.2 Environmental precautions

Isolate area and absorb spill with sand, vermiculite or other inert absorbent material. Place absorbed material in container suitable for disposal.

Do not allow the undiluted product to enter sewers/surface or ground water.

Dispose of all waste material in accordance with local and facility guidelines.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up

: As a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.
Radioactive material is subject to the regulations of each country.
Dispose of all waste material in accordance with local guidelines.

6.4 Reference to other sections

Exposure controls and personal protection, see section 8. Concerning disposal elimination after cleaning, see section 13.

7 Handling and storage**7.1 Precautions for safe handling**

Precautions for safe handling

: Ensure good ventilation of the work station. Wear personal protective equipment. Avoid contact with skin and eyes. Do not breathe vapour/aerosol.
Hygiene measures : Handle in accordance with good industrial hygiene and safety procedures. When using do not eat, drink or smoke. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work.

7.2 Conditions for safe storage, including any incompatibilities

Storage conditions

: Store at 2 to 8°C, as directed on the product label.
To maintain product quality, store according to the instructions in the product labeling.
Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

Prohibitions on mixed storage

: Keep away from food, drink and animal feeding stuffs.

Incompatible materials

: No additional information available.

7.3 Specific end use(s)

Laboratory reagent, Immunoassays

8 Exposure controls/personnel protection**8.1 Control parameters**

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

8.2 Exposure controls

Appropriate engineering controls

: Place vial behind a metal shield, away from the user.

Hand protection

: Wear suitable gloves (EN 374). Nitrile rubber, 0.35 mm. Butyl rubber, 0.5 mm. The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

Eye protection

: Wear safety glasses (EN 166).

Skin and body protection

: Wear suitable protective clothing.

Respiratory protection

: Under normal conditions, the use of this product should not require respiratory protection.

Environmental exposure controls

: Avoid release to the environment.

9 Physical and chemical properties**9.1 Information on basic physical and chemical properties**

Physical state

: Liquid

Colour

: Red

Odor

: Odorless

Melting point/freezing point

: No data available

Boiling point or initial boiling point and boiling range

: No data available

Flammability

: No data available

Lower and upper explosion limit

: No data available

Flash point

: No data available

Auto-ignition temperature

: No data available

Decomposition temperature

: No data available

pH

: [7.9 – 8.1] @ 20°C

Kinematic viscosity

: No data available

Solubility

: Miscible

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Partition coefficient n-octanol/water (log value)	: Not applicable
Vapour pressure	: No data available
Density and/or relative density	: 1.00 @ 20°C
Relative vapour density	: No data available
Particle size	: Not applicable

9.2 Other information**9.2.1 Information with regard to physical hazard classes**

Explosive properties	: No explosive properties
Oxidising properties	: No oxidising properties

9.2.2 Other safety characteristics

No additional information available

10 Stability and reactivity**10.1 Reactivity**

No dangerous reactions known under normal conditions of use.

10.2 Chemical stability

Stable under use and storage conditions as recommended in section 7.

10.3 Possibility of hazardous reactions

None under normal use.

10.4 Conditions to avoid

To maintain product performance keep away from strong acids, strong bases, strong oxidizers.

Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials

No additional information available.

10.6 Hazardous decomposition products

No hazardous decomposition products known at room temperature. In case of fire: Toxic gases may be formed. Carbon dioxide. Carbon monoxide.

11 Toxicological information**11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008**

reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC#220-239-6](3:1) (CAS N° 55965-84-9)	
LD50 dermal rabbit	87.12 mg/kg (ECHA_API)
LD50 oral rat	53 mg/kg (NLM_CIP)

Acute toxicity	: Not classified Based on available data, the classification criteria are not met
Skin corrosion/irritation	: Not classified Based on available data, the classification criteria are not met
Serious eye damage/irritation	: Not classified Based on available data, the classification criteria are not met
Respiratory or skin sensitization	: Not classified Based on available data, the classification criteria are not met
Germ cell mutagenicity	: Not classified Based on available data, the classification criteria are not met
Carcinogenicity	: This product does not contain a reportable concentration ($\geq 0.1\%$) of any ingredient listed as carcinogen by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.
Reproductive toxicity	: Not classified Based on available data, the classification criteria are not met
Specific target organ toxicity (single exposure)	: Not classified Based on available data, the classification criteria are not met
Specific target organ toxicity (repeated exposure)	: Not classified Based on available data, the classification criteria are not met
Aspiration hazard	: Not classified Based on available data, the classification criteria are not met

11.2 Information on other hazards

Potential adverse human health effects and symptoms : Based on available data, the classification criteria are not met

12 Ecological information**12.1 Toxicity**

Acute aquatic toxicity : Not classified
Chronic aquatic toxicity : Not classified

12.2 Persistence and degradability

Not required for inorganic substances.

12.3 Bioaccumulative potential

Not required for inorganic substances.

12.4 Mobility in soil

No additional information available.

12.5 Results of PBT and vPvB assessment

Not fulfilling Persistent, Bioaccumulative and Toxic (PBT), very Persistent and very Bioaccumulative (vPvB) criteria.

12.6 Endocrine disrupting properties

No additional information available.

12.7 Other adverse effects

No additional information available.

13 Disposal considerations**13.1 Waste treatment methods**

Regional legislation (waste) : Dispose in a safe manner in accordance with local/national regulations.
Waste treatment methods : Do not empty into drains. Dispose of this material and its container in a safe way.
Waste code : The waste code number according to the Ordinance on the European Waste Catalogue depends on the waste producer and can therefore vary for any given product. The waste code number is therefore to be gleaned separately from each waste producer.

14 Transport information

In accordance with ADR / IMDG / IATA

14.1 UN number or ID number

UN-No. (ADR) : Not applicable
UN-No. (IMDG) : Not applicable
UN-No. (IATA) : Not applicable

14.2 UN proper shipping name

Proper Shipping Name (ADR) : Not applicable
Proper Shipping Name (IMDG) : Not applicable
Proper Shipping Name (IATA) : Not applicable

14.3 Transport hazard class(es)

Transport hazard class(es) (ADR) : Not applicable
Transport hazard class(es) (IMDG) : Not applicable
Transport hazard class(es) (IATA) : Not applicable

14.4 Packing group

Packing group (ADR) : Not applicable
Packing group (IMDG) : Not applicable
Packing group (IATA) : Not applicable

14.5 Environmental hazards

Dangerous for the environment : No
Marine pollutant : No
Other information : No supplementary information available

14.6 Special precautions for user

Overland transport : Not applicable
Transport by sea : Not applicable
Air transport : Not applicable

14.7 Maritime transport in bulk according to IMO instruments

Not applicable

15 Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

15.1.1 EU-Regulations

Contains no substance on the REACH candidate list.

Contains no REACH Annex XIV substances.

15.1.2 National regulations

Comply with applicable local regulations.

15.2 Chemical safety assessment

No chemical safety assessment has been carried out.

16 Other information

Data sources : REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Change compared to the previous version : -

Abbreviations and acronyms:

ACGIH	American Conference of Governmental Industrial Hygienists
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
CLP	Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures
DFGMAK	Republic Germany's maximum exposure limit
DMEL	Derived Minimal Effect Level
DNEL	Derived No-Effect Level
EC50	The effective concentration of substance that causes 50% of the maximum response (Median Effective Concentration)
GHS	Globally Harmonized System of Classification and Labelling of Chemicals
HCS	Hazard Communication Standard
IARC	International Agency for Research on Cancer
IATA	International Air Transport Association
ICAO	International Civil Aviation Organization
IDLH	Immediately Dangerous to Life or Health
IMDG	International Maritime Dangerous Goods Code" for the transport of dangerous goods by sea
IMO	International Maritime Orga
IOELVs	European Unions' Indicative Occupational Exposure Limit Values
LC50	Lethal Concentration to 50 % of a test population (Median Lethal Concentration)
LD50	Lethal Dose to 50% of a test population (Median Lethal Dose)
LOAEL	Lowest Observed Adverse Effect Level
NIOSH	National Institute for Occupational Safety and Health
NOAEC/L	No Observed Adverse Effect Concentration/Level
NOEC/L	No Observed Effect Concentration/Level
NTP	National Toxicology Program
OECD	Organisation for Economic Cooperation and Development
OSHA	Occupational Safety and Health Administration
PBT	Persistent, Bioaccumulative and Toxic substance
PEL	Permissible Exposure Limit
PNEC	Predicted No-Effect Concentration
REACH	Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals
SARA	Superfund Amendments and Reauthorization Act
SDS	Safety Data Sheet
STEL	Short Term Exposure Limit
STLV	Short Term Limit Value
STP	Sewage Treatment Plant
STV	Short Term Value
TDG	Canadian Transportation of Dangerous Goods Regulations

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TLV	Threshold Limit Value
TWA	Time Weighted Average
UFI	Unique Formula Identifier
UN GHS	United Nations Globally Harmonized System
US DOT	United States Department of Transportation
US OSHA	United States Occupational Safety and Health Administration
vPvB	Very Persistent and Very Bioaccumulative
WHMIS	Workplace Hazardous Material Information System

Full text of H- and EUH-phrases:

Acute Tox. Dermal 2	Acute Toxicity Dermal, Category 2
Acute Tox. Inhal. 2	Acute Toxicity Inhalation, Category 2
Acute Tox. Oral 3	Acute Toxicity Oral, Category 3
Aquatic Acute 1	Aquatic Hazard Acute, Category 1
Aquatic Longterm 1	Aquatic Hazard Long term, Category 1
Eye Dam. 1	Eye Damage Category 1
Skin Corr. 1C	Skin Corrosion, Category 1C
Skin Sens. 1A	Skin Sensitization, Category 1A
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

SDS EU (REACH Annex II)

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

1 Identification of substance/mixture and company

1.1 Product identifier

Product form : Mixture
Product name : Control 1 CONTROL 1
Control 2 CONTROL 2
Catalog # : B33174 REF

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

1.2.1 Relevant identified uses

Use of the substance/mixture : Laboratory reagent, Immunoassays
Use by professionals

1.2.2 Uses advised against

No additional information available

1.3 Details of the supplier of the safety data sheet

Supplier/Manufacturer

DIAsource ImmunoAssays S.A.

Rue du Bosquet, 2

B-1348 Louvain-la-Neuve

Belgium

Tel. Nr. +32 (0)10/84.99.11

E-mail: products.support@diasource.be

1.4 Emergency telephone number

DIAsource (only office hours) : +32 (0)10/84.99.23

Centre Anti-Poisons (BE) : 070 245 245

Please refer to your local Anti-Poison Center!

2 Hazards identification

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) N° 1272/2008 (CLP)

Skin sensitization, Category 1 H317 May cause an allergic skin reaction.

Aquatic Hazard Long term, Category 3 H412 Harmful to aquatic life with long lasting effects.

(Full test of H-statements: see section16)

Adverse physicochemical, human health and environmental effects

Causes severe skin burns and eye damage

2.2 Label element

Labelling according to Regulation (EC) N° 1272/2008 (CLP)

Hazard symbol (CLP) :



Signal word (CLP) : Warning

Hazard statement (CLP) : H317 May cause an allergic skin reaction

H412 Harmful to aquatic life with long lasting effects

Precaution statement (CLP) : P261 Avoid breathing vapours

P272 Contaminated work clothing should not be allowed out of the workplace

P273 Avoid release to the environment

P280 Wear protective gloves, protective clothing, eye protection, face protection

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

P333+P313 If skin irritation or rash occurs: Get medical advice/attention

P362+P364 Take off contaminated clothing and wash it before use

P501 Dispose of contents/container in accordance with local/national regulations

2.3 Other hazards

The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605.

3 Composition/information on ingredients

3.1 Substances

Not applicable

3.2 Mixtures

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one (3:1)	(CAS N°) 55965-84-9 (EC N°) - (EC Index N°) 613-167-00-5	≤ 0,05	Acute Tox. Dermal 2, H310 Acute Tox. Inhal. 2, H330 Acute Tox. Oral 3, H301 Aquatic Acute 1, H400 Aquatic Longterm 1, H410 Eye Dam. 1, H318 Skin Corr. 1C, H314 Skin Sens. 1A, H317

Name	Product identifier	Specific concentration limits according to Regulation (EC) No. 1272/2008 [CLP]
reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one (3:1)	(CAS N°) 55965-84-9 (EC N°) - (EC Index N°) 613-167-00-5	(C ≥ 0,6) Skin Corr. 1B, H314 (0,06 ≤ C < 0,6) Skin Irrit. 2, H315 (0,06 ≤ C < 0,6) Eye Irrit. 2, H319 (C ≥ 0,0015) Skin Sens. 1, H317

Full text of H-statements: see section16

4 First aid measures

4.1 Description of first aid measures

First-aid measures general

: Get medical advice/attention if you feel unwell. If possible show him this sheet. Failing this, show him the packaging or label. Never give anything by mouth to an unconscious person. Place the affected person in the recovery position.

First-aid measures after inhalation

: If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration by trained personnel and obtain medical attention immediately.

First-aid measures after skin contact

: In case of skin contact, rinse with water as a precaution.

First-aid measures after eye contact

: If product enters eyes, rinse eyes gently with water as a precaution.

First-aid measures after ingestion

: If product is ingested, rinse mouth with water. If irritation or discomfort occurs, obtain medical attention immediately.

4.2 Most important symptom and effects, both acute and delayed

Symptoms/effects

: May cause an allergic skin reaction.
See Section 11 Toxicological Information for more detailed health information.

4.3 Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

5 Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media

: In case of fire use carbon dioxide (CO₂), dry chemical, water spray or foam.
For large fires use extinguishing media suitable for surrounding fire.

Unsuitable extinguishing media

: Do not use a heavy water stream.

5.2 Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire : No combustion products posing significant hazards are expected from this product.

5.3 Advice for firefighters

Firefighting instructions

: Prevent firefighting water from entering the environment. Use water spray or fog for cooling exposed containers.

Protection during firefighting

: Use a self-contained breathing apparatus and also a protective suit.

6 Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

General measures

: Ensure adequate air ventilation. Avoid contact with skin and eyes. Do not breathe vapours/spray.

6.1.1 For non-emergency personnel

Emergency procedures

: Evacuate unnecessary personnel.

6.1.2 For emergency responders

Protective equipment

: Use personal protective equipment as required. In case of inadequate ventilation wear respiratory protection.

6.2 Environmental precautions

Isolate area and absorb spill with sand, vermiculite or other inert absorbent material. Place absorbed material in container suitable for disposal. Do not allow the undiluted product to enter sewers/surface or ground water. Dispose of all waste material in accordance with local and facility guidelines.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up : As a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.

6.4 Reference to other sections

Exposure controls and personal protection, see section 8. Concerning disposal elimination after cleaning, see section 13.

7 Handling and storage

7.1 Precautions for safe handling

Precautions for safe handling : Ensure good ventilation of the work station. Wear personal protective equipment. Avoid contact with skin and eyes. Do not breathe vapour/aerosol.

Hygiene measures

: Handle in accordance with good industrial hygiene and safety procedures. When using do not eat, drink or smoke. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work.

7.2 Conditions for safe storage, including any incompatibilities

Storage conditions

: Store at 2 to 8°C, as directed on the product label. To maintain product quality, store according to the instructions in the product labeling. Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

Prohibitions on mixed storage

: Keep away from food, drink and animal feeding stuffs.

Incompatible materials

: No additional information available.

7.3 Specific end use(s)

Laboratory reagent, Immunoassays

8 Exposure controls/personnel protection

8.1 Control parameters

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

8.2 Exposure controls

Appropriate engineering controls

: Place vial behind a metal shield, away from the user.

Hand protection

: Wear suitable gloves (EN 374). Nitrile rubber, 0.35 mm. Butyl rubber, 0.5 mm. The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

Eye protection

: Wear safety glasses (EN 166).

Skin and body protection

: Wear suitable protective clothing.

Respiratory protection

: Under normal conditions, the use of this product should not require respiratory protection.

Environmental exposure controls

: Avoid release to the environment.

9 Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state

: Liquid

Colour

: Yellowish

Odor

: Odorless

Melting point/freezing point

: No data available

Boiling point or initial boiling point and boiling range

: No data available

Flammability

: No data available

Lower and upper explosion limit

: No data available

Flash point

: No data available

Auto-ignition temperature

: No data available

Decomposition temperature

: No data available

pH

: [7.2– 7.6] @ 20°C

Kinematic viscosity

: No data available

Solubility

: Miscible

Partition coefficient n-octanol/water (log value)

: Not applicable

Vapour pressure

: No data available

Density and/or relative density

: 1.02 @ 20°C

Relative vapour density

: No data available

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Particle size : Not applicable

9.2 Other information

9.2.1 Information with regard to physical hazard classes

Explosive properties : No explosive properties

Oxidising properties : No oxidising properties

9.2.2 Other safety characteristics

No additional information available

10 Stability and reactivity

10.1 Reactivity

No dangerous reactions known under normal conditions of use.

10.2 Chemical stability

Stable under use and storage conditions as recommended in section 7.

10.3 Possibility of hazardous reactions

None under normal use.

10.4 Conditions to avoid

To maintain product performance keep away from strong acids, strong bases, strong oxidizers.

Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials

No additional information available.

10.6 Hazardous decomposition products

No hazardous decomposition products known at room temperature. In case of fire: Toxic gases may be formed. Carbon dioxide. Carbon monoxide.

11 Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC#220-239-6](3:1) (CAS N° 55965-84-9)

LD50 dermal rabbit	87.12 mg/kg (ECHA_API)
LD50 oral rat	53 mg/kg (NLM_CIP)

Acute toxicity	: Not classified Based on available data, the classification criteria are not met
Skin corrosion/irritation	: Not classified Based on available data, the classification criteria are not met
Serious eye damage/irritation	: Not classified Based on available data, the classification criteria are not met
Respiratory or skin sensitization	: Not classified Based on available data, the classification criteria are not met
Germ cell mutagenicity	: Not classified Based on available data, the classification criteria are not met
Carcinogenicity	: This product does not contain a reportable concentration ($\geq 0.1\%$) of any ingredient listed as carcinogen by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.
Reproductive toxicity	: Not classified Based on available data, the classification criteria are not met
Specific target organ toxicity (single exposure)	: Not classified Based on available data, the classification criteria are not met
Specific target organ toxicity (repeated exposure)	: Not classified Based on available data, the classification criteria are not met
Aspiration hazard	: Not classified Based on available data, the classification criteria are not met

11.2 Information on other hazards

Potential adverse human health effects and symptoms : Based on available data, the classification criteria are not met

12 Ecological information

12.1 Toxicity

Acute aquatic toxicity : Not classified

Chronic aquatic toxicity : Not classified

12.2 Persistence and degradability

Not required for inorganic substances.

12.3 Bioaccumulative potential

Not required for inorganic substances.

12.4 Mobility in soil

No additional information available.

12.5 Results of PBT and vPvB assessment

Not fulfilling Persistent, Bioaccumulative and Toxic (PBT), very Persistent and very Bioaccumulative (vPvB) criteria.

12.6 Endocrine disrupting properties

No additional information available.

12.7 Other adverse effects

No additional information available.

13 Disposal considerations**13.1 Waste treatment methods**

Regional legislation (waste)	: Dispose in a safe manner in accordance with local/national regulations.
Waste treatment methods	: Do not empty into drains. Dispose of this material and its container in a safe way.
Waste code	: The waste code number according to the Ordinance on the European Waste Catalogue depends on the waste producer and can therefore vary for any given product. The waste code number is therefore to be gleaned separately from each waste producer.

14 Transport information

In accordance with ADR / IMDG / IATA

14.1 UN number or ID number

UN-No. (ADR)	: Not applicable
UN-No. (IMDG)	: Not applicable
UN-No. (IATA)	: Not applicable

14.2 UN proper shipping name

Proper Shipping Name (ADR)	: Not applicable
Proper Shipping Name (IMDG)	: Not applicable
Proper Shipping Name (IATA)	: Not applicable

14.3 Transport hazard class(es)

Transport hazard class(es) (ADR)	: Not applicable
Transport hazard class(es) (IMDG)	: Not applicable
Transport hazard class(es) (IATA)	: Not applicable

14.4 Packing group

Packing group (ADR)	: Not applicable
Packing group (IMDG)	: Not applicable
Packing group (IATA)	: Not applicable

14.5 Environmental hazards

Dangerous for the environment	: No
Marine pollutant	: No
Other information	: No supplementary information available

14.6 Special precautions for user

Overland transport	: Not applicable
Transport by sea	: Not applicable
Air transport	: Not applicable

14.7 Maritime transport in bulk according to IMO instruments

Not applicable

15 Regulatory information**15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture****15.1.1 EU-Regulations**

Contains no substance on the REACH candidate list.

Contains no REACH Annex XIV substances.

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15.1.2 National regulations

Comply with applicable local regulations.

15.2 Chemical safety assessment

No chemical safety assessment has been carried out.

16 Other information

Data sources : REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Change compared to the previous version : -

Abbreviations and acronyms:

ACGIH	American Conference of Governmental Industrial Hygienists
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
CLP	Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures
DFGMAK	Republic Germany's maximum exposure limit
DMEL	Derived Minimal Effect Level
DNEL	Derived No-Effect Level
EC50	The effective concentration of substance that causes 50% of the maximum response (Median Effective Concentration)
GHS	Globally Harmonized System of Classification and Labelling of Chemicals
HCS	Hazard Communication Standard
IARC	International Agency for Research on Cancer
IATA	International Air Transport Association
ICAO	International Civil Aviation Organization
IDLH	Immediately Dangerous to Life or Health
IMDG	International Maritime Dangerous Goods Code" for the transport of dangerous goods by sea
IMO	International Maritime Orga
IOELVs	European Unions' Indicative Occupational Exposure Limit Values
LC50	Lethal Concentration to 50 % of a test population (Median Lethal Concentration)
LD50	Lethal Dose to 50% of a test population (Median Lethal Dose)
LOAEL	Lowest Observed Adverse Effect Level
NIOSH	National Institute for Occupational Safety and Health
NOAEC/L	No Observed Adverse Effect Concentration/Level
NOEC/L	No Observed Effect Concentration/Level
NTP	National Toxicology Program
OECD	Organisation for Economic Cooperation and Development
OSHA	Occupational Safety and Health Administration
PBT	Persistent, Bioaccumulative and Toxic substance
PEL	Permissible Exposure Limit
PNEC	Predicted No-Effect Concentration
REACH	Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals
SARA	Superfund Amendments and Reauthorization Act
SDS	Safety Data Sheet
STEL	Short Term Exposure Limit
STLV	Short Term Limit Value
STP	Sewage Treatment Plant
STV	Short Term Value
TDG	Canadian Transportation of Dangerous Goods Regulations
TLV	Threshold Limit Value
TWA	Time Weighted Average
UFI	Unique Formula Identifier
UN GHS	United Nations Globally Harmonized System
US DOT	United States Department of Transportation

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US OSHA	United States Occupational Safety and Health Administration
vPvB	Very Persistent and Very Bioaccumulative
WHMIS	Workplace Hazardous Material Information System

Full text of H- and EUH-phrases:

Acute Tox. Dermal 2	Acute Toxicity Dermal, Category 2
Acute Tox. Inhal. 2	Acute Toxicity Inhalation, Category 2
Acute Tox. Oral 3	Acute Toxicity Oral, Category 3
Aquatic Acute 1	Aquatic Hazard Acute, Category 1
Aquatic Longterm 1	Aquatic Hazard Long term, Category 1
Eye Dam. 1	Eye Damage Category 1
Skin Corr. 1C	Skin Corrosion, Category 1C
Skin Sens. 1A	Skin Sensitization, Category 1A
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

SDS EU (REACH Annex II)

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

1 Identification of substance/mixture and company

1.1 Product identifier

Product form	:	Mixture
Product name	:	Calibrator 0 CAL 0
		Calibrator 1 CAL 1
		Calibrator 2 CAL 2
		Calibrator 3 CAL 3
		Calibrator 4 CAL 4
		Calibrator 5 CAL 5
Catalog #	:	B33175 REF

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

1.2.1 Relevant identified uses

Use of the substance/mixture	:	Laboratory reagent, Immunoassays
		Use by professionals

1.2.2 Uses advised against

No additional information available

1.3 Details of the supplier of the safety data sheet

Supplier/Manufacturer

DIAsource ImmunoAssays S.A.

Rue du Bosquet, 2

B-1348 Louvain-la-Neuve

Belgium

Tel. Nr. +32 (0)10/84.99.11

E-mail: products.support@diasource.be

1.4 Emergency telephone number

DIAsource (only office hours) :

+32 (0)10/84.99.23

Centre Anti-Poisons (BE) :

070 245 245

Please refer to your local Anti-Poison Center!

2 Hazards identification

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) N° 1272/2008 (CLP)

Skin sensitization, Category 1 H317 May cause an allergic skin reaction.

Aquatic Hazard Long term, Category 3 H412 Harmful to aquatic life with long lasting effects.

(Full test of H-statements: see section16)

Adverse physicochemical, human health and environmental effects

Causes severe skin burns and eye damage

2.2 Label element

Labelling according to Regulation (EC) N° 1272/2008 (CLP)

Hazard symbol (CLP) :



Signal word (CLP)

:

Warning

Hazard statement (CLP)

:

H317 May cause an allergic skin reaction

H412 Harmful to aquatic life with long lasting effects

Precaution statement (CLP)

:

P261 Avoid breathing vapours

P272 Contaminated work clothing should not be allowed out of the workplace

P273 Avoid release to the environment

P280 Wear protective gloves, protective clothing, eye protection, face protection

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

P333+P313 If skin irritation or rash occurs: Get medical advice/attention

P362+P364 Take off contaminated clothing and wash it before use

P501 Dispose of contents/container in accordance with local/national regulations

2.3 Other hazards

The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605.

3 Composition/information on ingredients

3.1 Substances

Not applicable

3.2 Mixtures

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one (3:1)	(CAS N°) 55965-84-9 (EC N°) - (EC Index N°) 613-167-00-5	≤ 0,05	Acute Tox. Dermal 2, H310 Acute Tox. Inhal. 2, H330 Acute Tox. Oral 3, H301 Aquatic Acute 1, H400 Aquatic Longterm 1, H410 Eye Dam. 1, H318 Skin Corr. 1C, H314 Skin Sens. 1A, H317

Name	Product identifier	Specific concentration limits according to Regulation (EC) No. 1272/2008 [CLP]
reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one (3:1)	(CAS N°) 55965-84-9 (EC N°) - (EC Index N°) 613-167-00-5	(C ≥ 0,6) Skin Corr. 1B, H314 (0,06 ≤ C < 0,6) Skin Irrit. 2, H315 (0,06 ≤ C < 0,6) Eye Irrit. 2, H319 (C ≥ 0,0015) Skin Sens. 1, H317

Full text of H-statements: see section16

4 First aid measures

4.1 Description of first aid measures

First-aid measures general

: Get medical advice/attention if you feel unwell. If possible show him this sheet. Failing this, show him the packaging or label. Never give anything by mouth to an unconscious person. Place the affected person in the recovery position.

First-aid measures after inhalation

: If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration by trained personnel and obtain medical attention immediately.

First-aid measures after skin contact

: In case of skin contact, rinse with water as a precaution.

First-aid measures after eye contact

: If product enters eyes, rinse eyes gently with water as a precaution.

First-aid measures after ingestion

: If product is ingested, rinse mouth with water. If irritation or discomfort occurs, obtain medical attention immediately.

4.2 Most important symptom and effects, both acute and delayed

Symptoms/effects

: May cause an allergic skin reaction.

See Section 11 Toxicological Information for more detailed health information.

4.3 Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

5 Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media

: In case of fire use carbon dioxide (CO₂), dry chemical, water spray or foam. For large fires use extinguishing media suitable for surrounding fire.

Unsuitable extinguishing media

: Do not use a heavy water stream.

5.2 Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire

: No combustion products posing significant hazards are expected from this product.

5.3 Advice for firefighters

Firefighting instructions

: Prevent firefighting water from entering the environment. Use water spray or fog for cooling exposed containers.

Protection during firefighting

: Use a self-contained breathing apparatus and also a protective suit.

6 Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

General measures

: Ensure adequate air ventilation. Avoid contact with skin and eyes. Do not breathe vapours/spray.

6.1.1 For non-emergency personnel

Emergency procedures : Evacuate unnecessary personnel.

6.1.2 For emergency responders

Protective equipment : Use personal protective equipment as required. In case of inadequate ventilation wear respiratory protection.

6.2 Environmental precautions

Isolate area and absorb spill with sand, vermiculite or other inert absorbent material. Place absorbed material in container suitable for disposal. Do not allow the undiluted product to enter sewers/surface or ground water. Dispose of all waste material in accordance with local and facility guidelines.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up : As a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.

6.4 Reference to other sections

Exposure controls and personal protection, see section 8. Concerning disposal elimination after cleaning, see section 13.

7 Handling and storage

7.1 Precautions for safe handling

Precautions for safe handling : Ensure good ventilation of the work station. Wear personal protective equipment. Avoid contact with skin and eyes. Do not breathe vapour/aerosol.

Hygiene measures

: Handle in accordance with good industrial hygiene and safety procedures. When using do not eat, drink or smoke. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work.

7.2 Conditions for safe storage, including any incompatibilities

Storage conditions

: Store at 2 to 8°C, as directed on the product label. To maintain product quality, store according to the instructions in the product labeling. Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

Prohibitions on mixed storage

: Keep away from food, drink and animal feeding stuffs.

Incompatible materials

: No additional information available.

7.3 Specific end use(s)

Laboratory reagent, Immunoassays

8 Exposure controls/personnel protection

8.1 Control parameters

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

8.2 Exposure controls

Appropriate engineering controls : Place vial behind a metal shield, away from the user.

Hand protection : Wear suitable gloves (EN 374). Nitrile rubber, 0.35 mm. Butyl rubber, 0.5 mm. The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

Eye protection

: Wear safety glasses (EN 166).

Skin and body protection

: Wear suitable protective clothing.

Respiratory protection

: Under normal conditions, the use of this product should not require respiratory protection.

Environmental exposure controls

: Avoid release to the environment.

9 Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state : Liquid

Colour : Yellowish

Odor : Odorless

Melting point/freezing point : No data available

Boiling point or initial boiling point and boiling range : No data available

Flammability : No data available

Lower and upper explosion limit : No data available

Flash point : No data available

Auto-ignition temperature : No data available

Decomposition temperature : No data available

pH : [6.9– 7.1] @ 20°C

Kinematic viscosity : No data available

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Solubility	: Miscible
Partition coefficient n-octanol/water (log value)	: Not applicable
Vapour pressure	: No data available
Density and/or relative density	: 1.03 @ 20°C
Relative vapour density	: No data available
Particle size	: Not applicable

9.2 Other information

9.2.1 Information with regard to physical hazard classes	
Explosive properties	: No explosive properties
Oxidising properties	: No oxidising properties

9.2.2 Other safety characteristics

No additional information available

10 Stability and reactivity

10.1 Reactivity

No dangerous reactions known under normal conditions of use.

10.2 Chemical stability

Stable under use and storage conditions as recommended in section 7.

10.3 Possibility of hazardous reactions

None under normal use.

10.4 Conditions to avoid

To maintain product performance keep away from strong acids, strong bases, strong oxidizers. Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials

No additional information available.

10.6 Hazardous decomposition products

No hazardous decomposition products known at room temperature. In case of fire: Toxic gases may be formed. Carbon dioxide. Carbon monoxide.

11 Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC#220-239-6](3:1) (CAS N° 55965-84-9)	
LD50 dermal rabbit	87.12 mg/kg (ECHA_API)
LD50 oral rat	53 mg/kg (NLM_CIP)

Acute toxicity	: Not classified Based on available data, the classification criteria are not met
Skin corrosion/irritation	: Not classified Based on available data, the classification criteria are not met
Serious eye damage/irritation	: Not classified Based on available data, the classification criteria are not met
Respiratory or skin sensitization	: Not classified Based on available data, the classification criteria are not met
Germ cell mutagenicity	: Not classified Based on available data, the classification criteria are not met
Carcinogenicity	: This product does not contain a reportable concentration ($\geq 0.1\%$) of any ingredient listed as carcinogen by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.
Reproductive toxicity	: Not classified Based on available data, the classification criteria are not met
Specific target organ toxicity (single exposure)	: Not classified Based on available data, the classification criteria are not met
Specific target organ toxicity (repeated exposure)	: Not classified Based on available data, the classification criteria are not met
Aspiration hazard	: Not classified Based on available data, the classification criteria are not met

11.2 Information on other hazards

Potential adverse human health effects and symptoms : Based on available data, the classification criteria are not met

12 Ecological information

12.1 Toxicity

Acute aquatic toxicity : Not classified
Chronic aquatic toxicity : Not classified

12.2 Persistence and degradability

Not required for inorganic substances.

12.3 Bioaccumulative potential

Not required for inorganic substances.

12.4 Mobility in soil

No additional information available.

12.5 Results of PBT and vPvB assessment

Not fulfilling Persistent, Bioaccumulative and Toxic (PBT), very Persistent and very Bioaccumulative (vPvB) criteria.

12.6 Endocrine disrupting properties

No additional information available.

12.7 Other adverse effects

No additional information available.

13 Disposal considerations

13.1 Waste treatment methods

Regional legislation (waste) : Dispose in a safe manner in accordance with local/national regulations.
Waste treatment methods : Do not empty into drains. Dispose of this material and its container in a safe way.
Waste code : The waste code number according to the Ordinance on the European Waste Catalogue depends on the waste producer and can therefore vary for any given product. The waste code number is therefore to be gleaned separately from each waste producer.

14 Transport information

In accordance with ADR / IMDG / IATA

14.1 UN number or ID number

UN-No. (ADR) : Not applicable
UN-No. (IMDG) : Not applicable
UN-No. (IATA) : Not applicable

14.2 UN proper shipping name

Proper Shipping Name (ADR) : Not applicable
Proper Shipping Name (IMDG) : Not applicable
Proper Shipping Name (IATA) : Not applicable

14.3 Transport hazard class(es)

Transport hazard class(es) (ADR) : Not applicable
Transport hazard class(es) (IMDG) : Not applicable
Transport hazard class(es) (IATA) : Not applicable

14.4 Packing group

Packing group (ADR) : Not applicable
Packing group (IMDG) : Not applicable
Packing group (IATA) : Not applicable

14.5 Environmental hazards

Dangerous for the environment : No
Marine pollutant : No
Other information : No supplementary information available

14.6 Special precautions for user

Overland transport : Not applicable
Transport by sea : Not applicable
Air transport : Not applicable

14.7 Maritime transport in bulk according to IMO instruments

Not applicable

15 Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

15.1.1 EU-Regulations

Contains no substance on the REACH candidate list.

Contains no REACH Annex XIV substances.

15.1.2 National regulations

Comply with applicable local regulations.

15.2 Chemical safety assessment

No chemical safety assessment has been carried out.

16 Other information

Data sources : REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Change compared to the previous version : -

Abbreviations and acronyms:

ACGIH	American Conference of Governmental Industrial Hygienists
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
CLP	Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures
DFGMAK	Republic Germany's maximum exposure limit
DMEL	Derived Minimal Effect Level
DNEL	Derived No-Effect Level
EC50	The effective concentration of substance that causes 50% of the maximum response (Median Effective Concentration)
GHS	Globally Harmonized System of Classification and Labelling of Chemicals
HCS	Hazard Communication Standard
IARC	International Agency for Research on Cancer
IATA	International Air Transport Association
ICAO	International Civil Aviation Organization
IDLH	Immediately Dangerous to Life or Health
IMDG	International Maritime Dangerous Goods Code" for the transport of dangerous goods by sea
IMO	International Maritime Orga
IOELVs	European Unions' Indicative Occupational Exposure Limit Values
LC50	Lethal Concentration to 50 % of a test population (Median Lethal Concentration)
LD50	Lethal Dose to 50% of a test population (Median Lethal Dose)
LOAEL	Lowest Observed Adverse Effect Level
NIOSH	National Institute for Occupational Safety and Health
NOAEC/L	No Observed Adverse Effect Concentration/Level
NOEC/L	No Observed Effect Concentration/Level
NTP	National Toxicology Program
OECD	Organisation for Economic Cooperation and Development
OSHA	Occupational Safety and Health Administration
PBT	Persistent, Bioaccumulative and Toxic substance
PEL	Permissible Exposure Limit
PNEC	Predicted No-Effect Concentration
REACH	Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals
SARA	Superfund Amendments and Reauthorization Act
SDS	Safety Data Sheet
STEL	Short Term Exposure Limit
STLV	Short Term Limit Value
STP	Sewage Treatment Plant
STV	Short Term Value
TDG	Canadian Transportation of Dangerous Goods Regulations

Date of issue: 01.07.2025

Revision date: -

Version/Replaced version: 1.0/-

TLV	Threshold Limit Value
TWA	Time Weighted Average
UFI	Unique Formula Identifier
UN GHS	United Nations Globally Harmonized System
US DOT	United States Department of Transportation
US OSHA	United States Occupational Safety and Health Administration
vPvB	Very Persistent and Very Bioaccumulative
WHMIS	Workplace Hazardous Material Information System

Full text of H- and EUH-phrases:

Acute Tox. Dermal 2	Acute Toxicity Dermal, Category 2
Acute Tox. Inhal. 2	Acute Toxicity Inhalation, Category 2
Acute Tox. Oral 3	Acute Toxicity Oral, Category 3
Aquatic Acute 1	Aquatic Hazard Acute, Category 1
Aquatic Longterm 1	Aquatic Hazard Long term, Category 1
Eye Dam. 1	Eye Damage Category 1
Skin Corr. 1C	Skin Corrosion, Category 1C
Skin Sens. 1A	Skin Sensitization, Category 1A
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

SDS EU (REACH Annex II)

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

1 Identification of substance/mixture and company

1.1 Product identifier

Product form : Mixture
Product name : Wash Solution (20X) **WASH|SOLN|CONC**
Catalog # : B33176 **REF**

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

1.2.1 Relevant identified uses

Use of the substance/mixture : Laboratory reagent, Immunoassays
Use by professionals

1.2.2 Uses advised against

No additional information available

1.3 Details of the supplier of the safety data sheet

Supplier/Manufacturer

DIAsource ImmunoAssays S.A.

Rue du Bosquet, 2

B-1348 Louvain-la-Neuve

Belgium

Tel. Nr. +32 (0)10/84.99.11

E-mail: products.support@diasource.be

1.4 Emergency telephone number

DIAsource (only office hours) : +32 (0)10/84.99.23
Centre Anti-Poisons (BE) : 070 245 245

Please refer to your local Anti-Poison Center!

2 Hazards identification

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) N° 1272/2008 (CLP)

Toxic to Reproductive, Category 1B (Repr. 1B) H360 May damage fertility or the unborn child

(Full test of H-statements: see section16)

2.2 Label element

Labelling according to Regulation (EC) N° 1272/2008 (CLP)

Hazard symbol (CLP) :



Signal word (CLP) : Danger

Hazard statement (CLP) : H360 May damage fertility or the unborn child

Precaution statement (CLP) : P201 Obtain special instructions before use

P280 Wear protective gloves/protective clothing/eye protection/face protection

P308+P313 IF exposed or concerned: Get medical advice/attention

P405 Store locked up

P501 Dispose of contents and container in accordance with all local, regional, national and international regulations

2.3 Other hazards

The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605.

3 Composition/information on ingredients

3.1 Substances

Not applicable

3.2 Mixtures

Name	Product identifier	%	Classification according to Regulation (EC) N° 1272/2008 [CLP]
Sodium Borate Decahydrate	(CAS N°) 1303-96-4 (EC N°) 215-540-4 (EC Index N°) 005-011-00-4	0.1 - <0.3	Repr. 1B, H360

Date of issue: 30.06.2025

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Version/Replaced version: 1.0/-

Boric Acid	(CAS N°) 10043-53-3 (EC N°) 233-139-2 (EC Index N°) 005-007-00-2	0.1 - <0.3	Repr. 1B, H360
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Full text of H-statements: see section16

4 First aid measures

4.1 Description of first aid measures

First-aid measures general

- : Get medical advice/attention if you feel unwell. If possible show him this sheet. Failing this, show him the packaging or label. Never give anything by mouth to an unconscious person. Place the affected person in the recovery position.

First-aid measures after inhalation

- : If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration immediately and obtain medical attention.

First-aid measures after skin contact

- : In case of skin contact, flush with copious amounts of water for at least 15 minutes. If pain or irritation occur, obtain medical attention.

First-aid measures after eye contact

- : If product enters eyes, wash eyes gently under running water for 15 minutes or longer, making sure that the eyelids are held open. If pain or irritation occur, obtain medical attention.

First-aid measures after ingestion

- : If ingested, wash mouth out with water. If irritation or discomfort occurs, seek medical attention.

4.2 Most important symptom and effects, both acute and delayed

Symptoms/effects

- : May damage fertility or the unborn child.
See Section 11 Toxicological Information for more detailed health information.

4.3 Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

5 Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media

- : In case of fire use carbon dioxide (CO2), dry chemical, water spray or foam. For large fires use extinguishing media suitable for surrounding fire.

Unsuitable extinguishing media

- : Do not use a heavy water stream.

5.2 Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire

- : No combustion products posing significant hazards are expected from this product (an aqueous solution).

5.3 Advice for firefighters

Firefighting instructions

- : Prevent firefighting water from entering the environment. Use water spray or fog for cooling exposed containers.

Protection during firefighting

- : Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations

6 Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

General measures

- : Ensure adequate air ventilation. Avoid contact with skin and eyes. Do not breathe vapours/spray.

6.1.1 For non-emergency personnel

- : Evacuate unnecessary personnel.

6.1.2 For emergency responders

- : Use personal protective equipment as required. In case of inadequate ventilation wear respiratory protection.

6.2 Environmental precautions

Contain spill to prevent migration. Do not allow the undiluted product to enter sewers/surface or ground water.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up

- : Absorb spilled material with an appropriate inert, non-flammable absorbent and dispose according to local regulations.

6.4 Reference to other sections

Exposure controls and personal protection, see section 8. Concerning disposal elimination after cleaning, see section 13.

7 Handling and storage

7.1 Precautions for safe handling

Precautions for safe handling

- : Ensure good ventilation of the work station. Wear personal protective equipment. Avoid contact with skin and eyes. Do not breathe vapour/aerosol.

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Hygiene measures : Handle in accordance with good industrial hygiene and safety procedures. When using do not eat, drink or smoke. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work.

7.2 Conditions for safe storage, including any incompatibilities

Storage conditions : Store at 2 to 8°C, as directed on the product label. To maintain product quality, store according to the instructions in the product labeling. Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

Prohibitions on mixed storage : Keep away from food, drink and animal feeding stuffs.

Incompatible materials : No additional information available.

7.3 Specific end use(s)

Laboratory reagent, Immunoassays

8 Exposure controls/personnel protection

8.1 Control parameters

Exposure limits : Boric Acid (CAS N° 10043-35-3)

US OSHA	None established
ACGIH	6 mg/m ³ STEL (inhalable particulate matter) (listed under Borate compounds, inorganic); 2 mg/m ³ TWA (inhalable particulate matter) (listed under Borate compounds, inorganic)
ACGIH Biological Exposure Indices (BEI)	None established
DFG MAK	10 mg/m ³ Peak (in case of a simultaneous presence of Boric acid and Tetraborates 0.75 mg Boron/m ³ applies) (as B) (inhalable fraction); 10 mg/m ³ TWA MAK (when boric acid and tetraborates are present together, the MAK value is 0.75 mg boron/m ³) (inhalable fraction) (as B)
Ireland	2 mg/m ³ TWA (listed under Borate compounds inorganic); 6 mg/m ³ STEL (calculated) (listed under Borate compounds inorganic)
IOELVs	None established
NIOSH	-
China	None established
Croatia	-
Japan	-
Sweden (AFS 2015:7 and amendments	-
Turkey	None established

Exposure limits : Sodiuim Borate Decahydrate (CAS N° 1303-96-4)

US OSHA	None established
ACGIH	6 mg/m ³ STEL (inhalable particulate matter) (listed under Borate compounds, inorganic); 2 mg/m ³ TWA (inhalable particulate matter) (listed under Borate compounds, inorganic)
ACGIH Biological Exposure Indices (BEI)	None established
DFG MAK	-
Ireland	5 mg/m ³ TWA (listed under Borates); 6 mg/m ³ STEL (calculated) (listed under Borates)
IOELVs	None established
NIOSH	5 mg/m ³ TWA
China	None established
Croatia	5 mg/m ³ TWA [GVI]; Reproductive Toxin Category 1B
Japan	2 mg/m ³ TLV NGV; 5 mg/m ³ Indicative STEL Vägledande KGV; Skin notation
Sweden (AFS 2015:7 and amendments	
Turkey	None established

8.2 Exposure controls

Appropriate engineering controls : Provide local exhaust or general room ventilation to minimize vapour concentrations.

Hand protection : Wear suitable gloves (EN 374). Nitrile rubber, 0.35 mm. Butyl rubber, 0.5 mm. The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

Eye protection : Wear safety glasses (EN 166).

Skin and body protection : Wear suitable protective clothing.

Respiratory protection : Under normal conditions, the use of this product should not require respiratory protection.

Environmental exposure controls : Avoid release to the environment.

9 Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state	: Liquid
Colour	: Colorless
Odor	: Odorless
Melting point/freezing point	: No data available
Boiling point or initial boiling point and boiling range	: No data available
Flammability	: Not flammable
Lower and upper explosion limit	: No data available
Flash point	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
pH	: 8.3
Kinematic viscosity	: No data available
Solubility	: Miscible
Partition coefficient n-octanol/water (log value)	: Not applicable
Vapour pressure	: No data available
Density and/or relative density	: 1.19 @ 20°C
Relative vapour density	: No data available
Particle size	: Not applicable

9.2 Other information

9.2.1 Information with regard to physical hazard classes

Explosive properties	: No explosive properties
Oxidising properties	: No oxidising properties

9.2.2 Other safety characteristics

No additional information available

10 Stability and reactivity

10.1 Reactivity

No dangerous reactions known under normal conditions of use.

10.2 Chemical stability

Stable under use and storage conditions as recommended in section 7.

10.3 Possibility of hazardous reactions

None under normal use.

10.4 Conditions to avoid

To maintain product performance keep away from strong acids, strong bases, strong oxidizers.

Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials

No additional information available.

10.6 Hazardous decomposition products

No hazardous decomposition products known at room temperature. In case of fire: Toxic gases may be formed. Carbon dioxide. Carbon monoxide.

11 Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Boric Acid (CAS N° 10043-35-3)	
LC50 inhalation rat	>2.12 mg/L 4 h (no deaths occurred)(dust)(ECHA_API)
LD50 dermal rabbit	>2000 mg/kg (NLM_HSDB)
LD50 oral rat	2660 mg/kg (JAPAN_GHS)

Sodium Borate Decahydrate (CAS N° 1303-96-4)

LD50 dermal rabbit	>10000 mg/kg (JAPAN_GHS)
LD50 oral rat	Rat 3493 mg/kg (NZ_CCID)
LC50 inhalation rat	>2 mg/m3 4 h (NLM_HSDB)

Acute toxicity : Not classified

Skin corrosion/irritation : Not classified

Based on available data, the classification criteria are not met

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Serious eye damage/irritation	: Not classified Based on available data, the classification criteria are not met
Respiratory or skin sensitization	: May cause skin and respiratory sensitization
Germ cell mutagenicity	: Not classified Based on available data, the classification criteria are not met
Carcinogenicity	: No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.
Reproductive toxicity	: May damage fertility or the unborn child.
Specific target organ toxicity (single exposure)	: Not classified Based on available data, the classification criteria are not met
Specific target organ toxicity (repeated exposure)	: Not classified Based on available data, the classification criteria are not met
Aspiration hazard	: Not classified Based on available data, the classification criteria are not met

11.2 Information on other hazards

Potential adverse human health effects and symptoms : Based on available data, the classification criteria are not met

12 Ecological information

12.1 Toxicity

Acute aquatic toxicity	: Not classified
Chronic aquatic toxicity	: Not classified

Boric Acid (CAS N° 10043-35-3)

Fresh water species	No information available
Microtox/organisms	No information available
Water flea	EC50 48 h Daphnia magna: 115 - 153 mg/L (EPA)
Fresh water algae	No information available

Sodium Borate Decahydrate (CAS N° 1303-96-4)

Fresh water species	No information available
Microtox/organisms	No information available
Water flea	No information available
Fresh water algae	No information available

12.2 Persistence and degradability

Not required for inorganic substances.

12.3 Bioaccumulative potential

Not required for inorganic substances.

12.4 Mobility in soil

No additional information available.

12.5 Results of PBT and vPvB assessment

Not fulfilling Persistent, Bioaccumulative and Toxic (PBT), very Persistent and very Bioaccumulative (vPvB) criteria.

12.6 Endocrine disrupting properties

No additional information available.

12.7 Other adverse effects

No additional information available.

13 Disposal considerations

13.1 Waste treatment methods

Regional legislation (waste)	: Dispose in a safe manner in accordance with local/national regulations.
Waste treatment methods	: Do not empty into drains. Dispose of this material and its container in a safe way.
Waste code	: The waste code number according to the Ordinance on the European Waste Catalogue depends on the waste producer and can therefore vary for any given product. The waste code number is therefore to be gleaned separately from each waste producer.

14 Transport information

In accordance with ADR / IMDG / IATA

14.1 UN number or ID number

UN-No. (ADR)	: Not applicable
UN-No. (IMDG)	: Not applicable

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UN-No. (IATA) : Not applicable

14.2 UN proper shipping nameProper Shipping Name (ADR) : Not applicable
Proper Shipping Name (IMDG) : Not applicable
Proper Shipping Name (IATA) : Not applicable**14.3 Transport hazard class(es)**Transport hazard class(es) (ADR) : Not applicable
Transport hazard class(es) (IMDG) : Not applicable
Transport hazard class(es) (IATA) : Not applicable**14.4 Packing group**Packing group (ADR) : Not applicable
Packing group (IMDG) : Not applicable
Packing group (IATA) : Not applicable**14.5 Environmental hazards**Dangerous for the environment : No
Marine pollutant : No
Other information : No supplementary information available**14.6 Special precautions for user**Overland transport : Not applicable
Transport by sea : Not applicable
Air transport : Not applicable**14.7 Maritime transport in bulk according to IMO instruments**

Not applicable

15 Regulatory information**15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture****15.1.1 EU-Regulations**

Contains no substance on the REACH candidate list.

Contains no REACH Annex XIV substances.

15.1.2 National regulations

Comply with applicable local regulations.

15.2 Chemical safety assessment

No chemical safety assessment has been carried out.

16 Other information

Data sources : REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Change compared to the previous version : -

Abbreviations and acronyms:

ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
CLP	Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures
DMEL	Derived Minimal Effect Level
DNEL	Derived No-Effect Level
EC50	The effective concentration of substance that causes 50% of the maximum response (Median Effective Concentration)
IATA	International Air Transport Association
IMDG	“International Maritime Dangerous Goods Code” for the transport of dangerous goods by sea
LC50	Lethal Concentration to 50 % of a test population (Median Lethal Concentration)
LD50	Lethal Dose to 50% of a test population (Median Lethal Dose)
LOAEL	Lowest Observed Adverse Effect Level
NOAEC/L	No Observed Adverse Effect Concentration/Level
NOEC/L	No Observed Effect Concentration/Level
OECD	Organisation for Economic Cooperation and Development
PBT	Persistent, Bioaccumulative and Toxic substance

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PNEC	Predicted No-Effect Concentration
REACH	Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals
SDS	Safety Data Sheet
STP	Sewage Treatment Plant
UFI	Unique Formula Identifier
vPvB	Very Persistent and Very Bioaccumulative

Full text of H- and EUH-phrases:

Repr. 1B	Toxic to Reproductive Category 1B
H360	May damage fertility or the unborn child.

SDS EU (REACH Annex II)

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.