

SAFETY DATA SHEET

Conforms to Regulation (EC) No. 1907/2006 (REACH), Annex II, as amended by UK REACH Regulation SI 2019/758

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

1.1 Product identifier

Product name

Detection reagent 2; part of 'ECL™ direct nucleic acid labelling and detection system'

Catalogue Number

RPN3000



Component Number

RPN3004V2

Product description

Not available.

Product type

Liquid.

Other means of identification

Not available.

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

Identified uses

Analytical chemistry.

Laboratory chemicals

Scientific research and development

1.3 Details of the supplier of the safety data sheet

Supplier

Cytiva
Amersham Place
Little Chalfont
Buckinghamshire
HP7 9NA United Kingdom
+44 1494 508000

Hours of operation

08.30 - 17.00

Person who prepared the SDS : sds_author@cytiva.com

1.4 Emergency telephone number

United Kingdom (UK)

Cytiva UK
Amersham Place
Little Chalfont
Buckinghamshire
HP7 9NA
t: 0870 606 1921

Call INFOTRAC 24 Hour number:
001-352-323-3500 (Call Collect).

National advisory body/Poison Centre

United Kingdom (UK)

Health professionals should contact the National Poisons Information Service (NPIS) by telephone, or use TOXBASE www.toxbase.org .

NPIS <http://www.npis.org/> advise that others seeking specific information on poisons should contact:
In England and Wales: NHS Direct - 0845 4647 or 111
In Scotland: NHS 24 - 08454 24 24 24
In N Ireland: Contact your local GP or pharmacist during normal hours; click here (www.gpoutofhours.hscni.net/) for GP services Out-of-Hours.



SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Product definition Mixture

Classification according to UK CLP/GHS

Repr. 1B, H360FD

The product is classified as hazardous according to UK CLP Regulation SI 2019/720 as amended.

See Section 16 for the full text of the H statements declared above.

See Section 11 for more detailed information on health effects and symptoms.

2.2 Label elements

Hazard pictograms



Signal word Danger

Hazard statements May damage fertility. May damage the unborn child.

Precautionary statements

General Not applicable.

Prevention Obtain special instructions before use. Wear protective gloves, protective clothing, eye protection, face protection, or hearing protection.

Response If exposed or concerned: Get medical advice or attention.

Storage Not applicable.

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

Supplemental label elements Contains reaction mass of 5-chloro-2- methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1). May produce an allergic reaction.

Annex XVII - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles

Restricted to professional users.

manufacture, placing on the

market and use of certain

dangerous substances,

mixtures and articles

Special packaging requirements

Containers to be fitted with child-resistant fastenings Not applicable.

Tactile warning of danger Not applicable.

2.3 Other hazards

Product meets the criteria for PBT or vPvB according to Regulation (EC) No. 1907/2006, Annex XIII

This mixture does not contain any substances that are assessed to be a PBT or a vPvB.

Other hazards which do not result in classification None known.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Mixture

Product/ingredient name	Identifiers	%	Classification	Type
boric acid	REACH #: 01-2119486683-25 EC: 233-139-2 CAS: 10043-35-3 Index: 005-007-00-2	0.5 - 1	Repr. 1B, H360FD	[1] [3]
sodium hydroxide	REACH #: 01-2119457892-27 EC: 215-185-5 CAS: 1310-73-2 Index: 011-002-00-6	0.1 - 0.5	Skin Corr. 1A, H314 Eye Dam. 1, H318	[1] [2]
reaction mass of 5-chloro-2- methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)	CAS: 55965-84-9 Index: 613-167-00-5	0.0005 - 0.00125	Acute Tox. 3, H301 Acute Tox. 2, H310 Acute Tox. 2, H330 Skin Corr. 1C, H314 Eye Dam. 1, H318 Skin Sens. 1A, H317	[1]



Aquatic Acute 1, H400
(M=100)
Aquatic Chronic 1, H410
(M=100)
EUH071

See Section 16 for the full text of the H statements declared above.

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as hazardous to health or the environment, are PBTs, vPvBs or Substances of equivalent concern, or have been assigned a workplace exposure limit and hence require reporting in this section.

Type

- [1] Substance classified with a physical, health or environmental hazard
- [2] Substance with a workplace exposure limit
- [3] Substance with carcinogenic, mutagenic or reproductive toxicity properties

Occupational exposure limits, if available, are listed in Section 8.

SECTION 4: First aid measures

4.1 Description of first aid measures

Eye contact	Flush immediately with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Continue to rinse for at least 10 minutes. Get medical attention if irritation occurs.
Inhalation	Remove victim to fresh air and keep at rest in a position comfortable for breathing. If not breathing, if breathing is irregular or if respiratory arrest occurs, provide artificial respiration or oxygen by trained personnel. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Get medical attention. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband.
Skin contact	Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Wash contaminated clothing thoroughly with water before removing it, or wear gloves. Continue to rinse for at least 10 minutes. Get medical attention. Wash clothing before reuse. Clean shoes thoroughly before reuse.
Ingestion	Wash out mouth with water. Remove dentures if any. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Stop if the exposed person feels sick as vomiting may be dangerous. Do not induce vomiting unless directed to do so by medical personnel. If vomiting occurs, the head should be kept low so that vomit does not enter the lungs. Get medical attention. Never give anything by mouth to an unconscious person. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband.
Protection of first-aiders	No action shall be taken involving any personal risk or without suitable training. If it is suspected that fumes are still present, the rescuer should wear an appropriate mask or self-contained breathing apparatus. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Wash contaminated clothing thoroughly with water before removing it, or wear gloves.

4.2 Most important symptoms and effects, both acute and delayed

Over-exposure signs/symptoms

Eye contact	No specific data.
Inhalation	Adverse symptoms may include the following: reduced foetal weight increase in foetal deaths skeletal malformations
Skin contact	Adverse symptoms may include the following: reduced foetal weight increase in foetal deaths skeletal malformations
Ingestion	Adverse symptoms may include the following: reduced foetal weight increase in foetal deaths skeletal malformations

4.3 Indication of any immediate medical attention and special treatment needed

Notes to physician	Treat symptomatically. Contact poison treatment specialist immediately if large quantities have been ingested or inhaled.
Specific treatments	No specific treatment.



SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media Use an extinguishing agent suitable for the surrounding fire.

Unsuitable extinguishing media None known.

5.2 Special hazards arising from the substance or mixture

Hazards from the substance or mixture In a fire or if heated, a pressure increase will occur and the container may burst.

Hazardous combustion products No specific data.

5.3 Advice for firefighters

Special precautions for fire-fighters Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training.

Special protective equipment for fire-fighters Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode. Clothing for fire-fighters (including helmets, protective boots and gloves) conforming to British standard BS EN 469 will provide a basic level of protection for chemical incidents.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel No action shall be taken involving any personal risk or without suitable training. Evacuate surrounding areas. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilt material. Avoid breathing vapour or mist. Provide adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Put on appropriate personal protective equipment.

For emergency responders If specialised clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials. See also the information in "For non-emergency personnel".

6.2 Environmental precautions

Avoid dispersal of spilt material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).

6.3 Methods and material for containment and cleaning up

Small spill Stop leak if without risk. Move containers from spill area. Absorb with an inert material and place in an appropriate waste disposal container. Dispose of via a licensed waste disposal contractor.

Large spill Stop leak if without risk. Move containers from spill area. Approach the release from upwind. Prevent entry into sewers, water courses, basements or confined areas. Wash spillages into an effluent treatment plant or proceed as follows. Dispose of via a licensed waste disposal contractor. Contaminated absorbent material may pose the same hazard as the spilt product. Contain and collect spillage with non-combustible, absorbent material e.g. sand, earth, vermiculite or diatomaceous earth and place in container for disposal according to local regulations.

6.4 Reference to other sections

See Section 1 for emergency contact information.

See Section 8 for information on appropriate personal protective equipment.

See Section 13 for additional waste treatment information.

SECTION 7: Handling and storage

The information in this section contains generic advice and guidance. The list of Identified Uses in Section 1 should be consulted for any available use-specific information provided in the Exposure Scenario(s).

7.1 Precautions for safe handling

Protective measures

Put on appropriate personal protective equipment (see Section 8). Avoid exposure - obtain special instructions before use. Avoid exposure during pregnancy. Do not handle until all safety precautions have been read and understood. Do not get in eyes or on skin or clothing. Do not ingest. Avoid breathing vapour or mist. If during normal use the material presents a respiratory hazard, use only with adequate ventilation or wear appropriate respirator. Keep in the original container or an approved alternative made from a compatible material, kept tightly closed when not in use. Empty containers retain product residue and can be hazardous. Do not reuse container.

Advice on general occupational hygiene

Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. Remove contaminated clothing and protective equipment before entering eating areas. See also Section 8 for additional information on hygiene measures.

7.2 Conditions for safe storage, including any incompatibilities

Store in accordance with local regulations. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see Section 10) and food and drink. Store locked up. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabelled containers. Use appropriate containment to avoid environmental contamination. See Section 10 for incompatible materials before handling or use.



7.3 Specific end use(s)

Recommendations	Analytical chemistry. Laboratory chemicals. Scientific research and development.
Industrial sector specific solutions	Not available.

SECTION 8: Exposure controls/personal protection**8.1 Control parameters****Occupational exposure limits**

Product/ingredient name	Exposure limit values
sodium hydroxide	EH40/2005 WELs (United Kingdom (UK), 1/2020) STEL 15 minutes: 2 mg/m ³ .

Biological exposure indices

No exposure indices known.

Recommended monitoring procedures

Reference should be made to monitoring standards, such as the following: British Standard BS EN 689 (Workplace atmospheres - Guidance for the assessment of exposure by inhalation to chemical agents for comparison with limit values and measurement strategy) British Standard BS EN 14042 (Workplace atmospheres - Guide for the application and use of procedures for the assessment of exposure to chemical and biological agents) British Standard BS EN 482 (Workplace atmospheres - General requirements for the performance of procedures for the measurement of chemical agents) Reference to national guidance documents for methods for the determination of hazardous substances will also be required.

DNELs/DMELs

Product/ingredient name	Result
boric acid	DNEL - General population - Short term - Oral 0.98 mg/kg bw/day <u>Effects:</u> Systemic
	DNEL - General population - Long term - Oral 0.98 mg/kg bw/day <u>Effects:</u> Systemic
	DNEL - General population - Long term - Inhalation 4.15 mg/m ³ <u>Effects:</u> Systemic
	DNEL - Workers - Long term - Inhalation 8.3 mg/m ³ <u>Effects:</u> Systemic
	DNEL - General population - Long term - Dermal 196 mg/kg bw/day <u>Effects:</u> Systemic
	DNEL - Workers - Long term - Dermal 392 mg/kg bw/day <u>Effects:</u> Systemic
sodium hydroxide	DNEL - General population - Long term - Inhalation 1 mg/m ³ <u>Effects:</u> Local
	DNEL - Workers - Long term - Inhalation 1 mg/m ³ <u>Effects:</u> Local
reaction mass of 5-chloro-2- methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3- one (3:1)	DNEL - General population - Long term - Inhalation 0.02 mg/m ³ <u>Effects:</u> Local
	DNEL - Workers - Long term - Inhalation 0.02 mg/m ³ <u>Effects:</u> Local
	DNEL - General population - Short term - Inhalation 0.04 mg/m ³ <u>Effects:</u> Local
	DNEL - Workers - Short term - Inhalation 0.04 mg/m ³ <u>Effects:</u> Local
	DNEL - General population - Long term - Oral 0.09 mg/kg bw/day <u>Effects:</u> Systemic
	DNEL - General population - Short term - Oral



0.11 mg/kg bw/day
Effects: Systemic

PNECs

Not available.

8.2 Exposure controls**Appropriate engineering controls**

If user operations generate dust, fumes, gas, vapour or mist, use process enclosures, local exhaust ventilation or other engineering controls to keep worker exposure to airborne contaminants below any recommended or statutory limits.

Individual protection measures**Hygiene measures**

Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.

Eye/face protection

Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: safety glasses with side-shields.

Skin protection**Hand protection**

Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary. Considering the parameters specified by the glove manufacturer, check during use that the gloves are still retaining their protective properties. It should be noted that the time to breakthrough for any glove material may be different for different glove manufacturers. In the case of mixtures, consisting of several substances, the protection time of the gloves cannot be accurately estimated.

Body protection

Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

Other skin protection

Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

Respiratory protection

Based on the hazard and potential for exposure, select a respirator that meets the appropriate standard or certification. Respirators must be used according to a respiratory protection program to ensure proper fitting, training, and other important aspects of use.

Environmental exposure controls

Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation. In some cases, fume scrubbers, filters or engineering modifications to the process equipment will be necessary to reduce emissions to acceptable levels.

SECTION 9: Physical and chemical properties

The conditions of measurement of all properties are at standard temperature and pressure unless otherwise indicated.

9.1 Information on basic physical and chemical properties**Appearance**

Physical state	Liquid.
Colour	Colourless.
Odour	Odourless.
Odour threshold	Not available.
pH	Not available.
Melting point/freezing point	Not available.
Initial boiling point and boiling range	Not available.
Flammability (solid, gas)	Not considered to be flammable .
Upper/lower flammability or explosive limits	Not available.
Flash point	Not applicable.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Solubility(ies)	
Media	Result
cold water	Easily soluble
hot water	Easily soluble
Solubility in water	Not available.
Miscible with water	Yes.



**Partition coefficient: n-octanol/
water**

Vapour pressure Not available.

Ingredient name	Vapour Pressure at 20°C			Vapour pressure at 50°C		
	mm Hg	kPa	Method	mm Hg	kPa	Method
Water	17.5	2.3				

Evaporation rate Not available.

Relative density Not available.

Vapour density Not available.

Explosive properties Not available.

Oxidising properties Not available.

Particle characteristics

Median particle size Not applicable.

9.2 Other information

Not available.

Burning time Not applicable.

Burning rate Not applicable.

Solubility in water Not available.

SECTION 10: Stability and reactivity

10.1 Reactivity No specific test data related to reactivity available for this product or its ingredients.

10.2 Chemical stability The product is stable.

10.3 Possibility of hazardous reactions Under normal conditions of storage and use, hazardous reactions will not occur.

10.4 Conditions to avoid No specific data.

10.5 Incompatible materials No specific data.

10.6 Hazardous decomposition products Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity

Product/ingredient name

Result

Water

Rat - Oral - LD50

2660 mg/kg

reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)

Rat - Oral - LD50

53 mg/kg

Toxic effects: Behavioral - Somnolence (general depressed activity)
Behavioral - Ataxia Lung, Thorax, or Respiration - Respiratory depression

Conclusion/Summary [Product] Not available.

Acute toxicity estimates

Product/ingredient name

Oral (mg/kg)

Dermal (mg/kg)

Inhalation (gases) (ppm)

Inhalation (vapours) (mg/l)

Inhalation (dusts and mists) (mg/l)

Water

2660

N/A

N/A

N/A

N/A

reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)

53

50

N/A

0.5

N/A

Skin corrosion/irritation

Product/ingredient name

Result

Water

Human - Skin - Severe irritant

Duration of treatment/exposure: 24 hours

Amount/concentration applied: 10 ppm

reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)

Human - Skin - Severe irritant

Amount/concentration applied: 0.01 %



Conclusion/Summary [Product] Not available.

Serious eye damage/eye irritation

Not available.

Conclusion/Summary [Product] Not available.

Respiratory corrosion/irritation

Not available.

Conclusion/Summary [Product] Not available.

Respiratory or skin sensitization

Not available.

Skin

Conclusion/Summary [Product] Not available.

Respiratory

Conclusion/Summary [Product] Not available.

Germ cell mutagenicity

Not available.

Conclusion/Summary [Product] Not available.

Carcinogenicity

Not available.

Conclusion/Summary [Product] Not available.

Reproductive toxicity

Not available.

Conclusion/Summary [Product] Not available.

Ingredient name

↳ boric acid

Conclusion/Summary

Reproductive toxin

Specific target organ toxicity (single exposure)

Not available.

Specific target organ toxicity (repeated exposure)

Not available.

Aspiration hazard

Not available.

Information on likely routes of exposure Routes of entry anticipated: Oral, Dermal, Inhalation, Eyes.

Potential acute health effects

Inhalation No known significant effects or critical hazards.

Ingestion No known significant effects or critical hazards.

Skin contact No known significant effects or critical hazards.

Eye contact No known significant effects or critical hazards.

Symptoms related to the physical, chemical and toxicological characteristics



Inhalation	Adverse symptoms may include the following: reduced foetal weight increase in foetal deaths skeletal malformations
Ingestion	Adverse symptoms may include the following: reduced foetal weight increase in foetal deaths skeletal malformations
Skin contact	Adverse symptoms may include the following: reduced foetal weight increase in foetal deaths skeletal malformations
Eye contact	No specific data.

Delayed and immediate effects as well as chronic effects from short and long-term exposure**Short term exposure**

Potential immediate effects Not available.

Potential delayed effects Not available.

Long term exposure

Potential immediate effects Not available.

Potential delayed effects Not available.

Potential chronic health effects

Not available.

Conclusion/Summary [Product] Not available.

General No known significant effects or critical hazards.

Carcinogenicity No known significant effects or critical hazards.

Mutagenicity No known significant effects or critical hazards.

Reproductive toxicity May damage fertility. May damage the unborn child.

Other information Not available.**SECTION 12: Ecological information****12.1 Toxicity****Product/ingredient name**

boric acid

Result**Chronic - NOEC - Fresh water**

Fish - Rainbow trout,donaldson trout - *Oncorhynchus mykiss*

2100 µg/l [87 days]

Effect: Mortality

Chronic - NOEC - Fresh water

Daphnia - Water flea - *Daphnia magna*

Age: <24 hours

6000 µg/l [21 days]

Effect: Reproduction

Acute - LC50 - Fresh water

US EPA

Crustaceans - Water flea - *Ceriodaphnia dubia*

Age: <24 hours

45.5 mg/l [48 hours]

Effect: Mortality

Acute - LC50 - Marine water

OECD

Fish - Red sea bream - *Pagrus major*

Weight: 0.6 g

75 mg/l [96 hours]

Effect: Mortality

sodium hydroxide

Acute - LC50 - Fresh water

Fish - Western mosquitofish - *Gambusia affinis* - Adult

125 ppm [96 hours]

Effect: Mortality

Conclusion/Summary [Product] Not available.

12.2 Persistence and degradability

Not available.



Conclusion/Summary [Product] Not available.**12.3 Bioaccumulative potential**

Product/ingredient name	LogP _{ow}	BCF	Potential
1	-1.09	-	Low

12.4 Mobility in soil**Soil/water partition coefficient** Not available.**Mobility** Not available.**12.5 Results of PBT and vPvB assessment**

boric acid	No	No	No	No	No	No	No
sodium hydroxide	No	No	No	No	No	No	No
reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)	No	N/A	N/A	No	N/A	N/A	N/A

12.6 Other adverse effects No known significant effects or critical hazards.**SECTION 13: Disposal considerations**

The information in this section contains generic advice and guidance. The list of Identified Uses in Section 1 should be consulted for any available use-specific information provided in the Exposure Scenario(s).

13.1 Waste treatment methods**Product**

Methods of disposal The generation of waste should be avoided or minimised wherever possible. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Waste should not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction.

Hazardous waste Within the present knowledge of the supplier, this product is not regarded as hazardous waste, as defined by EU Directive 2008/98/EC.

Packaging

Methods of disposal The generation of waste should be avoided or minimised wherever possible. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible.

Special precautions This material and its container must be disposed of in a safe way. Care should be taken when handling emptied containers that have not been cleaned or rinsed out. Empty containers or liners may retain some product residues. Avoid dispersal of spilt material and runoff and contact with soil, waterways, drains and sewers.

SECTION 14: Transport information

	ADR/RID	ADN	IMDG	IATA
14.1 UN number	Not regulated.	Not regulated.	Not regulated.	Not regulated.
14.2 UN proper shipping name	-	-	-	-
14.3 Transport hazard class(es)	-	-	-	-
14.4 Packing group	-	-	-	-
14.5 Environmental hazards	No.	No.	No.	No.
Additional information	-	-	-	-

14.6 Special precautions for user **Transport within user's premises:** always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.



14.7 Transport in bulk according to IMO instruments

Not available.

SECTION 15: Regulatory information

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

UK (GB)/REACH

Annex XIV - List of substances subject to authorisation

Annex XIV

None of the components are listed.

Substances of very high concern

Intrinsic property	Ingredient name	Status	Reference number	Date of revision
Toxic to reproduction	boric acid	Candidate	-	6/18/2010

Ozone depleting substances

Not listed.

Prior Informed Consent (PIC)

Not listed.

Persistent Organic Pollutants

Not listed.

Annex XVII - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles

Product/ingredient name	%	Designation [Usage]
Detection reagent 2; part of 'ECL direct nucleic acid labelling and detection system'	≥90	3
boric acid	30	30
	≤1	30

Labelling

Restricted to professional users.

Seveso Directive

This product is not controlled under the Seveso Directive.

EU regulations

Industrial emissions (integrated pollution prevention and control) - Air

Not listed

Industrial emissions (integrated pollution prevention and control) - Water

Not listed

International regulations

Chemical Weapon Convention List Schedules I, II & III Chemicals

Not listed.

Montreal Protocol

Not listed.

Stockholm Convention on Persistent Organic Pollutants

Not listed.

Rotterdam Convention on Prior Informed Consent (PIC)

Not listed.

UNECE Aarhus Protocol on POPs and Heavy Metals

Not listed.

Inventory list

United States

Not determined.

Canada inventory

Not determined.

China

All components are listed or exempted.

Japan

Japan inventory (CSCL): Not determined.

Japan inventory (ISHL): Not determined.

15.2 Chemical safety assessment

This product contains substances for which Chemical Safety Assessments are still required.



SECTION 16: Other information

 Indicates information that has changed from previously issued version.

Abbreviations and acronyms

ATE = Acute Toxicity Estimate
GB CLP = UK CLP (EC No 1272/2008) on the Classification, Labelling and Packaging of Substances and Mixtures as amended by (EU Exit) Regulations 2019 No. 720 and amendments
DMEL = Derived Minimal Effect Level
DNEL = Derived No Effect Level
E.UH statement = GB CLP-specific Hazard statement
N/A = Not available
PBT = Persistent, Bioaccumulative and Toxic
PNEC = Predicted No Effect Concentration
RRN = REACH Registration Number
SGG = Segregation Group
vPvB = Very Persistent and Very Bioaccumulative

Procedure used to derive the classification

Classification	Justification
Repr. 1B, H360FD	Calculation method

Full text of abbreviated H statements	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. H360FD May damage fertility. May damage the unborn child. 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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Full text of classifications	 Acute Tox. 2 Acute Tox. 3 Aquatic Acute 1 Aquatic Chronic 1 Eye Dam. 1 Repr. 1B Skin Corr. 1A Skin Corr. 1C Skin Sens. 1A	ACUTE TOXICITY - Category 2 ACUTE TOXICITY - Category 3 SHORT-TERM (ACUTE) AQUATIC HAZARD - Category 1 LONG-TERM (CHRONIC) AQUATIC HAZARD - Category 1 SERIOUS EYE DAMAGE/EYE IRRITATION - Category 1 REPRODUCTIVE TOXICITY - Category 1B SKIN CORROSION/IRRITATION - Category 1A SKIN CORROSION/IRRITATION - Category 1C SKIN SENSITISATION - Category 1A
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Version 8.04

Notice to reader

To the best of our knowledge, the information contained herein is accurate. However, neither the above-named supplier, nor any of its subsidiaries, assumes any liability whatsoever for the accuracy or completeness of the information contained herein.

Substances, assumes any liability whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.

