

**Positive Control GlutenTox ELISA Rapid G12**

Version number: 1.0

Date of compilation: 2020-03-23

**SECTION 1: Identification of the substance/mixture and of the company/undertaking****1.1 Product identifier**

Trade name **Positive Control GlutenTox ELISA Rapid G12**  
Registration number (REACH) not relevant (mixture)  
Product code(s) ASY3200

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

Relevant identified uses Laboratory and analytical use

**1.3 Details of the supplier of the safety data sheet**

Hygiena International  
8 Woodshots Meadow  
Herts Croxley Park  
United Kingdom

Telephone: +44 (0) 1923 818821  
Telefax: +44 (0)1923 818825  
e-mail: customerserviceuk@hygiena.com  
Website: www.Hygiena.com

**1.4 Emergency telephone number**

Emergency information service +44 (0) 1923 818821  
This number is only available during the following  
office hours: Mon-Fri 09:00 AM - 05:00 PM

**SECTION 2: Hazards identification****2.1 Classification of the substance or mixture**

Classification according to Regulation (EC) No 1272/2008 (CLP)

Section	Hazard class	Category	Hazard class and category	Hazard statement
2.6	flammable liquid	2	Flam. Liq. 2	H225

For full text of abbreviations: see SECTION 16.

The most important adverse physicochemical, human health and environmental effects

The product is combustible and can be ignited by potential ignition sources.

**2.2 Label elements**

Labelling according to Regulation (EC) No 1272/2008 (CLP)

- Signal word danger

- Pictograms

GHS02



- Hazard statements

H225 Highly flammable liquid and vapour.

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### - Precautionary statements

P210	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P233	Keep container tightly closed.
P303+P361+P353	IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water or shower.
P370+P378	In case of fire: Use sand, carbon dioxide or powder extinguisher to extinguish.
P403+P235	Store in a well-ventilated place. Keep cool.
P501	Dispose of contents/container to industrial combustion plant.

### 2.3 Other hazards

Results of PBT and vPvB assessment

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



## SECTION 3: Composition/information on ingredients

### 3.1 Substances

Not relevant (mixture)

### 3.2 Mixtures

Description of the mixture

Name of substance	Identifier	Wt%	Classification acc. to GHS	Pictograms
Pyrogen Free Water	CAS No 7732-18-5	≥ 90		
Ethyl alcohol	CAS No 64-17-5  EC No 200-578-6  Index No 603-002-00-5  REACH Reg. No 01-2119457610-43-xxxx	3 - < 5	Flam. Liq. 2 / H225 Eye Irrit. 2 / H319	
Bovine Serum Albumin	CAS No 9048-46-8	3 - < 5		
D-Sorbitol	CAS No 50-70-4	1 - < 3		
Tris	CAS No 77-86-1	0.1 - < 1		
PWG Gliadin		< 0.1		
CMIT/MIT dilution 2.5%	CAS No 55965-84-9  Index No 613-167-00-5	< 0.1	Acute Tox. 3 / H301 Acute Tox. 3 / H311 Acute Tox. 3 / H331 Skin Corr. 1B / H314 Eye Dam. 1 / H318 Skin Sens. 1 / H317 Aquatic Acute 1 / H400 Aquatic Chronic 1 / H410	

For full text of abbreviations: see SECTION 16.

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**SECTION 4: First aid measures****4.1 Description of first aid measures**

## General notes

Do not leave affected person unattended. Remove victim out of the danger area. Keep affected person warm, still and covered. Take off immediately all contaminated clothing. In all cases of doubt, or when symptoms persist, seek medical advice. In case of unconsciousness place person in the recovery position. Never give anything by mouth.

## Following inhalation

If breathing is irregular or stopped, immediately seek medical assistance and start first aid actions. Provide fresh air.

## Following skin contact

Wash with plenty of soap and water.

## Following eye contact

Remove contact lenses, if present and easy to do. Continue rinsing. Irrigate copiously with clean, fresh water for at least 10 minutes, holding the eyelids apart.

## Following ingestion

Rinse mouth with water (only if the person is conscious). Do NOT induce vomiting.

**4.2 Most important symptoms and effects, both acute and delayed**

Symptoms and effects are not known to date.

**4.3 Indication of any immediate medical attention and special treatment needed**

none

**SECTION 5: Firefighting measures****5.1 Extinguishing media**

## Suitable extinguishing media

Water spray, BC-powder, Carbon dioxide (CO<sub>2</sub>)

## Unsuitable extinguishing media

Water jet

**5.2 Special hazards arising from the substance or mixture**

In case of insufficient ventilation and/or in use, may form flammable/explosive vapour-air mixture. Solvent vapours are heavier than air and may spread along floors. Places which are not ventilated, e.g. unventilated below ground level areas such as trenches, conduits and shafts, are particularly prone to the presence of flammable substances or mixtures.

## Hazardous combustion products

Carbon monoxide (CO), Carbon dioxide (CO<sub>2</sub>)

**5.3 Advice for firefighters**

In case of fire and/or explosion do not breathe fumes. Co-ordinate firefighting measures to the fire surroundings. Do not allow firefighting water to enter drains or water courses. Collect contaminated firefighting water separately. Fight fire with normal precautions from a reasonable distance.

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**SECTION 6: Accidental release measures****6.1 Personal precautions, protective equipment and emergency procedures**

For non-emergency personnel

Remove persons to safety.

For emergency responders

Wear breathing apparatus if exposed to vapours/dust/spray/gases.

**6.2 Environmental precautions**

Keep away from drains, surface and ground water. Retain contaminated washing water and dispose of it.

**6.3 Methods and material for containment and cleaning up**

Advice on how to contain a spill

Covering of drains

Advice on how to clean up a spill

Wipe up with absorbent material (e.g. cloth, fleece). Collect spillage: sawdust, kieselgur (diatomite), sand, universal binder

Appropriate containment techniques

Use of adsorbent materials.

Other information relating to spills and releases

Place in appropriate containers for disposal. Ventilate affected area.

**6.4 Reference to other sections**

Hazardous combustion products: see section 5. Personal protective equipment: see section 8. Incompatible materials: see section 10. Disposal considerations: see section 13.

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

Recommendations

**- Measures to prevent fire as well as aerosol and dust generation**

Use local and general ventilation. Avoidance of ignition sources. Keep away from sources of ignition - No smoking. Take precautionary measures against static discharge. Use only in well-ventilated areas. Due to danger of explosion, prevent leakage of vapours into cellars, flues and ditches. Ground/bond container and receiving equipment. Use explosion-proof electrical/ventilating/lighting/equipment. Use only non-sparking tools.

**- Specific notes/details**

Places which are not ventilated, e.g. unventilated below ground level areas such as trenches, conduits and shafts, are particularly prone to the presence of flammable substances or mixtures. Vapours are heavier than air, spread along floors and form explosive mixtures with air. Vapours may form explosive mixtures with air.

Advice on general occupational hygiene

Wash hands after use. Do not eat, drink and smoke in work areas. Remove contaminated clothing and protective equipment before entering eating areas. Never keep food or drink in the vicinity of chemicals. Never place chemicals in containers that are normally used for food or drink. Keep away from food, drink and animal feedingstuffs.

**7.2 Conditions for safe storage, including any incompatibilities**

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### Managing of associated risks

#### - Explosive atmospheres

Keep container tightly closed and in a well-ventilated place. Use local and general ventilation. Keep cool. Protect from sunlight.

#### - Flammability hazards

Keep away from sources of ignition - No smoking. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Take precautionary measures against static discharge. Protect from sunlight.

### Control of effects

#### Protect against external exposure, such as

Frost

#### - Ventilation requirements

Use local and general ventilation. Ground/bond container and receiving equipment.

### 7.3 Specific end use(s)

See section 16 for a general overview.

## SECTION 8: Exposure controls/personal protection

### 8.1 Control parameters

#### Occupational exposure limit values (Workplace Exposure Limits)

Country	Name of agent	CAS No	Identifier	TWA [ppm]	TWA [mg/m <sup>3</sup> ]	STEL [ppm]	STEL [mg/m <sup>3</sup> ]	Ceiling-C [ppm]	Ceiling-C [mg/m <sup>3</sup> ]	Notation	Source
GB	ethanol	64-17-5	WEL	1,000	1,920						EH40/2005

#### Notation

##### Ceiling-C

ceiling value is a limit value above which exposure should not occur  
short-term exposure limit: a limit value above which exposure should not occur and which is related to a 15-minute period (unless otherwise specified)

##### TWA

time-weighted average (long-term exposure limit): measured or calculated in relation to a reference period of 8 hours time-weighted average (unless otherwise specified)

### 8.2 Exposure controls

#### Appropriate engineering controls

General ventilation.

#### Individual protection measures (personal protective equipment)

##### Eye/face protection

Wear eye/face protection.

##### Skin protection

#### - Hand protection

Wear suitable gloves. Chemical protection gloves are suitable, which are tested according to EN 374. Check leak-tightness/impermeability prior to use. In the case of wanting to use the gloves again, clean them before taking off and air them well. For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves.

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### - Other protection measures

Take recovery periods for skin regeneration. Preventive skin protection (barrier creams/ointments) is recommended. Wash hands thoroughly after handling.

### Respiratory protection

In case of inadequate ventilation wear respiratory protection.

### Environmental exposure controls

Use appropriate container to avoid environmental contamination. Keep away from drains, surface and ground water.

## SECTION 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

#### Appearance

Physical state	liquid
Colour	various
Odour	characteristic

#### Other safety parameters

pH (value)	not determined
Melting point/freezing point	not determined
Initial boiling point and boiling range	64.7 °C at 1,013 hPa
Flash point	9.7 °C at 1,013 hPa
Evaporation rate	not determined
Flammability (solid, gas)	not relevant, (fluid)

#### Explosive limits

- Lower explosion limit (LEL)	2.5 vol%
- Upper explosion limit (UEL)	13.5 vol%

Vapour pressure	169.3 hPa at 25 °C
Density	not determined
Vapour density	this information is not available
Relative density	information on this property is not available
Solubility(ies)	not determined

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## Partition coefficient

- n-octanol/water (log KOW)	this information is not available
Auto-ignition temperature	455 °C (auto-ignition temperature (liquids and gases))
Viscosity	not determined
Explosive properties	none
Oxidising properties	none

**9.2 Other information**

Solvent content	99 %
Solid content	1 %
Temperature class (EU, acc. to ATEX)	T1 (maximum permissible surface temperature on the equipment: 450°C)

**SECTION 10: Stability and reactivity****10.1 Reactivity**

Concerning incompatibility: see below "Conditions to avoid" and "Incompatible materials". The mixture contains reactive substance(s). Risk of ignition.

If heated:

Risk of ignition

**10.2 Chemical stability**

See below "Conditions to avoid".

**10.3 Possibility of hazardous reactions**

No known hazardous reactions.

**10.4 Conditions to avoid**

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

Hints to prevent fire or explosion

Use explosion-proof electrical/ventilating/lighting/equipment. Use only non-sparking tools. Take precautionary measures against static discharge.

**10.5 Incompatible materials**

Oxidisers

**10.6 Hazardous decomposition products**

Reasonably anticipated hazardous decomposition products produced as a result of use, storage, spill and heating are not known. Hazardous combustion products: see section 5.

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### SECTION 11: Toxicological information

#### 11.1 Information on toxicological effects

Test data are not available for the complete mixture.

##### Classification procedure

The method for classification of the mixture is based on ingredients of the mixture (additivity formula).

##### Classification according to GHS (1272/2008/EC, CLP)

##### Acute toxicity

Shall not be classified as acutely toxic.

Acute toxicity estimate (ATE) of components of the mixture

Name of substance	CAS No	Exposure route	ATE
CMIT/MIT dilution 2.5%	55965-84-9	oral	100 mg/kg
CMIT/MIT dilution 2.5%	55965-84-9	dermal	300 mg/kg

##### Skin corrosion/irritation

Shall not be classified as corrosive/irritant to skin.

##### Serious eye damage/eye irritation

Shall not be classified as seriously damaging to the eye or eye irritant.

##### Respiratory or skin sensitisation

Shall not be classified as a respiratory or skin sensitiser.

##### Germ cell mutagenicity

Shall not be classified as germ cell mutagenic.

##### Carcinogenicity

Shall not be classified as carcinogenic.

##### Reproductive toxicity

Shall not be classified as a reproductive toxicant.

##### Specific target organ toxicity - single exposure

Shall not be classified as a specific target organ toxicant (single exposure).

##### Specific target organ toxicity - repeated exposure

Shall not be classified as a specific target organ toxicant (repeated exposure).

##### Aspiration hazard

Shall not be classified as presenting an aspiration hazard.



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### SECTION 12: Ecological information

#### 12.1 Toxicity

Shall not be classified as hazardous to the aquatic environment.

#### 12.2 Persistence and degradability

Data are not available.

#### 12.3 Bioaccumulative potential

Data are not available.

#### 12.4 Mobility in soil

Data are not available.

#### 12.5 Results of PBT and vPvB assessment

Data are not available.

#### 12.6 Other adverse effects

Endocrine disrupting potential

None of the ingredients are listed.

### SECTION 13: Disposal considerations

#### 13.1 Waste treatment methods

Waste treatment-relevant information

Solvent reclamation/regeneration.

Sewage disposal-relevant information

Do not empty into drains. Avoid release to the environment. Refer to special instructions/safety data sheets.

Waste treatment of containers/packages

Completely emptied packages can be recycled. Handle contaminated packages in the same way as the substance itself.

#### Remarks

Please consider the relevant national or regional provisions. Waste shall be separated into the categories that can be handled separately by the local or national waste management facilities.

### SECTION 14: Transport information

#### 14.1 UN number

1993 not subject to transport regulations

#### 14.2 UN proper shipping name

FLAMMABLE LIQUID, N.O.S. not relevant

Technical name (hazardous ingredients)

Ethyl alcohol, CMIT/MIT dilution 2.5%

#### 14.3 Transport hazard class(es)

Class

3 (flammable liquids)

#### 14.4 Packing group

II (substance presenting medium danger)

#### 14.5 Environmental hazards

non-environmentally hazardous acc. to the dangerous goods regulations

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### 14.6 Special precautions for user

There is no additional information.

### 14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code

The cargo is not intended to be carried in bulk.

### Information for each of the UN Model Regulations

#### Transport of dangerous goods by road, rail and inland waterway (ADR/RID/ADN)

Not subject to ADR, RID and ADN.

#### International Maritime Dangerous Goods Code (IMDG)

Not subject to IMDG.

#### International Civil Aviation Organization (ICAO-IATA/DGR)

Not subject to ICAO-IATA.

## SECTION 15: Regulatory information

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

#### Relevant provisions of the European Union (EU)

#### Restrictions according to REACH, Annex XVII

Dangerous substances with restrictions (REACH, Annex XVII)				
Name of substance	Name acc. to inventory	CAS No	Restriction	No
Positive Control GlutenTox ELISA Rapid G12	this product meets the criteria for classification in accordance with Regulation No 1272/2008/EC		R3	3
Ethyl alcohol	flammable / pyrophoric		R40	40

#### Legend

R3

- Shall not be used in:
  - ornamental articles intended to produce light or colour effects by means of different phases, for example in ornamental lamps and ashtrays,
  - tricks and jokes,
  - games for one or more participants, or any article intended to be used as such, even with ornamental aspects,
- Articles not complying with paragraph 1 shall not be placed on the market.
- Shall not be placed on the market if they contain a colouring agent, unless required for fiscal reasons, or perfume, or both, if they:
  - can be used as fuel in decorative oil lamps for supply to the general public, and,
  - present an aspiration hazard and are labelled with R65 or H304,
- Decorative oil lamps for supply to the general public shall not be placed on the market unless they conform to the European Standard on Decorative oil lamps (EN 14059) adopted by the European Committee for Standardisation (CEN).
- Without prejudice to the implementation of other Community provisions relating to the classification, packaging and labelling of dangerous substances and mixtures, suppliers shall ensure, before the placing on the market, that the following requirements are met:
  - lamp oils, labelled with R65 or H304, intended for supply to the general public are visibly, legibly and indelibly marked as follows: 'Keep lamps filled with this liquid out of the reach of children'; and, by 1 December 2010, 'Just a sip of lamp oil - or even sucking the wick of lamps - may lead to life-threatening lung damage';
  - grill lighter fluids, labelled with R65 or H304, intended for supply to the general public are legibly and indelibly marked by 1 December 2010 as follows: 'Just a sip of grill lighter may lead to life threatening lung damage';
  - lamp oils and grill lighters, labelled with R65 or H304, intended for supply to the general public are packaged in black opaque containers not exceeding 1 litre by 1 December 2010.
- No later than 1 June 2014, the Commission shall request the European Chemicals Agency to prepare a dossier, in accordance with Article 69 of the present Regulation with a view to ban, if appropriate, grill lighter fluids and fuel for decorative lamps, labelled R65 or H304, intended for supply to the general public.
- Natural or legal persons placing on the market for the first time lamp oils and grill lighter fluids, labelled with R65 or H304, shall by 1 December 2011, and annually thereafter, provide data on alternatives to lamp oils and grill lighter fluids labelled R65 or H304 to the competent authority in the Member State concerned. Member States shall make those data available to the Commis-

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### Legend

- R40 sion.
1. Shall not be used, as substance or as mixtures in aerosol dispensers where these aerosol dispensers are intended for supply to the general public for entertainment and decorative purposes such as the following:
    - metallic glitter intended mainly for decoration,
    - artificial snow and frost,
    - 'whoopee' cushions,
    - silly string aerosols,
    - imitation excrement,
    - horns for parties,
    - decorative flakes and foams,
    - artificial cobwebs,
    - stink bombs.
  2. Without prejudice to the application of other Community provisions on the classification, packaging and labelling of substances, suppliers shall ensure before the placing on the market that the packaging of aerosol dispensers referred to above is marked visibly, legibly and indelibly with: 'For professional users only'.
  3. By way of derogation, paragraphs 1 and 2 shall not apply to the aerosol dispensers referred to Article 8 (1a) of Council Directive 75/324/EEC (2).
  4. The aerosol dispensers referred to in paragraphs 1 and 2 shall not be placed on the market unless they conform to the requirements indicated.

### List of substances subject to authorisation (REACH, Annex XIV) / SVHC - candidate list

none of the ingredients are listed

### Deco-Paint Directive (2004/42/EC)

VOC content	99 %
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### Directive on industrial emissions (VOCs, 2010/75/EU)

VOC content	99 %
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### Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS) - Annex II

none of the ingredients are listed

### Regulation 166/2006/EC concerning the establishment of a European Pollutant Release and Transfer Register (PRTR)

none of the ingredients are listed

### Directive 2000/60/EC establishing a framework for Community action in the field of water policy (WFD)

none of the ingredients are listed

## 15.2 Chemical Safety Assessment

Chemical safety assessments for substances in this mixture were not carried out.

## SECTION 16: Other information

### Abbreviations and acronyms

Abbr.	Descriptions of used abbreviations
Acute Tox.	Acute toxicity
ADN	Accord européen relatif au transport international des marchandises dangereuses par voies de navigation intérieures (European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways)

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Abbr.	Descriptions of used abbreviations
ADR	Accord européen relatif au transport international des marchandises dangereuses par route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
Aquatic Acute	Hazardous to the aquatic environment - acute hazard
Aquatic Chronic	Hazardous to the aquatic environment - chronic hazard
ATE	Acute Toxicity Estimate
CAS	Chemical Abstracts Service (service that maintains the most comprehensive list of chemical substances)
Ceiling-C	Ceiling value
CLP	Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures
DGR	Dangerous Goods Regulations (see IATA/DGR)
EC No	The EC Inventory (EINECS, ELINCS and the NLP-list) is the source for the seven-digit EC number, an identifier of substances commercially available within the EU (European Union)
EH40/2005	EH40/2005 Workplace exposure limits ( <a href="http://www.nationalarchives.gov.uk/doc/open-government-licence/">http://www.nationalarchives.gov.uk/doc/open-government-licence/</a> )
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of Notified Chemical Substances
Eye Dam.	Seriously damaging to the eye
Eye Irrit.	Irritant to the eye
Flam. Liq.	Flammable liquid
GHS	"Globally Harmonized System of Classification and Labelling of Chemicals" developed by the United Nations
IATA	International Air Transport Association
IATA/DGR	Dangerous Goods Regulations (DGR) for the air transport (IATA)
ICAO	International Civil Aviation Organization
IMDG	International Maritime Dangerous Goods Code
index No	The Index number is the identification code given to the substance in Part 3 of Annex VI to Regulation (EC) No 1272/2008
MARPOL	International Convention for the Prevention of Pollution from Ships (abbr. of "Marine Pollutant")
NLP	No-Longer Polymer
PBT	Persistent, Bioaccumulative and Toxic
ppm	Parts per million
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RID	Règlement concernant le transport International ferroviaire des marchandises Dangereuses (Regulations concerning the International carriage of Dangerous goods by Rail)
Skin Corr.	Corrosive to skin
Skin Irrit.	Irritant to skin
Skin Sens.	Skin sensitisation
STEL	Short-term exposure limit
SVHC	Substance of Very High Concern
TWA	Time-weighted average

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Abbr.	Descriptions of used abbreviations
VOC	Volatile Organic Compounds
vPvB	Very Persistent and very Bioaccumulative
WEL	Workplace exposure limit

### Key literature references and sources for data

Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures. Regulation (EC) No. 1907/2006 (REACH), amended by 2015/830/EU.

Transport of dangerous goods by road, rail and inland waterway (ADR/RID/ADN). International Maritime Dangerous Goods Code (IMDG). Dangerous Goods Regulations (DGR) for the air transport (IATA).

### Classification procedure

Physical and chemical properties: The classification is based on tested mixture.

Health hazards, Environmental hazards: The method for classification of the mixture is based on ingredients of the mixture (additivity formula).

### List of relevant phrases (code and full text as stated in chapter 2 and 3)

Code	Text
H225	Highly flammable liquid and vapour.
H301	Toxic if swallowed.
H311	Toxic in contact with skin.
H314	Causes severe skin burns and eye damage.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H331	Toxic if inhaled.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.

### Disclaimer

This information is based upon the present state of our knowledge. This SDS has been compiled and is solely intended for this product.