

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



## SARS-CoV-2 Rapid AG Test Nasal 25T. Var2

Version  
1.0

Revision Date:  
15.01.2021

Date of last issue: -  
Date of first issue: 15.01.2021

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

#### 1.1 Product identifier

Trade name : SARS-CoV-2 Rapid AG Test Nasal 25T. Var2  
Product code : 09365397043

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

Recommended restrictions : For use as part of an IVD method, only on use

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

Company : Roche Diagnostics Limited  
Charles Avenue  
Burgess Hill  
RH15 9RY West Sussex  
United Kingdom  
  
Telephone : +44 1444 256000  
Telefax : +44 1444 256239  
Responsible Department : +44 808 100 1920, +44 808 100 8010-  
E-mail address : -

#### 1.4 Emergency telephone number

In case of emergencies: : Health, Safety & Environ- +44 1444 256500 or +44 7802  
(Roche Diagnostics Ltd.) ment - 260498  
Product Safety / Vigilance +44 1444 256561 or +44 7710  
- 391653  
Toxicology 24Hr help-line: : NPIS: +44 844 892 0111  
Health Advice 24Hr help-line: NHS Direct: +44 845 4647  
NHS 24: +44 8454 242424

### SECTION 2: Hazards identification

#### 2.1 Classification of the substance or mixture

The product is a kit consisting of individual ingredients. The classification of the ingredients can be obtained from section 3. Section Label elements contains the resulting labelling for the kit.

#### 2.2 Label elements

##### Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms :



Signal word : Warning

Hazard statements : H317 May cause an allergic skin reaction.

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H319 Causes serious eye irritation.  
H412 Harmful to aquatic life with long lasting effects.

Precautionary statements : **Prevention:**

P261 Avoid breathing dust/ fume/ gas/ mist/ vapours/ spray.  
P273 Avoid release to the environment.  
P280 Wear protective gloves/ eye protection/ face protection.

**Response:**

P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.  
P337 + P313 If eye irritation persists: Get medical advice/ attention.  
P362 + P364 Take off contaminated clothing and wash it before reuse.

### 2.3 Other hazards

See SECTION 3

## SECTION 3: Composition/information on ingredients

### Buffer

#### Classification (REGULATION (EC) No 1272/2008)

Eye irritation, Category 2 H319: Causes serious eye irritation.  
Skin sensitisation, Category 1 H317: May cause an allergic skin reaction.  
Long-term (chronic) aquatic hazard, Category 3 H412: Harmful to aquatic life with long lasting effects.

#### Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
alpha-(4-(1,1,3,3-Tetramethylbutyl)phenyl)-omega-hydroxypoly(oxy-1,2-ethanediyl)	9002-93-1	Acute Tox. 4; H302 Eye Dam. 1; H318 Aquatic Chronic 2; H411	>= 1,0 - < 2,5
sodium azide	26628-22-8 247-852-1 011-004-00-7 01-2119457019-37-XXXX	Acute Tox. 2; H300 Acute Tox. 1; H310 STOT RE 2; H373 Aquatic Acute 1; H400 Aquatic Chronic 1; H410	>= 0,1 - < 0,25
reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)	55965-84-9 613-167-00-5	Acute Tox. 3; H301 Acute Tox. 2; H330 Acute Tox. 2; H310 Skin Corr. 1C; H314 Eye Dam. 1; H318	>= 0,0015 - < 0,0025

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		Skin Sens. 1A; H317 Aquatic Acute 1; H400 Aquatic Chronic 1; H410 <hr/> M-Factor (Acute aquatic toxicity): 100 M-Factor (Chronic aquatic toxicity): 100
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For explanation of abbreviations see section 16.

### ***Test Device (Positive Control Swab)***

#### **Classification (REGULATION (EC) No 1272/2008)**

Not a hazardous substance or mixture.

#### **Components**

Remarks : No hazardous ingredients

For explanation of abbreviations see section 16.

### ***Test Device (Negative Control Swab)***

#### **Classification (REGULATION (EC) No 1272/2008)**

Not a hazardous substance or mixture.

#### **Components**

Remarks : No hazardous ingredients

For explanation of abbreviations see section 16.

### ***Test Device (Test Stripe)***

#### **Classification (REGULATION (EC) No 1272/2008)**

Not a hazardous substance or mixture.

#### **Components**

Remarks : No hazardous ingredients

For explanation of abbreviations see section 16.

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## **SECTION 4: First aid measures**

### **4.1 Description of first aid measures**

General advice : Move out of dangerous area.  
Show this safety data sheet to the doctor in attendance.  
Do not leave the victim unattended.

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- If inhaled : Move to fresh air.  
If unconscious, place in recovery position and seek medical advice.  
If symptoms persist, call a physician.
- In case of skin contact : If skin irritation persists, call a physician.  
If on skin, rinse well with water.  
If on clothes, remove clothes.
- In case of eye contact : Immediately flush eye(s) with plenty of water.  
Remove contact lenses.  
Protect unharmed eye.  
Keep eye wide open while rinsing.  
If eye irritation persists, consult a specialist.
- If swallowed : Keep respiratory tract clear.  
Do not give milk or alcoholic beverages.  
Never give anything by mouth to an unconscious person.  
If symptoms persist, call a physician.  
Rinse mouth with water.

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

None known.

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

- Treatment : The first aid procedure should be established in consultation with the doctor responsible for industrial medicine.

## SECTION 5: Firefighting measures

### 5.1 Extinguishing media

- Suitable extinguishing media : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
- Unsuitable extinguishing media : High volume water jet

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

- Specific hazards during fire-fighting : Do not allow run-off from fire fighting to enter drains or water courses.
- Hazardous combustion products : Carbon oxides  
Nitrogen oxides (NOx)  
Gaseous hydrogen chloride (HCl).  
Sodium oxides

### 5.3 Advice for firefighters

- Special protective equipment for firefighters : Wear self-contained breathing apparatus for firefighting if necessary.
- Further information : Collect contaminated fire extinguishing water separately. This must not be discharged into drains.  
Fire residues and contaminated fire extinguishing water must

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be disposed of in accordance with local regulations.

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### SECTION 6: Accidental release measures

#### 6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Use personal protective equipment.  
Avoid dust formation.  
Avoid breathing dust.

#### 6.2 Environmental precautions

Environmental precautions : Prevent product from entering drains.  
Prevent further leakage or spillage if safe to do so.  
Local authorities should be advised if significant spillages cannot be contained.

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

Methods for cleaning up : Keep in suitable, closed containers for disposal.

#### 6.4 Reference to other sections

Treat recovered material as described in the section "Disposal considerations".

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### SECTION 7: Handling and storage

#### 7.1 Precautions for safe handling

Advice on safe handling : Avoid formation of respirable particles.  
Do not breathe vapours/dust.  
Avoid exposure - obtain special instructions before use.  
Avoid contact with skin and eyes.  
For personal protection see section 8.  
Smoking, eating and drinking should be prohibited in the application area.  
Dispose of rinse water in accordance with local and national regulations.  
Persons susceptible to skin sensitisation problems or asthma, allergies, chronic or recurrent respiratory disease should not be employed in any process in which this mixture is being used.

Advice on protection against fire and explosion : Avoid dust formation. Provide appropriate exhaust ventilation at places where dust is formed.

Hygiene measures : When using do not eat or drink. When using do not smoke.  
Wash hands before breaks and at the end of workday.

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

Requirements for storage areas and containers : Keep container tightly closed in a dry and well-ventilated place. Containers which are opened must be carefully resealed and kept upright to prevent leakage. Electrical installations / working materials must comply with the technological safety standards.

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Further information on storage conditions : See label, package insert or internal guidelines

Storage class (TRGS 510) : 13, Non Combustible Solids

Further information on storage stability : No decomposition if stored and applied as directed.

### 7.3 Specific end use(s)

Specific use(s) : This product contains a substance on REACH Annex XIV (substance of very high concern due to endocrine disrupting properties for the environment) at or above 0.1% w/w and may only be used under the exemption from authorisation for scientific research and development (including analytical activities, quality control and In-Vitro Diagnostics) under controlled conditions. Only trained and authorised personnel is allowed to handle the substance.

## SECTION 8: Exposure controls/personal protection

### 8.1 Control parameters

#### **Buffer**

#### **Occupational Exposure Limits**

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
sodium azide	26628-22-8	TWA	0,1 mg/m <sup>3</sup>	2000/39/EC
	Further information: Identifies the possibility of significant uptake through the skin, Indicative			
		STEL	0,3 mg/m <sup>3</sup>	2000/39/EC
	Further information: Identifies the possibility of significant uptake through the skin, Indicative			
		AGW	0,2 mg/m <sup>3</sup>	DE TRGS 900
	Peak-limit: excursion factor (category): 2;(I)			
reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)	55965-84-9	AGW (inhalable fraction)	0,2 mg/m <sup>3</sup>	DE TRGS 900
	Peak-limit: excursion factor (category): 2;(I)			
	Further information: Senate commission for the review of compounds at the work place dangerous for the health (MAK-commission)., When there is compliance with the OEL and biological tolerance values, there is no risk of harming the unborn child			

#### **Test Device (Positive Control Swab)**

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### Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
sodium azide	26628-22-8	TWA	0,1 mg/m <sup>3</sup>	2000/39/EC
	Further information: Identifies the possibility of significant uptake through the skin, Indicative			
		STEL	0,3 mg/m <sup>3</sup>	2000/39/EC
	Further information: Identifies the possibility of significant uptake through the skin, Indicative			
		AGW	0,2 mg/m <sup>3</sup>	DE TRGS 900
	Peak-limit: excursion factor (category): 2;(I)			

### Test Device (Negative Control Swab)

#### Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
sodium azide	26628-22-8	TWA	0,1 mg/m <sup>3</sup>	2000/39/EC
	Further information: Identifies the possibility of significant uptake through the skin, Indicative			
		STEL	0,3 mg/m <sup>3</sup>	2000/39/EC
	Further information: Identifies the possibility of significant uptake through the skin, Indicative			
		AGW	0,2 mg/m <sup>3</sup>	DE TRGS 900
	Peak-limit: excursion factor (category): 2;(I)			

### Test Device (Test Stripe)

#### Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
sodium azide	26628-22-8	TWA	0,1 mg/m <sup>3</sup>	2000/39/EC
	Further information: Identifies the possibility of significant uptake through the skin, Indicative			
		STEL	0,3 mg/m <sup>3</sup>	2000/39/EC
	Further information: Identifies the possibility of significant uptake through the skin, Indicative			
		AGW	0,2 mg/m <sup>3</sup>	DE TRGS 900
	Peak-limit: excursion factor (category): 2;(I)			

## 8.2 Exposure controls

### Engineering measures

No data available

### Personal protective equipment

Eye protection : Eye wash bottle with pure water  
Tightly fitting safety goggles  
Wear face-shield and protective suit for abnormal processing problems.

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### Hand protection

In case of contact through splashing:  
Material : Nitrile rubber  
Break through time : > 30 min  
Glove thickness : > 0,11 mm

In case of full contact:  
Material : butyl-rubber  
Break through time : > 480 min  
Glove thickness : > 0,4 mm

Remarks : The selected protective gloves have to satisfy the specifications of Regulation (EU) 2016/425 and the standard EN 374 derived from it. This recommendation is only valid for the product mentioned in the safety data sheet and provided by us and for the application specified by us. Please observe the instructions regarding permeability and breakthrough time which are provided by the supplier of the gloves. Also take into consideration the specific local conditions under which the product is used, such as the danger of cuts, abrasion, and the contact time. The suitability for a specific workplace should be discussed with the producers of the protective gloves.

Skin and body protection : Choose body protection according to the amount and concentration of the dangerous substance at the work place.

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## SECTION 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

#### **Buffer**

Appearance : liquid  
Colour : No data available  
Odour : No data available  
Odour Threshold : No data available  
pH : No data available  
Melting point/range : No data available  
Boiling point/boiling range : 100 °C  
Flash point : does not flash  
Evaporation rate : No data available  
Flammability (solid, gas) : Does not sustain combustion.  
Upper explosion limit / Upper : No data available



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flammability limit	
Lower explosion limit / Lower flammability limit	: No data available
Vapour pressure	: No data available
Relative vapour density	: No data available
Relative density	: No data available
Solubility(ies)	
Water solubility	: completely miscible
Solubility in other solvents	: No data available
Partition coefficient: n-octanol/water	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Viscosity	
Viscosity, dynamic	: No data available
Viscosity, kinematic	: No data available
Explosive properties	: Not explosive
Oxidizing properties	: The substance or mixture is not classified as oxidizing.

### **Test Device (Positive Control Swab)**

Appearance	: Liquid absorbed by inert carrier material
Colour	: red
Odour	: No data available
Odour Threshold	: No data available
pH	: No data available
Melting point/range	: No data available
Boiling point/boiling range	: 100 °C
Flash point	: does not flash
Evaporation rate	: No data available
Flammability (solid, gas)	: Does not sustain combustion.
Upper explosion limit / Upper	: No data available

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flammability limit

Lower explosion limit / Lower  
flammability limit : No data available

Vapour pressure : No data available

Relative vapour density : No data available

Relative density : No data available

Solubility(ies)

Water solubility : completely miscible

Solubility in other solvents : No data available

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

Auto-ignition temperature : No data available

Decomposition temperature : No data available

Viscosity

Viscosity, dynamic : No data available

Viscosity, kinematic : No data available

Explosive properties : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

### ***Test Device (Negative Control Swab)***

Appearance : liquid

Colour : green

Odour : No data available

Odour Threshold : No data available

pH : No data available

Melting point/range : No data available

Boiling point/boiling range : 100 °C

Flash point : does not flash

Evaporation rate : No data available

Flammability (solid, gas) : Does not sustain combustion.

Upper explosion limit / Upper : No data available

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flammability limit

Lower explosion limit / Lower flammability limit : No data available

Vapour pressure : No data available

Relative vapour density : No data available

Relative density : No data available

Solubility(ies)

Water solubility : completely miscible

Solubility in other solvents : No data available

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

Auto-ignition temperature : No data available

Decomposition temperature : No data available

Viscosity

Viscosity, dynamic : No data available

Viscosity, kinematic : No data available

Explosive properties : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

### ***Test Device (Test Stripe)***

Appearance : solid

Colour : No data available

Odour : odourless

Odour Threshold : Not applicable

pH : Not applicable

Melting point/range : No data available

Boiling point/boiling range : No data available

Flash point : does not flash

Evaporation rate : No data available

Flammability (solid, gas) : Does not sustain combustion.

Upper explosion limit / Upper : No data available

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flammability limit

Lower explosion limit / Lower  
flammability limit : No data available

Vapour pressure : No data available

Relative vapour density : Not applicable

Relative density : No data available

Solubility(ies)

Water solubility : insoluble

Solubility in other solvents : No data available

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

Auto-ignition temperature : No data available

Decomposition temperature : No data available

Viscosity

Viscosity, dynamic : Not applicable

Viscosity, kinematic : Not applicable

Explosive properties : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

### 9.2 Other information

#### **Buffer**

Flammability (liquids) : Does not sustain combustion.

Self-ignition : Not applicable

#### **Test Device (Positive Control Swab)**

Flammability (liquids) : Does not sustain combustion.

Self-ignition : Not applicable

#### **Test Device (Negative Control Swab)**

Flammability (liquids) : Does not sustain combustion.

Self-ignition : Not applicable

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### Test Device (Test Stripe)

Flammability (liquids) : Does not sustain combustion.  
Self-ignition : No data available

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## SECTION 10: Stability and reactivity

### 10.1 Reactivity

No dangerous reaction known under conditions of normal use.

### 10.2 Chemical stability

Stable under normal conditions.

### 10.3 Possibility of hazardous reactions

Hazardous reactions : No decomposition if stored and applied as directed.

### 10.4 Conditions to avoid

No data available

### 10.5 Incompatible materials

No data available

### 10.6 Hazardous decomposition products

No decomposition if stored and applied as directed.

In case of fire hazardous decomposition products may be produced such as:

Carbon oxides

Nitrogen oxides (NO<sub>x</sub>)

Gaseous hydrogen chloride (HCl).

Sodium oxides

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## SECTION 11: Toxicological information

### 11.1 Information on toxicological effects

#### Buffer

##### Acute toxicity

Not classified based on available information.

##### Components:

##### **alpha-(4-(1,1,3,3-Tetramethylbutyl)phenyl)-omega-hydroxypoly(oxy-1,2-ethanediyl):**

Acute oral toxicity : LD50 Oral (Rat): 1.900 - 5.000 mg/kg

Acute toxicity estimate: 500 mg/kg

Method: Expert judgement

Acute dermal toxicity : LD50 Dermal (Rabbit): > 3.000 mg/kg

##### **sodium azide:**

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Acute oral toxicity : LD50 Oral (Rat): 27 mg/kg  
Acute dermal toxicity : LD50 Dermal (Rabbit): 20 mg/kg  
LD50 Dermal (Rat): 50 mg/kg

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

Acute oral toxicity : LD50 Oral (Rat): 53 mg/kg  
Acute inhalation toxicity : Acute toxicity estimate: 3 mg/l  
Test atmosphere: vapour  
Method: Expert judgement  
Acute dermal toxicity : Acute toxicity estimate: 300 mg/kg  
Method: Expert judgement

### Skin corrosion/irritation

Not classified based on available information.

### Components:

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

Result : Causes burns.

### Serious eye damage/eye irritation

Causes serious eye irritation.

### Components:

### alpha-(4-(1,1,3,3-Tetramethylbutyl)phenyl)-omega-hydroxypoly(oxy-1,2-ethanediyl):

Result : Risk of serious damage to eyes.  
Remarks : May cause irreversible eye damage.

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

Remarks : May cause irreversible eye damage.

### Respiratory or skin sensitisation

#### Skin sensitisation

May cause an allergic skin reaction.

#### Respiratory sensitisation

Not classified based on available information.

### Components:

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

Assessment : May cause sensitisation by skin contact.  
Assessment : Toxic if swallowed, in contact with skin or if inhaled. May cause

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an allergic skin reaction.

### **Germ cell mutagenicity**

Not classified based on available information.

### **Carcinogenicity**

Not classified based on available information.

### **Reproductive toxicity**

Not classified based on available information.

### **STOT - single exposure**

Not classified based on available information.

### **Components:**

#### **sodium azide:**

Assessment : The substance or mixture is not classified as specific target organ toxicant, single exposure.

### **STOT - repeated exposure**

Not classified based on available information.

### **Components:**

#### **sodium azide:**

Assessment : May cause damage to organs through prolonged or repeated exposure.

### **Aspiration toxicity**

Not classified based on available information.

## ***Test Device (Positive Control Swab)***

### **Acute toxicity**

Not classified based on available information.

### **Skin corrosion/irritation**

Not classified based on available information.

### **Serious eye damage/eye irritation**

Not classified based on available information.

### **Respiratory or skin sensitisation**

#### **Skin sensitisation**

Not classified based on available information.

#### **Respiratory sensitisation**

Not classified based on available information.

### **Germ cell mutagenicity**

Not classified based on available information.

### **Carcinogenicity**

Not classified based on available information.

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### **Reproductive toxicity**

Not classified based on available information.

### **STOT - single exposure**

Not classified based on available information.

### **STOT - repeated exposure**

Not classified based on available information.

### **Aspiration toxicity**

Not classified based on available information.

### ***Test Device (Negative Control Swab)***

### **Acute toxicity**

Not classified based on available information.

### **Skin corrosion/irritation**

Not classified based on available information.

### **Serious eye damage/eye irritation**

Not classified based on available information.

### **Respiratory or skin sensitisation**

### **Skin sensitisation**

Not classified based on available information.

### **Respiratory sensitisation**

Not classified based on available information.

### **Germ cell mutagenicity**

Not classified based on available information.

### **Carcinogenicity**

Not classified based on available information.

### **Reproductive toxicity**

Not classified based on available information.

### **STOT - single exposure**

Not classified based on available information.

### **STOT - repeated exposure**

Not classified based on available information.

### **Aspiration toxicity**

Not classified based on available information.

### ***Test Device (Test Stripe)***

### **Acute toxicity**

Not classified based on available information.

### **Skin corrosion/irritation**

Not classified based on available information.

### **Serious eye damage/eye irritation**

Not classified based on available information.



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### Respiratory or skin sensitisation

#### Skin sensitisation

Not classified based on available information.

#### Respiratory sensitisation

Not classified based on available information.

#### Germ cell mutagenicity

Not classified based on available information.

#### Carcinogenicity

Not classified based on available information.

#### Reproductive toxicity

Not classified based on available information.

#### STOT - single exposure

Not classified based on available information.

#### STOT - repeated exposure

Not classified based on available information.

#### Aspiration toxicity

Not classified based on available information.

## SECTION 12: Ecological information

### 12.1 Toxicity

#### Buffer

##### Components:

##### **alpha-(4-(1,1,3,3-Tetramethylbutyl)phenyl)-omega-hydroxypoly(oxy-1,2-ethanediyl):**

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 4 - 8,9 mg/l  
Exposure time: 96 h

Toxicity to daphnia and other : EC50 (Daphnia magna (Water flea)): 18 - 26 mg/l  
aquatic invertebrates Exposure time: 48 h

##### **Ecotoxicology Assessment**

Chronic aquatic toxicity : Toxic to aquatic life with long lasting effects.

Toxicity Data on Soil : Not expected to adsorb on soil.

Other organisms relevant to : No data available  
the environment

##### **sodium azide:**

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 5,46 mg/l  
Exposure time: 96 h  
Method: OECD Test Guideline 203

Toxicity to daphnia and other : EC50 (Daphnia pulex (Water flea)): 4,2 mg/l

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aquatic invertebrates : Exposure time: 96 h

Toxicity to algae/aquatic plants : EC50 (Pseudokirchneriella subcapitata (green algae)): 0,35 mg/l  
Exposure time: 96 h  
Test Type: static test  
Method: OECD Test Guideline 201

Toxicity to microorganisms : EC50 (Photobacterium phosphoreum): 43 - 66 mg/l

### Ecotoxicology Assessment

Acute aquatic toxicity : Very toxic to aquatic life.

Chronic aquatic toxicity : Very toxic to aquatic life with long lasting effects.

Toxicity Data on Soil : Not expected to adsorb on soil.

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

Toxicity to fish : LC50 (Fish): 0,36 mg/l  
Exposure time: 96 h

M-Factor (Acute aquatic toxicity) : 100

M-Factor (Chronic aquatic toxicity) : 100

### Ecotoxicology Assessment

Toxicity Data on Soil : Not expected to adsorb on soil.

Other organisms relevant to the environment : No data available

### Test Device (Positive Control Swab)

No data available

### Test Device (Negative Control Swab)

No data available

### Test Device (Test Stripe)

No data available

## 12.2 Persistence and degradability

### Buffer

#### Components:

#### **alpha-(4-(1,1,3,3-Tetramethylbutyl)phenyl)-omega-hydroxypoly(oxy-1,2-ethanediyl):**

Biodegradability : Biodegradation: > 60 %  
Exposure time: 28 d  
Method: OECD Test Guideline 301B  
Remarks: According to the results of tests of biodegradability this product is not readily biodegradable.

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### ***Test Device (Positive Control Swab)***

No data available

### ***Test Device (Negative Control Swab)***

No data available

### ***Test Device (Test Stripe)***

No data available

## 12.3 Bioaccumulative potential

### ***Buffer***

#### **Components:**

#### **alpha-(4-(1,1,3,3-Tetramethylbutyl)phenyl)-omega-hydroxypoly(oxy-1,2-ethanediyl):**

Bioaccumulation : Remarks: No bioaccumulation is to be expected (log Pow <= 4).

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

#### **sodium azide:**

Partition coefficient: n-octanol/water : log Pow: 0,3

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

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

### ***Test Device (Positive Control Swab)***

No data available

### ***Test Device (Negative Control Swab)***

No data available

### ***Test Device (Test Stripe)***

No data available

## 12.4 Mobility in soil

### ***Buffer***

No data available

### ***Test Device (Positive Control Swab)***

No data available

### ***Test Device (Negative Control Swab)***

No data available

### ***Test Device (Test Stripe)***

No data available

## 12.5 Results of PBT and vPvB assessment

### ***Buffer***

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Not relevant

### ***Test Device (Positive Control Swab)***

Not relevant

### ***Test Device (Negative Control Swab)***

Not relevant

### ***Test Device (Test Stripe)***

Not relevant

## 12.6 Other adverse effects

### ***Buffer***

#### **Components:**

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

Additional ecological information : An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.  
Very toxic to aquatic life with long lasting effects.

### ***Test Device (Positive Control Swab)***

No data available

### ***Test Device (Negative Control Swab)***

No data available

### ***Test Device (Test Stripe)***

No data available

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## SECTION 13: Disposal considerations

### 13.1 Waste treatment methods

Product : The product contains a substance on REACH Annex XIV at or above 0.1% w/w. Cartridges / rests of product to be disposed of as if it was hazardous waste

The product should not be allowed to enter drains, water courses or the soil.  
Do not contaminate ponds, waterways or ditches with chemical or used container.  
Send to a licensed waste management company.

Contaminated packaging : Empty remaining contents.  
Dispose of as unused product.  
Empty containers should be taken to an approved waste handling site for recycling or disposal.  
Do not re-use empty containers.

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### SECTION 14: Transport information

#### 14.1 UN number

Not regulated as a dangerous good

#### 14.2 UN proper shipping name

Not regulated as a dangerous good

#### 14.3 Transport hazard class(es)

Not regulated as a dangerous good

#### 14.4 Packing group

Not regulated as a dangerous good

#### 14.5 Environmental hazards

Not regulated as a dangerous good

#### 14.6 Special precautions for user

Remarks : Not dangerous goods in the meaning of ADR/RID, ADN, IMDG-Code, ICAO/IATA-DGR

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

Remarks : Not applicable

### SECTION 15: Regulatory information

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

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.  
Not applicable

Water contaminating class : WGK 1 slightly hazardous to water  
(Germany)

#### **Buffer**

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII) : Conditions of restriction for the following entries should be considered:  
Number on list 3

Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals : Not applicable

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59) : alpha-(4-(1,1,3,3-Tetramethylbutyl)phenyl)-omega-hydroxypoly(oxy-1,2-ethanediyl)

REACH - List of substances subject to authorisation (Annex XIV) : alpha-(4-(1,1,3,3-Tetramethylbutyl)phenyl)-omega-

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hydroxypoly(oxy-1,2-ethanediyl)  
For customers in the European Economic Area: Contains SVHC: octyl/nonylphenol ethoxylates. For use as part of an IVD method and under controlled conditions only – acc. to Art. 56.3 and 3.23 REACH Regulation

Regulation (EC) No 1005/2009 on substances that deplete the ozone layer : Not applicable

Regulation (EU) 2019/1021 on persistent organic pollutants (recast) : Not applicable

### The components of this product are reported in the following inventories:

DSL : This product contains the following components that are not on the Canadian DSL nor NDSL.

Glycols  
Modified alkyl carboxylate

AICS : Not in compliance with the inventory

NZIoC : Not in compliance with the inventory

ENCS : Not in compliance with the inventory

ISHL : Not in compliance with the inventory

KECI : Not in compliance with the inventory

PICCS : Not in compliance with the inventory

IECSC : Not in compliance with the inventory

TCSI : Not in compliance with the inventory

TSCA : Product contains substance(s) not listed on TSCA inventory.

Volatile organic compounds : Directive 2010/75/EU of 24 November 2010 on industrial emissions (integrated pollution prevention and control)  
Not applicable

### Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms :



Signal word : Warning

Hazard statements : H317 May cause an allergic skin reaction.  
H319 Causes serious eye irritation.

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H412 Harmful to aquatic life with long lasting effects.

Precautionary statements : **Prevention:**  
P261 Avoid breathing dust/ fume/ gas/ mist/ vapours/ spray.  
P273 Avoid release to the environment.  
P280 Wear protective gloves/ eye protection/ face protection.  
**Response:**  
P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.  
P337 + P313 If eye irritation persists: Get medical advice/ attention.  
P362 + P364 Take off contaminated clothing and wash it before reuse.

Hazardous components which must be listed on the label:

55965-84-9 reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)

### Test Device (Positive Control Swab)

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII) : Not applicable

Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals : Not applicable

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59). : Not applicable

REACH - List of substances subject to authorisation (Annex XIV) : Not applicable

Regulation (EC) No 1005/2009 on substances that deplete the ozone layer : Not applicable

Regulation (EU) 2019/1021 on persistent organic pollutants (recast) : Not applicable

### The components of this product are reported in the following inventories:

DSL : This product contains the following components that are not on the Canadian DSL nor NDSL.

Albumins, beef serum  
Protein

AICS : Not in compliance with the inventory

NZIoC : On the inventory, or in compliance with the inventory

ENCS : Not in compliance with the inventory

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ISHL	:	Not in compliance with the inventory
KECI	:	Not in compliance with the inventory
PICCS	:	Not in compliance with the inventory
IECSC	:	Not in compliance with the inventory
TCSI	:	Not in compliance with the inventory
TSCA	:	Product contains substance(s) not listed on TSCA inventory.
Volatile organic compounds	:	Directive 2010/75/EU of 24 November 2010 on industrial emissions (integrated pollution prevention and control) Not applicable

### Labelling (REGULATION (EC) No 1272/2008)

Not a hazardous substance or mixture.

### Test Device (Negative Control Swab)

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII)	:	Not applicable
Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals	:	Not applicable
REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59).	:	Not applicable
REACH - List of substances subject to authorisation (Annex XIV)	:	Not applicable
Regulation (EC) No 1005/2009 on substances that deplete the ozone layer	:	Not applicable
Regulation (EU) 2019/1021 on persistent organic pollutants (recast)	:	Not applicable

### The components of this product are reported in the following inventories:

DSL	:	This product contains the following components that are not on the Canadian DSL nor NDSL.  Albumins, beef serum Proprietary Ingredients, non hazardous Protein
AICS	:	Not in compliance with the inventory
NZIoC	:	On the inventory, or in compliance with the inventory



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ENCS	:	Not in compliance with the inventory
ISHL	:	Not in compliance with the inventory
KECI	:	Not in compliance with the inventory
PICCS	:	Not in compliance with the inventory
IECSC	:	Not in compliance with the inventory
TCSI	:	Not in compliance with the inventory
TSCA	:	Product contains substance(s) not listed on TSCA inventory.
Volatile organic compounds	:	Directive 2010/75/EU of 24 November 2010 on industrial emissions (integrated pollution prevention and control) Not applicable

### Labelling (REGULATION (EC) No 1272/2008)

Not a hazardous substance or mixture.

### Test Device (Test Stripe)

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII)	:	Not applicable
Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals	:	Not applicable
REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59).	:	Not applicable
REACH - List of substances subject to authorisation (Annex XIV)	:	Not applicable
Regulation (EC) No 1005/2009 on substances that deplete the ozone layer	:	Not applicable
Regulation (EU) 2019/1021 on persistent organic pollutants (recast)	:	Not applicable

### The components of this product are reported in the following inventories:

DSL	:	This product contains the following components that are not on the Canadian DSL nor NDSL.  Antibodies Antigen / Protein, recombinant
AICS	:	Not in compliance with the inventory

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NZIoC	:	On the inventory, or in compliance with the inventory
ENCS	:	Not in compliance with the inventory
ISHL	:	Not in compliance with the inventory
KECI	:	Not in compliance with the inventory
PICCS	:	Not in compliance with the inventory
IECSC	:	Not in compliance with the inventory
TCSI	:	Not in compliance with the inventory
TSCA	:	Product contains substance(s) not listed on TSCA inventory.
Volatile organic compounds	:	Directive 2010/75/EU of 24 November 2010 on industrial emissions (integrated pollution prevention and control) Not applicable

### Labelling (REGULATION (EC) No 1272/2008)

Not a hazardous substance or mixture.

### 15.2 Chemical safety assessment

Chemical Safety Assessments for all substances in this product are either Complete or Not applicable.

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## SECTION 16: Other information

### Full text of H-Statements

H300	:	Fatal if swallowed.
H301	:	Toxic if swallowed.
H302	:	Harmful 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.
H373	:	May cause damage to organs through prolonged or repeated exposure.
H400	:	Very toxic to aquatic life.
H410	:	Very toxic to aquatic life with long lasting effects.
H411	:	Toxic to aquatic life with long lasting effects.

### Full text of other abbreviations

Acute Tox.	:	Acute toxicity
Aquatic Acute	:	Short-term (acute) aquatic hazard
Aquatic Chronic	:	Long-term (chronic) aquatic hazard
Eye Dam.	:	Serious eye damage
Skin Corr.	:	Skin corrosion
Skin Sens.	:	Skin sensitisation
STOT RE	:	Specific target organ toxicity - repeated exposure

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ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of Very High Concern; TCSI - Taiwan Chemical Substance Inventory; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

### Further information

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

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