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

1.1 Product identifier		
Trade name	:	SARS-CoV-2 & FluA/B Rapid Antigen Test
Product code	:	09366997043
	_	

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

Recommended restrictions	:	For professional users only.
on use		

1.3 Details of the supplier of the safety data sheet

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Company	Roche Diagnostics Limited Charles Avenue Burgess Hill RH15 9RY West Sussex United Kingdom	
Telephone Telefax Responsible Department E-mail address	+44 1444 256000 +44 1444 256239 +44 808 100 1920, +44 808 100 8010- -	
1.4 Emergency telephone number		
In case of emergencies: (Roche Diagnostics Ltd.)	Health, Safety & Environ- +44 1444 256500 or +44 ment - Product Safety / Vigilance +44 1444 256561 or +44 - 391653	
Toxicology 24Hr help-line: Health Advice 24Hr help-line:	NPIS: +44 844 892 0111 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

Warning

:

Signal word

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Hazard statements	H317 May cause an allergic skin reaction.H412 Harmful to aquatic life with long lasting effects.
Precautionary statements	Prevention:P261Avoid breathing mist or vapours.P273Avoid release to the environment.P280Wear protective gloves.
	Response: P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention. P362 + P364 Take off contaminated clothing and wash it before reuse.
	Disposal: P501 Dispose of contents/ container to an approved waste disposal plant.

2.3 Other hazards

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

SECTION 3: Composition/information on ingredients

Buffer

Classification (REGULATION (EC) No 1272/2008)

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)
Polidocanol	9002-92-0 500-002-6 01-2119968561-30	Acute Tox. 4; H302 Eye Irrit. 2; H319 Aquatic Acute 1; H400 Aquatic Chronic 1; H410	>= 1,0 - < 2,5





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sodium azide	26628-22-8 247-852-1 011-004-00-7 01-2119457019-37	M-Factor (Acute aquatic toxicity): 1 Acute toxicity esti- mate Acute oral toxicity: 1.000 mg/kg Acute Tox. 2; H300 Acute Tox. 2; H300 Acute Tox. 2; H330 Acute Tox. 1; H310 STOT RE 2; H373 Aquatic Acute 1; H400 Aquatic Chronic 1; H410 EUH032	>= 0,1 - < 0,25
		Acute toxicity esti- mate Acute oral toxicity: 27 mg/kg Acute inhalation tox- icity (dust/mist): > 0,05 mg/l Acute dermal toxicity: 20 mg/kg	0.0045
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 Skin Sens. 1A; H317 Aquatic Acute 1; H400 Aquatic Chronic 1; H410 EUH071 M-Factor (Acute aquatic toxicity): 100	>= 0,0015 - < 0,0025
		aquatic toxicity): 100 M-Factor (Chronic aquatic toxicity): 100 	

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0,06 - < 0,6 % Skin Sens. 1A; H317 >= 0,0015 % Eye Dam. 1; H318 >= 0,6 %
Acute toxicity esti- mate
Acute oral toxicity: 53 mg/kg Acute inhalation tox- icity (vapour): 3 mg/l Acute dermal toxicity: 300 mg/kg

Roch

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.

Flu A/B Antigen Control Swab-Positive

Classification (REGULATION (EC) No 1272/2008)

Not a hazardous substance or mixture.

Components

Remarks : No hazardous ingredients

For explanation of abbreviations see section 16.

SARS CoV 2 & Flu A/B Control Swab-negative

Classification (REGULATION (EC) No 1272/2008) Not a hazardous substance or mixture.

Components		
Remarks	:	No hazardous ingredients

For explanation of abbreviations see section 16.

SARS-CoV 2 Antigen Control Swab-Positive



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Classification (REGULATION (EC) No 1272/2008)

Not a hazardous substance or mixture.

Components

Remarks

: No hazardous ingredients

For explanation of abbreviations see section 16.

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.	
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 cir- cumstances and the surrounding environment.
Unsuitable extinguishing media	:	High volume water jet



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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 prod- ucts	:	In case of fire hazardous decomposition products may be produced such as: Carbon oxides Sodium oxides Gaseous hydrogen chloride (HCI).

5.3 Advice for firefighters

Special protective equipment for firefighters	:	Wear self-contained breathing apparatus for firefighting if nec- essary.
Further information	:	Collect contaminated fire extinguishing water separately. This must not be discharged into drains. Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures Personal precautions Use personal protective equipment. Refer to protective measures listed in sections 7 and 8. 6.2 Environmental precautions Environmental precautions Prevent product from entering drains.

Prevent further leakage or spillage if safe to do so.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Soak up with inert absorbent material (e.g. sand, silica gel, acid binder, universal binder, sawdust). Keep in suitable, closed containers for disposal.

6.4 Reference to other sections

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

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Advice on safe handling	: 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 ap-
	plication area.
	Dispose of rinse water in accordance with local and national
	regulations.



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		allergies, d	usceptible to skin sensitisation problems or asthma chronic or recurrent respiratory disease should not ed in any process in which this mixture is being
Advice on protection fire and explosion	on against :	Normal me	easures for preventive fire protection.
Hygiene measures	S :	When using do not eat or drink. When using do not sm Wash hands before breaks and at the end of workday.	
7.2 Conditions for saf Requirements for areas and contain	storage :	Keep cont place. Cor sealed and	ainer tightly closed in a dry and well-ventilated tainers which are opened must be carefully re- d kept upright to prevent leakage. Electrical installa- king materials must comply with the technological
Further information age conditions	n on stor- :	See label,	package insert or internal guidelines
Storage class (TR	GS 510) :	12, Non C	ombustible Liquids
Further information age stability	n on stor- :	No decom	position if stored and applied as directed.
7.3 Specific end use(s Specific use(s)	5)	Laboratory	chemicals

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

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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/m3	2000/39/EC
	Further information: Identifies the possibility of significant uptake through the skin, Indicative			
		STEL	0,3 mg/m3	2000/39/EC
	Further information: Identifies the possibility of significant uptake through the			
	skin, Indicative			
		AGW	0,2 mg/m3	DE TRGS 900
	Peak-limit: excursion factor (category): 2;(I)			
reaction mass of 5- chloro-2-methyl- 2H-isothiazol-3-	55965-84-9	AGW (inhalable fraction)	0,2 mg/m3	DE TRGS 900

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

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Test Device (Test Stripe)

Contains no substances with occupational exposure limit values.

Flu A/B Antigen Control Swab-Positive

Contains no substances with occupational exposure limit values.

SARS CoV 2 & Flu A/B Control Swab-negative

Contains no substances with occupational exposure limit values.

SARS-CoV 2 Antigen Control Swab-Positive

Contains no substances with occupational exposure limit values.

8.2 Exposure controls

Engineering measures No data available		
Personal protective equipm	nent	
Eye protection	:	Use eye protection according to EN 166.
		Eye wash bottle with pure water Tightly fitting safety goggles
Hand protection		
Material Break through time Glove thickness Material Break through time	:	In case of contact through splashing: Nitrile rubber > 30 min > 0,11 mm In case of full contact: butyl-rubber > 480 min
Glove thickness	:	> 0,4 mm
Remarks	:	The selected protective gloves have to satisfy the specifica- tions 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



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		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	:	Impervious clothing Choose body protection according to the amount and con- centration of the dangerous substance at the work place.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties *Buffer*

F	Physical state	:	liquid
C	Colour	:	colourless
C	Ddour	:	No data available
C	Ddour Threshold	:	No data available
Ν	felting point/range	:	No data available
E	Boiling point/boiling range	:	100 °C
F	lammability	:	Does not sustain combustion.
	Jpper explosion limit / Upper lammability limit	:	No data available
	ower explosion limit / Lower lammability limit	:	No data available
F	Flash point	:	does not flash
Α	Auto-ignition temperature	:	No data available
C	Decomposition temperature	:	No data available
p	Н	:	No data available
V	/iscosity Viscosity, dynamic	:	No data available
	Viscosity, kinematic	:	No data available
S	Solubility(ies) Water solubility	:	completely miscible
	Solubility in other solvents	:	No data available

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Partition coefficient: n- octanol/water	: No data available	
Vapour pressure	: No data available	
Relative density	: No data available	
Relative vapour density	: No data available	

Test Device (Test Stripe)

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Physical state	:	solid
Colour	:	No data available
Odour	:	odourless
Odour Threshold	:	Not applicable
Melting point/range	:	No data available
Boiling point/boiling range	:	No data available
Flammability	:	Does not sustain combustion.
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Flash point		does not flash
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
рН	:	Not applicable
Viscosity Viscosity, dynamic	:	Not applicable
Viscosity, kinematic	:	Not applicable
Solubility(ies) Water solubility	:	insoluble
Solubility in other solvents	:	No data available
Partition coefficient: n- octanol/water	:	No data available
Vapour pressure	:	No data available



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Relative density	:	No data available
Relative vapour density	:	Not applicable

Flu A/B Antigen Control Swab-Positive

Physical state	:	Liquid absorbed by inert carrier material
Colour	:	colourless
Odour	:	No data available
Odour Threshold	:	No data available
Melting point/range	:	No data available
Boiling point/boiling range	:	100 °C
Flammability	:	Does not sustain combustion.
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Flash point		does not flash
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
рН	:	No data available
Viscosity Viscosity, dynamic	:	No data available
Viscosity, kinematic	:	No data available
Solubility(ies) Water solubility	:	insoluble
Solubility in other solvents	:	No data available
Partition coefficient: n- octanol/water	:	No data available
Vapour pressure	:	No data available
Relative density	:	No data available
Relative vapour density	:	No data available



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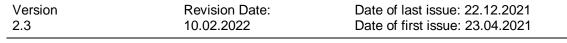
SARS CoV 2 & Flu A/B Control Swab-negative

Physical state	:	solid
Colour	:	colourless
Odour	:	No data available
Odour Threshold	:	No data available
Melting point/range	:	No data available
Boiling point/boiling range	:	100 °C
Flammability	:	Does not sustain combustion.
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Flash point		does not flash
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
рН	:	No data available
Viscosity Viscosity, dynamic	:	No data available
Viscosity, kinematic	:	No data available
Solubility(ies) Water solubility	:	insoluble
Solubility in other solvents	:	No data available
Partition coefficient: n- octanol/water	:	No data available
Vapour pressure	:	No data available
Relative density	:	No data available
Relative vapour density	:	No data available

SARS-CoV 2 Antigen Control Swab-Positive

Physical state

: Liquid absorbed by inert carrier material



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Colour	:	colourless
Odour	:	No data available
Odour Threshold	:	No data available
Melting point/range	:	No data available
Boiling point/boiling range	:	100 °C
Flammability	:	Does not sustain combustion.
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Flash point		does not flash
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
рН	:	No data available
pH Viscosity Viscosity, dynamic	:	
Viscosity	: : :	
· Viscosity Viscosity, dynamic	-	No data available No data available
Viscosity Viscosity, dynamic Viscosity, kinematic Solubility(ies)	:	No data available No data available
Viscosity Viscosity, dynamic Viscosity, kinematic Solubility(ies) Water solubility	:	No data available No data available insoluble
Viscosity Viscosity, dynamic Viscosity, kinematic Solubility(ies) Water solubility Solubility in other solvents Partition coefficient: n-	:	No data available No data available insoluble No data available
Viscosity Viscosity, dynamic Viscosity, kinematic Solubility(ies) Water solubility Solubility in other solvents Partition coefficient: n- octanol/water	:	No data available No data available insoluble No data available No data available
Viscosity Viscosity, dynamic Viscosity, kinematic Solubility(ies) Water solubility Solubility in other solvents Partition coefficient: n- octanol/water Vapour pressure	:	No data available No data available insoluble No data available No data available No data available

9.2 Other information <i>Buffer</i>		
Explosives	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.

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Flammability (liquids)	:	Does not sustain combustion.
Self-ignition	:	Not applicable
Evaporation rate	:	No data available
Test Device (Test Stripe)		
Explosives	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Flammability (liquids)	:	Does not sustain combustion.
Self-ignition	:	No data available
Evaporation rate	:	No data available

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Flu A/B Antigen Control Swab-Positive

Explosives	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Flammability (liquids)	:	Does not sustain combustion.
Self-ignition	:	Not applicable
Evaporation rate	:	No data available

SARS CoV 2 & Flu A/B Control Swab-negative

Explosives	: Not explosive
Oxidizing properties	: The substance or mixture is not classified as oxidizing.
Flammability (liquids)	: Does not sustain combustion.
Self-ignition	: Not applicable
Evaporation rate	: No data available

SARS-CoV 2 Antigen Control Swab-Positive

Explosives	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Flammability (liquids)	:	Does not sustain combustion.



ARS-COV-2 & FIUA/B Rapid Antigen Test

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Self-ignition	:	Not applicable
Evaporation rate	:	No data available

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 data available

SECTION 11: Toxicological information

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

Acute toxicity

Not classified based on available information.

Components:

Polidocanol:

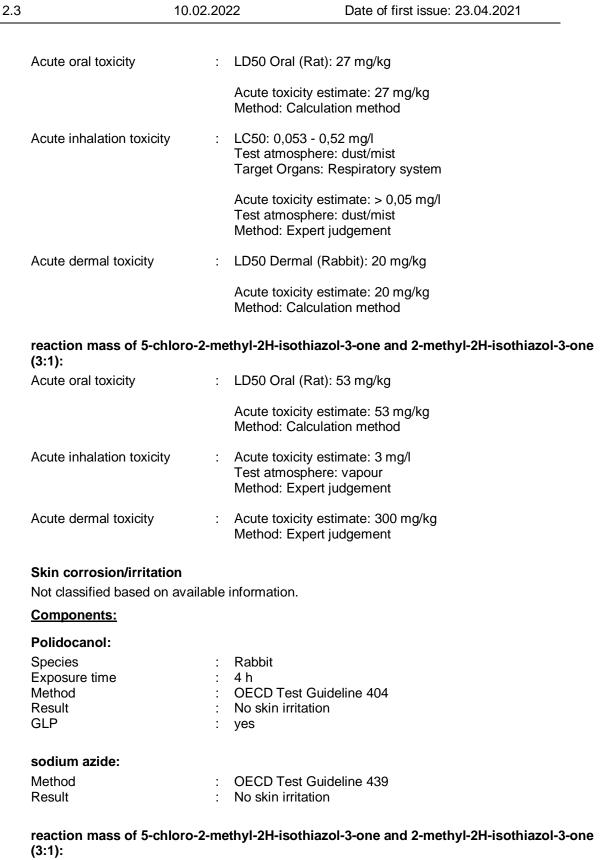
Acute oral toxicity :	LD50 Oral (Rat): 1.000 mg/kg Method: OECD Test Guideline 423 GLP: yes
	Acute toxicity estimate: 1.000 mg/kg Method: Calculation method
Acute dermal toxicity :	LD50 Dermal (Rat, male and female): > 2.000 mg/kg Method: OECD Test Guideline 402 GLP: yes

sodium azide:



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Result : Causes burns.



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Serious eye damage/eye irritation

Not classified based on available information.

Components:

Polidocanol:

Species	:	Rabbit
Method	:	OECD Test Guideline 405
Result	:	Irritating to eyes.
GLP	:	yes

sodium azide:

Species	:	Bovine cornea
Exposure time	:	4 h
Method	:	OECD Test Guideline 437
Result	:	No eye irritation

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:

Polidocanol:

Test Type	:	Draize Test
Species	:	Guinea pig
Result	:	Does not cause skin sensitisation.
GLP	:	no

sodium azide: Test Type Species Method Result	: : :	Local lymph node assay (LLNA) Mouse OECD Test Guideline 429 negative		
Assessment	:	Fatal if inhaled.		
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 an allergic skin reaction.		

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Germ cell mutagenicity Not classified based on a	vailable information.	
Components:		
Polidocanol:		
Genotoxicity in vitro	Metabolic ao Result: nega Test Type: 0	: Salmonella typhimurium tivation: with and without metabolic activation
		ctivation: with and without metabolic activation
		n vitro mammalian cell gene mutation test : mouse lymphoma cells ative
Genotoxicity in vivo	: Test Type: in Species: Mo Strain: B6C3 Cell type: Bo Application F Exposure tin Dose: 125 m Result: nega	buse (male) BF1 Rone marrow Route: Intraperitoneal injection ne: 72 h ng/kg
sodium azide:		
Genotoxicity in vitro		Chromosome aberration test in vitro : Chinese hamster ovary cells ative
		ister chromatid exchange assay : Chinese hamster ovary cells ative
		inscheduled DNA synthesis assay : Chinese hamster lung cells itive
Carcinogenicity Not classified based on a	vailable information.	
Reproductive toxicity Not classified based on a	vailable information.	
Components:		
Polidocanol:		
Effects on foetal develop- ment	· Test Type: T Species: Ra Application F	

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Developmental Toxicity: NOAEL: 50 mg/kg bw/day

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

Not classified based on available information.

Components:

sodium azide:

Assessment

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

Repeated dose toxicity

Components:

Polidocanol:

Species	:	Rat, male
NOAEL	:	390 mg/kg bw/day
Application Route	:	Oral
Exposure time	:	22 d

sodium azide:

Species	:	Rat
NOAEL	:	5 mg/kg
LOAEL	:	10 mg/kg
Application Route	:	Oral
Exposure time	:	24 Months
Method	:	OECD Test Guideline 453
Species	:	Rat
NOAEL	:	10 mg/kg
LOAEL	:	20 mg/kg
Application Route	:	Oral

: 90 d

Aspiration toxicity

Not classified based on available information. *Test Device (Test Stripe)*

Acute toxicity

Exposure time

Not classified based on available information.

Skin corrosion/irritation

Not classified based on available information.

Serious eye damage/eye irritation

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Respiratory or skin sensitisation

Skin sensitisation

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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. Flu A/B Antigen Control Swab-Positive

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.





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Aspiration toxicity

Not classified based on available information. SARS CoV 2 & Flu A/B Control Swab-negative

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.

SARS-CoV 2 Antigen Control Swab-Positive

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.



SARS-CoV-2 & FluA/B Rapid Antigen Te

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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.

11.2 Information on other hazards

Endocrine disrupting properties

Product:

Assessment

: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Buffer

Endocrine disrupting properties

Product:

Assessment

: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Test Device (Test Stripe)

Endocrine disrupting properties

Product:

Assessment

: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Flu A/B Antigen Control Swab-Positive

Endocrine disrupting properties

Product:



mg/l

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The substance/mixture does not contain components consid-Assessment ered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

SARS CoV 2 & Flu A/B Control Swab-negative

Endocrine disrupting properties

Product:

Assessment

The substance/mixture does not contain components consid-1 ered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

SARS-CoV 2 Antigen Control Swab-Positive

Endocrine disrupting properties

Product:

Assessment

The substance/mixture does not contain components consid-1 ered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

SECTION 12: Ecological information

12.1 Toxicity

Buffer

Components:

Polidocanol:		
Toxicity to fish	:	LC50 (Salmo salar (Atlantic salmon)): 1,5 mg/l End point: mortality Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): 6,46 mg/l Exposure time: 48 h
Toxicity to algae/aquatic plants	:	ErC50 (Desmodesmus subspicatus (green algae)): 0,237 n Exposure time: 72 h Method: OECD Test Guideline 201
		EbC50 (Desmodesmus subspicatus (green algae)): 1.502 mg/l Exposure time: 72 h Method: OECD Test Guideline 201



	evision Date 0.02.2022	
M-Factor (Acute aquatic to icity)	ox- : 1	
Toxicity to microorganism		notobacterium phosphoreum): 2,5 mg/l st Type: EC50
Toxicity to daphnia and ot aquatic invertebrates (Chr ic toxicity)	on- Exp Spe	EC: 0,144 mg/l posure time: 21 d ecies: Daphnia magna (Water flea) thod: QSAR
Ecotoxicology Assessm	ent	
Chronic aquatic toxicity	: Ver	y toxic to aquatic life with long lasting effects. narks: Expert judgement
sodium azide:		
Toxicity to fish	Exp Tes	50 (Pimephales promelas (fathead minnow)): 5,46 mg/l bosure time: 96 h st Type: flow-through test thod: OECD Test Guideline 203
	Exp Tes	50 (Oncorhynchus mykiss (rainbow trout)): 2,84 mg/l posure time: 96 h st Type: flow-through test thod: OECD Test Guideline 203
Toxicity to daphnia and ot aquatic invertebrates		50 (Daphnia magna (Water flea)): 0,4 mg/l bosure time: 48 h
Toxicity to algae/aquatic plants	mg, Exp Tes	50 (Pseudokirchneriella subcapitata (green algae)): 0,35 /l posure time: 96 h st Type: static test thod: OECD Test Guideline 201
Toxicity to microorganism	s : EC	50 (Tetrahymena pyriformis): 5,6 mg/l
Ecotoxicology Assessm	ent	
Acute aquatic toxicity		y toxic to aquatic life.
Chronic aquatic toxicity	: Ver	y toxic to aquatic life with long lasting effects.
Toxicity Data on Soil	: Not	expected to adsorb on soil.
reaction mass of 5-chlor (3:1):	o-2-methyl	-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-or
Toxicity to fish		50 (Fish): 0,36 mg/l posure time: 96 h
M-Factor (Acute aquatic to icity)	ox- : 100)



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M-Factor (Chronic aquatic : 100 toxicity)

Ecotoxicology Assessment

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

Other organisms relevant to : No data available the environment

Test Device (Test Stripe)

No data available

Flu A/B Antigen Control Swab-Positive

No data available SARS CoV 2 & Flu A/B Control Swab-negative

No data available SARS-CoV 2 Antigen Control Swab-Positive

No data available

12.2 Persistence and degradability

Buffer

Components:

Polidocanol:

Biodegradability

legradability	: Test Type: aerobic
	Inoculum: activated sludge
	Concentration: 30 mg/l
	Result: Readily biodegradable.
	Biodegradation: 74 %
	Exposure time: 28 d
	Method: OECD Test Guideline 301C

sodium azide:

Biodegradability : Remarks: The methods for determining biodegradability are not applicable to inorganic substances.

Test Device (Test Stripe)

No data available Flu A/B Antigen Control Swab-Positive

No data available SARS CoV 2 & Flu A/B Control Swab-negative

No data available SARS-CoV 2 Antigen Control Swab-Positive

No data available

12.3 Bioaccumulative potential

Buffer



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Components:

Polidocanol:

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

sodium azide:

Partition coefficient: n- : Remarks: Not applicable octanol/water

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

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

Test Device (Test Stripe)

No data available Flu A/B Antigen Control Swab-Positive

No data available

SARS CoV 2 & Flu A/B Control Swab-negative

No data available

SARS-CoV 2 Antigen Control Swab-Positive

No data available

12.4 Mobility in soil

Buffer

No data available Test Device (Test Stripe)

No data available

Flu A/B Antigen Control Swab-Positive

No data available

SARS CoV 2 & Flu A/B Control Swab-negative

No data available SARS-CoV 2 Antigen Control Swab-Positive

No data available

12.5 Results of PBT and vPvB assessment

Buffer

Not relevant Test Device (Test Stripe)

Not relevant Flu A/B Antigen Control Swab-Positive

Not relevant

SARS CoV 2 & Flu A/B Control Swab-negative

Not relevant



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SARS-CoV 2 Antigen Control Swab-Positive

Not relevant

12.6 Endocrine disrupting properties

Product:

Assessment	 The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.4% or bisher
	levels of 0.1% or higher.

Buffer

Assessment :	The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.
--------------	---

Test Device (Test Stripe)

Assessment

: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Flu A/B Antigen Control Swab-Positive

Assessment	: The substance/mixture does not contain components consid- ered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at
	levels of 0.1% or higher.

SARS CoV 2 & Flu A/B Control Swab-negative

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

SARS-CoV 2 Antigen Control Swab-Positive

Assessment	 The substance/mixture does not contain components co ered to have endocrine disrupting properties according t REACH Article 57(f) or Commission Delegated regulatio (EU) 2017/2100 or Commission Regulation (EU) 2018/6 levels of 0.1% or higher. 	o n



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12.7 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 infor- : An environmental hazard cannot be excluded in the event of

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 (Test Stripe)

No data available

Flu A/B Antigen Control Swab-Positive

No data available SARS CoV 2 & Flu A/B Control Swab-negative

No data available SARS-CoV 2 Antigen Control Swab-Positive

No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product	:	The product should not be allowed to enter drains, water courses or the soil. Do not contaminate ponds, waterways or ditches with chemi- cal 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 han- dling site for recycling or disposal. Do not re-use empty containers.

SECTION 14: Transport information

14.1 UN number or ID 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



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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 Maritime transport in bulk according to IMO instruments

:

Remarks

: Not applicable

SECTION 15: Regulatory information

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

Seveso III: Directive : Not applicable 2012/18/EU of the European Parliament and of the Council on the control of major- accident hazards involving dangerous substances.	
Water hazard class (Germa- : WGK 2 obviously haza ny)	ardous to water
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 fol- lowing entries should be considered: Number on list 3
REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59).	: Not applicable
Regulation (EC) No 1005/2009 on substances that deplete the ozone layer	: Not applicable
Regulation (EU) 2019/1021 on persistent organic pollu- tants (recast)	: Not applicable
Regulation (EC) No 649/2012 of the European Parlia- ment and the Council concerning the export and import of dangerous chemicals	: Not applicable
REACH - List of substances subject to authorisation (Annex XIV)	: Not applicable

Other regulations:

Take note of Law on the protection of mothers at work, in education and in studies (Maternity Protection Act - MuSchG).



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Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.

The components of this product are reported in the following inventories:		
AIIC	:	Not in compliance with the inventory
DSL	:	This product contains the following components that are not on the Canadian DSL nor NDSL.
		Animal serum /-plasma - different species Glycols Modified alkyl carboxylate
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.
TECI	:	Not in compliance with the inventory
Volatile organic compounds	:	Directive 2010/75/EU of 24 November 2010 on industrial emissions (integrated pollution prevention and control) Volatile organic compounds (VOC) content: 2,5 %

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms	:	
Signal word	:	Warning
Hazard statements	:	H317 May cause an allergic skin reaction.H412 Harmful to aquatic life with long lasting effects.
Precautionary statements	:	Prevention: P261 Avoid breathing mist or vapours.



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P273 Avoid release to the environment.

P280 Wear protective gloves.

Response:

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

P501 Dispose of contents/ container to an approved waste disposal plant.

Hazardous components which must be listed on the label:

55965-84-9

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

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
REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59).	:	Not applicable
Regulation (EC) No 1005/2009 on substances that deplete the ozone layer	:	Not applicable
Regulation (EU) 2019/1021 on persistent organic pollu- tants (recast)	:	Not applicable
Regulation (EC) No 649/2012 of the European Parlia- ment and the Council concerning the export and import of dangerous chemicals	:	Not applicable
REACH - List of substances subject to authorisation (Annex XIV)	:	Not applicable

Other regulations:

Take note of Law on the protection of mothers at work, in education and in studies (Maternity Protection Act - MuSchG).

The components of this product are reported in the following inventories:		
AIIC	:	Not in compliance with the inventory
DSL	:	This product contains the following components that are not on the Canadian DSL nor NDSL.



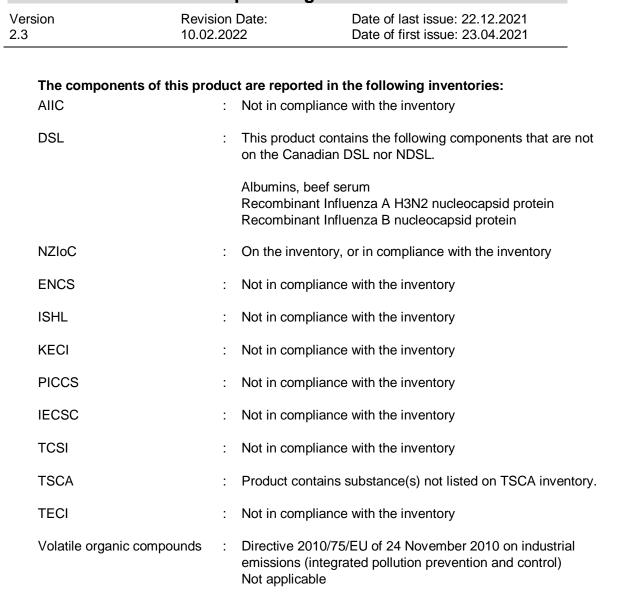
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	Antibodies	
NZIoC		bry, or in compliance with the inventory
ENCS	: Not in complia	nce with the inventory
ISHL	: Not in complia	nce with the inventory
KECI	: Not in complia	nce with the inventory
PICCS	: Not in complia	nce with the inventory
IECSC	: Not in complia	nce with the inventory
TCSI	: On the invento	ory, or in compliance with the inventory
TSCA	: Product contai	ns substance(s) not listed on TSCA inventory.
TECI	: Not in complia	nce with the inventory
Volatile organic compo		/75/EU of 24 November 2010 on industrial egrated pollution prevention and control)

Labelling (REGULATION (EC) No 1272/2008)

Not a hazardous substance or mixture.

Flu A/B Antigen Control Swab-Positive

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



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Labelling (REGULATION (EC) No 1272/2008)

Not a hazardous substance or mixture.

SARS CoV 2 & Flu A/B Control Swab-negative

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII)	:	Not applicable
REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59).	:	Not applicable
Regulation (EC) No 1005/2009 on substances that deplete the ozone layer	:	Not applicable
Regulation (EU) 2019/1021 on persistent organic pollu- tants (recast)	:	Not applicable

Revision Date:

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	Regulation (EC) No 649/20 ment and the Council cond of dangerous chemicals REACH - List of substance	cerning	the export and import	: Not applicable		
	(Annex XIV)	,				
	The components of this	produc	at are reported in the	following inventories:		
	AIIC	:	•	in compliance with the inventory		
	DSL	:	All components of th	is product are on the Canadian DSL		
	NZIoC	:	On the inventory, or	in compliance with the inventory		
	ENCS	:	Not in compliance w	th the inventory		
	ISHL	:	Not in compliance w	th the inventory		
	KECI	:	On the inventory, or	in compliance with the inventory		
	PICCS	:	On the inventory, or	in compliance with the inventory		
	IECSC	:	On the inventory, or	in compliance with the inventory		
	TCSI	:	On the inventory, or	in compliance with the inventory		
	TSCA	:	All substances listed	as active on the TSCA inventory		
	TECI	:	Not in compliance w	th the inventory		
	Volatile organic compound	ls :		J of 24 November 2010 on industrial d pollution prevention and control)		

Labelling (REGULATION (EC) No 1272/2008)

Not a hazardous substance or mixture.

SARS-CoV 2 Antigen Control Swab-Positive

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII)	:	Not applicable
REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59).	:	Not applicable
Regulation (EC) No 1005/2009 on substances that deplete the ozone layer	:	Not applicable

Revision Date:

10.02.2022



Regulation (EU) 2019/1021 on persistent organic pollu- tants (recast)	:	Not applicable	
Regulation (EC) No 649/2012 of the European Parlia- ment and the Council concerning the export and import of dangerous chemicals	:	Not applicable	
REACH - List of substances subject to authorisation (Annex XIV)	:	Not applicable	

Other regulations:

Version

2.3

Take note of Law on the protection of mothers at work, in education and in studies (Maternity Protection Act - MuSchG).

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The components of this product are reported in the following inventories:		
AIIC	:	Not in compliance with the inventory
DSL	:	This product contains the following components that are not on the Canadian DSL nor NDSL.
		Albumins, beef serum Covid 19 NP protein
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.
TECI	:	Not in compliance with the 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.



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15.2 Chemical safety assessment

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

SECTION 16: Other information

Full text of H-Statements

Skin Sens.

STOT RE

H301	:	Fatal if swallowed. 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.
H319	:	Causes serious eye irritation.
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.
Full text of other abbreviation	าร	
Acute Tox.	:	Acute toxicity
Aquatic Acute	:	Short-term (acute) aquatic hazard
Aquatic Chronic	:	Long-term (chronic) aquatic hazard
Eye Dam.	:	Serious eye damage
Eye Irrit.	:	Eye irritation
Skin Corr.	:	Skin corrosion

Skin sensitisation

Specific target organ toxicity - repeated exposure

2

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; AIIC - Australian Inventory of Industrial Chemicals; 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 - (Quanti-

SAFETY DATA SHEET according to Regulation (EC) No. 1907/2006 SARS-CoV-2 & FluA/B Rapid Antigen Test



tative) 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; TECI - Thailand Existing Chemicals Inventory; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

Roch

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.

DE / EN / 2104