Current version : 2.1.0, issued: 13.06.2023

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

Replaced version: 2.0.1, issued: 04.05.2022

1.1 **Product identifier** Trade name **UC-CONTROL** 1.2 Relevant identified uses of the substance or mixture and uses advised against Relevant identified uses of the substance or mixture For in-vitro diagnosis Uses advised against No data available. 1.3 Details of the supplier of the safety data sheet Address SYSMEX LTD Sysmex House Garamonde Drive Wymbush Milton Keynes Buckinghamshire MK8 8DF United Kingdom Telephone no. +44 (0)333 320 3460 +44 (0)1908 267 901 Fax no. Advice on Safety Data Sheet info@sysmex-europe.com

1.4 Emergency telephone number

For medical advice (in German and English): +49 (0)551 192 40 (Giftinformationszentrum Nord)

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification in accordance with Regulation (EC) No 1272/2008 (CLP) Aquatic Chronic 3; H412 Skin Sens. 1A; H317

Classification information

This product is assessed and classified using the methods and criteria below referred to in Article 9 of Regulation (EC) n° 1272/2008: Physical hazards: determined through assessment data based on the methods or standards referred to in part 2 of Annex I to CLP Health hazards and environmental hazards: determined through toxicological and ecotoxicological assessment data based on the methods or standards referred to in Part 3, 4 and 5 of Annex I to CLP.

2.2 Label elements

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

Hazard pictograms



 Signal word

 Warning

 Hazardous component(s) to be indicated on label:

 reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-2H -isothiazol-3-one (3:1)

 Hazard statement(s)

 H317
 May cause an allergic skin reaction.

 H412
 Harmful to aquatic life with long lasting effects.

 Precautionary statement(s)
 Vear protective gloves/protective clothing/eye protection/face protection.

2.3 Other hazards

No data available.

SECTION 3: Composition/information on ingredients



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3.1 Substances

Not applicable. The product is not a substance.

3.2 Mixtures

Chemical characterization Contains Human source material (10-60 %)

Hazardous ingredients

No	Substance name		Additional information	
	CAS / EC / Index /	Classification (EC) 1272/2008 (CLP)	Concentration	%
	REACH no			
1	acetone			
	67-64-1	EUH066	< 5.00	wt%
	200-662-2	Eye Irrit. 2; H319		
	606-001-00-8	Flam. Liq. 2; H225		
	-	STOT SE 3; H336		
2	reaction mass of: 5-c	hloro-2-methyl-4-isothiazolin-3-one and 2-methyl-2H -		
	isothiazol-3-one (3:1)			
	55965-84-9	Acute Tox. 2; H310	<= 0.0025 - < 0.025	wt%
	-	Acute Tox. 2; H330		
	613-167-00-5	Acute Tox. 3; H301		
	-	Aquatic Acute 1; H400		
		Aquatic Chronic 1; H410		
		EUH071		
		Eye Dam. 1; H318		
		Skin Corr. 1C; H314		
		Skin Sens. 1A; H317		

Full Text for all H-phrases and EUH-phrases: pls. see section 16

No	Note	Specific concentration limits	M-factor (acute)	M-factor (chronic)
2	В	Skin Sens. 1A; H317: C >= 0.0015% Eye Irrit. 2; H319: C >= 0.06% Skin Irrit. 2; H315: C >= 0.06% Skin Corr. 1C; H314: C >= 0.6% Eye Dam. 1; H318: C >= 0.6%	M = 100	M = 100

Full text for the notes: pls. see section 16 "Notes relating to the identification, classification and labelling of substances ((EC) No 1272/2008, Annex VI)".

3.3 Other information

All human source material used to manufacture this product was non-reactive for antigens to Hepatitis B (HBsAg) and HIV-1 Ag, negative by tests for antibodies to HIV (HIV-1/HIV-2) and Hepatitis C (HCV), when tested on single donor unit basis by the U.S. Food and Drug Administration accepted methods. Because no known test method can assure complete absence of human pathogens, this product should be handled with appropriate precautions.

SECTION 4: First aid measures

4.1 Description of first aid measures

General information

In case of persisting adverse effects, consult a physician. Remove contaminated clothing and shoes immediately, and launder thoroughly before reusing.

After inhalation

Remove affected person from the immediate area. Ensure supply of fresh air.

After skin contact

Wash off immediately with soap and water.

After eye contact

Separate eyelids, wash the eyes thoroughly with water (15 min.).

After ingestion

Call a doctor immediately. Do not induce vomiting. Never give anything by mouth to an unconscious person.

4.2 Most important symptoms and effects, both acute and delayed No data available.

4.3 Indication of any immediate medical attention and special treatment needed No data available.

SECTION 5: Firefighting measures

5.1 Extinguishing media

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Suitable extinguishing media

Foam; Extinguishing powder; Carbon dioxide; Water spray jet Unsuitable extinguishing media High power water jet

5.2 Special hazards arising from the substance or mixture

In the event of fire, the following can be released: Carbon dioxide (CO2); Carbon monoxide (CO); Sulphur oxides (SxOy); Nitrogen oxides (NOx); chlorine compounds

5.3 Advice for firefighters

Use self-contained breathing apparatus. Wear protective clothing. Run-off water from fire fighting must not be discharged into drains or enter surface water.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Refer to protective measures listed in sections 7 and 8. Ensure adequate ventilation. Avoid contact with skin, eyes and clothing. Do not inhale vapours. Keep away from ignition sources.

For emergency responders

No data available. Personal protective equipment (PPE) - see Section 8.

6.2 **Environmental precautions**

Do not discharge into the drains/surface waters/groundwater. Do not discharge into the subsoil/soil. In case of entry into waterways, soil or drains, inform the responsible authorities.

6.3 Methods and material for containment and cleaning up

Take up with absorbent material (e.g., sand, kieselguhr, universal binder). When collected, handle material as described under the section heading "Disposal considerations". Wash affected area with chlorine bleach.

6.4 **Reference to other sections**

No data available.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Advice on safe handling

Risks inherent to handling the product must be minimised by applying the appropriate protective and preventive measures. Working processes should - so far as possible, according to the state of the art - be designed to rule out bodily contact or the release of hazardous substances.

General protective and hygiene measures

Do not eat, drink or smoke during work time. Keep away from food, drink and animal feeding stuffs. Wash hands and skin before breaks and after work. Do not inhale vapours. Avoid contact with eyes and skin. Remove soiled or soaked clothing immediately. Have emergency shower available.

Advice on protection against fire and explosion

Keep away from sources of heat and ignition. Vapours can form an explosive mixture with air.

7.2 Conditions for safe storage, including any incompatibilities

Technical measures and storage conditions

Keep container tightly closed in a cool, well-ventilated place. Keep from freezing.

```
Recommended storage temperature
```

2 8

Requirements for storage rooms and vessels

Containers which are opened must be carefully closed and kept upright to prevent leakage. Protect from heat and direct sunlight. Incompatible products

°C

Do not store together with: oxidizing agents

7.3 Specific end use(s)

Value

No data available.

SECTION 8: Exposure controls/personal protection

8.1 **Control parameters**

Occupational exposure limit values

No	Substance name	CAS no.	EC no.
1	acetone	67-64-1	200-662-2
	2000/39/EC		

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Acetone				
WEL long-term (8-hr TWA reference period)	1210	mg/m³	500	ppm
List of approved workplace exposure limits (WELs) / EH40				
Acetone				
WEL short-term (15 min reference period)	3620	mg/m³	1500	ppm
WEL long-term (8-hr TWA reference period)	1210	mg/m³	500	ppm

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8.2 Exposure controls

Appropriate engineering controls

No data available.

Personal protective equipment

Respiratory protection

If workplace exposure limits are exceeded, a respiration protection approved for this particular job must be worn. In case of aerosol and mist formation, take appropriate measures for breathing protection in the event workplace threshold values are not specified.

Eye / face protection

Safety glasses (EN 166)

Hand protection

Sufficient protection is given wearing suitable protective gloves checked according to i.e. EN 374, in the event of risk of skin contact with the product. Before use, the protective gloves should be tested in any case for its specific work-station suitability (i.e. mechanical resistance, product compatibility and antistatic properties). Adhere to the manufacturer's instructions and information relating to the use, storage, care and replacement of protective gloves. Protective gloves shall be replaced immediately when physically damaged or worn. Design operations thus to avoid permanent use of protective gloves.

Other

Normal chemical work clothing.

Environmental exposure controls

No data available.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

State of aggregation	
liquid	
Form	
liquid	
Colour	
straw-coloured	
Odour	
weak	
pH value	
Value	5 - 6
Comments	UC-CONTROL -L
Boiling point / boiling range	
No data available	
Melting point/freezing point	
No data available	
Decomposition temperature	
No data available	
Flash point	
No data available	
Ignition temperature	
No data available	
Flammability	
No data available	
Lower explosion limit	
No data available	
Upper explosion limit	
No data available	
Vapour pressure	
No data available	
Relative vapour density	

No data available Relative density

Value

9.2

Comments

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Density		
No data available		
Solubility in water		
Comments	miscible	
Solubility		
No data available		
Partition coefficient n-octanol/water (log value)		
No data available		
Kinematic viscosity		
No data available		
Particle characteristics		
No data available		
2 Other information		
Other information		
pH value		
UC-CONTROL -H		

1.003

UC-CONTROL -L

-

Other information	
pH value	
UC-CONTROL -H	
7 - 9	
Relative density	
UC-CONTROL -H	
1,018 - 1,032	

SECTION 10: Stability and reactivity

10.1 Reactivity

Dangerous reactions are not expected if the product is handled according to its intended use.

10.2 Chemical stability

Stable under recommended storage and handling conditions (See section 7).

10.3 Possibility of hazardous reactions None, when used as directed.

10.4 Conditions to avoid Protect from heat and direct sunlight. Keep away sources of ignition. Keep from freezing.

10.5 Incompatible materials Oxidizing agents; strong acids; strong bases

10.6 Hazardous decomposition products None, if handled according to intended use.

SECTION 11: Toxicological information

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

Acute oral toxicity
No data available
Acute dermal toxicity
No data available
Acute inhalational toxicity
No data available
Skin corrosion/irritation
No data available
Serious eye damage/irritation
No data available
Respiratory or skin sensitisation
No data available
Germ cell mutagenicity
No data available



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1.017

Reproduction toxicity No data available Carcinogenicity No data available

STOT - single exposure No data available

STOT - repeated exposure

No data available. Other information No data available.

Information on other hazards Endocrine disrupting properties

No data available Aspiration hazard No data available

11.2

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No data available

12.8 Other information

Other information

Do not discharge product unmonitored into the environment. Do not discharge into drains or waters and do not dispose of in public landfills.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product

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SECTION 12: Ecological information 12.1 Toxicity Toxicity to fish (acute) No data available Toxicity to fish (chronic) No data available Toxicity to Daphnia (acute) No data available Toxicity to Daphnia (chronic) No data available Toxicity to algae (acute) No data available Toxicity to algae (chronic) No data available **Bacteria toxicity** No data available 12.2 Persistence and degradability

Inhalation of the vapours causes irritation of the respiratory tract and mucous membrane, headaches, nausea, giddiners, vomiting. Eye

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

contact with the product may lead to irritation. Frequent persistent contact with the skin can cause skin irritation.

No data available.

- 12.3 **Bioaccumulative potential** No data available.
- Mobility in soil 12.4 No data available.
- 12.5 Results of PBT and vPvB assessment No data available.
- 12.6 Endocrine disrupting properties No data available

Other adverse effects 12.7





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Allocation of a waste code number, according to the European Waste Catalogue, should be carried out in agreement with the regional waste disposal company.

Packaging

Residues must be removed from packaging and when emptied completely disposed of in accordance with the regulations for waste removal. Incompletely emptied packaging must be disposed of in the form of disposal specified by the regional disposer.

SECTION 14: Transport information

14.1 Transport ADR/RID/ADN

The product is not subject to ADR/RID/ADN regulations.

14.2 Transport IMDG

The product is not subject to IMDG regulations.

- 14.3 Transport ICAO-TI / IATA The product is not subject to ICAO-TI / IATA regulations.
- 14.4 Other information
 - No data available.
- **14.5** Environmental hazards Information on environmental hazards, if relevant, please see 14.1 - 14.3.
- **14.6** Special precautions for user No data available.
- 14.7 Maritime transport in bulk according to IMO instruments Not relevant

SECTION 15: Regulatory information

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

Regulation (EC) No 1907/2006 (REACH) Annex XIV (List of substances subject to authorisation) According to the data available and/or specifications supplied by upstream suppliers, this product does not contain any substances considered as substances requiring authorisation as listed on Annex XIV of the REACH regulation (EC) 1907/2006.

REACH candidate list of substances of very high concern (SVHC) for authorisation

According to available data and the information provided by preliminary suppliers, the product does not contain substances that are considered substances meeting the criteria for inclusion in annex XIV (List of Substances Subject to Authorisation) as laid down in Article 57 and article 59 of REACH (EC) 1907/2006.

Reg	Regulation (EC) No 1907/2006 (REACH) Annex XVII: RESTRICTIONS ON THE MANUFACTURE, PLACING ON THE MARKET				
AND	USE OF CERTAIN DANGEROUS SUBSTANCES, MIXTURES	AND ARTICLES			
The	The product is considered being subject to REACH regulation (EC) 1907/2006 annex XVII. No 3				
The product contains following substance(s) that are considered being subject to REACH regulation (EC) 1907/2006 annex XVII.					
No	Substance name	CAS no.	EC no.	No	
1	acetone	67-64-1	200-662-2	75	
2	reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-2H -isothiazol-3-one (3:1)	55965-84-9	-	75	
3	sodium hydroxide	1310-73-2	215-185-5	75	
Directive 2012/18/EU on the control of major-accident hazards involving dangerous substances					
This product is not subject to Part 1 or 2 of Annex I.					

15.2 Chemical safety assessment

A chemical safety assessment has not been carried out for this mixture.

SECTION 16: Other information

Sources of key	y data used to compile the data sheet:
Regulation (EC) No 1907/2006 (REACH), 1272/2008 (CLP) as amended in each case.
Directives 2000	//39/EC, 2006/15/EC, 2009/161/EU, (EU) 2017/164.
National Thresh	nold Limit Values of the corresponding countries as amended in each case.
Transport regul	ations according to ADR, RID, IMDG, IATA as amended in each case.
The data sourc	es used to determine physical, toxic and ecotoxic data, are indicated directly in the corresponding section.
Full text of the	H- and EUH- phrases drawn up in sections 2 and 3 (provided not already drawn up in these sections)
EUH066	Repeated exposure may cause skin dryness or cracking.
EUH071	Corrosive to the respiratory tract.
H225	Highly flammable liquid and vapour.
H301	Toxic if swallowed.



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H310	Fatal in contact with skin.
H314	Causes severe skin burns and eye damage.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H330	Fatal if inhaled.
H336	May cause drowsiness or dizziness.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
Notes relating to the identific	ation, classification and labelling of substances and mixtures ((EC) No 1272/2008, Annex VI)
В	Some substances (acids, bases, etc.) are placed on the market in aqueous solutions at various concentrations and, therefore, these solutions require different classification and labelling since the hazards vary at different concentrations. In Part 3 entries with Note B have a general designation of the following type: 'nitric acid %'. In this case the supplier must state the percentage concentration of the solution on the label. Unless otherwise stated, it is assumed that the percentage concentration is calculated on a weight/weight basis.

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Creation of the safety data sheet

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This information is based on our present knowledge and experience.

The safety data sheet describes products with a view to safety requirements.

It does not however, constitute a guarantee for any specific product properties and shall not establish a legally valid contractual relationship.

Alterations/supplements:

Alterations to the previous edition are marked in the left-hand margin.

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