

Safety data sheet

Rapid Test

Version 1.0

Effective date: 21-02-2023



SECTION 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY / UNDERTAKING

1.1 Product identifier.

Trade name: OnSite Rapid Test

Product catalog:

R0023C/S	R0063C	R0101C	R0151C	R0188C	R0224C
R0024C	R0066C	R0111C	R0160C	R0189C	R0234C
R0030C	R0069C	R0112C	R0161C	R0191C	R0243C
R0031C	R0080C	R0113C	R0162C	R0192C/S	R0253C
R0042C	R0085S	R0114C	R0171C	R0194C	R0310C
R0053C	R0090C	R0121C	R0180C	R0196C	R2010C
R0060C	R0092C	R0122C/S	R0181S	R0218C	R2011C
R0061C	R0095C	R0130C	R0184C/S	R0223C	R2011S
R0062C	R0096C	R0233C/S	R0186C		
R0011C	R0035C	R1000C/S	R2002C		
R0018C	R0049C	R1001C/S	R3001C		
R0028C	R0203C	R2000C/S	R3002C		
R0030C/S	R0213C	R2001C/S	R0187C/S		

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

Product use: Lateral flow immunochromatographic assay for the qualitative detection of protein or antibodies (total antibody or IgG/IgM) to various substances, such as infectious agents and allergens, in human specimens such as swabs, fecal, urine, serum, plasma or whole blood, to aid the determination of health conditions. These tests are for in vitro use only.

1.3 Details of the supplier of the safety data sheet:

Company: CTK Biotech, Inc
13855 Stowe Dr
Poway CA 92064
USA
Tel: 858-457-8698
Fax: 858-535-1739

Contact person: www.ctkbiotech.com

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1.4 Emergency telephone number:

Use your national or local emergency number.

United Kingdom: Contact The National Poisons Information Service (dial 111, 24 h service).

SECTION 2. HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture according to CLP No 1272/2008/GB CLP.

Skin Sens. 1A; H317.

2.2 Label elements CLP No 1272/2008/GB CLP.

Hazard pictogram(s):



Signal word:

Warning

Contains: Mixture of 5-Chloro-2-methyl-4-isothiazolin-3-one and 2-Methyl-2H -isothiazol-3-one (3:1).

According to European Directive 91/155/EEC and regulations (EC) 1272/2008 (CLP)

Hazardous labeling not required at concentration level listed in section 3.2

Hazard statements:

H317 May cause an allergic skin reaction.

Precautionary statements:

General:

P102 Keep out of reach of children.

Prevention:

P280 Wear protective gloves.

Response:

P302 + 352 IF ON SKIN: Wash with soap and water.

P333 + P313 If skin irritation or a rash occurs: Get medical advice/attention.

Storage:

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Disposal:

P501 Dispose of contents/ container in accordance with national regulations.

Additional information:

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2.3 Other hazards.

None known.

Contains no PBT or vPvB substances according to REACH No 1907/2006.

This mixture does not contain substances with endocrine disrupting properties in accordance with the criteria laid down in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605.

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SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

The product consists of Individually sealed pouch and Extraction Buffer.

Note: The strip is composed of nitrocellulose membrane, vinyl matte adhesive, fiber absorbent pad, fiber sample pad, fiber conjugate pad. The nitrocellulose membrane and the fiber conjugate pad contain dried biological substances preserved by Proclin-300. The identity of each biological substance is confidential.

3.2 Mixture in Extraction Buffer:

CAS/EC No.	Name	Content %	Classification CLP
55965-84-9 / 911-418-6	Mixture of 5-Chloro-2-methyl-4-isothiazolin-3-one and 2-Methyl-2H -isothiazol-3-one (3:1)*	<0.0025	Acute Tox. 3; H301, Acute Tox. 2; H310+H330, Skin Corr. 1C; H314, Skin Sens 1A; H317, Eye Dam. 1; H318, Aquatic Acute 1; H400 (M=100), Aquatic Chronic 1, H410 (M=100).
26628-22-8 / 247-852-1	Sodium azide	0.09	Acute Tox. 2; H300, Aquatic Acute 1; H400 (M=1), Aquatic Chronic 1; H410 (M=1).

*Specific concentration limits – CAS 55965-84-9:

Eye Dam. 1; H318: $C \geq 0,6 \%$

Eye Irrit. 2; H319: $0,06 \% \leq C < 0,6 \%$

Skin Corr. 1C; H314: $C \geq 0,6 \%$

Skin Irrit. 2; H315: $0,06 \% \leq C < 0,6 \%$

Skin Sens. 1A; H317: $C \geq 0,0015 \%$

All the biological substances are derived from in vitro culture system or animal materials which are free of known-pathogens for human. Thus, no bio-hazardous can be claimed in the product.

Occupational limits are listed in section 8, if these are available. See full text of H-phrases in section 16.

SECTION 4. FIRST AID MEASURES

4.1 Description of first aid measures:

General information:

In the case of symptoms or doubt: Contact a doctor or casualty department – take the label or this safety data sheet.

Inhalation:

Inhalation of any component in this kit is unlikely. If a component of this kit is inhaled and causes discomfort, move exposed individual to fresh air. Seek medical attention if breathing is difficult or symptoms persist.

Skin contact:

The product hazardous by skin contact. In case of contact, immediately clean skin with plenty of water. Remove contaminated clothing and shoes. Cold water may be used. Wash clothing before reuse. Thoroughly clean shoes before reuse. The animal proteins and dried reagents absorbed into the nitrocellulose membrane and the fiber conjugate pad are very unlikely to be hazardous by skin contact, but clean the skin after use is advisable.

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Eye contact: The test device is very unlikely to be contacted by eye, however, contact physician should a contact occur. In case of contact with the Sample Diluent, immediately flush eyes with plenty of water for at least 15 minutes. Cold water may be used. Get medical attention.

Ingestion: Ingestion of small amounts of the Sample Diluent is toxic; a physician should be contacted immediately. The animal proteins and dried reagents absorbed into the nitrocellulose membrane and the fiber conjugate pad are very unlikely to be ingested or be hazardous by ingestion. However, a physician should be consulted should ingestion occur.

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

May cause an allergic skin reaction.

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

Treat symptomatically.

SECTION 5. FIRE FIGHTING MEASURES

5.1 Extinguishing media: For small fires, use dry chemical, carbon dioxide, or alcohol-resistant foam. Use extinguishing material suitable to the surrounding fire.

Unsuitable extinguishing media:

No direct contact with water.

5.2 Special hazards arising from the substance or mixture:

This material will not significantly contribute to the intensity of a fire. When involved in a fire, this material can decompose and produce irritating fumes and toxic gases (e.g., Carbon monoxide, Carbon dioxide). Fire may produce toxic decomposition products, do not breathe.

5.3 Advice for firefighters:

Wear self-contained breathing apparatus and protective clothing to prevent contact. Move containers from fire area if it can be done without risk to personnel. If possible, prevent runoff water from entering storm drains, bodies of water, or other environmentally sensitive areas.

SECTION 6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures:

See section 8 for recommendations on the use of personal protective equipment. Avoid contact with skin and eyes. Keep unprotected people away.

6.2 Environmental precautions:

Avoid the ground to be contaminated, natural water courses and wastewater drainage.

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6.3 Methods and material for containment and cleaning up:

Small spills: wipe up with absorbent material (e.g. cloth, fleece).
Then rinse the spillage site with plenty of water. Dispose of in accordance with section 13.

6.4 Reference to other sections:

See section 8 for personal protection.

See section 13 for disposal.

SECTION 7. HANDLING AND STORAGE

7.1 Precautions for safe handling:

See section 8 for recommendations on the use of personal protective equipment. Avoid contact with skin and eyes. Do not eat, drink or smoke when using this product. Use according to instruction.
Keep away from heat, sources of ignition and direct sunlight.

7.2 Conditions for safe storage, including any incompatibilities:

Keep container tightly closed. Keep product at 2-30°C. Do not freeze or expose to temperature higher than 30°C. Keep away from children.
Store frost-free.

7.3 Specific end use(s):

This product should only be used for applications described in section 1.2.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters - occupational exposure limits:

CAS-no:	Name:	Limits 8 h:	Limits 15 min.:	Ref./comments:
26628-22-8	Sodium azide (as NaN ₃)	0.1 mg/m ³	0.3 mg/m ³	EH40/Sk

Sk: Can be absorbed through the skin.

DNEL/PNEC:

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8.2 Exposure controls.

Appropriate technical measures:

Airborne concentrations must be kept as low as possible. Use for example an exhaust system if the normal air flow in the work room is not sufficient.

General information / Hygiene measures:

Smoking, consumption of food or liquid, and storage of tobacco, food or liquid, are not allowed in the workroom. Always wash hands, forearms and face. Make sure that eyewash station are available.

Personal protective equipment:

Only CE-marked personal protection equipment should be used.



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Respiratory protection: Normally not necessary.

Hand protection: Wear impervious gloves. Gloves must conform to EN 374.
Option: Nitrile rubber ≥ 240 min.

Eye protection: Wear tightly safety goggles. EN 166.

Body protection: Work clothing
Lab coat as indicated by general lab practice guidelines.

Measures to avoid environmental exposure:
No special precautions are necessary.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties.

Physical state:	Liquid
Colour:	Product specific
Odour:	Weak
Melting point/freezing point:	Not relevant/no data
Boiling point:	Not relevant/no data
Flammability:	Not relevant/no data
Lower and upper explosion limit:	Not relevant/no data
Flash point:	Not relevant/no data
Auto-ignition temperature:	Not relevant/no data
Decomposition temperature:	Not relevant/no data
pH:	Not relevant/no data
Viscosity:	Not relevant/no data
Solubility in water:	Liquid is soluble in water
Partition coefficient n-octanol/water:	Not relevant/no data
Vapour pressure:	Not relevant/no data
Density and/or relative density:	Not relevant/no data
Relative vapour density:	Not relevant/no data
Particle characteristics:	Not relevant/no data

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9.2 Other information:

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SECTION 10. STABILITY AND REACTIVITY

- 10.1 Reactivity:** No dangerous reaction known under conditions of normal use and storage.
- 10.2 Chemical stability:** Stable under normal storage conditions.
- 10.3 Possibility of hazardous reactions:** None known.
- 10.4 Conditions to avoid:** Direct sunlight. Keep away from heat, hot surfaces, sparks, open flames and other sources of ignition. No smoking.
- 10.5 Incompatible materials:** Strong acids. Strong bases. Strong oxidizing agent.
- 10.6 Hazardous decomposition products:** None at recommended storage conditions and use.

SECTION 11. TOXICOLOGICAL INFORMATION

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

- Acute toxicity:** Not classified.
- Skin corrosion/irritation:** Not classified.
- Serious eye damage/irritation:** Not classified.
- Respiratory or skin sensitisation:** May cause an allergic skin reaction.
- Germ cell mutagenicity:** Not classified.
- Carcinogenicity:** Not classified.
- Reproductive toxicity:** Not classified.
- Specific target organ toxicity - single exposure:** Not classified.
- Specific target organ toxicity – repeated exposure:** Not classified.
- Aspiration hazard:** Not classified.

11.2 Information on other hazards:

- Endocrine disrupting properties:** The product/substance has no endocrine disrupting properties.

Other information: -

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SECTION 12. ECOLOGICAL INFORMATION

- 12.1 Toxicity:** Not classified.
- No adverse effects on the environment are expected from the components of this kit. There is no aquatic toxicity data for this kit at this time.
- 12.2 Persistence and degradability:** No data available for the components of this kit.
- 12.3 Bioaccumulative potential:** No data available for the components of this kit.
- 12.4 Mobility in soil:** No data available for the components of this kit.
- 12.5 Result of PBT and vPvB assesment:** Contains no PBT or vPvB substances.
- 12.6 Endocrine disrupting properties:** The product/substance has no endocrine disrupting properties.
- 12.7 Other adverse effects:** None known.

SECTION 13. DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods:

Avoid discharge to lakes, streams, sewers, etc. Not classified as hazardous waste. Dispose in a safe manner in accordance with local/national regulations. The coding of a waste stream is based on the application of the product by the consumer.

Contaminated packing: Properly cleaned container is disposed of according to packaging material, otherwise for incineration.

SECTION 14. TRANSPORT INFORMATION

Not a dangerous goods in the meaning of ADR/RID, IMDG-code, ICAO, 64th edition of the IATA DGR 2023 Regulation

	ADR/RID	IMDG/IMO
14.1 UN number or ID number	Not relevant	Not relevant
14.2 UN proper shipping name	Not relevant	Not relevant
14.3 Transport hazard class(es)	Not relevant	Not relevant
14.4 Packing group	Not relevant	Not relevant

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14.5 Environmental hazards – MP EmS:	No Not relevant	No Not relevant
Other informations	LQ: Not relevant Tunnel: Not relevant	LQ: Not relevant Tunnel: Not relevant

14.6 Special precautions for user:

Not relevant.

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:

Sources: Pressure Equipment (Amendment) Regulations 2011. Chemicals (Hazard Information and Packaging for Supply) Regulations 2009. Control of Substances Hazardous to Health Regulations 2002 (as amended). Merchant Shipping (Dangerous Goods and Marine Pollutants) Regulations 1997. Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 2013. Regulation (EU) 2016/425 of 9 March 2016 on personal protective equipment. Hazardous Waste (England and Wales) Regulations 2005 (as amended). EC regulation 1907/2006 (REACH) Directive 2000/532/EC. Seveso directive: 96/82/EC. EC regulation no. 2020/878. CLP regulation No 1272/2008. REACH regulation No. 1907/2006. GB CLP.

Additional information:

People under the age of 18 must not work with this product cf. Council Directive 94/33/EC.

15.2 Chemical safety assessment:

Chemical safety assessments have not been performed for this product.

SECTION 16. OTHER INFORMATION

Full text of H-phrases as mentioned in section 3:

H301 Toxic if swallowed.

H310+H330 Fatal in contact with skin or if inhaled.

H314 Causes severe skin burns and eye damage

H317 May cause an allergic skin reaction.

H318 Causes serious eye damage.

H400 Very toxic to aquatic life.

H410 Very toxic to aquatic life with long lasting effects.

Additional information:

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

Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we can not guarantee that these are the only hazards that exist.

Validated by:

SRS

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