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MATERIAL SAFETY DATA SHEET

According to EC Directive 1907/2006/EC **[REACH]** and to Regulation (EC) No 1272/2008 **[CLP]**

KIT

Date of Issue: 28-02-2008 ***Updated: 17-10-2023***

1. Identification of the substance/preparation and of the company

1.1 Product identifier:

Product name: **free T4 [I-125] RIA KIT**
Product code: RK-349CT
Kit components: Tracer
Calibrators
Control sera

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

Product use
Application of the substance/preparation: For In-vitro research test KIT

1.3 Details of the supplier of the safety data sheet

Manufacturer/Supplier:
Institute of Isotopes Co., Ltd.
Konkoly-Thege Miklós út 29-33
H-1121 Budapest, Hungary
Phone number: (36-1) 391-0826
Fax number: (36-1) 392-2575, 395-9247

Further information available from: www.izotop.hu
Email address of the competent person: **immuno@izotop.hu**

1.4 Emergency telephone number

Information in case of emergency: Health Toxicological Information Service
+36 80 201 199 (0-24 hours, toll free - only from Hungary)
+36 1 476 6464 (0-24 hours, also from abroad)

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2. Transport information

According to ADR and IATA (Chapter 10.3.1) regulations, shipment below the exemption quantity (1 MBq for Iodine 125) are considered as not dangerous goods. If the shipment exceed this quantity, please refer to the information given below:

Shipping information	IATA	IMDG	US DOT	European ADR	Canadian TDG
14.1 UN/ID number	2910	2910	2910	2910	2910
14.2 UN proper shipping name	Radioactive Material, excepted package-limited quantity of material				
14.3 Transport hazardclass(es)	7 Radioactive Material	7 Radioactive Material	7 Radioactive Material	7 Radioactive Material	7 Radioactive Material
Subsidiary risk	None	None	None	None	None
Classification code	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.4 Packing group					
Special provisions	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
Additional information					
IATA ERG code	7L	Not applicable	Not applicable	Not applicable	Not applicable
EmS	Not applicable	F-I, S-S	Not applicable	Not applicable	Not applicable
NAERG code	Not applicable	Not applicable	161	Not applicable	161
14.5 Environmental hazards					
Marine pollutant	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.6 Special precautions for user	No special precautions for users are required.				

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MATERIAL SAFETY DATA SHEET

According to EC Directive 1907/2006/EC **[REACH]** and to Regulation (EC) No 1272/2008 **[CLP]**

Tracer

1. Identification of the substance/preparation and of the company

1.1 Product identifier:

Product name: **Tracer**
Product code: Component of RK-349CT
Product formal name: Diagnostic reagent

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

Product use
Application of the substance/preparation: For In-vitro diagnostic test

1.3 Details of the supplier of the safety data sheet

Manufacturer/Supplier:

Institute of Isotopes Co., Ltd.
Konkoly-Thege Miklós út 29-33
H-1121 Budapest, Hungary
Phone number: (36-1) 391-0826
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Email address of the competent person: **immuno@izotop.hu**

1.4 Emergency telephone number

Information in case of emergency: Health Toxicological Information Service
+36 80 201 199 (0-24 hours, toll free - only from Hungary)
+36 1 476 6464 (0-24 hours, also from abroad)

2. Hazards identification:

2.1 Classification of the substance or mixture

Product description: In vitro diagnostic reagent; Red, Clear, Liquid, Odorless
Classification according to Regulation (EC) No 1272/2008 [CLP]
Not classified as hazardous per EC 1272/2008 [CLP].

2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008 [CLP]
Not classified as hazardous per EC 1272/2008 [CLP].

2.3 Other hazards

Additional information:

Results of PBT and vPvB assessment:
PBT: Not applicable.
vPvB: Not applicable.

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Sodium azide: This product contains concentrations of sodium azide below the hazardous level, which with repeated contact with lead and copper commonly found in plumbing drains may result in the build-up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

Biologically derived materials: This component contains human biologically derived materials and should be considered as potentially capable of transmitting infectious diseases.

Radioactive component - Iodine 125: Iodine-125 is a gamma-rays and X-rays emitter. Radiation can be protected by 1mm of lead. Half-life: 60.2 days.

See Section 11 Toxicological Information for more detailed health information.

3. Composition / Information on ingredients:

3.2 Mixtures

Hazardous ingredient(s):

<table>
<tr><td>International chemical identification</td><td colspan="2">CAS #</td><td colspan="3">EC no</td></tr>
<tr><td>Sodium azide</td><td colspan="2">26628-22-8</td><td colspan="3">247-852-1</td></tr>
<tr><td rowspan="6">(< 0.1 % by wt)</td><td colspan="2">Classification</td><td colspan="3">Labelling</td></tr>
<tr><td>Hazard class and Category Code(s)</td><td>Hazard statement Code(s)</td><td>Supplementary hazard statement Code(s)</td><td>Pictogram(s), signal word Code(s)</td><td></td></tr>
<tr><td>Acute tox. 2</td><td>H300</td><td rowspan="3">EUH 032</td><td rowspan="3">GHS05
GHS06
GHS09 Dgr</td><td rowspan="3"></td></tr>
<tr><td>Aquatic Acute 1</td><td>H400</td></tr>
<tr><td>Aquatic Chronic 1</td><td>H410</td></tr>
<tr><td colspan="2">Signal words</td><td colspan="3">Pictogram(s)</td></tr>
<tr><td colspan="2">Danger</td><td> 
Skull and crossbones</td><td> 
Environment</td><td> 
Corrosive to metals</td></tr>
</table>

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Hazard statements:

H300	Fatal if swallowed
H400	Very toxic to aquatic life
H410	Very toxic to aquatic life
EUH032	Contact with acids liberates very toxic gas

Precautionary statements:

P273	Avoid release to the environment.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P301 + P310 + P330	If swallowed immediately called a POISON CENTER or doctor/physician. Rinse mouth.
P302 + P352 + P310	If on skin gently wash with plenty of soap and water. Immediately called a POISON CENTER or doctor/physician.
P391	Collect spillage.
P501	Dispose of contents/container as waste: in an approved waste.

4. First Aid:

4.1 Description of first aid measures

After inhalation: Remove victim to fresh air. If breath laboured, administer oxygen as needed. If victim is not breathing, administer artificial respiration or CPR.

After eye contact: If product enters eyes, wash eyes gently under running water for 15 minutes or longer, making sure that the eyelids are held open. Immediately call in ophthalmologist. Remove contact lenses.

After skin contact: In case of skin contact, remove any contaminated clothing. Wash affected area with plenty of soap and water for at least 15 minutes. If pain or irritation occur, obtain medical attention.

After swallowing: After swallowing: immediately make victim drink water (two glasses at most). Consult a physician.

General information: If ingested, or in case of feeling unwell, seek medical advice urgently.

4.2 Most important symptoms and effects, both acute and delayed

No adverse symptoms or effects have been identified.

4.3 Indication of any immediate medical attention and special treatment needed

No data available

5. Fire extinguishing measures:

5.1 Extinguishing media: In case of fire use carbon dioxide (CO2), dry chemical, water spray or foam. For large fires use extinguishing media suitable for surrounding fire.

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5.2 Special hazards arising from the substance or mixture

Special fire and explosion hazards: No special hazards determined.
Hazardous combustion products: No combustion products posing significant hazards are expected from this product (an aqueous solution).

5.3 Advice for firefighters: Protective equipment Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

5.4 Additional information: No further relevant information available.

6. Accidental release measures:

6.1 Personal precaution, protective equipment and emergency procedures
Personal Precautions: This product contains a material of human origin. Observe general safety guidelines for protection during clean up procedures.
Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions
Contain spill to prevent migration. Place absorbed material in container suitable for disposal. Do not allow the undiluted product to enter sewers/surface or ground water. Dispose of all waste material in accordance with local and facility guidelines.

6.3 Methods and material for containment and cleaning-up
Spill and Leak Procedures: Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.
Radioactive material is subject to the regulations of each country.
Dispose of all waste material in accordance with local guidelines.

6.4 Reference to other sections
Refer sections 8 and 13.

7. Handling and storage:

7.1 Precautions for safe handling: Wear suitable personal protective equipment. Avoid splashing. Use the reagent in accordance with relevant package insert. Avoid high temperature and freezing. Do not eat, drink, smoke or apply cosmetics in laboratory areas.

7.2 Conditions for safe storage, including any incompatibilities: Store product in accordance with the relevant package insert. Do not store together with ignitable and flammable substances.

7.3 Specific end uses: No further relevant information available.

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8. Exposure controls/personal protection:

8.1 Control parameters:

Sodium Azide (CAS # 26628-22-8)
US OSHA: None established
ACGIH: 0.29 mg/m3 Ceiling (as Sodium azide); 0.11 ppm Ceiling (as Hydrazoic acid vapor)
DFG MAK: 0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)
Ireland: 0.1 mg/m3 TWA; 0.3 mg/m3 STEL; Potential for cutaneous absorption
IOELVs: Possibility of significant uptake through the skin; 0.1 mg/m3 TWA; 0.3 mg/m3 STEL
NIOSH: None established
Japan: None established

8.2 Exposure controls

Engineering Controls	Place vial behind a metal shield, away from the user.
Eye Protection	Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.
Skin Protection	Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin contact. Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 or appropriate government standards.
Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a qualified professional.

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9. Physical and chemical properties:

9.1 Information on basic physical and chemical properties

Physical state	liquid	**Transparency**	clear
Colour	red	**Decomposition Temperature**	not applicable
Odour	odourless	**pH**	7.3 – 7.5
Freezing point	0 °C	**Kinematic viscosity**	not determined
Boiling point	100 °C	**Solubility in water**	complete
Flammability	not applicable	**Solubility in organic**	not determined
Lower and upper explosion limit	not applicable	**Partition coefficient n-octanol/water (log value)**	not applicable
Flash Point	not applicable	**Vapour pressure**	not applicable
Autoignition Temp.	not applicable	**Density and/or relative density**	1.00 @20°C

9.2 Other information:

No further relevant information available.

10. Stability and reactivity:

10.1 Reactivity: Sodium azide: Contact with acids liberates very toxic gas.

10.2 Chemical Stability: The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions: Sodium azide: forms explosive compounds with heavy metals. Repeated contact of low concentrations of azide with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Do not allow the undiluted product to enter sewers/surface or ground water.

10.4 Conditions to avoid: Avoid contact with incompatible materials. Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials: Strong oxidizing agents, Strong acids, Aluminum, Heavy metals

10.6 Hazardous decomposition products: No decomposition products posing significant hazards would be expected from this product (an aqueous solution).

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11. Toxicological information:

11.1 Information on hazard classes

Toxicity data for hazardous ingredients - Sodium azide (CAS # 26628-22-8):

Acute toxicity:

LD50 Oral - Rat - 27 mg/kg Remarks: (RTECS)
LC50 Inhalation - Rat - male and female - 4 h - 0,054 - 0,52 mg/l - dust/mist
(US-EPA) LD50 Dermal - Rabbit - 20 mg/kg Remarks: (RTECS)

Skin corrosion/irritation:

Skin - In vitro study Result: No skin irritation (OECD Test Guideline 439)

Serious eye damage/eye irritation:

Eyes - Bovine cornea Result: No eye irritation - 4 h (OECD Test Guideline 437)

Respiratory or skin sensitization:

Local lymph node assay (LLNA) – Mouse Result: negative (OECD Test Guideline 429)

Germ cell mutagenicity:

Test Type: Mutagenicity (mammal cell test): chromosome aberration. Test system: Chinese hamster ovary cells
Metabolic activation: with and without metabolic activationMethod: OECD Test Guideline 473 Result: negative
Test Type: unscheduled DNA synthesis assay. Test system: Chinese hamster lung cells
Metabolic activation: without metabolic activation Method: OECD Test Guideline 482
Result: negative
Test Type: sister chromatid exchange assay Test system: Chinese hamster ovary cells
Metabolic activation: without metabolic activation Method: OECD Test Guideline 479
Result: negative

Carcinogenicity: No data available

Reproductive toxicity: No data available

Specific target organ toxicity - single exposure: No data available

Specific target organ toxicity - repeated exposure:

Oral - May cause damage to organs through prolonged or repeated exposure – Brain

Aspiration hazard: No data available

Primary routes of exposure Common routes of entry include inhalation, ingestion and eye/skin contact. Specific paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.

11.2 Information on other hazards

Endocrine disrupting properties:

Sodium azide (CAS # 26628-22-8):

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.

Other information:

This product contains materials of human and human origin and should be considered as potentially capable of transmitting infectious diseases.

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12. Ecological information:

Ecotoxical effects: Sodium Azide is toxic for aquatic organisms.

12.1 Toxicity
Sodium azide (CAS # 26628-22-8):
Toxicity to fish: flow-through test LC50 - Oncorhynchus mykiss (rainbow trout) - 2,75 mg/l - 96 h (OECD Test Guideline 203)
Toxicity to algae: static test ErC50 - Pseudokirchneriella subcapitata - 0,35 mg/l - 96 h (OECD Test Guideline 201)

12.2 Persistence and degradability
Sodium azide (CAS # 26628-22-8):
The methods for determining the biological degradability are not applicable to inorganic substances.

12.3 Bioaccumulative potential
No data available

12.4 Mobility in soil
No data available

12.5 Results of PBT and vPvB assessment
Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Endocrine disrupting properties:
This product does not have substance(s) of endocrine disrupting properties for environment according to REACH Article 57(f).

12.7 Other adverse effects: This product contains environmentally hazardous substance below the cutoff level. Refer section 3 for ingredient information. Do not allow undiluted product to enter sewer/surface or ground water.

13.Disposal considerations:

13.1 Waste treatment methods
Product Waste Disposal: Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.
Sodium azide preservative may form explosive compounds in metal drain lines.
See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).
To avoid the possible build-up of azide compounds, flush wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

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Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or and approved waste-disposal company for information.
Package disposal: Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional Information

Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

14.Transport information:

According to ADR and IATA (Chapter 10.3.1) regulations, shipment below the exemption quantity (1 MBq for Iodine 125) are considered as not dangerous goods. If the shipment exceed this quantity, please refer to the information given below:

Shipping information	IATA	IMDG	US DOT	European ADR	Canadian TDG
14.1 UN/ID number	2910	2910	2910	2910	2910
14.2 UN proper shipping name	Radioactive Material, excepted package-limited quantity of material				
14.3 Transport hazardclass(es)	7 Radioactive Material	7 Radioactive Material	7 Radioactive Material	7 Radioactive Material	7 Radioactive Material
Subsidiary risk	None	None	None	None	None
Classification code	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.4 Packing group					
Special provisions	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
Additional information					
IATA ERG code	7L	Not applicable	Not applicable	Not applicable	Not applicable
EmS	Not applicable	F-I, S-S	Not applicable	Not applicable	Not applicable
NAERG code	Not applicable	Not applicable	161	Not applicable	161
14.5 Environmental hazards					
Marine pollutant	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.6 Special precautions for user	No special precautions for users are required.				

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15. Regulatory information:

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

EU regulations: This SDS complies with EC Regulations 1907/2006 (REACH and amendments).

Labelling according to EU guidelines: The product has been classified and marked in accordance with EU Directives / Ordinance on Hazardous Materials. Harmonised classification - Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation)

Hazard-determining components of labelling: * NaN_3

** But as mentioned in the REGULATION (EC) No 1272/2008 under point 1.5(a) there is no hazard labelling necessary as the total volume of the components of the KIT is under 125 ml.*

Other information: Radioactive material in accordance with "A.R. of 28/02/1963 art. 31" and following, relating to the protection of the population and workers against the danger of ionising radiations.

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

16. Other information:

Izotop safety rating:

Flammability: 0	Code
Health: 1	0=None
Reactivity with water: 0	1=Slight
	2=Caution
Physical contact: 1	3=Severe

Revision changes: Revised to include EC 2020/878 amendment to REACH EC 1907/2006
Document version and issue/revision date: Revision Date (year/month/day) 2023/10/17
Description of hazard class and hazard statements from Section 3:
Aquatic Acute 1 - Aquatic Hazard Acute, Category 1
Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2
Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1
H300 - Fatal if swallowed.
H400 - Very toxic to aquatic life.
H410 - Very toxic to aquatic life with long lasting effects.

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Abbreviations and Acronyms:

ACGIH - American Conference of Governmental Industrial Hygienists
ADR - European Agreement Concerning The Inter. Carriage Of Dangerous Goods By Road
CLP - Classification, Labeling and Packaging
GHS - Globally Harmonized System
IATA - International Air Transport Association
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
TDG - Canadian Transportation Of Dangerous Goods Regulations.
US DOT - United States Department of Transportation
vPvB - Very persistent and very bioaccumulative substances
LC50 - Lethal Concentration, 50%
LD50 - Lethal Dose, 50%

Information and recommendations:

- All human products and derivatives are collected in healthy individuals without any disease.
- The BSA (Bovine Serum Albumin) originates from countries where BSE (Bovine Spongiform Encephalopathy) as not been reported.
- The information herein is believed to be correct as of the date hereof but is provided without warranty of any kind. The recipient of our products is responsible for observing any laws and guidelines.
- For in vitro diagnostics only.
- This radioactive product can be transferred to and used only by authorised persons; purchase, storage, use and exchange of radioactive products are subject to the legislation of the end-user's country.
- In no case the product must be administered to humans or animals.
- Do not smoke, drink, eat or apply cosmetics in the working area.
- Do not pipette by mouth.
- Use protective clothing and disposable gloves.
- All radioactive handling should be executed in a designated area, away from regular passage.
- A logbook for receipt and storage of radioactive materials must be kept in the lab.
- Laboratory equipment and glassware, which could be contaminated with radioactive substances, should be segregated to prevent cross contamination of different radioisotopes.
- Any radioactive spills must be cleaned immediately in accordance with the radio safety procedures.
- The radioactive waste must be disposed of following the local regulations and guidelines of the notified bodies holding jurisdiction over the laboratory.
- Adherence to the basic rules of the radiation safety provides adequate protection.

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MATERIAL SAFETY DATA SHEET

According to EC Directive 1907/2006/EC **[REACH]** and to Regulation (EC) No 1272/2008 **[CLP]**

Standard

1. Identification of the substance/preparation and of the company

1.1 Product identifier:

Product name: **Standard (1-6)**
Product code: Components of RK-349CT
Product formal name: Diagnostic reagents

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

Product use
Application of the substance/preparation: For In-vitro diagnostic test

1.3 Details of the supplier of the safety data sheet

Manufacturer/Supplier:

Institute of Isotopes Co., Ltd.
Konkoly-Thege Miklós út 29-33
H-1121 Budapest, Hungary
Phone number: (36-1) 391-0826
Fax number: (36-1) 392-2575, 395-9247

Further information available from: www.izotop.hu
Email address of the competent person: **immuno@izotop.hu**

1.4 Emergency telephone number

Information in case of emergency: Health Toxicological Information Service
+36 80 201 199 (0-24 hours, toll free - only from Hungary)
+36 1 476 6464 (0-24 hours, also from abroad)

2. Hazards identification:

2.1 Classification of the substance or mixture

Product description: In vitro diagnostic reagent; Yellow, Liquid
Classification according to Regulation (EC) No 1272/2008 [CLP]
Not classified as hazardous per EC 1272/2008 [CLP].

2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008 [CLP]
Not classified as hazardous per EC 1272/2008 [CLP].

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2.3 Other hazards

Additional information: Results of PBT and vPvB assessment:
PBT: Not applicable.
vPvB: Not applicable.

Sodium azide: This product contains concentrations of sodium azide below the hazardous level, which with repeated contact with lead and copper commonly found in plumbing drains may result in the build-up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

Kathon CG: is a mixture in the ratio 3:1 of 5-chloro-2methyl-4-isothiazolin-3-one (Methylchloroisothiazolinone; CMI) and 2-methyl-4-isothiazolin-3-one (Methylisothiazolinone; MI). This is a toxic substance. Avoid contact with components, which contain Kathon CG, and do not ingest.

Biologically derived materials: This product contains human biologically derived materials and should be considered as potentially capable of transmitting infectious diseases.

See Section 11 Toxicological Information for more detailed health information.

3. Composition / Information on ingredients:

3.2 Mixtures

Hazardous ingredient(s):

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International chemical identification	**CAS #**		**EC no**		
Sodium azide	26628-22-8		247-852-1		
(< 0.1 % by wt)	**Classification**		**Labelling**		
	Hazard class and Category Code(s)	*Hazard statement Code(s)*	*Supplementary hazard statement Code(s)*	*Pictogram(s), signal word Code(s)*	
	Acute tox. 2	H300	EUH 032	GHS05 GHS06 GHS09 Dgr	
	Aquatic Acute 1	H400			
	Aquatic Chronic 1	H410			
	Signal words		**Pictogram(s)**		
	Danger		 **Skull and crossbones**	 **Environment**	 **Corrosive to metals**

Hazard statements:

H300	Fatal if swallowed
H400	Very toxic to aquatic life
H410	Very toxic to aquatic life
EUH032	Contact with acids liberates very toxic gas

Precautionary statements:

P273	Avoid release to the environment.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P301 + P310 + P330	If swallowed immediately called a POISON CENTER or doctor/physician. Rinse mouth.
P302 + P352 + P310	If on skin gently wash with plenty of soap and water. Immediately called a POISON CENTER or doctor/physician.
P391	Collect spillage.
P501	Dispose of contents/container as waste: in an approved waste.

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International chemical identification	CAS #	EC no
Kathon CG	55965-84-9	-
Mixture of 5-Chloro-2-methyl-4-isothiazolin-3-one and 2-Methyl-2H -isothiazol-3-one (3:1)		

	Classification		**Labelling**		
	Hazard class and Category Code(s)	*Hazard statement Code(s)*	*Supplementary hazard statement Code(s)*	*Pictogram(s), signal word Code(s)*	
	Acute tox. 3	H301			
	Acute tox. 3	H311			
	Skin Corr. 1B	H314			
	Skin Irrit. 2	H315		GHS06	
	Skin Sens. 1	H317		GHS07	
	Eye Irrit. 2	H319		GHS09	
	Acute Tox. 3	H331		GHS05Dgr	
	Aquatic Acute 1	H400			
	Aquatic Chronic 1	H410			
	Signal words		**Pictogram(s)**		
	Danger		 **Skull and crossbones**	 **Irritant**	 **Environment**  **Corrosion**

Hazardous statements:

H301	Toxic if swallowed.
H311	Toxic in contact with skin.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H331	Toxic if inhaled.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.

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Precautionary statements:

P261	Avoid breathing dust/ fume/ gas/ mist/ vapors/ spray.
P272	Contaminated work clothing should not be allowed out of the workplace.
P280	Wear protective gloves/ protective clothing/ eye protection/ face protection.
P303 + P361 + P353	IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water.
P305 + P351 + P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
Supplemental Hazard Statements:	none

4. First Aid:

4.1 Description of first aid measures

After inhalation: Remove victim to fresh air. If breath laboured, administer oxygen as needed. If victim is not breathing, administer artificial respiration or CPR.

After eye contact: If product enters eyes, wash eyes gently under running water for 15 minutes or longer, making sure that the eyelids are held open. Immediately call in ophthalmologist. Remove contact lenses.

After skin contact: In case of skin contact, remove any contaminated clothing. Wash affected area with plenty of soap and water for at least 15 minutes. If pain or irritation occur, obtain medical attention.

After swallowing: After swallowing: immediately make victim drink water (two glasses at most). Avoid vomiting (risk of perforation). Call a physician immediately. Do not attempt to neutralise. Consult a physician.

General information: If ingested, or in case of feeling unwell, seek medical advice urgently.

4.2 Most important symptoms and effects, both acute and delayed

No adverse symptoms or effects have been identified.

4.3 Indication of any immediate medical attention and special treatment needed

No data available

5. Fire extinguishing measures:

5.1 Extinguishing media: In case of fire use carbon dioxide (CO2), dry chemical, water spray or foam. For large fires use extinguishing media suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture

Special fire and explosion hazards: No special hazards determined.

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Hazardous combustion products: No combustion products posing significant hazards are expected from this product (an aqueous solution).

5.3 Advice for firefighters: Protective equipment Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

5.4 Additional information: No further relevant information available.

6. Accidental release measures:

6.1 Personal precaution, protective equipment and emergency procedures

Personal Precautions: This product contains a material of human origin. Observe general safety guidelines for protection during clean up procedures.
Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions

Contain spill to prevent migration. Place absorbed material in container suitable for disposal. Do not allow the undiluted product to enter sewers/surface or ground water. Dispose of all waste material in accordance with local and facility guidelines.

6.3 Methods and material for containment and cleaning-up

Spill and Leak Procedures: As a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Dispose of all waste material in accordance with local guidelines.

6.4 Reference to other sections

Refer sections 8 and 13.

7. Handling and storage:

7.1 Precautions for safe handling: This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product. Wear suitable personal protective equipment. Avoid splashing. Use the reagent in accordance with relevant package insert. Avoid high temperature and freezing. Do not eat, drink, smoke or apply cosmetics in laboratory areas.

7.2 Conditions for safe storage, including any incompatibilities: Store at 2 to 8°C, as directed on the product label. To maintain product quality, store according to the instructions in the product labeling. Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 Specific end uses: No further relevant information available.

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8. Exposure controls/personal protection:

8.1 Control parameters:

Sodium Azide (CAS # 26628-22-8)

US OSHA: None established
ACGIH: 0.29 mg/m3 Ceiling (as Sodium azide); 0.11 ppm Ceiling (as Hydrazoic acid vapor)
DFG MAK: 0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)
Ireland: 0.1 mg/m3 TWA; 0.3 mg/m3 STEL; Potential for cutaneous absorption
IOELVs: Possibility of significant uptake through the skin; 0.1 mg/m3 TWA; 0.3 mg/m3 STEL
NIOSH: None established
Japan: None established

8.2 Exposure controls

Engineering Controls	No special engineering controls are required. Use with good general ventilation.
Eye Protection	Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.
Skin Protection	Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin contact. Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 or appropriate government standards.
Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection.

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9. Physical and chemical properties:

9.1 Information on basic physical and chemical properties

Physical state	liquid	**Transparency**	clear
Colour	yellow	**Decomposition Temperature**	not applicable
Odour	modest	**pH**	6.0 – 8.0
Freezing point	0 °C	**Kinematic viscosity**	not determined
Boiling point	100 °C	**Solubility in water**	complete
Flammability	not applicable	**Solubility in organic**	not determined
Lower and upper explosion limit	not applicable	**Partition coefficient n-octanol/water (log value)**	not applicable
Flash Point	not applicable	**Vapour pressure**	not applicable
Autoignition Temp.	not applicable	**Density and/or relative density**	1.00 @20°C

9.2 Other information:

No further relevant information available.

10. Stability and reactivity:

10.1 Reactivity: Sodium azide: Contact with acids liberates very toxic gas.

10.2 Chemical Stability: This product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions: Sodium azide: forms explosive compounds with heavy metals. Repeated contact of low concentrations of azide with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Do not allow the undiluted product to enter sewers/surface or ground water.

10.4 Conditions to avoid: Avoid contact with incompatible materials. Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials: Strong oxidizing agents, Strong acids, Metals and metallic compounds.

10.6 Hazardous decomposition products: No decomposition products posing significant hazards would be expected from these product (aqueous solutions).

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11. Toxicological information:

11.1 Information on hazard classes

Toxicity data for hazardous ingredients - Sodium azide (CAS # 26628-22-8):

Acute toxicity:
LD50 Oral - Rat - 27 mg/kg Remarks: (RTECS)
LC50 Inhalation - Rat - male and female - 4 h - 0,054 - 0,52 mg/l - dust/mist
(US-EPA) LD50 Dermal - Rabbit - 20 mg/kg Remarks: (RTECS)

Skin corrosion/irritation:
Skin - In vitro study Result: No skin irritation (OECD Test Guideline 439)

Serious eye damage/eye irritation:
Eyes - Bovine cornea Result: No eye irritation - 4 h (OECD Test Guideline 437)

Respiratory or skin sensitization:
Local lymph node assay (LLNA) – Mouse Result: negative (OECD Test Guideline 429)

Germ cell mutagenicity
Test Type: Mutagenicity (mammal cell test): chromosome aberration. Test system: Chinese hamster ovary cells
Metabolic activation: with and without metabolic activationMethod: OECD Test Guideline 473 Result: negative
Test Type: unscheduled DNA synthesis assay. Test system: Chinese hamster lung cells
Metabolic activation: without metabolic activation Method: OECD Test Guideline 482
Result: negative
Test Type: sister chromatid exchange assay Test system: Chinese hamster ovary cells
Metabolic activation: without metabolic activation Method: OECD Test Guideline 479
Result: negative

Carcinogenicity: No data available

Reproductive toxicity: No data available

Specific target organ toxicity - single exposure: No data available

Specific target organ toxicity - repeated exposure:
Oral - May cause damage to organs through prolonged or repeated exposure – Brain

Aspiration hazard: No data available

Primary routes of exposure Common routes of entry include inhalation, ingestion and eye/skin contact. Specific paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.

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Toxicity data for hazardous ingredients – Kathon CG (CAS # 55965-84-9):

Acute toxicity:
LD50 Oral - Rat - male and female - 66 mg/kg (OECD Test Guideline 401)
LC50 Inhalation - Rat - male and female - 4 h - 0,171 mg/l – aerosol (OECD Test G. 403)
LD50 Dermal - Rabbit - male - 87,12 mg/kg

Skin corrosion/irritation:
Skin – Rabbit Result: Corrosive, category 1C - where responses occur after exposures between 1 hour and 4 hours and observations up to 14 days. (OECD Test Guideline 404)

Serious eye damage/eye irritation:
Remarks: Mixture causes serious eye damage. Risk of blindness!
Eyes – Rabbit Result: Causes serious eye damage. Remarks: (ECHA)

Respiratory or skin sensitization:
May cause an allergic skin reaction. Maximization Test - Guinea pig Result: positive (OECD Test Guideline 406)

Germ cell mutagenicity:
Test Type: Ames test. Test system: Salmonella typhimurium. Result: positive
Test Type: In vitro mammalian cell gene mutation test. Test system: mouse lymphoma cells Result: positive.
Test Type: Ames test Test system: Salmonella typhimurium. Result: Positive results were obtained in some in vitro tests.
Test Type: UDS (Unscheduled DNA synthesis assay). Test system: rat hepatocytes Result: negative.
Test Type: Mutagenicity (mammal cell test): chromosome aberration. Test system: Human lymphocytes Result: positive. Method: OECD Test Guideline 475 Species: Mouse - male and female - Bone marrow Result: negative. Method: OECD Test Guideline 486 Species: Rat - male - Liver cells.
Result: negative.
Method: US-EPA Species: Mouse - male and female - Bone marrow
Result: negative.
Method: US-EPA Species: Rat - male - Liver cells
Result: negative.
Method: OECD Test Guideline 474 Species: Mouse - male and female - Red blood cells (erythrocytes)
Result: negative.

Carcinogenicity:
No data available.

Reproductive toxicity:
No data available.

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Specific target organ toxicity - single exposure:
No data available.

Specific target organ toxicity - repeated exposure:
No data available.

Aspiration hazard:
No data available.

11.2 Information on other hazards
Endocrine disrupting properties:
This product does not have substance(s) of endocrine disrupting properties for health according to REACH Article 57(f).

Other information:
This product contains materials of human origin and should be considered as potentially capable of transmitting infectious diseases.

12. Ecological information:

Ecotoxical effects:
Sodium Azide (CAS # 26628-22-8) is toxic for aquatic organisms.

12.1 Toxicity
Sodium Azide (CAS # 26628-22-8):
Toxicity to fish: flow-through test LC50 - Oncorhynchus mykiss (rainbow trout) - 2,75 mg/l - 96 h (OECD Test Guideline 203)
Toxicity to algae: static test ErC50 - Pseudokirchneriella subcapitata - 0,35 mg/l - 96 h (OECD Test Guideline 201)
Kathon CG (CAS # 55965-84-9):
Toxicity to fish flow-through test LC50 - Oncorhynchus mykiss (rainbow trout) - 0,19 mg/l - 96 h (US-EPA)
Toxicity to daphnia and other aquatic invertebrates flow-through test LC50 - Daphnia magna (Water flea) - 0,18 mg/l - 48 h (US-EPA)
Toxicity to bacteria static test EC50 - activated sludge - 4,5 mg/l - 3 h (OECD Test G. 209)
Toxicity to fish(Chronic toxicity) semi-static test NOEC - Oncorhynchus mykiss (rainbow trout) - 0,098 mg/l - 35 d (OECD Test Guideline 215)
Toxicity to daphnia and other aquatic flow-through test NOEC - Daphnia magna (Water flea) - 0,1 mg/l - 21 d invertebrates(Chronic toxicity). (US-EPA)

12.2 Persistence and degradability
Sodium Azide (CAS # 26628-22-8):
The methods for determining the biological degradability are not applicable to inorganic substances.
Kathon CG (CAS # 55965-84-9): No data available

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12.3 Bioaccumulative potential
No data available

12.4 Mobility in soil
No data available

12.5 Results of PBT and vPvB assessment
Not determined for this product. PBT: Not applicable, vPvB: Not applicable.

12.6 Endocrine disrupting properties:
This product does not have substance(s) of endocrine disrupting properties for environment according to REACH Article 57(f).

12.7 Other adverse effects: This product contains environmentally hazardous substance below the cutoff level. Refer section 3 for ingredient information. Do not allow undiluted product to enter sewer/surface or ground water.

13.Disposal considerations:

13.1 Waste treatment methods
Product Waste Disposal: Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.
Sodium azide preservative may form explosive compounds in metal drain lines.
See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).
To avoid the possible build-up of azide compounds, flush wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.
Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or and approved waste-disposal company for information.
Package disposal: Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional Information
Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

14.Transport information:

Transportation of this product is not regulated under ICAO, IATA DGR, IMDG, US DOT, European ADR and RID or Canadian TDG.

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14.1 UN/ID number: Not regulated for transportation
14.2 UN proper shipping name: Not regulated for transportation
14.3 Transport hazard class(es): Not regulated for transportation
14.4 Packing group: Not regulated for transportation
14.5 Environmental hazards: Not regulated for transportation
14.6 Special precautions for user: None
14.7 Maritime transport in bulk according to IMO instruments: Not applicable

15. Regulatory information:

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

EU regulations: This SDS complies with EC Regulations 1907/2006 (REACH and amendments).

Labelling according to EU guidelines: The product has been classified and marked in accordance with EU Directives / Ordinance on Hazardous Materials. Harmonised classification - Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation)

Hazard-determining components of labelling: * **NaN_3, Kathon CG**
** But as mentioned in the REGULATION (EC) No 1272/2008 under point 1.5(a) there is no hazard labelling necessary as the total volume of the components of the KIT is under 125 ml.*

National legislation:
Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.
Other regulations: Take note of Dir 94/33/EC on the protection of young people at work.

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

16. Other information:

Izotop safety rating:

Flammability: 0		Code
Health: 1		0=None
Reactivity with water: 0		1=Slight
		2=Caution
Physical contact: 1		3=Severe

Revision changes: Revised to include EC 2020/878 amendment to REACH EC 1907/2006
Document version and issue/revision date: Revision Date (year/month/day) 2023/10/17

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Description of hazard class and hazard statements from Section 3:

Aquatic Acute 1 - Aquatic Hazard Acute, Category 1
Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2
Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1

H300	Fatal if swallowed.
H301	Toxic if swallowed.
H311	Toxic in contact with skin.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H331	Toxic if inhaled.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.

Abbreviations and Acronyms:

ACGIH - American Conference of Governmental Industrial Hygienists
ADR - European Agreement Concerning The International Carriage Of Dangerous Goods By Road
CLP - Classification, Labeling and Packaging
GHS - Globally Harmonized System
IATA - International Air Transport Association
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
TDG - Canadian Transportation Of Dangerous Goods Regulations.
US DOT - United States Department of Transportation
vPvB - Very persistent and very bioaccumulative substances
LC50 - Lethal Concentration, 50%
LD50 - Lethal Dose, 50%

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MATERIAL SAFETY DATA SHEET

According to EC Directive 1907/2006/EC **[REACH]** and to Regulation (EC) No 1272/2008 **[CLP]**

Control sera

1. Identification of the substance/preparation and of the company

1.1 Product identifier:

Product name: **Control sera (CI, CII)**
Product code: Components of RK-349CT
Product formal name: Diagnostic reagents

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

Product use
Application of the substance/preparation: For In-vitro diagnostic test

1.3 Details of the supplier of the safety data sheet

Manufacturer/Supplier:

Institute of Isotopes Co., Ltd.
Konkoly-Thege Miklós út 29-33
H-1121 Budapest, Hungary
Phone number: (36-1) 391-0826
Fax number: (36-1) 392-2575, 395-9247

Further information available from: www.izotop.hu
Email address of the competent person: **immuno@izotop.hu**

1.4 Emergency telephone number

Information in case of emergency: Health Toxicological Information Service
+36 80 201 199 (0-24 hours, toll free - only from Hungary)
+36 1 476 6464 (0-24 hours, also from abroad)

2. Hazards identification:

2.1 Classification of the substance or mixture

Product description: In vitro diagnostic reagents; Yellow, Liquid
Classification according to Regulation (EC) No 1272/2008 [CLP]
Not classified as hazardous per EC 1272/2008 [CLP].

2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008 [CLP]
Not classified as hazardous per EC 1272/2008 [CLP].

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2.3 Other hazards

Additional information: Results of PBT and vPvB assessment:
PBT: Not applicable.
vPvB: Not applicable.

Sodium azide: This product contains concentrations of sodium azide below the hazardous level, which with repeated contact with lead and copper commonly found in plumbing drains may result in the build-up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

Kathon CG: is a mixture in the ratio 3:1 of 5-chloro-2methyl-4-isothiazolin-3-one (Methylchloroisothiazolinone; CMI) and 2-methyl-4-isothiazolin-3-one (Methylisothiazolinone; MI). This is a toxic substance. Avoid contact with components, which contain Kathon CG, and do not ingest.

Biologically derived materials: This product contains human biologically derived materials and should be considered as potentially capable of transmitting infectious diseases.

See Section 11 Toxicological Information for more detailed health information.

3. Composition / Information on ingredients:

3.2 Mixtures

Hazardous ingredient(s):

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International chemical identification	**CAS #**		**EC no**		
Sodium azide	26628-22-8		247-852-1		
(< 0.1 % by wt)	**Classification**		**Labelling**		
	Hazard class and Category Code(s)	*Hazard statement Code(s)*	*Supplementary hazard statement Code(s)*	*Pictogram(s), signal word Code(s)*	
	Acute tox. 2	H300	EUH 032	GHS05 GHS06 GHS09 Dgr	
	Aquatic Acute 1	H400			
	Aquatic Chronic 1	H410			
	Signal words		**Pictogram(s)**		
	Danger		 **Skull and crossbones**	 **Environment**	 **Corrosive to metals**

Hazard statements:

H300	Fatal if swallowed
H400	Very toxic to aquatic life
H410	Very toxic to aquatic life
EUH032	Contact with acids liberates very toxic gas

Precautionary statements:

P273	Avoid release to the environment.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P301 + P310 + P330	If swallowed immediately called a POISON CENTER or doctor/physician. Rinse mouth.
P302 + P352 + P310	If on skin gently wash with plenty of soap and water. Immediately called a POISON CENTER or doctor/physician.
P391	Collect spillage.
P501	Dispose of contents/container as waste: in an approved waste.

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International chemical identification	**CAS #**	**EC no**
Kathon CG	55965-84-9	-
Mixture of 5-Chloro-2-methyl-4-isothiazolin-3-one and 2-Methyl-2H -isothiazol-3-one (3:1)		

	Classification		**Labelling**		
	Hazard class and Category Code(s)	*Hazard statement Code(s)*	*Supplementary hazard statement Code(s)*	*Pictogram(s), signal word Code(s)*	
	Acute tox. 3	H301		GHS06 GHS07 GHS09 GHS05Dgr	
	Acute tox. 3	H311			
	Skin Corr. 1B	H314			
	Skin Irrit. 2	H315			
	Skin Sens. 1	H317			
	Eye Irrit. 2	H319			
	Acute Tox. 3	H331			
	Aquatic Acute 1	H400			
	Aquatic Chronic 1	H410			
	Signal words		**Pictogram(s)**		
	Danger		 **Skull and crossbones**	 **Irritant**	 **Environment**  **Corrosion**

Hazardous statements:

H301	Toxic if swallowed.
H311	Toxic in contact with skin.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H331	Toxic if inhaled.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.

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Precautionary statements:

P261	Avoid breathing dust/ fume/ gas/ mist/ vapors/ spray.
P272	Contaminated work clothing should not be allowed out of the workplace.
P280	Wear protective gloves/ protective clothing/ eye protection/ face protection.
P303 + P361 + P353	IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water.
P305 + P351 + P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
Supplemental Hazard Statements:	none

4. First Aid:

4.1 Description of first aid measures

After inhalation: Remove victim to fresh air. If breath laboured, administer oxygen as needed. If victim is not breathing, administer artificial respiration or CPR.

After eye contact: If product enters eyes, wash eyes gently under running water for 15 minutes or longer, making sure that the eyelids are held open. Immediately call in ophthalmologist. Remove contact lenses.

After skin contact: In case of skin contact, remove any contaminated clothing. Wash affected area with plenty of soap and water for at least 15 minutes. If pain or irritation occur, obtain medical attention.

After swallowing: After swallowing: immediately make victim drink water (two glasses at most). Avoid vomiting (risk of perforation). Call a physician immediately. Do not attempt to neutralise. Consult a physician.

General information: If ingested, or in case of feeling unwell, seek medical advice urgently.

4.2 Most important symptoms and effects, both acute and delayed

No adverse symptoms or effects have been identified.

4.3 Indication of any immediate medical attention and special treatment needed

No data available

5. Fire extinguishing measures:

5.1 Extinguishing media: In case of fire use carbon dioxide (CO2), dry chemical, water spray or foam. For large fires use extinguishing media suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture

Special fire and explosion hazards: No special hazards determined.

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Hazardous combustion products: No combustion products posing significant hazards are expected from this product (an aqueous solution).

5.3 Advice for firefighters: Protective equipment Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

5.4 Additional information: No further relevant information available.

6. Accidental release measures:

6.1 Personal precaution, protective equipment and emergency procedures

Personal Precautions: This product contains a material of human origin. Observe general safety guidelines for protection during clean up procedures.
Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions

Contain spill to prevent migration. Place absorbed material in container suitable for disposal. Do not allow the undiluted product to enter sewers/surface or ground water. Dispose of all waste material in accordance with local and facility guidelines.

6.3 Methods and material for containment and cleaning-up

Spill and Leak Procedures: As a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Dispose of all waste material in accordance with local guidelines.

6.4 Reference to other sections

Refer sections 8 and 13.

7. Handling and storage:

7.1 Precautions for safe handling: This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product. Wear suitable personal protective equipment. Avoid splashing. Use the reagent in accordance with relevant package insert. Avoid high temperature and freezing. Do not eat, drink, smoke or apply cosmetics in laboratory areas.

7.2 Conditions for safe storage, including any incompatibilities: Store at 2 to 8°C, as directed on the product label. To maintain product quality, store according to the instructions in the product labeling. Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).

7.3 Specific end uses: No further relevant information available.

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8. Exposure controls/personal protection:

8.1 Control parameters:

Sodium Azide (CAS # 26628-22-8)

US OSHA: None established
ACGIH: 0.29 mg/m3 Ceiling (as Sodium azide); 0.11 ppm Ceiling (as Hydrazoic acid vapor)
DFG MAK: 0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)
Ireland: 0.1 mg/m3 TWA; 0.3 mg/m3 STEL; Potential for cutaneous absorption
IOELVs: Possibility of significant uptake through the skin; 0.1 mg/m3 TWA; 0.3 mg/m3 STEL
NIOSH: None established
Japan: None established

8.2 Exposure controls

Engineering Controls	No special engineering controls are required. Use with good general ventilation.
Eye Protection	Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.
Skin Protection	Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin contact. Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 or appropriate government standards.
Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection.

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9. Physical and chemical properties:

9.1 Information on basic physical and chemical properties

Physical state	liquid	**Transparency**	clear
Colour	yellow	**Decomposition Temperature**	not applicable
Odour	modest	**pH**	6.0 – 8.0
Freezing point	0 °C	**Kinematic viscosity**	not determined
Boiling point	100 °C	**Solubility in water**	complete
Flammability	not applicable	**Solubility in organic**	not determined
Lower and upper explosion limit	not applicable	**Partition coefficient n-octanol/water (log value)**	not applicable
Flash Point	not applicable	**Vapour pressure**	not applicable
Autoignition Temp.	not applicable	**Density and/or relative density**	1.00 @20°C

9.2 Other information:

No further relevant information available.

10. Stability and reactivity:

10.1 Reactivity: Sodium azide: Contact with acids liberates very toxic gas.

10.2 Chemical Stability: This product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions: Sodium azide: forms explosive compounds with heavy metals. Repeated contact of low concentrations of azide with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Do not allow the undiluted product to enter sewers/surface or ground water.

10.4 Conditions to avoid: Avoid contact with incompatible materials. Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials: Strong oxidizing agents, Strong acids, Metals and metallic compounds.

10.6 Hazardous decomposition products: No decomposition products posing significant hazards would be expected from these product (aqueous solutions).

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11. Toxicological information:

11.1 Information on hazard classes

Toxicity data for hazardous ingredients - Sodium azide (CAS # 26628-22-8):

Acute toxicity:
LD50 Oral - Rat - 27 mg/kg Remarks: (RTECS)
LC50 Inhalation - Rat - male and female - 4 h - 0,054 - 0,52 mg/l - dust/mist
(US-EPA) LD50 Dermal - Rabbit - 20 mg/kg Remarks: (RTECS)

Skin corrosion/irritation:
Skin - In vitro study Result: No skin irritation (OECD Test Guideline 439)

Serious eye damage/eye irritation:
Eyes - Bovine cornea Result: No eye irritation - 4 h (OECD Test Guideline 437)

Respiratory or skin sensitization:
Local lymph node assay (LLNA) – Mouse Result: negative (OECD Test Guideline 429)

Germ cell mutagenicity
Test Type: Mutagenicity (mammal cell test): chromosome aberration. Test system: Chinese hamster ovary cells
Metabolic activation: with and without metabolic activationMethod: OECD Test Guideline 473 Result: negative
Test Type: unscheduled DNA synthesis assay. Test system: Chinese hamster lung cells
Metabolic activation: without metabolic activation Method: OECD Test Guideline 482
Result: negative
Test Type: sister chromatid exchange assay Test system: Chinese hamster ovary cells
Metabolic activation: without metabolic activation Method: OECD Test Guideline 479
Result: negative

Carcinogenicity: No data available

Reproductive toxicity: No data available

Specific target organ toxicity - single exposure: No data available

Specific target organ toxicity - repeated exposure:
Oral - May cause damage to organs through prolonged or repeated exposure – Brain

Aspiration hazard: No data available

Primary routes of exposure Common routes of entry include inhalation, ingestion and eye/skin contact. Specific paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.

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Toxicity data for hazardous ingredients – Kathon CG (CAS # 55965-84-9):

Acute toxicity:
LD50 Oral - Rat - male and female - 66 mg/kg (OECD Test Guideline 401)
LC50 Inhalation - Rat - male and female - 4 h - 0,171 mg/l – aerosol (OECD Test G. 403)
LD50 Dermal - Rabbit - male - 87,12 mg/kg

Skin corrosion/irritation:
Skin – Rabbit Result: Corrosive, category 1C - where responses occur after exposures between 1 hour and 4 hours and observations up to 14 days. (OECD Test Guideline 404)

Serious eye damage/eye irritation:
Remarks: Mixture causes serious eye damage. Risk of blindness!
Eyes – Rabbit Result: Causes serious eye damage. Remarks: (ECHA)

Respiratory or skin sensitization:
May cause an allergic skin reaction. Maximization Test - Guinea pig Result: positive (OECD Test Guideline 406)

Germ cell mutagenicity:
Test Type: Ames test. Test system: Salmonella typhimurium. Result: positive
Test Type: In vitro mammalian cell gene mutation test. Test system: mouse lymphoma cells Result: positive.
Test Type: Ames test Test system: Salmonella typhimurium. Result: Positive results were obtained in some in vitro tests.
Test Type: UDS (Unscheduled DNA synthesis assay). Test system: rat hepatocytes Result: negative.
Test Type: Mutagenicity (mammal cell test): chromosome aberration. Test system: Human lymphocytes Result: positive. Method: OECD Test Guideline 475 Species: Mouse - male and female - Bone marrow Result: negative. Method: OECD Test Guideline 486 Species: Rat - male - Liver cells.
Result: negative.
Method: US-EPA Species: Mouse - male and female - Bone marrow
Result: negative.
Method: US-EPA Species: Rat - male - Liver cells
Result: negative.
Method: OECD Test Guideline 474 Species: Mouse - male and female - Red blood cells (erythrocytes)
Result: negative.

Carcinogenicity:
No data available.

Reproductive toxicity:
No data available.

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Specific target organ toxicity - single exposure:
No data available.

Specific target organ toxicity - repeated exposure:
No data available.

Aspiration hazard:
No data available.

11.2 Information on other hazards
Endocrine disrupting properties:
This product does not have substance(s) of endocrine disrupting properties for health according to REACH Article 57(f).

Other information:
This product contains materials of human origin and should be considered as potentially capable of transmitting infectious diseases.

12. Ecological information:

Ecotoxical effects:
Sodium Azide (CAS # 26628-22-8) is toxic for aquatic organisms.

12.1 Toxicity
Sodium Azide (CAS # 26628-22-8):
Toxicity to fish: flow-through test LC50 - Oncorhynchus mykiss (rainbow trout) - 2,75 mg/l - 96 h (OECD Test Guideline 203)
Toxicity to algae: static test ErC50 - Pseudokirchneriella subcapitata - 0,35 mg/l - 96 h (OECD Test Guideline 201)
Kathon CG (CAS # 55965-84-9):
Toxicity to fish flow-through test LC50 - Oncorhynchus mykiss (rainbow trout) - 0,19 mg/l - 96 h (US-EPA)
Toxicity to daphnia and other aquatic invertebrates flow-through test LC50 - Daphnia magna (Water flea) - 0,18 mg/l - 48 h (US-EPA)
Toxicity to bacteria static test EC50 - activated sludge - 4,5 mg/l - 3 h (OECD Test G. 209)
Toxicity to fish(Chronic toxicity) semi-static test NOEC - Oncorhynchus mykiss (rainbow trout) - 0,098 mg/l - 35 d (OECD Test Guideline 215)
Toxicity to daphnia and other aquatic flow-through test NOEC - Daphnia magna (Water flea) - 0,1 mg/l - 21 d invertebrates(Chronic toxicity). (US-EPA)

12.2 Persistence and degradability
Sodium Azide (CAS # 26628-22-8):
The methods for determining the biological degradability are not applicable to inorganic substances.
Kathon CG (CAS # 55965-84-9): No data available

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12.3 Bioaccumulative potential
No data available

12.4 Mobility in soil
No data available

12.5 Results of PBT and vPvB assessment
Not determined for this product. PBT: Not applicable, vPvB: Not applicable.

12.6 Endocrine disrupting properties:
This product does not have substance(s) of endocrine disrupting properties for environment according to REACH Article 57(f).

12.7 Other adverse effects: This product contains environmentally hazardous substance below the cutoff level. Refer section 3 for ingredient information. Do not allow undiluted product to enter sewer/surface or ground water.

13.Disposal considerations:

13.1 Waste treatment methods
Product Waste Disposal: Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.
Sodium azide preservative may form explosive compounds in metal drain lines.
See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).
To avoid the possible build-up of azide compounds, flush wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.
Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or and approved waste-disposal company for information.
Package disposal: Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional Information
Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

14.Transport information:

Transportation of this product is not regulated under ICAO, IATA DGR, IMDG, US DOT, European ADR and RID or Canadian TDG.

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14.1 UN/ID number: Not regulated for transportation
14.2 UN proper shipping name: Not regulated for transportation
14.3 Transport hazard class(es): Not regulated for transportation
14.4 Packing group: Not regulated for transportation
14.5 Environmental hazards: Not regulated for transportation
14.6 Special precautions for user: None
14.7 Maritime transport in bulk according to IMO instruments: Not applicable

15. Regulatory information:

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

EU regulations: This SDS complies with EC Regulations 1907/2006 (REACH and amendments).

Labelling according to EU guidelines: The product has been classified and marked in accordance with EU Directives / Ordinance on Hazardous Materials. Harmonised classification - Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation)

Hazard-determining components of labelling: * **NaN_3, Kathon CG**
** But as mentioned in the REGULATION (EC) No 1272/2008 under point 1.5(a) there is no hazard labelling necessary as the total volume of the components of the KIT is under 125 ml.*

National legislation:
Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.
Other regulations: Take note of Dir 94/33/EC on the protection of young people at work.

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

16. Other information:

Izotop safety rating:

Flammability: 0		Code
Health: 1		0=None
Reactivity with water: 0		1=Slight
		2=Caution
Physical contact: 1		3=Severe

Revision changes: Revised to include EC 2020/878 amendment to REACH EC 1907/2006
Document version and issue/revision date: Revision Date (year/month/day) 2023/10/17

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Description of hazard class and hazard statements from Section 3:

Aquatic Acute 1 - Aquatic Hazard Acute, Category 1
Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2
Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1

H300	Fatal if swallowed.
H301	Toxic if swallowed.
H311	Toxic in contact with skin.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H331	Toxic if inhaled.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.

Abbreviations and Acronyms:

ACGIH - American Conference of Governmental Industrial Hygienists
ADR - European Agreement Concerning The International Carriage Of Dangerous Goods By Road
CLP - Classification, Labeling and Packaging
GHS - Globally Harmonized System
IATA - International Air Transport Association
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
TDG - Canadian Transportation Of Dangerous Goods Regulations.
US DOT - United States Department of Transportation
vPvB - Very persistent and very bioaccumulative substances
LC50 - Lethal Concentration, 50%
LD50 - Lethal Dose, 50%