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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: T3 [I-125] RIA KIT, coated tube
Product code: RK-609CT
Kit components: Tracer
Calibrators 0-5
Control sera CI, CII

This kit contains coated tubes that are considered articles and thereby those coated tubes are exempt from SDS requirements.

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 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 hazard class(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-609CT
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
Fax number: (36-1) 392-2575, 395-9247

Further information available from:

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from Hungary)
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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.

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.

Boric Acid: May damage fertility. May damage the unborn child. Wear protective gloves, protective clothing and eye/face protection. IF exposed or concerned: Get medical advice/attention. Included in the Candidate List of Substances of Very High Concern (SVHC) according to Regulation (EC) No. 1907/2006 (REACH)

di-Sodium tetraborate decahydrate: May damage fertility. May damage the unborn child. Wear protective gloves, protective clothing and eye/face protection. IF exposed or concerned: Get medical advice/attention.

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):

International chemical identification	CAS #	EC no			
Sodium azide	26628-22-8	247-852-1			
(< 0.1 % by wt)	Classification		Labelling		
	<i>Hazard class and Category Code(s)</i>	<i>Hazard statement Code(s)</i>	<i>Supplementary hazard statement Code(s)</i>	<i>Pictogram(s), signal word Code(s)</i>	
	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.



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			
	<i>Hazard class and Category Code(s)</i>	<i>Hazard statement Code(s)</i>	<i>Supplementary hazard statement Code(s)</i>	<i>Pictogram(s), signal word Code(s)</i>		
	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.



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

International chemical identification	CAS #	EC no	
Boric Acid	10043-35-3	-	
(< 0.5 % by wt)	Classification		Labelling
	<i>Hazard class and Category Code(s)</i>	<i>Hazard statement Code(s)</i>	<i>Supplementary hazard statement Code(s)</i>
	Reproductive toxicity 1B	H360FD	-
	Signal words		Pictogram(s)
	Danger		 Danger

Hazard Statements:

- H360FD May damage fertility. May damage the unborn child.

Precautionary statements:

- P201 Obtain special instructions before use.
 P202 Do not handle until all safety precautions have been read and understood.
 P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.
 P308 + P313 IF exposed or concerned: Get medical advice/ attention.
 P405 Store locked up.
 P501 Dispose of contents/ container to an approved waste disposal plant.
 Supplemental Hazard Statements: none



International chemical identification	CAS #	EC no			
di-Sodium tetraborate decahydrate	1303-96-4	215-540-4			
(< 1 % by wt)	Classification		Labelling		
	<i>Hazard class and Category Code(s)</i>	<i>Hazard statement Code(s)</i>	<i>Supplementary hazard statement Code(s)</i>	<i>Pictogram(s), signal word Code(s)</i>	
	Eye irritation 2	H319	-	GHS07	
	Reproductive toxicity 1B	H360FD		GHS08	
	Signal words		Pictogram(s)		
	Danger		 Irritant	 Danger	

Hazard Statements:

H319 Causes serious eye irritation
H360FD May damage fertility. May damage the unborn child.

Precautionary statements:

P202 Do not handle until all safety precautions have been read and understood.
P264 Wash skin thoroughly after handling.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.
P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P308 + P313 IF exposed or concerned: Get medical advice/ attention.
P337 + P313 If eye irritation persists: Get medical advice/ attention.
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). 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.

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: 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



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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.

8. Exposure controls/personal protection:

8.1 Control parameters:

Sodium Azide:

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

Kathon CG:

No additional information available

Boric Acid:

Predicted No Effect Concentration (PNEC)

Fresh water 2,02 mg/l

Sea water 2,02 mg/l

Aquatic intermittent release 13,7 mg/l

Sewage treatment plant 10 mg/l

Soil 5,4 mg/kg

di-Sodium tetraborate decahydrate:

Predicted No Effect Concentration (PNEC)

Fresh water 2,9 mg/l Remarks Expressed as, Boron

Sea water 2,9 mg/l Expressed as, Boron

Aquatic intermittent release 13,7 mg/l

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.

9. Physical and chemical properties:

9.1 Information on basic physical and chemical properties

Physical state	liquid	Transparency	clear
Colour	blue	Decomposition Temperature	not applicable
Odour	odourless	pH	8.5 – 9.0
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:

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).

11. Toxicological information:

11.1 Information on hazard classes

Toxicity data for hazardous ingredients:

Acute toxicity:

Sodium azide:

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)

Boric Acid:

LD50 Oral - Rat - male and female - 3.450 mg/kg Remarks: (ECHA)

LC50 Inhalation - Rat - male and female - 4 h - > 2,12 mg/l - dust/mist (OECD Test G. 403)

LD50 Dermal - Rabbit - male and female - > 2.000 mg/kg Remarks: (ECHA)

di-Sodium tetraborate decahydrate:

LD50 Oral - Rat - male - > 2.500 mg/kg (OECD Test Guideline 401)

LC50 Inhalation - Rat - male and female - 4 h - > 2,12 mg/l - dust/mist (OECD Test G. 403)

Remarks: The value is given in analogy to the following substances: boric acid

LD50 Dermal - Rabbit - male and female - > 2.000 mg/kg Remarks: (ECHA)

The value is given in analogy to the following substances: disodium tetraborate pentahydrate.



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Skin corrosion/irritation:

Sodium azide:

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

Boric Acid:

Skin – Rabbit Result: No skin irritation - 24 h Remarks: (ECHA)

di-Sodium tetraborate decahydrate:

Skin – Rabbit Result: No skin irritation - 24 h Remarks: (ECHA)

The value is given in analogy to the following substances: disodium tetraborate pentahydrate

Serious eye damage/eye irritation:

Sodium azide:

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

Boric Acid:

Skin – Rabbit Result: No skin irritation - 24 h Remarks: (ECHA)

di-Sodium tetraborate decahydrate:

Eyes – Rabbit Result: Causes serious eye irritation. - 14 Days (OECD Test Guideline 405)

Respiratory or skin sensitization:

Sodium azide:

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

Boric Acid:

Buehler Test - Guinea pig Result: negative (OECD Test Guideline 406)

di-Sodium tetraborate decahydrate:

Buehler Test - Guinea pig Result: negative (OECD Test Guideline 406)

Germ cell mutagenicity

Sodium azide:

Test Type: Mutagenicity (mammal cell test): chromosome aberration. Test system: Chinese hamster ovary cells

Metabolic activation: with and without metabolic activation Method: 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



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Boric Acid:

Test Type: sister chromatid exchange assay Test system: Chinese hamster ovary cells

Metabolic activation: with and without metabolic activation Result: negative

Remarks: (ECHA)

Test Type: Ames test Test system: S. typhimurium Metabolic activation: with and without metabolic activation Method: OECD Test Guideline 471 Result: negative

Test Type: In vitro mammalian cell gene mutation test Test system: mouse lymphoma cells
Metabolic activation: with and without metabolic activation Method: OECD Test Guideline 476 Result: negative

Test Type: Mutagenicity (mammal cell test): Test system: Chinese hamster ovary cells
Metabolic activation: with and without metabolic activation Method: OECD Test G. 482
Result: negative

Test Type: Micronucleus test Species: Mouse Application Route: Oral Method: OECD Test Guideline 474 Result: negative

di-Sodium tetraborate decahydrate:

Test Type: sister chromatid exchange assay. Test system: Chinese hamster ovary cells.
Metabolic activation: with and without metabolic activation. Result: negative.

Test Type: Ames test Test system: S. typhimurium Metabolic activation: with and without metabolic activation Method: OECD Test Guideline 471. Result: negative

Test Type: In vitro mammalian cell gene mutation test. Test system: mouse lymphoma cells.
Metabolic activation: with and without metabolic activation Method: OECD Test G. 476
Result: negative.

Test Type: Micronucleus test Species: Mouse Application Route: Oral Method: OECD Test Guideline 474. Result: negative.

Carcinogenicity: No data available

Reproductive toxicity:

Boric Acid:

May damage fertility. May damage the unborn child.

di-Sodium tetraborate decahydrate:

May damage fertility. May damage the unborn child.

Specific target organ toxicity - single exposure: No data available

Specific target organ toxicity - repeated exposure:

Sodium azide:

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

Aspiration hazard: No data available



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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:

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: No data available

12. Ecological information:

Ecotoxicological effects: Sodium Azide is toxic for aquatic organisms.

12.1 Toxicity

Sodium azide:

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:

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:

No data available

12.7 Other adverse effects:

di-Sodium tetraborate decahydrate: Herbicid. Discharge into the environment must be avoided.



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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 an 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 hazard class(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.				

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: * Sodium azide, Boric acid, di-Sodium tetraborate decahydrate

* 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.



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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	1=Slight
	water: 0	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:

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
H318	Serious eye damage (Category 1)
H319	Causes serious eye irritation
H331	Toxic if inhaled
H360FD	May damage fertility. May damage the unborn child.
H400	Very toxic to aquatic life
H410	Very toxic to aquatic life with long lasting effects
H411	Toxic to aquatic life with long lasting effects
EUH032	Contact with acids liberates very toxic gas



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Abbreviations and Acronyms:

ACGIH - American Conference of Governmental Industrial Hygienists
ADR - European Agreement Concerning The International Carriage Of Dangerous Goods By Road
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Classification, Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
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
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
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]

Calibrators

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

1.1 Product identifier:

Product name: Calibrators (0-5)
Product code: Components of RK-609CT
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:

Email address of the competent person:

www.izotop.hu
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):

International chemical identification	CAS #	EC no			
Sodium azide	26628-22-8	247-852-1			
(< 0.1 % by wt)	Classification		Labelling		
	<i>Hazard class and Category Code(s)</i>	<i>Hazard statement Code(s)</i>	<i>Supplementary hazard statement Code(s)</i>	<i>Pictogram(s), signal word Code(s)</i>	
	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.

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.



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.

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 activation Method: 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:**Ecotoxicological 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 an 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.



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14. Transport information:

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

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: * **NaN₃, 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.



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16. Other information:

Izotop safety rating: Flammability: 0	Code
Health: 1	0=None
Reactivity with	1=Slight
water: 0	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.

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-609CT
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:



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Konkoly-Thege Miklós út 29-33
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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].

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.

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):

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

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.



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.

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 activation Method: 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:**Ecotoxicological 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 an 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.



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14. Transport information:

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

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: * **NaN₃, 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.



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16. Other information:

Izotop safety rating: Flammability: 0	Code
Health: 1	0=None
Reactivity with water: 0	1=Slight
Physical contact: 1	2=Caution
	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.

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%