

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

1.1. Product identifier

Product Description: **Streptex Kit (200 tests) ®**
Cat No. : **R30164701**

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

Recommended Use Laboratory chemicals.
Uses advised against No Information available

1.3. Details of the supplier of the safety data sheet

Company Remel Europe Ltd.,
 Clipper Boulevard West, Crossways, Dartford
 Kent. DA2 6PT
 UK
 Tel: (+44) 1322 295600
 Fax: (+44) 1322 225413
 mbd-sds@thermofisher.com

EU entity/business name
 Thermo Fisher Diagnostics B.V., Scheepbouwersweg 1 B,
 1121 PC Landsmeer, The Netherlands

E-mail address mbd-sds@thermofisher.com

1.4. Emergency telephone number

Chemtrec US: (800) 424-9300
 Chemtrec EU: 001-703-527-3887
 Chemtrec China: 400 120 4937

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

CLP Classification - Regulation (EC) No 1272/2008

Physical hazards

Based on available data, the classification criteria are not met

Health hazards

Based on available data, the classification criteria are not met

Environmental hazards

Based on available data, the classification criteria are not met

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Full text of Hazard Statements: see section 16

2.2. Label elements

None required

Signal Word

None

2.3. Other hazards

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.2. Mixtures

Component	CAS No	EC No	Weight %	CLP Classification - Regulation (EC) No 1272/2008
Positive Control (Contains 0.1% Sodium Azide)	26628-22-8	EEC No. 247-852-1	0.1	Acute Tox. 2 (H300) (EUH032) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)
Latex Reagent (Contains 0.1% Sodium Azide)	26628-22-8	EEC No. 247-852-1	0.1	Acute Tox. 2 (H300) (EUH032) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)

Component	Specific concentration limits (SCL's)	M-Factor	Component notes
Positive Control (Contains 0.1% Sodium Azide)	-	1	-
Latex Reagent (Contains 0.1% Sodium Azide)	-	1	-

Full text of Hazard Statements: see section 16

SECTION 4: FIRST AID MEASURES

4.1. Description of first aid measures

Eye Contact

Rinse thoroughly with plenty of water, also under the eyelids. Get medical attention if symptoms occur.

Skin Contact

Wash off immediately with soap and plenty of water. Get medical attention if symptoms occur.

Ingestion

Clean mouth with water and drink afterwards plenty of water. Get medical attention.

Inhalation

Remove to fresh air. Get medical attention if symptoms occur.

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Self-Protection of the First Aider No special precautions required.

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

None reasonably foreseeable. . Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhea

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

Notes to Physician Treat symptomatically.

SECTION 5: FIREFIGHTING MEASURES

5.1. Extinguishing media

Suitable Extinguishing Media

Water spray, carbon dioxide (CO₂), dry chemical, alcohol-resistant foam.

Extinguishing media which must not be used for safety reasons

Use extinguishing method compatible with surroundings.

5.2. Special hazards arising from the substance or mixture

Thermal decomposition can lead to release of irritating gases and vapors.

Hazardous Combustion Products

None under normal use conditions.

5.3. Advice for firefighters

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Avoid contact with skin, eyes or clothing. Use personal protective equipment as required. Ensure adequate ventilation.

6.2. Environmental precautions

Should not be released into the environment.

6.3. Methods and material for containment and cleaning up

Soak up with inert absorbent material. Clean contaminated surface thoroughly.

6.4. Reference to other sections

Refer to protective measures listed in Sections 8 and 13.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

Ensure adequate ventilation. Avoid contact with skin, eyes or clothing. Wear personal protective equipment/face protection.

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Hygiene Measures

Handle in accordance with good industrial hygiene and safety practice. Keep away from food, drink and animal feeding stuffs. Do not eat, drink or smoke when using this product. Remove and wash contaminated clothing and gloves, including the inside, before re-use. Wash hands before breaks and after work.

7.2. Conditions for safe storage, including any incompatibilities

Keep container tightly closed. Keep at temperatures between 2° and 8 °C.

Technical Rules for Hazardous Substances (TRGS) 510 Class 12
Storage Class (LGK) (Germany)

7.3. Specific end use(s)

Use in laboratories

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

Exposure limits

List source(s): **EU** - Commission Directive (EU) 2019/1831 of 24 October 2019 establishing a fifth list of indicative occupational exposure limit values pursuant to Council Directive 98/24/EC and amending Commission Directive 2000/39/EC **UK** - EH40/2005 Work Exposure Limits, Third edition. Published 2018. **IRE** - 2018 Code of Practice for the Chemical Agents Regulations, Schedule 1. Published by the Health and Safety Authority

Component	The United Kingdom	European Union	Ireland
Positive Control (Contains 0.1% Sodium Azide)	STEL: 0.3 mg/m ³ 15 min TWA: 0.1 mg/m ³ 8 hr Skin	TWA: 0.1 mg/m ³ (8h) STEL: 0.3 mg/m ³ (15min) Skin	TWA: 0.1 mg/m ³ 8 hr. STEL: 0.3 mg/m ³ 15 min Skin
Latex Reagent (Contains 0.1% Sodium Azide)	STEL: 0.3 mg/m ³ TWA: 0.1 mg/m ³ Skin	TWA: 0.1 mg/m ³ (8h) STEL: 0.3 mg/m ³ (15min) Skin	TWA: 0.1 mg/m ³ 8 hr. STEL: 0.3 mg/m ³ 15 min Skin

Biological limit values

This product, as supplied, does not contain any hazardous materials with biological limits established by the region specific regulatory bodies

Derived No Effect Level (DNEL) / Derived Minimum Effect Level (DMEL)

See table for values

Component	Acute effects local (Dermal)	Acute effects systemic (Dermal)	Chronic effects local (Dermal)	Chronic effects systemic (Dermal)
Positive Control (Contains 0.1% Sodium Azide) 26628-22-8 (0.1)				DNEL = 46.7µg/kg bw/day
Latex Reagent (Contains 0.1% Sodium Azide) 26628-22-8 (0.1)				DNEL = 46.7µg/kg bw/day

Component	Acute effects local (Inhalation)	Acute effects systemic (Inhalation)	Chronic effects local (Inhalation)	Chronic effects systemic (Inhalation)
Positive Control (Contains 0.1% Sodium Azide) 26628-22-8 (0.1)				DNEL = 0.164mg/m ³
Latex Reagent (Contains 0.1% Sodium Azide)				DNEL = 0.164mg/m ³

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26628-22-8 (0.1)				
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Predicted No Effect Concentration (PNEC)

See values below.

Component	Fresh water	Fresh water sediment	Water Intermittent	Microorganisms in sewage treatment	Soil (Agriculture)
Positive Control (Contains 0.1% Sodium Azide) 26628-22-8 (0.1)	PNEC = 0.35µg/L	PNEC = 16.7µg/kg sediment dw	PNEC = 3.5µg/L	PNEC = 30µg/L	
Latex Reagent (Contains 0.1% Sodium Azide) 26628-22-8 (0.1)	PNEC = 0.35µg/L	PNEC = 16.7µg/kg sediment dw	PNEC = 3.5µg/L	PNEC = 30µg/L	

Component	Marine water	Marine water sediment	Marine water intermittent	Food chain	Air
Positive Control (Contains 0.1% Sodium Azide) 26628-22-8 (0.1)	PNEC = 15ng/L	PNEC = 0.72µg/kg sediment dw	PNEC = 150ng/L		
Latex Reagent (Contains 0.1% Sodium Azide) 26628-22-8 (0.1)	PNEC = 15ng/L	PNEC = 0.72µg/kg sediment dw	PNEC = 150ng/L		

8.2. Exposure controls

Engineering Measures

None under normal use conditions.

Personal protective equipment

Eye Protection

Wear safety glasses with side shields (or goggles) (European standard - EN 166)

Hand Protection

Protective gloves

Glove material	Breakthrough time	Glove thickness	EU standard	Glove comments
Disposable gloves	See manufacturers recommendations	-	EN 374	(minimum requirement)

Skin and body protection

Long sleeved clothing.

Inspect gloves before use.

Please observe the instructions regarding permeability and breakthrough time which are provided by the supplier of the gloves.

(Refer to manufacturer/supplier for information)

Ensure gloves are suitable for the task: Chemical compatability, Dexterity, Operational conditions, User susceptibility, e.g. sensitisation effects, also take into consideration the specific local conditions under which the product is used, such as the danger of cuts, abrasion.

Remove gloves with care avoiding skin contamination.

Respiratory Protection

No protective equipment is needed under normal use conditions.

Large scale/emergency use

Use a NIOSH/MSHA or European Standard EN 136 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced

Recommended Filter type: Particle filter

Small scale/Laboratory use

Maintain adequate ventilation

Environmental exposure controls

No information available.

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SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Physical State	Liquid or Pellets Solid	
Appearance	TEST LATEX - White POSITIVE CONTROL - Colourless EXTRACTION LATEX - Brown	
Odor	No information available	
Odor Threshold	No data available	
Melting Point/Range	No data available	
Softening Point	No data available	
Boiling Point/Range	Not applicable	
Flammability (liquid)	Not applicable	Solid
Flammability (solid,gas)	Not applicable	Liquid
Explosion Limits	No data available	
Flash Point	Not applicable	Method - No information available
Autoignition Temperature	No data available	
Decomposition Temperature	No data available	
pH	7.3 - 7.5	
Viscosity	Not applicable	Solid
Water Solubility	No information available	
Solubility in other solvents	No information available	
Partition Coefficient (n-octanol/water)		
Vapor Pressure	No data available	
Density / Specific Gravity	No data available	
Bulk Density	Not applicable	Liquid
Vapor Density	Not applicable	Solid
Particle characteristics	Not applicable (liquid)	

9.2. Other information

Evaporation Rate Not applicable - Solid

SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity

None known, based on information available

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

Hazardous Polymerization Hazardous polymerization does not occur.
Hazardous Reactions None under normal processing.

10.4. Conditions to avoid

Incompatible products. Excess heat.

10.5. Incompatible materials

None known.

10.6. Hazardous decomposition products

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None under normal use conditions.

SECTION 11: TOXICOLOGICAL INFORMATION

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

Product Information Product does not present an acute toxicity hazard based on known or supplied information

(a) acute toxicity;

Oral

Based on available data, the classification criteria are not met

Dermal

Based on available data, the classification criteria are not met

Inhalation

Based on available data, the classification criteria are not met

Toxicology data for the components

Component	LD50 Oral	LD50 Dermal	LC50 Inhalation
Positive Control (Contains 0.1% Sodium Azide)	LD50 = 27 mg/kg (Rat)	LD50 = 20 mg/kg (Rabbit)	LC50 0.054 - 0.52 mg/L (Rat) 4 h
Latex Reagent (Contains 0.1% Sodium Azide)	LD50 = 27 mg/kg (Rat)	LD50 = 20 mg/kg (Rabbit)	LC50 0.054 - 0.52 mg/L (Rat) 4 h

(b) skin corrosion/irritation; No data available

(c) serious eye damage/irritation; No data available

(d) respiratory or skin sensitization;

Respiratory

No data available

Skin

No data available

(e) germ cell mutagenicity; No data available

(f) carcinogenicity; No data available

There are no known carcinogenic chemicals in this product

(g) reproductive toxicity; No data available

(h) STOT-single exposure; No data available

(i) STOT-repeated exposure; No data available

Target Organs

No information available.

(j) aspiration hazard; Not applicable
Solid

Symptoms / effects, both acute and delayed Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhea.

11.2. Information on other hazards

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Endocrine Disrupting Properties Assess endocrine disrupting properties for human health. This product does not contain any known or suspected endocrine disruptors.

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Ecotoxicity effects

Component	Freshwater Fish	Water Flea	Freshwater Algae
Positive Control (Contains 0.1% Sodium Azide)	LC50: = 0.7 mg/L, 96h (Lepomis macrochirus) LC50: = 0.8 mg/L, 96h (Oncorhynchus mykiss) LC50: = 5.46 mg/L, 96h flow-through (Pimephales promelas)		
Latex Reagent (Contains 0.1% Sodium Azide)	LC50: = 0.7 mg/L, 96h (Lepomis macrochirus) LC50: = 0.8 mg/L, 96h (Oncorhynchus mykiss) LC50: = 5.46 mg/L, 96h flow-through (Pimephales promelas)		

Component	Microtox	M-Factor
Positive Control (Contains 0.1% Sodium Azide)		1
Latex Reagent (Contains 0.1% Sodium Azide)		1

12.2. Persistence and degradability No information available

12.3. Bioaccumulative potential No information available

12.4. Mobility in soil No information available

12.5. Results of PBT and vPvB assessment No data available for assessment.

12.6. Endocrine disrupting properties

Endocrine Disruptor Information This product does not contain any known or suspected endocrine disruptors

12.7. Other adverse effects

Persistent Organic Pollutant
Ozone Depletion Potential

This product does not contain any known or suspected substance
This product does not contain any known or suspected substance

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

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Waste from Residues/Unused Products	Disposal should be in accordance with applicable regional, national and local laws and regulations.
Contaminated Packaging	Dispose of in accordance with local regulations.
European Waste Catalogue (EWC)	According to the European Waste Catalog, Waste Codes are not product specific, but application specific.
Other Information	Waste codes should be assigned by the user based on the application for which the product was used.

SECTION 14: TRANSPORT INFORMATION

IMDG/IMO Not regulated

14.1. UN number
14.2. UN proper shipping name
14.3. Transport hazard class(es)
14.4. Packing group

ADR Not regulated

14.1. UN number
14.2. UN proper shipping name
14.3. Transport hazard class(es)
14.4. Packing group

IATA Not regulated

14.1. UN number
14.2. UN proper shipping name
14.3. Transport hazard class(es)
14.4. Packing group

14.5. Environmental hazards No hazards identified

14.6. Special precautions for user No special precautions required

14.7. Maritime transport in bulk according to IMO instruments Not applicable, packaged goods

SECTION 15: REGULATORY INFORMATION

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

International Inventories

Europe (EINECS/ELINCS/NLP), China (IECSC), Taiwan (TCSI), Korea (KECL), Japan (ENCS), Japan (ISHL), Canada (DSL/NDL), Australia (AICS), New Zealand (NZIoC), Philippines (PICCS). US EPA (TSCA) - Toxic Substances Control Act, (40 CFR Part 710)

Component	CAS No	EINECS	ELINCS	NLP	IECSC	TCSI	KECL	ENCS	ISHL
Positive Control (Contains 0.1% Sodium Azide)	26628-22-8	247-852-1	-	-	X	X	KE-31357	X	X
Latex Reagent (Contains 0.1% Sodium Azide)	26628-22-8	247-852-1	-	-	X	X	KE-31357	X	X

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Component	CAS No	TSCA	TSCA Inventory notification - Active-Inactive	DSL	NDSL	AICS	NZIoC	PICCS
Positive Control (Contains 0.1% Sodium Azide)	26628-22-8	X	ACTIVE	X	-	X	X	X
Latex Reagent (Contains 0.1% Sodium Azide)	26628-22-8	X	ACTIVE	X	-	X	X	X

Legend: X - Listed '-' - Not Listed

KECL - NIER number or KE number (<http://ncis.nier.go.kr/en/main.do>)

Authorisation/Restrictions according to EU REACH

Component	CAS No	Seveso III Directive (2012/18/EC) - Qualifying Quantities for Major Accident Notification	Seveso III Directive (2012/18/EC) - Qualifying Quantities for Safety Report Requirements
Positive Control (Contains 0.1% Sodium Azide)	26628-22-8	Not applicable	Not applicable
Latex Reagent (Contains 0.1% Sodium Azide)	26628-22-8	Not applicable	Not applicable

Regulation (EC) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of dangerous chemicals

Not applicable

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work .

Take note of Directive 2000/39/EC establishing a first list of indicative occupational exposure limit values

National Regulations

UK - Take note of Control of Substances Hazardous to Health Regulations (COSHH) 2002 and 2005 Amendment

WGK Classification

Water endangering class = non-hazardous to waters (self classification)

Component	Germany - Water Classification (VwVwS)	Germany - TA-Luft Class
Positive Control (Contains 0.1% Sodium Azide)	WGK2	
Latex Reagent (Contains 0.1% Sodium Azide)	WGK2	

15.2. Chemical safety assessment

Chemical Safety Assessment/Reports (CSA/CSR) are not required for mixtures

SECTION 16: OTHER INFORMATION

Full text of H-Statements referred to under sections 2 and 3

H300 - Fatal if swallowed

H400 - Very toxic to aquatic life

H410 - Very toxic to aquatic life with long lasting effects

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EUH032 - Contact with acids liberates very toxic gas

Legend

CAS - Chemical Abstracts Service

EINECS/ELINCS - European Inventory of Existing Commercial Chemical Substances/EU List of Notified Chemical Substances

PICCS - Philippines Inventory of Chemicals and Chemical Substances

IECSC - Chinese Inventory of Existing Chemical Substances

KECL - Korean Existing and Evaluated Chemical Substances

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

ENCS - Japanese Existing and New Chemical Substances

AICS - Australian Inventory of Chemical Substances

NZIoC - New Zealand Inventory of Chemicals

WEL - Workplace Exposure Limit

ACGIH - American Conference of Governmental Industrial Hygienists

DNEL - Derived No Effect Level

RPE - Respiratory Protective Equipment

LC50 - Lethal Concentration 50%

NOEC - No Observed Effect Concentration

PBT - Persistent, Bioaccumulative, Toxic

TWA - Time Weighted Average

IARC - International Agency for Research on Cancer

Predicted No Effect Concentration (PNEC)

LD50 - Lethal Dose 50%

EC50 - Effective Concentration 50%

POW - Partition coefficient Octanol:Water

vPvB - very Persistent, very Bioaccumulative

ADR - European Agreement Concerning the International Carriage of Dangerous Goods by Road

IMO/IMDG - International Maritime Organization/International Maritime Dangerous Goods Code

OECD - Organisation for Economic Co-operation and Development

BCF - Bioconcentration factor

Key literature references and sources for data

<https://echa.europa.eu/information-on-chemicals>

Suppliers safety data sheet, Chemadvisor - LOLI, Merck index, RTECS

ICAO/IATA - International Civil Aviation Organization/International Air Transport Association

MARPOL - International Convention for the Prevention of Pollution from Ships

ATE - Acute Toxicity Estimate

VOC - (Volatile Organic Compound)

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:

Physical hazards On basis of test data

Health Hazards Calculation method

Environmental hazards Calculation method

Training Advice

Chemical hazard awareness training, incorporating labelling, Safety Data Sheets (SDS), Personal Protective Equipment (PPE) and hygiene.

Creation Date 11-Apr-2012

Revision Date 10-Dec-2021

Revision Summary Not applicable.

**This safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006.
COMMISSION REGULATION (EU) 2020/878 amending Annex II to Regulation (EC) No
1907/2006**

Disclaimer

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text

End of Safety Data Sheet