

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

1.1. Product identifier

Product Description: SureTect E.coli O157:H7 PCR Tubes
Cat No. : PT0410A

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

Recommended Use In vitro diagnostic.
Uses advised against No Information available

1.3. Details of the supplier of the safety data sheet

Company Thermo Fisher Scientific Oy
Ratastie 2
FI-01621 Vantaa
Puh: +358 (10) 329 200
Fax: +358 9 3291 0301
Email: microbiology.techsupport.uk@thermofisher.com

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

Full text of Hazard Statements: see section 16

SAFETY DATA SHEET

SureTest E.coli O157:H7 PCR Tubes

Revision Date 10-Dec-2021

2.2. Label elements

None required

Signal Word

None

2.3. Other hazards

No information available

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

Component	CAS No	EC No	Weight %	CLP Classification - Regulation (EC) No 1272/2008
Tris (hydroxymethyl) aminomethane	77-86-1	201-064-4	0.57	-

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 with plenty of soap and water.
Ingestion	Clean mouth with water and drink afterwards plenty of water. Get medical attention if symptoms occur.
Inhalation	Remove to fresh air. Get medical attention if symptoms occur.
Self-Protection of the First Aider	Ensure that medical personnel are aware of the material(s) involved, take precautions to protect themselves and prevent spread of contamination.

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

No information available.

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

SAFETY DATA SHEET

SureTest E.coli O157:H7 PCR Tubes

Revision Date 10-Dec-2021

Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Water spray, carbon dioxide (CO₂), dry chemical, alcohol-resistant foam.

Extinguishing media which must not be used for safety reasons

No information available.

5.2. Special hazards arising from the substance or mixture

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

Hazardous Combustion Products

May emit toxic fumes under fire conditions - carbon monoxide, carbon dioxide, nitrogen oxides, and hydrogen chloride.

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 dust formation. Avoid contact with skin, eyes or clothing. Ensure adequate ventilation.

6.2. Environmental precautions

Prevent further leakage or spillage if safe to do so.

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

Avoid contact with skin, eyes or clothing. Ensure adequate ventilation.

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 only in the original container. Keep containers tightly closed in a dry, cool and well-ventilated place.

Technical Rules for Hazardous Substances (TRGS) 510 Class 13
Storage Class (LGK) (Germany)

7.3. Specific end use(s)

Use in laboratories

SAFETY DATA SHEET

SureTest E.coli O157:H7 PCR Tubes

Revision Date 10-Dec-2021

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

Exposure limits

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

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)
Tris (hydroxymethyl) aminomethane 77-86-1 (0.57)				DNEL = 166.7mg/kg bw/day

Component	Acute effects local (Inhalation)	Acute effects systemic (Inhalation)	Chronic effects local (Inhalation)	Chronic effects systemic (Inhalation)
Tris (hydroxymethyl) aminomethane 77-86-1 (0.57)				DNEL = 117.5mg/m ³

Predicted No Effect Concentration (PNEC)

See values below.

Component	Fresh water	Fresh water sediment	Water Intermittent	Microorganisms in sewage treatment	Soil (Agriculture)
Tris (hydroxymethyl) aminomethane 77-86-1 (0.57)				PNEC = 300mg/L	

8.2. Exposure controls

Engineering Measures

Ensure adequate ventilation, especially in confined areas.

Wherever possible, engineering control measures such as the isolation or enclosure of the process, the introduction of process or equipment changes to minimise release or contact, and the use of properly designed ventilation systems, should be adopted to control hazardous materials at source

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.

SAFETY DATA SHEET

SureTect E.coli O157:H7 PCR Tubes

Revision Date 10-Dec-2021

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 compatibility, 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

When workers are facing concentrations above the exposure limit they must use appropriate certified respirators.

To protect the wearer, respiratory protective equipment must be the correct fit and be used and maintained properly

Large scale/emergency use

In case of insufficient ventilation, wear suitable respiratory equipment

Small scale/Laboratory use

Use a NIOSH/MSHA or European Standard EN 149:2001 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced.

When RPE is used a face piece Fit Test should be conducted

Environmental exposure controls

No information available.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Physical State

Lyophilized Pellets

Appearance

White

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)

No data available

Flammability (solid,gas)

No information available

Explosion Limits

No data available

Flash Point

Not applicable

Method - No information available

Autoignition Temperature

No data available

Decomposition Temperature

No data available

pH

Not applicable

Viscosity

No data available

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

No data available

Vapor Density

No data available

(Air = 1.0)

Particle characteristics

No data available

9.2. Other information

SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity

None known, based on information available

SAFETY DATA SHEET

SureTect E.coli O157:H7 PCR Tubes

Revision Date 10-Dec-2021

10.2. Chemical stability

Stable under recommended storage conditions.

10.3. Possibility of hazardous reactions

Hazardous Polymerization Hazardous Reactions

Hazardous polymerization does not occur.
None under normal processing.

10.4. Conditions to avoid

Incompatible products. Excess heat.

10.5. Incompatible materials

No materials to be especially mentioned.

10.6. Hazardous decomposition products

May emit toxic fumes under fire conditions - carbon monoxide, carbon dioxide, nitrogen oxides, and hydrogen chloride.

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

No data available

Dermal

No data available

Inhalation

No data available

Component	LD50 Oral	LD50 Dermal	LC50 Inhalation
Tris (hydroxymethyl) aminomethane	LD50 = 5900 mg/kg (Rat)	LD50 > 5000 mg/kg (Rat)	-

(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

None known

(e) germ cell mutagenicity;

No data available

None known

(f) carcinogenicity;

No data available

There are no known carcinogenic chemicals in this product

(g) reproductive toxicity;

Reproductive Effects

No data available

Developmental Effects

None known.

None known.

SAFETY DATA SHEET

SureTect E.coli O157:H7 PCR Tubes

Revision Date 10-Dec-2021

(h) STOT-single exposure;	No data available
(i) STOT-repeated exposure;	No data available
Target Organs	No information available.
(j) aspiration hazard;	No data available
Symptoms / effects, both acute and delayed	No information available.

11.2. Information on other hazards

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	Contains no substances known to be hazardous to the environment or that are not degradable in waste water treatment plants.
---	---

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

Waste from Residues/Unused Products	Chemical waste generators must determine whether a discarded chemical is classified as a hazardous waste. Consult local, regional, and national hazardous waste regulations to ensure complete and accurate classification.
--	---

SAFETY DATA SHEET

SureTect E.coli O157:H7 PCR Tubes

Revision Date 10-Dec-2021

Contaminated Packaging	Empty remaining contents. Dispose of in accordance with local regulations. Do not re-use empty containers.
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/NDSL), 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
Tris (hydroxymethyl) aminomethane	77-86-1	201-064-4	-	-	X	X	KE-01403	X	X

Component	CAS No	TSCA	TSCA Inventory notification - Active-Inactive	DSL	NDSL	AICS	NZIoC	PICCS

SAFETY DATA SHEET

SureTect E.coli O157:H7 PCR Tubes

Revision Date 10-Dec-2021

Tris (hydroxymethyl) aminomethane	77-86-1	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
Tris (hydroxymethyl) aminomethane	77-86-1	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 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work.

National Regulations

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

WGK Classification Water endangering class = 2 (self classification)

Component	Germany - Water Classification (VwVwS)	Germany - TA-Luft Class
Tris (hydroxymethyl) aminomethane	WGK1	

15.2. Chemical safety assessment

A Chemical Safety Assessment/Report (CSA/CSR) has not been conducted

SECTION 16: OTHER INFORMATION

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

H335 - May cause respiratory irritation

H315 - Causes skin irritation

H319 - Causes serious eye irritation

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/NDL - 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

SAFETY DATA SHEET

SureTest E.coli O157:H7 PCR Tubes

Revision Date 10-Dec-2021

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/MDG - 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)

Training Advice

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

Creation Date 25-Oct-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