

according to Regulation UK SI 2019/758 and UK SI 2020/1577 as amended

Creation Date 26-Sep-2009

Revision Date 18-Oct-2023

Revision Number 11

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

## 1.1. Product identifier

Product Description: Cat No. : Synonyms CAS No EC No Molecular Formula	Tris(hydroxymethyl) aminomethane hydrochloride T/P631/53, T/P631/60, T/P631/48 Tromethane; 2-Amino-2-(hydroxymethyl)-1,3-propanediol, hydrochloride; TRIS; Tromethamine 1185-53-1 214-684-5 C4 H11 N O3 . H Cl
1.2. Relevant identified uses of the	substance or mixture and uses advised against
Recommended Use Uses advised against	Laboratory chemicals. No Information available
1.3. Details of the supplier of the s	afety data sheet
Company	UK entity/business name Fisher Scientific UK Bishop Meadow Road, Loughborough, Leicestershire LE11 5RG, United Kingdom EU entity/business name Thermo Fisher Scientific Janssen Pharmaceuticalaan 3a 2440 Geel, Belgium
E-mail address	begel.sdsdesk@thermofisher.com
<u>1.4. Emergency telephone number</u>	Tel: 01509 231166 Chemtrec US: (800) 424-9300 Chemtrec EU: 001-703-527-3887

## **SECTION 2: HAZARDS IDENTIFICATION**

## 2.1. Classification of the substance or mixture

## CLP Classification - According to GB-CLP Regulations UK SI 2019/720 and UK SI 2020/1567

## Physical hazards

Based on available data, the classification criteria are not met

## Tris(hydroxymethyl) aminomethane hydrochloride

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

2.2. Label elements

None required

## 2.3. Other hazards

Substance is not considered persistent, bioaccumulative and toxic (PBT) / very persistent and very bioaccumulative (vPvB)

This product does not contain any known or suspected endocrine disruptors

## **SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS**

## 3.1. Substances

Component	CAS No	EC No	Weight %	CLP Classification - According to GB-CLP Regulations UK SI 2019/720 and UK SI 2020/1567
1,3-Propanediol,	1185-53-1	EEC No. 214-684-5	99	-
2-amino-2-(hydroxymethyl)-, hydrochloride				

Full text of Hazard Statements: see section 16

## **SECTION 4: FIRST AID MEASURES**

## 4.1. Description of first aid measures

General Advice	If symptoms persist, call a physician.
Eye Contact	Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Get medical attention.
Skin Contact	Wash off immediately with plenty of water for at least 15 minutes. If skin irritation persists, call a physician.
Ingestion	Clean mouth with water and drink afterwards plenty of water. Get medical attention if symptoms occur.
Inhalation	Remove to fresh air. If not breathing, give artificial respiration. 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.

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 (CO<sub>2</sub>). Dry chemical. Chemical 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. Keep product and empty container away from heat and sources of ignition.

#### Hazardous Combustion Products

Nitrogen oxides (NOx), Carbon monoxide (CO), Carbon dioxide (CO<sub>2</sub>), Hydrogen chloride gas.

#### 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

Use personal protective equipment as required. Ensure adequate ventilation. Avoid dust formation.

## 6.2. Environmental precautions

Should not be released into the environment.

## 6.3. Methods and material for containment and cleaning up

Sweep up and shovel into suitable containers for disposal. Keep in suitable, closed containers for disposal.

## 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 ingestion and inhalation. Ensure adequate ventilation. Wear personal protective equipment/face protection. Avoid dust

## Tris(hydroxymethyl) aminomethane hydrochloride

formation. Do not get in eyes, on skin, or on clothing.

### **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 in a dry, cool and well-ventilated place. Keep container tightly closed. Store under an inert atmosphere. Keep container tightly closed in a dry and well-ventilated place. Protect from moisture.

Technical Rules for Hazardous Substances (TRGS) 510 Class 13 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**

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)
1,3-Propanediol, 2-amino-2-(hydroxymethyl)-,				DNEL = 216.6mg/kg bw/day
hydrochloride 1185-53-1 ( 99 )				

Component	Acute effects local (Inhalation)	Acute effects systemic (Inhalation)	Chronic effects local (Inhalation)	Chronic effects systemic (Inhalation)
1,3-Propanediol,				DNEL = 152.8mg/m <sup>3</sup>
2-amino-2-(hydroxymethyl)-,				-
hydrochloride				
1185-53-1 (99)				

## Predicted No Effect Concentration (PNEC)

No information available.

## 8.2. Exposure controls

## **Engineering Measures**

Ensure adequate ventilation, especially in confined areas. Ensure that eyewash stations and safety showers are close to the workstation location.

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	Goggles (European standard - EN 166)			
Hand Protection	tection Protective gloves			
Glove material Nitrile rubber Neoprene Natural rubber PVC	Breakthrough time See manufacturers recommendations	Glove thickness	EU standard EN 374	Glove comments (minimum requirement)

Skin and body protection Wear appropriate protective gloves and clothing to prevent skin exposure.

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	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	Use a NIOSH/MSHA or European Standard EN 136 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced <b>Recommended Filter type:</b> Particulates filter conforming to EN 143
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. <b>Recommended half mask:-</b> Particle filtering: EN149:2001 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	Solid	
Appearance Odor Odor Threshold Melting Point/Range	White Slight Characteristic No data available 150 - 151 °C / 302 - 303.8 °F	
Softening Point/Range Boiling Point/Range	No data available 225 °C / 437 °F	
Flammability (liquid) Flammability (solid,gas)	Not applicable No information available	Solid

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Explosion Limits	No data available	
Flash Point	No information available	Method - No information available
Autoignition Temperature	No data available	
Decomposition Temperature	No data available	
рН	3.5-5.0 @ 25°C	1 % aq.sol (25°C)
Viscosity	Not applicable	Solid
Water Solubility	Soluble	
-	8 g/100 ml	
Solubility in other solvents	No information available	
Partition Coefficient (n-octanol/w	vater)	
Component	log Pow	
1,3-Propanediol,	-3.6	
2-amino-2-(hydroxymethyl)-,		
hydrochloride		
Vapor Pressure	No information available	
Density / Specific Gravity	1.28 g/cm3	
Bulk Density	No data available	
Vapor Density	Not applicable	Solid
Particle characteristics	No data available	
9.2. Other information		
Molecular Formula	C4 H11 N O3 . H Cl	
Molecular Weight	157.6	
Explosive Properties	Not explosive	
Oxidizing Properties	Not oxidizing (according to A17 test)	

Not oxidizing (according to A17 test) Not applicable - Solid

## **SECTION 10: STABILITY AND REACTIVITY**

10.1. Reactivity	None known, based on information available
10.2. Chemical stability	Hygroscopic.
10.3. Possibility of hazardous reacti	ons
Hazardous Polymerization Hazardous Reactions	No information available. None under normal processing.
10.4. Conditions to avoid	Incompatible products. Exposure to moist air or water. Avoid dust formation.
10.5. Incompatible materials	Bases. Strong oxidizing agents.
10.6. Hazardous decomposition pro	ducts Nitrogen oxides (NOx). Carbon monoxide (CO). Carbon dioxide (CO <sub>2</sub> ). Hydrogen chloride gas.

## **SECTION 11: TOXICOLOGICAL INFORMATION**

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

Evaporation Rate

No acute toxicity information is available for this product

LC50 Inhalation

Study result non-sensitising

Study result negative

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Product Information

Oral Dermal Inhalation	Based on available data, the cla Based on available data, the cla No data available	
Component	LD50 Oral	LD50 Dermal
1,3-Propanediol,	OECD 425 (Rat)	OECD 402 (Rat)
2-amino-2-(hydroxymethyl)-, hydrochloride		LD50 > 5000 mg/kg bw
(b) skin corrosion/irritation;	Not classified	
Test method	OECD Test Guideline 439	
Test species	in vitro	
Observational endpoint	No skin irritation	
(c) serious eye damage/irritation;	Not classified	
Test method	OECD Test Guideline 437	
Test species	in vitro	
Observation end point	No eye irritation	
Respiratory Skin	No data available Based on available data, the cla	
Component	Test method	Test species
1,3-Propanediol, 2-amino-2-(hydroxymethyl)-, hydrochloride	OECD Test Guideline 406	guinea pig
1185-53-1(99)		
(e) germ cell mutagenicity;	Based on available data, the cl	assification criteria are not me
(e) germ cell mutagenicity; Component	Test method	Test species
(e) germ cell mutagenicity;	Test method OECD Test Guideline 471	
(e) germ cell mutagenicity; Component 1,3-Propanediol, 2-amino-2-(hydroxymethyl)-, hydrochloride	Test method OECD Test Guideline 471	Test species Mammalian
(e) germ cell mutagenicity; <u>Component</u> 1,3-Propanediol, 2-amino-2-(hydroxymethyl)-, hydrochloride 1185-53-1 (99)	Test method OECD Test Guideline 471 Bacterial Reverse Mutation Test	Test species Mammalian in vitro
(e) germ cell mutagenicity; <u>Component</u> 1,3-Propanediol, 2-amino-2-(hydroxymethyl)-, hydrochloride 1185-53-1 (99)	Test method OECD Test Guideline 471 Bacterial Reverse Mutation Test No data available	Test species Mammalian in vitro
(e) germ cell mutagenicity; Component 1,3-Propanediol, 2-amino-2-(hydroxymethyl)-, hydrochloride 1185-53-1 (99) (f) carcinogenicity;	Test method OECD Test Guideline 471 Bacterial Reverse Mutation Test No data available There are no known carcinoger	Test species Mammalian in vitro
(e) germ cell mutagenicity; <u>Component</u> 1,3-Propanediol, 2-amino-2-(hydroxymethyl)-, hydrochloride 1185-53-1 ( 99 ) (f) carcinogenicity; (g) reproductive toxicity;	Test method OECD Test Guideline 471 Bacterial Reverse Mutation Test No data available There are no known carcinoger No data available	Test species Mammalian in vitro
(e) germ cell mutagenicity; Component 1,3-Propanediol, 2-amino-2-(hydroxymethyl)-, hydrochloride 1185-53-1 (99) (f) carcinogenicity; (g) reproductive toxicity; (h) STOT-single exposure;	Test method OECD Test Guideline 471 Bacterial Reverse Mutation Test No data available There are no known carcinoger No data available No data available	Test species Mammalian in vitro

Other Adverse Effects The toxicological properties have not been fully investigated.

Symptoms / effects,both acute and No information available. delayed

## 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

Do not empty into drains. .

Component	Freshwater Fish	Water Flea	Freshwater Algae
1,3-Propanediol,		Daphnia Magna	
2-amino-2-(hydroxymethyl)-, hydrochloride		EC50 >100 mg/L (48h)	

Component	Microtox	M-Factor
1,3-Propanediol,	OECD 209	
2-amino-2-(hydroxymethyl)-, hydrochloride	EC50 > 1000 mg/L (3h)	

12.2. Persistence and degradability	Readily biodegradable
Persistence	Soluble in water, Persistence is unlikely, based on information available.

## 12.3. Bioaccumulative potential Bioaccumulation is unlikely

Component	log Pow	Bioconcentration factor (BCF)
1,3-Propanediol,	-3.6	No data available
2-amino-2-(hydroxymethyl)-, hydrochloride		

<u>12.4. Mobility in soil</u>	The product is water soluble, and may spread in water systems Will likely be mobile in the environment due to its water solubility. Highly mobile in soils
12.5. Results of PBT and vPvB assessment	Substance is not considered persistent, bioaccumulative and toxic (PBT) / very persistent and very bioaccumulative (vPvB).
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	This product does not contain any known or suspected substance
Ozone Depletion Potential	This product does not contain any known or suspected substance

## **SECTION 13: DISPOSAL CONSIDERATIONS**

## 13.1. Waste treatment methods

Waste from Residues/Unused Products	Waste is classified as hazardous. Dispose of in accordance with the European Directives on waste and hazardous waste. Dispose of in accordance with local regulations.
Contaminated Packaging	Dispose of this container to hazardous or special waste collection point.
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. Do not empty into drains.

## **SECTION 14: TRANSPORT INFORMATION**

IMDG/IMO	Not regulated
<u>14.1. UN number</u> <u>14.2. UN proper shipping name</u> <u>14.3. Transport hazard class(es)</u> <u>14.4. Packing group</u>	
ADR	Not regulated
<u>14.1. UN number</u> <u>14.2. UN proper shipping name</u> <u>14.3. Transport hazard class(es)</u> <u>14.4. Packing group</u>	
ΙΑΤΑ	Not regulated
<u>14.1. UN number</u> <u>14.2. UN proper shipping name</u> <u>14.3. Transport hazard class(es)</u> <u>14.4. Packing group</u>	
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
1,3-Propanediol, 2-amino-2-(hydroxymethyl)-, hydrochloride	1185-53-1	214-684-5	-	-	х	х	KE-34819	х	-

Component	CAS No	TSCA	TSCA Inventory notification - Active-Inactive	DSL	NDSL	AICS	NZIoC	PICCS
1,3-Propanediol, 2-amino-2-(hydroxymethyl)-, hydrochloride	1185-53-1	Х	ACTIVE	Х	-	Х	Х	Х

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

Not applicable

Component	CAS No	REACH (1907/2006) - Annex XIV - Substances Subject to Authorization	5	REACH Regulation (EC 1907/2006) article 59 - Candidate List of Substances of Very High Concern (SVHC)
1,3-Propanediol, 2-amino-2-(hydroxymethyl)-, hydrochloride	1185-53-1	-	-	-

## Seveso III Directive (2012/18/EC)

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
1,3-Propanediol, 2-amino-2-(hydroxymethyl)-, hydrochloride	1185-53-1	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

## Contains component(s) that meet a 'definition' of per & poly fluoroalkyl substance (PFAS)? 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 .

## National Regulations

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

## WGK Classification

See table for values

Component	Germany - Water Classification (AwSV)	Germany - TA-Luft Class
1,3-Propanediol,	WGK1	
2-amino-2-(hydroxymethyl)-,		
hydrochloride		

## 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

Tris(hydroxymethyl) aminomethane hydrochloride

## 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 al 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	<ul> <li>TWA - Time Weighted Average</li> <li>IARC - International Agency for Research on Cancer</li> <li>Predicted No Effect Concentration (PNEC)</li> <li>LD50 - Lethal Dose 50%</li> <li>EC50 - Effective Concentration 50%</li> <li>POW - Partition coefficient Octanol:Water</li> <li>vPvB - very Persistent, very Bioaccumulative</li> </ul>
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,	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) RTECS

## **Training Advice**

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

Use of personal protective equipment, covering appropriate selection, compatibility, breakthrough thresholds, care, maintenance, fit and standards.

First aid for chemical exposure, including the use of eye wash and safety showers.

Creation Date	26-Sep-2009
Revision Date	18-Oct-2023
Revision Summary	Not applicable.

# This safety data sheet complies with Regulation UK SI 2019/758 and UK SI 2020/1577 as amended.

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