

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

Revision Date 17-Mar-2024 Revision Number 3

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

1.1. Product identifier

Product Description: Factor XA protease digestion buffer

Cat No. : J63878

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

Avocado Research Chemicals Ltd. (Part of Thermo Fisher Scientific)

Shore Road, Heysham Lancashire, LA3 2XY, United Kingdom

Office Tel: +44 (0) 1524 850506 Office Fax: +44 (0) 1524 850608

E-mail address begel.sdsdesk@thermofisher.com

1.4. Emergency telephone number

For information **US** call: 001-800-227-6701 / **Europe** call: +32 14 57 52 11 Emergency Number **US**:001-201-796-7100 / **Europe**: +32 14 57 52 99 **CHEMTREC** Tel. No. **US**:001-800-424-9300 / **Europe**: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

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

2.3. Other hazards

This product does not contain any known or suspected endocrine disruptors

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.2. Mixtures

Component	CAS No	EC No	Weight %	CLP Classification - According to GB-CLP Regulations UK SI 2019/720 and UK SI 2020/1567
Water	7732-18-5	231-791-2	99.37	-
1,3-Propanediol,	1185-53-1	EEC No. 214-684-5	0.32	-
2-amino-2-(hydroxymethyl)-, hydrochloride				
Sodium chloride	7647-14-5	231-598-3	0.29	-
Calcium chloride, dihydrate	10035-04-8		0.02	Eye Irrit. 2 (H319)

Full text of Hazard Statements: see section 16

SECTION 4: FIRST AID MEASURES

4.1. Description of first aid measures

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. Get medical attention

immediately if symptoms occur.

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 immediately if symptoms occur.

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.

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SECTION 5: FIREFIGHTING MEASURES

5.1. Extinguishing media

Suitable Extinguishing Media

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

None reasonably foreseeable.

Hazardous Combustion Products

Nitrogen oxides (NOx), Hydrogen chloride, Calcium oxides, Sodium oxides.

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

Ensure adequate ventilation. Use personal protective equipment as required.

6.2. Environmental precautions

Should not be released into the environment. See Section 12 for additional Ecological Information.

6.3. Methods and material for containment and cleaning up

Sweep up and shovel into suitable 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

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

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 in a dry and well-ventilated place.

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

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7.3. Specific end use(s)

Use in laboratories

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

Exposure limits

List source(s):

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	Acute effects	Chronic effects local			
	(Dermal)	systemic (Dermal)	(Dermal)	systemic (Dermal)		
1,3-Propanediol,				DNEL = 216.6mg/kg		
2-amino-2-(hydroxymethyl)-,				bw/day		
hydrochloride				-		
1185-53-1 (0.32)						
Sodium chloride		DNEL = 295.52mg/kg		DNEL = 295.52mg/kg		
7647-14-5 (0.29)		bw/day		bw/day		

Component	Acute effects local (Inhalation)	Acute effects systemic (Inhalation)	Chronic effects local (Inhalation)	Chronic effects systemic (Inhalation)
1,3-Propanediol,				DNEL = 152.8mg/m ³
2-amino-2-(hydroxymethyl)-,				_
hydrochloride				
1185-53-1 (0.32)				
Sodium chloride		$DNEL = 2068.62 \text{mg/m}^3$		$DNEL = 2068.62 \text{mg/m}^3$
7647-14-5 (0.29)		_		_

Predicted No Effect Concentration (PNEC)

See values below.

	Component	Fresh water		Water Intermittent	Microorganisms in	` ` '
L			sediment		sewage treatment	
Γ	Sodium chloride	PNEC = 5mg/L			PNEC = 500mg/L	PNEC = 4.86mg/kg
L	7647-14-5 (0.29)					soil dw

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)

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Hand Protection

Protective gloves

Glove material Breakthrough time Glove thickness EU standard Glove comments

Natural rubber See manufacturers - EN 374 (minimum requirement)

Nitrile rubber recommendations

Neoprene

Skin and body protection Long sleeved clothing.

Inspect gloves before use.

PVC

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 ProtectionNo 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.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Physical State Liquid

Appearance

Odor
Odor No information available
No data available
No information available
Rammability (liquid)
No data available

Flammability (solid,gas) Not applicable Liquid

Explosion Limits No data available

Flash Point No information available Method - No information available

Autoignition Temperature
Decomposition Temperature
pH
Viscosity
Vater Solubility

No data available
No data available
No information available
Immiscible

Solubility in other solvents No information available

Partition Coefficient (n-octanol/water)

Component log Pow 1,3-Propanediol, -3.6

2-amino-2-(hydroxymethyl)-,

hydrochloride

Calcium chloride, dihydrate 0.05

Vapor Pressure No data available

Density / Specific Gravity No data available

 Bulk Density
 Not applicable
 Liquid

 Vapor Density
 No data available
 (Air = 1.0)

 Particle characteristics
 Not applicable (liquid)

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9.2. Other information

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 No information available.
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

Nitrogen oxides (NOx). Hydrogen chloride. Calcium oxides. Sodium oxides.

SECTION 11: TOXICOLOGICAL INFORMATION

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

Product Information

(a) acute toxicity;

Oral Based on available data, the classification criteria are not met 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
Water	-	-	-
1,3-Propanediol,	OECD 425 (Rat)	OECD 402 (Rat)	=
2-amino-2-(hydroxymethyl)-, hydrochloride	LD50 > 5000 mg/kg bw	LD50 > 5000 mg/kg bw	
Sodium chloride	LD50 = 3 g/kg (Rat)	LD50 > 10000 mg/kg (Rabbit)	LC50 > 42 mg/L (Rat) 1 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

Component	Test method	Test species	Study result
1,3-Propanediol,	OECD Test Guideline 406	guinea pig	non-sensitising
2-amino-2-(hydroxymethyl)-, hydrochloride			_
1185-53-1 (0.32)			

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(e) germ cell mutagenicity; No data available

Component	Test method	Test species	Study result
1,3-Propanediol,	OECD Test Guideline 471	Mammalian	negative
2-amino-2-(hydroxymethyl)-, hydrochloride	Bacterial Reverse Mutation Test	in vitro	-
1185-53-1 (0.32)			

(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; No data available

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

Component Freshwater Fish Water Flea Freshwater Algae 1,3-Propanediol, Daphnia Magna 2-amino-2-(hydroxymethyl)-, hydrochloride EC50 >100 mg/L (48h) Sodium chloride Pimephals prome: LC50: 7650 EC50: 1000 mg/L/48h mg/L/96h Calcium chloride, dihydrate Lepomis macrochirus: LC50: EC50: 3005 mg/L/48h 10650 mg/L/96h

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

12.2. Persistence and degradability

Persistence Immiscible with water.

12.3. Bioaccumulative potential May have some potential to bioaccumulate

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

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2-amino-2-(hydroxymethyl)-, hydrochloride

Calcium chloride, dihydrate

0.05

No data available

12.4. Mobility in soil Spillage unlikely to penetrate soil Is not likely mobile in the environment due its low water

solubility.

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

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ensure complete and accurate classification.

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

<u>IATA</u> Not regulated

14.1. UN number

14.2. UN proper shipping name

14.3. Transport hazard class(es)

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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
Water	7732-18-5	231-791-2	-	-	X	X	KE-35400	X	-
1,3-Propanediol, 2-amino-2-(hydroxymethyl)-, hydrochloride	1185-53-1	214-684-5	-	-	Х	Х	KE-34819	Х	-
Sodium chloride	7647-14-5	231-598-3	-	-	X	X	KE-31387	X	X
Calcium chloride, dihydrate	10035-04-8	-	-	-	Х	Х	-	Χ	Х

Component	CAS No	TSCA	TSCA Inventory notification - Active-Inactive	DSL	NDSL	AICS	NZIoC	PICCS
Water	7732-18-5	X	ACTIVE	Х	ı	X	Х	X
1,3-Propanediol, 2-amino-2-(hydroxymethyl)-, hydrochloride	1185-53-1	Х	ACTIVE	Х	1	Х	Х	Х
Sodium chloride	7647-14-5	Х	ACTIVE	Х	-	X	Х	Х
Calcium chloride, dihydrate	10035-04-8	-	-	-	-	Χ	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

Component	CAS No	REACH (1907/2006) - Annex XIV - Substances Subject to Authorization	REACH (1907/2006) - Annex XVII - Restrictions on Certain Dangerous Substances	REACH Regulation (EC 1907/2006) article 59 - Candidate List of Substances of Very High Concern (SVHC)
Water	7732-18-5	-	-	-
1,3-Propanediol, 2-amino-2-(hydroxymethyl)-, hydrochloride	1185-53-1	-	-	-
Sodium chloride	7647-14-5	-	-	-
Calcium chloride, dihydrate	10035-04-8	-	Use restricted. See item 75. (see link for restriction details)	-

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
Water	7732-18-5	Not applicable	Not applicable
1,3-Propanediol, 2-amino-2-(hydroxymethyl)-, hydrochloride	1185-53-1	Not applicable	Not applicable
Sodium chloride	7647-14-5	Not applicable	Not applicable

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Calcium chloride, dihydrate 10035-04-8 Not applicable Not applicable

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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

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

	Component Germany - Water Classification (AwS		Germany - TA-Luft Class	
	1,3-Propanediol,	WGK1		
	2-amino-2-(hydroxymethyl)-,			
	hydrochloride			
Γ	Sodium chloride	WGK1		

Component	France - INRS (Tables of occupational diseases)	
Sodium chloride		

Component	Switzerland - Ordinance on the Reduction of Risk from handling of hazardous substances preparation (SR 814.81)	Switzerland - Ordinance on Incentive Taxes on Volatile Organic Compounds (OVOC)	Switzerland - Ordinance of the Rotterdam Convention on the Prior Informed Consent Procedure
Sodium chloride 7647-14-5 (0.29)	Prohibited and Restricted Substances		

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

H319 - Causes serious eye irritation

Legend

CAS - Chemical Abstracts Service

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

EINECS/ELINCS - European Inventory of Existing Commercial Chemical DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances/EU List of Notified Chemical Substances

Substances List

PICCS - Philippines Inventory of Chemicals and Chemical Substances **IECSC** - Chinese Inventory of Existing Chemical Substances

ENCS - Japanese Existing and New Chemical Substances AICS - Australian Inventory of Chemical Substances

KECL - Korean Existing and Evaluated Chemical Substances

NZIoC - New Zealand Inventory of Chemicals

WEL - Workplace Exposure Limit **ACGIH** - American Conference of Governmental Industrial Hygienists TWA - Time Weighted Average IARC - International Agency for Research on Cancer

DNEL - Derived No Effect Level

Predicted No Effect Concentration (PNEC)

Transport Association

ATE - Acute Toxicity Estimate

VOC - (Volatile Organic Compound)

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ICAO/IATA - International Civil Aviation Organization/International Air

MARPOL - International Convention for the Prevention of Pollution from

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RPE - Respiratory Protective Equipment LD50 - Lethal Dose 50% LC50 - Lethal Concentration 50% EC50 - Effective Concentration 50% NOEC - No Observed Effect Concentration POW - Partition coefficient Octanol:Water

PBT - Persistent, Bioaccumulative, Toxic 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

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

Ships

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.

Health, Safety and Environmental Department **Prepared By**

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Revision Summary New emergency telephone response service provider.

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