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Safety Data Sheet according to Regulation (EC) No. 1907/2006. COMMISSION REGULATION (EU) 2020/878 amending Annex II to Regulation (EC) No 1907/2006

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1 Identification of substance

Product details

Trade name: Elution buffer Article number: Part of PCCSKU16004, PCCSKU16006, PCCSKU16007, PCCSKU16020, PCCSKU16025, PCCSKU16045, PCCSKU16067, PCCSKU16068, PCCSKU16069, PCCSKU16070, PCCSKU16072, PCCSKU16074, PCCSKU16075 Details of supplier of the MSDS/Manufacturer/Supplier: Procomcure Biotech GmbH, Breitwies 1, 5303 Thalgau, Austria; FN 289033z

2 Hazards identification

2.1. Classification of the substance or mixture

Classification according to regulation (EC) No 11272/2008 (CLP) and amendments Not applicable

2.2. Label elements Hazard pictograms Not applicable **Signal Word** Danger **Hazard Statements** Not applicable Supplementary statements EUH208: Contains EDTA disodium salt. May produce allergic reactions. Precautionary statements prevention Not applicable Precautionary statements response Not applicable Precautionary statements storage Not applicable Precautionary statements disposal Not applicable

2.3. Other hazards

REACh – Art. 57-59: The mixture does not contain Substances of Very High Concern (SVHC) at the SDS print ate.

3 Composition/information on ingredients

3.1 Substances

See "Composition on ingredients" in Section 3.2. **3.2. Mixtures**





Identifiation	Component	Weight (%)
CAS: 1185-53-1	Tris(hydroxymethyl)aminomethane	1 507
EINECS: 214-684-5	Not applicable	1-5%
CAS: 6381-92-6	EDTA disodium salt	>1%
EINECS: 205-358-3	H: 302-315-317-319	>1%

4 First aid measures

4.1 Description of first aid measures

General information:

If exposed or in case of symptoms caused by eye or skin contact, inhalation or swallowing, consult a physician.

After inhalation:

Supply fresh air; consult doctor in case of symptoms.

After skin contact:

Instantly wash with water and soap and rinse thoroughly. If skin irritation continues, consult a doctor.

After eye contact:

Rinse opened eye for several minutes under running water. Consult a doctor.

After swallowing:

Do not induce vomiting; instantly call for medical help.

Most important symptoms and effects, both acute and delayed: No further relevant information available.

Indication of any immediate medical attention and special treatment needed: No further relevant information available.

5 Firefighting measures

5.1. Extinguishing media

There is no restriction on the type of extinguisher which may be used. Use extinguishing media suitable for surrounding area.

5.2. Special hazards arising from the substance mixture

None known

5.3. Advice for firefighters

Stay in danger area only with self-contained breathing apparatus. Prevent skin contact by keeping a safe distance or by wearing suitable protective clothing.

6 Accidental release measures

6.1. Personal precautions, protective equipment, and emergency procedures:

See Section 8

6.1. Environmental precautions

See section 12

6.3. Methods and material for containment and cleaning up:

Remove all ignition sources, clean up al spills immediately, avoid breathing vapors and contact with skin and eyes, control personal contact with the substance, by using protective equipment.





6.4. Reference to other sections

See Section 7 for information on safe handling. See Section 8 for information on personal protection equipment. See Section 13 for disposal information.

7 Handling and storage

7.1. Handling

Information for safe handling:

Wear protective clothing Use in a well-ventilated area Always wash hands with soap and a copious amount of water after handling Keep containers securely sealed when not in use Avoid physical damage to containers Limit unnecessary personal contact When handling, do not eat, drink or smoke Information about protection against explosions and fires: See section 5

7.2. Conditions for safe storage, including any incompatibilities

Keep tightly closed in a dry and cool place.

Store in the dark.

Keep locked up.

Avoid contamination of water, foodstuffs, feed or seed.

Requirements to be met by storerooms and containers:

Polyethylene or polypropylene container. Packing as recommended by manufacturer. Check all containers are clearly labelled and free of leaks. Avoid contamination of water, foodstuffs, feed or seed.

7.3. Specific end use(s)

Kit component. Consult IFU for intended use.

8 Exposure controls and personal protection

8.1. Control parameters

Component	DNELs	PNECs	
	Exposure Pattern Worker	Compartment	
Tris(hydroxymethyl) aminomethane	Dermal 166.7 mg/kg bw/day (Systemic, Chronic) Inhalation 117.5 mg/m ³ (Systemic, Chronic) Dermal 83.3 mg/kg bw/day (Systemic, Chronic) * Inhalation 29 mg/m ³ (Systemic, Chronic) * Oral 8.3 mg/kg bw/day (Systemic, Chronic) *	300 mg/L (STP)	
EDTA disodium salt	Inhalation 1.5 mg/m³ (Local,	2.2 mg/L (Water (Fresh))	
	Chronic)	0.22 mg/L (Water - Intermittent	
	Inhalation 3 mg/m³ (Local, Acute)	release)	





Oral 25 mg/kg bw/day (Systemic, Chronic) * Inhalation 0.6 mg/m ³ (Local, Chronic) *	1.2 mg/L (Water (Marine)) 0.72 (Soil) 43 mg/L (STP)
Chronic) * Inhalation 1.2 mg/m³ (Local, Acute)*	

* Values for general population

Occupational Exposure Limits (OEL)

Not Available

Emergency Limits

Component	TEEL-1	TEEL-2	TEEL-3
Tris(hydroxymethyl) aminomethane	18 mg/m ³	190 mg/m ³	1200 mg/m ³
EDTA disodium salt	30 mg/m ³	330 mg/m ³	2000 mg/m ³

8.2. Exposure controls

Appropriate engineering controls

Eye and face protection:

Safety glasses with side shields

Chemical googles

Contact lenses might be a special hazard as contact lenses may absorb and concentrate irritants. Medical and first-aid personnel should be trained in their removal and suitable equipment should be readily available. In the event of chemical exposure, remove contact lens as soon as practicable. Lens should be removed at any sign of eye redness or irritation in a clean environment only after workers have washed hands thoroughly.

Skin protection

See Hand protection below

Hands/feet protection

Wear gloves of a stable material.

Wear safety footwear or safety gumboots.

The selection of suitable gloves does not only depend on the material, but also on further marks of quality which vary with the manufacturer. Where the chemicals is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior application.

The exact break through time for substances has to be obtained from the manufacturer of the protective gloves and has to be observed when making a final choice.

Personal hygiene is a key element of effective hand care. Gloves must only be worn on clean hands. After using gloves, hands should be washed and dried thoroughly. Application of a non-perfumed moisturizer is recommended. Suitability and durability of glove type is dependent on usage. Important factors in the selection of gloves include:

· frequency and duration of contact,

· chemical resistance of glove material,

- ·glove thickness and
- · dexterity





Select gloves tested to a relevant standard (e.g. Europe EN 374, US F739, AS/NZS 2161.1 or national equivalent).

• When prolonged or frequently repeated contact may occur, a glove with a protection class of 5 or higher (breakthrough time greater than 240 minutes according to EN 374, AS/NZS 2161.10.1 or national equivalent) is recommended.

• When only brief contact is expected, a glove with a protection class of 3 or higher (breakthrough time greater than 60 minutes according to EN 374, AS/NZS 2161.10.1 or national equivalent) is recommended.

 \cdot Some glove polymer types are less affected by movement and this should be taken into account when considering gloves for long-term use.

· Contaminated gloves should be replaced.

- As defined in ASTM F-739-96 in any application, gloves are rated as:
- \cdot Excellent when breakthrough time > 480 min
- \cdot Good when breakthrough time > 20 min
- \cdot Fair when breakthrough time < 20 min
- $\cdot\, \text{Poor}$ when glove material degrades

For general applications, gloves with a thickness typically greater than 0.35 mm, are recommended.

It should be emphasized that glove thickness is not necessarily a good predictor of glove resistance to a specific chemical, as the permeation efficiency of the glove will be dependent on the exact composition of the glove material. Therefore, glove selection should also be based on consideration of the task requirements and knowledge of breakthrough times.

Glove thickness may also vary depending on the glove manufacturer, the glove type and the glove model. Therefore, the manufacturers technical data should always be taken into account to ensure selection of the most appropriate glove for the task.

Note: Depending on the activity being conducted, gloves of varying thickness may be required for specific tasks. For example:

• Thinner gloves (down to 0.1 mm or less) may be required where a high degree of manual dexterity is needed. However, these gloves are only likely to give short duration protection and would normally be just for single use applications, then disposed of.

• Thicker gloves (up to 3 mm or more) may be required where there is a mechanical (as well as a chemical) risk i.e., where there is abrasion or puncture potential

Gloves must only be worn on clean hands. After using gloves, hands should be washed and dried thoroughly. Application of a non-perfumed moisturizer is recommended.

Respiratory protection

Respiratory protection required when dusts are generated.

8.3. Environmental exposure controls

See section 12

9 Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance	Not available		
Physical state	Liquid	Relative density (Water = 1)	Not available
Odor	Not available	Partition coefficient n-octanol / water	Not available
Odor threshold	Not available	Auto-ignition temperature (°C)	Not available
pH (as supplied)	Not available	Decomposition temperature (°C)	Not available





Melting point / freezing pint (°C)	Not available	Viscosity (cSt)	Not available
Initial boiling point and boiling range (°C)	Not available	Molecular weight (g/mol)	Not available
Flash point (°C)	Not available	Taste	Not available
Evaporation rate	Not available	Explosive properties	Not available
Flammability	Not available	Oxidizing properties	Not available
Upper explosive limit (%)	Not available	Surface tension (dyn/cm or mN/m)	Not available
Lower explosive limit (%)	Not available	Volatile component (%vol)	Not available

9.2. Other information

Not available

10 Stability and reactivity

10.1 Reactivity

Risk of dust explosion. Vapors may form explosive mixture with air.

The following applies in general to flammable organic substances and mixtures: in correspondingly fine distribution, when whirled up a dust explosion potential may generally be assumed.

Contact with acids liberates very toxic gas.

10.2 Chemical stability

Hygroscopic

This product is chemically stable under standard ambient conditions (room temperature). Unstable in the presence of incompatible materials.

Thermal decomposition / conditions to be avoided:

Strong oxidizing agents and acids.

10.3 Possibility of hazardous reactions

Risk of explosion with: Chlorates Phosgene organic nitro compounds hydrogen peroxide perchlorates strong oxidizing agents Nitric acid nitrogen dioxide Risk of ignition or formation of inflammable gases or vapours with: Alkali metals Alkaline earth metals chromium(VI) oxide Exothermic reaction with: Aldehydes Amines fuming sulfuric acid Iron

Aluminum





Chlorine Strong acids halogen compounds potassium tert-butanolate

10.4 Conditions to avoid Warming

10.5 Incompatible maerials

Rubber, various plastics, oils

10.6 Hazardous decomposition products

In the event of fire see Section 5

11 Toxicological information

Acute toxicity

Component	Toxicity	Irritation
Tris(hydroxymethyl) aminomethane	Dermal (Rabbit) LD50: >5000 mg/kgª Oral (rat) LD50: > 5000 mg/kgª	Eye: no adverse effect observed (not irritating) ^a Skin: no adverse effect observed (no irritating) ^a
EDTA disodium	Oral (rat) LD50: 400 mg/kg ^b Inhalation	Not available

° Value obtained from Europe ECHA registered substances – Acute toxicity 2.

^b Value obtained from manufacturer's SDS.

Tris(hydrxymethyl) aminomethane

Asthma-like symptoms may continue for months or even years after exposure to the material ends. This may be due to a non-allergic condition known as reactive airways dysfunction syndrome (RADS) which can occur after exposure to high levels of highly irritating compound. Main criteria for diagnosing RADS include the absence of previous airways disease in a nonatopic individual, with sudden onset of persistent asthma-like symptoms within minutes to hours of a documented exposure to the irritant. Other criteria for diagnosis of RADS include a reversible airflow pattern on lung function tests, moderate to severe bronchial hyperreactivity on methacholine challenge testing, and the lack of minimal lymphocytic inflammation, without eosinophilia. RADS (or asthma) following an irritating inhalation is an infrequent disorder with rates related to the concentration of and duration of exposure to the irritating substance. On the other hand, industrial bronchitis is a disorder that occurs because of exposure due to high concentrations of irritating substance (often particles) and is completely reversible after exposure ceases. The disorder is characterized by difficulty breathing, cough and mucus production. TRIS AMINO and its surrogate chemicals have very little, if any, toxicity. They are mildly irritating to eyes at moderate concentrations, and do not cause allergic skin reactions. Ingestion of relatively high dosages can cause liver changes. Patients with decreased liver function should not be given these substances over extended treatment periods. They have been known to have a harmful effect on the fetus if taken during pregnancy.

EDTA disodium

EDTA is a strong organic acid, with a high affinity for alkaline-earth ions (for example, calcium and magnesium) and heavy-metal ions (such as lad and mercury), resulting in highly stable chelate complexes. The ability of EDTA to complex is used commercially to either promote or





inhibit chemical reactions, depending on application. EDTA and its salts are expected to be absorbed by the lungs and the gastrointestinal tract; absorption through skin is unlikely. They cause mild skin irritation, and severe eye irritation. The greatest risk in the human body will occur when the EDTA attempts to scavenge the trace metals used and required by the body. The binding of divalent and trivalent cations by EDTA can cause mineral deficiencies, such as zinc deficiency. These appear to be responsible for all the known pharmacological effects. EDTA and its salts are mostly eliminated through the urine, with 5% eliminated via the bile, along with the metal ions which are bound to it. Trisodium EDTA has not been found to cause cancer. EDTA and its salts are not likely to cause harm to children and infants at levels likely to be encountered.

Acute toxicity	No	Carcinogenicity	No
Skin irritation/corrosion	No	Reproductivity	No
Serious eye damage/irritation	No	STOT-Single exposure	No
Respiratory or skin sensitization	No	STOT-Repeated exposure	No
Mutagenicity	No	Aspiration Hazard	No

12 Ecological information

12.1. Toxicity

Component	Endpoint	Test duration (h)	Species	Value (mg/L)
Tric/by/drown arby/l	NOEC (ECx)	72	Algae or other aquatic plants	100
Tris(hydroxymethyl) aminomethane	EC50 72		Algae or other aquatic plants	397
	EC50	48	Crustacea	>980
	EC50	72	Algae or other aquatic plants	2.77ª
EDTA disodium	LC50 96		Fish	41ª
EDTA disodium	EC50 48		Crustacea	140ª
	NOEC (ECx)	72	Algae or other aquatic plants	0.39ª

^a Europe ECHA Registered Substances – Ecotoxicological information – Aquatic toxicity

12.2. Persistence and degradability

Component	Persistence (Water/soil)	Persistence (air)
Tris(hydroxymethyl)	LOW	LOW
aminomethane		
EDTA disodium salt	LOW	LOW

12.3. Bio accumulative potential

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Component	Bio accumulation
Tris(hydroxymethyl)	LOW (LogKOW = -1.5606)
aminomethane	
EDTA disodium	LOW (LogKOW = -3.8573)





12.4. Mobility in soil

Component	Mok	bility				
Tris(hydroxymethyl)	HIGI	H (KOC = 1)				
aminomethane						
EDTA disodium	HIG	H (KOC = 1046)				
12.5. Results of PBT and vPvB assessment						
Assessment		Р	В		Т	
Relevant available data		No data available	No data availak	ble	No data available	
PBT		No	No		No	

No

No

12.6. Endocrine Disruption properties

No

Not available

vPvB

12.7. Other adverse effects

Not available

13 Disposal considerations

13.1. Waste treatment methods

Product or packaging disposal

Containers may still present a chemical hazard/ danger when empty. If container cannot be cleaned sufficiently well to ensure that residuals do not remain or if the container cannot be used to store the same product, then puncture containers, to prevent re-use, and bury at an authorized landfill. Where possible retain label warnings and SDS and observe all notices pertaining to the product. Legislation addressing waste disposal requirements may differ by country, state and/ or territory. Each user must refer to laws operating in their area. In some areas, certain wastes must be tracked.

A Hierarchy of Controls seems to be common - the user should investigate:

Reduction

Reuse

Recycling

Disposal (if all else fails)

This material may be recycled if unused, or if it has not been contaminated so as to make it unsuitable for its intended use. If it has been contaminated, it may be possible to reclaim the product by filtration, distillation, or some other means. Shelf-life considerations should also be applied in making decisions of this type. Note that properties of a material may change in use, and recycling or reuse may not always be appropriate. Do not allow wash water from cleaning or process equipment to enter drains. It may be necessary to collect all wash water for treatment before disposal. In all cases disposal to sewer may be subject to local laws and regulations and these should be considered first. Where in doubt contact the responsible authority. Recycle wherever possible or consult manufacturer for recycling options. Consult State Land Waste Authority for disposal. Bury or incinerate residue at an approved site. Recycle containers if possible or dispose of in an authorized landfill.

14 Transport information

Section	ADR/RID	IMDG	IATA
UN number	Not applicable	Not applicable	Not applicable
UN proper shipping name	Not applicable	Not applicable	Not applicable





Transport hazard class(es)	Not applicable	Not applicable	Not applicable
Packaging group	Not applicable	Not applicable	Not applicable
Environmental hazards	Not applicable	Not applicable	Not applicable
Special precautions for user	Not applicable	Not applicable	Not applicable

15 Regulatory information

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

EDTA disodium is found on the following regulatory lists:

- Europe EC inventory.
- European Union European Inventory of Existing Commercial Chemical Substances (EINECS).

Tris(hydroxymethyl) aminomethane is found on the following regulatory lists:

- US DOE Temporary Emergency Exposure Limits (TEELs)
- US Toxic Substances Control Act (TSCA) Chemical Substance Inventory
- US TSCA Chemical Substance Inventory Interim List of Active Substances

16 Other information

This version replaces all previous versions. 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. However, they shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

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.