

Safety Data Sheet

according to Regulation (EU) 2020/878 Issue date: 08/05/2023 Version: 1.0

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product form Trade name Other means of identification	 Mixture Oxalate Reagent A Oxalate Reagent A, Component part number(s): 591-10, Kit part number(s): 591-C, 591-D, 591-10

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

1.2.1. Relevant identified uses Use of the substance/mixture	: Medical Diagnostics
1.2.2. Uses advised against Restrictions on use	: No additional information available
1.3. Details of the supplier of the safety data sheet	
Trinity Biotech	

Irinity Biotech I.D.A Business Park Southern Cross Road A98 H5C8 Bray, Co. Wicklow - Ireland Technical Support Group 00353 1 276 9800 www.trinitybiotech.com Clinicalchemistry.techsupport@trinitybiotech.com

1.4. Emergency telephone number

Emergency number

: Contact your local Emergency Health Care Provider; Ireland-Technical Support Group 00353-1-276-9800 (operating hours 7:00-18:00)

Country	Organisation/Company	Address	Emergency number	Comment
Ireland	National Poisons Information Centre Beaumont Hospital	PO Box 1297 Beaumont Road 9	+353 1 809 2566 (Healthcare professionals- 24/7) +353 1 809 2166 (public, 8am - 10pm, 7/7)	

SECTION 2: Hazards identification 2.1. Classification of the substance or mixture Classification according to Regulation (EC) No. 1272/2008 [CLP] Serious eye damage/eye irritation, Category 2 H319 Full text of H- and EUH-statements: see section 16 Adverse physicochemical, human health and environmental effects

Causes serious eye irritation.

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP] Hazard pictograms (CLP)

> GHS07 : Warning

Signal word (CLP)

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Hazard statements (CLP)	: H319 - Causes serious eye irritation.
Precautionary statements (CLP)	: P264 - Wash hands thoroughly after handling.
	P280 - Wear protective gloves, protective clothing, eye protection, face protection.
	P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove
	contact lenses, if present and easy to do. Continue rinsing.
	P337+P313 - If eye irritation persists: Get medical advice/attention.
	P501 - Dispose of contents/container to hazardous or special waste collection point, in
	accordance with local, regional, national and/or international regulation.

2.3. Other hazards

Contains no PBT/vPvB substances ≥ 0.1% assessed in accordance with REACH Annex XIII

The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Name	Product identifier	Conc.	Classification according to Regulation (EC) No. 1272/2008 [CLP]
succinic acid	CAS-No.: 110-15-6 EC-No.: 203-740-4 REACH-no: 01-2119896114- 34	≥1-≤2	Eye Dam. 1, H318

Full text of H- and EUH-statements: see section 16

SECTION 4: First aid measures 4.1. Description of first aid measures First-aid measures general : Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible). First-aid measures after inhalation If inhaled and if breathing is difficult, remove victim to fresh air and keep at rest in a position : comfortable for breathing. If experiencing respiratory symptoms: Call a poison center or a doctor. First-aid measures after skin contact : Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse. Wash contaminated clothing before reuse. Get medical attention if symptoms occur. First-aid measures after eye contact : Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention. First-aid measures after ingestion : Rinse mouth out with water. Do NOT induce vomiting unless directed to do so by medical personnel. Call a POISON CENTER/doctor if you feel unwell. 4.2. Most important symptoms and effects, both acute and delayed Symptoms/effects after inhalation : Not expected to present a significant hazard under anticipated conditions of normal use. Symptoms/effects after skin contact : Redness. Itching. Swelling. Symptoms/effects after eye contact : Causes serious eye irritation. Redness. Itching. Lacrimation. Blurred vision.

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

Treat symptomatically.

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SECTION 5: Firefighting measures			
5.1. Extinguishing media			
Suitable extinguishing media Unsuitable extinguishing media	 Dry chemical, CO2, or water spray or regular foam. Use extinguishing agent suitable for surrounding fire. Do not use a heavy water stream. 		
5.2. Special hazards arising from the substance or mixture			
Fire hazard Hazardous decomposition products in case of fire	 Presents no particular fire or explosion hazard. Burning produces stinking and toxic fumes. In case of fire and/or explosion do not breathe fumes. Toxic fumes may be released. 		
5.3. Advice for firefighters			
Firefighting instructions	: Evacuate the danger area. Fight fire from safe distance and protected location. Move containers from fire area if it can be done without personal risk. Use extinguishing media appropriate for surrounding fire. Use water spray or fog for cooling exposed containers. Prevent fire fighting water from entering the environment.		
Protection during firefighting	: Wear a self contained breathing apparatus. Wear fire/flame resistant/retardant clothing. Do not enter fire area without proper protective equipment, including respiratory protection.		

SECTION 6: Accidental release measures			
6.1. Personal precautions, protective equipr	nent and emergency procedures		
General measures	: Avoid all contact with skin, eyes, or clothing. Do not inhale vapour.		
6.1.1. For non-emergency personnel			
Protective equipment Emergency procedures	 Wear recommended personal protective equipment. Refer to section 8.2. No action shall be taken without appropriate training or involving any personal risk. Evacuate unnecessary personnel. Ventilate spillage area. Avoid contact with skin and eyes. Do not touch or walk on the spilled product. 		
6.1.2. For emergency responders			
Protective equipment Emergency procedures	Do not attempt to take action without suitable protective equipment.Stop leak if safe to do so. Ventilate area. Do not touch spilled material.		

6.2. Environmental precautions

Avoid release to the environment. Notify authorities if product enters sewers or public waters.

6.3. Methods and material for containment and cleaning up		
For containment	: Stop leak without risks if possible. Contain any spills with dikes or absorbents to prevent migration and entry into sewers or streams. Caution : this product can cause the floor to be slippery.	
Methods for cleaning up	: Move containers from spill area. Ventilate spillage area. Soak up spills with inert solids, such as clay or diatomaceous earth as soon as possible. Clean contaminated surfaces with an excess of water. Keep in suitable, closed containers for disposal.	
Other information	: Dispose of via an authorised person/ licensed waste disposal contractor or by other suitable waste treatment techniques. Dispose of materials or solid residues at an authorized site.	
6.4. Reference to other sections		

For further information refer to section 13. For further information refer to section 8: "Exposure controls/personal protection".

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SECTION 7: Handling and storage			
7.1. Precautions for safe handling			
	Take all necessary technical measures to avoid or minimize the release of the product on the workplace. Obtain special instructions before use. Ensure good ventilation of the work station. Provide local exhaust or general room ventilation. Do not breathe vapours, mist. Do not get in eyes, on skin, or on clothing. Wear recommended personal protective equipment – refer to Section 8.2. Handle in accordance with good industrial hygiene and safety procedures. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Always wash hands after handling the product. Do not eat, drink or smoke when using this product. Wash contaminated clothing before reuse.		
7.2. Conditions for safe storage, including any incompatibilities			
Storage conditions :	Keep only in the original container in a cool, well ventilated place away from : Direct sunlight, Incompatible materials, Protect from freezing, Avoid high temperatures. Keep away from food, drink and animal feedingstuffs. Keep container tightly closed. Containers which are opened should be properly resealed and kept upright to prevent leakage. Store in accordance with local, regional, national or international regulation.		

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1 National occupational exposure and biological limit values

No additional information available

8.1.2. Recommended monitoring procedures

Monitoring methods		
	Workplace exposure - General requirements for the performance of procedures for the measurement of chemical agents. Refer to all applicable national, international and local regulations or provisions. Workplace atmospheres. Guide for the application and use of procedures for the assessment of exposure to chemical and biological agents. Workplace atmospheres. Guidance for the assessment of exposure by inhalation to chemical agents for comparison with limit values and measurement strategy.	

8.1.3. Air contaminants formed

No additional information available

8.1.4. DNEL and PNEC

No additional information available

8.1.5. Control banding

No additional information available

8.2. Exposure controls

8.2.1. Appropriate engineering controls

Appropriate engineering controls:

Handle in accordance with good industrial hygiene and safety procedures. Ensure good ventilation of the work station. Avoid all unnecessary exposure.

8.2.2. Personal protection equipment

Personal protective equipment:

Wear recommended personal protective equipment. Personal protective equipment should be chosen according to the CEN standards and in discussion with the supplier of the protective equipment.

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8.2.2.1. Eye and face protection

Eye protection:

Chemical goggles or safety glasses. ISO 16321-1

8.2.2.2. Skin protection

Skin and body protection:

Wear suitable protective clothing. Skin protection appropriate to the conditions of use should be provided

Hand protection:

Chemical resistant gloves (according to European standard ISO 374-1 or equivalent). Please follow the instructions related to the permeability and the penetration time provided by the manufacturer

8.2.2.3. Respiratory protection

Respiratory protection:

No respiratory protection needed under normal use conditions. Where excessive vapour, mist, or dust may result, use approved respiratory protection equipment. EN 143

8.2.2.4. Thermal hazards

No additional information available

8.2.3. Environmental exposure controls

Environmental exposure controls:

Avoid release to the environment. Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil.

SECTION 9: Phy	vsical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Liquid
Colour	: According to product specification.
Odour	: According to product specification.
Odour threshold	: Not available
Melting point	: Not available
Freezing point	: Not available
Boiling point	: Not available
Flammability	: Not applicable
Lower explosion limit	: Not available
Upper explosion limit	: Not available
Flash point	: Not available
Auto-ignition temperature	: Not available
Decomposition temperature	: Not available
рН	: Not available
Viscosity, kinematic	: Not available
Solubility	: Not available
Partition coefficient n-octanol/water (Log Kow)	: Not available
Vapour pressure	: Not available
Vapour pressure at 50°C	: Not available
Density	: Not available
Relative density	: 1.27269
Relative vapour density at 20°C	: Not available
Particle characteristics	: Not applicable

9.2. Other information

9.2.1. Information with regard to physical hazard classes

No additional information available

9.2.2. Other safety characteristics

No additional information available

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SECTION 10: Stability and reactivity

10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport. No dangerous reactions known.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use. Hazardous polymerisation: Will not occur.

10.4. Conditions to avoid

None under recommended storage and handling conditions (see section 7).

10.5. Incompatible materials

Strong bases. Strong acids. Strong oxidizing agents. Strong reducing agents.

10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

11.1. Information on hazard classes	as defined in Regulation (EC) No 1272/2008
Acute toxicity (oral) Acute toxicity (dermal) Acute toxicity (inhalation)	 Not classified (Based on available data, the classification criteria are not met) Not classified (Based on available data, the classification criteria are not met) Not classified (Based on available data, the classification criteria are not met)
succinic acid (110-15-6)	
LD50 oral rat	2260 mg/kg
LC50 Inhalation - Rat	> 1.284 mg/l (4 h, OECD 403)
Skin corrosion/irritation Serious eye damage/irritation Respiratory or skin sensitisation Germ cell mutagenicity Carcinogenicity Reproductive toxicity STOT-single exposure STOT-repeated exposure Aspiration hazard	 Not classified (Based on available data, the classification criteria are not met) Causes serious eye irritation. Not classified (Based on available data, the classification criteria are not met) Not classified (Based on available data, the classification criteria are not met) Not classified (Based on available data, the classification criteria are not met) Not classified (Based on available data, the classification criteria are not met) Not classified (Based on available data, the classification criteria are not met) Not classified (Based on available data, the classification criteria are not met) Not classified (Based on available data, the classification criteria are not met) Not classified (Based on available data, the classification criteria are not met) Not classified (Based on available data, the classification criteria are not met) Not classified (Based on available data, the classification criteria are not met) Not classified (Based on available data, the classification criteria are not met)

11.2.1. Endocrine disrupting properties

Adverse health effects caused by endocrine	: The mixture does not contain substance(s) included in the list established in accordance
disrupting properties	with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified
	as howing and arrive discusting properties in accordance with the aritaria set out in

11.2.2. Other information

Other information

as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %

: No experimental study on the product is available. The information given is based on our knowledge of the components and the classification of the product is determined by calculation

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SECTION 12: Ecological information	
12.1. Toxicity	
Hazardous to the aquatic environment, short-term (acute)	: Not classified (Based on available data, the classification criteria are not met)
Hazardous to the aquatic environment, long-term (chronic)	: Not classified (Based on available data, the classification criteria are not met)
Additional information	: No experimental study on the product is available. The information given is based on our knowledge of the components and the classification of the product is determined by calculation.
succinic acid (110-15-6)	
LC50 - Fish [1]	> 100 mg/l (96 h, Danio rerio, OECD 203, semi-static test)
EC50 - Crustacea [1]	> 100 mg/l (48 h, Daphnia magna, OECD 202, immobilization)
EC50 72h - Algae [1]	> 100 mg/l (72 h, Pseudokirchneriella subcapitata, OECD 201, growth inhibition test)
12.2. Persistence and degradability	
Oxalate Reagent A	
Persistence and degradability	Biodegradability in water: no data available.
succinic acid (110-15-6)	
Persistence and degradability	Readily biodegradable.
Biodegradation	96.55 % (28 days)
12.3. Bioaccumulative potential	
Oxalate Reagent A	
Bioaccumulative potential	No data available concerning bioaccumulation.
12.4. Mobility in soil	
Oxalate Reagent A	
Ecology - soil	No additional information available.
12.5. Results of PBT and vPvB assessment	t
No additional information available	
12.6. Endocrine disrupting properties	
Adverse effects on the environment caused by endocrine disrupting properties	: The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %.
12.7. Other adverse effects	
Other adverse effects	: No additional information available.
SECTION 13: Disposal considerations	
13.1. Waste treatment methods	
Waste treatment methods	: Dispose of contents/container in accordance with licensed collector's sorting instructions.

Disposal must be carried out using appropriate EWC code.

: Dispose in a safe manner in accordance with local/national regulations.

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Ecology - waste materials

: Avoid release to the environment.

accordance with ADR / IMI	DG / IATA / ADN / RID			
ADR	IMDG	ΙΑΤΑ	ADN	RID
14.1. UN number or ID n	umber	·	·	
Not regulated for transport				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.2. UN proper shippin	g name	·	·	
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.3. Transport hazard	class(es)	·	·	
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.4. Packing group		·	·	
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.5. Environmental haz	zards	·		
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated

14.6. Special precautions for user

Overland transport Not regulated

Transport by sea Not regulated

Air transport Not regulated

Inland waterway transport

Not regulated

Rail transport

Not regulated

14.7. Maritime transport in bulk according to IMO instruments

Not applicable

SECTION 15: Regulatory information

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

15.1.1. EU-Regulations

REACH Annex XVII (Restriction List)

Contains no substance(s) listed on REACH Annex XVII (Restriction Conditions)

REACH Annex XIV (Authorisation List)

Contains no substance(s) listed on REACH Annex XIV (Authorisation List)

REACH Candidate List (SVHC)

Contains no substance(s) listed on the REACH Candidate List

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PIC Regulation (Prior Informed Consent)

Contains no substance(s) listed on the PIC list (Regulation EU 649/2012 concerning the export and import of hazardous chemicals)

POP Regulation (Persistent Organic Pollutants)

Contains no substance(s) listed on the POP list (Regulation EU 2019/1021 on persistent organic pollutants)

Ozone Regulation (1005/2009)

Contains no substance(s) listed on the Ozone Depletion list (Regulation EU 1005/2009 on substances that deplete the ozone layer)

Explosives Precursors Regulation (2019/1148)

Contains no substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

Drug Precursors Regulation (273/2004)

Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances)

15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Abbreviations and acronyms:		
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways	
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road	
ATE	Acute Toxicity Estimate	
BLV	Biological limit value	
CAS-No.	Chemical Abstract Service number	
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008	
DMEL	Derived Minimal Effect level	
DNEL	Derived-No Effect Level	
EC50	Median effective concentration	
EC-No.	European Community number	
EN	European Standard	
ΙΑΤΑ	International Air Transport Association	
IMDG	International Maritime Dangerous Goods	
LC50	Median lethal concentration	
LD50	Median lethal dose	
LOAEL	Lowest Observed Adverse Effect Level	
NOAEC	No-Observed Adverse Effect Concentration	
NOAEL	No-Observed Adverse Effect Level	
NOEC	No-Observed Effect Concentration	
OEL	Occupational Exposure Limit	
РВТ	Persistent Bioaccumulative Toxic	
PNEC	Predicted No-Effect Concentration	
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006	

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Abbreviations and acronyms:		
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail	
SDS	Safety Data Sheet	
vPvB	Very Persistent and Very Bioaccumulative	
WGK	Water Hazard Class	

Data sources

 ECHA (European Chemicals Agency). Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 and all its amendments and modifications. Supplier's safety documents.
 Training staff on good practice.

Training advice

Full text of H- and EUH-statements:		
Eye Dam. 1	Serious eye damage/eye irritation, Category 1	
H318	Causes serious eye damage.	
H319	Causes serious eye irritation.	

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:		
Eye Irrit. 2	H319	Calculation method

Safety Data Sheet (SDS), EU

SDS prepared by: H2 Compliance

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.