

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

1.1. Product identifier

Product form : Mixture
Trade name : Anti-dsDNA tracer
Other means of identification : Anti-dsDNA tracer, Component part number(s): 295-990, Kit part number(s): IM77/IM771

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

Reproductive toxicity, Category 1B H360FD

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

Adverse physicochemical, human health and environmental effects

May damage fertility. May damage the unborn child.

2.2. Label elements

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

Hazard pictograms (CLP) :



GHS08

Signal word (CLP) :

Danger

Contains :

disodium tetraborate decahydrate

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Hazard statements (CLP)	: H360FD - May damage fertility. May damage the unborn child.
Precautionary statements (CLP)	: P201 - Obtain special instructions before use. P202 - Do not handle until all safety precautions have been read and understood. P280 - Wear protective gloves, protective clothing, eye protection, face protection. P308+P313 - IF exposed or concerned: Get medical advice/attention. P405 - Store locked up. P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.
Extra phrases	: Restricted to professional users.

2.3. Other hazards

Contains no PBT/vPvB substances $\geq 0.1\%$ assessed in accordance with REACH Annex XIII

Other information	: Caution! Contains radioactive material, I-125, for the use of authorized persons in clinical laboratories or hospitals for "in vitro" tests only, not involving internal or external administration to humans or animals.
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Component	
disodium tetraborate decahydrate (1303-96-4)	This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII This substance/mixture does not meet the vPvB criteria of REACH regulation, 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 %

Component	
disodium tetraborate decahydrate(1303-96-4)	The substance is not 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

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]
disodium tetraborate decahydrate substance listed as REACH Candidate (Disodium tetraborate, anhydrous) substance with national workplace exposure limit(s) (IE)	CAS-No.: 1303-96-4 EC-No.: 215-540-4 EC Index-No.: 005-011-00-4 REACH-no: 01-2119490790-32	< 1	Repr. 1B, H360FD

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. Get medical advice/attention if you feel unwell.
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.

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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. Get medical attention if symptoms occur. Wash contaminated clothing before reuse.
First-aid measures after eye contact	: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical advice/attention if you feel unwell.
First-aid measures after ingestion	: Do NOT induce vomiting unless directed to do so by medical personnel. Rinse mouth out with water. 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	: Redness. Itching. Lacrimation.
Symptoms/effects after ingestion	: May cause gastrointestinal irritation, nausea, vomiting and diarrhoea.
Chronic symptoms	: May damage fertility. May damage the unborn child.

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

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media	: Dry chemical, CO ₂ , or water spray or regular foam. Use extinguishing agent suitable for surrounding fire.
Unsuitable extinguishing media	: Do not use a heavy water stream.

5.2. Special hazards arising from the substance or mixture

Fire hazard	: Presents no particular fire or explosion hazard. Burning produces stinking and toxic fumes. In case of fire and/or explosion do not breathe fumes.
Hazardous decomposition products in case of fire	: 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 equipment and emergency procedures

General measures	: Avoid all contact with skin, eyes, or clothing. Do not inhale vapour.
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6.1.1. For non-emergency personnel

Protective equipment	: Wear recommended personal protective equipment. Refer to section 8.2.
Emergency procedures	: No action shall be taken without appropriate training or involving any personal risk. Do not touch or walk on the spilled product. Evacuate unnecessary personnel. Ventilate spillage area. Avoid contact with skin and eyes.

6.1.2. For emergency responders

Protective equipment	: Do not attempt to take action without suitable protective equipment.
Emergency procedures	: 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.

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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".

SECTION 7: Handling and storage

7.1. Precautions for safe handling

- Precautions for safe handling : Do not get in eyes, on skin, or on clothing. Ensure good ventilation of the work station. Obtain special instructions before use. Do not breathe vapours, mist. Wear recommended personal protective equipment – refer to Section 8.2. Take all necessary technical measures to avoid or minimize the release of the product on the workplace. Provide local exhaust or general room ventilation. Avoid contact during pregnancy and while nursing.
- Hygiene measures : 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. Do not eat, drink or smoke when using this product. Always wash hands after handling the 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

disodium tetraborate decahydrate (1303-96-4)	
Ireland - Occupational Exposure Limits	
Local name	Borate compounds inorganic: Borates, tetra, sodium, decahydrous [Disodium tetraborate, decahydrate]
OEL TWA [1]	2 mg/m ³
Remark	Repr.1B (Substances which are presumed human reproductive toxicants)
Regulatory reference	Chemical Agents Code of Practice 2021

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8.1.2. Recommended monitoring procedures

Monitoring methods	
Monitoring methods	Workplace exposure - General requirements for the performance of procedures for the measurement of chemical agents. 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. Refer to all applicable national, international and local regulations or provisions.

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:

Ensure good ventilation of the work station. Handle in accordance with good industrial hygiene and safety procedures. Avoid all unnecessary exposure. Avoid contact during pregnancy/while nursing.

8.2.2. Personal protection equipment

Personal protective equipment:

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

8.2.2.1. Eye and face protection

Eye protection:

Even though no specific eye irritation data are available, wear eye protection appropriate to conditions of use when handling this material. 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:

Wear suitable gloves resistant to chemical penetration. Please follow the instructions related to the permeability and the penetration time provided by the manufacturer. ISO 374-1

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 149

8.2.2.4. Thermal hazards

No additional information available

8.2.3. Environmental exposure controls

Environmental exposure controls:

Avoid release to the environment.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Liquid
Colour : According to product specification.

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Odour	: odourless.
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
pH	: 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	: 1.00243
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

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.

SECTION 11: Toxicological information

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

Acute toxicity (oral)	: Not classified (Based on available data, the classification criteria are not met)
Acute toxicity (dermal)	: Not classified (Based on available data, the classification criteria are not met)
Acute toxicity (inhalation)	: Not classified (Based on available data, the classification criteria are not met)

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disodium tetraborate decahydrate (1303-96-4)

LD50 oral rat	4500 – 5000 mg/kg
LC50 Inhalation - Rat	> 2.04 mg/l (4 h, OECD 403)

Skin corrosion/irritation	: Not classified (Based on available data, the classification criteria are not met)
Serious eye damage/irritation	: Not classified (Based on available data, the classification criteria are not met)
Respiratory or skin sensitisation	: Not classified (Based on available data, the classification criteria are not met)
Germ cell mutagenicity	: Not classified (Based on available data, the classification criteria are not met)
Carcinogenicity	: Not classified (Based on available data, the classification criteria are not met)
Reproductive toxicity	: May damage fertility. May damage the unborn child.
STOT-single exposure	: Not classified (Based on available data, the classification criteria are not met)
STOT-repeated exposure	: Not classified (Based on available data, the classification criteria are not met)
Aspiration hazard	: Not classified (Based on available data, the classification criteria are not met)

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Adverse health effects 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 %
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11.2.2. Other information

Other 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
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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.

disodium tetraborate decahydrate (1303-96-4)

EC50 - Crustacea [1]	1085 – 1402 (48 h, Daphnia magna)
EC50 72h - Algae [1]	158 mg/l (96 h, Desmodesmus subspicatus)

12.2. Persistence and degradability

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Persistence and degradability	Biodegradability in water: no data available.
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12.3. Bioaccumulative potential

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Bioaccumulative potential	No data available concerning bioaccumulation.
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disodium tetraborate decahydrate (1303-96-4)

Partition coefficient n-octanol/water (Log Pow)	≤ 4
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12.4. Mobility in soil

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Ecology - soil : No additional information available.

12.5. Results of PBT and vPvB assessment

Component

disodium tetraborate decahydrate (1303-96-4) : This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII
This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

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.
Product/Packaging disposal recommendations : Dispose in a safe manner in accordance with local/national regulations.
Ecology - waste materials : Avoid release to the environment.

SECTION 14: Transport information

In accordance with ADR / IMDG / IATA / ADN / RID

ADR	IMDG	IATA	ADN	RID
14.1. UN number or ID number				
Not regulated for transport				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.2. UN proper shipping 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 hazards				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
No supplementary information available				

14.6. Special precautions for user

Overland transport

Not regulated

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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 substance(s) listed on the REACH Candidate List in concentrations $\geq 0.1\%$ or SCL: Disodium tetraborate, anhydrous (EC 215-540-4, CAS 1303-96-4)

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

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Abbreviations and acronyms:	
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
IATA	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
PBT	Persistent Bioaccumulative Toxic
PNEC	Predicted No-Effect Concentration
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
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 advice : Training staff on good practice.

Full text of H- and EUH-statements:	
H360FD	May damage fertility. May damage the unborn child.
Repr. 1B	Reproductive toxicity, Category 1B

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:		
Repr. 1B	H360FD	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.