

**SECTION 1: Identification of the substance/mixture and of the company/undertaking****1.1. Product identifier**

Product form	: Mixture
Trade name	: Premier Buffer A, Menarini Buffer A, Premier Buffer B, Menarini Buffer B, Tri-stat Reagent Kit
Other means of identification	: 01-03-0095 Premier Buffer A, 940mL, 01-03-0080 Premier Buffer A, 3.8L, 42663 Menarini Buffer A, 940mL, 45065 Menarini Buffer A, 3.8L, 01-03-0096 Premier Buffer B, 940mL, 01-03-0081 Premier Buffer B, 3.8L, 42664 Menarini Buffer B, 940mL, 45066 Menarini Buffer B, 3.8L, 03-06-0070 Tri-stat Reagent Kit (30), 03-06-0072 Tri-stat Reagent Kit (90)

**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 device

**1.2.2. Uses advised against**

Restrictions on use : No additional information available

**1.3. Details of the supplier of the safety data sheet****Manufacturer**

Trinity Biotech  
4231 E. 75th Terrace  
Kansas City, MO 64132 USA

**Authorized representative**

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  
haemoglobins.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)

**SECTION 2: Hazards identification****2.1. Classification of the substance or mixture****Classification according to Regulation (EC) No. 1272/2008 [CLP]**

Skin corrosion/irritation, Category 2 H315

Serious eye damage/eye irritation, Category 2 H319

Skin sensitisation, Category 1 H317

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

**Adverse physicochemical, human health and environmental effects**

Causes skin irritation. Causes serious eye irritation. May cause an allergic skin reaction.

**2.2. Label elements****Labelling according to Regulation (EC) No. 1272/2008 [CLP]**

Hazard pictograms (CLP) :



GHS07

Signal word (CLP) : Warning

# Premier Buffer A, Menarini Buffer A, Premier Buffer B, Menarini Buffer B, Tri-stat Reagent Kit

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according to Regulation (EU) 2020/878

Contains	: 2-methylisothiazol-3(2H)-one
Hazard statements (CLP)	: H315 - Causes skin irritation. H317 - May cause an allergic skin reaction. H319 - Causes serious eye irritation.
Precautionary statements (CLP)	: P264 - Wash hands thoroughly after handling. P280 - Wear protective gloves, protective clothing, eye protection, face protection. P302+P352 - IF ON SKIN: Wash with plenty of soap and water. P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P333+P313 - If skin irritation or rash occurs: Get medical advice/attention. P337+P313 - If eye irritation persists: Get medical advice/attention. P501 - Dispose of contents and 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  $\geq 0.1\%$  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]
ethanol substance with national workplace exposure limit(s) (IE)	CAS-No.: 64-17-5 EC-No.: 200-578-6 EC Index-No.: 603-002-00-5	> 3 - < 4	Flam. Liq. 2, H225
ammonia (Note B)	CAS-No.: 1336-21-6 EC-No.: 215-647-6 EC Index-No.: 007-001-01-2	> 0.5 - < 3	Met. Corr. 1, H290 Skin Corr. 1B, H314 STOT SE 3, H335 Aquatic Acute 1, H400
acetic acid substance with national workplace exposure limit(s) (IE); substance with a Community workplace exposure limit (Note B)	CAS-No.: 64-19-7 EC-No.: 200-580-7 EC Index-No.: 607-002-00-6	> 0.5 - < 1.5	Flam. Liq. 3, H226 Met. Corr. 1, H290 Acute Tox. 4 (Dermal), H312 Acute Tox. 4 (Inhalation), H332 Skin Corr. 1A, H314
methanol substance with national workplace exposure limit(s) (IE); substance with a Community workplace exposure limit	CAS-No.: 67-56-1 EC-No.: 200-659-6 EC Index-No.: 603-001-00-X	$\leq 0.2$	Flam. Liq. 2, H225 Acute Tox. 3 (Inhalation), H331 Acute Tox. 3 (Dermal), H311 Acute Tox. 3 (Oral), H301 STOT SE 1, H370
propan-2-ol substance with national workplace exposure limit(s) (IE)	CAS-No.: 67-63-0 EC-No.: 200-661-7 EC Index-No.: 603-117-00-0	$\leq 0.2$	Flam. Liq. 2, H225 Eye Irrit. 2, H319 STOT SE 3, H336

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Name	Product identifier	Conc.	Classification according to Regulation (EC) No. 1272/2008 [CLP]
2-methylisothiazol-3(2H)-one	CAS-No.: 2682-20-4 EC-No.: 220-239-6 EC Index-No.: 613-326-00-9	≤ 0.005	Acute Tox. 2 (Inhalation), H330 Acute Tox. 3 (Dermal), H311 Acute Tox. 3 (Oral), H301 Skin Corr. 1B, H314 Eye Dam. 1, H318 Skin Sens. 1A, H317 Aquatic Acute 1, H400 (M=10) Aquatic Chronic 1, H410 (M=1)

Specific concentration limits:		
Name	Product identifier	Specific concentration limits (Conc.)
ammonia	CAS-No.: 1336-21-6 EC-No.: 215-647-6 EC Index-No.: 007-001-01-2	(5 ≤ C ≤ 100) STOT SE 3, H335
acetic acid	CAS-No.: 64-19-7 EC-No.: 200-580-7 EC Index-No.: 607-002-00-6	(10 ≤ C < 25) Skin Irrit. 2, H315 (10 ≤ C < 25) Eye Irrit. 2, H319 (25 ≤ C < 90) Skin Corr. 1B, H314 (90 ≤ C ≤ 100) Skin Corr. 1A, H314
methanol	CAS-No.: 67-56-1 EC-No.: 200-659-6 EC Index-No.: 603-001-00-X	(3 ≤ C < 10) STOT SE 2, H371 (10 ≤ C ≤ 100) STOT SE 1, H370
2-methylisothiazol-3(2H)-one	CAS-No.: 2682-20-4 EC-No.: 220-239-6 EC Index-No.: 613-326-00-9	(0.0015 ≤ C ≤ 100) Skin Sens. 1A, H317

Note B: Some substances (acids, bases, etc.) are placed on the market in aqueous solutions at various concentrations and, therefore, these solutions require different classification and labelling since the hazards vary at different concentrations. In Part 3 entries with Note B have a general designation of the following type: '... %'. In this case the supplier must state the percentage concentration of the solution on the label. Unless otherwise stated, it is assumed that the percentage concentration is calculated on a weight/weight basis.

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 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 you feel unwell, seek medical advice.
First-aid measures after skin contact	: Wash skin thoroughly with mild soap and water. Take off contaminated clothing and wash it before reuse. If skin irritation or rash occurs: Get medical advice/attention.
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	: Do not induce vomiting. Rinse mouth out with water. Get medical advice/attention if you feel unwell.

### 4.2. Most important symptoms and effects, both acute and delayed

Symptoms/effects after inhalation	: At high concentrations, the vapours can be irritating to the respiratory system.
Symptoms/effects after skin contact	: Causes skin irritation. May cause an allergic skin reaction. Rednesses. Itching. Swelling. Allergic skin rash.
Symptoms/effects after eye contact	: Causes serious eye irritation. Blurred vision. redness, itching, tears.
Symptoms/effects after ingestion	: Abdominal pain, nausea.

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### 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 powder. Carbon dioxide. Water spray. 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. Carbon dioxide. Carbon monoxide.

### 5.3. Advice for firefighters

- Firefighting instructions : Evacuate the danger area. Move containers from fire area if it can be done without personal risk. Use water spray or fog for cooling exposed containers. Fight fire from safe distance and protected location. Use extinguishing media appropriate for surrounding fire. 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 attempt to take action without suitable protective equipment.

## SECTION 6: Accidental release measures

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

- General measures : Avoid all contact with skin, eyes, or clothing.

#### 6.1.1. For non-emergency personnel

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

#### 6.1.2. For emergency responders

- Protective equipment : Do not attempt to take action without suitable protective equipment.
- Emergency procedures : Evacuate unnecessary personnel. Ventilate area.

### 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. Recover small spills with a suitable absorbent, like diatomaceous earth. For large spills, confine the spill in a dike and charge it with wet sand or earth for subsequent safe disposal. Ventilate spillage area. Clean contaminated surfaces with an excess of water. Prevent entry to sewers and public waters.
- 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

- Precautions for safe handling : Take all necessary technical measures to avoid or minimize the release of the product on the workplace. Ensure good ventilation of the work station. Provide local exhaust or general room ventilation. Do not breathe vapours. Wear personal protective equipment. Do not get in eyes, on skin, or on clothing.
- 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. 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, Strong oxidizers, Store in a dry place. 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

methanol (67-56-1)	
<b>EU - Indicative Occupational Exposure Limit (IOEL)</b>	
Local name	Methanol
IOEL TWA	260 mg/m <sup>3</sup>
IOEL TWA [ppm]	200 ppm
Remark	Skin
Regulatory reference	COMMISSION DIRECTIVE 2006/15/EC
<b>Ireland - Occupational Exposure Limits</b>	
Local name	Methanol [Methyl alcohol]
OEL TWA [1]	260 mg/m <sup>3</sup>
OEL TWA [2]	200 ppm
Remark	Sk (Substances which have the capacity to penetrate intact skin when they come in contact with it, and be absorbed into the body), IOELV (Indicative Occupational Exposure Limit Values)
Regulatory reference	Chemical Agents Code of Practice 2021
<b>Ireland - Biological limit values</b>	
Local name	Methanol
Ireland - BMGV	15 mg/l Parameter: methanol - Medium: urine - Sampling time: End of shift - Notations: B (Background), Ns (Non-specific)
Regulatory reference	Biological Monitoring Guidelines (HSA, 2011)

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<b>ethanol (64-17-5)</b>	
<b>Ireland - Occupational Exposure Limits</b>	
Local name	Ethanol [Ethyl alcohol]
OEL STEL [ppm]	1000 ppm
Regulatory reference	Chemical Agents Code of Practice 2021
<b>propan-2-ol (67-63-0)</b>	
<b>Ireland - Occupational Exposure Limits</b>	
Local name	Isopropyl alcohol [Propan-2-ol]
OEL TWA [2]	200 ppm
OEL STEL [ppm]	400 ppm
Remark	Sk (Substances which have the capacity to penetrate intact skin when they come in contact with it, and be absorbed into the body)
Regulatory reference	Chemical Agents Code of Practice 2021
<b>Ireland - Biological limit values</b>	
Local name	2-Propanol
Ireland - BMGV	40 mg/l Parameter: acetone - Medium: urine - Sampling time: End of shift at end of workweek - Notations: B (Background), Ns (Non-specific)
Regulatory reference	Biological Monitoring Guidelines (HSA, 2011)

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acetic acid (64-19-7)	
<b>EU - Indicative Occupational Exposure Limit (IOEL)</b>	
Local name	Acetic acid
IOEL TWA	25 mg/m <sup>3</sup>
IOEL TWA [ppm]	10 ppm
IOEL STEL	50 mg/m <sup>3</sup>
IOEL STEL [ppm]	20 ppm
Regulatory reference	COMMISSION DIRECTIVE (EU) 2017/164
<b>Ireland - Occupational Exposure Limits</b>	
Local name	Acetic acid
OEL TWA [1]	25 mg/m <sup>3</sup>
OEL TWA [2]	10 ppm
OEL STEL	50 mg/m <sup>3</sup>
OEL STEL [ppm]	20 ppm
Remark	IOELV (Indicative Occupational Exposure Limit Values)
Regulatory reference	Chemical Agents Code of Practice 2021

### 8.1.2. Recommended monitoring procedures

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

### 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

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### 8.2. Exposure controls

#### 8.2.1. Appropriate engineering controls

##### Appropriate engineering controls:

Provide local exhaust or general room ventilation. Ensure exposure is below occupational exposure limits (where available). Handle in accordance with good industrial hygiene and safety procedures. 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.

##### 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 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. Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil.

## SECTION 9: Physical 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
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



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Relative density : Not available  
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 of use.

### 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). Protect from sunlight. Overheating. Extremely high or low temperatures.

### 10.5. Incompatible materials

Oxidising 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)

ethanol (64-17-5)	
LD50 oral rat	10470 mg/kg (OECD 401)
LD50 oral	3450 mg/kg mouse
LC50 Inhalation - Rat	117 – 125 mg/l/4h (OECD 403)
propan-2-ol (67-63-0)	
LD50 oral rat	5840 mg/kg
LD50 dermal rat	13900 mg/kg
LD50 dermal rabbit	12870 mg/kg
LC50 Inhalation - Rat	72.6 mg/l/4h

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acetic acid (64-19-7)	
LD50 oral rat	3310
LD50 dermal rabbit	1060
LC50 Inhalation - Rat	11.4 mg/l (4 h)

Skin corrosion/irritation	: Causes skin irritation.
Serious eye damage/irritation	: Causes serious eye irritation.
Respiratory or skin sensitisation	: May cause an allergic skin reaction.
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	: Not classified (Based on available data, the classification criteria are not met)
STOT-single exposure	: Not classified (Based on available data, the classification criteria are not met)

methanol (67-56-1)	
STOT-single exposure	Causes damage to organs.

propan-2-ol (67-63-0)	
STOT-single exposure	May cause drowsiness or dizziness.

ammonia (1336-21-6)	
STOT-single exposure	May cause respiratory irritation.

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.

ethanol (64-17-5)	
LC50 - Fish [1]	14200 mg/l (96 h, Pimephales promelas)
EC50 - Crustacea [1]	9268 mg/l (48 h)
EC50 - Crustacea [2]	10800 mg/l (24 h)
EC50 - Other aquatic organisms [1]	34634 mg/l (30 min, Photobacterium phosphoreum)

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<b>ethanol (64-17-5)</b>	
EC50 - Other aquatic organisms [2]	35470 mg/l (5 min, Photobacterium phosphoreum)
EC50 72h - Algae [1]	275 mg/l (72 h, Chlorella vulgaris)
<b>propan-2-ol (67-63-0)</b>	
LC50 - Fish [1]	9640 (96 h, Pimephales promelas, flow-through test)
LC50 - Fish [2]	> 1400000 µg/l
EC50 - Crustacea [1]	13299 mg/l (48 h)
EC50 - Crustacea [2]	9714 mg/l (24 h)
EC50 - Other aquatic organisms [1]	35390 mg/l (5 min, Photobacterium phosphoreum)
EC50 72h - Algae [1]	> 1000 mg/l (72 h, Desmodesmus subspicatus)
EC50 96h - Algae [1]	> 1000 mg/l (96 h, Desmodesmus subspicatus)
<b>acetic acid (64-19-7)</b>	
LC50 - Fish [1]	75 mg/l (96 h, Lepomis macrochirus)
EC50 - Crustacea [1]	65 mg/l (48 h, Daphnia magna)

### 12.2. Persistence and degradability

<b>Premier Buffer A, Menarini Buffer A, Premier Buffer B, Menarini Buffer B, Tri-stat Reagent Kit</b>	
Persistence and degradability	Biodegradability in water: no data available.

### 12.3. Bioaccumulative potential

<b>Premier Buffer A, Menarini Buffer A, Premier Buffer B, Menarini Buffer B, Tri-stat Reagent Kit</b>	
Bioaccumulative potential	No data available concerning bioaccumulation.

<b>ethanol (64-17-5)</b>	
Partition coefficient n-octanol/water (Log Pow)	-0.32

<b>propan-2-ol (67-63-0)</b>	
Partition coefficient n-octanol/water (Log Pow)	0.05

<b>ammonia (1336-21-6)</b>	
Partition coefficient n-octanol/water (Log Pow)	-1.38

### 12.4. Mobility in soil

<b>Premier Buffer A, Menarini Buffer A, Premier Buffer B, Menarini Buffer B, Tri-stat Reagent Kit</b>	
Ecology - soil	No additional information available.

### 12.5. Results of PBT and vPvB assessment

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 %.

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### 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.  
Sewage disposal recommendations : Do not dispose of waste into sewer.  
Product/Packaging disposal recommendations : Dispose in a safe manner in accordance with local/national regulations.  
Ecology - waste materials : Avoid release to the environment.  
European List of Waste (LoW) code : Disposal must be carried out using appropriate EWC code

## SECTION 14: Transport information

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

ADR	IMDG	IATA	ADN	RID
<b>14.1. UN number or ID number</b>				
Not regulated for transport				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
<b>14.2. UN proper shipping name</b>				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
<b>14.3. Transport hazard class(es)</b>				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
<b>14.4. Packing group</b>				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
<b>14.5. Environmental hazards</b>				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
No supplementary information available				

### 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

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### 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) in concentrations above or equal to the limit values

###### REACH Candidate List (SVHC)

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

###### 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
IATA	International Air Transport Association
IMDG	International Maritime Dangerous Goods

# Premier Buffer A, Menarini Buffer A, Premier Buffer B, Menarini Buffer B, Tri-stat Reagent Kit

## Safety Data Sheet

according to Regulation (EU) 2020/878

Abbreviations and acronyms:	
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:	
Acute Tox. 2 (Inhalation)	Acute toxicity (inhal.), Category 2
Acute Tox. 3 (Dermal)	Acute toxicity (dermal), Category 3
Acute Tox. 3 (Inhalation)	Acute toxicity (inhal.), Category 3
Acute Tox. 3 (Oral)	Acute toxicity (oral), Category 3
Acute Tox. 4 (Dermal)	Acute toxicity (dermal), Category 4
Acute Tox. 4 (Inhalation)	Acute toxicity (inhal.), Category 4
Aquatic Acute 1	Hazardous to the aquatic environment – Acute Hazard, Category 1
Aquatic Chronic 1	Hazardous to the aquatic environment – Chronic Hazard, Category 1
Eye Dam. 1	Serious eye damage/eye irritation, Category 1
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
Flam. Liq. 2	Flammable liquids, Category 2
Flam. Liq. 3	Flammable liquids, Category 3
H225	Highly flammable liquid and vapour.
H226	Flammable liquid and vapour.
H290	May be corrosive to metals.
H301	Toxic if swallowed.
H311	Toxic in contact with skin.
H312	Harmful in contact with skin.
H314	Causes severe skin burns and eye damage.

# Premier Buffer A, Menarini Buffer A, Premier Buffer B, Menarini Buffer B, Tri-stat Reagent Kit

## Safety Data Sheet

according to Regulation (EU) 2020/878

Full text of H- and EUH-statements:	
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H330	Fatal if inhaled.
H331	Toxic if inhaled.
H332	Harmful if inhaled.
H335	May cause respiratory irritation.
H336	May cause drowsiness or dizziness.
H370	Causes damage to organs.
H371	May cause damage to organs.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
Met. Corr. 1	Corrosive to metals, Category 1
Skin Corr. 1A	Skin corrosion/irritation, Category 1, Sub-Category 1A
Skin Corr. 1B	Skin corrosion/irritation, Category 1, Sub-Category 1B
Skin Irrit. 2	Skin corrosion/irritation, Category 2
Skin Sens. 1A	Skin sensitisation, category 1A
STOT SE 1	Specific target organ toxicity – single exposure, Category 1
STOT SE 2	Specific target organ toxicity – Single exposure, Category 2
STOT SE 3	Specific target organ toxicity – Single exposure, Category 3, Narcosis

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:		
Skin Irrit. 2	H315	Calculation method
Eye Irrit. 2	H319	Calculation method
Skin Sens. 1	H317	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.