

# SAFETY DATA SHEET

according to Regulation (EC) No 1907/2006 (REACH) as amended

## DryFlowEx PNH High-Sensitivity Assay Kit

Date of creation 21st July 2023

Date of revision 24th February 2026

Version

2

### PRODUCT IDENTIFICATION

| Cat. No. | Product name                             |
|----------|------------------------------------------|
| ED7750   | DryFlowEx PNH High-Sensitivity Assay Kit |

### COMPONENTS OF THE KIT

| Code     | Name                 | Classification                                                                      |
|----------|----------------------|-------------------------------------------------------------------------------------|
| ED7750-1 | PNH WBC 7-color      | Not classified as hazardous.                                                        |
| ED7750-2 | PNH RBC 3-color      | Not classified as hazardous.                                                        |
| ED7750-3 | Lysing Solution      |  |
| ED7750-4 | PNH Compensation Set | Not classified as hazardous.                                                        |

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according to Regulation (EC) No 1907/2006 (REACH) as amended

## PNH WBC 7-color, PNH RBC 3-color, PNH Compensation Set

|               |                    |              |   |
|---------------|--------------------|--------------|---|
| Creation date | 21st July 2023     | Revision no. | 1 |
| Revision date | 24th February 2026 | Version      | 2 |

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

#### 1.1. Product identifier

|                     |                                                              |
|---------------------|--------------------------------------------------------------|
| Substance / mixture | PNH WBC 7-color,<br>PNH RBC 3-color,<br>PNH Compensation Set |
| Number              | mixture<br>ED7750-1<br>ED7750-2<br>ED7750-4                  |

#### 1.2. Relevant identified uses of the substance or mixture and uses advised against Mixture's intended use

Diagnostic reagent

##### The use descriptors

|         |                                     |
|---------|-------------------------------------|
| SU 24   | Scientific research and development |
| PC 21   | Laboratory chemicals                |
| PROC 15 | Use as laboratory reagent           |

##### Mixture uses advised against

The product should not be used in ways other than those referred in Section 1.

#### 1.3. Details of the supplier of the safety data sheet

##### Manufacturer

|                    |                                                       |
|--------------------|-------------------------------------------------------|
| Name or trade name | EXBIO Praha, a.s.                                     |
| Address            | Nad Safinou II / 341, Vestec, 25250<br>Czech Republic |
| Phone              | +420261090666                                         |
| E-mail             | orders@exbio.cz                                       |
| Web address        | www.exbio.cz                                          |

##### Competent person responsible for the safety data sheet

|        |                   |
|--------|-------------------|
| Name   | EXBIO Praha, a.s. |
| E-mail | orders@exbio.cz   |

#### 1.4. Emergency telephone number

National Health Service (NHS) 111  
National poisoning information centre Scotland, NHS 24: 111

### SECTION 2: Hazards identification

#### 2.1. Classification of the substance or mixture

##### Classification of the mixture in accordance with Regulation (EC) No 1272/2008

The mixture is not classified as dangerous according to Regulation (EC) No 1272/2008.

Full text of all classifications and hazard statements is given in the section 16.

#### 2.2. Label elements

none

#### 2.3. Other hazards

The mixture does not contain substances with endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605. Mixture does not contain any substance meet the criteria for PBT or vPvB in accordance with Annex XIII of Regulation (EC) No. 1907/2006 (REACH) as amended. Dust may form explosive mixture with air.

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according to Regulation (EC) No 1907/2006 (REACH) as amended

## PNH WBC 7-color, PNH RBC 3-color, PNH Compensation Set

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### SECTION 3: Composition/information on ingredients

#### 3.2. Mixtures

**Mixture contains these hazardous substances and substances with the highest permissible concentration in the working environment**

| Identification numbers                                  | Substance name | Content in % weight | Classification according to Regulation (EC) No 1272/2008                                                                                               | Note |
|---------------------------------------------------------|----------------|---------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------|------|
| Index: 011-004-00-7<br>CAS: 26628-22-8<br>EC: 247-852-1 | sodium azide   | 0,1-0,2             | Acute Tox. 2, H300+H330<br>Acute Tox. 1, H310<br>STOT RE 2, H373 (ingestion)<br>Aquatic Acute 1, H400 (M=1)<br>Aquatic Chronic 1, H410 (M=1)<br>EUH032 | 1    |

#### Notes

1 A substance for which exposure limits are set.

Full text of all classifications and hazard statements is given in the section 16.

### SECTION 4: First aid measures

#### 4.1. Description of first aid measures

Take care of your own safety. If any health problems are manifested or if in doubt, inform a doctor and show him information from this safety data sheet.

##### If inhaled

Terminate the exposure immediately; move the affected person to fresh air.

##### If on skin

Remove contaminated clothes.

##### If in eyes

Rinse eyes immediately with a flow of running water, open the eyelids (also using force if needed); remove contact lenses immediately if worn by the affected person.

##### If swallowed

Rinse out the mouth with clean water. In the event of issues, find medical help.

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

##### If inhaled

Not expected.

##### If on skin

Not expected.

##### If in eyes

Not expected.

##### If swallowed

Not expected.

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

Symptomatic treatment.

### SECTION 5: Firefighting measures

#### 5.1. Extinguishing media

##### Suitable extinguishing media

Accommodate extinguishing components to the location of fire.

##### Unsuitable extinguishing media

not available

#### 5.2. Special hazards arising from the substance or mixture

In the event of fire, carbon monoxide, carbon dioxide and other toxic gases may arise. Inhalation of hazardous degradation (pyrolysis) products may cause serious health damage.

#### 5.3. Advice for firefighters

Self-Contained Breathing Apparatus (SCBA) with chemical resistant gloves. Use a self-contained breathing apparatus and full-body protective clothing.

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### SECTION 6: Accidental release measures

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

Follow the instructions in the Sections 7 and 8.

#### 6.2. Environmental precautions

Prevent contamination of the soil and entering surface or ground water.

#### 6.3. Methods and material for containment and cleaning up

Place the product mechanically in an appropriate manner. Dispose of the collected material according to the instructions in the section 13.

#### 6.4. Reference to other sections

See the Section 7, 8 and 13.

### SECTION 7: Handling and storage

#### 7.1. Precautions for safe handling

Prevent formation of gases and vapours in concentrations exceeding the occupational exposure limits. Use personal protective equipment as per Section 8. Observe valid legal regulations on safety and health protection.

#### 7.2. Conditions for safe storage, including any incompatibilities

Store in tightly closed containers in cold, dry and well ventilated areas designated for this purpose.

#### 7.3. Specific end use(s)

not available

### SECTION 8: Exposure controls/personal protection

#### 8.1. Control parameters

The mixture contains substances for which occupational exposure limits are set.

#### United Kingdom

#### EH40/2005 Workplace exposure limits (Fourth Edition 2020)

| Substance name (component)                            | Type      | Value                 | Note                                                                                                                                                    |
|-------------------------------------------------------|-----------|-----------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------|
| sodium azide (as NaN <sub>3</sub> ) (CAS: 26628-22-8) | WEL 8h    | 0,1 mg/m <sup>3</sup> | Can be absorbed through the skin. The assigned substances are those for which there are concerns that dermal absorption will lead to systemic toxicity. |
|                                                       | WEL 15min | 0,3 mg/m <sup>3</sup> |                                                                                                                                                         |

#### 8.2. Exposure controls

Do not eat, drink and smoke during work. Wash your hands thoroughly with water and soap after work and before breaks for a meal and rest.

##### Eye/face protection

It is not needed.

##### Skin protection

Hand protection: Protective gloves resistant to the product. When handling in long-term or repeatedly, use protective gloves.

##### Respiratory protection

It is not needed.

##### Thermal hazard

Not available.

##### Environmental exposure controls

Observe usual measures for protection of the environment, see Section 6.2.

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### SECTION 9: Physical and chemical properties

#### 9.1. Information on basic physical and chemical properties

|                                              |                    |
|----------------------------------------------|--------------------|
| Appearance                                   |                    |
| physical state                               | solid at 20 °C     |
| color                                        | colourless         |
| Odour                                        | without fragrance  |
| pH                                           | data not available |
| Melting point/freezing point                 | data not available |
| Initial boiling point and boiling range      | data not available |
| Flash point                                  | data not available |
| Flammability (solid, gas)                    | data not available |
| Upper/lower flammability or explosive limits |                    |
| explosive limits                             | data not available |
| Vapour pressure                              | data not available |
| Solubility(ies)                              |                    |
| solubility in water                          | soluble            |
| Partition coefficient: n-octanol/water       | data not available |
| Auto-ignition temperature                    | data not available |
| Decomposition temperature                    | data not available |
| Viscosity                                    |                    |
| Kinematic viscosity                          | data not available |

#### 9.2. Other information

not available

### SECTION 10: Stability and reactivity

#### 10.1. Reactivity

The mixture is not reactive under normal conditions of use and storage. Sodium azide can react with metals contained in sewage to form lead or copper azide, which can explode on impact. When reacting with acids, sodium azide can release highly toxic hydrogen azide acid / hydrogen azide gas.

#### 10.2. Chemical stability

The product is stable under normal conditions.

#### 10.3. Possibility of hazardous reactions

Sodium azide can react with metals contained in sewage to form lead or copper azide, which can explode on impact.

#### 10.4. Conditions to avoid

The product is stable and no degradation occurs under normal use. Protect against flames, sparks, overheating and against frost.

#### 10.5. Incompatible materials

Protect against strong acids, bases and oxidizing agents.

#### 10.6. Hazardous decomposition products

Not developed under normal uses. Dangerous outcomes such as carbon monoxide and carbon dioxide are formed at high temperature and in fire.

### SECTION 11: Toxicological information

#### 11.1. Information on toxicological effects

Inhalation of solvent vapors above values exceeding exposure limits for working environment may result in acute inhalation poisoning, depending on the level of concentration and exposure time. No toxicological data is available for the mixture.

##### Acute toxicity

Data for the mixture are not available. Based on the available data, the criteria for classification of the mixture are not met.

| sodium azide      |                  |          |               |                         |     |
|-------------------|------------------|----------|---------------|-------------------------|-----|
| Route of exposure | Parameter        | Value    | Exposure time | Species                 | Sex |
| Oral              | LD <sub>50</sub> | 27 mg/kg |               | Rat (Rattus norvegicus) |     |
| Dermal            | LD <sub>50</sub> | 20 mg/kg |               | Rabbit                  |     |

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| Inhalation    | LC50 | 0.054 mg/l         | 4 hours | Rat (Rattus norvegicus) |  |   |  |

### Skin corrosion/irritation

No data are available for either the mixture or the components. Based on the available data, the criteria for classification of the mixture are not met.

### Serious eye damage/irritation

No data are available for either the mixture or the components. Based on the available data, the criteria for classification of the mixture are not met.

### Respiratory or skin sensitisation

No data are available for either the mixture or the components. Based on the available data, the criteria for classification of the mixture are not met.

### Germ cell mutagenicity

No data are available for either the mixture or the components. Based on the available data, the criteria for classification of the mixture are not met.

### Carcinogenicity

No data are available for either the mixture or the components. Based on the available data, the criteria for classification of the mixture are not met.

### Reproductive toxicity

No data are available for either the mixture or the components. Based on the available data, the criteria for classification of the mixture are not met.

### Toxicity for specific target organ - single exposure

No data are available for either the mixture or the components. Based on the available data, the criteria for classification of the mixture are not met.

### Toxicity for specific target organ - repeated exposure

No data are available for either the mixture or the components. Based on the available data, the criteria for classification of the mixture are not met.

### Aspiration hazard

No data are available for either the mixture or the components. Based on the available data, the criteria for classification of the mixture are not met.

## SECTION 12: Ecological information

### 12.1. Toxicity

Data for the mixture are not available. Based on the available data, the criteria for classification of the mixture are not met.

#### Acute toxicity

| sodium azide     |          |               |                       |             |
|------------------|----------|---------------|-----------------------|-------------|
| Parameter        | Value    | Exposure time | Species               | Environment |
| EC <sub>50</sub> | 5.6 mg/l | 48 hours      | Aquatic invertebrates |             |

### 12.2. Persistence and degradability

No data are available for either the mixture or the components.

### 12.3. Bioaccumulative potential

No data are available for either the mixture or the components.

### 12.4. Mobility in soil

No data are available for either the mixture or the components.

### 12.5. Results of PBT and vPvB assessment

Product does not contain any substance meeting the criteria for PBT or vPvB in accordance with the Annex XIII of

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Regulation (EC) No 1907/2006 (REACH) as amended.

### 12.6. Other adverse effects

The mixture does not contain substances with endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605.

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

Hazard of environmental contamination; dispose of the waste in accordance with the local and/or national regulations. Proceed in accordance with valid regulations on waste disposal. Any unused product and contaminated packaging should be put in labelled containers for waste collection and submitted for disposal to a person authorised for waste removal (a specialized company) that is entitled for such activity. Do not empty unused product in drainage systems. The product must not be disposed of with municipal waste. Empty containers may be used at waste incinerators to produce energy or deposited in a dump with appropriate classification. Perfectly cleaned containers can be submitted for recycling.

#### Waste management legislation

Producer Responsibility Obligations (Packaging Waste) Regulations 2007 (S.I. No. 871 of 2007). Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste, as amended. Decision 2000/532/EC establishing a list of wastes, as amended.

## SECTION 14: Transport information

### 14.1. UN number

not subject to transport regulations

### 14.2. UN proper shipping name

not relevant

### 14.3. Transport hazard class(es)

not relevant

### 14.4. Packing group

not relevant

### 14.5. Environmental hazards

not relevant

### 14.6. Special precautions for user

Reference in the Sections 4 to 8.

### 14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

not relevant

## SECTION 15: Regulatory information

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

Clean Air Act 1993 as amended. The Chemicals (Hazard Information and Packaging for Supply) Regulations 2009 as amended. Public health act 1961. Environmental Protection Act 1990 as amended. Regulation (EC) No. 1907/2006 of the European Parliament and of the Council of 18th December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing the European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No. 793/93 and Commission Regulation (EC) No. 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, as amended. REGULATION (EC) No. 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL as amended. Commission Regulation (EU) 2020/878 of 18 June 2020 amending Annex II to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

### 15.2. Chemical safety assessment

not available

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### SECTION 16: Other information

#### A list of standard risk phrases used in the safety data sheet

|           |                                                                                 |
|-----------|---------------------------------------------------------------------------------|
| H310      | Fatal in contact with skin.                                                     |
| H373      | May cause damage to organs through prolonged or repeated exposure if swallowed. |
| H400      | Very toxic to aquatic life.                                                     |
| H410      | Very toxic to aquatic life with long lasting effects.                           |
| H300+H330 | Fatal if swallowed or if inhaled.                                               |

#### A list of additional standard phrases used in the safety data sheet

|        |                                              |
|--------|----------------------------------------------|
| EUH032 | Contact with acids liberates very toxic gas. |
|--------|----------------------------------------------|

#### Other important information about human health protection

The product must not be - unless specifically approved by the manufacturer/importer - used for purposes other than as per the Section 1. The user is responsible for adherence to all related health protection regulations.

#### Key to abbreviations and acronyms used in the safety data sheet

|                  |                                                                                                   |
|------------------|---------------------------------------------------------------------------------------------------|
| ADR              | European agreement concerning the international carriage of dangerous goods by road               |
| BCF              | Bioconcentration Factor                                                                           |
| CAS              | Chemical Abstracts Service                                                                        |
| CLP              | Regulation (EC) No 1272/2008 on classification, labelling and packaging of substance and mixtures |
| EC               | Identification code for each substance listed in EINECS                                           |
| EC <sub>50</sub> | Concentration of a substance when it is affected 50% of the population                            |
| EINECS           | European Inventory of Existing Commercial Chemical Substances                                     |
| EmS              | Emergency plan                                                                                    |
| EU               | European Union                                                                                    |
| EuPCS            | European Product Categorisation System                                                            |
| IATA             | International Air Transport Association                                                           |
| IBC              | International Code For The Construction And Equipment of Ships Carrying Dangerous Chemicals       |
| ICAO             | International Civil Aviation Organization                                                         |
| IMDG             | International Maritime Dangerous Goods                                                            |
| INCI             | International Nomenclature of Cosmetic Ingredients                                                |
| ISO              | International Organization for Standardization                                                    |
| IUPAC            | International Union of Pure and Applied Chemistry                                                 |
| LC <sub>50</sub> | Lethal concentration of a substance in which it can be expected death of 50% of the population    |
| LD <sub>50</sub> | Lethal dose of a substance in which it can be expected death of 50% of the population             |
| log Kow          | Octanol-water partition coefficient                                                               |
| MARPOL           | International Convention for the Prevention of Pollution from Ships                               |
| OEL              | Occupational Exposure Limits                                                                      |
| PBT              | Persistent, Bioaccumulative and Toxic                                                             |
| ppm              | Parts per million                                                                                 |
| REACH            | Registration, Evaluation, Authorisation and Restriction of Chemicals                              |
| RID              | Agreement on the transport of dangerous goods by rail                                             |
| UN               | Four-figure identification number of the substance or article taken from the UN Model Regulations |
| UVCB             | Substances of unknown or variable composition, complex reaction products or biological materials  |
| VOC              | Volatile organic compounds                                                                        |
| vPvB             | Very Persistent and very Bioaccumulative                                                          |
| Acute Tox.       | Acute toxicity                                                                                    |
| Aquatic Acute    | Hazardous to the aquatic environment                                                              |
| Aquatic Chronic  | Hazardous to the aquatic environment (chronic)                                                    |
| STOT RE          | Specific target organ toxicity - repeated exposure                                                |

#### Training guidelines

Inform the personnel about the recommended ways of use, mandatory protective equipment, first aid and prohibited ways of handling the product.

#### Recommended restrictions of use



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not available

### Information about data sources used to compile the Safety Data Sheet

REGULATION (EC) No. 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL (REACH) as amended.  
REGULATION (EC) No. 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL as amended. Data from the manufacturer of the substance / mixture, if available - information from registration dossiers.

### The changes (which information has been added, deleted or modified)

Revision of the SDS component ED7750-3

### More information

Classification procedure - calculation method.

### Statement

The safety data sheet provides information aimed at ensuring safety and health protection at work and environmental protection. The provided information corresponds to the current status of knowledge and experience and complies with valid legal regulations. The information should not be understood as guaranteeing the suitability and usability of the product for a particular application.

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## Lysing Solution

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

**1.1. Product identifier**  
Substance / mixture  
Lysing Solution  
mixture  
Number  
ED7750-3

**1.2. Relevant identified uses of the substance or mixture and uses advised against**  
**Mixture's intended use**  
diagnostic reagent

#### The use descriptors

|         |                                     |
|---------|-------------------------------------|
| SU 24   | Scientific research and development |
| PC 21   | Laboratory chemicals                |
| PROC 15 | Use as laboratory reagent           |

#### Mixture uses advised against

The product should not be used in ways other than those referred in Section 1.

### 1.3. Details of the supplier of the safety data sheet

#### Manufacturer

|                    |                                                       |
|--------------------|-------------------------------------------------------|
| Name or trade name | EXBIO Praha, a.s.                                     |
| Address            | Nad Safinou II / 341, Vestec, 25250<br>Czech Republic |
| Phone              | +420261090666                                         |
| E-mail             | orders@exbio.cz                                       |
| Web address        | www.exbio.cz                                          |

#### Competent person responsible for the safety data sheet

|        |                   |
|--------|-------------------|
| Name   | EXBIO Praha, a.s. |
| E-mail | orders@exbio.cz   |

### 1.4. Emergency telephone number

National Health Service (NHS) 111  
National poisoning information centre Scotland, NHS 24: 111

### SECTION 2: Hazards identification

#### 2.1. Classification of the substance or mixture

##### Classification of the mixture in accordance with Regulation (EC) No 1272/2008

The mixture is classified as dangerous.

Acute Tox. 4, H302  
Skin Irrit. 2, H315  
Skin Sens. 1, H317  
Eye Irrit. 2, H319  
Acute Tox. 3, H331  
STOT SE 3, H335  
Muta. 2, H341  
Carc. 1B, H350  
STOT SE 2, H371  
STOT RE 2, H373 (kidneys) (ingestion)

Full text of all classifications and hazard statements is given in the section 16.

#### Most serious adverse effects on human health and the environment

May cause damage to the kidneys through prolonged or repeated exposure if swallowed. Causes skin irritation. May cause an allergic skin reaction. Causes serious eye irritation. May cause respiratory irritation. May cause cancer. Suspected of causing genetic defects. May cause damage to organs. Harmful if swallowed. Toxic if inhaled.

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### 2.2. Label elements

#### Hazard pictogram



#### Signal word

Danger

#### Hazardous substances

Diethylene glycol  
formaldehyde  
methanol

#### Hazard statements

|        |                                                                                      |
|--------|--------------------------------------------------------------------------------------|
| H302   | Harmful if swallowed.                                                                |
| H315   | Causes skin irritation.                                                              |
| H317   | May cause an allergic skin reaction.                                                 |
| H319   | Causes serious eye irritation.                                                       |
| H331   | Toxic if inhaled.                                                                    |
| H335   | May cause respiratory irritation.                                                    |
| H341   | Suspected of causing genetic defects.                                                |
| H350   | May cause cancer.                                                                    |
| H371   | May cause damage to organs.                                                          |
| H373   | May cause damage to the kidneys through prolonged or repeated exposure if swallowed. |
| EUH071 | Corrosive to the respiratory tract                                                   |

#### Precautionary statements

|           |                                                                  |
|-----------|------------------------------------------------------------------|
| P201      | Obtain special instructions before use.                          |
| P260      | Do not breathe vapours.                                          |
| P280      | Wear protective gloves/eye protection/face protection.           |
| P308+P313 | IF exposed or concerned: Get medical advice/attention.           |
| P403+P233 | Store in a well-ventilated place. Keep container tightly closed. |

#### Supplemental label elements

Restricted to professional users

### 2.3. Other hazards

The mixture does not contain substances with endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605. Mixture does not contain any substance meet the criteria for PBT or vPvB in accordance with Annex XIII of Regulation (EC) No. 1907/2006 (REACH) as amended.

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### SECTION 3: Composition/information on ingredients

#### 3.2. Mixtures

Mixture contains these hazardous substances and substances with the highest permissible concentration in the working environment

| Identification numbers                                                                                 | Substance name    | Content in % weight | Classification according to Regulation (EC) No 1272/2008                                                                                                                                                                                                                                                                             | Note       |
|--------------------------------------------------------------------------------------------------------|-------------------|---------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------|
| Index: 603-140-00-6<br>CAS: 111-46-6<br>EC: 203-872-2<br>Registration number:<br>01-2119457857-21-XXXX | Diethylene glycol | 20-30               | Acute Tox. 4, H302<br>STOT RE 2, H373 (kidneys)<br>(ingestion)                                                                                                                                                                                                                                                                       | 3          |
| Index: 605-001-00-5<br>CAS: 50-00-0<br>EC: 200-001-8<br>Registration number:<br>01-2119488953-20       | formaldehyde      | <13                 | Acute Tox. 4, H302<br>Skin Corr. 1B, H314<br>Skin Sens. 1A, H317<br>Acute Tox. 2, H330<br>Muta. 2, H341<br>Carc. 1B, H350<br>EUH071<br>Specific concentration limit:<br>STOT SE 3, H335: C ≥ 5 %<br>Skin Corr. 1B, H314: C ≥ 25 %<br>Skin Irrit. 2, H315: 5 % ≤ C < 25 %<br>Eye Irrit. 2, H319: 5 % ≤ C < 25 %<br>Acute Tox. 4, H302 | 1, 2, 3, 4 |
| Index: 603-001-00-X<br>CAS: 67-56-1<br>EC: 200-659-6<br>Registration number:<br>01-2119433307-44       | methanol          | <4                  | Flam. Liq. 2, H225<br>Acute Tox. 3, H301+H311+H331<br>STOT SE 1 (**), H370<br>Specific concentration limit:<br>STOT SE 1, H370: C ≥ 10 %<br>STOT SE 2, H371: 3 % ≤ C < 10 %                                                                                                                                                          | 3, 4       |

#### Notes

\*\* another exposure route cannot be ruled out

- 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: 'nitric acid ... %'. 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.
- Note D: Certain substances which are susceptible to spontaneous polymerisation or decomposition are generally placed on the market in a stabilised form. It is in this form that they are listed in Part 3 of Annex VI to Regulation (EC) No 1272/2008. However, such substances are sometimes placed on the market in a non-stabilised form. In this case, the supplier who places such a substance on the market must state on the label the name of the substance followed by the words "non-stabilised".
- A substance for which exposure limits are set.
- The use of the substance is restricted by Annex XVII of REACH Regulation

Full text of all classifications and hazard statements is given in the section 16.

### SECTION 4: First aid measures

#### 4.1. Description of first aid measures

Take care of your own safety. If any health problems are manifested or if in doubt, inform a doctor and show him information from this safety data sheet. If unconscious, put the person in the stabilized (recovery) position on his side with his head slightly bent backwards and make sure that airways are free; never induce vomiting. If the person vomits by himself, make sure that the vomit is not inhaled. In life threatening conditions first of all provide resuscitation of the affected person and ensure medical assistance. Respiratory arrest - provide artificial respiration immediately. Cardiac arrest - provide indirect cardiac massage immediately.

#### If inhaled

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Terminate the exposure immediately; move the affected person to fresh air. Protect the person against growing cold. Provide medical treatment if irritation, dyspnoea or other symptoms persist.

### **If on skin**

Remove contaminated clothes. Wash the affected area with plenty of water, lukewarm if possible. Soap, soap solution or shampoo should be used if there is no skin injury. Provide medical treatment if skin irritation persists.

### **If in eyes**

Rinse eyes immediately with a flow of running water, open the eyelids (also using force if needed); remove contact lenses immediately if worn by the affected person. Rinsing should continue at least for 10 minutes. Provide medical treatment, specialized if possible.

### **If swallowed**

Provide medical treatment. For persons with no symptoms, call the Toxicological Information Centre to decide about the need of medical treatment; provide information about the substances or composition of the product from the original packaging or the Safety Data Sheet of the product.

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

### **If inhaled**

Cough, headache. May cause respiratory irritation.

### **If on skin**

May cause an allergic skin reaction.

### **If in eyes**

Causes serious eye irritation.

### **If swallowed**

Irritation, nausea.

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

Symptomatic treatment.

## **SECTION 5: Firefighting measures**

### **5.1. Extinguishing media**

#### **Suitable extinguishing media**

Alcohol-resistant foam, carbon dioxide, powder, water spray jet, water mist.

#### **Unsuitable extinguishing media**

Water - full jet.

### **5.2. Special hazards arising from the substance or mixture**

In the event of fire, carbon monoxide, carbon dioxide and other toxic gases may arise. Inhalation of hazardous degradation (pyrolysis) products may cause serious health damage.

### **5.3. Advice for firefighters**

Self-Contained Breathing Apparatus (SCBA) with a chemical protection suit only where personal (close) contact is likely. Use a self-contained breathing apparatus and full-body protective clothing. Do not allow run-off of contaminated fire extinguishing material to enter drains or surface and ground water.

## **SECTION 6: Accidental release measures**

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

Use personal protective equipment for work. Follow the instructions in the Sections 7 and 8. Do not inhale mist/vapours/spray. Prevent contact with skin and eyes.

### **6.2. Environmental precautions**

Prevent contamination of the soil and entering surface or ground water.

### **6.3. Methods and material for containment and cleaning up**

Spilled product should be covered with suitable (non-flammable) absorbing material (sand, diatomaceous earth, earth and other suitable absorption materials); to be contained in well closed containers and removed as per the Section 13. In the event of leakage of the substantial amount of the product, inform fire brigade and other competent bodies. After removal of the product, wash the contaminated site with plenty of water. Do not use solvents.

### **6.4. Reference to other sections**

See the Section 7, 8 and 13.

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### SECTION 7: Handling and storage

#### 7.1. Precautions for safe handling

Prevent formation of gases and vapours in concentrations exceeding the occupational exposure limits. Do not inhale mist/vapours/spray. Prevent contact with skin and eyes. Contaminated work clothing should not be allowed out of the workplace. Obtain special instructions before use. Do not eat, drink or smoke when using this product. Wash hands and exposed parts of the body thoroughly after handling. Do not handle until all safety precautions have been read and understood. Use only outdoors or in a well-ventilated area. Use personal protective equipment as per Section 8. Observe valid legal regulations on safety and health protection.

#### 7.2. Conditions for safe storage, including any incompatibilities

Store in tightly closed containers in cold, dry and well ventilated areas designated for this purpose. Store locked up. Keep container tightly closed.

#### 7.3. Specific end use(s)

diagnostic reagent

### SECTION 8: Exposure controls/personal protection

#### 8.1. Control parameters

The mixture contains substances for which occupational exposure limits are set.

#### United Kingdom

#### EH40/2005 Workplace exposure limits (Fourth Edition 2020)

| Substance name (component)         | Type      | Value                 | Note                                                                                                                                                    |
|------------------------------------|-----------|-----------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------|
| 2,2'-oxybisethanol (CAS: 111-46-6) | WEL 8h    | 101 mg/m <sup>3</sup> |                                                                                                                                                         |
|                                    | WEL 8h    | 23 ppm                |                                                                                                                                                         |
| formaldehyde ...% (CAS: 50-00-0)   | WEL 8h    | 2,5 mg/m <sup>3</sup> |                                                                                                                                                         |
|                                    | WEL 8h    | 2 ppm                 |                                                                                                                                                         |
|                                    | WEL 15min | 2,5 mg/m <sup>3</sup> |                                                                                                                                                         |
|                                    | WEL 15min | 2 ppm                 |                                                                                                                                                         |
| methanol (CAS: 67-56-1)            | WEL 8h    | 266 mg/m <sup>3</sup> | Can be absorbed through the skin. The assigned substances are those for which there are concerns that dermal absorption will lead to systemic toxicity. |
|                                    | WEL 8h    | 200 ppm               |                                                                                                                                                         |
|                                    | WEL 15min | 333 mg/m <sup>3</sup> |                                                                                                                                                         |
|                                    | WEL 15min | 250 ppm               |                                                                                                                                                         |

#### 8.2. Exposure controls

Follow the usual measures intended for health protection at work and especially for good ventilation. This can be achieved only by local suction or efficient general ventilation. If exposure limits cannot be observed in this mode, suitable protection of airways must be used. Do not eat, drink and smoke during work. Wash your hands thoroughly with water and soap after work and before breaks for a meal and rest.

##### Eye/face protection

Protective goggles.

##### Skin protection

Hand protection: Protective gloves resistant to the product. When choosing appropriate thickness, material and permeability of the gloves, observe recommendations of their particular manufacturer. Observe other

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recommendations of the manufacturer. Other protection: protective workwear. Contaminated skin should be washed thoroughly.

### Respiratory protection

Halfmask with a filter against organic vapours or a self-contained breathing apparatus as appropriate if exposure limit values of substances are exceeded or in a poorly ventilated environment.

### Thermal hazard

Not available.

### Environmental exposure controls

Observe usual measures for protection of the environment, see Section 6.2.

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

|                                              |                                 |
|----------------------------------------------|---------------------------------|
| Appearance                                   |                                 |
| physical state                               | liquid at 20 °C                 |
| color                                        | colourless                      |
| Odour                                        | characteristic, sweet / pungent |
| pH                                           | data not available              |
| Melting point/freezing point                 | data not available              |
| Initial boiling point and boiling range      | 64.7 - 245 °C                   |
| Flash point                                  | data not available              |
| Flammability (solid, gas)                    | data not available              |
| Upper/lower flammability or explosive limits |                                 |
| explosive limits                             | data not available              |
| Vapour pressure                              | data not available              |
| Solubility(ies)                              |                                 |
| solubility in water                          | soluble                         |
| Partition coefficient: n-octanol/water       | data not available              |
| Auto-ignition temperature                    | data not available              |
| Decomposition temperature                    | data not available              |
| Viscosity                                    |                                 |
| Kinematic viscosity                          | data not available              |

### 9.2. Other information

not available

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

not available

### 10.2. Chemical stability

The product is stable under normal conditions.

### 10.3. Possibility of hazardous reactions

Unknown.

### 10.4. Conditions to avoid

The product is stable and no degradation occurs under normal use. Protect against flames, sparks, overheating and against frost.

### 10.5. Incompatible materials

Protect against strong acids, bases and oxidizing agents.

### 10.6. Hazardous decomposition products

Not developed under normal uses. Dangerous outcomes such as carbon monoxide and carbon dioxide are formed at high temperature and in fire.

## SECTION 11: Toxicological information

### 11.1. Information on toxicological effects

Inhalation of solvent vapors above values exceeding exposure limits for working environment may result in acute inhalation poisoning, depending on the level of concentration and exposure time. No toxicological data is available for the mixture.

#### Acute toxicity

Toxic if inhaled. Harmful if swallowed.

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### 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

Suspected of causing genetic defects.

### Carcinogenicity

May cause cancer.

### Reproductive toxicity

Based on available data the classification criteria are not met.

### Toxicity for specific target organ - single exposure

May cause respiratory irritation. May cause damage to organs.

### Toxicity for specific target organ - repeated exposure

May cause damage to the kidneys through prolonged or repeated exposure if swallowed.

### Aspiration hazard

Based on available data the classification criteria are not met.

## SECTION 12: Ecological information

### 12.1. Toxicity

not available

#### Acute toxicity

| 2,2'-oxybisethanol |            |               |                            |             |
|--------------------|------------|---------------|----------------------------|-------------|
| Parameter          | Value      | Exposure time | Species                    | Environment |
| LC <sub>50</sub>   | 75.2 mg/kg | 96 hours      | Fish (Pimephales promelas) |             |

### 12.2. Persistence and degradability

not available

### 12.3. Bioaccumulative potential

Not available.

### 12.4. Mobility in soil

Not available.

### 12.5. Results of PBT and vPvB assessment

Product does not contain any substance meeting the criteria for PBT or vPvB in accordance with the Annex XIII of Regulation (EC) No 1907/2006 (REACH) as amended.

### 12.6. Other adverse effects

Not available.



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### SECTION 13: Disposal considerations

#### 13.1. Waste treatment methods

Hazard of environmental contamination; dispose of the waste in accordance with the local and/or national regulations. Proceed in accordance with valid regulations on waste disposal. Any unused product and contaminated packaging should be put in labelled containers for waste collection and submitted for disposal to a person authorised for waste removal (a specialized company) that is entitled for such activity. Do not empty unused product in drainage systems. The product must not be disposed of with municipal waste. Empty containers may be used at waste incinerators to produce energy or deposited in a dump with appropriate classification. Perfectly cleaned containers can be submitted for recycling.

#### Waste management legislation

Producer Responsibility Obligations (Packaging Waste) Regulations 2007 (S.I. No. 871 of 2007). Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste, as amended. Decision 2000/532/EC establishing a list of wastes, as amended.

### SECTION 14: Transport information

#### 14.1. UN number

not subject to transport regulations

#### 14.2. UN proper shipping name

not relevant

#### 14.3. Transport hazard class(es)

not relevant

#### 14.4. Packing group

not relevant

#### 14.5. Environmental hazards

not relevant

#### 14.6. Special precautions for user

Reference in the Sections 4 to 8.

#### 14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

not relevant

### SECTION 15: Regulatory information

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

Clean Air Act 1993 as amended. The Chemicals (Hazard Information and Packaging for Supply) Regulations 2009 as amended. Public health act 1961. Environmental Protection Act 1990 as amended. Regulation (EC) No. 1907/2006 of the European Parliament and of the Council of 18th December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing the European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No. 793/93 and Commission Regulation (EC) No. 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, as amended. REGULATION (EC) No. 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL as amended. Commission Regulation (EU) 2020/878 of 18 June 2020 amending Annex II to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

#### Restrictions pursuant to Annex XVII of Regulation (EC) No. 1907/2006 (REACH), as amended

| Substance name (component) | CAS     | Restrictions (Column 1) |
|----------------------------|---------|-------------------------|
| formaldehyde               | 50-00-0 | 28, 72, 75, 77          |
| methanol                   | 67-56-1 | 69, 75                  |

#### 15.2. Chemical safety assessment

not available

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### SECTION 16: Other information

#### A list of standard risk phrases used in the safety data sheet

|      |                                                                                      |
|------|--------------------------------------------------------------------------------------|
| H225 | Highly flammable liquid and vapour.                                                  |
| H301 | Toxic if swallowed.                                                                  |
| H302 | Harmful if swallowed.                                                                |
| H311 | Toxic in contact with skin.                                                          |
| H314 | Causes severe skin burns and eye damage.                                             |
| H315 | Causes skin irritation.                                                              |
| H317 | May cause an allergic skin reaction.                                                 |
| H319 | Causes serious eye irritation.                                                       |
| H330 | Fatal if inhaled.                                                                    |
| H331 | Toxic if inhaled.                                                                    |
| H335 | May cause respiratory irritation.                                                    |
| H341 | Suspected of causing genetic defects.                                                |
| H350 | May cause cancer.                                                                    |
| H370 | Causes damage to organs.                                                             |
| H371 | May cause damage to organs.                                                          |
| H373 | May cause damage to the kidneys through prolonged or repeated exposure if swallowed. |

#### Guidelines for safe handling used in the safety data sheet

|           |                                                                  |
|-----------|------------------------------------------------------------------|
| P201      | Obtain special instructions before use.                          |
| P260      | Do not breathe vapours.                                          |
| P280      | Wear protective gloves/eye protection/face protection.           |
| P308+P313 | IF exposed or concerned: Get medical advice/attention.           |
| P403+P233 | Store in a well-ventilated place. Keep container tightly closed. |

#### Other important information about human health protection

The product must not be - unless specifically approved by the manufacturer/importer - used for purposes other than as per the Section 1. The user is responsible for adherence to all related health protection regulations.

#### Key to abbreviations and acronyms used in the safety data sheet

|                     |                                                                                                   |
|---------------------|---------------------------------------------------------------------------------------------------|
| ADR                 | European agreement concerning the international carriage of dangerous goods by road               |
| BCF                 | Bioconcentration Factor                                                                           |
| CAS                 | Chemical Abstracts Service                                                                        |
| CLP                 | Regulation (EC) No 1272/2008 on classification, labelling and packaging of substance and mixtures |
| EC                  | Identification code for each substance listed in EINECS                                           |
| EINECS              | European Inventory of Existing Commercial Chemical Substances                                     |
| EmS                 | Emergency plan                                                                                    |
| EU                  | European Union                                                                                    |
| EuPCS               | European Product Categorisation System                                                            |
| IATA                | International Air Transport Association                                                           |
| IBC                 | International Code For The Construction And Equipment of Ships Carrying Dangerous Chemicals       |
| ICAO                | International Civil Aviation Organization                                                         |
| IMDG                | International Maritime Dangerous Goods                                                            |
| INCI                | International Nomenclature of Cosmetic Ingredients                                                |
| ISO                 | International Organization for Standardization                                                    |
| IUPAC               | International Union of Pure and Applied Chemistry                                                 |
| LC <sub>50</sub>    | Lethal concentration of a substance in which it can be expected death of 50% of the population    |
| LD <sub>50</sub>    | Lethal dose of a substance in which it can be expected death of 50% of the population             |
| log K <sub>ow</sub> | Octanol-water partition coefficient                                                               |
| MARPOL              | International Convention for the Prevention of Pollution from Ships                               |
| OEL                 | Occupational Exposure Limits                                                                      |
| PBT                 | Persistent, Bioaccumulative and Toxic                                                             |
| ppm                 | Parts per million                                                                                 |
| REACH               | Registration, Evaluation, Authorisation and Restriction of Chemicals                              |
| RID                 | Agreement on the transport of dangerous goods by rail                                             |

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|            |                                                                                                   |
|------------|---------------------------------------------------------------------------------------------------|
| UN         | Four-figure identification number of the substance or article taken from the UN Model Regulations |
| UVCB       | Substances of unknown or variable composition, complex reaction products or biological materials  |
| VOC        | Volatile organic compounds                                                                        |
| vPvB       | Very Persistent and very Bioaccumulative                                                          |
| Acute Tox. | Acute toxicity                                                                                    |
| Carc.      | Carcinogenicity                                                                                   |
| Flam. Liq. | Flammable liquid                                                                                  |
| Muta.      | Germ cell mutagenicity                                                                            |
| Skin Corr. | Skin corrosion                                                                                    |
| Skin Sens. | Skin sensitization                                                                                |
| STOT RE    | Specific target organ toxicity - repeated exposure                                                |
| STOT SE    | Specific target organ toxicity - single exposure                                                  |

### Training guidelines

Inform the personnel about the recommended ways of use, mandatory protective equipment, first aid and prohibited ways of handling the product.

### Recommended restrictions of use

not available

### Information about data sources used to compile the Safety Data Sheet

REGULATION (EC) No. 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL (REACH) as amended.  
REGULATION (EC) No. 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL as amended. Data from the manufacturer of the substance / mixture, if available - information from registration dossiers.

### The changes (which information has been added, deleted or modified)

Revision of the classification of mixtures containing formaldehyde based on Regulation (EU) 2024/2564.

### More information

Classification procedure - calculation method.

### Statement

The safety data sheet provides information aimed at ensuring safety and health protection at work and environmental protection. The provided information corresponds to the current status of knowledge and experience and complies with valid legal regulations. The information should not be understood as guaranteeing the suitability and usability of the product for a particular application.