

# SAFETY DATA SHEET

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

## EXCELLYSE I

Creation date	21st July 2023	Version	2
Revision date	13th March 2026		

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

- 1.1. Product identifier**  
Substance / mixture EXCELLYSE I  
Number ED7065
- 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  
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.

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

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

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

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. Toxic if inhaled.

- 2.2. Label elements**

#### Hazard pictogram



#### Signal word

Danger

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### Hazardous substances

Formaldehyde  
Methanol

### Hazard statements

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.
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.

## 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: 605-001-00-5 CAS: 50-00-0 EC: 200-001-8 Registration number: 01-2119488953-20	formaldehyde	<5	Acute Tox. 4, H302 Skin Corr. 1B, H314 Skin Sens. 1A, H317 Acute Tox. 2, H330 Muta. 2, H341 Carc. 1B, H350 EUH071 Specific concentration limit: STOT SE 3, H335: C ≥ 5 % Skin Corr. 1B, H314: C ≥ 25 % Skin Irrit. 2, H315: 5 % ≤ C < 25 % Eye Irrit. 2, H319: 5 % ≤ C < 25 %	1, 2, 3, 4
Index: 603-001-00-X CAS: 67-56-1 EC: 200-659-6 Registration number: 01-2119433307-44	methanol	<2	Flam. Liq. 2, H225 Acute Tox. 3, H301+H311+H331 STOT SE 1 (**), H370 Specific concentration limit: STOT SE 1, H370: C ≥ 10 % STOT SE 2, H371: 3 % ≤ C < 10 %	3, 4

### Notes

\*\* another exposure route cannot be ruled out

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- 1 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.
- 2 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".
- 3 A substance for which exposure limits are set.
- 4 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**

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**

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.

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### 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.

## 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
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.

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

Substance name (component)	Type	Value	Note
methanol (CAS: 67-56-1)	WEL 8h	200 ppm	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	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 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	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

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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

When used in the standard way, there is not any dangerous reaction with other substances.

### 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.

#### 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.

#### Toxicity for specific target organ - repeated exposure

Based on available data the classification criteria are not met.

#### Aspiration hazard

Based on available data the classification criteria are not met.

## SECTION 12: Ecological information

### 12.1. Toxicity

not available

### 12.2. Persistence and degradability

Data not available.

### 12.3. Bioaccumulative potential

Not available.

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### 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.

## 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

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### 15.2. Chemical safety assessment

not available

### 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.

#### 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.

#### List of supplementary standard hazard phrases used in the safety data sheet

EUH071	Corrosive to the respiratory tract
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#### 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
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

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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
Carc.	Carcinogenicity
Flam. Liq.	Flammable liquid
Muta.	Germ cell mutagenicity
Skin Corr.	Skin corrosion
Skin Sens.	Skin sensitization
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.

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### 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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