

SAFETY DATA SHEET

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


SpermFlowEx Kit

Date of creation	22nd December 2015	Version	5
Date of revision	01st August 2022		

PRODUCT IDENTIFICATION

Cat. No.	Product name
ED7079	SpermFlowEx Kit

COMPONENTS OF THE KIT

Code	Name	Classification
ED7079-1	Intra-acrosomal protein FITC	Not classified as hazardous.
ED7079-2	CD45 PE-Cy™5	Not classified as hazardous.
ED7079-3	Fluorescent Count Standard	Not classified as hazardous.
ED7079-4	Propidium iodide	Not classified as hazardous.
ED7079-5	Permeabilizing Solution	

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

- 1.1. Product identifier**
Substance / mixture Permeabilizing Solution
Number ED7079-5
- 1.2. Relevant identified uses of the substance or mixture and uses advised against**
Mixture's intended use
diagnostic 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**
European emergency number: 112

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.

Flam. Liq. 3, H226

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

Most serious adverse physico-chemical effects

Flammable liquid and vapour.

- 2.2. Label elements**
Hazard pictogram



Signal word
Warning

Hazardous substances

ethanol

Hazard statements

H226 Flammable liquid and vapour.

Precautionary statements

P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P260 Do not breathe spray.
P301+P312 IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.
P302+P352 IF ON SKIN: Wash with plenty of water and soap.

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P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P403+P235 Store in a well-ventilated place. Keep cool.
P501 Dispose of contents/container to in accordance with local regulations.

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: 603-002-00-5 CAS: 64-17-5 EC: 200-578-6 Registration number: 01-2119457610-43-XXXX	ethanol	<50	Flam. Liq. 2, H225	

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. Rinse skin with water or shower.

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.

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

Possible irritation of airways, cough, headache.

If on skin

Repeated exposure may cause skin dryness or cracking.

If in eyes

Possible irritation.

If swallowed

Nausea, stomach pain, vomiting, diarrhoea.

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

Symptomatic treatment.

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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. Closed containers with the product near the fire should be cooled with water. 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

Provide sufficient ventilation. Flammable liquid and vapour. Remove all ignition sources. Use personal protective equipment for work. 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

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 flammable or explosive concentrations and concentrations exceeding the occupational exposure limits. The product should be used only in the areas where it is not in contact with open fire and other ignition sources. Use non-sparking tools. Use of antistatic clothes and footwear is recommended. No smoking. Use personal protective equipment as per Section 8. Observe valid legal regulations on safety and health protection. Ground and bond container and receiving equipment. Use explosion-proof electrical/ventilating/lighting equipment. Take action to prevent static discharges.

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. Do not expose to sunlight. Keep container tightly closed. Keep cool.

The specific requirements or rules relating to the substance/mixture

Solvent vapours are heavier than air and accumulate especially near the floor where they may form an explosive mixture with the air.

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.

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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

Protective goggles.

Skin protection

Hand protection: Protective gloves resistant to the product. 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

Physical state	liquid
Colour	colourless
Odour	containing alcohol
Melting point/freezing point	data not available
Boiling point or initial boiling point and boiling range	78 °C
Flammability	data not available
Lower and upper explosion limit	
bottom	3,3 %
upper	19 %
Flash point	>24 °C
Auto-ignition temperature	363 °C
Decomposition temperature	data not available
pH	data not available
Kinematic viscosity	data not available
Solubility in water	data not available
Partition coefficient n-octanol/water (log value)	-0,349
Vapour pressure	data not available
Density and/or relative density	data not available
Relative vapour density	data not available
Particle characteristics	data not available

9.2. Other information

not available

SECTION 10: Stability and reactivity

10.1. Reactivity

The mixture is flammable.

10.2. Chemical stability

The product is stable under normal conditions.

10.3. Possibility of hazardous reactions

Unknown.

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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 hazard classes as defined in Regulation (EC) No 1272/2008

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

Based on available data the classification criteria are not met.

Skin corrosion/irritation

Prolonged or repeated contact with the product causes skin degreasing and drying.

Serious eye damage/irritation

May cause irritation and reversible damage if in contact with eyes.

Respiratory or skin sensitisation

Based on available data the classification criteria are not met.

Germ cell mutagenicity

Based on available data the classification criteria are not met.

Carcinogenicity

Based on available data the classification criteria are not met.

Reproductive toxicity

Based on available data the classification criteria are not met.

Toxicity for specific target organ - single exposure

Based on available data the classification criteria are not met.

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.

11.2. Information on 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.

SECTION 12: Ecological information

12.1. Toxicity

Acute toxicity

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. Endocrine disrupting properties

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.

12.7. 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

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 or ID number

UN 1170

14.2. UN proper shipping name

ETHANOL SOLUTION

14.3. Transport hazard class(es)

3 Flammable liquids

14.4. Packing group

III - substances presenting low danger

14.5. Environmental hazards

not relevant

14.6. Special precautions for user

Reference in the Sections 4 to 8.

14.7. Maritime transport in bulk according to IMO instruments

not relevant

Additional information

Hazard identification No.

30

UN number

1170

Classification code

F1

Safety signs

3



Air transport - ICAO/IATA

Packaging instructions passenger

355

Cargo packaging instructions

366

Marine transport - IMDG

EmS (emergency plan)

F-E, S-D

MFAG

305

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SECTION 15: Regulatory information

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

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.

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.
H226 Flammable liquid and vapour.

Guidelines for safe handling used in the safety data sheet

P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P403+P235 Store in a well-ventilated place. Keep cool.
P501 Dispose of contents/container to in accordance with local regulations.
P260 Do not breathe spray.
P301+P312 IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.
P302+P352 IF ON SKIN: Wash with plenty of water and soap.
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

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
EINECS European Inventory of Existing Commercial Chemical Substances
EmS Emergency plan
ES Identification code for each substance listed in EINECS
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
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
Flam. Liq.	Flammable liquid

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)

Overall revision of the safety data sheet according to Commission Regulation (EU) 2020/878.

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.