

According to Regulation UE 2020/878, Annex II Revision 1 of 21<sup>st</sup> MAR 2023 Language **ENG** 

Catalogue code/number: 005.5L

Product name: FLUID A + TWEEN80 3% + LECITHIN 0.3% + HISTIDINE 0.1%

#### 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

# 1.1 PRODUCT IDENTIFIERS

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#### 1.2 RELEVANT IDENTIFIED USES OF THE SUBSTANCE OR MIXTURE AND USES ADVISED AGAINST

Use of the products: Solution used to dilute and rinse membranes during filtration. It is used during sterility tests. Recommended by several pharmacopoeias.

# 1.3 DETAILS OF THE SUPPLIER OF THE SAFETY DATA SHEET

Company identification
(legal and production site)

CPC BIOTECH s.r.l.
Via L. Galvani, 1

20875 Burago di Molgora (MB), Italy

Company identification

CPC BIOTECH s.r.l.

Via L. Galvani, 1

(production site) Via L. Galvani, 1 20875 Burago di Molgora (MB), Italy

 Telephone number
 0039-039-6898029

 Fax number
 0039-039-6898029

 E-mail
 info@cpcbiotech.it

Responsible person of the Safety department ACS Dobfar

MSDS

#### 1.4 EMERGENCY TELEPHONE NUMBER

Emergency number - Italy Unique number for emergency: 112

# 2. HAZARDS IDENTIFICATION

# 2.1 CLASSIFICATION OF THE SUBSTANCE OR MIXTURE

Not a hazardous product according to Regulation n.1272/2008.

#### 2.2 LABEL ELEMENTS

Not applicable. Mixture classified as not hazardous according to Regulation n.1272/2008.

#### 2.3 OTHER HAZARDS

Not known.

#### 3. COMPOSITION/INFORMATION ON THE INGREDIENTS

#### 3.1 SUBSTANCES

Not available



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#### 3.2 MIXTURES

Ingredients not dangerous according to Regulation (CE) nr.1272/2008.

Formula (grams for liter of deionized water):		CAS number:
Tween 80	30.00 g/L	9005-65-6
Lecithin	3.00  g/L	65154-06-5
Histidine	1.00 g/L	71-00-1
Peptone	1.0 g/L	ND

# 4. FIRST AID MEASURES

# 4.1 DESCRIPTION OF FIRST AID MEASURES

Recommended to wear personal protective equipment for first aid.

In case of inhalation Provide fresh air

In case of skin contact Wash with soap and water

In case of eye contact Wash out eyes with plenty of water

In case of ingestion

Wash out mounth with water. Give to the victim 1 or 3 glasses of water in order to dilute stomach content

# 4.2 MOST IMPORTANT SYMPTOMS AND EFFECTS, BOTH ACUTE AND DELAYED

No additional information available.

# 4.3 INDICATION OF ANY IMMEDIATE MEDICAL ATTENTION AND SPECIAL TREATMENT NEEDED

No additional information available.

#### 5. FIREFIGHTING MEASURES

#### **5.1 EXTINGUISHING MEDIA**

The product is not combustible. Use extinguishing systems compatible with the local situation and with the surrounding environment.

# 5.2 SPECIAL HAZARDS ARISING FROM THE SUBSTANCE OR MIXTURE

Nature of decomposition products not known.

# **5.3 ADVICE FOR FIREFIGHTERS**

Wear self-contained breathing apparatus and protective clothing for firefighting if necessary.

# 6. ACCIDENTAL RELEASE MEASURES

# 6.1 PERSONAL PRECAUTIONS, PROTECTIVE EQUIPMENT AND EMERGENCY PROCEDURES

For non-emergency personnel

Wear suitable protective equipment. Don't breathe the

vapors, evacuate the danger area.

For emergency responders

Use protective devices.



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See section 8.

# **6.2 ENVIRONMENTAL PRECAUTIONS**

Prevent entry to sewers and public waters.

# 6.3 METHODS AND MATERIALS FOR CONTAINMENT AND CLEANING UP

Sweep up and dispose properly.

#### **6.4 REFERENCE TO OTHER SECTIONS**

For individual protection, refer to section 8. For information about waste, refer to section 13.

#### 7. HANDLING AND STORAGE

#### 7.1 PRECAUTIONS FOR SAFE HANDLING

Ensure good ventilation of the workstation where dust is formed. Handle in accordance with good industrial hygiene and safety procedures.

# 7.2 CONDITIONS FOR SAFE STORAGE, INCLUDING ANY INCOMPATIBILITIES

Store in cool place. Keep container tightly closed in a dry and well-ventilated place. The correct storage refers to intact product in its tightly closed package.

Recommended storage temperature: 2-25°C.

#### 7.3 SPECIFIC END USE(S)

No additional information available.

# 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### **8.1 CONTROL PARAMETERS**

No additional information available.

#### **8.2 EXPOSURE CONTROLS**

Appropriate engineering

controls

Individual protection

measures, such as personal

protective equipment

Eye protection

Skin protection

Respiratory protection

Thermal hazards

Environmental exposure

controls

Wear protective clothing. See section 7.1.

Personal protective equipment must be chosen in

accordance with cen standards and with the supplier of personal protective equipment.

Wear compliant safety glasses.

Wear protective gloves. Wear disposable coveralls.

Wear disposable mask.

Not applicable

Do not let the product flow into the drains.

# 9. PHYSICAL AND CHEMICAL PROPERTIES

# 9.1 INFORMATION ON BASIC PHYSICAL AND CHEMICAL PROPERTIES



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Product name: FLUID A + TWEEN80 3% + LECITHIN 0.3% + HISTIDINE 0.1%

Appearance Yellow liquid
Odour Not available
Odour threshold Not available

pH Between 6.9 and 7.3

Melting point/freezing point Not available Not available Boiling point Flash point Not available Evaporation rate Not available Flammability Not available Vapour pressure Not available Vapour density Not available Relative density Not available Solubility Not available Partition coefficient Not available Auto-ignition temperature Not available Decomposition temperature Not available Viscosity Not available Explosive properties Not available Oxidising properties Not available

# 9.2 OTHER SAFETY INFORMATION

No additional information available.

# 10. STABILITY AND REACTIVITY

# **10.1 REACTIVITY**

No data available.

#### **10.2 CHEMICAL STABILITY**

The product is stable if store in adequate conditions (see section 7.2).

# 10.3 POSSIBILITY OF HAZARDOUS REACTIONS

No data available.

#### **10.4 CONDITIONS TO AVOID**

The product is stable if store in adequate conditions (see section 7.2).

# 10.5 INCOMPATIBLE MATERIALS

Strong oxidizing agents.

#### 10.6 HAZARDOUS DECOMPOSITION PRODUCTS

In case of fire see section 5.

#### 11. TOXOLOGICAL INFORMATION

# 11.1 INFORMATION ON TOXICOLOGICAL EFFECTS



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Product name: FLUID A + TWEEN80 3% + LECITHIN 0.3% + HISTIDINE 0.1%

Acute toxicity

The product doesn't represent acute toxicity in base of

known information.

Skin corrosion/irritation Not identified. Respiratory or skin Not identified. sensitisation Germ cell mutagenicity Not identified. carcinogenicity Not identified. Reproductive toxicity Not identified. STOT-single exposure Not identified. STOT-repeated exposure Not identified. Aspiration hazard Not identified.

#### 12. ECOLOGICAL INFORMATION

#### **12.1 TOXICITY**

No data available.

# 12.2 PERSISTENCE AND DEGRADABILITY

No data available.

#### 12.3 BIOACCUMULATION POTENTIAL

No data available.

# **12.4 MOBILITY IN SOIL**

No data available.

#### 12.5 RESULTS OF PBT AND vPvB ASSESSMENT

No data available.

# 12.6 OTHER ADVERSE EFFECTS

No data available.

# 13. DISPOSAL CONSIDERATION

# **13.1 WASTE TREATMENT METHODS**

Do not disperse the product in the environment.

Dispose in a safe manner in accordance with local/national regulations.

# 14. TRANSPORT INFORMATION

# **14.1 UN NUMBER**

Not applicable.

# 14.2 UN PROPER SHIPPING NAME

Not applicable.

# 14.3 TRANSPORT HAZARD CLASS(ES)

# CPC BIOTECH S.R.L.

#### **MATERIAL SAFETY DATA SHEET**

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Not applicable.

# 14.4 PACKAGING GROUP

Not applicable.

# 14.5 ENVIRONMENTAL HAZARDS

ADR Not dangerous goods according to the current regulation.

RID Not dangerous goods according to the current regulation.

ADN Not relevant.

IATA Not dangerous goods according to the current regulation.

IMDG Not dangerous goods according to the current regulation.

#### 14.6 SPECIAL PRECAUTIONS FOR USER

Not dangerous goods according to the current regulation.

# 14.7 TRANSPORT IN BULK ACCORDING TO ANNEX II OF MARPOL AND THE IBC CODE

No data available.

# 15. REGULATORY INFORMATION

# 15.1 SAFETY, HEALTH AND ENVIRONMENTAL REGULATIONS/LEGISLATION SPECIFIC FOR THE SUBSTANCE OR MIXTURE

This safety data sheet is in compliant to the Regulation UE 2020/878.

# 15.2 CHEMICAL SAFETY ASSESSMENT

Chemical safety assessment is not required for this product.

#### **16. OTHER INFORMATION**

Revision information New revision, it replaces the previous ones.

Revision carried out for alignment with the regulation.

List of abbreviation Not available.

References Listed in the appropriate paragraphs.

Full text of any H phrases not mentioned in full in sections 2

to 5

Not available.



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# Disclaimer

The information in this safety data sheet is correct according to our best knowledge of the product at the time of publication. However, all statements, recommendations or suggestions are indicated without any implicit or explicit guarantee or assurance on our part. This information is provided for the sole purpose of allowing the most correct and safe use, storage, transport and disposal of the preparation.

This information should not be considered a guarantee or a specification of the quality of the preparation.

They refer only to the material specifically indicated and are not valid for the same when used in combination with other materials or in other processes not specifically indicated in the text of the safety data sheet.

As a technician, the user should verify the suitability of this information for the specific use of the product and adopt the appropriate safety information