

Date of update: 02.04.2021	SAFETY DATA SHEET CYTOFIX	Version 5
Safety data sheet prepared in accordance with reach Regulation 1907/2006 as amended by Commission Regulation (EU) 2020/878.		

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING
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1.1. Product identifier

Trade name: **CYTOFIX**

1.2. Relevant identified uses of the substance or mixture and uses advised against

Identified uses:

Aerosol product for the preservation of biological smears taken on the glass, before their subsequent assessment. The use of Cytofix provides coverage of the smear with a thin, transparent protective coating.

Uses advised against:

All uses other than those mentioned above.

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

Producer:

SAMKO Zakład Produkcji Kosmetyków

Irmina Krakowiak-Wiśniowska

ul. Ogrodowa 16; Dobczyn; 05-205 Klembów.

Tel./fax: (029) 777 06 70

Fax: (029) 777 06 70,

e-mail: samko@post.pl

E-mail address of the competent person responsible for the safety data sheet: samko@post.pl

1.4 Emergency telephone number

Tel/fax.: (029) 777 06 70 (active from 9:00 to 17:00)

SECTION 2. HAZARDS IDENTIFICATION
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2.1. Classification of the substance or mixture

Classification of the mixture according to the criteria of Regulation 1272/2008/EC:

Hazards by reason of physical and chemical properties:

Aerosol 1; H222; H229

Health hazards.

Not applicable.

Environmental hazards:

Not applicable.

2.2. Label elements



Pictogram

Signal word: Danger.

Phrases indicating the type of hazard (H phrases):

H222 - Extremely flammable aerosol.

H229 - Pressurised container. Heating may cause an explosion.

Precautionary statements (P phrases):

P210 - Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

P211 - Do not spray on an open flame or other ignition source.

P251 - Do not pierce or burn, even after use.

P403 - Store in a well ventilated place.

P410 + P412 - Protect from sunlight. Do not expose to temperatures exceeding 50°C/ 122°F.

P501 - Dispose of contents/container according to local/national regulations.

2.3. Other hazards

Under conditions of insufficient ventilation, it can produce explosive vapour-air mixtures.

The mixture does not contain substances meeting the PBT or vPvB criteria.

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SECTION 3. COMPOSITION / INFORMATION ON INGREDIENTS
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3.1. Substances

Not applicable.

3.2. Mixtures

The product is a mixture of the following substances:

Ethanol (*)

Content: approx. 63%

Index No.: 603-002-00-5

CAS No.: 64-17-5

EC No: 200-578-6

Registration number: no data

Classification according to the criteria of Regulation (EC) No. 1272/2008:

Flam. Liq. 2; H225

Isobutane

Content: approx. 35%

Index number: 601-004-00-0

CAS number: 75-28-5

EC number: 200-857-2

Registration number: no data

Classification according to the criteria of Regulation (EC) No. 1272/2008:

Flam. Gas.1; H220

Press. Gas; H280

Remarks: C, U

or a mixture of n-butane and n-propane with a total content of 35% instead of isobutane.

n-Butane (*)

Index number: 601-004-00-0

CAS number: 106-97-8

EC number: 203-448-7

Registration number: no data

Classification according to the criteria of Regulation (EC) No. 1272/2008:

Flam. Gas.1; H220

Press. Gas; H280

Remarks: C, U

Propane (*)

Index number: 601-003-00-5

CAS number: 74-98-6

EC number: 200-827-9

Registration number: no data.

Mixture classification in compliance with the criteria of Regulation (EC) No. 1272/2008:

Flam. Gas.1; H220

Press. Gas; H280

Note: U

Section 16 gives the meaning of H-phrases and hazard categories and classes.

(*) substance with maximum allowable concentrations (EL) in the work environment.

SECTION 4. FIRST AID MEASURES

4.1. Description of first aid measures

Inhalation

Remove the injured person from the danger area. Provide fresh air and seek medical advice if a medical condition occurs or persists. Place the unconscious person in a steady lateral position and seek medical advice. Present this safety data sheet.

Skin contact

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Wash the skin contaminated with the product with plenty of soap and water and rinse thoroughly. Immediately remove contaminated clothing. If you experience symptoms of skin irritation (redness, etc.), consult your doctor. Take off contaminated clothing and wash before reuse.

Contact with eyes

With eyelids rolled, rinse eyes immediately with a gentle stream of water for at least 15 minutes. In the meantime, remove contact lenses, if present and easy to do. Seek medical advice (if possible, show the label).

Ingestion

Rinse mouth with water. Give plenty of water to drink in small portions. Seek medical advice if any discomfort persists. Present this safety data sheet. Do not induce vomiting without your doctor's advice.

4.2. The most important acute and delayed symptoms and effects of exposure

The product is not classified as hazardous under acute or chronic exposure conditions.

4.3. Indications of any immediate medical attention and special treatment of the injured person

General recommendations

If you feel unwell, call a doctor immediately and, if possible, show the product label.

Instructions for the doctor

No special instructions.

SECTION 5. FIREFIGHTING MEASURES

5.1. Extinguishing media

Suitable extinguishing media:

Sprayed water, alcohol-resistant fire-fighting foam, carbon dioxide (CO₂), dry extinguishing powders depending on the environment. Remove fire hazard containers if possible or cool them with water from a safe distance. Under the influence of high temperature, the pressure in the container increases, which threatens its bursting and explosion.

Unsuitable extinguishing media: Water jets.

5.2. Special hazards arising from the substance or mixture

Vapours may form flammable and explosive mixtures with air. Do not inhale gases and fumes produced during a fire. See also section 10.

5.3. Advice for firefighters

Depending on the size and severity of the fire, wear appropriate respiratory protective equipment – breathing apparatus with independent air supply, complete gas-tight protective clothing, etc. Collect and remove used up extinguishing media in compliance with applicable regulations.

SECTION 6. ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For persons not belonging to the personnel providing assistance

Prohibit access to the place of contamination by unauthorized persons.

6.1.2. For helpers

Avoid contamination of eyes and skin. Remove all sources of ignition and open flames – do not smoke. Wear suitable respiratory protective equipment under conditions of inadequate ventilation – see section 8.

6.2. Environmental precautions

Do not allow product to enter drains, sewers, ditches, watercourses. Secure sewer grates.

Notify the relevant services in the event of environmental pollution.

6.3. Methods and materials to prevent the spread of contamination and to remove contamination

Leave damaged packaging to be emptied out into the air. Cover larger quantity of the released product with non-combustible absorbent material – sand, soil, vermiculite, diatomaceous earth and collect to

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labelled waste containers. Dispose of waste and residues in accordance with applicable regulations.

6.4. Reference to other sections

Protective equipment and clothing - see section 8.

Waste neutralization – see section 13 and 15.

SECTION 7. HANDLING AND STORAGE

7.1. Precautions for safe handling

Use in accordance with the instructions for use. Observe the recommendations in force when working with chemical agents. Do not eat, drink or smoke while working with the product. Avoid direct contact with eyes and skin.

Fire-fighting and anti-explosion recommendations:

Remove all sources of ignition and open flames – do not smoke. Pressurized container: protect from sunlight and heat above 50°C. Do not pierce or incinerate, even after use. Do not spray on a naked flame or any incandescent material. Apply appropriate measures to prevent electrostatic discharges. Ensure adequate ventilation of rooms where the product is used or stored. Use equipment (tools, devices) in explosion protection.

7.2. Conditions for safe storage, including any incompatibilities.

Store only in original, tightly closed containers. Observe the recommendations in force when storing extremely flammable products in the form of aerosolized products. Keep away from sources of heat, ignition and open flame – do not smoke. Do not store together with strong acids, strong bases and oxidizing or reducing agents. Protect from direct sunlight and temperatures above 50°C. Recommended storage temperature from minus 10°C to +25°C. Storage with other materials – see section 10.

Do not keep together with food, beverages and animal feed.

7.3. Specific end use(s)

No information available on specific end uses.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

Ethanol (ethyl alcohol) (CAS: 64-17-5)

EL - 1900 mg/m³; STEL - not specified; CEIL - not specified.

Butane (CAS: 106-97-8)

EL -1900 mg/m³; STEL - 3000 mg/m³; CEIL - not specified.

PN-Z-04252-1:2012

PiMOŚP 2010, No. 1(63)

Propane (CAS: 74-98-6)

EL - 1800 mg/m³; STEIL - not specified; CEIL - not specified

PN-Z-04252-2:2012

PiMOŚP 2010, No. 1(63)

Permissible concentration values of substances – product components in biological material: Not specified.

DNEL – Derived No-Effect Level – Estimated no-effect level.

DNEL values of the substance – product components under acute and chronic exposure conditions:

Ethanol (CAS: 64-17-5) Data for employees

Exposure route	Exposure period	Effects	DNEL value
Skin	Long-term	System-wide	343 mg/kg/day
Respiratory tract	Long-term	System-wide	950 mg/m ³

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(inhalation)			
Respiratory tract (inhalation)	Short-term	System-wide	1900 mg/m ³
Data for consumers			
Exposure route	Exposure period	Effects	DNEL value
Ingestion	Long-term	System-wide	87 mg/kg body weight per day
Skin	Long-term	System-wide	206 mg/kg body weight per day
Respiratory tract (inhalation)	Long-term	System-wide	114 mg/m ³
Skin	Short-term	System-wide	950 mg/kg body weight per day
Respiratory tract (inhalation)	Short-term	System-wide	950 mg/m ³

PNEC values of substances – components of the product for the aquatic environment and biological wastewater treatment plants:

PNEC – Predicted No-Effect Concentration.

PNEC values for Ethanol (CAS: 64-17-5)

Environmental compartment	PNEC
Fresh water	0.96 mg/L
Sea water	0.79 mg/L
Mixed water	2.75 mg/L
Fresh water sediment	3.6 mg/kg
Marine sediment	2.9 mg/kg
Soil	0.63 mg/kg
Wastewater treatment plants	580 mg/L

8.2. Exposure controls

8.2.1. Appropriate technical control measures

Ensure adequate general and local ventilation of production rooms, especially enclosed ones. If it is not possible to keep the vapour concentrations of the product components below the limit values, wear appropriate respiratory protective equipment.

8.2.2. Individual protection measures, such as personal protective equipment:

Respiratory protection:

There is no need under normal conditions. Ensure proper ventilation. Wear adequate respiratory protection when exposed to concentrations exceeding the acceptable NDS values.

Eye protection:

Avoid contact with eyes. There is no need under normal conditions.

Hand skin protection:

No special requirements.

The protective properties of gloves depend not only on the type of material they are made of. The duration of protective action may vary from glove manufacturer to glove manufacturer. For many substances, the protective duration of the gloves cannot be accurately estimated. Taking into account the parameters of the gloves given by the manufacturer, care should be taken when using the product whether the gloves still retain their protective properties.

Body protection:

There is no need under normal conditions.

General recommendations:

Ensure proper ventilation. Do not eat, drink or smoke at work. Wash hands before and after each break.

8.2.3. Environmental exposure controls:

Not applicable under conditions of use as recommended.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties.

a) State: Aerosol product

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- b) Colour: Colourless
- c) Odour: Specific-alcohol.
- d) Melting/freezing point: Not specified.
- e) Boiling point or initial boiling point and boiling range: Not specified.
- f) Flammability of materials: Not specified.
- g) Lower and upper explosive limits: Not specified.
- h) Flash point: Not specified.
- i) Self-ignition point: Not specified.
- j) Decomposition temperature: Not specified.
- k) pH: Not specified.
- l) Kinematic viscosity: Not specified.
- m) Solubility: Ethanol is dissolved in water; propane/butane is not dissolved in water.
- n) Partition coefficient n-octanol/water (log value): Not specified.
- o) Vapour pressure: at 20°C: 4.5 bar
- p) Density or relative density: Not specified
- q) Relative vapour density: Not specified.
- r) Characteristics of particles: Not applicable.

9.2. Other information

9.2.1. Information on physical hazard classes

Category 1 aerosol device. Under conditions of insufficient ventilation, it can produce explosive vapour-air mixtures.

9.2.2. Other safety features

No data.

SECTION 10. STABILITY AND REACTIVITY

10.1. Reactivity

No data.

10.2. Chemical stability

The product is stable under the conditions specified in section 7. Avoid open flames, sources of heat, ignition and sparks. avoid the direct sunlight

10.3. Possibility of hazardous reactions

With inadequate materials. Contact with strong acids, strong bases, oxidants or reducing agents can cause dangerous reactions.

10.4. Conditions to avoid

Avoid temperatures below 10°C and above 50°C.

10.5. Incompatible materials

Strong acids, strong bases, strong oxidants or reducing agents.

10.6. Hazardous decomposition products

Not known under the recommended conditions of use.

SECTION 11. TOXICOLOGICAL INFORMATION

11.1. Information on hazard classes as defined in Regulation (EC) No. 1272/2008

Substance

Not applicable

Mixture

Relevant hazard classes:

a) Acute toxicity

No experimental data available for this product. According to the information provided by the manufacturer, it does not pose a health hazard under the recommended conditions of use.

b) Skin corrosion/irritation

No data available for the product. The product is not classified as hazardous in this class.

c) Serious eye damage/eye irritation

No data available for the product. The product is not classified as hazardous in this class.

d) Respiratory or skin sensitisation

No data available for this product. The product is not classified as hazardous in this class.

e) Germ cell mutagenicity

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There are no data for this product. The product is not classified as hazardous in this class.

f) Carcinogenicity

No data are available for the product. The product is not classified as hazardous in this class.

g) Toxicity for reproduction

No data are available for the product. The product is not classified as hazardous in this class.

h) Specific target organ toxicity

Single exposure

No data are available for the product. The product is not classified as hazardous in this class.

Repeated exposure

No data are available for the product. The product is not classified as a hazard in this class.

i) Aspiration hazard:

No data are available for the product. The product is not classified as a hazard in this class.

Delayed, direct and chronic short- and long-term effects of exposure

Routes of absorption into the body: No data.

Acute exposure effects: No data for the product.

Chronic exposure effects: No data for the product.

11.2. Information on other hazards

Toxicological information for the ingredients of the product.

Butane:

Prolonged exposure to butane vapours can cause drowsiness, unconsciousness, collapse and death.

Ethanol:

Irritation

Type of test: standard Draize test.

Route of exposure: dermal use.

Species: rabbits

Dose: 20 mg/24 h

Test result - moderate irritating effect.

Type of test: standard Draize test.

Route of exposure: administration into the conjunctival sac of the eye

Species: rabbits

Dose: 500 mg

Test result – severe irritation

The value of the lowest published human lethal dose after ingestion – 1400 mg/kg body weight.

Behavioural disorders – drowsiness, headaches, gastrointestinal disorders – nausea, vomiting have been described.

After oral administration to rats, the median lethal dose DL₅₀ was 7060 mg/kg body weight.

The median lethal concentration CL₅₀ following 4 hours of inhalation exposure in rats is 20,000 ppm (approximately 38,000 mg/m³) over 10 hours.

Fetotoxicity was observed in animal tests.

SECTION 12. ECOLOGICAL INFORMATION

12.1. Toxicity

Acute aquatic toxicity:

No data for the product. The product is not classified as harmful to the environment according to the criteria of EU legislation.

Chronic toxicity to the aquatic environment:

No data for the product.

Toxicity to micro-organisms:

No data for the product.

Toxicity to organisms in the terrestrial environment:

No data for the product.

Environmental toxicity:

No data.

12.2. Persistence and degradability

No data for the product.

12.3. Bioaccumulative potential

No data for this product. Butane and propane do not bioaccumulate.

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12.4. Mobility in soil

No data for the product.

12.5. Results of PBT and vPvB assessment

No data for the product.

12.6. Endocrine disrupting properties

No data for the product.

12.7. Other adverse effects

The product is not classified as dangerous for the environment.

SECTION 13. WASTE MANAGEMENT

13.1. Waste disposal methods

Handling product waste

Do not dispose of in sewers, drains, ditches, waterways.

The product and its packaging should be disposed of in a safe manner, in a suitable place, in accordance with applicable regulations. Do not remove labels from emptied containers.

Waste classification:

Product waste:

16 05 04* – Gases in containers (including halons) containing dangerous substances.

* - hazardous waste.

Packaging waste

15 01 04 – Metal packaging

Waste disposal method:

Do not pierce or burn, even after use.

The waste disposal method should be agreed upon with the competent local Environmental Protection Department.

SECTION 14. TRANSPORT INFORMATION

	Road and rail transport; ADR/RID	Sea transport; IMDG	Air transport; IATA
14.1 UN or ID number	1950	1950	1950
14.2 UN proper shipping name	AEROSOLS, flammable (contains: butane, propane, isobutane).	AEROSOLS, FLAMMABLE (contains: butane, propane, isobutane).	AEROSOLS, FLAMMABLE (contains: butane, propane, isobutane).
14.3 Transport hazard class(es):			
Class	2	2.1	2.1
Classification code	5F		
Sticker			
14.4 Packaging group	2.1	2.1	2.1
14.5 Environmental hazards	-	-	-
14.6 Special precautions for users	Note: Gases.	Marine pollutant: No	No
14.7 Sea transport in bulk according to IMO instruments:	EmS: F-D, S-U		
Additional information restricted quantities (LQ)	Not applicable		
	1 L	1 L	-

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Excluded quantities (EQ) Code: E0 Not permitted. E0 Not permitted.
 Tunnel code D -
 Transport category 2 -
 UN "Model Regulation": UN1950, AEROSOLS,
 2.1

SECTION 15. REGULATORY INFORMATION

15.1. Safety, health and environmental regulations regarding the substance or mixture.

REGULATION (EC) No. 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a 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/EEC and 2000/21/EC, as amended.

Commission Regulation (EU) 2020/878 of 18 June 2020 amending Annex II to the Regulation (EC) No. 1907/2006 of the European Parliament and of the Council.

REGULATION (EC) No. 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 r. on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No. 1907/2006, as amended.

Commission Regulation (EU) 2018/1480 of 4 October 2018.

Announcement of the Marshal of the Sejm of the Republic of Poland of 6 June 2019 on the announcement of a consolidated text of the Act on chemical substances and their mixtures (Journal of Laws of 2019, item 1225).

Announcement of the Minister of Health of 12 January 2015 on the publication of a consolidated text of the Regulation of the Minister of Health on the criteria and method of classification of chemical substances and their mixtures (Journal of Laws 2015 No. 0, item 208).

GOVERNMENT DECLARATION of 16 January 2009 on the entry into force of amendments to Annexes A and B of the European Agreement concerning the international carriage of dangerous goods by road (ADR), made in Geneva on 30 September 1957 (Journal of Laws 2009, 27, 162, as amended).

Regulation of the Minister of Family, Labour and Social Policy of 12 June 2018 on maximum permissible concentration and intensity of agents harmful to health in the working environment (Journal of Laws of 2018, item 1286 (as amended by Journal of Laws of 2020, item 61).

Commission Directives 2000/39/EC, 2006/15/EC, 2009/161/EU, (EU) 2017/164 on the establishment of a 1, 2, 3 and 4 list of indicative occupational exposure limit values.

Regulation of the Minister of Climate of 2 January 2020 on the waste catalogue (Journal of Laws of 2020, item 10)
 Corrigendum to Commission Regulation (EU) 2015/830 of 28 May 2015 amending Regulation (EC) No. 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (Journal of Laws L 132 of 29.5.2015).

Announcement of the Marshal of the Sejm of the Republic of Poland of 29 May 2020 on the announcement of a consolidated text of the Act on the management of packaging and packaging waste. (Journal of Laws of 2020, item 1114).

Announcement of the Marshal of the Sejm of the Republic of Poland of 29 May 2020 on the announcing of the consolidated text of the Waste Act (Journal of Laws of 2020, item 797).

15.2 Chemical safety assessment

The safety assessment of the substance – the components of the product – has not been performed.

SECTION 16. OTHER INFORMATION

Meaning of the hazard categories and hazard classes listed in the safety data sheet.

Aerosol 1 - Flammable aerosol, category 1

Flam. Gas 1 - Flammable gas, category 1.

Flam. Liq. 2 - Flammable liquid; category 2.

Press. Gas - Gas under pressure

Meaning of the H-phrases listed in the safety data sheet.

H220 - Extremely flammable gas.

H222 - Extremely flammable aerosol.

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H229 - Pressurized container: Heating may cause an explosion.

H225 - Highly flammable liquid and vapour.

H280 Contains gas under pressure; may explode if heated.

Note C: Some organic substances may be marketed either in a specific isomeric form or as a mixture of several isomers. In this case, the supplier must indicate on the label whether the substance is a set out specific isomer or a mixture of isomers.

Note U: When put on the market gases have to be classified as "gases under pressure", in one of the groups compressed gas, liquefied gas, refrigerated liquefied gas or dissolved gas. The group depends on the physical state in which the gas is packaged and therefore has to be assigned case by case.

Reason for update: Updating the sheet in accordance with REACH Regulation 1907/2006, as amended by Commission Regulation (EU) 2020/878.

The sheet was prepared on the basis of the Polish safety data sheet of 28.04.2017, version 4, received from the client, taking into account the provisions in force in Poland regarding chemical substances and mixtures by Eko-Futura Sp. z o.o.

The data included in the data sheet should be treated solely as an aid for safe handling in transport, distribution, application and storage.

The data sheet is not a product quality certificate.

The information contained in the data sheet apply solely to the product mentioned in the title and may be insufficient for the product used in combination with other material or in unidentified applications.

The entity applying the product is obliged to observe all applicable norms and regulations and shall be responsible for improper use of the information included in the data sheet or misapplication of the product.

End of Safety Data Sheet