

**9922 - EUXYL PE 9010****1. IDENTIFICATION OF THE SUBSTANCE OR PREPARATION.****1.1. Identification of the substance or preparation**

Name: Euxyl PE 9010

Bulk code: 9922

Internal code: 405424

**1.2. Synonyms.**

No information available.

**2. DESCRIPTION.**

Appearance: Liquid.

Colour: Clear, almost colourless.

Odour: Characteristic.

Geographical origin: USA.

Origin: Synthetic, using only synthetic raw materials.

**3. COMPOSITION/INFORMATION ON COMPONENTS.**

CAS: Mixture

EINECS: Mixture

UFI: 1Q90-Y07H-G007-EKED

**Composition:**

PRODUCT COMPOSITION	COMPONENT 1	COMPONENT 2
INCI	Phenoxyethanol	Ethylhexylglycerin (stabilised with synthetic alpha-tocopherol*)
CAS	122-99-6	70445-33-9
EC	204-589-7	408-080-2
Concentration	88.5-91.5%	8.5-11.5%

\*The product is stabilised with 0.1% alpha-tocopherol. This product is a necessary ingredient in the manufacturing process for ethylhexylglycerin, ensuring stability. The amount of tocopherol in the final cosmetic product is practically undetectable. Thus, it is considered a technical subsidiary of the material used to prepare ethylhexylglycerin without being present in the final cosmetic product.

Therefore, tocopherol can be excluded from the INCI labelling in accordance with the EU's and the ASEAN's Cosmetics Directives.

**Method of production:** The raw materials stored in tanks are transferred to a mixing tank, before the product is then sent to a filling tank and then to finished product storage tanks.

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### 4. PHYSICO-CHEMICAL DATA.

For more information, see the analysis report.

**Solubility:** The product is slightly soluble in water (10 g/l at 20°C), highly soluble in polar solvents like 1,2-propylene glycol, propanol or acetone, moderately soluble in polyalcohols like glycerol and sorbitol, and practically insoluble in aliphatic hydrocarbons with hydrophilic groups like 2-octyldodecanol and isopropyl myristate. In pure aliphatic solvents it is slightly soluble.

### 5. PROPERTIES/USES.

Cosmetic use.

Industrial use.

Patented preservative agent for cosmetic use.

The product is compliant with Regulation (EC) 1223/2009 on cosmetic products and its amendments.

The product reduces the surface tension of the cell membrane in microorganisms and improves microbiological activity.

#### **Microbiological efficacy:**

Euxyl PE 9010 acts in the same way against bacteria, yeast and mould. Depending on the dosage used, product contamination and the accompanying substances in the cosmetic, the action time required to eliminate microorganisms (biocide efficacy) is greater than 48 hours. Euxyl PE 9010's action is based on chemical reactions with microorganisms. Therefore, if it is used in highly contaminated products, active substance depletion must be considered. Hygiene during production and using raw materials with very low contamination levels are key to producing finished products in good microbiological conditions.

General information	Resistant to hydrolysis, temperature and pH. Given euxyl's good solubility, it easily disperses in different types of systems, including at low temperatures. Use in a pH range up to 12.
Applications	Liquid cosmetic preservative suitable for rinse and no-rinse products, wet wipes and more sensitive applications. Soluble in solutions. Tolerates a high salt content. A high load of surfactants can result in a loss of effectiveness. It does not interact with sulphite ions or as pigments like TiO <sub>2</sub> . In general, it presents good compatibility with cosmetic products, for which reason no bleaching has been detected. Suitable for the formation of transparent gels.
Natural products	Formulas containing raw materials of natural origin present a higher risk of microbiological contamination. The microorganisms inserted via this pathway are easily eliminated.

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Material compatibility	In material compatibility tests with the Euxyl™ PE 9010 preservative concentrate, stainless steel, brass, copper, zinc and aluminium, as well as polyethylene (PE), polyoxymethylene (POM), polyamide (PA) and rigid polyvinyl chloride (PVC) were proven to be suitable materials for handling the undiluted product. Other non-metal materials should have their suitability reviewed. Polycarbonate (PC), poly(methyl methacrylate) (PMMA), polyethylene terephthalate (PET) and the copolymer acrylonitrile butadiene styrene (ABS) should not be used. Fluoride rubber, ethylene propylene diene monomer (EPDM) and polytetrafluoroethylene (PTFE) are preferable as a sealant when handling undiluted. Other sealant materials can suffer swelling or lead to pronounced bleaching of the preservative.
Dilutions	The preservative's behaviour at 1.0% in an aqueous solution with regard to material compatibility was not significantly different to that observed with the water used for dilution. No incompatibilities with plastics were observed in products preserved with this product.
Effect on surface tension	Water's surface tension is reduced significantly when the product is added. At 1.0% in aqueous solution it is 32.1 mN/m (water: 72.6 mN/m)
Foaming behaviour	In the foam formation test, according to DIN 53 902, a solution at 1.0% of euxyl™ PE 9010 preservative in demineralised water showed no foam formation.
Maximum use temperature	120°C

### CMSI:

The product's effectiveness against the germs specified next has been checked, in accordance with DGHM directives (German Society of Hygiene and Microbiology). When determining the minimum inhibitory concentration (MIC) using the serial dilution procedure, the following results were obtained (product MIC %)

Gram-negative bacteria	Gram-positive bacteria	Yeast
<i>Enterobacter gergoviae</i> 0.50	<i>Staphylococcus aureus</i>	<i>Candida albicans</i> 0.25
<i>Escherichia Coli</i> 0.50	<i>Staphylococcus epidermidis</i>	
<i>Klebsiella pneumoniae</i> 0.25		Mould
<i>Pseudomonas aeruginosa</i> 0.50		<i>Aspergillus niger</i> 0.25
<i>Pseudomonas fluorescens</i> 0.25		<i>Penicillium funiculosum</i> 0.25
<i>Pseudomonas putida</i> 0.50		

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### 6. DOSAGE.

The dosage refers to the total formulation. These figures are approximate.

Recommendations for use	No-rinse	Rinse
Manufacturer	0.5-1%	0.5-1%
Cosmetics Regulation (EU)	Max. 1.11%	Max. 1.11%
CIR (USA)	Max. 1.11%	Max. 1.11%
AESAN (Cosmetics Directive)	Max. 1.11%	Max. 1.11%
TSSC 2015 (China)	Max. 1.11%	Max. 1.11%
MERCOSUR	Max. 1.11%	Max. 1.11%

The concentrations for individual use of the product depend on how sensitive the product is to microbiological contamination, the choice of starting materials, and hygiene throughout the production process.

The right exact dose must be determined via preservative challenge testing and efficacy testing, as it may be impacted by the other ingredients used in the finished formulation.

The product may be added at any phase of the manufacturing process (aqueous phase, oil phase, or finished emulsion).

Given its molecular structure, ethylhexylglycerin may have an impact on the viscosity and stability of some emulsions. For this reason, and depending on the formulation, adding it during one phase or another in the manufacturing process may improve stability or viscosity.

### 7. REMARKS.

#### **STORAGE:**

Store at room temperature in a cool, dry place in a tightly closed container away from sunlight, heat sources and moisture.

The documentation available related to the product's regulatory compliance is included below.

#### **BSE/TSE:**

No raw material of animal or plant origin is used to produce the product and it does not come into contact with materials of animal or plant origin during its manufacturing processes.

#### **GMOs:**

No raw material of animal or plant origin is used to produce the product and it does not come into contact with materials of animal or plant origin during its manufacturing processes. Therefore, GMOs are not expected to be present in the product.

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### CMR:

The product does not contain ingredients classed as carcinogenic, mutagenic or reprotoxic (CMR Cat. 1a, 1b and 2) as per the Regulation on classifying, labelling and packaging substances and mixtures (CLP. EC 1272/2008/EC).

### SVHC:

The manufacturer is aware of the latest updated Candidate List of substances that, at the present time, are considered substances of very high concern (SVHC) by the European REACH Regulation. In accordance with the latest SVHC list (available on <http://echa.europa.eu/candidate-list-table>) the manufacturer must ensure the product and all the primary and secondary packaging used to package the above-mentioned products do not contain any of the substances that, at the present time, are considered substances of very high concern (SVHC) by the European REACH Regulation.

### NANOPARTICLES:

The product does not contain nanoparticles.

The product is not considered a microplastic in accordance with the ECHA's definition. The product is not classified as a polymer.

### VOCs:

The product does not contain volatile organic compounds (VOCs) in accordance with Directive 2010/75/EC on limiting VOCs emissions, in accordance with its recipe, nor are these added intentionally at any point in the manufacturing process.

### IRRADIATION:

The product has not undergone irradiation at any stage of the production process, nor during the packaging or sampling process.

### PRESERVATIVES:

The product is a water-free system with preservative properties.

### RESIDUAL SOLVENTS:

The product complies with the ICH Q3C Guides on impurities (Residual Solvents Guide of 04.2021).

No class 1, 2 or 3 solvents are added during the manufacturing process.

### CONTAMINANTS/IMPURITIES:

- The product does not contain the following, nor are any of the following added at any point in the production process:
  - o Formaldehyde or formaldehyde releasers
  - o Phthalates
  - o Aflatoxins
  - o Furanocoumarins
  - o Boric acid
  - o Nitrosamines

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- o Latex
  - o Hydroquinone
  - o 1,4-Dioxane
  - o Melamine
  - o Silicones
- The product contains phenoxyethanol (ethylene glycol monophenyl ether), a glycol ether, as an active ingredient. No other glycol ethers are present in the product or have been added during any part of the manufacturing process.

### HEAVY METALS:

The product does not contain heavy metals. However, given the fact there may be inevitable traces of impurities or unexpected traces of heavy metals, these will be found in amounts below 20 ppm in total.

### NAGOYA PROTOCOL:

Not applicable.

### ALLERGENS:

- **Food allergens:** The product does not contain substances or products that cause allergies or intolerances in accordance with Appendix II of Regulation (EC) 1169/2011 on the provision of food information to consumers. Furthermore, these are not added at any point in the manufacturing process.
- **Cosmetic allergens:** The product does not contain the substances listed in Appendix II on prohibited substances, of Regulation (EC) 1223/2009. The product does not contain the substances listed in Appendix III of Regulation (EC) 1223/2009 on restricted substances, except for phenoxyethanol, which is the product of a reaction between ethylene oxide and phenol. Therefore, phenoxyethanol is a technically inevitable impurity derived from the production process, with < 10 ppm phenol and < 2 ppm ethylene oxide.

### KOSHER:

The product does not contain any of the following materials, nor have they been used in the manufacturing process or as processing aids:

Alcohol (ethanol or grain alcohol), natural L-cysteine extracted from hair or feathers, animal fat, animal extracts, blood of any origin, plasma, pork and/or other meat derivatives.

The machinery used to manufacture the product is not used to manufacture any products of animal origin, or any products that contain ingredients of animal origin.

### HALAL:

The product does not contain any of the following materials, nor have they been used in the manufacturing process or as processing aids:

Alcohol (ethanol or grain alcohol), natural L-cysteine extracted from hair or feathers, animal fat, animal extracts, blood of any origin, plasma, pork and/or other meat derivatives.

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The machinery used to manufacture the product is not used to manufacture any products of animal origin, or any products that contain ingredients of animal origin.

### VEGAN/VEGETARIAN:

This product and its processing aids have not involved the use of animal products, substitutes or derivatives.

Furthermore, the product has not been tested on animals and has been manufactured using methods in line with GMP in order to minimise any presence of unintentional impurities (including any source of animal material), avoiding cross-contamination of the product and its ingredients within the limits of reasonable practice.

### TESTED ON ANIMALS:

The product has not been tested on animals in accordance with Reg. (EC) 1223/2009.

### RSPO:

The product does not contain palm oil or palm kernel oil, nor have these been used in the manufacturing process.

### COSMETIC INVENTORIES:

CAS-No.	EINECS-Name	EINECS-No	TSCA	ECL	DSL	ENCS	PICCS	AICS	IECSC	NZIoC	TCSI	VNECI	INSQ
70445-33-9	3-[(2-Ethylhexyl)oxy] 1,2-propandiol (Sensiva SC 50)	ELINCS Nº 408-080-2	X	X <sup>(2)</sup>	X	X <sup>(1)</sup>	X	X	X	X	X	X	X
122-99-6	2-phenoxyethanol	204-589-7	X	X	X	X	X	X	X	X	X	X	X

<sup>(1)</sup> Registered in Japan/ENCS as glycerin monoalkyl (or alkenyl, C 8-24) ether (No.2-414).

<sup>(2)</sup> KE No: 2004-3-2572

Europe: EINECS/ELINCS USA: TSCA Korea: ECL Canada: DSL/NDSL Japan: ENCS Australia: AICS Philippines: PICCS China: IECSC New Zealand: NZIoC Taiwan: TCSI  
 Vietnam: VNECI Mexico: INSQ

The National Chemical Ingredient Status Inventory is designed to be used as a tool that provides regulatory information on chemical substances. A list of chemical inventories is not required in all countries for exclusive use in cosmetic products. In some countries, its approval for use in cosmetic products may be regulated separately. For example, in the USA certain substances are generally excluded from the TSCA, including, among others, foodstuffs, medicines and cosmetics.

### ISO 16128:

The result of the calculation for the product is 0%.

### REACH:

2-phenoxyethanol: 01-2119488943-21-0020

3-(2-ethylhexyloxy)propane-1,2-diol: 01-0000015745-65-XXXX

### NMPA:

100157-01260-9485