

schülke -+

euxyl® PE 9010

Preservative for cosmetics & toiletries

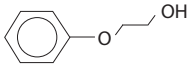


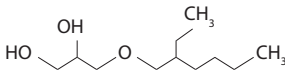
the plus of pure
performance

euxyl® PE 9010

General information

Descriptions of individual substances

	$C_8H_{10}O_2$ 138.17 g/mol
CAS no.:	122-99-6
INCI name:	Phenoxyethanol
Name according to 76/768/EEC:	Phenoxyethanol
No. according to 76/768/EEG:	29
EINECS name:	2-Phenoxyethanol
EINECS no.:	204-589-7

	$C_{11}H_{24}O_3$ 204.31 g/mol
CAS no.:	70445-33-9
CAS-name:	3-[(2-Ethylhexyl)oxy]-1,2-propandiol
INCI name:	Ethylhexylglycerin
ELINCS name:	sensiva® SC 50
ELINCS no.:	408-080-2

Physical-chemical data

Appearance:	clear, colorless – nearly colorless liquid
Color index (Gardner):	max. 2
Odor:	characteristic
Refractive index n_D^{20} :	approx. 1.53
Density (20°C):	approx. 1.09 g/ml
Vapour pressure (20°C):	< 1 hPa
Flash point (ISO 2719):	> 100°C
Flow time (DIN 53 211/20°C):	< 15 DIN seconds
Viscosity (Brookfield-RVT; 20°C):	UL-Adapter/100 Upm: approx. 68 mPa s
Water solubility (20°C):	approx. 10 g/l (at 60°C approx. 15 g/l)

Storage

We recommend storing in the original container at room temperature.

Environmental information

schülke has DIN EN ISO 9001 and DIN EN 14001 certification and a validated environmental management system in accordance with the Eco Audit Regulation.

The canisters and drums used by schülke are made of polyethylene (HDPE) and are labeled accordingly.

The 1000 kg containers are affiliated to a recycling system that guarantees free pick-up and sensible utilisation of used containers throughout Europe. The labels are made of PE. Our packaging materials contain no PVC and are recyclable.

Toxicology

euxyl® PE 9010 is used as a preservative for cosmetics and toiletries. The product is used at a recommended use concentration of 0.5 – 1.0 %. In accordance with the conditions stipulated in Directive 76/768/EEC euxyl® PE 9010 may be used in cosmetic preparations (leave-on and rinse-off) in a use concentration up to a maximum of 1.1%.

As active substance phenoxyethanol (90%) is used in euxyl® PE 9010. As an auxiliary compound the formulation additionally contains ethylhexylglycerin in a concentration of 10%. Both substances have undergone extensive toxicological testing. On the basis of the results with the given upper concentration limit of 1.1%

euxyl® PE 9010 can be considered safe for the preservation of cosmetics and toiletries.

Furthermore, a skin tolerability study (occlusive patch test) of euxyl® PE 9010 compared to phenoxyethanol showed that there is no difference in skin tolerability between euxyl® PE 9010 and phenoxyethanol. During the entire test period no reactions to either phenoxyethanol or euxyl® PE 9010 used in the maximum use concentrations could be observed. This skin tolerability test has been carried out on Caucasian skin in Germany and on Japanese skin in Japan.

Expert opinions

“A new Concept to Boost the Preservative Efficacy of Phenoxyethanol”, W. Beilfuss, Dr. M. Leschke, Dr. K. Weber, SÖFW Journal, 2005, 11, 30 – 36 (German edition)

“A Reliable Alternative for Traditional Preservative Systems”, Dr. M. Leschke, S. Wüstermann, SÖFW Journal, 2006 (English version)

“Can new biodegradable Complexing Agents replace Tetrasodium EDTA to boost preservatives?”, W. Siegert, SÖFW Journal, 2008, 1 – 2, 22 – 26 (English edition)

“The Toxicology and Tolerance of the Preservative euxyl® PE 9010”, Dr. Susanne Hendrich, Schülke & Mayr GmbH, July 2008

euxyl® PE 9010

Product description

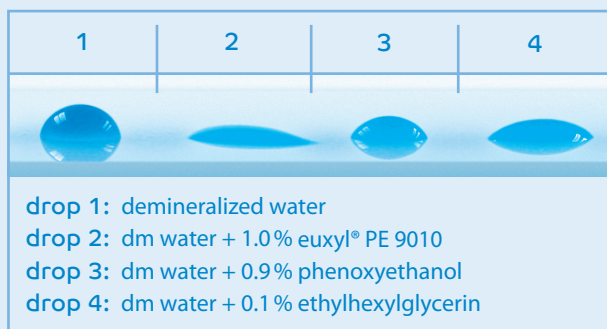
euxyl® PE 9010 is a liquid cosmetic preservative based on phenoxyethanol and ethylhexylglycerin. The addition of ethylhexylglycerin affects the interfacial tension at the cell membrane of microorganisms, improving the preservative activity of phenoxyethanol.

euxyl® PE 9010 has a broad, balanced spectrum of effect against bacteria, yeast and mold fungi.

Contact angle of aqueous solutions on polyethylene

euxyl® PE 9010 reduces the contact angle of water significantly.

The wetting of surfaces is improved. The picture clearly demonstrates this phenomenon on polyethylene. With ethylhexylglycerin, the contact of phenoxyethanol with the cell membrane of microorganisms can also be optimized. The antimicrobial efficacy of phenoxyethanol is improved.



EU INCI declaration

Phenoxyethanol
Ethylhexylglycerin

US INCI declaration

Phenoxyethanol
Ethylhexylglycerin

Microbiological effectiveness

euxyl® PE 9010 is equally effective against bacteria, yeast and mold fungi. It is a typically biostatic product with the biocidal properties necessary for practical use.

For euxyl® PE 9010 to perform effectively in destroying organisms in products already contaminated a minimum contact time of 48 hours is necessary. Since the effect of euxyl® PE 9010 takes place through chemical reactions with the microorganisms when it is used in heavily contaminated products loss of active ingredient must be taken into account.

Good production hygiene as well as the use of raw materials with low microorganism levels as a result of correct raw material control are of course vital prerequisites for the production of microbiologically faultless finished products.

MIC values

Determination of the minimum inhibitory concentration in serial dilution tests produced the following values:

Species	ATCC No.	euxyl® PE 9010 [%]	Phenoxyethanol [%]
Gram negative:			
<i>Enterobacter gergoviae</i>	33028	0.5	0.5
<i>Escherichia coli</i>	11229	0.5	0.5
<i>Klebsiella pneumoniae</i>	4352	0.25	0.5
<i>Pseudomonas aeruginosa</i>	15442	0.5	0.5
<i>Pseudomonas fluorescens</i>	17397	0.25	0.5
<i>Pseudomonas putida</i>	12633	0.5	0.5
Gram positive:			
<i>Staphylococcus aureus</i>	6538	0.5	1.0
<i>Staphylococcus epidermidis</i>	12228	0.5	1.0
Mold fungi:			
<i>Aspergillus niger</i>	6275	0.25	0.5
<i>Penicillium funiculosum</i>	36839	0.25	0.25
Yeast:			
<i>Candida albicans</i>	10231	0.25	0.5

euxyl® PE 9010 is proven to have better efficacy against many microorganisms than phenoxyethanol alone.

Germ count reduction test

Dilutions of euxyl® PE 9010 are prepared with sterile tap water. 50 ml portions of the end solutions are each inoculated with 0.5 ml microorganism suspension (initial microorganism count approx. 10⁸ cfu/ml) and stirred.

Test organisms	ATCC No.
<i>Pseudomonas aeruginosa</i>	15442
<i>Escherichia coli</i>	11229
<i>Candida albicans</i>	10231
<i>Aspergillus niger</i>	6275

These solutions are streaked out onto tryptone soya agar or Sabouraud-dextrose 4 % agar after 3, 6, 24, 48, 72 and 168 hours depending on the test organism. The cultures are incubated for 48 hours at 37°C, except for *Aspergillus niger*, which is incubated for 72 hours at 25 – 27°C.

The evaluation is made on the basis of semi-quantitative assessment of the microbial growth of the streaks.

euxyl® PE 9010

In the table below, the microorganism reduction achieved by euxyl® PE 9010 as a function of the contact time and use concentration is presented for the various test organisms:

Test organism	Use concentration [%]	Contact time (h)					
		3	6	24	48	72	168
<i>Pseudomonas aeruginosa</i>	0.0 (blank value)	C	C	C	C	C	C
	0.5	C	C	C	C	C	-
	0.75	C	++	-	-	-	-
	1.0	-	-	-	-	-	-
<i>Escherichia coli</i>	0.0 (blank value)	C	C	C	C	C	C
	0.5	C	C	-	-	-	-
	0.75	+	-	-	-	-	-
	1.0	-	-	-	-	-	-
<i>Candida albicans</i>	0.0 (blank value)	C	C	C	C	C	C
	0.5	C	C	C	C	C	-
	0.75	C	C	++++	+	-	-
	1.0	C	++++	-	-	-	-
<i>Aspergillus niger</i>	0.0 (blank value)	C	C	C	C	C	C
	0.5	C	C	C	C	C	-
	0.75	C	C	+++	+++	-	-
	1.0	C	++++	-	-	-	-

Symbol	Finding	Germ count/ml
-	no growth	< 100
+	slight growth	approx. 10 ²
++	moderate growth	approx. 10 ³
+++	heavy growth	approx. 10 ⁴
++++	massive growth	approx. 10 ⁵
C	surface covered	approx. 10 ⁶

Repeated challenge test (schülke Koko test)

This method is used to determine the preservative effect of chemical preservatives in cosmetic formulations, e.g. creams, lotions and shampoos. For this, in various test series the preservative to be tested is added in different concentrations to unpreserved samples. A constant microorganism load is achieved by means of periodic inoculation (inoculation cycles) of the test preparations. Immediately before inoculation samples of the individual preparations are streaked out onto nutrient media.

The preservative effect is evaluated on the basis of the microorganism growth on the nutrient media. The longer the time before the occurrence of the first microbial growth, the more effective is the preservative. Experience has shown that a well preserved product should remain growth-free for six inoculation cycles in order to ensure the shelf-life in the original packaging required in practice (30 months).

Oil-in-water, water-in-oil systems, shampoos and bath additives preserved with use concentrations of between 0.5 and 1.0 % euxyl® PE 9010 proved to be well preserved, even after three months storage at +40°C.

International approvals

Use concentrations	acc. schülke recommendation	acc. EU and ASEAN Cosmetics Directive	acc. CIR (USA)
Leave-on (i.e. creams, lotions etc.)	0.5 – 1.0 %	max. 1.1 %	max. 5.5 %
Rinse-off (i.e. shampoos, bath preparations etc.)	0.5 – 1.0 %*	max. 1.1 %	max. 5.5 %

* A high load of ethoxylated surfactants result in a loss of efficacy.

Recommended use concentrations are based on average active content. Please pay attention to the corresponding certificate of analysis.

The schülke recommended percentages relate to the complete formulation in each case. The values given are recommended guides. The individual use concentration is dependent on the sensitivity of the product to microbial contamination, the choice of raw materials and production hygiene.

The efficacy and optimum use concentration should always be determined in the end product with the aid of a preservation load test (i.e. Schülke & Mayr GmbH Technical Service Department and Microbiology).

All responsibility for determining the most effective percentage for a given use remains with the final product manufacturer since the optimal use concentration level will vary due to product-specific variables such as choice of raw materials, production, hygiene etc.

Australia

Phenoxyethanol:	AICS; TGA
Ethylhexylglycerin:	NICNAS (File No: NA/966); AICS; TGA

Canada

Phenoxyethanol:	listed on DSL
Ethylhexylglycerin:	listed on DSL

Japan

Phenoxyethanol:	is approved as a cosmetic preservative up to 1.0 % for all types of cosmetics and toiletries without restrictions.
Ethylhexylglycerin:	listed on ENCS (No.: - 414) listed in JSQI [Code: 540033 (51)] listed in Japanese INCI list

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Indications for use

General

euxyl® PE 9010 is stable to hydrolysis, temperature and pH. As a result of the good solubility of euxyl® PE 9010, an easy dispersion in the various systems even at low temperature is possible. euxyl® PE 9010 is effective in pH-ranges up to 12.

Emulsions

In practice emulsions are preserved with 0.5 – 1.0% euxyl® PE 9010.

Solutions

euxyl® PE 9010 is clearly soluble in use concentration of 0.5 – 1.0%. It can tolerate high salt content. A high load of surfactants can result in a loss of efficacy.

Wet wipes

For wet tissues, good preservation results are achieved with 0.5 – 1.0% euxyl® PE 9010.

Natural products

Formulas containing natural raw materials have a higher risk for microbial contamination. Microorganisms introduced by this pathway are quickly eliminated by euxyl® PE 9010.

For other uses please contact your local representative.

Chemical compatibility

In general it is possible for interactions to occur between various active ingredients and auxiliary substances in cosmetic formulations. Thus, certain incompatibilities of euxyl® PE 9010 with other ingredients have been established and are listed below.

General

euxyl® PE 9010 shows a good compatibility with salts. euxyl® PE 9010 can be used in pH-ranges up to 12.

Discoloration

In general euxyl® PE 9010 displays good compatibility with the ingredients of cosmetics. No discolorations have been detected.

Compatibility with sulfite ions

euxyl® PE 9010 shows no interaction with sulfite ions.

Compatibility with pigments

euxyl® PE 9010 shows no interaction with pigments, such as TiO₂.

Product-specific properties

Material compatibility

Concentrate

In the material compatibility tests with the concentrate of euxyl® PE 9010 stainless steel, brass, copper, zinc and aluminum as well as polyethylene (PE), polyoxymethylene (POM), polyamide (PA) and hard polyvinyl chloride (hard PVC) proved to be suitable materials for handling the undiluted product. Other non-metallic materials should be checked for their suitability. Polycarbonate (PC), polymethylmethacrylate (PMMA), polyethyleneterephthalate (PET) and acrylnitrilbutadienestyrolcopolymer (ABS) should not be used. As sealing material when handling undiluted euxyl® PE 9010 fluorine rubber or ethylene-propylene terpolymers (EPDM) or polytetrafluorethylene (PTFE) should be preferred. Other sealing materials can show swelling or lead to pronounced discoloration of euxyl® PE 9010.

Dilutions

The behavior of euxyl® PE 9010 in 1.0% aqueous solution with regard to material compatibility was not significantly different from that of the tap water used for the dilution. No incompatibilities with plastics have been observed with products preserved with euxyl® PE 9010.

Effect on surface tension

The surface tension of water is significantly reduced by the addition of euxyl® PE 9010. A 1.0% solution in water is 32.1 mN/m (water: 72.6 mN/m).

Foaming behavior

In the foaming test in accordance with DIN 53 902, a 1.0% solution of euxyl® PE 9010 in demineralized water proved to be non-foaming.

Solubility

euxyl® PE 9010 exhibits limited solubility in water. 100 g of water at 20 °C dissolves 1.0 g of euxyl® PE 9010. In polar solvents such as 1,2-propylene glycol, propanol or acetone, euxyl® PE 9010 is readily soluble. In polyalcohols such as glycerol and sorbitol, euxyl® PE 9010 is moderately soluble. In aliphatic hydrocarbons with hydrophilic groups such as 2-octyldecanol and isopropyl myristate, euxyl® PE 9010 exhibits limited solubility. In pure aliphatic solvents it is slightly soluble.



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