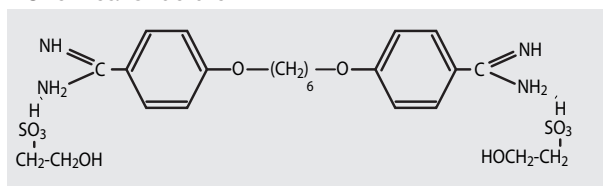


DEFINITION / COMPOSITION

ELESTAB® HP 100 is a hydrosoluble antimicrobial cationic substance with a wide spectrum of activity against bacteria, fungi and yeasts.

ELESTAB® HP 100 may be used as a polyvalent preservative, as well as a cutaneous aseptizer.

- Chemical denomination:
4,4'-diamidino- α - ω -diphenoxyhexane, bis (β -hydroxyethane sulfonate),
- DCI: Hexamidine diisethionate,
- Chemical structure:



- Molecular formula: C₂₄ H₃₈ N₄ O₁₀ S₂,
- Molecular weight: 606.72.

ANTIMICROBIAL PROPERTIES

- ELESTAB® HP 100 has strong microbiostatic and/or microbicidal activity against:
 - Gram (+) bacteria: Staphylococcus, Sarcina, Streptococcus, Corynebacterium, Propionibacterium, Bacillus,
 - Gram (-) bacteria: Escherichia, Proteus, Klebsiella, Salmonella, Serratia,
 - Gram (-) bacteria, oxydase (+): Pseudomonas,
 - Fungi: Aspergillus, Penicillium, Actinomyces^[1], Geotrichum^[1], Trichophyton^[1], Hormodendron^[1],
 - Yeasts: Candida, Pityrosporum.
- The antimicrobial effects of ELESTAB® HP 100 vary according to:
 - the concentration and duration of contact with the anti-microbial agent,
 - the number of micro-organisms,
 - the nature and virulence of the germs,
 - the properties and characteristics of the medium.

COSMETIC USE

ELESTAB® HP 100 is suitable for incorporation into cosmetic and hygiene preparations, such as emulsions, masks, gels, aqueous and alcoholic solutions, foaming preparations, sprays, sticks:

1. for their microbiological stabilization. We recommend a special study for each cosmetic formulation (see overleaf),
2. for a local aseptizing activity on skin and relative areas (hair...). For example:
 - care of oily skin and/or skin with acneic tendencies because of:
 - its antimicrobial effect on specific strains,
 - its inhibiting effect of the lipase of *P. acnes*,
 - its indirect anti-irritating effect (slows the hydrolysis of the sebaceous triglycerides),
 - anti-dandruff care (action on *Pityrosporum ovale*),
 - deodorant preparations.

ADVANTAGES

ELESTAB® HP 100 contains neither free nor combined formaldehyde, has a good cutaneous/mucous local tolerance and has an excellent coefficient of security compared to other antiseptics. It resists to inactivation by sebum, and is a substantive and an indirect anti-irritant for the skin.

DOSAGE / SOLUBILITY / MODE OF INCORPORATION

1. Dose of use:

- as a cutaneous aseptizer: 0.10%,
- as a preservative: 0.01% to 0.1%.

The relevant antimicrobial protection of the cosmetic product has to be checked by a challenge test.

2. **Solubility:** ELESTAB® HP 100 is soluble in water (80°C) and propylene glycol (60°C), soluble in ethanol and insoluble in oils and fats.

3. **Mode of incorporation:** ELESTAB® HP 100 must be dissolved under stirring into the formula's water previously heated to 80°C. It can also be introduced as a mother solution in propylene glycol. This way is recommended in the case of anionic emulsions and nonionic emulsions with alkyl-glucosides and sucrose esters.

COMPATIBILITY / INCOMPATIBILITY

ELESTAB® HP 100 is a cationic substance, thus it is incompatible or interacts with all anionic raw materials. In most cases, this incompatibility leads either to a crystallization of ELESTAB® HP 100, or to a more complex precipitation. To avoid this phenomenon, particularly in the formulation of limpid, transparent products, it is imperative to "neutralize" ELESTAB® HP 100 with anionic surfactants, before its introduction into the product.

The suitable pH is between 3 and 8, avoid high alkaline medium.

ANALYTICAL CHARACTERISTICS

1. Aspect: white powder with a weak odor.
2. Specifications: upon request.

TOLERANCE

Good.

EFFICACY

Test summaries overleaf.

STORAGE

In its original packaging, at 15 - 25°C.

REGULATORY STATUS

Approved: USA, EC, Australia, Canada.

INCI NAME

Hexamidine Diisethionate.

SUPPLIER

BASF Beauty Care Solutions France SAS
3 rue de Seichamps - 54425 Pulnoy (France)

[1] Wien R., Harrison J., Freeman W.A.: Diamidines as antibacterial compounds in "Brit. J. Pharmacol.". 3, 211-218, 1948

EFFICACY TESTS

AS A PRESERVATIVE: WIDE SPECTRUM, POLYVALENT

When using ELESTAB® HP 100 as preservative for cosmetic products, a microbiological study should be performed to check:

- the absence of incompatibilities,
- the exact dosage according to the panel of micro-organisms tested and the kinetics of negativation, selected by the challenge test,
- the possible necessity to associate other preservatives with ELESTAB® HP 100.

Such synergistic associations of preservatives are supplied by BASF Beauty Care Solutions as ELESTAB® 4112, ELESTAB® 388...

Strains				ELESTAB® HP 100	
				Concentration (µg/ml)	
				MIC	MMC
Bacteria					
Staphylococcus aureus	ATCC	6538	0.8	25	
Staphylococcus epidermidis	NCIB	8853	0.8	25	
Bacillus subtilis	ATCC	6633	3.2	6.4	
Escherichia coli	NCTC	8196	1.6	25	
Klebsiella pneumoniae	NCIB	10341	12.5	50	
Proteus vulgaris	NCIB	4175	25	50	
Pseudomonas aeruginosa	ATCC	9027	50	50	
Salmonella typhimurium	NCIB	10258	100	> 100	
Serratia marcescens	ATCC	14041	50	> 100	
Fungi					
Aspergillus niger	ATCC	16404	0.8	0.8	
Penicillium funiculosum	ATCC	9644	0.8	1.6	
Yeast					
Candida albicans	ATCC	10231	3.2	6.4	

Table 1 – ELESTAB® HP 100 as a polyvalent preservative. Minimum Inhibitory Concentration (MIC) and Minimum Microbicidal Concentration (MMC) of ELESTAB® HP 100 against a range of bacteria, fungi and yeasts.

AS A SKIN ASEPTIZER

ELESTAB® HP 100 can be used at 0.10% in topical preparations to kill harmful micro-organisms on the skin's surface.

ELESTAB® HP 100 can be used for:

- care of oily skin with acneic tendency,
- care of pityrospores of the face (= seborrheic state) and the scalp (pityriasis capitis or dandruff state).
- deodorant preparations.

Strains				ELESTAB® HP 100	
				Concentration (µg/ml)	
				MIC	MMC
Sarcina lutea	ATCC	9341	0.8	1.6	
Streptococcus pyogenes	NCTC	8198	1.6	1.6	
Corynebacterium xerosis	NCTC	8481	3.2	3.2	
Propionibacterium acnes	NCTC	521	0.1	12.5	
Propionibacterium granulosum	ATCC	25564	0.1	12.5	
Pytirosporum ovale	NCYC	0218	12.5	100	

Table 2 – ELESTAB® HP 100 as a skin asepticizer. MIC and MMC of ELESTAB® HP 100 against a range of specific strains.

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