

LANETTE® N PH

Further Product Name

Ph. Eur.: Cetostearylalcohol (type A), emulsifying"
BP: "Selfemulsifying Cetostearylalcohol - Type A"

General Characterization

Lanette® N PH is a product with faint characteristic odour which is supplied in pellets. This anionic self emulsifying base is suited for the preparation of pharmaceutical O/W creams and lotions.

Chemical description

Mixture of Cetyl stearyl alcohol with Sodium cetylstearyl sulfate

Characteristic Values

The specifications stated below finally and conclusively describe the properties of the product.

Quality control data

Data which is used for quality release and is specified for each batch.

Identification A	conforms	Ph. Eur. 2.2.27
Identification B	conforms	Ph. Eur. 2.2.28
Identification C	conforms	Ph. Eur. 0801
Identification D	conforms	Ph. Eur. 0801
Acid value	max 2.0	Ph. Eur. 2.5.1
Iodine value	max 3.0	Ph. Eur. 2.5.4 method A
Saponification value	max 2.0	Ph. Eur. 2.5.6
Water	max 3.0 %	Ph. Eur. 2.5.12
Cetostearyl alcohol *	min 80.0 %	Ph. Eur. 2.2.28
Sodium Cetostearyl sulphate *	min 7.0 %	Ph. Eur. 0801
* of the water-free substance		
Pesticide residues	conforms	Ph. Eur. 2.8.13 table 1
Microbiological status	conforms	Ph. Eur. 5.1.4 category 2 & 3a
Aflatoxines	conforms	Federal Health Gazette Ban V 2000
Heavy Metals	conforms	Federal Health Gazette 1985, 1992

Methods of identification

As described in the current Monograph of the Ph. Eur.

Methods of analysis

All test and assay methods are as described in the current Monograph of the Ph. Eur.

Storage, Packaging and Shelflife

Storage Conditions

Storage and transportation In sealed original containers, protected from moisture and at temperatures below 30 °C Lanette® N PH remains stable for at least two years. Lanette® N PH is stabilized with 0.12 % phosphate buffer.

Labeling Information & Registrations

INCI name(s)

Cetearyl Alcohol (and) Sodium Cetearyl Sulfate

Officially listed in / Quality conforms to

Ph. Eur.	Conforms to the current analytical specification in the monograph "Cetostearylalcohol (type A), emulsifying"
BP	Conforms to the current analytical specification in the monograph "Selfemulsifying Cetostearylalcohol - Type A"
US DMF no. (Typ IV)	#16823
JCIC	listed by individual components
CAS-No.	67762-27-0 & 68955-20-4
EINECS-No.	267-008-6 & 273-258-7
Residual solvents	Conforms to current ICH Guideline (CPMP/ICH/283/95) & Residual solvents <467>
Minimising animal spongiform encephalopathy agents	Conforms to requirements Ph. Eur. 5.2.8

Disclaimer

All products in the text marked with an ® are trademarks of the Cognis group. The information on product specifications provided herein is only binding to the extent confirmed by Cognis in a written Sales Agreement. COGNIS EXPRESSLY DISCLAIMS ANY RESPONSIBILITY FOR THE SUITABILITY OF THE PRODUCTS FOR ANY SPECIFIC OR PARTICULAR PURPOSES INTENDED BY THE USER. Suggestions for the use and application of the products and guide formulations are given for information purposes only and without commitment. Such suggestions do not release Cognis' customers from testing the products as to their suitability for the customer's intended processes and purposes. Cognis does not assume any liability or risk involved in the use of its products as the conditions of use are beyond its control. The user of the products is solely responsible for compliance with all laws and regulations applying to the use of the products, including intellectual property rights of third parties.