

HD-EUTANOL[®] V PH**Further Product Name**

Ph. Eur.: "Oleyl Alcohol"

NF: "Oleyl Alcohol"

General Characterization

HD-EUTANOL[®] V PH is a clear, slightly yellowish, almost odourless weak polar oil with a mean molecular weight. HD-EUTANOL[®] V PH is suited for application in pharmaceutical skin care preparations, such as low-fattening emulsions and skin oils.

Chemical description

Oleyl Alcohol

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. 2073
Identification B	conforms	Ph. Eur. 2073
Appearance	pass	Ph. Eur. 2.2.1 / 2.2.2 Method II
Refractive index	1.458 - 1.460	Ph. Eur. 2.2.6
Cloud point	max 10°C	Ph. Eur. 2073
Acid value	max 1.0	Ph. Eur. 2.5.1
Hydroxyl value	205 - 215	Ph. Eur. 2.5.3 Method A
Saponification value	max 2.0	Ph. Eur. 2.5.6
Composition of fatty alcohols		
Palmityl alcohol	max 8.0	Ph. Eur. 2.2.28
Stearyl alcohol	max 5.0	Ph. Eur. 2.2.28
Oleyl alcohol (sum oleyl & elaidyl)	min 80.0	Ph. Eur. 2.2.28
Linoleyl alcohol	max 3.0	Ph. Eur. 2.2.28
Linolenyl alcohol	max 0.5	Ph. Eur. 2.2.28
Arachidyl alcohol	max 0.3	Ph. Eur. 2.2.28
Cloud point	max 10°C	USP/NF
Refractive index	1.458 - 1.460	USP/NF <831>
Acid value	max 1	USP/NF <401>
Hydroxyl value	205 - 215	USP/NF <401>
Iodine value	85 - 95	USP/NF <401>
Residual solvents	meets the requirements	USP/NF <467>
Peroxide value	max 5	DGF C-VI 6a (Sully)
Heavy metals	pass	Federal Health Gazette 1985
Pesticides	pass	Ph. Eur 2.8.13 - T1
Aflatoxines	pass	Federal Health Gazette Ban V 2000
Microbiology	pass	Ph. Eur. 5.1.4 category 2 & 3a

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. and USP/NF

Storage, Packaging and Shelflife

Storage Conditions

HD-EUTANOL® V PH can be stored in the original unopened containers for at least one year, protected from moisture at below 30° C. Through addition of mixed tocopherols and synergists (CONTROX® KS) the product is protected from autoxidation.

Labeling Information & Registrations

INCI name(s)

Oleyl Alcohol

Officially listed in / Quality conforms to

Ph. Eur.	Oleyl Alcohol
USP/NF	Oleyl Alcohol
US DMF no. (Typ IV)	#16497
JCIC	Oleyl Alcohol (Ingredient Code: 104831-41)
CAS-No	68002-94-8
EINECS-No	268-106-1
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

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