

EUMULGIN® B 2 PH

(Ph. Eur.: "Macrogol cetostearyl ether 20"
BP: "Macrogol cetostearyl ether 20")

Registrations

Ingredient	CASR-No.	EINECS/ELINCS-No.
	68439-49-6*	polymer

Officially listed in / Quality conforms to

Ph. Eur.:	Conforms to the current analytical specification in the monograph "Macrogoli aether cetostearylicus 20 (Macrogol cetostearyl ether 20)"
BP:	Conforms to the current analytical specification in the monograph "Macrogol cetostearyl ether 20" (copy of the Ph. Eur. Monograph)
US DMF no. (Typ IV):	#17198
JCIC:	POE Cetyl/Stearyl Ether (Ingredient Code 501125)
Residual solvents	Conforms to current ICH Guideline (CPMP/ICH/283/95).
Minimising animal spongiform encephalopathy agents	Conforms to requirements Ph. Eur. 5.2.8

Product properties

Appearance

EUMULGIN® B 2 PH is supplied in white to slightly yellowish pellets.

Example of use

The product is used as universally applicable, non-ionic emulsifier for the manufacture of pharmaceutical O/W emulsions.

Characteristic values

The specifications stated in the paragraphs 'Quality control data' and 'Additional product descriptive data' finally and conclusively describe the properties of the Product.

Quality control data

(Data which is used for quality release and is certified for each batch.)

Appearance (colour)	conforms
Alkalinity	<= 0.5 ml
Acid value	<= 1.0
Hydroxyl value	40 - 55
Iodine value	<= 2.0
Saponification value	<= 3.0
Ethylene oxide	<= 1 ppm
Dioxan	<= 10 ppm
Water	<= 3.0 %
Total ash	<= 0.2 %

Further certification:

Pesticide residues complies to the limits defined in Ph. Eur. 2.8.13 (table 1).

Microbiological status	complies with criteria defined in Ph. Eur. 5.1.4 (category 2 - topical applications; category 3A - oral applications).
Aflatoxine	conforms to German ordinance requirements regulating aflatoxine contamination (July 2000).
Heavy Metals	conforms to German Federal Health Gazette 28, 216 1985 and supplements 1992 for heavy metals.

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.

Stabilising additives / Auxiliaries

(type and concentration)

Preservatives

not present

Antioxidants

not present

Solvents

not present

Others

not present

Storage and transportation

In sealed original containers, protected from moisture and at temperatures below 30° C EUMULGIN® B 2 PH remains stable for at least two years. Depending on the temperature, the pH value may decrease during storage. However, the product quality is not negatively influenced above a pH value of 4.0.

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