

93791-SELF-EMULSIFYING NEO PCL W/O

1. IDENTIFICATION OF THE SUBSTANCE OR PREPARATION

1.1 Identification of the substance or preparation

Name: Self-emulsifying Neo-PCL W/O

Bulk code: 93791

Internal code: 405280

1.2 Synonyms

No information available.

2. DESCRIPTION

Appearance: Waxy mass.

Colour: Off-white to white.

Odour: Characteristic.

Geographical origin: The product is manufactured in Germany.

3. COMPOSITION/INFORMATION ON COMPONENTS

Global INCI Name: Beeswax (Cera Alba), Cetearyl Ethylhexanoate, Stearyl Alcohol, Stearyl Heptanoate, Cetyl Palmitate, Steareth-10, Steareth-7, Stearyl Caprylate, Myristyl Alcohol, Dimethicone, Mineral Oil (Paraffinum Liquidum), Isopropyl Myristate

EU INCI Name: Cera Alba, Cetearyl Ethylhexanoate, Stearyl Alcohol, Stearyl Heptanoate, Cetyl Palmitate, Steareth-10, Steareth-7, Stearyl Caprylate, Myristyl Alcohol, Dimethicone, Paraffinum Liquidum, Isopropyl Myristate

Components: Self-emulsifying Neo-PCL W/O is a non-ionic absorption base consisting of ethoxylated fatty alcohol, beeswax, solid PCL, liquid PCL, wax ester, fatty alcohol, paraffin oil and silicone oil.

INCI-Name	INCI-Key	CAS-No	EC-No
Beeswax (Cera Alba)	C	8012-89-3	232-383-7
Cetearyl Ethylhexanoate	C	90411-68-0	291-445-1
		59130-69-7	261-619-1
		59130-70-0	261-620-7
Stearyl Alcohol	C	112-92-5	204-017-6
Stearyl Heptanoate	C	66009-41-4	266-065-4
Cetyl Palmitate	C	540-10-3	208-736-6
Steareth-10	D	9005-00-9	500-017-8
Steareth-7	D	9005-00-9	500-017-8
Stearyl Caprylate	D	18312-31-7	242-200-2
Myristyl Alcohol	E	112-72-1	204-000-3
Dimethicone	E	63148-62-9	
Mineral Oil (Paraffinum Liquidum)	E	8042-47-5	232-455-8
Isopropyl Myristate	E	110-27-0	203-751-4



GUINAMA. Laboratory distributor of raw materials for the pharmaceutical and cosmetics industries.

Type of document:

TECHNICAL DATA SHEET

Review date:

20.12.2022

Version:

2.0

93791-SELF-EMULSIFYING NEO PCL W/O

- A - > 50%
- B - > 25% ≤ 50%
- C - > 10% ≤ 25%
- D - > 5% ≤ 10%
- E - > 1% ≤ 5%
- F - > 0.1% ≤ 1%
- G - ≤ 0.1%

4. PHYSICO-CHEMICAL DATA

For more information, see the analysis report.

Solubility: The product is immiscible with water. Once melted, it mixes well with oils and fats.

Its melting point is approximately 75°C.

5. PROPERTIES/USES

Excipient for pharmaceutical use.

Self-emulsifying Neo-PCL O/W can be used to prepare mild, stable emulsions with both acidic and alkaline properties. Neo-PCL O/W is ideal for manufacturing skin creams with a medium-to-low fat content for cosmetic and pharmaceutical purposes.

The advantage of this absorption base lies in its non-ionic character and the consequent higher resistance to electrolysis. It is the perfect base for moisturisers, day creams, glycerine creams and make-up from solid to viscous consistencies.

6. DOSAGE

To obtain stable emulsions, it is advisable to adjust the water content to c. 60%. As the base is odourless, its emulsions can be easily perfumed, so adding only 0.2% is often sufficient.

7. REMARKS

STORAGE

Store in a cool, dry place protected from sunlight in a tightly closed container, away from heat and moisture.

The documentation available related to the product's regulatory compliance is included below.



GUINAMA. Laboratory distributor of raw materials for the pharmaceutical and cosmetics industries.

Type of document:

TECHNICAL DATA SHEET

Review date:

20.12.2022

Version:

2.0

93791-SELF-EMULSIFYING NEO PCL W/O

BSE/TSE:

The product does not contain any ingredients of animal origin (bovine, porcine, ovine and caprine) except for beeswax (Cera Alba) (metabolic product of bees). It is not expected to be present.

GMOs:

The product has not been manufactured using genetic engineering, nor does it contain genetically modified proteins or modified DNA.

CMR substances:

The product does not contain in its composition any of the substances classified as CMR.

SVHC:

This product has not been formulated with musk xylene and/or any other substances listed in the current Candidate List of Substances of Very High Concern published by the European Chemicals Agency (ECHA), including the first candidate list published on 28 October 2008 up to the latest published list.
(Declaration limit: 0.1%)

NANOMATERIALS:

This product does not contain any intentionally added ingredients that are considered nanoparticles as defined by Cosmetic Regulation (EC) No 1223/2009 on cosmetic products.

VOCs:

The product does not contain any volatile organic compounds, according to Swiss Regulation 814.018.

IONISING RADIATION:

The product has not been treated with ionising radiation in the manufacturing process.

RESIDUAL SOLVENTS:

The following residual solvents specified in Q3C on impurities (EMA/CHMP/ICH/82260/2006) may be present in the product due to the raw materials used: 2-Propanol 80 ppm (calculated values).

PRESERVATIVES/ANTIOXIDANTS:

The product does not contain preservatives or antioxidants.

IMPURITIES:

The product may contain the following impurities, which are technically unavoidable and derive from the manufacturing process following good practices. The calculated content from the starting materials is: Ethylhexanoic acid CAS 149-57-5 <20 ppm



GUINAMA. Laboratory distributor of raw materials for the pharmaceutical and cosmetics industries.

Type of document:

TECHNICAL DATA SHEET

Review date:

20.12.2022

Version:

2.0

93791-SELF-EMULSIFYING NEO PCL W/O

CALIFORNIA SB 484:

This product has not been formulated with materials that are reportable under SB484, the California Safe Cosmetics Act, as causing cancer or reproductive toxicity.

CALIFORNIA PROPOSITION 65:

The product does not contain any of the ingredients listed in California Proposition 65 regarding carcinogenic or toxic substances for development or reproduction.

ALLERGENS:

- **Food allergens:** The product has not been formulated in the presence of food allergens such as peanuts, tree nuts, eggs, fish, seafood, milk, soy or gluten-containing ingredients.
- **Cosmetic allergens:** The product does not contain any of the 26 substances considered fragrance allergens according to Regulation 1223/2009, Annex III.

VEGAN/VEGETARIAN:

The product contains animal-derived ingredients (beeswax, as a metabolic product of bees).

TESTED ON ANIMALS:

The product is compliant with Article 18 of Regulation (EC) 1223/2009 on cosmetic products. It has not been tested on animals.

RSPO:

The product contains palm oil derivatives of Asian origin.

Suppliers of palm oil grades follow RSPO ("Roundtable on Sustainable Palm Oil") guidelines and obtain their palm oil according to the defined RSPO rules.

However, if required, the manufacturer reserves the right to use non-certified palm oil.



GUINAMA. Laboratory distributor of raw materials for the pharmaceutical and cosmetics industries.

Type of document:
TECHNICAL DATA SHEET

Review date:
20.12.2022

Version:
2.0

93791-SELF-EMULSIFYING NEO PCL W/O

ISO 12168:

Ingredient	Origin	Source
Beeswax (Cera Alba)	Natural	Animal
Cetearyl Ethylhexanoate	Natural	Plant/petrochemical
Stearyl Alcohol	Natural derivative (100% natural origin)	Plant
Stearyl Heptanoate	Natural derivative	Plant/petrochemical
Cetyl Palmitate	Natural derivative (100% natural origin)	Plant
Steareth-10	Natural derivative	Plant
Steareth-7	Non-natural	-
Stearyl Caprylate	Natural derivative (100% natural origin)	Plant/petrochemical
Myristyl Alcohol	Non-natural	Synthetic
Dimethicone	Non-natural	-
Mineral Oil (Paraffinum Liquidum)	Non-natural	-
Isopropyl Myristate	Natural derivative	Plant/Chemical

The calculations on the product's naturalness index in accordance with ISO 16128 are:

Natural content % (including water): 19.4%

Natural origin content % (including water): 76.4%

COSMETIC INVENTORIES:

Ingredient	EINECS	ELINCS	TSCA*	DSL	NDSL	AICS	AIIC	NICNAS	ENCS	PICCS	KECI	IECSC	ISHL
Beeswax (Cera Alba)	Y	N	Y	Y	N	Y	N	N	Y	Y	Y	Y	Y
Cetearyl Ethylhexanoate	Y	N	Y	Y	N	Y	N	N	Y	R	Y	R	Y
Cetyl Palmitate	Y	N	Y	Y	N	Y	N	N	Y	Y	Y	Y	Y
Dimethicone	N	N	Y	Y	N	Y	N	N	Y	Y	Y	Y	Y
Isopropyl Myristate	Y	N	Y	Y	N	Y	N	N	Y	Y	Y	Y	Y
Mineral Oil (Paraffinum Liquidum)	Y	N	Y	Y	N	Y	N	N	Y	Y	Y	Y	Y
Myristyl Alcohol	Y	N	Y	Y	N	Y	N	N	Y	Y	Y	Y	Y
Steareth-10	N	N	Y	Y	N	Y	N	N	Y	Y	Y	Y	Y
Steareth-7	N	N	Y	Y	N	Y	N	N	Y	Y	Y	Y	Y
Stearyl Alcohol	Y	N	Y	Y	N	Y	N	N	Y	Y	Y	Y	Y
Stearyl Caprylate	Y	N	Y	Y	N	Y	N	N	Y	Y	Y	Y	Y
Stearyl Heptanoate	Y	N	Y	Y	N	Y	N	N	Y	Y	Y	Y	Y

Y = Yes ; N = No ; R = Registration

* TSCA registration not required for cosmetics

TARIFF ITEM NUMBER:

34021300900

China NMPA submission code:

Not available.