DDS RETINOL

TECHNICAL DOSSIER

Name: DDS RETINOL

Ref.: DDS RETINOL_03

Ver.: 04 (09/11/2020)

INdermal

INDEX

PRODUCT IDENTIFICATION

Tradename: DDS RETINOL (Previous name: Lipo-RETINOL)

Reference: DDS RETINOL_03

Description: Retinyl palmitate (3 %) encapsulated in Deep release nano-vesicles (DDS – Deep Delivery System) to add in cosmetic, cosmeceutical or dermo pharmaceutical formulations.

INCI

AQUA, MANNITOL, PHOSPHATIDILCOLINE, GLYCERIN, RETINYL PALMITATE, CHOLESTEROL, POLYSORBATE 80, SODIUM BENZOATE, POTASSIUM SORBATE, XANTHAN GUM, SODIUM CHLORIDE

COMPOSITION

Ingredient	CAS	% (w/w)
AQUA	7732-18-5	Q.S. 100
MANNITOL	69-65-8	4.50 - 6.50
PHOSPHATIDILCOLINE	8002-43-5	3.20 - 5.20
GLYCERIN	56-81-5	2.60 - 3.60
RETINYL PALMITATE	79-81-2	2.50 - 3.50
CHOLESTEROL	57-88-5	1.10 - 3.10
POLYSORBATE 80	9005-65-6	0.50 – 1.50
SODIUM BENZOATE	532-32-1	0.50 - 0.70
POTASSIUM SORBATE	24634-61-5	0.50 - 0.70
XANTHAN GUM	11138-66-2	0.10 - 0.30
SODIUM CHLORIDE	7647-14-5	0.05 - 0.15

ORIGIN

Ingredient	Origin	Country of origin
AQUA	MINERAL	SPAIN
MANNITOL	VEGETABLE	WORLDWIDE
PHOSPHATIDILCOLINE	VEGETABLE	WORLDWIDE
GLYCERIN	VEGETABLE	SOUTH EAST ASIA AND EUROPE
RETINYL PALMITATE	SYNTHETIC	SWITZERLAND
CHOLESTEROL	ANIMAL	SINGAPORE
POLYSORBATE 80	SYNTHETIC	EUROPEAN UNION
SODIUM BENZOATE	SYNTHETIC	NETHERLANDS
POTASSIUM SORBATE	SYNTHETIC	GERMANY
XANTHAN GUM	BIOTECHNOLOGY	EUROPE
SODIUM CHLORIDE	SYNTHETIC	NETHERLANDS OR FRANCE

SPECIFICATIONS

Appearance: LIQUID
Color: PALE YELLOW
Odor: CHARACTERISTIC
pH: 5.0 – 6.0

COUNTRY OF MANUFACTURE

Spain

EXPIRATION AND STORAGE

12 months if the product is kept in the original sealed container

The product has been packed in a protective nitrogen atmosphere. Once opened, it is recommended to use all the product at once or repackage the excess using nitrogen.

Store in a clean, dark and cool place (8 - 25°).

Do not freeze

RECOMMENDED DOSE

1 % - 10 % According to the frequency of application of the final product and the intensity of the effect that you want to achieve.

Examples: Daily cream: 3% – 5 % Serum: 4% – 8% Mask: 3% - 7% Ampoules: 5% - 10%

Professional use: 7% - 10%

DISPERSABILITY

Dispersible product in aqueous media. (See incompatibilities)

HOW TO USE

Shake before using

Add to bulk during the final phase of the production process, ensuring that the temperature does not exceed 40°C to avoid degradation of the encapsulated molecules. If you need to add it to higher temperatures, please consult our technical service

Maximum homogenization: 20.000 rpm

Formulation pH: 3 – 11

INCOMPATIBILITIES

Ethanol concentrations higher than 15% may damage liposomes (contact our technical service for advice)

Detergents may break liposomes.

Do not add to oil. In emulsions W/O or O/W add it in the aqueous solution.

ISO 16128-1:2016 and 16128-2:2017

In accordance with the guidelines on definitions of natural and organic cosmetic ingredients (ISO 16128-1: 2016 and ISO 16 128-2: 2017), we certify according to the information provided by our suppliers and our production process, the following information

Naturally origin content:	94.50 %
Natural content:	88.79 %

TESTS ON ANIMALS

This product has not been tested on animals by or on behalf of INdermal - Nanovex Biotechnologies SL, in accordance with European Regulation (EC) No. 1223/2009

HEAVY METALS

Max. 0.5 ppm

REACH

Ingredient	REACH
AQUA	Exempt (Ocurring in nature)
MANNITOL	Exempt (Annex IV Article 2(7)(a))
PHOSPHATIDILCOLINE	Exempt (Annex IV Article 2(7)(a))
GLYCERIN	Exempt (Annex V Article 2(7)(b))
RETINYL PALMITATE	01-2119480425-37-XXXX
CHOLESTEROL	01-2119976283-30-XXXX
POLYSORBATE 80	Exempt (< 1 tonne/year)
SODIUM BENZOATE	01-2119460683-35-XXXX
POTASSIUM SORBATE	01-2119950315-41-XXXX
XANTHAN GUM	Exempt (Article 2 (9))
SODIUM CHLORIDE	01-2119485491-33-XXXX

INGREDIENTS STATEMENTS*

Cosmetic allergens	This product does not contain any of the substances introduced in Annex III of the European Cosmetic Regulation by the Seventh Amendment (EC) No. 2003/15 based on SCCNFP opinion.
GMO	According to our knowledge, this product does not contain any ingredient considered a genetically modified organism.
CMR	According to our knowledge, this product does not contain any ingredient classified as carcinogenic, mutagenic or reprotoxic according to Regulation (EC) No. 1272/2008.
SVHC	According to our knowledge, this product does not contain any substance considered extremely worrying.
COV	According to our knowledge, this product does not contain any compound considered volatile organic
Ftalatos	This product does not contain phthalates as an ingredient
Nanomaterials	This product cannot be considered a nanomaterial as defined in Regulation (EC) No. 1223/2009
Formaldehyde	This product does not contain formaldehydes or derivatives
Palm Oil	This product contain palm (RSPO certified)
BSE / TSE	According to our knowledge, this product does not contain any compound related to Bovine Spongiform Encephalopathy or Transmissible Spongiform Encephalopathies
Dioxins	This product is not expected to contain Dioxins
Pesticides	This product is not expected to contain Pesticides
Vegetarian / Vegan	This product is not suitable for vegetarians and vegans.
Halal	This product does not have Halal certification
COSMOS certified	This product does not have COSMOS certification

* Information based on our manufacturing process and information provided by our suppliers

REGULATIONS

Geographical Area	Regulation
European Union	This product is in accordance with Regulation (EC) No. 1223/2009
USA	None of the compounds of this product are prohibited or restricted by FDA regulations.
Canada	Retinyl palmitate is included in the Cosmetic Ingredient Hotlist of Canada (2019) of Ingredients that are Restricted for Use un Cosmetic Products. The maximum concentration permitted in finale product is 1.83 % (w/w)
China	All INCI names are included in the last version of IECIC list (2015)

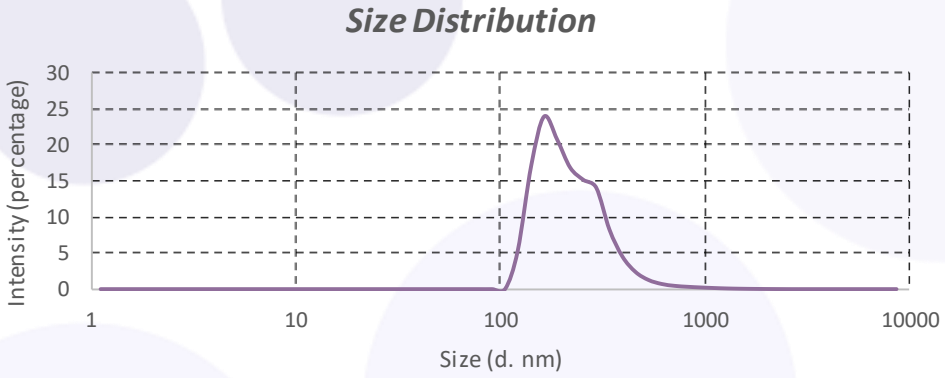
CHARACTERIZATION

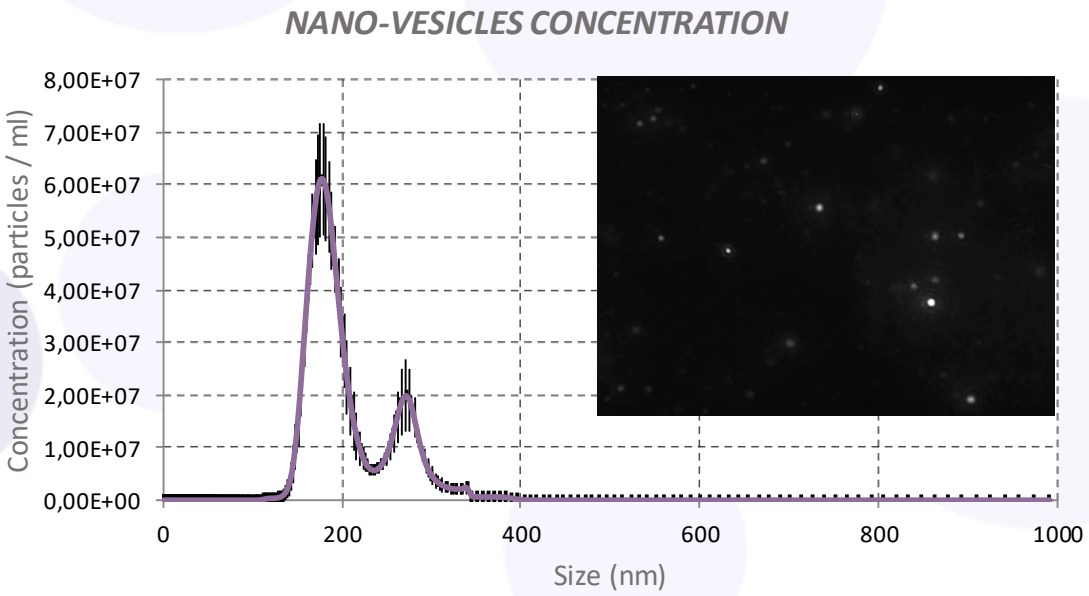
Product characterization is based on the particle analysis using nanotechnology characterization techniques such as; Dynamic Light Scattering, Nanoparticle Track Analysis or Phase analysis Light Scattering. The main properties analyzed are; Average Size, Size Distribution, Zeta-Potential and Particle concentration.

Average size: Average Size = 262 nm ± 40 nm

Average size of nano-vesicles can be determined using Dynamic Light Scattering (DLS) and Nanoparticle Track Analysis (NTA) techniques. Both are based on the Brownian motion of the particle and the light scattering from it. They apply Stokes-Einstein equation to relate diffusion to size (Hydrodynamic diameter). Additionally, DLS offers an ensemble measurement, whereas NTA delivers a particle-by-particle measurement.

Measurement data by DLS





Measurement data by NTA and video capture of Nano-vesicles.

Size distribution: Polydispersity Index (PDI) = 0.242 ± 0.025

Size distribution was determined using the DLS technique. The distribution is represented by the polydispersity index PDI, whose values are in the range between 0 and 1. Values near 0 represent a monodispersed sample and values near 1 represent polydisperse sample. It can be considered that values below 0.5 have good distribution values.

Z-Potential: ζ-Potential = -4.42 mV ± 0.1 mV

For Zeta-potential analysis, an electric field is applied to a dispersion of particles, which then move with a velocity related to their zeta potential. This velocity is measured using a laser interferometric technique called M3-PALS (Phase analysis Light Scattering). This enables the calculation of electrophoretic mobility, and from this, the Zeta-potential.

Liposomes concentration (particles/ml): 2.43 x 10^{14} nanovesicles/ml ± 0.1 x 10^{14} nanovesicles/ml

Nanovesicle concentration can be determined by Nanoparticle Tracking Analysis (NTA) as it is a nanoparticle visualization technique that provides size, count and concentration measurements.

PRODUCTION PROCESS FLOW CHART