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CBD Heating Balm

Article No.: HASS0033

Product name: CBD Heating balm
Ingredients: Caprylic/Capric/Myristic/Stearic Triglyceride, Helianthus Annuus Seed Cera, Helianthus Annuus Seed Oil, Vanillyl Butyl Ether, Camphor, Methyl Nicotinate, Mentha Arvensis Leaf Oil, Melaleuca Leucadendron Cajaput Oil, Eugenol, Eucalyptol, Cannabidiol, Capsaicin, Cinnamal, Eugenia Caryophyllus Flower Oil, Ascorbyl Palmitate, Tocopherol, Limonene, Linalool, Coumarin, Cinnamomum Cassia Leaf Oil.

Cannabidiol
Origin: Synthesis
CAS No.: 13956-29-1
IUPAC: 2-[(1R,6R)-3-methyl-6-prop-1-en-2-ylcyclohex-2-en-1-yl]-5-pentylbenzene-1,3-diol
Molecular formula: $C_{21}H_{30}O_2$
Molecular weight: 314,46 g/mol

Description
For flexible muscles and joints. Use CBD muscle balm on sore muscles and joints.

Safety and precautions
Avoid contact with eyes and mucous membranes and avoid contact with delicate areas, such as around the eyes. If contact with eyes occurs, rinse eyes thoroughly with water.
If you experience irritation, rinse from skin and discontinue use. For localized use only. Skin may turn red or feel tingly upon application. If irritation or adverse events persists, seek medical attention. Keep out of reach of children. Do not use when pregnant / breastfeeding.
If you are allergic to any of the product ingredients (see ingredients section for detailed information), individuals should consult their personal healthcare provider prior to use.

How to use
Using clean fingertips, apply thinly and evenly to your lips.

General information

Application and Use	Skin product / cosmetic
Appearance	Red / orange
Shelf life	6 months after opening
Storing conditions	Store at temperature: 8 – 25°C, cool, dry and dark. Protect from direct sunlight.
Packaging	26g plastic stick*
Dermatologically tested	YES – 'Harmless'
Food Safety System	FSSC22000 certified
Cosmetic Safety System	ISO22716
Country of Origin	Cosmetic from The Netherlands. CBD from Switzerland.
Vegan	No

* No estimated sign (℮) protocol.

Specification/Ingredients

CBD (HPLC-UV)	52 mg
THC (HPLC-UV)	detection limit is 0,05% (500 PPM)

Microbiologic assay

Next values are guidelines:

Enterobacteriaceae	<10	cfu/g
Total aerobic count	<100	cfu/g
Fungi/ mold	<100	cfu/g
yeast	<100	cfu/g

Legal notice

The information given in this publication is based on our current knowledge and experience, and may be used at your discretion and risk. Labocan does not hold any liability regarding the product or its use.

General

REACH

The material does not contain any substance meeting the criteria for PBT (Persistant, Bio accumulative, Toxic) or vPvB (very Persistant, very Bio accumulative) in accordance with Annex XIII of Regulation (EC) 1907/2006 (REACH) as amended.

CMR substances

The material does not contain a carcinogenic-, mutagenic or reprotoxic (CMR) substance (category 1A, 1B or 2) as listed under part 3 of Annex VI of Regulation (EC) 1272/2008 consolidated.

SVHC substances

The material does not fulfil any of the criteria as defined in article 57 of Regulation (EC) 1907/2006 (REACH) as amended, and is therefore not identified as SVHC (Substance of Very High Concern).

Other Contaminants

Based on the manufacturing and purification process, the material is free from contaminants such as asbestos, amines, nitrosamines, phthalates, bisphenol A, ethylene-oxide, or any constituent mentioned in Annex XIV / XVII of Regulation (EC) 1907/2006 (REACH) as amended.

The material does not contain heavy metals such as lead or mercury, or any other constituent mentioned in Annex II of Regulation (EC) 1223/2009 consolidated.

The material complies with CPMP/ICH/283/95 and EP 5.4 / USP <467> for residual solvents (class 2/3). During synthesis and purification, no class 1 solvents are used.

Animal testing

The material has not been tested by Labocan on animals, nor evaluated for safety through animal testing.

Allergens

No allergens or substances causing intolerances have been identified in the material, nor in the materials used for its production.

GMO's

No genetically modified organisms, nor products thereof have been used in the manufacturing process. It therefore complies to EC/1829/2003, consolidated, and EC/1830/2003, consolidated, for GMO's/GMO labeling.

Nanomaterials

No nanomaterials, nor products containing nanomaterials have been used in the manufacturing process. It therefore complies to (EC) 1169/2011, consolidated, for nanomaterials/nanomaterial labeling.

TOXICOLOGICAL INFORMATION

Tested on the actual material

The material has been found non -irritant/-damaging to the eye in the **Bovine Corneal Opacity and Permeability assay** (OECD guideline 437), and the **EpiOcular™** test (OECD guideline 492).

The material has been found non -irritant/-corrosive (to the human skin) in the human skin model test on **EpiDermTM** as a skin model (OECD guideline 431, Regulation (EC) 440/2008), and **EpiSkin**™ (OECD guideline 439, Regulation (EC) 440/2008) as the skin models.

The material CBD was found to be nonirritant with less than 15 genes overexpressed. Under the experimental conditions of this **SENS-IS assay** study CBD was found a weak sensitizer.

General, based on literature data

LD50 values (intravenous) have been established in mice (50 mg/kg) and dogs (> 254 mg/kg). The LD50 value after intravenous administration to rhesus monkeys was 212 mg/kg. An oral LD50 has not been established, but is was shown that an oral dose up to 10 g/kg was required to initiate severe intoxications in the monkeys.

Cannabidiol failed to induce teratogenic- or mutagenic effects, as tested in numerous studies.

Due to the high log P (water/ocatanol) value of 5.8, cannabidiol after dermal application is unlikely to penetrate largely into the systemic circulation. Using a human skin permeation model, an average flux of 0.73 nmolcm-2h-1 was established for cannabidiol dissolved in mineral oil.

Based on studies done in humans (minimum duration 30 days), an oral NOAEL (No-Observed-Adverse-Effect-Level) of 180 – 300 mg/day up to 1200 – 1500 mg/day can be established.

I. van Delft, Quality manager