



ERKLÄRUNG

Die Formulierung von *Ad.Mont Massage Öl* (CPNP-Referenz: 3583032) entspricht der Formulierung von *Flihoa Massage Öl* (CPNP-Referenz: 3353261). Der Safety Report von *Flihoa Massage Öl* gilt daher auch für *Ad.Mont Massage Öl*.

Wien, am 20. Jänner 2021

DECLARATION

The formulation of *Ad.Mont Massage Öl* (CPNP Reference: 3583032) correlates with the formulation of *Flihoa Massage Öl* (CPNP Reference: 3353261). The Safety Report of *Flihoa Massage Öl* therefore also applies to *Ad.Mont Massage Öl*.

Vienna, 20th January 2021

PART B
COSMETIC PRODUCT SAFETY ASSESSMENT

B1. Assessment conclusion

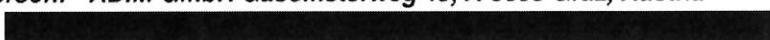
The legal framework – Regulation (EC) No 1223/2009 on cosmetic products

Name of the cosmetic product: *Flinoa Massage Öl*

CPNP Reference: 3353261

Category of the product: *Cosmetic product for the skin care – body care product*

Responsible person: AD.M GmbH Gasometerweg 45, A-8055 Graz, Austria

Manufacturer: 

Ingredients:

Ingredients (INCI EU): *Prunus Amygdalus Dulcis Oil, Helianthus Annuus Seed Oil, Cannabis Sativa Seed Oil, Olea Europaea Fruit Oil, Simmondsia Chinensis Seed Oil, Camphor, Tocopherol, Hypericum Perforatum Flower Extract, Cannabidiol*

Concluding remarks

- Estimated daily amount of *Flinoa Massage Öl* applied is 7.82 g/day - Retention factor is 1; Calculated daily exposure is 7.82 g/day. Calculated relative daily exposure (mg/kg bw/day) is 123.20mg/kg/day.
- On the basis of the toxicological profile of the ingredients, *Flinoa Massage Öl* may be considered as a safe cosmetic product and does not cause irritation, sensitization, allergic and systemic toxicological effects upon normal conditions of use.
- There are no data on dermal absorption of ingredients from the product.
- *Flinoa Massage Öl* is a stable cosmetic product.
- *Flinoa Massage Öl* is efficaciously protected from microbiological contamination and oxidation.
- Shelf life of *Flinoa Massage Öl* is at least 24 months.
- Monitoring procedures of eventual side effects are listed in the report.

According to all data and information related to *Flinoa Massage Öl*, we can conclude that it is a safe cosmetic product.

Ljubljana, 12th July 2020



B2. Labelled warnings and instructions of use

Warning statements arising from the requirements of Annexes III to VI of Regulation 1223/ 2009:

None.

Other:

- *Flinoa Massage Öl* should be applied only on healthy skin avoiding contact to eyes.
- *Flinoa Massage Öl* is designed for external use.
- *Flinoa Massage Öl* should be stored at room conditions (temperature at or below 25°C), protected from light and out of reach of children.

Instruction for use

Flinoa Massage Öl is applied to the skin in thin layer twice a day. It spreads easily. It makes the skin elastic and supple.

B3. Reasoning

Any cosmetic product that goes on the market must be safe for human health. The European Community is the legal regulated by Regulation 1223/2009. Article 11 of Regulation 1223/2009 provides that when a cosmetic product is placed on the market, the responsible person shall keep a product information file for it. Part of the product information file is **safety report (Article 11, b) referred to Article 10 (1)**. The content of the report is defined in Annex I of Regulation 1223/2009.

The target population to which the product is intended is adults.

Flinoa Massage Öl should be applied only to healthy skin. The product has no therapeutic effect.

The product has a harmonized composition. The quantities of the individual ingredients (%) are within the range of safety for health. Each component is covered by the analysis certificate, which is variable category (new certificate for each batch of ingredients). The analysis certificate provides physical, chemical and microbiological quality, especially with regard to the content of impurities. All processes like handling with ingredients, manufacturing processes and packaging of the product take place under conditions, in which there is no creation of traces. Physical, chemical and toxicological characteristics of the individual ingredients are described in the Material Safety Data Sheet (MSDS) that are supplements to the report.

SUMMARY OF THE RISK ASSESSMENT BASED ON THE LOCAL AND SYSTEMIC EFFECTS

EXPECTED DAILY EXPOSURE

Estimated daily amount of *Flinoa Massage Öl* applied is 7.82 g/day - Retention factor is 1.00; calculated daily exposure is 7.82 g/day. Calculated relative daily exposure (mg/kg bw/day) is 123.20mg/kg/day.

MoS for ingredients with known NOAEL are above 100.

IRRITATION

Flinoa Massage Öl contains ingredients, which at concentration used in the product do not cause skin irritation. *Flinoa Massage Öl* irritates the eyes.

SENSITIZATION – ALLERGY

The product does not contain compounds, which are listed as allergens (REGULATION (EC) No 1223/2009 Annex III).

Persons who may be allergic to any of the ingredients should be guided based on information about the product - rubric Ingredients.

PHOTOTOXICITY

No impact. The product does not contain ingredients with proved phototoxic effect.

CRITICAL INGREDIENTS – substances with restrictions in cosmetic products

Cannabidiol (CBD) is extracted from seeds and fibers of industrial hemp, *Cannabis sativa*, Cannabaceae).

DERMAL ABSORPTION

There are no data on dermal absorption of ingredients of the product itself (specific physico-chemical system). No significant impact is expected. **Dermal absorption of CBD is significantly limited due to the polarity deficit in its chemical structure. So CBD would tend to accumulate in the outer layers of the skin hardly penetrating its deeper layers.**

SYSTEMIC EFFECTS

On the basis of qualitative and quantitative data relating to the composition of *Flinoa Massage Öl*, data on the toxicological profile of individual ingredients and the available data on dermal absorption, any systemic effects of *Flinoa Massage Öl* is not expected – that is developmental and repeated toxicity, mutagenicity (genotoxicity), carcinogenicity and reproductive toxicity.

OTHER FACTOR THAT INFLUENCE THE SAFETY ASSESSMENT

STABILITY

Stability of the product is important for the safety assessment of the product, since stable product with a homogeneous distribution of the particles ensures a proper safety assessment.

Flinoa Massage Öl is a stable homogenous oil solution under conditions of normal handling and warehousing (reasoning section A2).

MICROBIOLOGICAL QUALITY

Flinoa Massage Öl is a product of low microbiological risk (ISO 29621).

Flinoa Massage Öl is adequately protected against microbial contamination for at least 24 months.

DATE OF MINIMUM DURABILITY

On the basis of information on the physicochemical characteristics and stability, microbiological quality of the product *Flinoa Massage Öl*, protection against oxidation, absence of interaction between the ingredients, suitable packaging, on the implementation of good manufacturing practices, provided the necessary warnings about the storage and handling of the product, we can conclude the minimum shelf life *of at least 24 months* is properly determined.

DATA ON UNDESIRABLE EFFECTS

Undesirable effects on human health reported during usage of the product were not observed.

The procedure for monitoring of the eventual side effects is described in section A9.

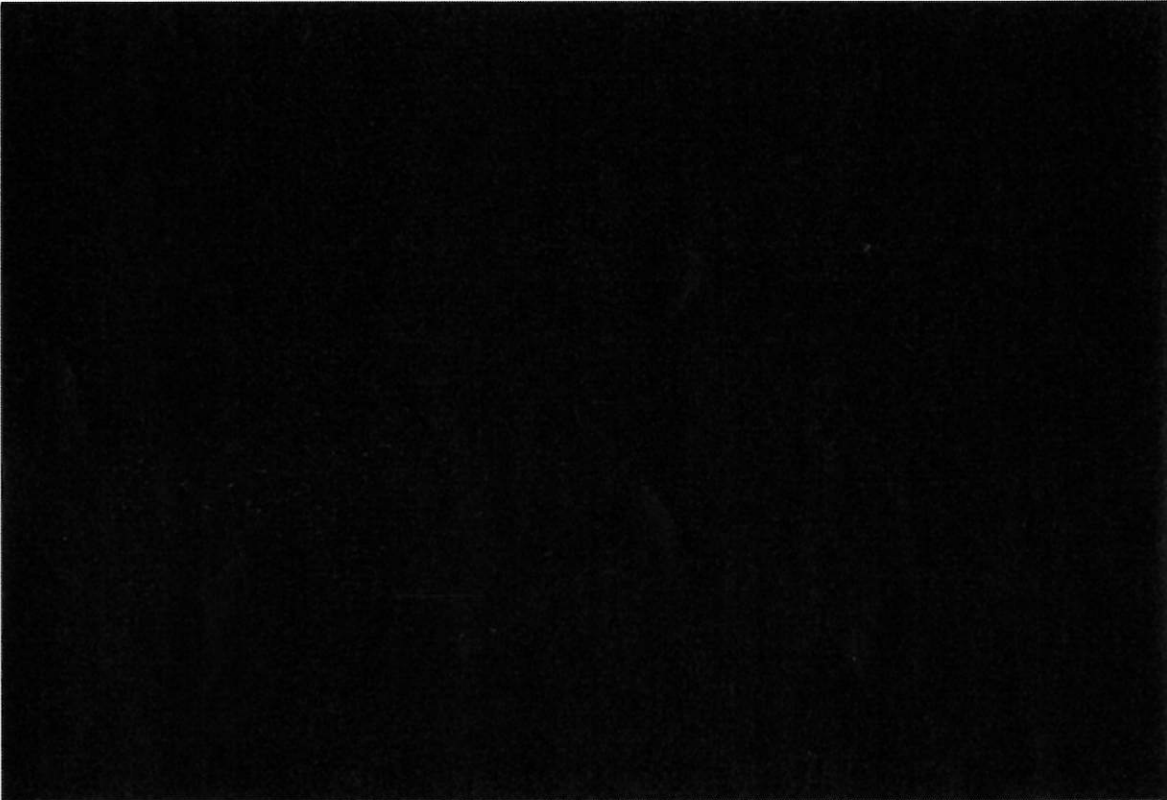
REVIEWAL, UPDATE

The safety assessment should also be reviewed and, if necessary, updated, where one or more of the following circumstances apply:

- *New scientific findings and toxicological data on the substances become available which could modify the result of the existing safety assessment;*
- *Changes occurring in the formulation or specifications of raw materials;*
- *A rising trend in terms of the nature, severity and frequency of undesirable effects, both under reasonably foreseeable conditions of use and in the case of misuse*
- *Change in legislation*

B4. Assessor's credentials and approval of Part B

In accordance with Article 10(2) of Regulation (EC) No 1223/2009, the safety assessor is required to be "a person in possession of a diploma or other evidence of formal qualifications awarded on completion of a university course of theoretical and practical study in pharmacy, toxicology, medicine or a similar discipline or a course recognised as equivalent by a Member State". At the same time safety assessor must have the appropriate knowledge and experience to prepare proper safety assessment.



The assessor's statement

I stand for and signing all information, data, observations, calculations, results, reasoning and conclusions set out in the safety report, Part A, Chapter A1-A10; Part B, Chapter B1-B4, cosmetic product Flinoa Massage Öl (CPNP Ref. 3353261). I do hereby certify that the safety assessment of a cosmetic product on the basis of adequate information and that a report on the safety of the cosmetic product Flinoa Massage Öl (CPNP Ref. 3353261) in accordance with Annex I (Regulation 1223/2009, Article 10).

