COSMETIC PRODUCT INFORMATION FILE

According to EC Regulation 1223/2009

FITODENTA DEEP RELIEF GEL FORTE

UAB FITODENTA (VILNIUS, LITHUANIA)

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1. QUANTITATIVE AND QUALITATIVE FORMULA

The quantities of Qualitative-Quantitative analysis have been restricted for view. The assessor has reviewed the formulation and PASSED the assessment. Complete information could be asked from the Safety Assessor or Manufacturer of the product. The aim of that section of the cosmetic product safety report is to provide the exactquantitative and qualitative composition of the finished product, starting from the rawmaterials. Raw materials are substances or mixtures used in the manufacturing of the cosmetic product (TABLE I). The intended function of each substance is to be indicated.
The complete product composition is specified, stating the name and identity (qualitative) of each raw material (including chemical name, INCI, CAS, EINECS/ELINCS, where possible),
and the amount of each raw material, stating the weight percentage (quantitative).
Ranges are not used, unless this can be justified (e.g. viscosity or pH adjusters). If concentration ranges are unavoidable, toxicological considerations and calculations are based on the highest concentration figure. All substances entering the composition of commercial mixtures supplied as raw materials (including directly added preservatives, antioxidants, chelators, buffering agents, solvents, other additives, etc.) are identified and quantified in the formula of the finished product.
This also applies to all substances indirectly added to the product, such as preservatives used for preserving raw materials. The intended function of each substance is to be indicated.
The visibility of Qualitative-Quantitative analysis is limited as per manufacturer's request. Please contact either Safety Assessor or manufacturer for full details.

TABLE I

INCI
Almond Sweet Oil
Fumed silica (Aerosil 300)
CBD Isolate (purified form of cannabidiol)
Eugenia Caryophyllus (Clove) Bud Oil
Rosmarinus Officinalis (Rosemary) Leaf Extract
CBG Isolate (purified form of cannabigerol)
Peppermint leaf CO2-se extract
beta Caryophyllene
Myrcene
Humulene

2. PHYSICAL/CHEMICAL CHARACTERISTICS AND STABILITY

The aim of that section of the cosmetic product safety report is to describe the relevant physical and chemical specifications of the substances or mixtures used and the cosmetic product itself. These specifications are crucial for an appropriate safety assessment, as they may influence the safety of a cosmetic product. For example, physico-chemical properties, in combination with other information, can help the safety assessor determine the need to investigate relevant toxicological parameters. In addition, the physico-chemical characteristics of the substances or mixtures and finished products set the benchmark against which the products and the raw materials can be considered acceptable from a quality point of view. Composition of the product used for stability testing corresponds to the product placed on the market. No stability problems are induced by the type of container and packaging used, physical stability tests are currently carried out with inert containers and those intended to be used on the market.

3. MICROBIOLOGICAL QUALITY

Concerning microbiological susceptibility, there is a Low microbiological risk product based on organic solvents, which neither a preservation challenge test nor microbiological quality tests on the finished product are necessary. A scientific justification is to be provided.

4. IMPURITIES, TRACES AND PACKAGING INFORMATION

Cosmetic product contains no substances that have not been intentionally added to the formulation, and which may have an impact on its safety. For the analysis of impurities and packaging material, data from suppliers were preferred.

5. NORMAL AND REASONABLY FORESEEABLE USE

The section on normal and reasonably foreseeable use of the product is essential for the safety assessor to be able to determine a relevant exposure scenario. The intended use should be appropriately communicated to the consumer in order to avoid misuse of the product. As a practical approach, If available, we include a photo of the packaging or the artwork in the labelling section to show the presentation of the product and its intended use. All of the ingredients included in the formulation are widely used in cosmetic industry & its products already available in the market place and have good safety profiles and have documentations to support this.
In case of eye contact, wash with clean, warm water immediately.
We have calculated the possible margin of safety in sections ahead as per the intended use of product.
In case of any adverse reaction, seek medical assistance.

6. EXPOSURE TO COSMETIC PRODUCT

According to European Statistical Population Model of exposure to cosmetic products the daily exposure to product is 123,20 mg/kG (bodyweight) (Food and Chemical Toxicology Volume 49, Issue 2, February 2011, Pages 408-422).

7. EXPOSURE TO SUBSTANCES

There are no substances classified by EU cosmetics legislation as carcinogenic, mutagenic, or toxic for reproduction (CMR substances) in this product.

8. TOXICOLOGICAL PROFILE OF THE SUBSTANCES

In accordance with Point 8 part A of Annex I to Regulation (EC) No 1223/2009, systemic effects and margin of safety are to be considered in Part A of the safety report. As they are mandatory, the omission of these steps is to be duly justified. An example where this could apply would be the presence of a substance in the cosmetic product at a low level, with the expected (worst case) exposure levels being below the appropriate threshold of toxicological concern (TTC) values.
According to the procedures described in the SCCS Notes of Guidance (37), the margin of safety (MoS) for a specific route of exposure can be calculated using the following formula: SED = DAa (μg/cm²) x 10-3mg/μg x SSA (cm²) x F (day-1) 60 kg where the Systemic Exposure Dose (SED) is obtained by combining the external exposure (mg/kg bw/day) with the absorption rate (typically expressed in % or μg/cm2), frequency and retention factors.
It is generally accepted that the margin of safety should be at least 100 to declare a substance safe for use in a finished product.
In the case of route-to-route extrapolation, the respective bioavailability via each route should ideally be taken into consideration. The assumption of 100 % oral bioavailability might overestimate the systemic exposure in a toxicity study via the oral route. Therefore,

in the absence of data, it should be assumed that not more than 50 % of an orally administered dose is systemically available. If there is evidence to suggest poor oral bioavailability, for example if the substance is a poorly soluble particulate, it may be more appropriate to assume that only 10 % of the administered dose is systemically available. Whenever oral absorption data are available, these should be included in the calculations.
The NOAEL chosen for calculating the margin of safety is taken from long-term repeated dose toxicity studies (sub-acute, sub-chronic, and/or chronic toxicity tests, carcinogenesis tests, teratogenesis tests, reproduction toxicity, etc.).
The value used will be the lowest NOAEL obtained by the most pertinent study with respect to the conditions of use of the substance, to species sensitivity, etc.

9. UNDESIRABLE EFFECTS AND SERIOUS UNDESIRABLE EFFECTS

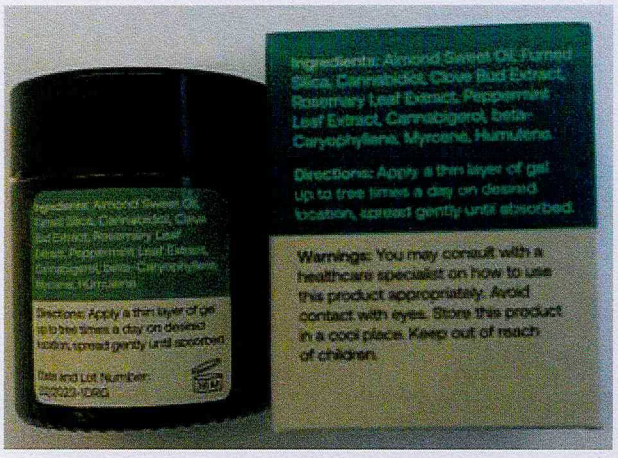
The aim of that section of the cosmetic product safety report is to monitor the safety of the product after it has been placed on the market and to take corrective action, where necessary. To this end, the responsible person (in collaboration with the distributors) is required to set up a system to collect, document, establish the causality of and manage the undesirable effects caused by the product after its use in the Union. When the undesirable effects are serious, the responsible person (and the distributors) are to notify the competent authority of the Member State where the effects occurred.
The product is understood to be new or reformulation of existing product in the market.
If subsequent details of undesirable or serious undesirable effects are known, manufacturing company or safety assessor or a poison center must be informed immediately to re-evaluate the product safety.

10. INFORMATION ON THE COSMETIC PRODUCT

This section allows the inclusion of any additional information which is not covered under the other headings but is considered relevant in order to carry out the safety assessment of the product.
Internal organs: This product is unlikely to cause damage to the internal organs following application to the body.
Eye area: This product may cause irritation to the eye area.
Ingestion: This product is likely to cause irritation
Overall Safety assessment: The ingredients contained within this product are well within the Cosmetic Regulations (EC) No 1223/2009 and its amendments.
The finished product Fitodenta Deep Relief Gel Forte does not contain any undisclosed chemicals.
Warnings to be listed:

- no suitable on pregnancy and maternity (on label).
- not suitable for babies (on label).

Product photo:



11. ASSESSOR'S CREDENTIALS AND APPROVAL OF PART A

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DATE	:	26/06/2023

SIGNATURE .....

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1. INFORMATION FOR THE EVALUATION OF THE INGREDIENTS AND FINAL PRODUCT

1.1 IDENTIFICATION OF THE PRODUCT

A. COMMERCIAL NAME:

Fitodenta Deep Relief Gel Forte

B. INGREDIENTS

Have been reviewed. Raw materials known, not forbidden and listed.

C. SPECIFICATIONS OF INGREDIENTS

Supplier's specifications for each raw material have been reviewed.

D. INCI NAMES OF INGREDIENTS

Have been reviewed. Are referred in detail in supplier's raw material MSDS.

E. CAS NUMBERS OF INGREDIENTS

Are referred in detail in supplier's raw material MSDS.

1.2 SAFETY DATA SHEETS OF INGREDIENTS (MSDS)

Have been reviewed especially for the toxicological data.

1.3 PRODUCTION METHOD AND SPECIFICATIONS OF FINAL PRODUCT– GMP COMPLIANCE – STABILITY OF THE PRODUCT

PRODUCTION METHOD: has been reviewed.

SPECIFICATIONS OF FINAL PRODUCT: have been reviewed.

G.M.P. COMPLIANCE: exists and the company is supervised under National Public Health Centre by the Ministry of Health (July 22, 2019).

STABILITY OF THE PRODUCT: Has been reviewed and it is acceptable.

1.4 MICROBIOLOGICAL QUALITY – PRESERVATION EFFICACY TEST

MICROBIOLOGICAL QUALITY: The product, due to not presence of water in the formula, is unlikely to present, under normal production conditions, any kind of bio burden.
CHALLENGE TEST: A cosmetics challenge preservative efficacy test is not performed because, due to the package characteristics (pressurized airless containers) according to requirements of ISO 29621:2017, the likelihood of microbiological contamination for such products is very low or even non-existent.

1.5 IMPURITIES - TRACES IN THE FINAL PRODUCT OR SUBSTANCES – PROPERTIES OF PACKAGING MATERIAL

Type of Packaging Material: PP. According to the presentation and the formula of the product, package is considered unlikely to affect its purity and stability.

1.6. WAY OF USE-EXPOSURE TO THE PRODUCT - EXPOSURE TO THE SUBSTANCES (1223/2009 ANNEX I-PART A.5-6-7)

WAY OF USE:
The product is applied on the body and it is not rinsed off. **External use only**.

WAY OF EXPOSURE:
The product is applied on the body so taking also under consideration guidelines from SCCS/1501/12 opinion it can be foreseen to be studied as a body lotion with an estimated

daily amount applied 7.63 g and a calculated relative daily exposure approx.**123.20 mg/Kg bw/day.**

1.7 INFORMATION ON THE PRODUCT (STUDIES ON HUMAN VOLUNTEERS / RELEVANT LITERATURE) (1223/2009 ANNEX I-PART A.10)

PATCH TEST: Non irritant

OTHER TESTS: Not Applicable

LITERATURE DATA: Not Applicable

2 LABELED WARNINGS & INSTRUCTIONS OF USE

-Producer's data have been reviewed. There is no need for further instructions of the use as this is clear to the consumer from its presentation.

3 TOXICOLOGICAL PROFILE OF THE SUBSTANCES (1223/2009 ANNEX I-PART A.8)

The product itself has not been tested on animals (Article 18).

MSDS TOXICOLOGICAL REVIEW:

Respiratory

Not required for consumer use of this product. Inhalation exposure is not applicable for this type of product.

Skin

This product is unlikely to be sensitizing to human skin. It is not expected to produce allergy by skin contact, except the cases of people with known allergic reaction in the specific allergens referred on the label. The absorption through the skin is considered limited.

Eye

As with any material contacting the eye its accidental exposure may result in slight eye irritation.

Ingestion

Although some ingredients used in the manufacture of this product are considered hazardous on an individual basis, the final formulation of this product is considered non-hazardous.

All information available refers to the relevant MSDS of each raw material that takes part in the formula of the product. The specific ingredients that have been chosen for the production of this product have been used for years, for same products, without any known toxicity problems, under foreseeable conditions of use.

Especially for „hazardous" raw materials (substances under restrictions listed in the Annexes (Chapter IV, Article 14, i.e. preservatives,) there are already limits in legislation (Annex V) and they comply.

There is a nanomaterial Fumed silica is bound with an oil; there are no free nanoparticles in the product's mass.
There are no data for evaluation in the product of any impurities of the substances and raw material used.
There is no evidence from the formula of the product for interaction of substances.
There are no colorants in the formula.
Based on current **Cosmetic legislation 1223/2009**, margin of safety **(MoS)** based on a no observed adverse effects level (NOAEL) for every ingredient.
For ingredients without NO(A)EL values and total lack of safety reference, the calculation below is a **'worst case approach'**, where, taking under consideration the pure maximum concentrated material of the formula, the minimum NO(A)EL (**ora**l) is calculated, according to the Estimated daily exposure (A) of the product (§ 1.6).
In this way „dangerous" ingredients are considered only those with „hypothetical" NO(A)EL values lower than the minimum NO(A)EL calculated value and concentrations, even not greater than the pure maximum concentrated material, but able to result (under Safety calculation) in MoS<100.
The combination above is statistically difficult to yield in MoS<100 as:
1) The existence in calculations of the maximum concentrated material of the formula (without NOAEL), minimizes the possibilities of any other material to be so potent (in view of a NO(A)EL value),
2) in this approach the calculation of the minimum NO(A)EL, is usually lower than 1000 mg/Kg/ bw/day, depending on the type of the product. The minimum NO(A)EL values at these levels can be found only in ingredients like biocides/preservatives (SCCP/0125/99 & SCCP/0873/05, respectively).
3) Ingredients with low NO(A)EL values (<1000 mg/Kg/ bw/day) are very well defined in toxicological literature and there are exact data that have already been taken into consideration for calculation of the relevant MoS.

Calculation of the 'Worst Case Approach':
MoS= NO(A)EL / SED > 100, With:
SED (mg/Kg bw/day) = Systemic Exposure Dosage
A (mg/Kg bw/day) = Estimated daily exposure to a cosmetic product per kg body weight, based upon the amount applied and the frequency of application **(123.20)**.
C (%) = the Concentration of the ingredient under study in the finished cosmetic product on the application site.
DAp (%) = Dermal Absorption expressed as a percentage of the test dose assumed to be applied in real-life conditions (**100%**).
SED = **A** (mg/kg bw/day) x **C** (%)/100 x **DAp** (%)/100= 123.20 x 0.5/100 x 1= **0.616** mg/kg bw/day
- The minimum NO(A)EL, according to the above suggested calculations (SCCS/1416/11) for the pure maximum concentrated ingredient should be:

Minimum NO(A)EL= MoS x SED = 100 * 0.616=61.6 extrapolated at **62 mg/Kg/ bw/day** and is satisfactory (acceptable minimum NO(A)EL <1000 mg/Kg/ bw/day)

Conclusion: It is unlike for the ingredients of the specific formula, without NO(A)EL values and total lack of safety reference, to present NO(A)EL values lower than the minimum NOA(E)L calculated according to the *'Worst Case Approach'* and consequently, with present concentrations, to yield in MoS<100.

The „Worst case approach" is in compliance with Annex I, point 8: "All significant toxicological routes of absorption shall be considered as well as the systemic effects and margin of safety (MoS) based on a no observed adverse effects level (NOAEL) shall be calculated. The absence of these considerations shall be duly justified."

The following table (TABLE II) includes the relevant available NOAEL and MoS calculated for each ingredient of the formula.

TABLE II

INCI	NOAEL (mg/Kg/bw/day)	MoS (> 100)	REFERENCE OF SAFETY
Almond Sweet Oil	No safety concern	N/A	https://www.nordictattoosupplies.com/WebRoot/NTS/Shops/24052010-172317/MediaGallery/MSDS_CTL/SorryMom-Tattoo_Lotion_296_15_pro4care_EN.pdf
Fumed silica (Aerosil 300)	2000	162	Int. J. Mol. Sci. 2022, 23, 4023
CBD Isolate (purified form of cannabidiol)	N/A	N/A	Mateus Machado Bergamaschi, Regina Helena Costa Queiroz, Antonio Waldo Zuardi and Jose Alexandre S. Crippa. Safety and Side Effects of Cannabidiol, a Cannabis sativa Constituent. Current Drug Safety, Volume 6, Issue 4, 2011
Eugenia Caryophyllus (Clove) Bud Oil	1000	406	Toxicol Rep. 2016; 3: 439–449.
Rosmarinus Officinalis (Rosemary) Leaf Extract	300	244	EC number: 283-291-9 | CAS number: 84604-14-8 https://echa.europa.eu/lt/registration-dossier/-/registered-dossier/5479/7/9/1#
CBG Isolate (purified form of cannabigerol)	N/A	N/A	Mateus Machado Bergamaschi, Regina Helena Costa Queiroz, Antonio Waldo Zuardi and Jose Alexandre S. Crippa. Safety and Side Effects of Cannabidiol, a Cannabis sativa Constituent. Current Drug Safety, Volume 6, Issue 4, 2011
Peppermint leaf CO2-se extract	500	812	Flavex Naturextrakte GmbH, SDS Peppermint leaf CO2-se extract_036.001, Print Date: 16/05/2019
beta Caryophyllene	222	360	Based on the NOAEL for β-caryophyllene of 222 mg/kg bw per day, a margin of safety of 3500 can be calculated, and accordingly this substance is not expected to be of safety concern at the estimated level of intake. EFSA Journal 2015;13(4):4069
Myrcene	44	357	EFSA Journal 2016;14(1):4339
Humulene	222	721	Ravendra et al., Journal of Herbal Drugs, Vol. 8, No. 1: 59-69, 2017

SAFETY OF CANABIDIOL

As of 1 February 2021, the European Union officially recognizes cannabidiol – (CBD), derived from cannabis extract or tincture or resin – among the ingredients used by the cosmetics industry and included in the CosIng, the reference document for cosmetic raw materials for countries in the European Union. Until now, only synthetic cannabidiol was recognized by the EU (https://www.cosmoprof.com/en/media-room/news/cbdbeauty-natural-cannabidiol-recognized-for-cosmetic-use-in-europe/)
It is currently not possible to perform an adequate safety assessment of CBD-containing cosmetic. products. To date, the safety of dermal absorption has not been demonstrated in any of the safety reports available to the cantonal enforcement authorities (insufficient data concerning uptake through the skin), and gaps in the data mean that precisely the same safety concerns exist regarding only oral cosmetics as those relating to foodstuffs.
Adverse reactions and intoxications caused by a synthetic cannabinoids in clinical development: the BIA 10-2474 case: severe adverse reactions of currently marketed pharmaceutical cannabinoids have not been recorded. The adverse reactions most often described are mild to moderate, with dizziness, fatigue, ataxia, and difficulty concentrating (Int J Med Sci. 2018; 15(12): 1286–1295.).
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6158663/

ALLERGEN FACTORS

No declared *(>0.001%)* allergens on the final product.
No perfume is on the final product.

There are no detailed data for all allergens existing in the fragrance and the plant extracts (opinion 1459/11, Conclusions-question 1). The corrections must be performed as soon as the perfume and plant extracts manufacturers will supply the relevant data as well as the EC gives final guidelines on the subject.
The SCCS is of the opinion that for substances identified as posing a high risk to the consumer and for which no individual thresholds could be derived (Table 13-5), the general **threshold of 0.01%** would limit the problem of fragrance allergy in the consumer significantly. (For this product: **beta Caryophyllene**).

4 UNDESIRABLE EFFECTS AND SERIOUS UNDESIRABLE EFFECTS (1223/2009 ANNEX I-PART A.9)

NOT KNOWN OR REPORTED

5 CLAIM SUPPORT

There is no need for special claims and the already existing are satisfactory.

6 SAFETY ASSESSMENT REPORT-REASONING

6.1 PRODUCT NAME : **Fitodenta Deep Relief Gel Forte**
6.2 PRODUCT CATEGORY: **Body Care (Oleogel)**

6.3 NAME AND ADDRESS OF RESPONSIBLE PERSON

Tomas Andrejauskas. Adress**: Raudondvario pl. 148, Kaunas, Lithuania**

6.4 NAME AND ADDRESS OF PRODUCT MANUFACTURER - **UAB Fitodenta**

Address: **Raudondvario pl. 148, Kaunas, Lithuania** Phone: **+370 686 69366**

6.5 REASONING

Taking under consideration:

- The composition of the product;
- The physicochemical properties of the raw material contained in the final product;
- The manufacturing process of the product;
- The microbial purity of the raw materials and final; product;
- Impurities –Traces in the final product or substances Properties of packaging material;
- The preservation efficacy of the final product;
- The chemical structure and toxicological properties of the raw materials;
- Studies on human volunteers / relevant literature;
- The level of exposure of the consumer to the final product;
- Data on documented undesirable effects to the product (no such data reported/available);
- Labeled warnings & instructions of use.

Additionally the Product Manufacturer / Responsible Person is aware of the following:

- All necessary measurements have been followed for the product to comply with the article 18 (Animal testing) of Regulation 1223/2009.
- All coloring agents whose number is preceded by the letter „E" in accordance with the EEC Directive of 1962 concerning foodstuffs and purity criteria as set out in Commission Directive 95/45/EC (ANNEX IV)

The Responsible person / Product manufacturer is responsible for the accuracy of primary information contained in the product dossier.

All information provided by the technical dossier may be used, for any legal purpose within the EU, and according to the best current scientific knowledge, the product fulfills the requirements for safety for the consumers, under conditions of normal use, as long as data contained will be updated in accordance with the SUGGESTIONS (regarding safety) mentioned above and the guidelines of the current Regulation 1223/2009.

In the case that any complaint is communicated to the Responsible person and/or Product manufacturer, this should be also taken into the consideration of the signatory of this

contained will be updated in accordance with the **SUGGESTIONS** (regarding safety) mentioned above and the guidelines of the current Regulation 1223/2009.

In the case that any complaint is communicated to the Responsible person and/or Product manufacturer, this should be also taken into the consideration of the signatory of this certificate.

7 ASSESSOR'S CREDENTIALS AND APPROVAL OF PART B

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