**SAFETY ASSESSMENT REPORT**

***“ \*\*\*\* CREAM”***

Product Information File (R.1223/2009/EC, art. 11)

Cosmetic Product Safety Report (R.1223/2009/EC, art. 10, Annex I)

Safety Assessment (R.1223/2009/EC, art. 10, Annex I)

These information comply with (R.1223/2009/EC, art. 10, 11, Annex I)

*This document has been prepared on behalf of*

***CREAM***

**COSMETIC PRODUCT SAFETY ASSESSMENT REPORT**

**Product Name:**

**Manufacturerer Name:**

**Address:**

**Telephone:**

**Fax:**

**Web Address:**

**PAO:**

**PART A – Cosmetic product safety information**

**1.Quantitative and qualitative composition of the cosmetic product** Raw materials components;

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  |  |  | **Amount of raw** |  |  |
| **Raw Material’s INCI Name** | **CAS NO** | **EINECS/ELINCS** | **material in** | **Intended Use** | **Regulatory Compliance of 1223/2009** |
| **Number** | **finished product** | **EC** |
|  |  |  |
|  |  |  | **(% Concentration)** |  |  |
|  |  |  |  |  |  |
| Aqua | 7732-18-5 | 231-791-2 |  | Solvent | There is not any restriction for usage |
| amount and usage area. Appropriate |
|  |  |  |  |  |
|  |  |  |  |  |  |
| Stearyl Alcohol | 112-92-5 | 204-017-6 |  | Emolient | There is not any restriction for usage |
| amount and usage area. Appropriate |
|  |  |  |  |  |
|  |  |  |  |  |  |
| Cetyl Alcohol | 36653-82-4 | 253-149-0 |  | Emolient | There is not any restriction for usage |
| amount and usage area. Appropriate |
|  |  |  |  |  |
|  |  |  |  |  |  |
| Propylene Glycol | 57-55-6 | 200-338-0 |  | Humectant | There is not any restriction for usage |
| amount and usage area. Appropriate |
|  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

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Parfum component;

**Parfum Supplier’s Name:**

**Parfum Supplier’s Address:**

**Parfum Supplier’s Tel. No:**

**Parfum Supplier’s Fax No:**

**Parfum Supplier’s Web Address:**

**Parfum Supplier’s E-Mail Address:**

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | **Amount of** |  | **Amount of raw** |  |  |  |  |
| **Raw Material’s INCI** | **CAS NO** | **EINECS/ELIN** | **Concentration in** | **Concentration** | **material in** |  | **Regulatory Compliance of** |
| **Name** | **CS Number** | **Raw Material (%** | **(%)** | **finished product** |  |  | **1223/2009 EC** |
|  |  |  |
|  |  |  | **Concentration)** |  | **(% Concentration)** |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  | Annex III List of Substances Which |
|  |  |  |  |  |  | Cosmetic Products Must Not Contain |
|  |  |  |  |  |  | Except Subject To The Restrictions |
|  |  |  |  |  |  | Laid Down The presence of the |
|  |  |  |  |  |  | substance must be indicated in the list |
| Benzyl Alcohol | 100-51-6 | 202-859-9 |  |  |  | of ingredients referred to in Article 19 |
|  |  |  |  |  |  | (1) (g) when its concentration |
|  |  |  |  |  |  | exceeds: | —0,001 % in leave-on |
|  |  |  |  |  |  | products | —0,01 % in rinse-off |
|  |  |  |  |  |  | products Appropriate |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  | Annex III List of Substances Which |
|  |  |  |  |  |  | Cosmetic Products Must Not Contain |
|  |  |  |  |  |  | Except Subject To The Restrictions |
|  |  |  |  |  |  | Laid Down The presence of the |
|  |  | 203-375-0 , 247- |  |  |  | substance must be indicated in the list |
| Citronellol | 106-22-9 |  |  |  | of ingredients referred to in Article 19 |
| 737-6 |  |
|  |  |  |  |  | (1) (g) when its concentration |
|  |  |  |  |  |  |
|  |  |  |  |  |  | exceeds: | —0,001 % in leave-on |
|  |  |  |  |  |  | products | —0,01 % in rinse-off |
|  |  |  |  |  |  | products Appropriate |
|  |  |  |  |  |  |  |

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1. **Physical/chemical characteristics and stability of the cosmetic product a) Physical/chemical characteristics:**

|  |  |  |
| --- | --- | --- |
| **Parameter** | **Specifications** | **Result** |
|  |  |  |  |
| **OrganolepticCharacteristics** | **Appearance** | Cream | Approved |
|  |  |  |
| **Color** | Characteristic | Approved |
|  |  |  |
| **Odor** | Characteristic | Characteristic |
|  |  |  |
|  |  |  |  |
| **Physicochemical** | **pH** |  | Approved |
| **Characteristic** |
|  |  |  |  |

Safety Assessor’s Comment :

1. **Stability:**

**3. Microbiological quality**

**4. Impurities, traces, information about the packaging material**

**5. Normal and reasonably foreseeable use**

Product usage: \*\*\*is used for

Product use frequency:

Label information:

Preparation:

Instruction for use on the label: Preparation:

Application:

Attention:

Waiting Time:

Warning:

Color Distribution:

Emulsion time:

Correctors:

Rinsing:

Warnings on the label: Warnings:

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**6. Exposure to the cosmetic product**

1. The site(s) of application: 1/2
2. The surface area(s) of application (cm2): cm2
3. The amount of product daily applied (g): g
4. The duration and frequency of use: day ( a month)
5. The normal and reasonably foreseeable exposure route(s): Exposure with .
6. The targeted (or exposed) population(s). Potential exposure of a specific population shall also be taken into account: The targeted population is adults.
7. Possibility of secondary exposure: There is no possibility of secondary exposure way.

**7. Exposure to the substances**

**SED = A (mg/kg body weight/day) × C(%) / 100 × DAp** **(%)/100**

*SED (mg/kg body weight/day):* The Systemic Exposure Dosage of a cosmetic ingredient is theamount expected to enter the blood stream (and therefore be systemically available) per kg body weight and per day. It is expressed in mg/kg body weight/day.

*A (mg/kg body weight/day):* Estimated daily exposure to a cosmetic product per kg body

weight, based upon the amount applied and the frequency of application

*C(%):*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 appliedin real-life conditions

DAp was considered as 100 in calculations for all raw materials. A= [60 g x 1000 mg x 2/30 day x 0,1] / 60 kg = 6,67 mg/kg bw/day

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SED Table for raw materials except parfum components is below.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **Amount of Raw Material** | **Retention Factor** | **Dermal Absorption** | **Dermal Absorption DAp** |  |
| **Raw Material’s INCI Name** | **in Finished Product (%** | **SED (mg/kg bw/day)** |
| **(R)** | **DAa (μg/cm2)** | **(%)** |
|  | **Concentration)** |  |
|  |  |  |  |  |
|  |  |  |  |  |  |
| Aqua |  | 0,1 | - | 100 |  |
|  |  |  |  |  |  |
| Stearyl Alcohol |  | 0,1 | - | 100 |  |
|  |  |  |  |  |  |
| Cetyl Alcohol |  | 0,1 | - | 100 |  |
|  |  |  |  |  |  |
| Propylene Glycol |  | 0,1 | - | 100 |  |
|  |  |  |  |  |  |
|  |  | 0,1 | - | 100 |  |
|  |  |  |  |  |  |

SED Table for parfum components is below.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **Amount of Raw Material in** | **Retention Factor** | **Dermal Absorption DAa** | **Dermal Absorption DAp** | **SED (mg/kg** |
| **Raw Material’s INCI Name** | **Finished Product (%** |
| **(R)** | **(μg/cm2)** | **(%)** | **bw/day)** |
|  | **Concentration)** |
|  |  |  |  |  |
|  |  |  |  |  |  |
| Benzyl Alcohol |  | 0,1 | - | 100 |  |
|  |  |  |  |  |  |
| Citronellol |  | 0,1 | - | 100 |  |
|  |  |  |  |  |  |
| Geraniol |  | 0,1 | - | 100 |  |
|  |  |  |  |  |  |
|  |  | 0,1 | - | 100 |  |
|  |  |  |  |  |  |

**Toxicological profile of the substances**

MoS calculations for raw materials are below.

* MoS calculation for Stearyl Alcohol : NOAEL: 2000 mg/kg bw/day

SED: 0,933800 mg/kg bw/day MoS=NOAEL/SED

MoS = 2000 / 0,933800 MoS = 2142

MoS > 100

* MoS calculation for Cetyl Alcohol : NOAEL: 750 mg/kg bw/day

SED: 0,333500 mg/kg bw/day MoS=NOAEL/SED

MoS = 750 / 0,333500 MoS = 2249

MoS > 100

* MoS calculation for Propylene Glycol : NOAEL: 240 mg/kg bw/day

SED: 0,266800 mg/kg bw/day MoS=NOAEL/SED

MoS = 240 / 0,266800 MoS = 900

MoS Table for raw materials except parfum componenets is below.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Amount of Raw Material in** |  |  |  |
| **Raw Material’s INCI Name** | **Finished Product (%** | **SED (mg/kgbw/day)** | **NOAEL (mg/kg bw/day)** | **MoS** |
|  | **Concentration)** |  |  |  |
|  |  |  |  |  |
| Aqua |  |  | Not found | Not calculated |
|  |  |  |  |  |
| Stearyl Alcohol |  |  | 2000 |  |
|  |  |  |  |  |
| Cetyl Alcohol |  |  | 750 |  |
|  |  |  |  |  |
| Propylene Glycol |  |  | 240 |  |
|  |  |  |  |  |
|  |  |  |  |  |

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MoS Table for parfum components is below

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Amount of Raw Material in** |  |  |  |
| **Raw Material’s INCI Name** | **Finished Product (%** | **SED (mg/kgbw/day)** | **NOAEL (mg/kg bw/day)** | **MoS** |
|  | **Concentration)** |  |  |  |
|  |  |  |  |  |
| Benzyl Alcohol |  |  | 550 |  |
|  |  |  |  |  |
| Citronellol |  |  | 49,21 |  |
|  |  |  |  |  |
| Geraniol |  |  | 19,69 |  |
|  |  |  |  |  |
| Linalool |  |  | 500 |  |
|  |  |  |  |  |
|  |  |  |  |  |

**Undesirable effects and serious undesirable effects**

**10. Information on the cosmetic product**

**PART B – Cosmetic product safety assessment**

**1. Assessment conclusion**

The assessment was based on the chemical specification and toxicological profile of the ingredients, including parfum, together with the toxicological profile of the complete product. \*\*\*\*\* Cream is a rinse off product after waiting for awhile. MoS value was calculated for the raw materials which have NOAEL value. Calculated MoS values are greater than 100 for all raw materials. For this reason, the amount of raw materials in this formulation are safe.

The all raw material’s compliance of 1223/2009 EC is searched and endorsed. All raw materials are not toxic under normal or reasonably unforeseeable conditions of use at this concentration. The product does not contain prohibited substances listed in annexes of Regulation (EC) No. 1223/2009.

The product contains parfum’s components. All parfum’s components certain concentrations in the parfum are not known. Only allergens amounts are known certainly. For this reason, maximum parfum’s components concentrations\*\*\*\*



23.05.2005 tarihli Resmi Gazete’de yayımlanan Kozmetik Yönetmeliği Madde 12 (d): Kozmetik ürün güvenlilik değerlendirmesi, eczacılık diplomasına sahip bir kişi tarafından veya tıp, diş hekimliği,  biyoloji, kimya, biyokimya, mikrobiyoloji veya eşdeğer diplomaya sahip toksikoloji dalında veya kozmetik ürün güvenlilik değerlendirmesi alanında sunulan teorik ve uygulamalı müfredat programını tamamlayanlara verilen bir belgeye sahip kişi tarafından yapılır.

Bu doğrultuda güvenlilik değerlendirme raporunu hazırlayıp imzalayan kişinin yetki belgesinin de rapora eklenmesi gerekmektedir.