CilsJo

Safety Data Sheet

according to chapter III, article 10 of
Regulation (EC) No. 1223/2009 of the
European Parliament and of the Council

Date: 02/2023
Codification: HR20230210

1 – IDENTIFICATION OF PRODUCT AND COMPANY

1.1. Identification oft the preparation

Product name: BE BASE

1.2. Type of use

Product type: cosmetic product
Formula: n.a.

1.3. Supplier identification

Details of the supplier of the safety data sheet

Company:

Cils'Jo Johana Tomaszewski
6 rue de Markdorf
68190 Markdorf
France

1.4. Emergency phone Nr:

Contact the nearest emergency center

A.1. Formula with INCI names

Ingredients: AQUA, MARIS SAL, SD ALCOHOL 39-C, POLYSORBATE-20, PROPYLENE GLYCOL, PHENOXYETHANOL, CUCUMIS SATIVUS FRUIT WATER, PANTHENOL, HAMAMELIS VIRGIANA DESTILLAT, GLYCINE SOJA SEED EXTRACT, PARFUM, ALLANTOIN, BENZOID ACID, DEHYDROACETIC ACID, ETHYLHEXYLGLYCERIN, LACTIC ACID, SODIUM BENZOATE, POTASSIUM SORBATE

INCI name	CAS #	EINECS/ELINCS #
AQUA	7732-18-5	231-791-2
MARIS SAL	---	310-127-6
ALCOHOL DENAT	---	---
POLYSORBATE-20	9005-64-5	---
PROPYLENE GLYCOL	57-55-6	200-338-0
PHENOXYETHANOL	122-99-6	204-589-7
CUCUMIS SATIVUS FRUIT WATER	89998-01-6	789-738-4
PANTHENOL	81-13-0	201-327-3
HAMAMELIS VIRGINANA LEAF WATER	84696-19-5	283-637-9
GLYCINE SOJA SEED EXTRACT	---	---
PARFUM	---	---
ALLANTOIN	97-59-6	202-592-8
BENZOIC ACID	65-85-0	200-618-2
DEHYDROACETIC ACID	520-45-6	208-293-9
ETHYLHEXYLGLYCERIN	70445-33-0	408-080-2
LACTIC ACID	50-21-5	200-018-0
SODIUM BENZOATE	532-32-1	208-534-8
POTASSIUM SORBATE	24634-61-5	246-376-1

A.2 Physical/chemical characteristics and stability of the cosmetic product

A.2.1 Product specification
The product lash fusion is developed for daily face care
The main active ingredients are Hamamelis Virginiana Leaf Water, Panthenol, Cucumis Sativus Fruit Water and Glycine Soja Seed Extract.

A.2.2 Product type
Skin care product: Leave-on-product

A.2.3 Emulsion type: liquid
A.2.4 Ph value: 6,40
A.2.5 Appearance Slightly yellow liquid

A.3 Microbiological quality

A.3.1 Microbial Contamination/Specification

A Challenge Test according to the European Pharmacopoeia 2011:5.1.3 was rouled out by Dr. Straetmans GmbH. Test result After addition of pathogenic microorganism there was a completely reduction of the germs and the product fulfill Criteria A of the Ph.EUR. The sample was germfree before starting the test

A.3.2 Stability/Shelf Life
Storage test over a period of 6 months at room temperature, 5 ° C and 40° C was rouled out. Test result: No visible changements of the product
PAO 6 months

A.4 Impurities, traces information about the packaging material

The packaging material is usable as packaging for cosmetic products according European regulatins and German laws.

A.5 Normal and reasonable foreseeable use
The application according to the product label as follows:
Face care

A.6 Exposure of the cosmetic product

A.6.1 The site(s) of application — Face, neck and décolleté

A.6.2 The surface area(s) of application — Circa 565 cm2

A.6.3 The amount of product applied — The maximum amount: 1,0 g

A.6.4 The duration and frequency of use 2 times per day

A.6.5 The normal and reasonably foreseeable exposure route(s)
Application on the face, neck and décolleté

A.6.6 The target (or exposed) population(s). Potential exposure of
Adults

A.6.7 Foreseeable use
Contact with eyes is possible, if the product will be applicate on the eye area

A.6.8 Calculation of Exposure
Parameter:

Default of human body weight: 60-70 kg
Route of exposure: dermal
Kind of exposure: rinse-off Product
Retention factor: R: 1,0

Skin surface area: 565 cm2
Typical amount per application: 1,ßg
Frequency of application of the finished product: 2/day
The total daily amount is: 2,0 g/day

A.7 Exposure of the substances

Dermal absorption reported as a percentage of the amount of substance applied:
The calculation of the SED will be as follows:
SED= A (G/day) x 1000 mg/g x C (%)/100 x DAp (%)/100
SED (mg/kg bw/day)=Systemic Exposure Dosage
A (g/day)= Amount of the cosmetic product applied daily
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
D in leave-on-products: 100 % (worst case)
D in rinse-off-products: 1 %
60 kg = default human body weight

A.8 Toxicological profile of the substance

INCI: Aqua
Specification of the raw material:
Microbiological specification:
Total plate count: < 100 KBE/ml
Fullfill the requirements of the TrinkwV.

INCI: Hamamelis Virginiana Leaf Water
Acute orale toxicity: LD50 mouse oral: 4610 mg//kg [9]
Subchronic toxicity: NOAEL: 2920 mg/kg/bw/90d [9]
Percutanous permeation: no data available
Dermale Irritation: non irritating [9]
Mucosal/Eye Irritation: non irritating [9]
Sensitization Potential: no sensitization potential [9]
Mutagenicity: no mutagenic potential [9]

INCI: Alcohol denat.
Acute oral toxicity: TDLo woman oral: 1200 mg/kg [9]
Subchronic toxicity: NOAEL: 19 g/ kg/bw/90d [9]
Percutanous permeation: no data available
Dermal Irritation: skin rabbit: 400 mg open MLD [9]
Mucosal/Eye Irritation: eye rabbit: 500mg SEV [9]
Sensitization Potential: no sensitization known [9]
Mutagenicity: no data available

Specification of the raw material:
Total plate count: <100 KBE/g
Yeast & Molds: < 10 KBE/g
Staphylococcus aureus, Pseudomonas aeruginosa, Candida albicans, E. Coli: not detectable

INCI: Allantoin
Acute oral toxicity: LD 50 rat oral: >5000 mg/kg [9]
Subchronic toxicity: no data available
Percutaneous permeation: no data available
Dermal Irritation: non irritant [Eggensperger]
Mucosal/Eye Irritation: non irritant (Draize) [Eggensperger]
Sensitization Potential: no data available
Mutagenicity: no data available
CIR-Compendium: Safe up to 2%

INCI: Panthenol
Acute oral toxicity: LD 50 rat oral: 15000mg/kg [9]
Subchronic toxicity: no data availabe
Percutanous permeation: no data available
Mucosal/Eye Irritation: 500µg MLD [9]
Skin Irriation: rabbit 500mg/4H MLD
Sensitization Potential: no data available
Mutagenicity:: no data available
CIR Compendium: Safe up to 6 %

INCI: Cucumis Sativus Fruit Water
CIR Compendium: Safe up to 3%

INCI: Potassium Sorbate
In the Annex 6 I, No. 4 are the following restrictions:
Maximum authorized concentration: 0,6% (acid)

INCI: Sodium Benzoate
In the Annex 6 A, No. 1 are the following restrictions:
Maximum authorized concentration: 0,5% leave-on-products

Specification of the raw material:
Total plate count: <100 KBE/g
Yeast & Molds: < 10 KBE/g
Staphylococcus aureus, Pseudomonas aeruginosa, Candida albicans, E. Coli: not detectable

INCI: Propylene Glycol
Acute oral toxicity: LD 50 rat oral: 20g/kg [9]
Subchronic toxicity: NOAEL: 425 mg/kg/bw/90d [9]
Percutaneous permeation: no data available
Dermal Irritation: 500mg/7DMLD [9]
Mucosal/Eye Irritation: 100 mg MLD [9]
Sensitization Potential: no data available

Mutagenicity: no data available

INCI: Glycine Soja Seed Extract
Acute oral toxicity: LD 50 mouse oral: 22100 mg/kg [9]
Subchronic toxicity: TDLo mouse oral: 168g/kg/26 w [9]
Percutanous permeation: no data available
Mucosal/Eye Irritation: no data available
Sensitization Potential: no data available
Mutagenicity:: no data available
CIR-Compendium: Safe

INCI: Potassium Sorbate
In the Annex 6 I, No. 4 are the following restrictions:
Maximum authorized concentration: 0,6% (acid)

INCI: Sodium Benzoate
In the Annex 6 A, No. 1 are the following restrictions:
Maximum authorized concentration: 0,5% leave-on-products

INCI: Lactic Acid
Subchronic toxicity: no data available
Percutanous permeation: no data available
Dermale Irritation: skin rabbit: 100mg/24 H MOD
Mucosal/Eye Irritation: eye rabbit 750 µg/SEV [9]
Sensitization Potential: no data available
Mutagenicity: no data available
JECFA: ADI not limited in food
CIR-Compendium: Safe < 10%

INCI: Maris Sal, Aqua
Classification of the substance or mixture: Not classified as dangerous according to the regulation (EC) n˚ 1272/2008 (GHS/CLP)
Label elements : Not applicable.
Identification of specific danger for human beings or environment : No hazardous components for labelling
Aspect: Liquid
Solubility: Soluble in water
Colour : Light yellow
pH: 5,0 – 6,0
Smell: Light
Boiling point: Not studied
Taste: Not concerned
Flash point: Not studied
Humidity: <= 35.0 %
Explosion hazardous: None
Density : 1300 – 1400 g/l
Stability: Stable
Conditions to avoid: Warmth
Incompatible materials: None
Hazardous decomposition products: None

INCI: Alcohol denat.
Acute oral toxicity: TDLo woman oral: 1200 mg/kg [9]
Subchronic toxicity: NOAEL: 19 g/ kg/bw/90d [9]
Percutanous permeation: no data available
Dermal Irritation: skin rabbit: 400 mg open MLD [9]
Mucosal/Eye Irritation: eye rabbit: 500mg SEV [9]
Sensitization Potential: no sensitization known [9]
Mutagenicity: no data available
The Alcohol is denaturated with: 0,024%Diethylphtalate

INCI: Diethyl Phthalate
Subchronic toxicity: no data available
Percutanous permeation: no data available
Dermale Irritation: no data available
Mucosal/Eye Irritation: no data available
Sensitization Potential: no data available
Mutagenicity: no data available
JECFA: ADI not limited in food
CIR-Compendium: Safe up to 99%

INCI: Polysorbate-20
Acute oral toxicity: LD 50 mouse oral: > 33g/kg [9]
Subchronic toxicity: no data available
Percutanous permeation: no data available
Dermal Irritation: non irritating to the skin [9]
Mucosal/Eye Irritation: no data available
Sensitization Potential: no data available
Mutagenicity:: no data available
CIR Compendium: Safe up to > 50%

INCI: Parfum
See IFRA Conformity Certificate
The product contains the following allergenic substances:
Contains Benzyl Alcohol: Annex III/I No.:34 Concentration: 0,000006%
Contains Benzyl Benzoate: Annex III/I, No.:85 Concentration: 0,000003%
Contains Benzyl Salicylate: Annex III/I , No.:75 Concentration: 0,000004%
Contains Cinnamyl Alcohol: Annex III/!I No.:69 Concentration: 0,000004%
Declaration is required if the concentration is higher than 0,01% in rinse-off product or more than 0,001% in leave-on- products.
The perfume contains 0,000058 Methyl Benzoate and 0,000014% BHT
In the Annex 6 A, No. 1 are the following restriction for Methyl Benzoate
Maximum authorized concentration: 0,5% leave-on-products.
Due to the low concentration, it`s not necessary to indicate them on the label.

INCI: Phenoxyethanol
In the Annex 6 I, No. 29 are the following restrictions:
Maximum authorized concentration: 1,0%

INCI: Benzoic Acid

In the Annex 6 A, No. 1 are the following restrictions:
Maximum authorized concentration: 0,5% leave-on-products

INCI: Dehydroacetic Acid
In the Annex 6 I, No. 13 are the following restrictions:
Maximum authorized concentration: 0,6% (acid)
Prohibited in aerosol dispensers

INCI: Ethylhexylglycerin
Subchronic toxicity: NOAEL: 96mg/kg/bw/90d [9]
Percutaneous permeation: no data available
Dermal Irritation: Skin rabbit:500mg/24H MLD [9]
Mucosal/Eye Irritation: Eye rabbit: 126 mg MLD [9]
Sensitization Potential: no data available
Mutagenicity: no data available
Specification of the raw material:
Ethylhexylglycerin is stabilized with Tocopherol

A.9 Calculation of exposure
The MOS should be at least 100 to declare a substance safe for use.
The margin of safety is defined as the ratio between the maximum dose tolerated without unwanted effects (NOEL) and the systemically absorbed dose both expressed as mg/kg body weight.

Margin of Safety (MOS) = NO(A)EL : SED

The systemically absorbed dose (in mg/kg body eight) is calculated from the exposition dose (in mg) divided by an “average user body weight” of 60 kg.
In accordance with the SCC the NO(A)EL used for the calculation of the MOS refers to the subacute/chronic toxicity effects wherever the respective data exist.

A.10 Undesirable effects and serious undesirable effects
No undesirable effects and serious undesirable effects will be expected

---

A.11 Information on the cosmetic product
Statistic of complaints:
There are no complaints

A.12 Literature
1. Beck‘sche Textsammlung Lebensmittelrecht, Kosmetik Verordnung

2. Notes of guidance for testing of cosmetic ingredients for their safety evaluation, SCCNFP/0321/00 Final
3. H.P. Fiedler, Lexikon der Hilfsstoffe für Pharmazie, Kosmetik und angrenzende Gebiete, Editio Cantor Verlag Aulendorf, 4. Auflage
4. Hagers Handbuch der Pharmazeutischen Praxis, 5. Auflage,1990
5. Römpp Chemie Lexikon, 9. Auflage
6. M. Fey, J. Otte: Wörterbuch der Kosmetik, 3. Auflage, 1991
7. Blaue Liste, 2. Auflage, 1993
8. W. Umbach: Kosmetik, Thieme Verlag
9. Data Base: RTECS, Toxline, Toxcas
10. Material Safety Data Sheets
11. Technical Data Sheet

Assessment conclusion and reasoning
The cosmetic product lash fusion is safe concerning:

· instructions for use and disposal
· purity of the raw materials
· packaging material.
· Stability Testing
· Microbiological assessment
The MOS of all ingredients is more than 100.

Safety Assessment

according to Chapter III, Article 10 of Regulation (EC) No 1223/2009
of the European Parliament and of the Council

Product name: lBE BASE
Formula: n.a.
Company:

Cils'Jo Johana Tomaszewski
6 rue de Markdorf
68190 Markdorf
France

is in consideration of the toxicological profile of the ingredients, their chemical structures and of the levels of exposures, according to the principles of the GLP and in consideration of the warning notices and the conditions of applications, harmless in the directed and foreseeable use for the human health.

This assessment is based on

· toxicological profile
of the ingredients, toxicological/dermatological documentations of the raw materials, material safety data sheets, legal regulations, microbiological assessment

· chemical structure
as well as on the relevant standard operating procedures for manufacturing and production, on the operating procedures for quality control of the finished products and for the raw materials including physical and chemical testing where necessary.

· level of exposure
based on the conditions of applications. To avert danger, we refer to the voluntary and legal warning notices and other information if they are part of the presentation of the product.
An assessment of the GMP is not enclosed.

All the information and instructions contained in the safety data sheet are based on the current state id scientific and technical knowledge at the date indicated on the present safety data sheet. The supplier shall not be held responsible for any defect in the product covered by this safety data sheet. The information contained herein is based on the present state of knowledge and does not therefore guarantee contain properties. Recipients of this product must be take responsibility for observing exiting law and regulations.
Disclaimer:
The information including the claims and supporting data provided in this publication are provided for informational purposes only, upon the express condition that the User mat its own assessment of the appropriate use of such information. While the information contained herein is believed to be reliable, there are no representations, guarantee, or warranties of any kind made as to its accuracy, suitability for particular applications, how the product(s) will perform in combination with other substance or in User´s process or the result obtained. All expressed and implied warranties are disclaimed. The supplier and its affiliates make no warranties, express or implied, including, but not limited to, the implied warranties of merchantability and fitness for a particular porpose. The User is solely responsible for ensuring that products marketed to consumers comply with all relevant laws and regulations and assumes all risk ant liability of any use or handling of any materials. User agrees to indemnify and hold harmless The supplier and its affiliates for any and all actions arising from User´s use a of any information including claims in this publication, including, but not limited to, use in advertising and finishes product label claims, and not present this publication as evidence of finished product claim substantiation to any regulatory authority. It is the User´s sole responsibility to determine of there any issues relating to patent infringement relating to be supplied information. Nothing contained herein is to be considered as a permission, recommendation, not as an inducement to practice any patent invention with permission of the patent owner.