MOJOMAY

PRODUCT INFORMATION FILE

Product Information

Trade Name: MOJOMAY BIO-REVIVE ALL IN ONE SERUM
Physical Form of the Product: Leave-on product, anti-aging serum

Information About the Responsible Person

Responsible Person: BAMED MEDİKAL ÜRÜNLER VE MAKİNA SANAYİ TİCARET ANONİM ŞİRKETİ
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Section A: COSMETIC PRODUCT SAFETY INFORMATION

1. Qualitative and Quantitative Composition of the Cosmetic Product

INCI Name	CAS Number	EINECS/ ELICS Number	Amount (w/w %)	Function
AQUA	7732-18-5	231-791-2	80,0000-98,0000	SOLVENT
XYLITYLGLUCOSIDE	-	-	1,0000-5,0000	HUMECTANT SKIN CONDITIONING
ANHYDROXYLITOL	53448-53-6	258-560-9	0,8000-3,0000	HUMECTANT SKIN CONDITIONING
PHENOXYETHANOL	122-99-6	204-589-7	0,80001,0000	PRESERVATIVE
PEG-40 HYDROGENATED CASTOR OIL	61788-85-0	-	0,5000-0,9000	SURFACTANT- EMULSIFYING
TRIDECETH-9	24938-91-8/69011-36-5	*607-463-3/500-241-6	0,5000-0,8000	SURFACTANT- EMULSIFYING
SODIUM HYALURONATE	9067-32-7	-	0,1000-0,7800	HUMECTANT SKIN CONDITIONING
HYDROLYZED COLLAGEN	92113-31-0/73049-73-7	295-635-5/-	0,1000-0,7700	ANTISTATIC FILM FORMING HAIR CONDITIONING HUMECTANT SKIN CONDITIONING SKIN CONDITIONING-EMOLLIENT
XYLITOL	87-99-0	201-788-0	0,1000-0,7600	SKIN CONDITIONING-HUMECTANT
LECITHIN	8002-43-5/8030-76-0 (soybean)	232-307-2/310-129-7	0,1000-0,7500	ANTISTATIC SKIN CONDITIONING-EMOLLIENT SURFACTANT- EMULSIFYING
ETHYLHEXYLGLYCERIN	70445-33-9	408-080-2	0,0100-0,3000	DEODORANT SKIN CONDITIONING
PARFUM			0,0050-0,0,080	FRAGRANCE PERFUMING
ACETYL GLUTAMINE	2490-97-3	219-647-7	0,0050-0,0720	SKIN CONDITIONING
BACILLUS/FOLIC ACID FERMENT FILTRATE EXTRACT	-	-	0,0050-0,0710	ANTIOXIDANT HUMECTANT SKIN CONDITIONING
BUTYLENE GLYCOL	107-88-0 (i), 6290-03-5 (ii)	203-529-7 (i), 228-532-0 (ii)	0,0050-0,0700	FRAGRANCE HUMECTANT SKIN CONDITIONING SOLVENT VISCOSITY CONTROLLING
CAPRYLYL GLYCOL	1117-86-8	214-254-7	0,0050-0,0690	DEODORANT HAIR CONDITIONING SKIN CONDITIONING SKIN CONDITIONING-EMOLLIENT
1,2-HEXANEDIOL	6920-22-5	230-029-6	0,0050-0,0680	SKIN CONDITIONING SOLVENT
SH-OLIGOPEPTIDE-1	-	-	0,0050-0,0670	SKIN CONDITIONING
SH-OLIGOPEPTIDE-2	-	-	0,0050-0,0660	SKIN CONDITIONING SKIN PROTECTING
SH-POLYPEPTIDE-1	-	-	0,0050-0,0650	SKIN CONDITIONING
SH- POLYPEPTIDE-9	-	-	0,0050-0,0640	SKIN CONDITIONING
SH-POLYPEPTIDE-11	-	201-069-1	0,0001-0,0620	SKIN CONDITIONING
LIMONENE	5989-27-5	-	0,0001-0,0610	DEODORANT PERFUMING SOLVENT
HEXYL CINNAMAL	101-86-0	227-813-5	0,0001-0,0600	PERFUMING

PRODUCT INFORMATION FILE

It has been prepared according to Regulation (EC) no 1223/2009 of the European Parliament and of the Council of November 30, 2009 on cosmetic

ALPHA-ISOMETHYL IONONE	127-51-5	202-983-3/639-566-4	0,0001-0,0590	PERFUMING SKIN CONDITIONING
CITRONELLOL	106-22-9 / 26489-01-0 / 7540-51-4 / 1117-61-9	204-846-3	0,0001-0,0580	PERFUMING
CITRIC ACID	77-92-9/5949-29-1	203-375-0/247-737-6/231-415-7/ 214-250-5	0,0050-0,0630	BUFFERING CHELATING MASKING

Perfume name	BARBY BLOND
Code Number	4288141
Supplier Identity	GÜLÇİÇEK
Perfume Concentration (%)	0,05

2. Physical / Chemical Properties, and Stability of the Cosmetic Product

a) Physical / Chemical Character of the Cosmetic Product

PARAMETER	SPECIFICATION	METHOD
Appearance	COLORLESS-PALE YELLOW LIQUID	Visual
Odour	CHARACTERISTIC	Sensorial
Viscosity (20-30 ºC) cP (Viscometer)	850-1600	Ph. Eur 2.2.8 01/2008:20210
pH (20-30 ºC) (pH Meter)	5,0-6,0	Ph. Eur 2.2.3 01/2008:20203
Density (20 ºC) g/ml (Anton Paar DMA 501 Density Meter)	0,9-1,1	Ph. Eur 2.2.5 01/2008:20205
Brix (20-30 ºC)	-	Ph. Eur 2.2.6 01/2008:20206

b) Durability/ Stability Information:

The stability of the product was tested for 36 months at 25 ºC ± 2 ºC ± 2 ºC 65% RH ± 5% RH room conditions and for 12 months at 40 ºC ± 2 ºC 75% RH ± 5% RH in a drying oven in the original package of the product. During this period, appearance, odour, viscosity, pH, density, and microbiological evaluation were tested. During the stability tests, it was stated that no deviation from the original form of the product was observed.

The stability test report is in the table below:

STABILITY AND REACTIVITY		
	ROOM TEMPERATURE	OVEN
CONDITIONS	25 ºC ±2 ºC %65 RH ±%5 RH	40 ºC ± 2 ºC %75 RH ±%5 RH
TIME	36 Month	12 Month
SHELF LIFE	The manufacturer proposed max. 36 months shelf-life.	
PERIOD AFTER OPENING (PAO)	Samples were submitted to different conditions of accelerated ageing (thermic and physical stress), and the subsequent alterations were evaluated by microbiological, physical and chemical assays an PAO and PAO of 12 months is determined.	
STORAGE CONDITION	Store at room temperature. Keep away from direct sunlight.	
CONDITIONS TO AVOID	The product is stable into a follow temperature range: 5°C – 40°C	

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INCOMPAIBILITY WITH OTHER SUBSTANCES	None.
DANGEROUS PRODUCTS OF DECOMPOSITION	None at the temperatures of use.

The product has a minimum shelf life of 36 months as stipulated time by the manufacturer. The shelf life of the product after opening is indicated on the label as 12 months for 30 ml.

3. Microbiological Quality

Microbiological screening tests of cosmetic products applied to the eye area, mucous membranes, damaged skin, children under three years of age, the elderly, and people with the severely compromised immune system should ensure that the number of colonies forming microorganisms complies with the authorized limits.
The acceptance criteria for the finished product are as follows:

- The total number of aerobic mesophilic microorganisms should be less than 1000 cfu/g.
- The total number of mold and yeast should be less than 1000 cfu/g.
- The total number of microorganisms in eye contour and baby products should be less than 100 cfu/g.
- Pathogenic microorganisms such as *Pseudomonas aeruginosa*, *Staphylococcus aureus*, and *Candida albicans* must not be contained in the finished cosmetic product.

Microbiology test report is in the table below:

MICROBIOLOGICAL REQUIREMENTS OF PRODUCT	
Parameter	**Result**
Total number of aerobic mesophilic microorganisms in a sample of 1 gr or 1 ml	< 100 cfu
Yeast and Mould in a sample of 1 gr or 1 ml	< 10 cfu
Staphylococus aureus in a sample of 1 gr or 1 ml	Absent
Pseudomonas aeroginosa in a sample of 1 gr or 1 ml	Absent
Escherichia coli in a sample of 1 gr or 1 ml	Absent
Candida albicans in a sample of 1 gr or 1 ml	Absent

Challenge Test Result and Evaluation:

In order to ensure the microbiological stability of the product during storage and use, it is necessary to evaluate the effectiveness of the preservative in the formulation of the cosmetic product under development. This evaluation is done by means of a screening test. This test is required for all cosmetics as it provides assurance that the product can be protected by the preservative(s) in the formula against the risk of deterioration or infection from the time of manufacture until it is consumed under normal storage and use conditions.

Protective Activity Test of the Product Acto Pharma Hijyen San.Tic. Inc. It was made by as stated in the European Pharmacopoeia. *Escherichia coli* ATCC 8739, *Pseudomonas aeruginosa* ATCC 9027, *Staphylococcus aureus* ATCC 6538, *Candida albicans* ATCC 10231 and *Aspergillus niger* ATCC 16404 were used. 2nd day, 7th day, 14th day and 28th day results Acto Pharma Hijyen San.Tic. Inc. It was evaluated according to the ISO11930 method. According to the test results, the manufacturer has experimentally guaranteed that the preservative is effective in this product through the Preservative Efficacy Test.

Challenge test report is attached as Annex 1

4. Information on Impurities, Residues, and Packaging Material

A - Impurities and Residues

PRODUCT INFORMATION FILE

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There is no available data on impurities and residues.

B – Packaging Material

As the packaging material, glass is used in the bottle body, PP cap in the dropper packaging material. The product is offered for sale in a 30 ml bottle.

The product packaging image is as follows:

5. Normal and Reasonably Predictable Use

a) **Product Label Information:**
Product label information is attached as Annex 2.

b) **Normal and Reasonably Predictable Place of Use and Amount of Use of the Product:** It is a product used in facial care and not rinsed. SCCS Guidance Notes In the 11th revision, the total area in which the product comes into contact with the skin is 565 cm2, the frequency of use is 2/day, the amount used is 5.0 g, the skin retention factor (R) is 1.0.

c) **Method of Use and Frequency of Use of the Product:** Apply to clean and dry face, especially to the areas where wrinkles are observed, twice a day, morning and evening.

6. Exposure to Cosmetic Product

(The SCCS's Notes Of Guidance For The Testing Of Cosmetic Ingredients And Their Safety Evaluation 11th Revision)	
Implementation area(s)	Face, neck and decollete area
The area where the applied product touches the skin (cm^2)	565 cm^2
Amount of product applied (g)	5,0 g
The contact time of the application product and the frequency of application	2/day
Normal and reasonably foreseeable routes of exposure	Face
Person(s) targeted or exposed	Adults

PRODUCT INFORMATION FILE

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7. Exposure to Cosmetic Product Ingredients

- If the amount of dermal absorption per unit surface (μg/cm^2) is known:
  SED = [**DA$_a$** (μg/cm^2) x 10^{-3}(mg/μg) x **SSA** (cm^2) x **F** (day^{-1}) x **R**] / [60 (kg)]
- If the dermal absorption percentage of the applied product is known:
  SED = **A** (mg/kg body weight/day) X **C** (%) / 100 X **DA$_p$** (%) / 100

SED (mg/kg body weight/day): Systematic Exposure Dosage

A (mg/kg body weight/day): Daily exposure to a cosmetic product is based on the amount of product applied per kg of body weight and the frequency of application.

C (%): % concentration of the substance whose exposure is to be calculated in the finished product

DAp (%): Dermal absorption expressed as a percentage of the test dose assumed to be applied under real-life conditions. (If it is obtained as a result of the experiment by imitating the conditions of use and is unknown, it is assumed that the absorbance of the product is 100%)

MOJOMAY BIO-REVIVE ALL IN ONE value calculated for A amount of daily exposure: 8,33 mg/kg body weight/day and surface area 565 cm^2. Average body weight was considered to be 60 kg for adults.
(The SCCS's Notes Of Guidance For The Testing Of Cosmetic Ingredients And Their Safety Evaluation 11th Revision)

Measurement of the Safety Interval (MoS):
MoS= NOAEL / SED

The A value for preservatives is 269.00 mg/kg body weight/day in the 11th Revision of the SCCS Guidance Notes. (The SCCS's Notes Of Guidance For The Testing Of Cosmetic Ingredients And Their Safety Evaluation 11th Revision)

In order for the substance to be declared safe for the consumer, the result MoS>100

INCI name of Raw Material	Amount (w/w %)	Retention Factor R	Dermal Absorption DA$_a$ (μg/cm^2)	Dermal Absorption Dap (%)	SED (mg/kg bw/day)	NOAEL (mg/kg bw/day)	MoS (NOAEL/SED)
AQUA	80,0000-98,0000	1,0	-	100	8,1634	-	-
XYLITYLGLUCOSIDE	1,0000-5,0000	1,0	-	100	0,4165	-	-
ANHYDROXYLITOL	0,8000-3,0000	1,0	-	100	0,2499	1000	4002
PHENOXYETHANOL	0,80001,0000	1,0	-	100	2,6900	500	186
PEG-40 HYDROGENATED CASTOR OIL	0,5000-0,9000	1,0	-	100	0,075	-	-
TRIDECETH-9	0,5000-0,8000	1,0	-	100	0,0666	-	-
SODIUM HYALURONATE	0,1000-0,7800	1,0	-	100	0,0650	1500	23077
HYDROLYZED COLLAGEN	0,1000-0,7700	1,0	-	100	0,0641	1000	15601
XYLITOL	0,1000-0,7600	1,0	-	100	0,0633	4000	63492
LECITHIN	0,1000-0,7500	1,0	-	100	0,0625	1000	16000
ETHYLHEXYLGLYCERIN	0,0100-0,3000	1,0	-	100	0,0250	2000	80000
PARFUM	0,0050-0,0,080	1,0	-	100	0,0067	-	-
ACETYL GLUTAMINE	0,0050-0,0720	1,0	-	100	0,0060	-	-
BACILLUS/FOLIC ACID FERMENT FILTRATE EXTRACT	0,0050-0,0710	1,0	-	100	0,0059	-	-
BUTYLENE GLYCOL	0,0050-0,0700	1,0	-	100	0,0058	10000	1724138
CAPRYLYL GLYCOL	0,0050-0,0690	1,0	-	100	0,0057	300	172414

PRODUCT INFORMATION FILE

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1,2-HEXANEDIOL	0,0050-0,0680	1,0	-	100	0,0057	-	-
SH-OLIGOPEPTIDE-1	0,0050-0,0670	1,0	-	100	0,0056	-	-
SH-OLIGOPEPTIDE-2	0,0050-0,0660	1,0	-	100	0,0055	-	-
SH-POLYPEPTIDE-1	0,0050-0,0650	1,0	-	100	0,0054	-	-
SH- POLYPEPTIDE-9	0,0050-0,0640	1,0	-	100	0,0053	-	-
SH-POLYPEPTIDE-11	0,0001-0,0620	1,0	-	100	0,0052	-	-
LIMONENE	0,0001-0,0610	1,0	-	100	0,0052	250	48077
HEXYL CINNAMAL	0,0001-0,0600	1,0	-	100	0,0051	-	-
ALPHA-ISOMETHYL IONONE	0,0001-0,0590	1,0	-	100	0,0050	-	-
CITRONELLOL	0,0001-0,0580	1,0	-	100	0,0049	300	61225
CITRIC ACID	0,0050-0,0630	1,0	-	100	0,0048	1200	250000

8. Toxicological Profile of Cosmetic Product Ingredients

a) Toxicological Profile of the Substances in the Formula:

INCI name of Raw Material	Toxicological Information	Ecotoxicological Information
AQUA	No data available.	No data available.
XYLITYLGLUCOSIDE	No assessment and notably no DNEL is required for the general public, as the latter is only exposed to the substances via the use of final cosmetic products. Assessment of human health effects for such exposure is not required by REACH (ECHA 2023).	he substance is not classified for the environment according to the tests results available. (ECHA 2023).
ANHYDROXYLITOL	No data available.	No data available.
PHENOXYETHANOL	2-Phenoxyethanol displayed low acute oral toxicity in rats. 2-Phenoxyethanol displayed very low acute dermal toxicity tested in rats and rabbits. 2-Phenoxyethanol displayed no effects following inhalation exposure in rats. (ECHA 2022)	Concerning aquatic short-term toxicity effects of 2-phenoxyethanol, tests for representatives of each trophic level (fish, Daphnia, algae) are available. The test results presented hereby confirmed that the toxicity profile of 2-phenoxyethanol for aquatic species is of low concern. The most sensitive species were fish (Pimephales promelas, LC50 of 344 mg/L). Also long-term toxicity data are available for all three trophic levels (fish, Daphnia, algae) in tests with 2-phenoxyethanol. The most sensitive species were daphnids with a NOEC value of 9.43 mg/L (reproduction). (ECHA 2022)
PEG-40 HYDROGENATED CASTOR OIL	In a fixed dose procedure 5 female rats received a single dose of 2000 mg/kg bw by gavage. Rats were observed for 14 days thereafter. No mortality occurred. One female showed hunched posture, ataxia, noisy respiration, increased salivation and lethargy during the first day. The other females showed hunched posture during the first 2 hours after dosing. There were no effects on body weight and no macroscopic findings. Based on these findings the oral LD50 of the substance is > 2000 mg/kg bw. As the substance is of low acute oral toxicity, is not classified as STOT SE and there are no other signs of systemic toxicity, the acute dermal toxicity study has been waived. As the inhalation exposure route is not relevant for this substance no acute study via the inhalation route is included (ECHA 2023)	Biodegradation in water: Readily biodegradable: 83.6% (CO2 evolution) in 28 days (OECD 301B) Bioaccumulation in organisms is negligible, due to biotransformation and excretion of alcohol ethoxylates. Acute toxicity: - to Fish: LC50 (96h) = 108 mg/L for Danio rerio - to Crustacea: EL50 (48h) = 51 mg/L for Daphnia magna - to Algae: EL50 (72h) > 10 mg/L for Pseudokirchneriella subcapitata Chronic toxicity: The risk assessment is based on alcohol ethoxylate specific QSARs - to Fish: EC20 (30d) = 0.269 mg/L for Pimephales promelas - to Crustacea: EC20 (21d) = 0.0542 mg/L for Daphnia magna -to Algae: ECr20 (72h)= 0.159 mg/L for Desmodesmus subspicatus Classification justification according to CLP Based on the data above, alcohol ethoxylate (C18, < 2.5 EO) is considered rapidly biodegradable. The acute aquatic toxicity L(E)C50 is > 1 mg/L. Based on QSAR calculations the lowest expected long-term effect value is 0.0542 mg/L. Therefore, alcohol ethoxylate (C18, < 2.5 EO) needs to be classified and labelled as environmental hazard Chronic Cat. 2 according to the consolidated version of Regulation (EC) No 1272/2008 and further amendments (ATPs) (ECHA 2023)

PRODUCT INFORMATION FILE

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TRIDECETH-9	Oral (rat): LD50 >2000 mg/kg bw Read-across (Weight-of-Evidence approach) based on the analogue source substances isotridecanol, ethoxylated, 3 EO (CAS No. 69011-36-5), isotridecanol, ethoxylated, 3-4 EO (CAS No. 69011-36-5) and 11-methyldodecan-1-ol (isotridecanol, CAS No. 27458-92-0, EC No. 248-469-2). Inhalation: No study required as the inhalation route of exposure is considered less relevant than the dermal route for isotridecanol, ethoxylated, <2.5 EO (CAS No. 69011-36-5, EC No. 500-241-6). Dermal: LD50 >2000 mg/kg bw Read-across (Weight-of-Evidence approach) based on the analogue source substances alcohols, C12-13, ethoxylated, <2.5 EO (CAS No. 66455-14-9, EC No. 500-165-3) and 11-methyldodecan-1-ol (isotridecanol, CAS No. 27458-92-0, EC No. 248-469-2) (ECHA 2023).	Acute aquatic data for three trophic levels are available (fish, aquatic invertebrates, algae). The most sensitive organism group in short-term testing were aquatic invertebrates. The determined effect concentration in available acute toxicity test with Daphnia magna was EC50 (48 h): 0.544 mg/L (geom. mean measured). The effect concentrations reported for fish and algae were LL50 (96h) > 1.1 mg/L (geom. mean measured) and ErC50 (72h): 3.4 mg/L (meas. arith. mean), respectively. Long-term data is available for aquatic invertebrates and algae. Daphnia were also the most sensitive test organism in the available chronic toxicity tests. The determined NOEC (21 d) based on the reproduction rate of the daphnids was 0.218 mg/L (TWA). For algal growth an ErC10 (72h) of 1.33 mg/L (meas. arith. mean) was determined An inhibition of sewage sludge organisms is not expected based on the results of an inhibition control (ECHA 2023)
SODIUM HYALURONATE	No data available.	No data available.
HYDROLYZED COLLAGEN	No adverse effects have been reported up to the limit dose regarding systemic repeated dose toxicity, toxicity to reproduction, genotoxicity, acute and local effects (ECHA 2023).	According to Regulation (EC) No. 1272/2008, the test substance is not classified for aquatic hazards: No adverse effects to aquatic organisms were detected up to or even above the limit concentration of 100 mg/L, and the substance lacks any bioaccumulation potential (ECHA 2023)
XYLITOL	Oral: rat and mouse LD50 4000 mg/kg. Reliability = 2 Inhalation: No study available Dermal: No study available (ECHA 2023).	A QSAR approach based on the baseline narcosis equation using LogKow as an input variable exploiting the functionality encoded in ECOSAR was undertaken to derive information to characterise the aquatic toxicity to fish, daphnia and algae species. Xylitol was found to be of low concern to all 3 aquatic species. Screening studies available in Ceriodaphnia dubia and Pimephales promelas substantiate the predicted low toxicity of the substance. Therefore, the test substance is not classified for acute or chronic aquatic toxicity according to EU Classification, Labelling and Packaging of Substances and Mixtures (CLP) Regulation (EC) No. 1272/2008 (ECHA 2023).
LECITHIN	No data available.	No data available.
ETHYLHEXYLGLYCERIN	No data available.	No data available.
PARFUM	No data available.	No data available.
ACETYL GLUTAMINE	No data available.	No data available.
BACILLUS/FOLIC ACID FERMENT FILTRATE EXTRACT	No data available.	No data available.
BUTYLENE GLYCOL	In the absence of reliable data on repeated inhalation and dermal toxicity and in light of the observation that no toxicity was observed in subacute and chronic oral studies as well as the observation that no acute toxicity was observed up to the highest doses/concentrations tested no DNELs for workers need to be derived (ECHA 2023).	Classification according to Regulation (EC) No 1272/2008 (CLP) Acute hazard category: There are adequate short-term studies available covering three trophic levels, i.e. algae, daphnia and fish. No hazard was identified. According to the classification criteria laid down in Regulation No (EC) 2008/1272, the submission substance does not need to be classified. Chronic hazard category: There are adequate chronic toxicity data available, e.g. for aquatic algae and daphnia. No hazard was identified in the available long-term and short-term studies. The submission substance is readily biodegradable and the log Kow is -0. According to the classification criteria laid down in Regulation No (EC) 2008/1272, the submission substance does not need to be classified. In conclusion, the submission substance is not classified for the environment according to Regulation (EC) No 1272/2008 (ECHA 2023).
CAPRYLYL GLYCOL	In the acute oral toxicity study, all animals survived the limit dose of 2000 mg/kg. Therefore, classification of octane-1,2 -diol for acute oral toxicity is not required [REGULATION (EC) 1272/2008]. Based on the general low oral toxicity of octane-1,2 -diol (LD50 > 2000 mg/kg, no deaths at 1000 mg/kg/day in a repeated dose oral study during 90 days) high acute dermal toxicity is not to be expected. Therefore, classification of octane-1,2 -diol for acute dermal toxicity is not required. Acute inhalation toxicity of octane-1,2 -diol is concluded by read-across from a study performed with pentane-1,2 -diol. The LC50 was > 7015 mg/m^3. Additionally, octane-1,2 -diol has a very low acute toxicity. Accordingly, classification of octane-1,2 -diol for	The results from the aquatic toxicity studies are as follows: LC50 (96h) fish= between 2.2 and 22 mg/L (nominal concentration). EC50 (48 h) Daphnia > 100 mg/L (nominal concentration). ErC50 (72 h) algae = 35 mg/L (measured concentration). EC50 microorganisms > 100 mg/L. The substance is readily biodegradable and has a log Pow of < 4. The data available do not warrant any classification with regard to environmental hazards according to Regulation (EC) 1272/2008 (ECHA 2023).

PRODUCT INFORMATION FILE

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	acute inhalation toxicity is not required (ECHA 2023).	
1,2-HEXANEDIOL	1,2-hexandiol can be absorbed well mainly via oral and dermal exposure (80% absorption assumed). The absorption via inhalation is considered irrelevant due to negligible exposure (i.e. low vapour pressure). No accumulation in the body is expected due to efficient metabolic pathways and formation of soluble degradation products with established elimination routes (ECHA 2023)	No effects/mortality were seen in acute tests up to 100 mg/L with 1,2-hexanediol or structural similar substances. Therefore, 1,2 - hexanediol is not classified for acute aquatic toxicity as per EU CLP (Regulation (EC) No 1272/2008) or DSD (Directive 67/548/EEC). As the substance is readily biodegradable and the log Pow is < 3 (4), also classification for chronic aquatic toxicity is not required (ECHA 2023).
SH-OLIGOPEPTIDE-1	No data available.	No data available.
SH-OLIGOPEPTIDE-2	No data available.	No data available.
SH-POLYPEPTIDE-1	No data available.	No data available.
SH- POLYPEPTIDE-9	No data available.	No data available.
CITRIC ACID	The calculation of DNELs for citric acid is considered to be unnecessary because: 1. Citric acid is naturally present in common fruit and vegetables, which means there is a long history of human exposure; it has been estimated that maximum daily intake of citric acid can reach up to 500 mg/kg/day. (OECD SIDS 2001) In addition citric acid is an intermediate in the human metabolic pathway (WHO Food Additives, Series 5, 1973). 2. Citric acid is a permitted EU Food Additive and, according to the JECFA (Joint Expert Committee on Food Additives of the WHO/ FAO), these products may be used without limitation, according to Good Manufacturing Practice 3. The US Food and Drug Administration also classifies citric acid as GRAS (Generally Recognized as Safe) food ingredients (www.accessdata.fda.gov,1977) (ECHA 2022)	Short term toxicity Reliable acute toxicity tests results are available for freshwater fish (Leuciscus idus and Pimephales promelas), invertebrates (Daphnia magna) and algae (Scenedesmus quadricauda). LC50 values for the fish were between >100 and 1000 mg/L, while the EC50 for invertebrates was 1535 mg/L. A TT of 640 mg/L was determined in the algal test from which a NOEC of 425 mg/L was derived. the long-term aquatic toxicity to fish study and the long-term aquatic toxicity to invertebrate study do not need to be conducted as the chemical safety assessment indicates that they are not necessary: Citric acid is an essential element in the metabolic pathway of all living organisms; Low short-term toxicity has been reported; The substance is readily biodegradable, has low potential for bioaccumulation (Log Kow <3) and is soluble in water (ECHA 2022)
SH-POLYPEPTIDE-11	No data available.	No data available.
LIMONENE	No data available.	No data available.
HEXYL CINNAMAL	No data available.	No data available.
ALPHA-ISOMETHYL IONONE	Based on the available data summarized and CLP criteria ,the test chemical 3-methyl-4-(2,6,6-trimethyl-2-cyclohexen-1-yl)-3-buten-2-one is not likely to classify as a toxicant upon repeated application by the oral and dermal route of exposure (ECHA 2023)	EC50 for freshwater algae: 20 mg/L EC50 for microorganisms: 100 mg/L (ECHA 2023)
CITRONELLOL	Acute toxicity: - oral: LD50 = 3450 mg/kg bw - dermal: LD50 = 2650 mg/kg bw (ECHA 2023)	Taking the available information into account (ecotoxicity 1 -10 mg/l, readily biodegradable, log Kow 3.4), a classification with N, R51/53 (67/548) is warranted. Citronellol has not to be classified under the CLP (1272/2008). (ECHA 2023)

MoS calculations as well as the IFRA certificate of conformity supplied by the manufacturer were used in the safety assessment of this product. The concentration of perfume in the product (0,05 %) is below the maximum concentration that can be used according to IFRA's acceptance criteria for this category (Class 5, maximum usage rate 33,3 %).

IFRA Certificate of Conformity is attached as Annex 3.

b) Control of Legislative Compliance of Substances According to the Cosmetics Regulation Prepared According to Article 7 of the Cosmetics Law No. 5324:

ANNEX II: LIST OF SUBSTANCES THAT COSMETIC PRODUCTS SHOULD NOT CONTAIN
ANNEX-III SECTION 1: LIST OF SUBSTANCES THAT COSMETIC PRODUCTS SHOULD NOT CONTAIN, EXCEPT FOR LIMITATIONS AND CONDITIONS
ANNEX-III SECTION 2: LIST OF MATERIALS CONDITIONALLY PERMITTED TO USE IN COSMETIC PRODUCTS
ANNEX IV SECTION 1: LIST OF DYEING AGENTS ALLOWED TO BE USED IN COSMETIC PRODUCTS
ANNEX IVSECTION 2: LIST OF DYEING AGENTS TEMPORARILY ALLOWED FOR USE IN COSMETIC PRODUCTS

PRODUCT INFORMATION FILE

It has been prepared according to Regulation (EC) no 1223/2009 of the European Parliament and of the Council of November 30, 2009 on cosmetic

ANNEX V: LIST OF MATERIALS EXCLUDED FROM THE COSMETICS REGULATION
ANNEX VI: LIST OF PRESERVATIVES THAT COSMETIC PRODUCTS MAY CONTAIN
ANNEX VI SECTION 1: LIST OF PRESERVATIVES ALLOWED TO BE USED IN COSMETIC PRODUCTS
ANNEX VI SECTION 2: LIST OF PRESERVATIVES CONDITIONALLY ALLOWED FOR USE IN COSMETIC PRODUCTS
ANNEX VI SECTION 1: LIST OF UV FILTERS THAT COSMETIC PRODUCTS MAY CONTAIN
ANNEX VI SECTION 2: LIST OF UV FILTERS THAT COSMETIC PRODUCTS MAY TEMPORARILY CONTAIN

INCI Name of Substance	Application and/or area of use	Highest concentration authorized in cosmetics	Other limitations and requirements	Instructions for use and precautions to be indicated on the label	Concentration of the substance in the finished product	Compliance	Annex No
PHENOXYETHANOL	-	1,0 %	-	-	0,9000	Convenient	V/29
LIMONENE	-	-	*0.001% for leave-on products *0.01% in rinse-off products	-	-	The presence of this substance must be stated in the Product ingredients list in accordance with Article 10 (g) of the Cosmetics Regulation.	III/88
HEXYL CINNAMAL	-	-	*0.001% for leave-on products *0.01% in rinse-off products	-	-	The presence of this substance must be stated in the Product ingredients list in accordance with Article 10 (g) of the Cosmetics Regulation.	III/87
ALPHA-ISOMETHYL IONONE	-	-	*0.001% for leave-on products *0.01% in rinse-off products	-	-	The presence of this substance must be stated in the Product ingredients list in accordance with Article 10 (g) of the Cosmetics Regulation.	III/90
CITRONELLOL	-	-	*0.001% for leave-on products *0.01% in rinse-off products	-	-	The presence of this substance must be stated in the Product ingredients list in accordance with Article 10 (g) of the Cosmetics Regulation.	III/86

9. Adverse Effects and Serious Adverse Effects

No adverse effects and serious adverse effects have been reported.

10. Information about Cosmetic Product

Other information contained in the file is as follows:

1- Product SDS
2- Specification and certification of analysis
3- GMP Certificate
4- Challenge Test Report
5- Product label information
6- IFRA Certificate of Conformity

Section B: COSMETIC PRODUCT SAFETY EVALUATION

1. Evaluation Report

PRODUCT INFORMATION FILE

It has been prepared according to Regulation (EC) no 1223/2009 of the European Parliament and of the Council of November 30, 2009 on cosmetic

While preparing the cosmetic product safety report, product components and their toxicological profile, chemical composition, expected reactions (with TDS, MSDS, allergen determination documents), legal requirements for the product and raw materials and compliance with the legislation, product durability data and compatibility with the packaging material were evaluated.

It is a non-rinsing product used in face care. The target audience is adults.

Finished product specifications and manufacturers' raw material specifications for each raw material were evaluated. Product stability was assessed according to the stability test report provided by the manufacturer.

The product has a minimum shelf life of 36 months as stipulated time by the manufacturer. The shelf life of the product after opening is indicated on the label as 12 months for 30 ml.

Protective Activity Test of the Product Acto Pharma Hijyen San.Tic. Inc. It was made by as stated in the European Pharmacopoeia. Escherichia coli ATCC 8739, Pseudomonas aeruginosa ATCC 9027, Staphylococcus aureus ATCC 6538, Candida albicans ATCC 10231 and Aspergillus niger ATCC 16404 were used. 2nd day, 7th day, 14th day and 28th day results Acto Pharma Hijyen San.Tic. Inc. It was evaluated according to the ISO11930 method. According to the test results, the manufacturer has experimentally guaranteed that the preservative is effective in this product through the Preservative Efficacy Test.

There is no available data on impurities and residues.

The packaging material does not have a negative impact on the purity and stability of the product according to the product formulation and stability test results.

Manufacturer information, warnings, and instructions for use have been evaluated on the finished product label. All raw materials included in the list of product ingredients on the label must be listed in order of INCI names and % concentration, in descending order of concentration.

The safety assessment report is for anti-aging serum used by adults. A value for anti-aging serum 8,33 mg/kg body weight/day was utilized.

In the safety assessment for adults, the MoS (safety interval) was evaluated according to the MoS>100 in the SCCS notes. Safety intervals were calculated for raw materials for which NOAEL values were available. The safety interval for all raw materials calculated was greater than 100. The raw materials are safe to use at this concentration in this product.

MoS calculations as well as the IFRA certificate of conformity supplied by the manufacturer were used in the safety assessment of this product. The concentration of perfume in the product (0,05 %) is below the maximum concentration that can be used according to IFRA's acceptance criteria for this category (Class 5, maximum usage rate 33,3%).

SCCS Opinion:

The ingredients contained in the product are raw materials that are authorized and suitable for use in cosmetics. All raw materials are non-toxic when used at these concentrations under normal and foreseeable conditions. The product does not contain the substances on the list of prohibited substances in the Cosmetic Law No. 5324, the Regulation on the Amendment of the Cosmetic Regulation and the Annexes to the Regulation. Product composition complies with Cosmetics legislation.

No adverse effects and serious adverse effects have been reported.

This report has been prepared in line with available data. The report should be revised in case of changes in product content, stability information, allergens and concentrations in the perfume or packaging material.

Since the MoS values of the product are found to be safe, the product is appropriate with the normal and reasonably foreseeable use of the product under normal conditions according to the place of use, intended use and quantity.

The product safety assessment has been prepared by me and cannot be delegated to others.

PRODUCT INFORMATION FILE

It has been prepared according to Regulation (EC) no 1223/2009 of the European Parliament and of the Council of November 30, 2009 on cosmetic

2. Warnings and Instruction for Use on the Label

a) Product Label Information: MOJOMAYBIO-REVIVE ALL IN ONE SERUM

b) Usage of the Product: Apply to clean and dry face, especially to the areas where wrinkles are observed, twice a day, morning and evening.

c) Warnings on the Label of the Product: Only for external use. Avoid contact with eyes. In case of contact, rinse immediately with plenty of water. Keep out of reach of children. Keep out of direct sunlight. Keep at room temperature. It should not be used in case of hypersensitivity to any of the ingredients. Consult your doctor if any side effects occur.

3. Justification

The safety assessment report has been prepared with reference to the Cosmetic Law No. 5324, the Regulation Amending the Cosmetic Regulation and its Annexes, the Guideline on Safety Assessment of Cosmetic Products, the 11th Revision of the SCCS Guidance Notes and the European Cosmetic Product Directive 1223/2009.

In accordance with the REGULATION ON THE AMENDMENT OF THE COSMETICS REGULATION published in the Official Journal dated 15/07/2015 and numbered 29417, Article 12 of the Cosmetic Regulation published in the Official Journal dated 23/5/2005 and numbered 25823. The part referred to in clause (ç) and Annex 1/B, Part B of Article 12 of the Cosmetic Regulation published in the Official Journal dated 23/5/2005 and numbered 25823 is amended to 'cosmetic product safety assessment shall be carried out by a person who has a degree in pharmacy or in medicine, dentistry, biology, chemistry, biochemistry, microbiology, or toxicology with an equivalent degree or a certificate issued to those who have completed the theoretical and practical curriculum program offered in the field of cosmetic product safety assessment."

The attached information and documents, and the references at the end of the report were used in the evaluations. (Challenge test report, Product label information, IFRA Certificate of Conformity, Product SDS, Specification and certification of analysis, etc.)

4. Information on the Person Performing the Safety Assessment, and Approval of Part B

a) Name, Education and Address of the Preparer of the Safety Assessment Report:

Name, Surname : Nilay TEKER

Address : ACTO PHARMA HİJYEN SANAYİ TİCARET A.Ş.
Akçaburgaz Mahallesi 3038 Sokak No: 1
34522 Esenyurt-İSTANBUL/TÜRKİYE
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b) Diploma and Experience of the Preparer of the Safety Assessment Report:

Licence: Süleyman Demirel University, Department of Chemistry
Master of Science: Trakya University, Department of Chemistry-Organic Chemistry

c) Signature and Date of the preparer of the Safety Assessment report: 28.08.2024

PRODUCT INFORMATION FILE

It has been prepared according to Regulation (EC) no 1223/2009 of the European Parliament and of the Council of November 30, 2009 on cosmetic

REFERANCES

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https://echa.europa.eu/de/registration-dossier/-/registered-dossier/23613/6/1

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