Manufacturer	E.L Erman	Formulation nr:	
Commercial Name	TODDA-SCIENCE BEHIND BEAUTY-WRINKLE&BLEMISH CORRECTOR		
Safety assessment number	SA#2341	Date issued	12.12.2016

Cosmetic product safety report

(This safety assessment relates to the formulation & data supplied by the customer)

Safety assessor: Rok Devjak MD PhD

Signature:

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PART A – Cosmetic product safety information

1. Quantitative and qualitative composition of the cosmetic product

The chemical names shown below refer to the raw materials used to formulate this product. The identity of the raw materials is not necessarily based on the International Nomenclature of Cosmetic Ingredients (INCI) and does not represent the INCI listing that must be shown on the product label and is for assessment purposes only. An outline INCI label can be prepared on request.

Trade Name	INCI/Chemical Names present in the raw material	CAS No.	EINECS/ ELINCS	% weight breakdown (for ingredients that are mixtures or are actives in water)	Concentration (%) of raw material	Molecular Formula	Purity (test method)	Impurities OR Manufacturing and Purification Processes	Function
	AQUA	7732-18-5	231-791-2	100	93.1400				SOLVENT
ROSE HIPS KERNEL OIL	ROSA CANINA FRUIT OIL	84696-47-9 / 84603-93-0	283-652-0 / -	100	1.5000				EMOLLIENT, SKIN CONDITIONING
ARGAN OIL	ARGANIA SPINOSA KERNEL OIL	223747-87-3	-	100	1.0000				EMOLLIENT, SKIN CONDITIONING
SEPIMAX ZEN	POLYACRYLATE CROSSPOLYMER-6	-	-	100	1.0000				EMULSION STABILISING, VISCOSITY CONTROLLING

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glycerin usp 99.5%	GLYCERIN	56-81-5	200-289-5	100	0.3000				DENATURANT, HUMECTANT, PERFUMING, SOLVENT
SOLU-MAR ELASTIN	HYDROLYZED ELASTIN	91080-18-1	293-509-4	100	0.2000				ANTISTATIC, FILM FORMING, HAIR CONDITIONING, HUMECTANT, SKIN CONDITIONING
ZEOLITEA -4	ZEOLITE	1318-02-1	215-283-8/930-915-9/930-985-0/930-993-4	100	0.2000				ABSORBENT, ANTICAKING, BULKING, DEODORANT
FM K-90	PVP	9003-39-8	-	100	0.1500				ANTISTATIC, BINDING, EMULSION STABILISING, FILM FORMING, HAIR FIXING, VISCOSITY CONTROLLING
KRONOS 1171	TITANIUM DIOXIDE	13463-67-7	236-675-5	100	0.1500				OPACIFYING, UV ABSORBER,

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									UV FILTER
	AQUA	7732-18-5	231-791-2	76.87					SOLVENT
	GLYCERIN	56-81-5	200-289-5	15.00					DENATURANT, HUMECTANT, PERFUMING, SOLVENT
	HESPERIDIN METHYL CHALCONE	24292-52-2	246-128-2	5.00					ANTIOXIDANT
	STEARETH-20	9005-00-9 (Generic)	-	3.00	2.0000				CLEANSING, EMULSIFYING, SURFACTANT
	DIPEPTIDE-2	-	-	0.10					SKIN CONDITIONING
EYELISS	PALMITOYL TETRAPEPTIDE-7	-	-	0.03					SKIN CONDITIONING
MARI COLL NPNF (42-91TE)	HYDROLYZED COLLAGEN	92113-31-0 / 73049-73-7	295-635-5 / -	100	0.1000				ANTISTATIC, EMOLLIENT, FILM FORMING, HAIR CONDITIONING, HUMECTANT, SKIN

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									CONDITIONING
DOMINO RICE	parfum	-	-	100	0.0050				DEODORANT, MASKING, PERFUMING
HYALURONIC ACID	HYALURONIC ACID	9004-61-9	232-678-0	100	0.0008				ANTISTATIC, HUMECTANT, MOISTURISING, SKIN CONDITIONING
BONT-L Peptide Solution (PF)	AQUA	7732-18-5	231-791-2	99.5960	0.2500				SOLVENT
	PALMITOYL HEXAPEPTIDE-19	-	-	0.0040					SKIN CONDITIONING
	PHENOXYETHANOL	122-99-6	204-589-7	0.4000					PRESERVATIVE

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

Substance (INCI) / Mixture	**Chemical identification**	**Physical form**	**Molecular weight**	**Solubility (at RT)**	**Partition coefficient Log P_{ow} (at RT)**	**Purity (test method)**	**Average molecular weight and range (polymers)**	**Particle size distribution (nanomaterials)**	**Absorption spectra (UV absorbers)**	**Reference method**

Specifications of the finished product:	**Accepted result (range):**	**Reference method:**
Physical state	Gel	-
Type of mixture	-	-
Organoleptic properties (Odour, Colour)	Orange	-
pH (at RT)	11.80 +/- 0,5	-
Viscosity (at RT)	400 000 +/-10,000	-
Other	-	-

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Stability of the cosmetic product:

It is assumed that the responsible person has selected all pertinent criteria required to evaluate the stability of this cosmetic product during reasonable foreseeable conditions of storage. The stability report provided by the supplier and based upon the conclusions made therein, this cosmetic product appears to be stable under reasonably foreseeable storage conditions.

The preservative Challenge test results for this product have been supplied (the test was performed according to Eur. Phr.) and based upon the conclusions made therein appear to meet the industry requirements specified in the Notes of guidance for testing of cosmetic ingredients for their safety evaluation, Annex 8 - Guidelines on the Microbiological Quality of the Cosmetic Product, 1999 Edition.

The product's PAO assessment is based on the following sources of information: Challenge test results, Stability test, Analytical data, Type of packaging, experience with similar formulations and products, consumer habits and practices. Based on all the above, the conclusion is that the product's Period After Opening (PAO) is equal to 12 M.

3. Microbiological quality

Parameter	Method	Result
TVC	Eur. Ph. 2.6.12	100 / 1000 CFU/g or ml
Pathogens (*P. aeruginosa*, *S. aureus*, *C. albicans)*	Eur. Ph. 2.6.13	Absent

Other products

This product belongs to Category 2 according Guidelines on the Microbiological Quality (SCCNFP/0004/98): Other cosmetic products for which both a preservation challenge test and microbiological quality tests on the finished product are necessary. For this product type following maximum limits apply: TVC: 1000 cfu/g or ml in 0.1 g or ml of the product. *Pseudomonas aeruginosa*, *Staphylococcus aureus* and *Candida albicans* must not be detectable in 0.1 g or ml of the cosmetic product The producer provided relevant analysis certificate proving the products microbiological quality.

4. Impurities, traces, information about the packaging material

As far as the analysis of impurities and the packaging material is concerned, data from suppliers should be preferred (11/SANCO/COS/56).

The product is a cream with basic pH 11.8. 30%LLDPE+70%HD tube which is suitable for cosmetic products and the barrier properties of the packaging are adequate.

(Accelerated) stability test was carried out for 3 months at 42°C temperature so it can be concluded that the product is stable for 36 months at room temperature (and even at short increase or decrease of that temperature).
Stability data available at the time of review proved that there was no interactions and no deterioration of the product occured.
It is assumed that the responsible person has identified the most applicable testing required to determine the packaging stability and its interaction with the cosmetic product contained within it. Taking into consideration the information supplied to the assessor, there appears to be no immediate health concern due to the characteristics of packaging materials in direct contact with the final product.

Primary & secondary packaging specification: 20 ml 30%LLDPE+70%HD tube in Paper Box

5. Normal and reasonably foreseeable use

Specific warnings and instructions of use are written on the packaging as follows:

- DIRECTIONS: "Prior to application, thoroughly cleanse your skin. Gently tap a small amount of the product with your ring finger over cleansed, dry skin. Application should be performed directly to the wrinkles or blemishes you wish to smooth. Allow the actives to work for 4-8 minutes, during the wait keep your face expressionless.

- CAUTION: Do not rinse off. It is recommended to avoid the use of any liquid skin care in order to keep best results. Avoid any contact with the eyes. Do not rub and do not massage the cream.

This instruction of use indicates the explicit use of the finished product as aa around the eyes cream. The following phrase also indicates that the product should be used on previously mentioned area: »Wrinkle & blemish corrector«.

A reasonably foreseeable mistaken use (not a misuse) is not recognisable

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6. Exposure to the cosmetic product

Product Class:	Leave-on
IFRA Product type:	Facial Creams
IFRA Category:	5
Targeted Population:	Adults
Estimated daily amount applied (g):	0.1363 *
Skin Surface Area of Application (cm^2):	50 *
Calculated daily exposure (g/day):	0.2726 *
Relative Daily Exposure (mg/kg/day):	4.5 *
Amount Per Unit Area of Skin per day ($mg/cm^2/day$):	5.45 *
Retention factor:	1
Exposure Time Neat:	12h
Exposure Time Dilute:	Not applicable
Exposure time Solvent Inhalation:	Not applicable
Exposure time Aerosol Inhalation:	Not applicable
Frequency of application:	2 *
Physical form:	Cream
Part of body exposed to undiluted	Eye Contour
Dilution factor	Not applicable
Part of body exposed to diluted product	Not applicable

7. Exposure to the substances

Skin contact is the main route of the exposure for this type of product. Unintended eye and oral exposure is possible but as the amounts are expected to be minimum therefore no significant risk to health is expected via these routes of exposure.

The formulation has a relatively low potential of irritation and sensitation. The manufacturer provided relevant IFRA certification. Allergen analysis proofed that known allergens are not present at concentration > 0.001%.

This product, which is formulated with ingredients that are widely used with demonstrable safety in human, is unlikely to cause any significant adverse effects. Where it applied, all the ingredients in the product appear within the concentration limits restricted in the EU and they should meet the purity specifications set by the directive. This has been checked where the purity specification has been supplied during assessment. The formulation does not contain impurities that are CMR or residual solvents at a level that would constitute a risk for the consumer. Taking into account the existence similar cosmetic marketed formulations, how this product is intended to be used, the toxicological profiles of the individual ingredients and the well reported history of safe use in cosmetic products, if used as directed, this product is not expected to pose a risk to the health of the majority of consumers.

The use application suggests that the risk of irritation and skin sensitization would be low in the majority, but a few individuals might find it intolerable. This product does not contain allergens that must be declared on the product label: however, these are at concentrations unlikely to elicit an allergic response or induce skin sensitization in the majority of the general population. However, the possibility cannot be discounted that a small number of users may experience an allergic reaction or other idiosyncratic reaction to an ingredient in the formulation if they have been previously sensitized to the ingredient.

Effects of the product as supplied on the skin:
The formulation as supplied may cause skin irritation especially if exposure is prolonged and/or repeated. However, under normal conditions of use exposure time will be short and the likelihood of causing skin irritation will be very low.
There are low concentrations of substances present in this product, which have allergenic activity. The concentrations present are sufficiently low for the level of use to ensure that people do not become sensitised. However, people who are already sensitised to a substance may react adversely to any product containing that substance even when present at extremely low concentrations.
Exposure to this product is unlikely to result in phototoxic effects.
It is unlikely to cause damage to internal organs following absorption through the skin.

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Effects of the product as supplied on the eye

Accidental exposure of the eye to the product would likely result in eye irritation.

Effects following ingestion of the product as supplied

The formulation as supplied if swallowed is likely to cause irritation to the mouth and upper digestive tract.

Effects of inhaling the product

Inhalation is an unlikely route of exposure.

INCI	% in the final product	NOAEL	SED	MoS
AQUA	94.9264		2.15	>100
ROSA CANINA FRUIT OIL	1.5000	*	0.03	No NOAEL available
ARGANIA SPINOSA KERNEL OIL	1.0000	*	0.02	No NOAEL available
POLYACRYLATE CROSSPOLYMER-6	1.0000	*	0.02	No NOAEL available
GLYCERIN	0.6000	*	0.01	No NOAEL available
HYDROLYZED ELASTIN	0.2000		0.00	>100
ZEOLITE	0.2000		0.00	>100
PVP	0.1500		0.00	>100
TITANIUM DIOXIDE	0.1500		0.00	>100
HESPERIDIN METHYL CHALCONE	0.1000		0.00	>100
HYDROLYZED COLLAGEN	0.1000		0.00	>100
STEARETH-20	0.0600		0.00	>100
Parfum	0.0050		0.00	>100
DIPEPTIDE-2	0.0020		0.00	>100
PHENOXYETHANOL	0.0010		0.00	>100
HYALURONIC ACID	0.0008		0.00	>100
PALMITOYL TETRAPEPTIDE-7	0.0006		0.00	>100
PALMITOYL HEXAPEPTIDE-19	0.0000		0.00	>100

The calculation of the SED was performed as follows:

SED = A (mg/kg bw/day) x C(%)/100 x DA(%)/100

MoS = NOAEL/SED,

Where

$NOAEL_{sys}$ was used in the calculation, as no oral bioavailability data is available ($NOAEL_{sys}$= 50% NOAEL; SCCS/1564/15)

100% dermal absorption (DA) is included in the calculation as a worse case scenario.

Estimated daily exposure to a cosmetic product per kg body weight A= 4.5 mg/kg bw/day

Default body weight: 61 kg

8. Toxicological profile of substances

INCI Name	AQUA
Cosmetic restriction (Cosing)	None
General description	Simply water unlikely to cause irritation, allergy or harm. Used in many cosmetic products as a solvent and necessary to sustain biological life. The source of water should be known, monitored to GMP and either a deionised or high purity grade free from toxins, pollutants and bacteriological contamination should be used in cosmetic products.
Acute toxicity via relevant routes of exposure	Not toxic. The actual or estimated LD50 value: 100000 mg/kg. Oral Rat LD50: >90 mL/kg.
Irritation and corrosivity	Not irritating
Skin irritation and skin corrosivity	Not irritating
Mucous membrane irritation (eye irritation)	Not irritating

Skin sensitisation	Not sensitizing
Dermal/ percutaneous absorption	Non-permeator by skin
Repeated dose toxicity (normally 28- or 90-day studies)	Not available
Mutagenicity/ genotoxicity	Not available
Carcinogenicity	Not available
Reproduction toxicity	Not available
Toxicokinetics (ADME studies)	Not available
Photo-induced toxicity	Not available
Relevant endpoints assessment (particle size, impurities)	Not available
Reference toxicology	(1) Dweck A. C. Handbook of Cosmetics Ingredients - their use, safety and toxicology. Third edition, 2012.

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SCCS	0

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INCI Name	ARGANIA SPINOSA KERNEL OIL
Cosmetic restriction (Cosing)	None
General description	The safety of Plant-Derived Fatty Acid Oils including Argania Spinosa Kernel Oil have been assessed by the CIR Expert Panel. CIR Expert Panel concluded that Argania Spinosa Kernel Oil is safe in the present practices of use and concentrations 0.001-10%. There are no reported adverse effects or expected adverse effects from the topical application of this oil.
Acute toxicity via relevant routes of exposure	The actual or estimated LD50 value: 5000 mg/kg
Irritation and corrosivity	Not available
Skin irritation and skin corrosivity	5% Argania Spinosa Kernel Oil in a face serum was not an irritant (HRIPT)
Mucous membrane irritation (eye irritation)	Not available
Skin sensitisation	5% Argania Spinosa Kernel Oil in a face serum and 10% Argania Spinosa Kernel Oil in a skin salve were not sensitizers (HRIPT)
Dermal/ percutaneous absorption	Not available

Repeated dose toxicity (normally 28- or 90-day studies)	Not available
Mutagenicity/ genotoxicity	Not available
Carcinogenicity	Not available
Reproduction toxicity	Not available
Toxicokinetics (ADME studies)	Not available
Photo-induced toxicity	Not available
Relevant endpoints assessment (particle size, impurities)	Not available
Reference toxicology	(1) CIR Expert Panel. Plant-Derived Fatty Acid Oils as Used in Cosmetics, Final Report. March 4, 2011. (2) Dweck A. C. Handbook of Cosmetics Ingredients - Their Use, Safety and Toxicology. Third edition, 2012.
SCCS	0

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INCI Name	POLYACRYLATE CROSSPOLYMER-6
Cosmetic restriction (Cosing)	None
General description	Polyacrylate Crosspolymer-6 is a copolymer of ammonium acryloyldimethyltaurate, dimethylacrylamide, lauryl methacrylate and laureth-4 methacrylate, crosslinked with trimethylolpropane triacrylate. The following data are for the material Sepimax Zen (containing the polyacrylate crosspolymer-6 at >90% concentration). Ingredient is assumed to be of low hazard.
Acute toxicity via relevant routes of exposure	Not available
Irritation and corrosivity	Not available
Skin irritation and skin corrosivity	Not irritating (>90%, rabbit); not irritating (5%, human)
Mucous membrane irritation (eye irritation)	Slightly irritating (rabbit)
Skin sensitisation	Not sensitizing (human)
Dermal/ percutaneous absorption	Not available

Repeated dose toxicity (normally 28- or 90-day studies)	Not available
Mutagenicity/ genotoxicity	Negative in bacterial reverse mutation tests.
Carcinogenicity	Not available
Reproduction toxicity	Not available
Toxicokinetics (ADME studies)	Not available
Photo-induced toxicity	Not available
Relevant endpoints assessment (particle size, impurities)	Not available
Reference toxicology	(1) NICNAS. POLYMER OF LOW CONCERN FULL PUBLIC REPORT, Polyacrylate Crosspolymer-6 (Sepimax Zen). File No PLC/977. May 2011. Accessed August 2015 at NICNAS webpage at https://www.google.si/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&cad=rja&uact=8&ved=0CB8QFjAAahUKEwiN6sb4t6XHAhULiRoKHbJfAhU&url=http%3A%2F%2Fwww.nicnas.gov.au%2F__data%2Fassets%2Fword_doc%2F0010%2F7210%2FPLC977-FR.docx&ei=8DnMVY2yDYuSarK_iagB&usg=AFQjCNFTMO9kwCJC7rPROfjHCl7yk_X3wg&bvm=bv.99804247,d.d2s
SCCS	0

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INCI Name	GLYCERIN
Cosmetic restriction (Cosing)	None
General description	Glycerol is widely distributed in food as a natural constituent, and it has undergone review and approval for use as both a direct and indirect food additive and is GRAS by US FDA. Animal studies involving single or repeated exposure by various routes indicated a low order of toxicity, the possible target sites (particularly following repeated oral administration) being the kidney and gastrointestinal tract. Glycerol appears to be of generally low oral toxicity in humans.
Acute toxicity via relevant routes of exposure	The reported oral LD50 of glycerin ranged from 2530-58400 mg/kg in rats, 4090-38000 mg/kg in mice, 27000 mg/kg in rabbits, and 77500 mg/kg in guinea pigs. The dermal LD50 of glycerin in rats was reported to be > 21900 mg/kg and >18700 mg/kg in rabbits. The approximate Lt50 for rats was determined to be 423 min for exposure to glycerin vapors at 11.0 mg/L. The intraperitoneal LD50 of glycerin in rats ranged from 4420-10100 mg/kg and 8600-9500 mg/kg in mice. The subcutaneous LD50 of glycerin was 100 mg/kg in rats and ranged from 91-10000 mg/kg in mice. The intravenous LD50 of glycerin ranged from 5200-6600 mg/kg in rats, 4250-6700 mg/kg in mice, and 53000 mg/kg in rabbits.
Irritation and corrosivity	Not considered as an irritant.
Skin irritation and skin corrosivity	Not dermally irritating to rabbits when applied at concentrations up to 100% to up to 30% of the body surface. Mild dermal irritant at 100% in guinea pigs.
Mucous membrane irritation (eye irritation)	Undiluted glycerin was not irritating when administered to the eyes of human subjects. There was a strong burning and stinging sensation, with tear production but no injury was observed.
Skin sensitisation	A moisturizer containing 65.9% glycerin was not sensitizing to human subjects. Natural and synthetic glycerin were not sensitising to white male guinea pigs at 0.1%.
Dermal/ percutaneous absorption	No data

Repeated dose toxicity (normally 28- or 90-day studies)	There were no signs of toxicity or effects on blood or on urine production when human subjects were orally administered approximately 1300-2200 g/kg/d glycerin for 50 days. The NOAEL was ≥2200 mg/kg/d. There were no treatment effects when 100% glycerin was topically applied daily to 30% of the body surfaces of rabbits for 45 weeks. The inhalation LOAEL was 1000 mg/m3 for glycerin administered 6 h/d, 5 d/week for 2 weeks in rats. The inhalation NOAEL was 0.167 mg/L for glycerin administered for 5 h/d, 5 d/week for 13 weeks in rats.
Mutagenicity/ genotoxicity	Glycerin was not genotoxic in multiple Ames tests using multiple strains of S. typhimurium at concentrations up to 50 mg/plate. It was not genotoxic in a cytogenetic assay, X-linked HGPRT, sister chromatid exchange assay, unscheduled DNA synthesis assay, and chromosome aberration test at concentrations up to 1.0 mg/mL.
Carcinogenicity	Glycerin administered in the feed of rats at doses up to 20% in feed for 1 year or up to 10 g/kg for 2 years did not increase the incidence of tumors. Orally administered glycerin, in concentrations up to 5%, had a potentiating effect on the carcinogenicity of 4NQO in mice.
Reproduction toxicity	No convincing evidence of reproductive effects have been seen in rats treated orally or dermally, or in mice fed glycerol during pregnancy. Glycerin is transferred across the plancenta in small amounts. May cause some adverse reproductive effects based on animal data, but there was no evidence of teratogenicity. No effects on fertility and reproductive performance were observed in a two generation study with glycerol administered by gavage (NOAEL 2000 mg/kg bw/day).
Toxicokinetics (ADME studies)	Glycerin is rapidly absorbed in the intestine and the stomach, distributed throughout the extracellular fluids through much of the body. It is mostly metabolized by the liver and kidneys with the remainder excreted in urine. Free glycerin is naturally present in humans, primarily in plasma.
Photo-induced toxicity	No data
Relevant endpoints assessment (particle size, impurities)	The weight of evidence indicates that glycerol is of low toxicity when ingested, inhaled or in contact with the skin.

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Reference toxicology	(1) CIR Expert Panel. Safety assessment of glycerin as used in cosmetics - final report (January 14,2015). (2) ECHA. Retrieved from http://echa.europa.eu/information-on-chemicals/registered-substances
SCCS	NOAEL reliability - 1

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INCI Name	HYDROLYZED ELASTIN
Cosmetic restriction (Cosing)	None
General description	Elastin is a protein found in the skin and tissue of the body. No adverse effects are reported or experienced with the application of this material.
Acute toxicity via relevant routes of exposure	The actual or estimated LD50 value: 2000 mg/kg
Irritation and corrosivity	Not available
Skin irritation and skin corrosivity	Not irritating (undiluted, rabbit)
Mucous membrane irritation (eye irritation)	Not irritating (undiluted, rabbit)
Skin sensitisation	Not sensitizing (25% in corn oil, HRIPT)
Dermal/ percutaneous absorption	Not available

Repeated dose toxicity (normally 28- or 90-day studies)	Not available
Mutagenicity/ genotoxicity	Not available
Carcinogenicity	Not available
Reproduction toxicity	Not available
Toxicokinetics (ADME studies)	Not available
Photo-induced toxicity	Not available
Relevant endpoints assessment (particle size, impurities)	Not available
Reference toxicology	(1) Dweck A. C. Handbook of Cosmetics Ingredients - Their Use, Safety and Toxicology. Third edition, 2012. (2) CIR Expert Panel. Draft Report for CIR Expert Panel Review. Safety Assessment of Hydrolyzed Proteins as Used in Cosmetics. November, 2012. Retrieved from http://www.cir-safety.org/sites/default/files/hp.pdf
SCCS	0

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INCI Name	ZEOLITE
Cosmetic restriction (Cosing)	None
General description	The safety of Zeolite has been assessed by the CIR Expert Panel. The CIR Expert Panel evaluated the scientific data and concluded that this ingredient is safe for use in cosmetics and personal care products.
Acute toxicity via relevant routes of exposure	The acute oral and dermal toxicity is considered as very low; Oral LD50 > 5000 mg/kg
Irritation and corrosivity	Not available
Skin irritation and skin corrosivity	Not irritating (animal studies)
Mucous membrane irritation (eye irritation)	Slightly irritating to non-irritating to eyes (animal studies). The powder of the substance may cause reactions due to mechanical friction.
Skin sensitisation	Not sensitizing (guinea pig studies, human patch test)
Dermal/ percutaneous absorption	It is questionable, whether sodium aluminium silicate as almost insoluble compound, is absorbed. If skin absorption occurs, it should be very low.

Repeated dose toxicity (normally 28- or 90-day studies)	Substance did not cause any gross signs of adverse systemic effects after oral ingestion. The only adverse effects related to the test compound was observed with regard to the kidney and urinary bladder. These effects have been consistently reported in the repeated dose toxicity studies. A chronic 2-year oral toxicity study in rats did not show any toxic effects at the highest dose, 60 mg/kg/day, which is the lowest NOAEL determined after oral administration.
Mutagenicity/ genotoxicity	No indication of genetic toxicity in in vitro and in vivo test systems.
Carcinogenicity	Not available
Reproduction toxicity	No indication of toxicity to reproductive organs have been observed in long term studies and no structure activity relationship is known that indicates a concern. Not teratogenic in experimental animals. The NOAEL in the studies performed was 1600 mg/kg for maternal toxicity and for teratogenicity.
Toxicokinetics (ADME studies)	Not available
Photo-induced toxicity	Not available
Relevant endpoints assessment (particle size, impurities)	Not available
Reference toxicology	(1) HERA. Human and Environmental Risk Assessment on ingredients of household cleaning products - Zeolite A (1344-00-9, 1318-02-1). Version 3.0, January 2004. Accessed May 2015 at http://www.mma.gov.br/port/conama/processos/D10B4F0E/08HERA-ineos.pdf
SCCS	0

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Safety assessment number	SA#2341	Date issued	12.12.2016

INCI Name	TITANIUM DIOXIDE
Cosmetic restriction (Cosing)	IV/143 VI/27
General description	The SCCNFP is of the opinion that titanium dioxide is safe for use in cosmetic products at a maximum concentration 25% in order to protect the skin from certain harmful effects of UV radiation. The toxicological profile of this material does not give rise to concern in human use, since the substance is not absorbed through the skin; in view, also, of the lack of percutaneous absorption, a calculation of the margin of safety has not been carried out by SCCNFP. This ingredient is used also as a white pigment for application in foodstuffs (E 171) and pharmaceuticals.
Acute toxicity via relevant routes of exposure	Oral LD50 (rat) > 2000 mg/kg; Dermal LD50 (rat) > 2000 mg/kg
Irritation and corrosivity	Not available
Skin irritation and skin corrosivity	Irritation of the skin is low or absent, both in animals and humans subjects.
Mucous membrane irritation (eye irritation)	Irritation of mucous membranes is low or absent.
Skin sensitisation	No evidence of sensitization in animals and humans
Dermal/ percutaneous absorption	Results of in vitro studies show that absorption does not occur.

Repeated dose toxicity (normally 28- or 90-day studies)	Not available
Mutagenicity/ genotoxicity	Numerous tests for mutagenicity and clastogenicity have been carried out, and consistently show negative results.
Carcinogenicity	Long term feeding studies in rat and mouse with uncoated pigmentary material showed no evidence of carcinogenesis. The NOAEL found in various carcinogenicity experiments was calculated to be about 375 and 750 mg/kg/day in rats and mice respectively.
Reproduction toxicity	An in vitro test produced negative results.
Toxicokinetics (ADME studies)	Not available
Photo-induced toxicity	Titanium dioxide did not show photo-toxic activity in studies in vivo or in vitro, and no photo-sensitisation or photo-irritation was observed.
Relevant endpoints assessment (particle size, impurities)	Inhalation studies in rats, and epidemiological evidence in man, using uncoated finely divided material, suggest that it causes an increase in the incidence of lung tumours. This, however, probably reflects the actions of irritating dusts generally.
Reference toxicology	(1) SCCNFP opinion concerning titanium dioxide. SCCNFP/0005/98. 24 October 2000. (2) SCCS Revision of the opinion on Titanium Dioxide, nano form. SCCS/1516/13. 22 July 2013
SCCS	0

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Commercial Name	TODDA-SCIENCE BEHIND BEAUTY-WRINKLE&BLEMISH CORRECTOR		
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INCI Name	HESPERIDIN METHYL CHALCONE
Cosmetic restriction (Cosing)	None
General description	Hesperidin methyl is methylated derivative of the flavonoid hesperidin. Commercial hesperidin methyl (chalcone) is obtained by chemical synthesis from Hesperidin (extracted from immature citrus fruit). Except for acute toxicity estimate, no known or reported relevant toxicological information available for this ingredient.
Acute toxicity via relevant routes of exposure	The actual or estimated LD50 value: 5000 mg/kg
Irritation and corrosivity	Not available
Skin irritation and skin corrosivity	Not available
Mucous membrane irritation (eye irritation)	Not available
Skin sensitisation	Not available
Dermal/ percutaneous absorption	Not available

Repeated dose toxicity (normally 28- or 90-day studies)	Not available
Mutagenicity/ genotoxicity	Not available
Carcinogenicity	Not available
Reproduction toxicity	Not available
Toxicokinetics (ADME studies)	Not available
Photo-induced toxicity	Not available
Relevant endpoints assessment (particle size, impurities)	Not available
Reference toxicology	(1) Dweck A. C. Handbook of Cosmetics Ingredients - Their Use, Safety and Toxicology. Third edition, 2012.
SCCS	0

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Commercial Name	TODDA-SCIENCE BEHIND BEAUTY-WRINKLE&BLEMISH CORRECTOR		
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INCI Name	HYDROLYZED COLLAGEN
Cosmetic restriction (Cosing)	None
General description	Substance obtained by acidic, alkaline, or enzymatic hydrolysis of hoofs and horns composed primarily of amino acids, peptides, and proteins. It may contain impurities consisting chiefly of carbohydrates and lipids along with smaller quantities of miscellaneous organic substances of biological origin. The safety of hydrolyzed collagen has been assessed by the CIR Expert Panel. The CIR Expert Panel evaluated the scientific data and concluded that this ingredient is safe as used in cosmetics at concentrations up to 6%.
Acute toxicity via relevant routes of exposure	Practically nontoxic when administered orally or dermally in acute animal toxicity studies. The actual or estimated LD50 value: 5000 mg/kg
Irritation and corrosivity	Not available
Skin irritation and skin corrosivity	Non to minimally irritating (undiluted, rabbit). Not irritating in clinical studies.
Mucous membrane irritation (eye irritation)	Minimally irritating (undiluted, rabbit)
Skin sensitisation	Not sensitizing (guinea pig). Not sensitizing in clinical studies.
Dermal/ percutaneous absorption	Not available

Repeated dose toxicity (normally 28- or 90-day studies)	Subchronic dermal studies on 2 cosmetic formulations containing 2% hydrolyzed collagen were negative for systemic toxicity.
Mutagenicity/ genotoxicity	Not available
Carcinogenicity	Not available
Reproduction toxicity	Not available
Toxicokinetics (ADME studies)	Not available
Photo-induced toxicity	No indication of phototoxicity based on clinical studies.
Relevant endpoints assessment (particle size, impurities)	Not available
Reference toxicology	(1) CIR Expert Panel. Final Report on the Safety Assessment of Hydrolyzed Collagen. JACT 4(5)199- 221, 1985 confirmed 06/04 IJT 25(S2), 2006. (2) Dweck A. C. Handbook of Cosmetics Ingredients - Their Use, Safety and Toxicology. Third edition, 2012.
SCCS	0

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Commercial Name	TODDA-SCIENCE BEHIND BEAUTY-WRINKLE&BLEMISH CORRECTOR		
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INCI Name	DIPEPTIDE-2
Cosmetic restriction (Cosing)	None
General description	Dipeptide-2 is the dipeptide composed of valine and tryptophan. Except for acute toxicity estimate, no known or reported relevant toxicological information available for this ingredient.
Acute toxicity via relevant routes of exposure	The actual or estimated LD50 value: 2000 mg/kg
Irritation and corrosivity	Not available
Skin irritation and skin corrosivity	Not available
Mucous membrane irritation (eye irritation)	Not available
Skin sensitisation	Not available
Dermal/ percutaneous absorption	Not available

Repeated dose toxicity (normally 28- or 90-day studies)	Not available
Mutagenicity/ genotoxicity	Not available
Carcinogenicity	Not available
Reproduction toxicity	Not available
Toxicokinetics (ADME studies)	Not available
Photo-induced toxicity	Not available
Relevant endpoints assessment (particle size, impurities)	Not available
Reference toxicology	(1) Dweck A. C. Handbook of Cosmetics Ingredients - Their Use, Safety and Toxicology. Third edition, 2012.
SCCS	0

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INCI Name	HYALURONIC ACID
Cosmetic restriction (Cosing)	None
General description	The safety of hyaluronic acid has been assessed by the CIR Expert Panel. The CIR Expert Panel evaluated the scientific data and concluded that this ingredient is safe as used in cosmetics at concentrations up to 1%. Acute, short-term, and chronic toxicological studies indicated low toxicity. There were no reported reactions to topically applied hyaluronic acid, further supporting that hyaluronic acid at levels currently used in cosmetics applied to the skin should not be of concern.
Acute toxicity via relevant routes of exposure	Hyaluronic acid was not toxic in a wide range of acute animal toxicity studies, over several species and with different exposure routes. Oral LD50 (rat) > 800 mg/kg; Oral LD50 (mouse) > 2400 mg/kg
Irritation and corrosivity	Not available
Skin irritation and skin corrosivity	Not available
Mucous membrane irritation (eye irritation)	Not available
Skin sensitisation	Not sensitizing (animal)
Dermal/ percutaneous absorption	In mice and humans, hyaluronic acid penetrated to the dermis.

Repeated dose toxicity (normally 28- or 90-day studies)	Not available
Mutagenicity/ genotoxicity	Not genotoxic in reverse mutagenicity tests on S. typhimurium and E. coli, or in vivo micronucleus test using mice, or in vitro and in vivo chromosomal aberration tests.
Carcinogenicity	Not available
Reproduction toxicity	Not a reproductive or developmental toxicant.
Toxicokinetics (ADME studies)	Not available
Photo-induced toxicity	Not available
Relevant endpoints assessment (particle size, impurities)	Widespread clinical use of hyaluronic acid, primarily by injection, has been free of significant adverse reactions. Sources of hyaluronic acid are bacterial fermentation and rooster combs. Impurities include proteins, DNA, and chondroitin sulfate when derived from animal sources. Bacterial sources of hyaluronic acid should be free of pyrogens.
Reference toxicology	(1) CIR Expert Panel. Final Report of the Safety Assessment of Hyaluronic Acid, Potassium Hyaluronate, and Sodium Hyaluronate. IJT 28(Suppl. 1):5-67, 2009. (2) Dweck A. C. Handbook of Cosmetics Ingredients - Their Use, Safety and Toxicology. Third edition, 2012.
SCCS	0

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INCI Name	PALMITOYL TETRAPEPTIDE-7
Cosmetic restriction (Cosing)	None
General description	Palmitoyl Tetrapeptide-7 is the reaction product of palmitic acid and tetrapeptide-7, wherein tetrapeptide-7 is the synthetic peptide consisting of amino acids gly-gln-pro-arg. The safety of Palmitoyl Tetrapeptide-7 has been assessed by the CIR Expert Panel. The CIR Expert Panel evaluated the scientific data and concluded that this ingredient is safe as used in cosmetics. The low use concentrations (< 0.002%) and negative safety test data reviewed obviate any concerns relating to the safety of this ingredient in cosmetic products.
Acute toxicity via relevant routes of exposure	The actual or estimated LD50 value: 2000 mg/kg
Irritation and corrosivity	Not available
Skin irritation and skin corrosivity	Not irritating (500 ppm, human)
Mucous membrane irritation (eye irritation)	Slightly irritating (500 ppm, non-human)
Skin sensitisation	Not sensitizing (500 ppm, human)
Dermal/ percutaneous absorption	Not available

Repeated dose toxicity (normally 28- or 90-day studies)	Not available
Mutagenicity/ genotoxicity	Not genotoxic in Ames test.
Carcinogenicity	Not available
Reproduction toxicity	Not available
Toxicokinetics (ADME studies)	Not available
Photo-induced toxicity	Not available
Relevant endpoints assessment (particle size, impurities)	Not available
Reference toxicology	(1) CIR Expert Panel. Safety Assessment of Tripeptide-1, Hexapeptide-12, their Metal Salts and Fatty Acyl Derivatives, and Palmitoyl Tetrapeptide-7 as Used in Cosmetics, Final Report. June 30, 2014. (2) Dweck A. C. Handbook of Cosmetics Ingredients - Their Use, Safety and Toxicology. Third edition, 2012.
SCCS	0
INCI Name	PHENOXYETHANOL
Cosmetic restriction	V/29

(Cosing)	
General description	European Cosmetics Regulation Annex V (Line 29) lists phenoxyethanol as an approved preservative in the EU at concentrations up to 1%. In terms of Regulation (EC) No 1272/2008 (CLP) the following hazard classes are assigned to this ingredient (EU harmonized classification): Acute Tox. 4, Eye Irrit. 2.
Acute toxicity via relevant routes of exposure	Oral LD50 (rat): 1386 - 4013 mg/kg; Dermal LD50 (rat): 14300 mg/kg
Irritation and corrosivity	Not available
Skin irritation and skin corrosivity	Not skin irritating (humans); slightly irritating (animals)
Mucous membrane irritation (eye irritation)	Irritating (rabbit)
Skin sensitisation	Not sensitizing (human, animal)
Dermal/ percutaneous absorption	Rapidly absorbed through the rat skin.
Repeated dose toxicity (normally 28- or 90-day studies)	The critical impact of phenoxyethanol is assessed to be kidney toxicity if swallowed. A 90 days repeated test with oral exposure of rats with the doses 80, 400 and 2000 mg/kg/day showed no impacts at 80 mg/kg/day (NOAEL value). At 400 mg/kg/day kidney toxicity and changes ingrooming behavior were seen. At a dose of 2000 mg/kg/day toxicity towards red blood corpuscles was seen.
Mutagenicity/ genotoxicity	Nonmutagenic in the Ames test and in the mouse micronucleus test.
Carcinogenicity	Not expected to be carcinogenic.
Reproduction toxicity	Phenoxyethanol has shown damaging impacts on reproduction and developmental toxicity in animal tests with mice. In several reproduction studies with mice the impacts were decreasing body weight on the mice and their progeny as well as increased liver weight at high doses of between 1875 and 4000 mg/kg/day.
Toxicokinetics (ADME studies)	Tests with rats show that more than 75% and up to 99% of the phenoxyethanol after either oral or dermal exposure can be found unchanged in the urine together with small quantities of two substances to which the phenoxyethanol has metabolized. One of the metabolism products is phenoxyacetic acid.

Photo-induced toxicity	In clinical studies phenoxyethanol was nonphototoxic.
Relevant endpoints assessment (particle size, impurities)	Not available
Reference toxicology	(1) Danish Ministry of Environment, EPA. A survey and health assessment of cosmetic products for children. Survey of Chemical Substances in Consumer Products,No. 88 2007. (2) CIR Expert Panel. Final Report on the Safety Assessment of Phenoxyethanol. JACT 9(2):259-277, 1990.
SCCS	0

INCI Name	STEARETH-20
Cosmetic restriction (Cosing)	None
General description	Steareth-20 is a synthetic polymer composed of PEG (polyethylene glycol) and stearyl alcohol. The FDA permits fatty alcohols (including stearic alcohol) reacted with polyethylene glycol to be used as indirect food additives as components of textiles and textile fibers. The safety of Steareth-2, Steareth-4, Steareth-6, Steareth-7, Steareth-10, Steareth-11, Steareth-13, Steareth-15 and Steareth-20 has been assessed by the Cosmetic Ingredient Review (CIR) Expert Panel. The CIR Expert Panel evaluated the scientific data and concluded that these ingredients were safe as cosmetic ingredients in the present practices of use and concentration.
Acute toxicity via relevant routes of exposure	The actual or estimated LD50 value: 5,000 mg/kg body weight. Oral LD50 value (rat): 5,000 mg/kg. In subchronic testing, Steareth-20 was nontoxic when administered dermally at concentrations of 4%.

Irritation and corrosivity	Not primary irritant (human skin)
Skin irritation and skin corrosivity	Not primary irritant (human skin)
Mucous membrane irritation (eye irritation)	Not available
Skin sensitisation	Not sensitizing (human skin)
Dermal/ percutaneous absorption	Not available
Repeated dose toxicity (normally 28- or 90-day studies)	Not available
Mutagenicity/ genotoxicity	Not available
Carcinogenicity	Not available
Reproduction toxicity	Not available
Toxicokinetics (ADME studies)	Not available
Photo-induced toxicity	Not phototoxic
Relevant endpoints assessment (particle size, impurities)	CIR: Maximum "as used" concentration for safe as used conclusion: up to 15%. Small amounts of 1,4-dioxane, a by-product of ethoxylation, may be found in the Steareth ingredients. The potential presence of this material is well known and can be controlled through purification steps to remove it from the ingredients before blending into cosmetic formulations.

Reference toxicology	(1) Handbook of Cosmetic Ingredients, Their use, safety and toxicology; Anthony C. Dweck; 3rd Edition 2012 (2) CosmeticsInfo
SCCS	0

INCI Name	PALMITOYL HEXAPEPTIDE-19
Cosmetic restriction (Cosing)	None
General description	Palmitoyl Hexapeptide-19 is the reaction product of palmitic acid and Hexapeptide-19. It has been shown to be non-cytotoxic, non- mutagenic, non-irritating and non-sensitizing.
Acute toxicity via relevant routes of exposure	The actual or estimated LD50 value: 2000 mg/kg
Irritation and corrosivity	Not available
Skin irritation and skin corrosivity	Not available

Mucous membrane irritation (eye irritation)	Not available
Skin sensitisation	Not available
Dermal/ percutaneous absorption	Not available
Repeated dose toxicity (normally 28- or 90-day studies)	Not available
Mutagenicity/ genotoxicity	Not available
Carcinogenicity	Not available
Reproduction toxicity	Not available
Toxicokinetics (ADME studies)	Not available
Photo-induced toxicity	Not available
Relevant endpoints assessment (particle size, impurities)	Not available
Reference toxicology	(1) Dweck A. C. Handbook of Cosmetics Ingredients - Their Use, Safety and Toxicology. Third edition, 2012.
SCCS	0

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INCI Name	PVP
Cosmetic restriction (Cosing)	None
General description	Not available
Acute toxicity via relevant routes of exposure	It was of low acute toxicity when administered by the intravenous route in humans or by the oral and intravenous routes in various species of laboratory animals. In man, injections have resulted in PVP deposits in various tissues (particularly in the reticulo- endothelial system) and structural changes in some instances. The actual or estimated LD50 value: 2,000 mg/kg body weight. Oral LD50 value (rat): 2,000 mg/kg.
Irritation and corrosivity	Non-irritant
Skin irritation and skin corrosivity	Not irritating
Mucous membrane irritation (eye irritation)	Not irritating (rabbit eye)
Skin sensitisation	Not available
Dermal/ percutaneous absorption	Not available

Repeated dose toxicity (normally 28- or 90-day studies)	Repeated oral administration in rabbits, dogs and rats has been associated with deposits and effects in a number of tissues including the liver and lymph nodes.
Mutagenicity/ genotoxicity	No genotoxic activity was seen in a range of screening assays including the Ames bacterial test and rodent injection studies.
Carcinogenicity	There was no evidence of carcinogenicity in limited studies in rats treated by the oral route, but there were some signs of an association between tumour development and PVP injection in rodents.
Reproduction toxicity	Not available
Toxicokinetics (ADME studies)	Not available
Photo-induced toxicity	Not available
Relevant endpoints assessment (particle size, impurities)	CIR: Maximum "as used" concentration for safe as used conclusion: up to 35%.
Reference toxicology	(1) Handbook of Cosmetic Ingredients, Their use, safety and toxicology; Anthony C. Dweck; 3rd Edition 2012
SCCS	0

INCI Name	ROSA CANINA FRUIT OIL
Cosmetic restriction (Cosing)	None

General description	Rosa Canina Fruit Oil is an oil from the Hip Rose, Rosa canina L., Rosaceae. Rosa Canina (Dog Rose) Hip Seed Oil is a natural lipid high in gamma-linolenic acid that enhances skin's hydration, barrier repair and moisture- retention abilities. Rosa Canina fruit is rich in VIT C and lycopene.
Acute toxicity via relevant routes of exposure	The actual or estimated LD50 value: 2,000 mg/kg body weight.
Irritation and corrosivity	Not available
Skin irritation and skin corrosivity	Not available
Mucous membrane irritation (eye irritation)	Not available
Skin sensitisation	Not available
Dermal/ percutaneous absorption	Not available
Repeated dose toxicity (normally 28- or 90-day studies)	Not available
Mutagenicity/ genotoxicity	In an anti-genotoxicity assay, Rosa canina fruit decreased the genotoxicity of sodium azide by 44%.
Carcinogenicity	Not available

Reproduction toxicity	Not available
Toxicokinetics (ADME studies)	Not available
Photo-induced toxicity	Not available
Relevant endpoints assessment (particle size, impurities)	Rosa canina-derived ingredients are being used in cosmetics at maximum ingredient use concentrations up to 7%. This ingredient is considered safe as Rosa Canina fruit is used as tea.
Reference toxicology	(1) Handbook of Cosmetic Ingredients, Their use, safety and toxicology; Anthony C. Dweck; 3rd Edition 2012 (2) Safety Assessment of Rosa canina-derived Ingredients as Used in Cosmetics, 2016
SCCS	0

9. Undesirable effects and serious undesirable effects

The responsible person (in collaboration with the distributors) collects, documents, establish causality and manages the undesirable effects caused by the product after its use in the EU.
In case of undesirable effects to the cosmetic product the data will be included in the safety report. In the event of serious undesirable effects, the responsible person and distributors will without delay notify the following to the competent authority of the Member State where the serious undesirable effect occurred (Regulation (EC) No 1223/2009, Article 23). The notification forms sent to the competent authorities should be attached to the cosmetic product safety report. The information on undesirable effects must be kept up-to-date and regularly made available to the safety assessor.
From the market launch until today there are no reports known of serious undesirable effect or undesirable effect on the cosmetic product, or where relevant, other similar cosmetic products and this cannot be commented upon.
In case of abnormally high level of customer complaints the responsible person must bring this to the attention of the safety assessor and submit this formulation for reassessment and notify the competent authorities of corrective actions taken.

10. Information on the cosmetic product

There were no additional studies (safety tests) performed on this cosmetic product. /

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PART B – Cosmetic product safety assessment

Assessment conclusion

The cosmetic product: TODDA-SCIENCE BEHIND BEAUTY-WRINKLE&BLEMISH CORRECTOR
Formula number SA#2341
can be assessed as

SAFE with restrictions

for normal and reasonably foreseeable use in accordance with the European Council Directive (76/768/EEC) and the European Cosmetics Regulation (EC) No 1223/2009 (as amended) respectively. The ingredients are legally permitted as per Cosmetic Regulation (EC) No. 1223/2009 and its amendments and the safety assessment has been carried out in accordance to this regulation. They must comply with the relevant purity standards for cosmetic ingredients. It is assumed that these ingredients do not contain any undisclosed impurities/contaminants that would affect the conclusions reached. The product must be manufactured in accordance with EU Guidance on Good Manufacturing Practice.

SWR: This cosmetic product is assessed as SAFE WITH RESTRICTION because: due ti high pH value of the product and around the eye usage – a statement of the side effects or a patch test is needed.

Labelled warnings and instructions of use

Specific warnings and instructions of use are written on the packaging as follows:

- DIRECTIONS: Prior to application, thoroughly cleanse your skin. Gently tap a small amount of the product with your ring finger over cleansed, dry skin. Application should be performed directly to the wrinkles or blemishes you wish to smooth.
  Allow the actives to work for 4-8 minutes, during the wait keep your face expressionless.

- CAUTION: Avoid any contact with the eyes. Do not rub and do not massage the cream. Do not rinse off. It is recommended to avoid the use of any liquid skin care in order to keep best results

The product labelling as “Wrinkle & blemish corrector” in combination with the brand name “Todda” and the general description of the product indicate the explicit use of the finished product as a leave-on around the eyes product for adults intended for daily use. A reasonably foreseeable mistaken use additional to this use (not a misuse) is not recognisable.

There are no ingredients incorporated in the finished product, which require additional indications, specific directions or warnings due to their toxicological and/or physical-chemical properties or because of their concentration in the finished product.

Reasoning

Physical/chemical characteristics, stability and microbiological quality of the cosmetic product

The stability data (microbiological and physical-chemical stability) of the formula after storage meet the previously specified characteristics of the - internal product specifications. They confirm a sufficient stability of the tested formula.

Based on the tests of accelerated stability program that includes physical stability results (refer to Stability testing), analytical results (refer to Stability testing) and microbiological results (refer to Stability testing document): The shelf life for the final product is 36 months. The final product is released with a PAO of 12 months. Based on the above-mentioned physico-chemical and microbiological test results the product is rated as safe.

Packaging information

The package consists of a 20 ml 30%LLDPE+70%HD tube in Paper Box. The packaging of the product is made to protect the product during shelf life and use and to enable the safe use of the product. No interaction with packaging material is expected, as the packaging compatibility with the formulation was confirmed during its stability test. Similar formulation/packaging combinations are also already on the market. Based on that the packaging is rated to be suitable and safe for this specific product type. This package does not contain hazardous materials that require special markings or labelling on the shippers.

Exposure to the cosmetic product and the substances

The calculation of the exposition to the product and the single ingredients was carried out according to the „SCCS's Notes of Guidance for the testing of cosmetic ingredients and their safety evaluation, 9th revision 2015". Specific exposure consideration for the targeted consumer group (adults) has been taken into account as documented in the exposure and MoS calculation.

All ingredients (where the NOAEL value was available) have a sufficiently large MoS (>100), which is supporting the safety of the finished product.

Raw materials (impurities, traces, toxicological profile)

All raw materials used in the finished product meet the purity-requirements for cosmetic ingredients and were assessed as safe for the use as cosmetic ingredients, if necessary for the safety of the finished product, with limited conditions.

Concerning to the safety of the ingredients the following parameters were taken into account for the safety assessment:

a) the kind of cosmetic product,

b) the pH-value of the cosmetic product,
c) the conditions for use of the cosmetic product,
d) the degree of exposition of the assessed ingredient,
e) the permissible maximum concentration of the assessed ingredient,
f) possible combination effects, such as one ingredients that can increase absorption rate of another ingredient and
g) possible indications, directions, and/or warnings due to the toxicological profile of single ingredients.

On the basis of the calculation of the exposition of every single ingredient carried out, taken into account the conditions for use and the calculation of the exposition of the finished product, all ingredients can be assessed as safe and harmless, as single ingredients as well as in the current combination in the finished product. The assessments were drawn up based on the recent level of knowledge.
Fragrance DominoRIce has been evaluated for safety when used up to 45% (W/W) in this kind of product. In the product it is used up to 0.5%. Fragrance DominoRice conforms to 47th Amendment, the currently applicable Standard of the International Fragrance Association (IFRA).

Undesirable effects and serious undesirable effects

Data about undesirable effects and serious undesirable effects to cosmetic products in the EU are stored in the Consumer Response System (CRS) of the manufacturer of Consumer Companies.
From the market launch until today the complaint statistics as documented in the Consumer Response System (CRS) of the manufacturer of Consumer Companies of this product show no remarkable raised consumer complaints regarding undesirable effects or serious undesirable effects in general.

Information on the cosmetic product

This is a This is a around the eyes cream.

The packaging of cosmetic product should include the following information in indelible, easily legible and visible lettering:

- Brand name
- Name of the product
- Function of the cosmetic product (unless it is clear from its presentation)
- Ingredients list (ingredients present ***in more than 1%*** in the end product should follow in the same order as here): **AQUA, ROSA CANINA FRUIT OIL, ARGANIA SPINOSA KERNEL OIL, POLYACRYLATE CROSSPOLYMER-6**, GLYCERIN, HYDROLYZED ELASTIN, ZEOLITE, PVP, TITANIUM DIOXIDE, HESPERIDIN METHYL CHALCONE, HYDROLYZED COLLAGEN, STEARETH-20, Parfum, DIPEPTIDE-2, PHENOXYETHANOL, HYALURONIC ACID, PALMITOYL TETRAPEPTIDE-7, PALMITOYL HEXAPEPTIDE-19
- Particular precautions for use
- Date of minimum durability (for products with a minimum durability ≤ 30 months) or PAO (for products with a minimum durability > 30 months)

- Nominal quantity (except for packaging containing less than 5 grams or 5 milliliters, free samples and single-application packs)
- Batch number or the reference for identifying the cosmetic product
- Responsible person name and address
- Manufacturer name and address
- Products' country of origin

Concerning the skin tolerance, the final product is expected to be well tolerated and to have a good cosmetic acceptability.

SUMMARY

The safety assessment is based on the chemical specification and toxicological profile of the ingredients as supplied at the time of assessment and an assessment of the final cosmetic product.

The supplier to this safety assessment is advised to ask for a new safety evaluation if any change in formulation occurs, change in raw materials used, abnormally high number of adverse events are recorded, changes in recommended uses or other circumstances that may affect the safety of this product.

Based on the outlined considerations the product is rated to be SAFE as stated in B.1.

Date and Signature

All statements in this safety assessment were elaborated on the recent level of knowledge. Every change in the formulation or changes and/or additional information of relevant data respectively will require an immediate re-evaluation of this safety assessment.

Assessor's credentials and approval of part B

Safety assessor: Rok Devjak MD PhD

Signature: 

Name, address, proof of qualification of safety assessor can be found on the respective Curriculum Vitae, stored centrally in an internal database.

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REFERENCES:

- Handbook of Cosmetic Ingredients, Their use, safety and toxicology; Anthony C. Dweck; 3rd Edition 2012
- SCCS Notes of Guidance For testing of Cosmetic Ingredients and their Safety Evaluation, 9th Revision, 2015
- IFRA Standards, 47th Amendment, June 2013
- IFRA Standards, 48th Amendment, June 2015
- RIVM report 320104001/2006, Cosmetics Fact Sheet, H.J. Bremmer, L.C.H. Prud'homme de Lodder, J.G.M. van Engelen
- ECHA, European chemical agency, echa.europa.eu