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COSMETIC PRODUCT SAFETY ASSESSMENT

HAT STORE COLOUR POWDER

Customer Reference:

Part B: Cosmetic Product Safety Assessment

CONFIDENTIAL

DELIVERED TO:

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DATE:

August 20, 2019
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Intertek ID: 23175





Cosmetic Product Safety Assessment

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Product Information

A product to be used by adults intended to be applied on nails of adults for professional use only such as nail salons (client information). Predominant exposure would be to the nails and cuticle. Exposure to the skin, although not intended –may sometimes be inevitable in normal and reasonably foreseeable conditions of use. Due to the nature of the product, exposure to the eyes, inhalation and ingestion is unlikely.

Formulation

See Appendix One for product formulation data

Assessment Conclusion

This cosmetic product is considered as safe under normal and reasonable foreseeable conditions of use. 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 Article 3 of 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

Under normal or reasonably foreseeable conditions of use, a product made to this formulation is unlikely to produce an abnormally high number of adverse reactions. The product will give users the level of safety they can reasonably expect when used as directed.

The toxicological data available on the individual substances and the end product, including all chemical and/or biological interactions and human exposure via intended and likely routes have been taken into account in this assessment. Whenever a NO(A)EL value is available for a specific substance, its Margin of Safety (MoS) has been calculated and taken into account. Where applicable, relevant systemic and local toxicity end points of the chemicals ingredients in this formulation have been considered as part of this risk assessment.

Labelling Warnings and instructions for use

Warnings

N/A



Instructions of Use

As per manufacturer's instruction.

Fragrance Allergen Labelling

THERE ARE NO ALLERGENS WHICH ARE REQUIRED TO BE DECLARED ON THE PRODUCT LABEL AS PER ANNEX III TO COSMETIC REGULATION (EC) NO 1223/2009.

Reasoning

Product Toxicity Review

If used as directed, use of this product formulation should be uneventful in the majority of the general population.

Effects of the product as provided on the skin

The formulation as supplied may cause only minimal skin irritation even if exposure is prolonged and/or repeated.

Repeated exposure to the formulation as supplied is unlikely to produce allergy by skin contact.

Unlikely to cause damage to internal organs following absorption through the skin.

Exposure to this product is unlikely to result in phototoxic effects.

Effects of the product as provided on the eye

Eye contact is unlikely to occur during normal use.

The particulate matter within the product may cause a foreign body reaction should it accidentally enter the eye.

Effects following ingestion of the product as provided

Ingestion is an unlikely route of exposure.

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

Effects following inhaling of the product as provided

Inhalation is an unlikely route of exposure.

Accidental Inhalation may cause slight irritation of the nose and upper respiratory tract.

Ingredient Toxicity Review



Most of the ingredients are widely used and have history of safe use in humans. Polymethyl Methacrylate is the polymer of methyl methacrylate. It has been approved by US FDA as indirect food additive. It has also been reviewed by CIR Expert Panel and concluded as safe in cosmetics when formulated to be non-irritating. These ingredients are large molecules and thus will not likely cross the stratum corneum to induce systemic toxicity.

Mica (CI 77019) is considered to be chemically inert and has low acute toxicity. It is not considered to be irritating to the skin or eyes and not known to cause skin sensitisation or elicitation of allergic reaction. Titanium dioxide (CI 77891) is a naturally occurring mineral. FDA lists titanium dioxide as a color additive used in coloring products, including cosmetics and personal care products applied to the lips, and the eye area, provided it meets certain specifications. Titanium dioxide is also an approved colorant for food, drugs and medical devices. FDA includes titanium dioxide on its list of indirect food additives. The supplier has stated that the colorants used in the formulation meets the requirements of Regulation (EC) No.1223/2009, and those colorants requiring food grade purity criteria meets the requirements of Regulation (EC) 231/2012.

As a leave-on product, repeated and long-term exposure is expected albeit limited systemic exposure is anticipated. Due to nature and/or the expected exposure levels of the ingredients, the formulation is expected to be of low systemic toxicity. Therefore, significant systemic toxicity is not expected in the short, medium or long term with repeated exposure to the product under normal and reasonably foreseeable use. Where adequate data is available, a Margin of Safety (MoS) has been calculated to be > 100, thus supporting the safety of the ingredient as formulated in this product.

Overall, taking into account the intended application, frequency of exposure and, the toxicological profiles of the individual ingredients as well as the supplier ensuring that the ingredients are of high purity, the product is not expected to cause damage to human health in the short, medium or long term under normal and reasonably foreseeable conditions. Although it cannot be totally discounted that a few susceptible individuals may experience allergic or other idiosyncratic reaction with the product particularly if already sensitised to one of the ingredients.

Margin of Safety Review

Where a NOAEL is available for a chemical ingredient that is considered as a toxicological concern, the Margin of Safety (MoS) has been calculated as greater than 100 taking into consideration any known data on dermal absorption and bioavailability. It is generally accepted that the MoS should be a least 100 to declare a substance safe for use in a finished product and the safety of this formulation is further supported by this uncertainty factor.

See Appendix One for a toxicological review of the formulation ingredients



Exposure Scenario

Product Class: Nail and cuticle products	IFRA Category: Category 8
Product Subclasses: Other nail and cuticle products, Other nail and cuticle products,	Product Group: Other nail and cuticle products
Product Group: Cosmetic	Part of body exposed to undiluted: Apply on nails
Product Name: HAT Store Colour Powder	
Targeted Population: Adult	

Amount per application (g): 0.3	Number of applications per day: 2-3 times per week
Physical Form: Powder	Total Amount applied per day (g): 0.05
Skin Surface Area of Application (cm²): 4	Amount per Unit Area of Skin per day (mg/cm²/day): 12.5
Exposure Time Neat: 3360 min, 156 x / year	Estimated Daily Exposure (mg/kg/day): 0.833
Exposure Time Dilute: Not Applicable	Retention Factor: 1
Exposure Time Solvent Inhalation: Inhalation - 5mins. Inhalation rate: 23.1 litres/min	Exposure Time Aerosol Inhalation: Not Applicable

Fragrance Composition

This formulation does not contain a synthetic fragrance and therefore a fragrance safety evaluation as per IFRA code of practice is not applicable to this product.



Microbiological Quality

Microbiological specifications:

To comply with the EN ISO 17516:2014 standard for Cosmetics — Microbiology — Microbiological limits, the following maximum limits apply:

Category 2: Other cosmetic products.

Total Aerobic Mesophilic Microorganisms (Bacteria plus yeast and mould): ≤ 1000 cfu/g or 1000 cfu/ml of the product. Escherichia coli, Pseudomonas aeruginosa, Staphylococcus aureus and Candida albicans must not be detectable in 1 g or 1 ml of the cosmetic product.

The microbiological specifications for the product have been supplied and based upon the conclusions therein, meet the minimum industry requirements specified in European Standard EN ISO 17516:2014 Cosmetics – Microbiology – Microbiological limits for cosmetic products.

Ref.: MICROBIOLOGY QUALITY ANALYSIS TEST REPORT, 19/01131/01 -HAT Store Colour Powder, Date: 25 February 2019

Microbial Limits Test Report, HAT Store Colour Powder, Date: 19-Feb-19

Preservative challenge test:

The efficacy of the preservation of a cosmetic product has to be assessed experimentally in order to ensure microbial stability and preservation during storage and use.

The preservative efficacy test results for this product have been supplied and based upon the conclusions made therein appear to meet the industry standard requirements specified in ISO 11930:2012 (E), Cosmetics — Microbiology — Evaluation of the antimicrobial protection of a cosmetic product.

Ref.: Preservative Efficacy (Challenge) Test –ISO 11930:2012, HAT Store Colour Powder, Date: 02/04/2019
PRESERVATIVE EFFICACY (CHALLENGE) TEST REPORT ISO 11930:2012, HAT Store Colour Powder, Date: 10 April 2019

Property	Method	Specification
Aerobic Mesophilic Bacteria		<10 CFU/g
Yeasts and Moulds		<10 CFU/g
Pseudomonas aeruginosa, Candida albicans, Escherichia coli, Staphylococcus aureus,		Absent

Product Stability

The physical stability of the finished product should be established, ensuring that no changes in its physical state

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occur during transport, storage or handling of the product. To make sure that no stability problems are induced by the type of container and packaging used, physical stability tests should be carried out with inert containers and those intended to be used on the market.

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 has been provided by the supplier and based upon the conclusions made therein, this cosmetic product appears to be stable under reasonably foreseeable storage conditions.

Ref.: Cosmetic Stability Report, HAT Store Colour Powder, Date: 04/06/2019

Stability Test Report, HAT Store Colour Powder, Date: 06/06/2019

Packaging Material Information

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 grade and characteristics of packaging materials in direct contact with the final product.

Impurities/Traces/Prohibited Substances

Where the specification is provided it is noted that this product does not contain any impurities at levels likely to cause harm to the user. The purity specification of the raw material ingredients have been reviewed where they have been provided by the supplier at the time of assessment. It is found that the raw materials do not contain any prohibited ingredients listed in Annex II to Regulation (EC) No 1223/2009 at concentration likely to cause harm to the user when used as directed under normal and reasonably foreseeable conditions of use.

Presence of Nanomaterials

In accordance to Cosmetic Regulation (EC) No 1223/2009, a nanomaterial is an insoluble or biopersistent and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale from 1 to 100 nm.

The supplier has confirmed that this cosmetic product does not contain any nanomaterials that are known to them with the meaning of the definition as stated in Cosmetic Regulation (EC) No 1223/2009.

Serious/Undesirable effects

The following data of the serious undesirable effects and/or undesirable effects have been supplied at the time of assessment and these are detailed below.



The manufacturer has clarified that this product has been introduced into the market recently. Therefore, there is no known undesirable effect and/or serious undesirable effect data.

Ref.: Clarification statement, Date: 21 March 2019.

Specific Use Considerations

N/A

Assessor's Credentials and Approval of Part B

This product was evaluated by N. KACHHELA who is qualified by education, training and experience to evaluate the safety of cosmetic product formulations.

N. KACHHELA, M.S. Pharm (Pharmacology & Toxicology)
Intertek Health, Environmental & Regulatory Services (HERS)

Date: August 20, 2019

This product was reviewed by D. SANCHEZ CARVAJAL who is qualified by education, training and experience to evaluate the safety of cosmetic product formulations.

D. SANCHEZ CARVAJAL, BSc (Veterinary), MSc (Toxicology)
Intertek Health, Environmental & Regulatory Services (HERS)

Date: August 20, 2019



Appendix One: Product Formulation Data and Toxicological Review of Ingredients

Formulation

The chemical names shown below refer to the raw materials used to formulate this product. The identity of the raw materials may be based on alternative nomenclature such as IUPAC name, Chemical name, INCI name or generic trade name. Furthermore, there may be instances where several CAS number exist for the same chemical ingredient. Where this has occurred, the most appropriate substitute will have been used where one has not been provided.

INCI Name	% Concentration	% Active	Activity in Product	CAS No	Chemical Name
POLYMETHYL METHACRYLATE	90	100	90	9011-14-7	POLYMETHYL METHACRYLATE, 2-PROPENOIC ACID, 2-METHYL-, METHYL ESTER, HOMOPOLYMER
CI 77891	5	100	5	13463-67-7, 1317-70-0, 1317-80-2	CI 77891 (TITANIUM DIOXIDE)
MICA	5	100	5	12001-26-2	MICA (CI 77019)



Toxicological Review of Ingredients

Chemical Name: Polymethyl Methacrylate, 2-Propenoic acid, 2-methyl-, methyl ester, homopolymer

Function: Film forming (CIR, 2011; CosIng, 2013)

Regulatory Status (Toxicological Risk Assessment Report):

Exposure	NOAEL	Safety Factors	MoS
		0	MoS For Adult:

Summary Data:

Cosmetic functions: Film forming and viscosity-increasing agents. Polymethyl Methacrylate (PMMA) is a polymer of methyl methacrylate. VCRP Frequency of Use as of 01/2015 : 895 cosmetic formulations. Classified as an indirect food additives (21CFR175.105, 21CFR175.300, 21CFR176.180, 21CFR177.1010, 21CFR178.3790) (PCPC). VCRP Frequency of Use as of 01/2018: 922 cosmetic formulations (CIR 2019). PMMA with its other related compounds, methyl methacrylate crosspolymer and methyl methacrylate/glycol dimethacrylate crosspolymer widely used as cosmetic ingredients are polymers which have been evaluated by the FDA for their safety in in several medical devices from human and animal safety data and by the Cosmetic Ingredient Review (CIR) Expert Panel. Polymethyl methacrylate bone cement has been approved by the FDA as a class II (special controls) medical device that requires premarket notification and adherence to standards. Polymethyl methacrylate beads are incorporated into collagen as dermal fillers. Intraocular lenses are made of PMMA. (CIR 2019)

Purity profile: The impurity of concern in PMMA is the monomer, methyl methacrylate (MMA). Analysis of PMMA beads used in cosmetic formulations found MMA to be present at < 100 ppm. The Nail Manufacturers Council reported that the residual monomer is typically < 1.5%; averages of 0.7% and 1.2% have been reported. (CIR 2019)

Dermal absorption: Polymethyl methacrylate-based cosmetic ingredients are large molecules and remain in particulate form (dispersed) in final preparations and thus will not likely cross the stratum corneum to induce systemic toxicity. (CIR 2019)

Irritation/Sensitisation: PMMA is known as a safe material used in contact lenses for a long time. However, PMMA microspheres may cause irritation by mechanical phenomena (CIR 2011). PMMA was not a dermal irritant to rabbits. PMMA was not irritating or sensitizing at 6.8% in an HRIPT test using 52 participants. The same result was obtained in another HRIPT test of PMMA at 2.0% (n = 106). In an EpiOcular test, PMMA had a Draize ocular irritation score of 0. PMMA was mildly irritating in rabbit eyes. (CIR 2019)

The CIR Expert Panel concluded that Polymethyl Methacrylate is safe in cosmetics in the present practices of use and concentration described in the safety assessment when formulated to be non-irritating (up to 44.6%) (CIR 2019)

Ref.:

PCPC Online database. <https://online.personalcarecouncil.org/jsp/IngredientDetail.jsp?monoid=5111> on February 12, 2019

CIR. Final Report of the Cosmetic Ingredient Review Expert Panel Safety Assessment of Polymethyl Methacrylate (PMMA), Methyl Methacrylate Crosspolymer, and Methyl Methacrylate/Glycol Dimethacrylate Crosspolymer. 2011

CIR. Amended Safety Assessment of Acrylates Copolymers as Used in Cosmetics. January 23, 2019
Cosmetic functions: Film forming and viscosity-increasing agents. Polymethyl Methacrylate (PMMA) is a polymer of methyl methacrylate. VCRP Frequency of Use as of 01/2015 : 895 cosmetic formulations. Classified as an indirect food additives (21CFR175.105, 21CFR175.300, 21CFR176.180, 21CFR177.1010, 21CFR178.3790) (PCPC). VCRP Frequency of Use as of 01/2018: 922 cosmetic formulations (CIR 2019). PMMA with its other related compounds, methyl methacrylate crosspolymer and methyl methacrylate/glycol dimethacrylate crosspolymer widely used as cosmetic ingredients are polymers which have been evaluated by the FDA for their safety in in several medical



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PCPC Online database. <https://online.personalcarecouncil.org/jsp/IngredientDetail.jsp?monoid=5111> on February 12, 2019

CIR. Final Report of the Cosmetic Ingredient Review Expert Panel Safety Assessment of Polymethyl Methacrylate (PMMA), Methyl Methacrylate Crosspolymer, and Methyl Methacrylate/Glycol Dimethacrylate Crosspolymer. 2011

CIR.Amended Safety Assessment of Acrylates Copolymers as Used in Cosmetics. January 23, 2019

Chemical Name: CI 77891 (Titanium Dioxide)			
Function: Colour			
Regulatory Status (Toxicological Risk Assessment Report):			
Exposure	NOAEL	Safety Factors	MoS
ORAL	2500 mg/kg bw/day	0	MoS For Adult: 11999040.1

Summary Data:

Function: Colourant, opacifying/uv absorber. Titanium dioxide may be in the anatase or rutile form. It is an approved food color (E171) with an unspecified acceptable daily intake. Bioaccessibility data on titanium released from titanium dioxide were determined when exposed to synthetic biological media of varying pH and composition. Only a small fraction of titanium was released / dissolved from the titanium dioxide powder during exposure to any of the media matrices of varying acidity and composition. A trend with somewhat higher release rates with increasing acidity and exposure period was evident. Not classified in the EU. Titanium dioxide (dust) is classified by IARC as Category 2B, "Possibly carcinogen to humans" (IARC, 2010). Food and Drug Administration (FDA) has authorized the use of titanium dioxide in food, in general, at a limit not to exceed 1% by weight of the food. It has approved the use of titanium dioxide for use in OTC sunscreen drug products at concentrations up to 25%. Acute toxicity: Not acutely toxic or harmful by the oral, inhalation or dermal route. Acute oral toxicity studies in animals (rats or mice) with micro/non micro crystalline/coated/uncoated forms of titanium dioxide were conducted, in general, the LD50 >5000 mg/kg



bw. The dermal LD50 for rats is determined to be >2000 mg/kg bw (SCCNFP, 2000). The inhalation LC50 in rats was > 2 mg/L (4 hour exposure). Irritation: Non-irritating. Results of different skin irritation studies with various types of titanium dioxide showed varying degree of erythema and completely recovered at 72 hours after application. Results of animal studies demonstrated that coated and uncoated titanium dioxide is non-irritating to the eye (SCCNFP, 2000). Sensitisation: No sensitisation was observed with both coated and uncoated titanium dioxide in both animal and human studies. Mutagenicity/Genotoxicity: In vitro and in vivo studies indicate that titanium dioxide is non mutagenic or genotoxic. It was negative in a battery of standard assays. Repeat dose toxicity: Results of subchronic feeding study in mice with anatase titanium dioxide demonstrates that it has no specific systemic effects. Titanium dioxide administered by oral gavage at a dose level of 24 g/kg bw/d to rats for 28 days showed no adverse effects (REACH Dossier). Benign tumours (bronchioloalveolar adenomas and cystic keratinising squamous cell carcinoma) were reported in a 2-year inhalation study in rats at 250 mg/m³. The NOEC (No observed effect concentration) for non-neoplastic changes was reported as 10 mg/m³. Titanium dioxide administered in the diet at doses of 25000 (~1250 mg/kg bw/d) or 50000 ppm (2500 mg/kg bw/d) to rats for 2 years showed no treatment-related increased in tumour incidence or any systemic toxicity effects. NOEL was > 2500 mg/kg bw/d. Photo-induced toxicity: Titanium dioxide is neither photo-irritant nor photo-allergenic to rabbits and guinea pigs respectively. It showed no evidence of sensitization in human volunteers. Photo genotoxicity assays have been conducted with the results showing that titanium dioxide is not photogenotoxic (SCCNFP, 2000). Human data: The working group of the International Agency for Research on Cancer (IARC) concluded that the epidemiological studies on titanium dioxide provide inadequate evidence of carcinogenicity (IARC Monograph, Volume 93, 2010). Others: Derived No Effect Level (DNEL) of 700 mg/kg bw/d for long term systemic exposure to titanium dioxide is given in the REACH Dossier. Dermal / percutaneous absorption: In vitro percutaneous absorption studies with coated or uncoated titanium dioxide indicate no dermal absorption. The in vitro absorption of microfine zinc oxide and titanium dioxide through porcine skin was reported in the REACH dossier (accessed on 05/03/2013 at <http://echa.europa.eu>). Titanium dioxide was not recovered in the receptor fluid; the potentially absorbable dose (total in the skin, stratum corneum and epidermis) was 0.1- 0.5%. Titanium dioxide applied in an oil/water emulsion base to the external surface of the arms showed deposition of the substance in the upper layer of the stratum corneum without any evidence of absorption reported. "Worst case" dermal absorption value of 0.5% is assumed. Margin of Safety (MoS): NOEL: 2500 mg/kg bw/d; Dermal absorption (Dap): 0.5%

Chemical Name: Mica (CI 77019)**Function:**Opacifying (CosIng, 2013)**Regulatory Status (Toxicological Risk Assessment Report):**

Exposure	NOAEL	Safety Factors	MoS
		0	MoS For Adult:

Summary Data:

Mica is silicate mineral with diverse chemical composition. Used in the production of pearlescent pigments and as a bulking agent in cosmetic products. The material is considered to be "chemically inert" and of a size unlikely to be inhaled (i.e. > 100 µm). There is low concern for systemic toxicity with non-respirable mica. It is not considered to be irritating to the skin or eyes and not known to cause skin sensitisation or elicitation of allergic reaction. Inhalation of mica dust over a period of years may cause fibrogenic response resulting in scarring of the lungs. Permitted for use in US, Canada and Saudi regulatory regimes.

High LD50 and not of toxicological concern (except for Mica that may contain crystalline quartz, which is known to be carcinogenic to humans [WHO, 2012; HSDB, 2012]. Because of the physico-chemical properties of mica, no cutaneous penetration is anticipated.



21CFR73.1496 - Mica may be safely used in amounts consistent with good manufacturing practice to color dentifrices and externally applied drugs, including those for use in the area of the eye.

21CFR73.2496 - Mica is safe for use in coloring cosmetics generally, including cosmetics applied to the area of the eye, in amounts consistent with good manufacturing practice.

21CFR176.170 - INDIRECT FOOD ADDITIVES: PAPER AND PAPERBOARD COMPONENTS.

21CFR177.2600 - INDIRECT FOOD ADDITIVES: POLYMERS, Rubber articles intended for repeated use

21CFR178.3297 - INDIRECT FOOD ADDITIVES: ADJUVANTS, PRODUCTION AIDS, AND SANITIZERS, Colorants for polymers.

Margin of Safety Calculation

INCI Name	Conc. (% w/w)	SED mg/kg	NOAEL/NOEL mg/kg bw/day	MoS
POLYMETHYL METHACRYLATE	90	0.75000000		
CI 77891	5	0.00000000	2500	11999040.1
MICA	5	0.00000000		

Note: In the absence of NO(A)EL data, the Margin of Safety (MoS) has not been calculated.

Unless otherwise determined and in the absence of literature or other experimental data, a Dermal Absorption (DAp) of 100% is taken as the worst case scenario.

NO(A)EL: No Observed Adverse Effect Level; MoS: Margin of Safety; SED Systemic Exposure Dosage

Calculation of Margin of Safety: $MoS = NO(A)EL / SED$

References for skin surface area, exposures, body weight and application quantities are derived from EU guidance and literature sources.

These are held on file at intertek.

The following conditions apply to this assessment:

1. This product was not evaluated for heavy metal or lead content by the undersigned.
 2. This product was not assessed for compliance with regulations, other than as described above, by the undersigned.
 3. This product has not been evaluated for potential physical injury such as choking hazard, aspiration risk, or mechanical irritation by the undersigned.
 4. It was assumed that all ingredients in the product were disclosed and are accurate as listed in the report table, subject to valid request.
 5. Based upon the information supplied, unless otherwise stated in this report and subject to a valid request, being made, it was assumed that neither this product, nor the ingredients used in the product, contained any impurities/contaminants that would cause toxicity in a consumer.
 6. This evaluation is relevant solely to the conditions described herein. Any substitution of ingredients, increase in concentrations of use, or change of use pattern will necessitate a new evaluation.
 7. "Valid request" refers to request from supplier of formulation to Intertek.
- Toxicological profiles are stored within an in-house database at Intertek.

For European Legislation only: This formulation will be assessed by Intertek in accordance with PART B , Annex I to Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (Official Journal L 342, 22 December 2009, pp. 59–209). The safety assessment is based upon 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.



END OF REPORT

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