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**NATURAL CLASSIC HENNA TREATMENT WAX  
FML 25**

**PART A – Safety Information**

**INCI**

Aqua/Water/Eau, Stearyl Alcohol, Sodium Lauryl Sulfate, Cetyl Alcohol, Alcohol Denat., Methylparaben, Propylparaben, Citric Acid, Parfum (Fragrance), Lawsonia Inermis (Henna) Extract, Magnesium Nitrate, Methylchloroisothiazolinone, Magnesium Chloride, Methylisothiazolinone, Benzyl Alcohol

**1. Quantitative and qualitative composition of the cosmetic product**

INCI NAME	CAS NO.	FUNCTION	% In FINISHED PRODUCT
Aqua	7732-18-5	Solvent	75-100
Stearyl Alcohol	112-92-5	Emollient	5-10
Sodium Lauryl Sulfate	151-21-3	Cleansing	1-5
Cetyl Alcohol	36653-82-4	Emollient	1-5
Alcohol Denat.	64-17-5	Solvent	0.1-1
Methylparaben	99-76-3	Preservative	0.1-1
Propylparaben	94-13-3	Preservative	0.01-0.1
Citric Acid	77-92-9	Viscosity Controller	0.01-0.1
Benzyl Alcohol	100-51-6	Preservative	0.01-0.1
Parfum	NA	Diluent	0.01-0.1
Lawsonia Inermis Extract	84988-66-9	Hair Conditioning	<0.01
Magnesium Nitrate	10377-60-3	Stabilizer	<0.01
Methylchloroisothiazolinone	26172-55-4	Preservative	<0.01
Magnesium Chloride	7786-30-3	Stabilizer	<0.01
Methylisothiazolinone	2682-20-4	Preservative	<0.01
Total			100

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

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

## **3. Microbiological quality**

To comply with the guidelines on the microbiology quality (ssnfp/0004/98), the following maximum limits apply:

Category 1: Products specifically intended for children under 3 years, eye area and mucous membranes

TVC:- 100 cfu/g or ml in 0.5g or ml of the product

Pseudomonas aeruginosa, staphylococcus aureus and candida albicans must not be detected in 0.5 g or ml of the cosmetic product.

Category 2: other cosmetic product

TVC:- 1000 cfu/g or ml in 0.1g or ml of the product

Pseudomonas aeruginosa, staphylococcus aureus and candida albicans must not be detected in 0.1 g or ml of the cosmetic product.

The microbiology specifications for the product have been supplied and based upon the conclusions therein; meet the industry recruitments specified in the guidelines on the Microbiology Quality of the Cosmetic product, 1999 edition.

The preservative challenge test results for this product have been supplied and based upon the conclusions made their it appear to meet the industry requirements specified in the notes of the guidance for testing of the cosmetic ingredients for their safety evaluation.

Annex 8 – Guidelines on the microbiological quality of the cosmetic product, 1999 edition.

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

It is assumed 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 characteristic of packaging materials in direct contact with the final product.

## **5. Normal and reasonably foreseeable use**

A formulation for Natural Classic Henna Treatment Wax indicated for the adult general population. It will be applied to the hair and a rinse off product. All of the ingredients

included in the formulation are widely used in cosmetic industry & its products already available in the market place and have good safety profiles and have documentations to support this. Inhalation of some volatile in the mouth is possible but expected to be minimal. Eye contact is not expected.

**6. Exposure to the cosmetic product**

- 1) The site(s) of application; **hair**
- 2) The amount of product applied; **14.0 g**
- 3) The duration and frequency of use; **0.5/day**
- 4) The normal and reasonably foreseeable exposure route(s); **cutaneous & dermal**
- 5) The targeted (or exposed) population(s). Potential exposure of a specific population shall also be taken into account; **adult**
- 6) Product type: **Hair Treatment Product**

## 7. Exposure to the substances

**Acute effects:** This Natural Classic Henna Treatment Wax is predicted to have almost no acute toxicity if used correctly, following the manufactures directions. Some of the Raw materials are known allergens but are used in such a low level that they pose no known health risk.

INCI NAME	SED
Aqua	23.33
Stearyl Alcohol	2.333
Sodium Lauryl Sulfate	1.1665
Cetyl Alcohol	1.1665
Alcohol Denat.	0.2333
Methylparaben	0.2333
Propylparaben	0.02333
Citric Acid	0.02333
Benzyl Alcohol	0.02333
Parfum	0.02333
Lawsonia Inermis Extract	0.00233
Magnesium Nitrate	0.00233
Methylchloroisothiazolinone	0.00233
Magnesium Chloride	0.00233
Methylisothiazolinone	0.00233

## 8. Toxicological Profile of the Substances

### Toxicological Profile of AQUA

**Chemical name:** Deionized Water

**INCI Name:** AQUA

**CAS Number:** 7732-18-5

**Function of Chemical:** Solvent

**EINECS:** 231-791-2

**Toxicological Summary** : Water is used in the formulation of virtually every type of cosmetic and personal care product. It can be found in lotions, creams, bath products, cleansing products, deodorants, makeup, moisturizers, oral hygiene products, personal cleanliness products, skin care products, shampoo, hair conditioners, shaving products, and suntan products.

The quality of water used in the production of cosmetics and personal care products, called process water, is monitored according to Good Manufacturing Practices outlined in FDA's Guidance on Cosmetic Manufacturing Practice Guidelines, and in international guidelines on Good Manufacturing Practices known as ISO 22716. Some companies may also comply with the U.S. Pharmacopeia (USP) standards for the purity of water used in drugs, devices and diagnostics published in the Purified Water monograph. USP Purified Water is prepared from water complying with the regulations of the U.S. Environmental Protection Agency (EPA) with respect to drinking water. It contains no intentionally added substances.

Water is primarily used as a solvent in cosmetics and personal care products in which it dissolves many of the ingredients that impart skin benefits, such as conditioning agents and cleansing agents. Water also forms emulsions in which the oil and water components of the product are combined to form creams and lotions. These are sometimes referred to as oil-in-water emulsions or as water-in-oil depending on the ratios of the oil phase and water phase.

Deionized Water at concentrations 1% - 99%. In clinical studies, Deionized Water was neither a primary irritant nor sensitizer. Deionized Water was not phototoxic in clinical studies.

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### Toxicological Profile Of ALCOHOL

**Chemical name:** Ethanol

**INCI Name:** ALCOHOL

**CAS Number:** 64-17-5

**Function of Chemical:** Solvent, antimicrobial, astringent

**EINECS:** 200-578-6

**Water Solubility:** Soluble

#### Toxicological Summary

Alcohols are used widely in industry as solvents, antifreeze or plasticizers. Have very limited use in medicine, as antiseptics (dehydrate cells), antipyretics (cause evaporative cooling), as vehicles / solvents in drug solutions (ethanol / propylene glycol) or as an antidote for methanol, isopropanol or ethylene glycol intoxication (ethanol). Absolute ethanol injected into sensory ganglia causes neurolysis (destruction) to stop the relay of intractable pain in terminal diseases like cancer.

The Food and Drug Administration (FDA) includes Alcohol (ethanol) on its list of direct food substances considered Generally Recognized as Safe (GRAS). Alcohol may also be used as an indirect food additive. For example, it may be used as a component of adhesives in contact with food. The FDA has also approved Alcohol for use in Over-the-Counter (OTC) antimicrobial drug products.

The safety of Alcohol Denat. has been assessed by the Cosmetic Ingredient Review (CIR) Expert Panel. The safety of other denaturants such as t-Butyl Alcohol, Diethyl Phthalate and Methyl Alcohol were reviewed by the CIR Expert Panel in other reports and found safe for use. The CIR Expert Panel evaluated the scientific data and concluded that Alcohol Denat. were safe for use in cosmetic products. The data were also considered sufficient to support the safety of Denatonium Benzoate when used as a denaturant. The CIR Expert Panel also concluded that the data were insufficient to support the safety Quassin, Brucine and Brucine Sulfate as denaturants, and Alcohol denatured with these denaturants.

**CONCLUSION :** Alcohol has been shown to be safe at much higher concentrations than the 15.28% used within this formulation, therefore Alcohol is considered safe for use in cosmetic formulations .

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### Toxicological Profile of STEARYL ALCOHOL

**Chemical name:** Octadecan-1-ol

**INCI Name:** STEARYL ALCOHOL

**CAS Number:** 112-92-5

**EINECS:** 204-017-6

**Function of Chemical:** Emollient, emulsifying, masking, opacifying

#### Toxicological Summary

Stearyl Alcohol is long chain fatty alcohols. It is a white, waxy solid with a faint odour. This ingredient is found in wide variety of products such as hair conditioners, foundations, eye makeup, skin moisturizers, skin cleansers and other skin care products. They are used in

numerous cosmetic product categories at concentrations of less than 0.1 percent to greater than 50 percent.

The metabolism of Stearyl Alcohol and Oleyl Alcohol in rats is described. The results of acute oral toxicity studies indicate a very low order of toxicity. In rabbit irritation tests, these alcohols produced minimal ocular irritation and minimal to mild cutaneous irritation. Stearyl Alcohol produced no evidence of contact sensitization or comedogenicity.

Clinical patch testing indicates a very low order of skin irritation potential and sensitization. Photo reactivity studies on products containing these ingredients were negative for phototoxicity or photosensitization.

Stearyl Alcohol helps to form emulsions and prevent an emulsion from separating into its oil and liquid components. It also reduces the tendency of finished products to generate foam when shaken. When used in the formulation of skin care products, Stearyl Alcohol act as a lubricants on the skin surface, which gives the skin a soft, smooth appearance.

The safety of Stearyl Alcohol and related ingredients has been assessed by the Cosmetic Ingredient Review (CIR) Expert Panel. The CIR Expert Panel evaluated the scientific data and concluded that Stearyl Alcohol is safe for use in cosmetics and personal care products. In 2004, the CIR Expert Panel considered available new data on Stearyl Alcohol reaffirmed the above conclusion.

The CIR Expert Panel noted that Stearyl Alcohol is found naturally in various mammalian tissues and the metabolism of Stearyl Alcohol in animals is well described. Due to the chemical nature and benign biological activity of these compounds, they are not suspected of significant potential for carcinogenesis, reproductive or developmental effects.

Furthermore, tests in humans of products containing these ingredients demonstrated low potential for skin irritation or sensitization.

The Food and Drug Administration (FDA) reviewed the safety of Stearyl Alcohol and approved its use as a multipurpose additive for direct addition to food. Stearyl Alcohol is also been approved for use as indirect food additives.

If they are made from plants, Stearyl Alcohol may be used in cosmetics and personal care products marketed in Europe according to the general provisions of the Cosmetics Directive of the European Union. Ingredients of animal origin must comply with the European Union animal by-products regulations.

**CONCLUSION:** There is a considerable body of information about the safety of Stearyl Alcohol. These resources are consulted to ensure the safety of these materials as they are used in cosmetics.

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### **Toxicological Profile of CETYL ALCOHOL**

**Chemical name:** Hexadecan-1-ol

**INCI Name:** CETYL ALCOHOL

**CAS Number:** 36653-82-4

**Function of Chemical:** Emollient, Emulsifying, Emulsion Stabilising, Foam Boosting, Masking, Opacifying, Surfactant, Viscosity Controlling

**EINECS:** 253-149-0

#### **Toxicological Summary**

Cetyl Alcohol is a white, waxy solid. Cetyl Alcohol and Stearyl Alcohol are the two major components of Cetearyl Alcohol. The long-chain aliphatic alcohols are alcohols resulting from the reduction of corresponding fatty acids.

These ingredients are all fatty alcohols and that are widely used in cosmetics and personal care products, especially in skin lotions and creams. Cetyl Alcohol and the other fatty alcohols keep an emulsion from separating into its oil and liquid components. These ingredients are also used to alter the thickness of liquid products and to increase foaming capacity or to stabilize foams.

The Food and Drug Administration (FDA) includes synthetic fatty alcohols including Cetyl Alcohol, on its list of food additives permitted for direct addition to food as multipurpose food additives. Synthetic fatty alcohols are also permitted as indirect food additives as adjuvants and production aids.

The inhalation of Cetyl Alcohol vapour (26 ppm) by mice, rats, and guinea pigs caused slight irritation of the mucous membranes of the eyes, nose, throat, and respiratory passages. There were no signs of systemic toxicity, and no deaths were reported. Alternatively, exposure to a Cetyl Alcohol concentration of 2220 mg/m<sup>3</sup> resulted in death of all animals. Ataxia and moderate nasal irritation were observed in albino rats exposed to bursts of a 3.0% Myristyl Alcohol aerosol. No deaths were reported. The oral LD<sub>50</sub> of Cetyl Alcohol in fasted rats was >8.2 g/kg. The animals had signs of central nervous system depression and labored respiration. In acute oral toxicity studies (rats) of formulations containing 2.0, 3.25, and 4.0% Cetyl Alcohol, there were predominantly no toxic effects.

The oral administration of Myristyl Alcohol and a product containing 0.8% Myristyl Alcohol to albino rats resulted in LD<sub>50</sub>s of >8.0 and >5.0 g/kg, respectively. The oral administration of up to 20.0 g/kg of Isostearyl Alcohol to rats failed to cause a significant number of deaths that would have permitted calculation of an LD<sub>50</sub>.

No mortalities were noted following the intragastric administration of a heated mixture of 1.0% Behenyl Alcohol in olive oil (dose, 10.0 g/kg). In acute dermal toxicity studies (rabbits), doses of up to 2.6 g/kg of Cetyl Alcohol and 2.0 g/kg of a product containing 4.0% Cetyl Alcohol induced little toxicity, as did 2.0 g/kg of a product containing 0.8% Myristyl Alcohol. Reactions of minimal to mild irritation were observed after the ocular administration of lipstick products containing 27.0 and 25.0% Isostearyl Alcohol into the eyes of albino rabbits. Transient iridial and conjunctival irritation was observed in albino rabbits during ocular irritation studies of two pump spray antiperspirants (5.0 and 10.0% Isostearyl Alcohol). Cornea<sup>1</sup> irritation was noted at the conclusion of the study involving the 5.0% Isostearyl Alcohol antiperspirant. Conjunctival irritation was observed 2 and 6 hours after

instillation of a 1.0% Behenyl Alcohol in oil mixture into the eyes of New Zealand rabbits. Reactions had cleared by 24 h post instillation. Irritation was not noted in the cornea or iris. The safety of Cetyl Alcohol has been assessed by the Cosmetic Ingredient Review (CIR) Expert Panel. The CIR Expert Panel evaluated the scientific data and concluded that these fatty alcohols were safe for use as cosmetic ingredients. In 2005, the CIR Expert Panel considered available new data on Cetearyl Alcohol and the other fatty alcohols and reaffirmed the above conclusion.

The toxicological data for the Cetyl alcohol included in this report revealed no significant toxicity.

**CONCLUSION:** Based on the available data included in this report, the Expert Panel concludes that Cetyl Alcohol is safe as cosmetic ingredients in the present practices of use.

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### Toxicological Profile of METHYLPARABEN

**Chemical name:** Methylparaben

**INCI Name:** METHYLPARABEN

**CAS Number:** 99-76-3

**Function of Chemical:** Preservative, perfuming

**EINECS:** 202-785-7

**Water Solubility:** Very slightly soluble in cold water, hot water

**Toxicological Summary:**

The Food and Drug Administration (FDA) includes Methylparaben on its list of substances considered Generally Recognized As Safe ([GRAS](#)) as a direct food substance. Butyl-, Methyl- and Propylparaben are also permitted for use as synthetic flavoring substances and adjuvants for direct addition to food.

The safety of Parabens has been assessed by the Cosmetic Ingredient Review (CIR) Expert Panel. The CIR Expert Panel evaluated scientific data and concluded that Methylparaben, Ethylparaben, Propylparaben, Isopropylparaben, Butylparaben and Isobutylparaben were safe for use as ingredients in cosmetics and personal care products.

CIR Safety Review: Data reviewed by the CIR Expert Panel included negative genotoxicity data, negative carcinogenicity data, and negative developmental toxicity data. Parabens were practically non-irritating and nonsensitizing in populations with normal skin. The CIR Expert Panel discussed “paraben paradox” in which paraben-sensitive patients can tolerate paraben-containing cosmetics applied to normal, unbroken skin but not when applied to eczematous or ulcerated skin.

The CIR Expert Panel recognized that Parabens penetrate the stratum corneum and noted that the metabolism of Parabens in the skin was likely to result in as little as 1% of unmetabolized parabens available for absorption into the body.

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### Toxicological Profile of PROPYLPARABEN

**Chemical name:** Propylparaben

**INCI Name:** PROPYLPARABEN

**CAS Number:** 94-13-3

**Function of Chemical:** Preservative, perfuming

**EINECS:** 202-307-7

**Water Solubility:** Very slightly soluble in cold water, hot water

**Toxicological Summarisation**

**Effects on Animals:** Acute toxicity studies in animals indicate that propyl paraben is relatively non-toxic by both oral and parenteral routes, although it is mildly irritating to the skin. Following chronic administration, no-observed-effect levels (NOEL) as high as 1200–4000 mg/kg have been reported and a no-observed-adverse-effect level (NOAEL) in the rat of 5500 mg/kg is posited.

**Effects on Humans:** Allergic reactions to ingested parabens have been reported, although rigorous evidence of the allergenicity of ingested paraben is lacking. The major adverse effects of concern caused by propyl paraben involve the male reproductive system. Especially the cumulative cosmetic exposure value of 17.79 g/day is a clear overestimation for the normal male population. Human-based *in vitro* data show an increasing potential for endocrine modifying effects with increasing chain length. PHBA, a common metabolite of all paraben esters, however, appears to exhibit no endocrine modifying effects.

#### **Effects of prolonged exposure**

**Acute exposure:** Potential endocrine modifying effects of parabens of higher chain length including propyl paraben, Very hazardous in case of inhalation. Hazardous in case of eye contact (irritant), of ingestion. Slightly hazardous in case of skin contact (irritant).

**Chronic exposure:** Very hazardous in case of inhalation. Hazardous in case of eye contact (irritant). Slightly hazardous in case of skin contact (irritant), of ingestion. The substance is toxic to lungs. Repeated or prolonged exposure to the substance can produce target organs damage.

**CONCLUSION:** Safety Assessor concludes that the chemical substance Propyl Paraben is identified as a safe product to be used in cosmetic product as ingredient and unlikely to cause adverse effect.

If the consumer follows the directions of this product is not expected to pose a risk to the health of the majority of consumers through any path of irritation.

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## **Toxicological Profile of BENZYL ALCOHOL**

**Chemical name:** Benzyl Alcohol

**Function of chemical:** Preservative

**INCI name:** BENZYL ALCOHOL

**CAS:** 100-51-6

**EINECS:** 202-859-9

### **Toxicological Summary:**

LD50 Oral - rat - 1.230 mg/kg Remarks: Behavioral: Somnolence (general depressed activity).

Behavioral: Excitement. Behavioral: Coma.

Inhalation: no data available

LD50 Dermal - rabbit - 2.000 mg/kg Skin corrosion/irritation Skin - rabbit - Irritating to skin. -

24 h serious eye damage/eye irritation no data available

Respiratory or skin sensitization no data available

Germ cell mutagenicity no data available

Carcinogenicity IARC: No components of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

Reproductive toxicity no data available Specific target organ toxicity - single exposure no

data available Specific target organ toxicity - repeated exposure no data available

Aspiration hazard no data available Potential health effects Inhalation Ingestion Skin

Harmful if inhaled.

It causes respiratory tract irritation.

Harmful if swallowed.

Harmful if absorbed through skin. Causes skin irritation

**CONCLUSION:** Benzyl Alcohol is considered safe for use in cosmetic formulations when formulated to the above criteria

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### **Toxicological Profile of METHYLCHLOROISOTHIAZOLINONE**

**Chemical name:** 5-Chloro-2-methyl-2H-isothiazol-3-one

**INCI Name:** METHYLCHLOROISOTHIAZOLINONE

**CAS Number:** 26172-55-4

**Function of Chemical:** Preservative

**EINECS:** 247-500-7

#### **Toxicological Summary**

Methylchloroisothiazolinone is a preservative. Although Methylisothiazolinone may be used in cosmetics and personal care products alone, it is often used in combination with Methylchloroisothiazolinone. In cosmetics and personal care products, Methylisothiazolinone may be used in the formulation of hair products, shampoos, skin care products, bath products, eye and facial makeup, and suntan products.

The Food and Drug Administration (FDA) permits the use of Methylisothiazolinone (2-methyl-4-isothiazoline-3-one) as indirect food additives, as antimicrobial agents, as components of adhesives (at a ratio of 1:3), and as components of coatings at a concentration not to exceed 50 ppm.

The safety of Methylchloroisothiazolinone has been assessed by the Cosmetic Ingredient Review (CIR) Expert Panel. The CIR Expert Panel evaluated the scientific data and concluded that Methylisothiazolinone may be safely used in rinse-off products at a concentration not to exceed 15 ppm and in leave-on products at a concentration not to exceed 7.5 ppm. The stated safe use concentration refers to a mixture containing 23.3% Methylchloroisothiazolinone.

The CIR Expert Panel has also assessed the safety of Methylchloroisothiazolinone when used alone and concluded that Methylchloroisothiazolinone was safe for use as a cosmetic ingredient at concentrations up to 100 ppm.

Methylchloroisothiazolinone and the mixture, Methylisothiazolinone and Methylchloroisothiazolinone, are used to prevent or retard bacterial growth, and thus protect cosmetics and personal care products from spoilage.

**CIR Safety Review:** The CIR Expert Panel reviewed data showing that Methylchloroisothiazolinone were absorbed after oral administration and then excreted in the urine or feces. The amount remaining in the tissues was minimal. Twenty-four hours after dermal exposure to a mixture of Methylisothiazolinone and Methylchloroisothiazolinone about 39-62% was bound to the skin - the studies all showed significant absorption or binding to the skin (many were done at concentrations higher than use concentrations).

The CIR Expert Panel noted the in vitro evidence of neurotoxicity, but concluded that the absence of any neurotoxicity findings in the many in vivo studies, including sub chronic, chronic, and reproductive and developmental studies suggests that Methylchloroisothiazolinone would not be neurotoxic as used in cosmetics.

Methylchloroisothiazolinone was not a cumulative ocular irritant when tested at 55 ppm. The dermal irritation of the mixture was concentration dependent but non-irritating to skin at 560 ppm; well above the maximum recommended use concentration for cosmetics and personal care products. Doses of Methylchloroisothiazolinone up to 2.8 mg/kg/day applied dermally, 5 days per week for 3 weeks, produced moderate irritation at the application site but no systemic toxicity. Dermal application of Methylchloroisothiazolinone up to 0.4 mg/kg/day for 3 months produced no systemic toxicity. No toxicologically significant treatment-related effects were observed at doses up to 30 mg/kg/day.

The CIR Expert Panel evaluated the scientific data and concluded that genotoxicity was not a concern. Dermal application of Methylchloroisothiazolinone, 3 times per week for 30 months, had no carcinogenic effects. Methylchloroisothiazolinone did not cause developmental effects.

The CIR Expert Panel's review of studies of Methylchloroisothiazolinone used alone indicated that depending on concentration and formulation about 50% can be absorbed through the skin. Concentrations of 0.01% (100 ppm) Methylchloroisothiazolinone were not irritating and did not cause dermal sensitization. Methylisothiazolinone alone was not mutagenic in in vitro assays, nor did Methylisothiazolinone cause reproductive or developmental effects.

There is some clinical evidence of weak sensitization potential from Methylchloroisothiazolinone when used in products together. When used together, Methylchloroisothiazolinone is thought to be the sensitizer, although persons sensitized to Methylchloroisothiazolinone may also react to Methylisothiazolinone. Because of the greater sensitization potential of Methylchloroisothiazolinone, the CIR Expert Panel limited use of the mixture to 15 ppm in rinse-off products and 7.5 ppm in leave-on products. When Methylisothiazolinone is used alone, the CIR Expert Panel limited the use to 100 ppm (0.01%).

A mixture of Methylchloroisothiazolinone and Methylisothiazolinone is also listed in Annex VI, Part I, and is authorized for use as a 3:1 mixture at a maximum concentration of 0.0015% (15 ppm).

Health Canada permits the use of Methylisothiazolinone/Methylchloroisothiazolinone, in combination, at concentrations equal to or less than 0.0015% (15 ppm) in rinse-off products and 0.00075% (7.5 ppm) in leave-on products. When used alone, Methylisothiazolinone may be used at concentrations up to 0.1% (100 ppm).

**CONCLUSION:** Methylchloroisothiazolinone is safe as used in cosmetic formulations and unlikely to cause any adverse effect. The raw material contained at the concentration used has no known or documented carcinogenic, mutagenic or reproductive effect. If the consumer follows the directions of this product is not expected to pose a risk to the health of the majority of consumers through any path of irritation.

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### **Toxicological Profile of METHYLISOTHIAZOLINONE**

**Chemical name:** 2-Methyl-2H-isothiazol-3-one

**INCI Name:** METHYLISOTHIAZOLINONE

**CAS Number:** 2682-20-4

**Function of Chemical:** Preservative

**EINECS:** 220-239-6

#### **Toxicological Summary**

Methylisothiazolinone and Methylchloroisothiazolinone are often mixed together and sold as ingredients in commercial microbiocides and preservatives. This mixture is reported to be effective against bacteria, fungi and yeast, which protects products from inadvertent contamination by the consumer during use.

Methylisothiazolinone may also be used alone as a preservative to protect products from inadvertent contamination by the consumer during use. Although Methylisothiazolinone may be used in cosmetics and personal care products alone, it is often used in combination with Methylchloroisothiazolinone. In cosmetics and personal care products, Methylisothiazolinone, or the mixture, Methylisothiazolinone and Methylchloroisothiazolinone, may be used in the formulation of hair products, shampoos, skin care products, bath products, eye and facial makeup, and suntan products.

The Food and Drug Administration (FDA) permits the use of Methylisothiazolinone (2-methyl-4-isothiazoline-3-one) and Methylchloroisothiazolinone (5-Chloro-2-methyl-4-isothiazolin-3-one) as indirect food additives, as antimicrobial agents, as components of adhesives (at a ratio of 1:3), and as components of coatings at a concentration not to exceed 50 ppm.

The safety of Methylisothiazolinone and Methylchloroisothiazolinone has been assessed by the Cosmetic Ingredient Review (CIR) Expert Panel. The CIR Expert Panel evaluated the scientific data and concluded that the mixture, Methylisothiazolinone and Methylchloroisothiazolinone may be safely used in rinse-off products at a concentration not to exceed 15 ppm and in leave-on products at a concentration not to exceed 7.5 ppm. The stated safe use concentration refers to a mixture containing 23.3% Methylisothiazolinone and 76.7% Methylchloroisothiazolinone.

The CIR Expert Panel has also assessed the safety of Methylisothiazolinone when used alone and concluded that Methylisothiazolinone was safe for use as a cosmetic ingredient at concentrations up to 100 ppm.

Methylisothiazolinone and the mixture, Methylisothiazolinone and Methylchloroisothiazolinone, are used to prevent or retard bacterial growth, and thus protect cosmetics and personal care products from spoilage.

**CIR Safety Review:** The CIR Expert Panel reviewed data showing that Methylisothiazolinone and Methylchloroisothiazolinone were absorbed after oral administration and then excreted in the urine or feces. The amount remaining in the tissues was minimal. Twenty-four hours

after dermal exposure to a mixture of Methylisothiazolinone and Methylchloroisothiazolinone about 39-62% was bound to the skin - the studies all showed significant absorption or binding to the skin (many were done at concentrations higher than use concentrations).

The CIR Expert Panel noted the in vitro evidence of neurotoxicity, but concluded that the absence of any neurotoxicity findings in the many in vivo studies, including subchronic, chronic, and reproductive and developmental studies suggests that Methylisothiazolinone would not be neurotoxic as used in cosmetics.

Methylisothiazolinone/Methylchloroisothiazolinone was not a cumulative ocular irritant when tested at 55 ppm. The dermal irritation of the mixture was concentration dependent but nonirritating to skin at 560 ppm; well above the maximum recommended use concentration for cosmetics and personal care products. Doses of Methylisothiazolinone/Methylchloroisothiazolinone up to 2.8 mg/kg/day applied dermally, 5 days per week for 3 weeks, produced moderate irritation at the application site but no systemic toxicity. Dermal application of Methylisothiazolinone/Methylchloroisothiazolinone up to 0.4 mg/kg/day for 3 months produced no systemic toxicity. No toxicologically significant treatment-related effects were observed at doses up to 30 mg/kg/day.

The CIR Expert Panel evaluated the scientific data and concluded that genotoxicity was not a concern. Dermal application of Methylisothiazolinone/ Methylchloroisothiazolinone, 3 times per week for 30 months, had no carcinogenic effects. Methylisothiazolinone/Methylchloroisothiazolinone did not cause developmental effects.

The CIR Expert Panel's review of studies of Methylisothiazolinone used alone indicated that depending on concentration and formulation about 50% can be absorbed through the skin. Concentrations of 0.01% (100 ppm) Methylisothiazolinone were not irritating and did not cause dermal sensitization. Methylisothiazolinone alone was not mutagenic in in vitro assays, nor did Methylisothiazolinone cause reproductive or developmental effects.

There is some clinical evidence of weak sensitization potential from Methylisothiazolinone/Methylchloroisothiazolinone when used in products together. When used together, Methylchloroisothiazolinone is thought to be the sensitizer, although persons sensitized to Methylchloroisothiazolinone may also react to Methylisothiazolinone. Because of the greater sensitization potential of Methylchloroisothiazolinone, the CIR Expert Panel limited use of the mixture to 15 ppm in rinse-off products and 7.5 ppm in leave-on products. When Methylisothiazolinone is used alone, the CIR Expert Panel limited the use to 100 ppm (0.01%).

Methylisothiazolinone is listed the Cosmetics Directive of the European Union (Annex VI, Part I) and is authorized for use at a maximum concentration of 0.01% (100 ppm). A mixture of Methylchloroisothiazolinone and Methylisothiazolinone is also listed in Annex VI, Part I,

and is authorized for use as a 3:1 mixture at a maximum concentration of 0.0015% (15 ppm).

Health Canada permits the use of Methylisothiazolinone/Methylchlorisothiazolinone, in combination, at concentrations equal to or less than 0.0015% (15 ppm) in rinse-off products and 0.00075% (7.5 ppm) in leave-on products. When used alone, Methylisothiazolinone may be used at concentrations up to 0.1% (100 ppm).

**CONCLUSION:** Methylisothiazolinone is safe as used in cosmetic formulations and unlikely to cause any adverse effect. The raw material contained at the concentration used has no known or documented carcinogenic, mutagenic or reproductive effect. If the consumer follows the directions of this product is not expected to pose a risk to the health of the majority of consumers through any path of irritation.

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### **Toxicological Profile of MAGNESIUM NITRATE**

**Chemical name:** Magnesium nitrate

**INCI Name:** MAGNESIUM NITRATE

**CAS Number:** 10377-60-3

**Function of Chemical:** Hair Conditioning

**EINECS:** 233-826-7

#### **Toxicological Summary**

Hazardous in case of skin contact (irritant), of eye contact (irritant), of ingestion, of inhalation (lung irritant). Prolonged exposure may result in skin burns and ulcerations. Over-exposure by inhalation may cause respiratory irritation.

Hazardous in case of ingestion, of inhalation. CARCINOGENIC EFFECTS: Not available.

MUTAGENIC EFFECTS: Not available. TERATOGENIC EFFECTS: Not available.

DEVELOPMENTAL TOXICITY: Not available. The substance may be toxic to blood, kidneys, lungs, gastrointestinal tract. Repeated or prolonged exposure to the substance can produce target organs damage.

**CONCLUSION:** Magnesium Nitrate is safe as used in cosmetic formulations and unlikely to cause any adverse effect. The raw material contained at the concentration used has no known or documented carcinogenic, mutagenic or reproductive effect. If the consumer follows the directions of this product is not expected to pose a risk to the health of the majority of consumers through any path of irritation.

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## **Toxicological Profile of MAGNESIUM CHLORIDE**

**Chemical name:** Magnesium chloride

**INCI Name:** MAGNESIUM CHLORIDE

**CAS Number:** 7786-30-3

**Function of Chemical:** Viscosity Controller

**EINECS:** 232-094-6

### **Toxicological Summary**

Magnesium Chloride is a colourless crystalline material that occurs naturally as the mineral bischofite. In cosmetics and personal care products, Magnesium Chloride is used to formulate many types of products including baby products, bath products, soaps and detergents; body and hand lotions, cleansing products, eye makeup and hair care products. The Food and Drug Administration (FDA) includes Magnesium Chloride on its list of direct food substances affirmed as Generally Recognized as Safe (GRAS). Magnesium Chloride is also permitted for as an indirect food additive for use in polymers used in food contact surfaces.

**CONCLUSION:** Magnesium Chloride is safe as used in cosmetic formulations and unlikely to cause any adverse effect. The raw material contained at the concentration used has no known or documented carcinogenic, mutagenic or reproductive effect. If the consumer follows the directions of this product is not expected to pose a risk to the health of the majority of consumers through any path of irritation.

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**Toxicological Profile of LAWSONIA INERMIS EXTRACT**

Chemical name: Lawsonia Inermis Extract

Function: Hair Conditioning

INCI: Lawsonia Inermis Extract

CAS: 84988-66-9

EINECS: 284-854-1

Symstetic Exposure Dosage / Margin Of Safety / Non Observed Adverse Effect Level:

SED: 12863.85 mg/kg Bw/ day

NOAEL: 0.00297 mg/kg Bw/ day

MoS:  $4.17 \times 10^7$

TYPRE OF TEST: LD 50

ROUTE OF EXPOSURE: Oral

DOSE/DURATION: > 8000 mg/kg

SPECIES OBSERVED: Rodent-Rat.

TYPRE OF TEST: LD50

ROUTE OF EXPOSURE: Dermal

DOSE/DURATION: Acute: 5000 mg/kg

SPECIES OBSERVED: Rodent –Rabbit

**TOXICOLOGICAL SUMMARY**

The uses of henna are known to the tradition, it and is widely used. Its sale is free in all the traditional market in Morocco and among the herbalists where there are leaves and seeds mixed in a single packet after the harvest, which exposes at the risks of poisoning. This product could have a pharmacological effect on the central nervous system; causing a loss of inhibition and restoration of the desire to escape and flee, the inhibition of curiosity and the

reaction of exploration in the animal and consequently a sedative effect. Comparing the three parts of the plant; seeds, root and leaves, the toxicity is present but different and significant remaining in the leaves. Because of the widespread use of henna in the Mediterranean area; North Africa and the Middle East as far as India and considering the absence until today of data on the toxic kinetic parameters, its use must be limited and regulated.

On the basis of the available data, it is concluded that Lawsonia Inermis Extract is safe as cosmetic ingredients in the present practices of use and concentration.

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### **Toxicological Profile of Sodium Laureth Sulfate**

**Chemical name:** sodium 2-(2-dodecyloxyethoxy) ethyl sulphate

**INCI Name:** SODIUM LAURETH SULFATE

**CAS Number:** 3088-31-1 / 9004-82-4 / 68891-38-3 / 1335-72-4 / 68585-34-2 / 91648-56-5

**Function of Chemical:** Cleansing, Denaturant, Emulsifying, Foaming, Surfactant

**EINECS:** 221-416-0/ - / 500-234-8 / - / 500-223-8 / 293-918-8

#### **Toxicological Summary**

SLES is a very effective ingredients used in cleansing products and as creams and lotions. In this function, surfactants wet body surfaces, emulsify or solubilize oils, and suspend soil. These ingredients contribute foaming and lathering properties to cleansing products and bubble baths

SLES is safe for use in cosmetic products. It was reviewed in 1983 and re-reviewed in 2002 by the Cosmetic Ingredient Review (CIR) Expert Panel and found to be safe for use in cosmetic and personal care products. SLES can cause skin irritation in some persons. Substances known to be carcinogenic have been classified and registered by several international organizations, such as the World Health Organization or the International Agency for the Research of Cancer as well as the US Environment Protection Agency and the European Union. None of these organizations have classified SLES as carcinogens.

There is no direct or circumstantial evidence that this ingredient have any carcinogenic potential. The studies that have been conducted SLES indicate to be safe under proper conditions of use.

**CONCLUSION:** Sodium Laureth Sulfate is safe as used in cosmetic formulations and unlikely to cause any adverse effect. The raw material contained at the concentration used has no known or documented carcinogenic, mutagenic or reproductive effect. If the consumer follows the directions of this product is not expected to pose a risk to the health of the majority of consumers through any path of irritation.

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### **Toxicological Profile of CITRIC ACID**

**Chemical name:** 2-Hydroxy-1,2,3-propanetricarboxylic acid

**INCI Name:** CITRIC ACID

**CAS Number:** 77-92-9

**Function of Chemical:** Buffering, chelating, masking

**EINECS:** 201-069-1

**Water Solubility:** 676 g/l (25 °C) soluble

**Systemic Exposure Dosage:** Based on wide spectrum of data relating to experimental animals and on human experience citric acid has a low acute toxicity; only one case of near fatal human intoxication was found.

#### **Toxicological Summarisation**

**Effects on Animals:** Citric acid has a low acute toxicity by oral application in both rat (LD50 = 3,000– 12,000 mg/kg, 3 different values) and mouse (LD50 = 5,400 mg/kg). General effects comprised physiological disturbances (acidosis and calcium deficiency), while “high” doses caused nervous system effects as well as severe damage to the stomach mucosa.

By subcutaneous application, LD50 values of 5,500 mg/kg in rats and 2,700 mg/kg in mice were reported. Injection of citric acid by various routes in rats, mice and rabbits (no doses stated) caused nervous system, lung, spleen and liver effects that were in part attributed to acidosis and Calcium deficiency.

**Effects on Humans:** In human physiology, citric acid is a very common intermediate in one of the central biochemical cycles, the Krebs or tricarboxylic acid cycle. In man approximately 2 kg of citric acid are formed and metabolised every day. This physiological pathway is very well developed and capable of processing very high amounts of citric acid as long as it occurs in low concentrations. Part of the circulating (mainly metabolic but also ingested) citric acid is excreted in urine, with 24-hour urine reference values between 1.5 and 3.68 mmol, corresponding to 0.29– 0.71 g citric acid excreted per person per day. Systemic effects after repeated exposure through oral doses of potassium citrate, either solid or dissolved in water: minor gastrointestinal disturbances, diarrhoea, indigestion, nausea, “burning”. The lowest concentration of inhaled citric acid required to produce involuntary coughing ranged from 0.5 to 32 mg/ml.

### **Effects of prolonged exposure**

#### **Acute exposure:**

Repeated exposure of up to 15 g/d of potassium and sodium citrate as medications did not cause any reported marked side effects, but minor gastrointestinal disturbances (diarrhoea, indigestion, nausea, “burning”) were experienced by 22 out of 81 patients taking Potassium citrate in water and 7 out of 75 taking solid potassium citrate (doses not stated in both groups) for the treatment of renal calculi.

**Chronic exposure:** In general, chronic toxic effects seem to be limited to changes in blood chemistry respectively metal absorption and excretion kinetics, even at high doses.

### **CONCLUSION:**

Safety Assessor concludes that the chemical substance citric acid is identified as a safe product to be used in cosmetic product as ingredient and unlikely to cause adverse effect. If the consumer follows the directions of this product is not expected to pose a risk to the health of the majority of consumers through any path of irritation.

The raw material contained at the concentration used has no known or documented carcinogenic, mutagenic or reproductive effect.

### **Toxicological Profile of PARFUM**

**Chemical Description:** Perfume and aromatic compositions and their raw materials

**INCI Name:** PARFUM

**Function of Chemical:** Deodorant, masking, perfuming

#### **Toxicological Summary**

Perfumes are ingredients used in a wide variety of cosmetics and personal care products to make the products more pleasant and to make them recognizable to the users. Fine fragrances, or perfumes, are used specifically to provide a pleasant and attractive odour for the user, while functional fragrances are added to products that serve some function such as cleaning or moisturizing.

According to the U.S. Food and Drug Regulation, the term “fragrance” on a product label signifies “any natural or synthetic substance or substances used solely to impart an odour to a cosmetic product.” In Europe, the labelling name for Fragrance is Parfum.

Parfum encompass a wide variety of natural and synthetic materials that are used alone or in combinations to produce a unique fragrance in products. Studies have shown that users associate a pleasant parfum with a clean environment. In other words, consumers know an area is clean because of the pleasant smell that remains following cleaning. It’s impossible to know if a product without fragrance has been applied; without fragrance there is no perceived effectiveness.

The safety of Parfum ingredients is assessed by a comprehensive program operated by the International Fragrance Association (IFRA). This comprehensive program, in operation since 1973, includes a Code of Practice (the Code) that provides recommendations for good operating practice and guidelines on fragrance ingredient safety assessment, and includes fragrance safety Standards which limit or ban the usage of certain fragrance materials. IFRA oversees the gathering of information about the safety of individual fragrance ingredients and reviews this information to determine the safety under conditions of use. The conclusions of the IFRA safety review are published in the IFRA “Code of Practice” which provides critical guidance to Parfum formulators and users to ensure that their products are safe.

Scientific review of fragrance ingredients is conducted by the Research Institute for Fragrance Materials (RIFM). RIFM is the scientific arm of IFRA and is a non-profit scientific institute, founded in 1966 for the purpose of generating and evaluating safety data on fragrance ingredients. The scientific foundation of RIFM is built around its independent Expert Panel (REXPAN), made up of toxicologists, pharmacologists, dermatologists and environmental scientists, none of whom has any other connection to the fragrance industry, and whose work involves the safety evaluation of fragrance ingredients under conditions of intended use.

The results of the RIFM Expert Panel evaluations are published in peer-reviewed scientific journals, and their decisions regarding restrictions of use are published in the IFRA

Standards. RIFM evaluates and distributes scientific data on the safety assessment of fragrance raw materials found in perfumes, cosmetics, shampoos, creams, detergents, air fresheners, candles and other personal and household products. RIFM's Database of Fragrance and Flavour Materials is the most comprehensive source worldwide for toxicology data, literature and information on the safety evaluation of fragrance and flavour materials.

The Cosmetic Ingredient Review (CIR) defers review of individual fragrance ingredients to the IFRA/RIFM program unless the ingredient has significant uses other than as a fragrance. In this case, the ingredient may be assessed by both the CIR Expert Panel and REXPAN.

**CONCLUSION:** Parfum is considered safe for use in cosmetic formulations when formulated to avoid irritation.

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## CARVANSONS LLP

PERFUME COMPOUNDS, ESSENTIAL OILS, INDUSTRIAL DEODORANTS

HOLLINS VALE WORKS

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DATE NOVEMBER 2012  
FRAGRANCE NAME PERFUME M97 P0353

### ANNEX 2. FRAGRANT CHEMICAL ALLERGENS

	CAS NO.	% concentration
AMYL CINNAMIC ALDEHYDE	122-40-7	1.700
AMYL CINNAMYL ALCOHOL	101-85-9	
ANISYL ALCOHOL	105-13-5	
BENZYL ALCOHOL	100-51-6	63.000
BENZYL BENZOATE	120-51-4	
BENZYL CINNAMATE	103-41-3	
BENZYL SALICYLATE	118-58-1	
CINNAMIC ALCOHOL	104-54-1	
CINNAMIC ALDEHYDE	104-55-2	
CITRAL	5392-40-5	0.425
CITRONELLOL	106-22-9	
COUMARIN	91-64-5	
EUGENOL	97-53-0	
FARNESOL	4602-84-0	
GERANIOL	106-24-1	
HEXYL CINNAMIC ALDEHYDE	101-86-0	
HYDROXYCITRONELLAL	107-75-5	
HYDROXYMETHYLPENTYL CYCLO- HEXENECARBOXALDEHYD (LYRAL)	31906-04-4	
ISO EUGENOL	97-54-1	0.900
2-(4-TERT-BUTYLBENZYL) PROPIONALDEHYDE	80-54-6	
LINALOL	78-70-6	3.440
METHYL HEPTINE CARBONATE	111-12-6	
METHYL IONONE (INCL. AIMIS)	127-51-5	3.600
LIMONENE	5989-27-5	0.003
TREEMOSS	90028-67-4	
OAKMOSS RESIN	90028-68-5	

### PART B – Cosmetic product safety assessment

#### 1. Assessment conclusion

This product Natural Classic Henna Treatment Wax has been formulated with ingredients, widely used in the cosmetic industry, and have been safely used and unlikely to cause

adverse effects. The formulation does not contain any impurities or residual chemicals that are toxic to human health.

If the consumer follows the directions and taking into account similar products containing similar raw materials with a long history of safety, this product is not expected to pose a risk to the health of the majority of consumers through any path of irritation.

The finished product Natural Classic Henna Treatment Wax and the raw material contained at the concentration used has no known or documented carcinogenic, mutagenic or reprotoxic effect.

2. **Labelled warnings and instructions of use**

**20% EXTRA FREE**  
480gm FOR THE PRICE OF 400gm

**20% EXTRA FREE**  
480gm FOR THE PRICE OF 400gm



**NATURAL CLASSIC**  
**HENNA**  
**TREATMENT WAX**  
ORIGINAL FORMULA  
**HAIR CONDITIONER**  
WILL NOT  
COLOUR HAIR

**NATURAL CLASSIC  
HENNA TREATMENT WAX**

1. This is the original Henna Treatment Wax formula made from the finest ingredients.  
2. Pure Henna is extracted from Henna (Lawsonia) leaves which makes it an excellent ingredient for deep penetrating hair conditioners. Natural Classic Henna Treatment Wax revitalises all types of hair, particularly the hair which has been damaged by bleaching, perming or tinting; use it regularly to make your hair lustrous and strong.

**IMPORTANT:** We recommend that you use all **NATURAL CLASSIC PRODUCTS** to ensure the consistent improvement of your hair condition and manageability.

**DIRECTIONS:** 1. Wash hair thoroughly, 2. Using the fingers, massage Natural Classic Treatment Wax thoroughly into the hair and scalp, 3. Cover hair with a damp hot towel for 15 to 30 minutes depending on the condition of the hair or apply before taking a hot bath as the steam will activate the process, 4. Rinse thoroughly with warm water and style hair as required.

**INGREDIENTS:** Aqua/Water/Eau, Stearyl Alcohol, Sodium Lauryl Sulfate, Cetyl Alcohol, Alcohol Denat, Methylparaben, Propylparaben, Citric Acid, Parfum (Fragrance), Lawsonia Inermis (Henna) Extract, Magnesium Nitrate, Methylchlorisothiazolinone, Magnesium Chloride, Methylisothiazolinone, Benzyl Alcohol

**CAUTION:** Keep away from eyes, in case of contact, rinse immediately with clean water.

Richard & Appleby, Gwent, NP22 5RL, UK 480gm e 

MADE IN THE UK



5045 4617

### 3. Reasoning

#### **Effects of the finished product on the body**

**Internal organs:** This Natural Classic Henna Treatment Wax is unlikely to cause damage to the internal organs following application to the body.

**Eye area** Natural Classic Henna Treatment Wax may cause irritation to the eye area

**Ingestion:** Natural Classic Henna Treatment Wax is likely to cause irritation

**Inhalation:** of some volatile vapours in the nose is possible but expected to be minimal.

**Overall Safety assessment:** The ingredients contained within Natural Classic Henna Treatment Wax are well within the Cosmetic Regulations (EC) No 1223/2009 and its amendments; the finished product Natural Classic Henna Treatment Wax does not contain any undisclosed chemicals.

The product Natural Classic Henna Treatment Wax is manufactured in accordance with EU Cosmetic goods manufacturing guide.

Warnings: As on the label attached

The product is not suitable for babies.

Under normal conditions and following the manufacturing instructions, Natural Classic Henna Treatment Wax is unlikely to cause adverse reaction, Natural Classic Henna Treatment Wax is deemed safe to be used by the end user.

### 4. Assessor's credentials and Approval



RAJAT NARANG

SAFETY ASSESSOR on Behalf of Richards and Appleby Ltd

BS, MS (Cosmetics Science-Physical & Biological Sciences)

Unit 3  
Heads of the Valleys Industrial Estate  
Rhymney, Tredegar, Gwent  
NP22 5RL  
United Kingdom

DATE: 22.05.2018