CERTIFICATE OF ANALYSIS

FACIAL TONER

Batch No: 4372806
Best Before End: September 2022

Analysis Description	Minimum Value	Maximum Value	Result	Compliance
Appearance			Clear mobile liquid	Pass
Colour			Colourless	Pass
Odour			Characteristic	Pass
Specific Gravity at 20°C	0.990	1.100	0.995	Pass
pH @ 20 Degrees C	3.0	4.0	3.54	Pass
Total Viable Count cfu/g		100	<100	Pass
Gram Negative Bacteria			Absent	Pass

Shelf life of this product depends very much on storage conditions, particularly temperature and exposure to light and air.

Expiry date must be considered as subjective; the expiry date given here is based on the best of our knowledge and experience of the material when stored under recommended conditions in original unopened containers.

Due to the natural ingredients contained in many of our products, there may be a slight batch to batch variation in the colour, odour or consistency. However, we ensure that this does not affect the quality and efficacy of the products in any way.

We hereby certify that the above material meets the required specification and is released for free sale.

DECLARATION OF ALLERGENS

FACIAL TONER BASE

Material	CAS Number	Total Allergen Inclusion Level (%)
ALPHA-ISOMETHYL IONONE	127-51-5	-
AMYL CINNAMAL	122-40-7	-
AMYL CINNAMYL ALCOHOL	101-85-9	-
ANISE ALCOHOL	105-13-5	-
BENZYL ALCOHOL	100-51-6	-
BENZYL BENZOATE	120-51-4	-
BENZYL CINNAMATE	103-41-3	-
BENZYL SALICYLATE	118-58-1	-
BUTYLPHENYL METHYLPROPIONAL	80-54-6	-
CINNAMAL	104-55-2	-
CINNAMYL ALCOHOL	104-54-1	-
CITRAL	5392-40-5	-
CITRONELLOL	106-22-9	-
COUMARIN	91-64-5	-
EUGENOL	97-53-0	-
EVERNIA FURFURACEA EXTRACT	90028-67-4	-
EVERNIA PRUNASTRI EXTRACT	90028-68-5	-
FARNESOL	4602-84-0	-
GERANIOL	106-24-1	-
HEXYL CINNAMAL	101-86-0	-
HYDROXYCITRONELLAL	107-75-5	-
HYDROXYISOHEXYL 3-CYCLOHEXENE CARBOXALDEHYDE	31906-04-4	-
ISO EUGENOL	97-54-1	-
LIMONENE	5989-27-5	-
LINALOOL	78-70-6	-
METHYL 2-OCTYNOATE	111-12-6	-
		No allergens

Revision Date: 14/04/2015
Revision: 0

CPNP INCI BANDING

FACIAL TONER BASE

	Banding	INCI Name
INCI Listing	>75.0 to ≤100.0	Aqua
	>5.0 to ≤10.0	Alcohol Denat.
	>5.0 to ≤10.0	Propylene Glycol
	≤0.1	Lactuca sativa Leaf Extract
	≤0.1	Cucumis sativus Fruit Extract
	≤0.1	Tilia cordata Flower Extract
	≤0.1	Salvia officinalis Leaf Extract
	>0.1 to ≤1	Allantoin
	≤0.1	Sodium Hyaluronate
	≤0.1	Citric Acid
	>0.1 to ≤1	Caprylyl Glycol
	>0.1 to ≤1	Phenoxyethanol

Allergens		Nil

Ingredients in grey area are below 1% and can be listed in any order

INCI names listed have been sourced from the CosIng European Commission database

The INCI listing is to the best of our knowledge, based on the information supplied, correct at the time of sending

Issue Date: 12/03/2015

BOM: 1 Revision: 0

SAFETY DATA SHEET
FACIAL TONER BASE

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product name FACIAL TONER BASE

Product number TBFACITONE

1.2. Relevant identified uses of the substance or mixture and uses advised against

Identified uses Cosmetics.

1.3. Details of the supplier of the safety data sheet

Supplier MADAR Corporation Limited
19-20 Sandleheath Industrial Estate
Fordingbridge
Hampshire
SP6 1PA

Approved Sellers Cosmetic Butters, Mystic Moments, New Directions, World of Moulds

Telephone +44 (0) 1425 655555

1.4. Emergency telephone number

Emergency telephone +44 (0) 1425 655555 Office Hours are 09:00 - 16:30 weekdays only

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification

Physical hazards Flam. Liq. 3 - H226

Health hazards Not Classified

Environmental hazards Not Classified

Classification (67/548/EEC or 1999/45/EC) R10

2.2. Label elements

Pictogram

Signal word Warning

Hazard statements H226 Flammable liquid and vapour.

FACIAL TONER BASE

Precautionary statements	P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. P233 Keep container tightly closed. P280 Wear protective gloves/protective clothing/eye protection/face protection. P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower. P370+P378 In case of fire: Use foam, carbon dioxide, dry powder or water fog to extinguish. P501 Dispose of contents/container in accordance with national regulations.
Supplementary precautionary statements	P240 Ground/bond container and receiving equipment. P241 Use explosion-proof electrical equipment. P242 Use only non-sparking tools. P243 Take precautionary measures against static discharge. P403+P235 Store in a well-ventilated place. Keep cool.

2.3. Other hazards

SECTION 3: Composition/information on ingredients

3.2. Mixtures

ALCOHOL **5-10%**

CAS number: 64-17-5 EC number: 200-578-6 REACH registration number: 01-2119457610-43-XXXX

Classification	Classification (67/548/EEC or 1999/45/EC)
Flam. Liq. 2 - H225	F; R11

PROPYLENE GLYCOL **5-10%**

CAS number: 57-55-6 EC number: 200-338-0

Classification
Not Classified

T-BUTYL ALCOHOL **<1%**

CAS number: 75-65-0 EC number: 200-889-7 REACH registration number: 01-2119444321-51-XXXX

Classification	Classification (67/548/EEC or 1999/45/EC)
Flam. Liq. 2 - H225 Acute Tox. 4 - H332 Eye Irrit. 2 - H319 STOT SE 3 - H335 STOT SE 3 - H335	F; R11. Xn; R20. Xi; R36/37

The Full Text for all R-Phrases and Hazard Statements are Displayed in Section 16.

FACIAL TONER BASE

SECTION 4: First aid measures

4.1. Description of first aid measures

Inhalation Move affected person to fresh air at once. Get medical attention if any discomfort continues.

Ingestion Rinse mouth thoroughly with water. Give plenty of water to drink. Get medical attention immediately.

Skin contact Remove contaminated clothing immediately and wash skin with soap and water. Get medical attention if symptoms are severe or persist after washing.

Eye contact Remove any contact lenses and open eyelids wide apart. Rinse immediately with plenty of water. Continue to rinse for at least 15 minutes. Get medical attention if any discomfort continues.

4.2. Most important symptoms and effects, both acute and delayed

General information Persons suffering from asthma, eczema or skin problems should avoid contact, including dermal contact, with this product. See Section 11 for additional information on health hazards.

4.3. Indication of any immediate medical attention and special treatment needed

Notes for the doctor No specific recommendations.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media Extinguish with the following media: Foam, carbon dioxide or dry powder.

5.2. Special hazards arising from the substance or mixture

Specific hazards Toxic gases or vapours.

5.3. Advice for firefighters

Protective actions during firefighting Containers close to fire should be removed or cooled with water.

Special protective equipment for firefighters Wear positive-pressure self-contained breathing apparatus (SCBA) and appropriate protective clothing.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions Wear suitable protective equipment, including gloves, goggles/face shield, respirator, boots, clothing or apron, as appropriate. No smoking, sparks, flames or other sources of ignition near spillage.

6.2. Environmental precautions

Environmental precautions Do not discharge into drains or watercourses or onto the ground.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up Keep combustible materials away from spillage. Eliminate all sources of ignition. Provide adequate ventilation. Contain and absorb spillage with sand, earth or other non-combustible material. The contaminated absorbent may pose the same hazard as the spilled material. Collect and place in suitable waste disposal containers and seal securely. Label the containers containing waste and contaminated materials and remove from the area as soon as possible. Wash thoroughly after dealing with a spillage.

6.4. Reference to other sections

FACIAL TONER BASE

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Usage precautions Wear protective clothing as described in Section 8 of this safety data sheet. Avoid contact with skin, eyes and clothing.

Advice on general occupational hygiene Do not eat, drink or smoke when using this product. Wash at the end of each work shift and before eating, smoking and using the toilet.

7.2. Conditions for safe storage, including any incompatibilities

Storage precautions Store in tightly-closed, original container in a dry, cool and well-ventilated place. Keep away from heat, sparks and open flame. Protect from freezing and direct sunlight.

7.3. Specific end use(s)

SECTION 8: Exposure Controls/personal protection

8.1. Control parameters

Occupational exposure limits

ALCOHOL

Long-term exposure limit (8-hour TWA): WEL 1000 ppm 1920 mg/m³

PROPYLENE GLYCOL

Long-term exposure limit (8-hour TWA): WEL 10 mg/m³ particulate
Long-term exposure limit (8-hour TWA): WEL 150 ppm 474 mg/m³ total vapour and particulates

T-BUTYL ALCOHOL

Long-term exposure limit (8-hour TWA): WEL 100 ppm 308 mg/m³
Short-term exposure limit (15-minute): WEL 150 ppm 462 mg/m³
WEL = Workplace Exposure Limit

8.2. Exposure controls

Protective equipment

Appropriate engineering controls Provide adequate ventilation.

Eye/face protection Eyewear complying with an approved standard should be worn if a risk assessment indicates eye contact is possible. The following protection should be worn: Chemical splash goggles or face shield.

Hand protection Chemical-resistant, impervious gloves complying with an approved standard should be worn if a risk assessment indicates skin contact is possible.

Other skin and body protection Wear appropriate clothing to prevent any possibility of skin contact. Wear apron or protective clothing in case of contact.

Hygiene measures No specific hygiene procedures recommended but good personal hygiene practices should always be observed when working with chemical products.

Respiratory protection No specific recommendations. Respiratory protection may be required if excessive airborne contamination occurs.

Environmental exposure controls Residues and empty containers should be taken care of as hazardous waste according to local and national provisions.

FACIAL TONER BASE

SECTION 9: Physical and Chemical Properties

9.1. Information on basic physical and chemical properties

Appearance	Liquid.
Colour	Colourless.
Odour	Characteristic.
pH	pH (concentrated solution): ~ 3.5
Flash point	56°C PMCC (Pensky-Martens closed cup).
Relative density	~ 1.000 @ 20°C

9.2. Other information

SECTION 10: Stability and reactivity

10.1. Reactivity

10.2. Chemical stability

Stability	Stable at normal ambient temperatures.

10.3. Possibility of hazardous reactions

Possibility of hazardous reactions	Will not polymerise.

10.4. Conditions to avoid

Conditions to avoid	Avoid heat, flames and other sources of ignition.

10.5. Incompatible materials

Materials to avoid	Strong oxidising agents. Strong acids. Strong alkalis.

10.6. Hazardous decomposition products

Hazardous decomposition products	Thermal decomposition or combustion may liberate carbon oxides and other toxic gases or vapours.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity - oral

ATE oral (mg/kg)	175,925.93

General information	No specific health hazards known.
Inhalation	No specific health hazards known.
Ingestion	No specific health hazards known. No harmful effects expected from quantities likely to be ingested by accident.
Skin contact	No specific health hazards known.
Eye contact	Vapour or spray in the eyes may cause irritation and smarting.
Acute and chronic health hazards	No specific health hazards known.
Medical symptoms	No specific symptoms noted, but this chemical may still have adverse health impact, either in general or on certain individuals.

FACIAL TONER BASE

Medical considerations May cause allergic contact eczema. Prolonged or repeated exposure may cause the following adverse effects: Allergic rash. Get medical attention.

SECTION 12: Ecological Information

Ecotoxicity No negative effects on the aquatic environment are known.

12.1. Toxicity

12.2. Persistence and degradability

Persistence and degradability The product is expected to be biodegradable.

12.3. Bioaccumulative potential

Bioaccumulative potential The product does not contain any substances expected to be bioaccumulating.

12.4. Mobility in soil

Mobility The product is soluble in water.

12.5. Results of PBT and vPvB assessment

Results of PBT and vPvB assessment This product does not contain any substances classified as PBT or vPvB.

12.6. Other adverse effects

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Disposal methods Dispose of waste product or used containers in accordance with local regulations

SECTION 14: Transport information

14.1. UN number

UN No. (ADR/RID) 1993

UN No. (IMDG) 1993

UN No. (ICAO) 1993

UN No. (ADN) 1993

14.2. UN proper shipping name

Proper shipping name (ADR/RID) FLAMMABLE LIQUID, N.O.S. (CONTAINS ALCOHOL)

Proper shipping name (IMDG) FLAMMABLE LIQUID, N.O.S. (CONTAINS ALCOHOL)

Proper shipping name (ICAO) FLAMMABLE LIQUID, N.O.S. (CONTAINS ALCOHOL)

Proper shipping name (ADN) FLAMMABLE LIQUID, N.O.S. (CONTAINS ALCOHOL)

FACIAL TONER BASE

14.3. Transport hazard class(es)

ADR/RID class	3
ADR/RID classification code	F1
ADR/RID label	3
IMDG class	3
ICAO class/division	3
ADN class	3

Transport labels

14.4. Packing group

ADR/RID packing group	III
IMDG packing group	III
ADN packing group	III
ICAO packing group	III

14.5. Environmental hazards

Environmentally hazardous substance/marine pollutant
No.

14.6. Special precautions for user

EmS	F-E, S-E
ADR transport category	3
Emergency Action Code	•3Y
Hazard Identification Number (ADR/RID)	30
Tunnel restriction code	(D/E)

14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	Not applicable.

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

EU legislation	Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures (as amended). Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (as amended).
Guidance	Workplace Exposure Limits EH40.

15.2. Chemical safety assessment

FACIAL TONER BASE

SECTION 16: Other information

Key literature references and sources for data	European Chemicals Agency, http://echa.europa.eu/
Issued by	Regulatory Manager
Revision date	26/05/2016
Revision	1
Risk phrases in full	R10 Flammable. R11 Highly flammable. R20 Harmful by inhalation. R36/37 Irritating to eyes and respiratory system.
Hazard statements in full	H225 Highly flammable liquid and vapour. H226 Flammable liquid and vapour. H319 Causes serious eye irritation. H332 Harmful if inhaled. H335 May cause respiratory irritation.

This information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process. Such information is, to the best of the company's knowledge and belief, accurate and reliable as of the date indicated. However, no warranty, guarantee or representation is made to its accuracy, reliability or completeness. It is the user's responsibility to satisfy himself as to the suitability of such information for his own particular use.

MATERIAL SPECIFICATION

FACIAL TONER BASE

Analysis Description	Minimum Value	Maximum Value	Description
Appearance			Clear mobile liquid
Colour			Colourless
Odour			Characteristic
Specific Gravity at 20°C	0.990	1.100	
pH @ 20 Degrees C	3.0	4.0	
Total Viable Count cfu/g		100	<100
Gram Negative Bacteria			Absent

Issue Date: 26/02/15

Revision: 0 Revision Date: 29/07/14

Shelf life of this product depends very much on storage conditions, particularly temperature and exposure to light and air. Shelf life must be considered as subjective; the shelf life given here is based on the best of our knowledge and experience of the material when stored under recommended conditions, see SDS, in original unopened containers. Due to the natural ingredients contained in many of our products, there may be a slight batch to batch variation in the colour, odour or consistency. However, we ensure that this does not affect the quality and efficacy of the the products in any way.

STATEMENT ON GENETICALLY MODIFIED ORGANISMS

FACIAL TONER 20195A

Part Number: 20195A

We confirm to the best of our knowledge that the above product does not contain, nor has been produced with the aid of any genetically modified organism. In consequence, this product will not contain any detectable residues of protein or DNA resultant from genetic modification.

PRODUCT INFORMATION FILE

Prepared according to EC 1223/2009

Product Name:
Facial Toner S&P Free

Product Code:
TBFACITONE

Manufacturer:
CONFIDENTIAL

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Name and Place of Manufacture

The product is manufactured at:
Our suppliers address in the UK

Good Manufacturing Practice Statement

The management system of our supplier has been assessed by SGS United Kingdom Ltd and certified as meeting the requirements of ISO 22716:2007, Cosmetics – Guidelines on Good Manufacturing Practices (GMP). A copy of the certificate can be seen in Appendix 1.

It is confirmed that the product is manufactured to Cosmetic Good Manufacturing Practice (GMP).

A description of the method of manufacturing is held on file at our supplier.

Animal Non-testing Declaration

It is confirmed that the product, and the individual ingredients in the product, have not been the subject of animal testing or retesting.

It is also confirmed that no animal testing is carried out via third parties on behalf of the company.

Composition of the Product

The detailed quantitative formulation (exact % of each ingredient) is held on file at our supplier.

Physical/Chemical Characteristics

The raw material specifications and the finished product specification are held on file at our supplier.

Raw Material Quality/Purity

Raw Material Manufacturers' material safety data sheets, specifications and certificates of analysis are held on file at our supplier

Stability

The stability of the product is acceptable. Stability data is held on file at our supplier

The product has successfully completed 18 weeks stability testing under accelerated conditions validating a 30 plus month shelf life and a period after opening (PAO) of 6 months.

Where there is slight change in odour characterisitics this change is to aesthetic properties only and safety will not be affected.

Where there is a slight change in appearance this change is to aesthetic properties only and safety will not be affected.

Microbial Quality - Ingredients

It is a requirement that all raw materials / ingredients meet a microbial quality of < 1000 cfu/gram for adult products (from the SCCS Notes of Guidance for the Testing of Cosmetic Ingredients and their Safety Evaluation, 8th Revision, 2012). All the raw materials / ingredients comply with this requirement.

Microbial Quality – Finished Product

It is a requirement that the finished product meets a microbial quality of < 1000 cfu / gram for adult products and zero harmfuls (from the SCCS Notes of Guidance for the Testing of Cosmetic Ingredients and their Safety Evaluation, 8th Revision, 2012). The finished product complies with this requirement.

Finished Product Safety

The microbial content (Total Viable Count) at time of manufacture must be within recognised limits: nmt 1000 cfu and zero harmfuls / gram (from the SCCS Notes of Guidance for the Testing of Cosmetic Ingredients and their Safety Evaluation, 8th Revision, 2012). The microbial content at time of manufacture complies with these recognised limits.

Challenge Test Data

The product will pass a Microbial Challenge Test. Challenge Test data is held on file at our supplier.

Packaging Information

Packaging Information is held on file at our supplier.

Allergens Declarations

Allergens Declarations are held on file at our supplier.

IFRA Statement

IFRA Statements are held on file at our supplier.

Wording or Artwork for the Pack Labelling

The product is supplied commercially as a cosmetic base product to which a number of additional ingredients may be added by the end user and, therefore, there is no retail pack labelling or artwork.

Undesirable Effects and Serious Undesirable Effects

Our supplier is not aware of any available data on undesirable effects and serious undesirable effects relating to the product, or other similar cosmetic products.

Allison Leveridge

……

Technical and Regulatory Department

07th March 2017

Appendix 1 – GMP Certificate

Certificate GB13/87972

The management system of

CONFIDENTIAL

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Has been assessed and certified as meeting the requirements of

ISO 22716
Cosmetics – Guidelines on Good Manufacturing Practices (GMP)
(First edition 2007-11-15)

For the following activities

Manufacture of cosmetics and personal care liquids, emulsions, creams, lotions, oils, gels and balms, this includes both ambient and hot fill.

The responsibility for the quality of the individual batches of the cosmetic products labelled, packed and stored lies with the organization

This certificate is valid from 19/02/2016 until 19/02/2019
and remains valid subject to satisfactory surveillance audits.
Issue 2. Certified since 19/02/2013

Authorised by

Pieter Weteringa
Certification Manager
SGS Belgium NV, Systems and Services Certification
SGS House Noorderlaan 87 2030 Antwerp Belgium
t +32 (0)3 545-48-48 f +32 (0)3 545-48-49 www.sgs.com

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VOLUME 2

Cosmetic Product Safety Report

Conforming to

REGULATION (EC) No 1223/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 30 November 2009 on Cosmetic Products

By

Cosmetic Safety Consultants Ltd on behalf of the named manufacturer below

CSC Reference –	**II151114TB20195A**
Product:	**Toner Base**
Manufacturer's Reference	**XXXXX**
Product Category -	**Toner - hydroalcoholic**
Manufacturer	**our supplier**

Safety Report Part A

1. Quantitative and qualitative composition of the product

INCI Name	INCI Banding (%)	CAS Number
Aqua	>75.0 to ≤100.0	7732-18-5
Alcohol Denat.	>5.0 to ≤10.0	-
Propylene Glycol	>5.0 to ≤10.0	57-55-6
Sodium Hyaluronate	≤0.1	9067-32-7
Allantoin	>0.1 to ≤1	97-59-6
Caprylyl Glycol	>0.1 to ≤1	1117-86-8
Lactuca sativa Leaf Extract	≤0.1	-
Cucumis sativus Fruit Extract	≤0.1	89998-01-6
Tilia cordata Flower Extract	≤0.1	84929-52-2
Salvia officinalis Leaf Extract	≤0.1	84082-79-1 / 8022-56-8
Citric Acid	≤0.1	77-92-9 / 5949-29-1
Phenoxyethanol	>0.1 to ≤1	122-99-6

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

Analysis Description	Minimum Value	Maximum Value	Description
Appearance			Clear mobile liquid
Colour			Colourless
Odour			Characteristic
Specific Gravity at 20°C	0.990	1.100	
pH @ 20 Degrees C	3.0	4.0	
Total Viable Count cfu/g		100	<100
Gram Negative Bacteria			Absent

Raw Materials

Physical/chemical characteristics - detailed as appropriate to individual ingredients in the supplier Material Safety Data Sheets (reviewed and approved by assessor) – see Annex 1

Stability Testing

The product has successfully completed stability testing under accelerated conditions. All stability data have been considered and the product may be described as nominally stable with a shelf life of minimum 36 months un-opened (assuming the temperature dependence of the stability kinetics does not deviate substantially from the Arrhenius model)

Slight variation in product pH is not significant and is typical of the precision associated with pH measurement of this type of sample matrix

See stability test report - Annex 1

3. Microbiological quality

The product has successfully completed preservative efficacy testing according to British Pharmacopoeia criteria for topical products.

Donnington Laboratories Ltd. Report reference M-4E186-4 – see Annex 1

4. Impurities, traces, information about the packaging material

Ingredient Purity

None of the ingredients used have specific prescribed purity criteria according to Regulation (EC) No 1223/2009 . General purity criteria apply and a review of supplier specifications and certificates of analysis indicate that general ingredient purity is acceptable.

The nature of the raw materials used in this formulation, together with associated manufacturing techniques indicate that the introduction of contaminants during production is unlikely – EU standard GMP procedures are in place. The presence of trace contaminants with toxicological significance (heavy metals, polycyclic aromatic hydrocarbons etc.) in raw materials is also unlikely – none of the components used are associated with the presence of these types of contamination.

– see Annex 1

Packaging

The product is supplied in a number of different containers composed of a number of generally inert polymeric materials. The materials used conform to EU regulations relating to suitability for food contact and hence, are acceptable for use with the cosmetic product matrices associated with this product formulation. Packaging material purity with regard to presence of trace monomeric materials and other toxicologically significant substances (e.g. heavy metals) is acceptable. The potential for migration of substance from packaging to product is negligible

See Packaging Statement – Annex 1

5. Normal and reasonably foreseeable use

The product is intended for use as facial tonic. The product is supplied commercially as a cosmetic base product to which a number of additional active ingredients may be included by the end user, however this assessment relates to the use of this formulation as a finished cosmetic product.

Variations on this formulation, based on the inclusion of additional ingredients by subsequent users of this product would require a separate, specific safety report.

Target Population
Marketed as a product for general population – not specifically marketed for infant use or for application to mucous membranes.

6. Exposure to the cosmetic product

7. Exposure to the substances

Typical product exposure characteristics have been calculated based on the end use of the formulation. Values used for amount of product, site of exposure and frequency of application are derived from the Scientific Committee on Consumer Safety NOTES OF GUIDANCE FOR THE TESTING OF COSMETIC INGREDIENTS AND THEIR SAFETY EVALUATION – 7th revision and Regulatory Toxicology and Pharmacology VOLUME 52, NUMBER 1, OCTOBER 2008

Route of exposure to the product is primarily dermal. Inhalation is not likely because there are no volatile components present and the product is applied by hand, rather than spray or aerosol. Ingestion is unlikely – potential incidental ingestion of product during use is included in the 100% retention factor.

Summary of exposure product and substance characteristics are as follows.

	Product Category	Amount per application / g	Frequency of application	g / day applied	Retention factor	g/day exposure	Surface Area Exp cm3	Systemic Exposure Dose (mg/kg) (based on 60kg average)	Specific Exposure mg/cm2
Maximum weight / volume component (%)	Facial Toner	1.54	1	1.54	100%	1.540	565	25.67	2.7257
100	Aqua	1.540	1	1.540	100%	1.540	565	25.667	2.7257
10	Alcohol Denat.	0.154	1	0.154	100%	0.154	565	2.567	0.2726
10	Propylene Glycol	0.154	1	0.154	100%	0.154	565	2.567	0.2726
0.1	Sodium Hyaluronate	0.002	1	0.002	100%	0.002	565	0.026	0.0027
1	Allantoin	0.015	1	0.015	100%	0.015	565	0.257	0.0273
1	Caprylyl Glycol	0.015	1	0.015	100%	0.015	565	0.257	0.0273
0.1	Lactuca sativa Leaf Extract	0.002	1	0.002	100%	0.002	565	0.026	0.0027
0.1	Cucumis sativus Fruit Extract	0.002	1	0.002	100%	0.002	565	0.026	0.0027
0.1	Tilia cordata Flower Extract	0.002	1	0.002	100%	0.002	565	0.026	0.0027
0.1	Salvia officinalis Leaf Extract	0.002	1	0.002	100%	0.002	565	0.026	0.0027
0.1	Citric Acid	0.002	1	0.002	100%	0.002	565	0.026	0.0027
1	Phenoxyethanol	0.015	1	0.015	100%	0.015	565	0.257	0.0273

8. Toxicological profile of the substances

Margins of safety are based on maximum Systemic Exposure Doses derived from the exposure characteristics detailed above (Facial product)

INCI Name LACTUCA SCARIOLA SATIVA LEAF EXTRACT
Description Lactuca Scariola Sativa Leaf Extract is an extract of the leaves of the Cabbage Lettuce, Lactuca scariola L. var. sativa, Compositae

INN Name
Ph. Eur. Name
CAS # 84776-66-9 / 90046-10-9
EINECS/ELINCS # 283-995-6 / 289-977-4

Chemical/IUPAC Name

Cosmetic Restriction
Other Restriction(s)

Functions SKIN CONDITIONING

SED = 0.03 mg/kg bw/ day

MOS information / References

Extract of lettuce - no toxicological significance - edible

INCI Name CUCUMIS SATIVUS EXTRACT

Description

Cucumis Sativus Extract is the extract obtained from the whole plant of the Cucumber, Cucumis sativus L., Cucurbitaceae

INN Name

Ph. Eur. Name

CAS # 89998-01-6

EC # 289-738-4

Chemical/IUPAC Name

Cosmetic Restriction

Other Restriction(s)

Functions SKIN CONDITIONING

SED = 0.03 mg/kg bw/ day

MOS information / References

Extract of cucumber - no toxicological significance - edible

INCI Name TILIA CORDATA FLOWER EXTRACT
Description
Tilia Cordata Flower Extract is the extract of the flowers of the Linden, Tilia cordata, Tiliaceae

INN Name
Ph. Eur. Name
CAS # 84929-52-2
EC # 284-536-2
Chemical/IUPAC Name
Cosmetic Restriction
Other Restriction(s)

Functions REFRESHING, SKIN CONDITIONING, SKIN PROTECTING, SMOOTHING, SOOTHING

SED = 0.03 mg/kg bw/ day

MOS information / References

Not a documented source of methyleugenol or pyrollizidine alkaloids. Presence of quercetin is indic ated, but in the cosmetic context this is present at several orders of magnitude below typical dietary intake. Linden Blossom tea is widely consumed Safety survey of active ingredients used in cosmetics - Prepared by the Committee of Experts on Cosmetic Products, Plants in cosmetics – Potentially harmful components
Volume III - prepared by the Committee of Experts on Cosmetic Products
National Toxicology Program (1992): NTP Technical Report on the Toxicology and Carcinogenesis
Studies of Quercetin (CAS No. 117-39-5) in F344/N Rats, NTP TR 409, NIH Publication No. 92-3140,
1992.
IARC (1999 et 1987): Cancer review, Monograph vol 31, 1983, 213-29, suppl 7, 1987, 71,
Monograph vol 73, 1999, 497-515.

Threshold of Toxicological Concern approach, based on Category I substance profile
SED = 0.03 x 60000 x 0.5(dermal uptake max) = 900 μg per day
TTC limit = 1800 μg per day

INCI Name SALVIA OFFICINALIS LEAF EXTRACT
Description
Salvia Officinalis Leaf Extract is an extract of the leaves of the Sage, Salvia officinalis L., Lamiaceae

INN Name
Ph. Eur. Name
CAS # 84082-79-1 / 8022-56-8
EC # 282-025-9 / -
Chemical/IUPAC Name
Cosmetic Restriction
Other Restriction(s)

Functions ANTIDANDRUFF, CLEANSING, ORAL CARE, SKIN CONDITIONING
TONIC

SED = 0.03 mg/kg bw/ day

MOS information / References
Extract of sage - no toxicological significance due to negligible essential oil content (<0.01%)

INCI Name ALCOHOL DENAT.
Description
Ethanol denatured in accordance with Customs and Excise regulations

INN Name
Ph. Eur. Name
CAS # -
EC # -
Chemical/IUPAC Name
Cosmetic Restriction
Other Restriction(s)

Functions

ANTIFOAMING, ANTIMICROBIAL, ASTRINGENT, MASKING, SOLVENT

SED = 2.57 mg/kg bw/ day

MOS information / References

Systemic exposure is several orders of magnitude below EU publicised values for safe alcohol consumption. SED to approved De-naturing agents is negligible (methanol <5%)

INCI Name PROPYLENE GLYCOL

Description

INN Name propylene glycol

Ph. Eur. Name propylenglycolum

CAS # 57-55-6

EINECS/ELINCS # 200-338-0

Chemical/IUPAC Name Propane-1,2-diol

Functions HUMECTANT, SKIN CONDITIONING, SOLVENT, VISCOSITY CONTROLLING

SED 2.57 mg/kg bw/ day

MOS information / References

MOS – based on lowest value of 1200mg / kg/bw /2.57 = >450

SIDS Initial Assessment Report for Chemical Name :Propylene glycol

CAS No: 57 -55-6 11th SIAM (USA, January 23-26, 2001)

INCI Name ALLANTOIN
Description

INN Name allantoin
Ph. Eur. Name
CAS # 97-59-6
EC # 202-592-8
Chemical/IUPAC Name Urea, (2,5-dioxo-4-imidazolidinyl)-
Cosmetic Restriction
Other Restriction(s)

Functions SKIN CONDITIONING SKIN PROTECTING SOOTHING

SED 0.26 mg/kg bw/ day

MOS information / References

MOS information
CIR panel supports use at 2%
Product concentration is 1% which is a factor of 2 below the safe limit , determined by a calculated MOS >100, the MOS value for Allantoin in this formulation is equivalent to >200
"Final report of the safety assessment of allantoin and its related complexes" Becker, Lillian C; Bergfeld, Wilma F; Belsito, Donald V; Klaassen, Curtis D; Marks, James G Jr; Shank, Ronald C; Slaga, Thomas J; Snyder, Paul W; Alan Andersen, F INTERNATIONAL JOURNAL OF TOXICOLOGY. 2010 May;29(3 Suppl):84S-97S

INCI Name SODIUM HYALURONATE
Description

INN Name Hyaluronate Sodium [USAN:JAN]

Ph. Eur. Name
CAS # 9067-32-7

EC # -
Chemical/IUPAC Name Hyaluronic acid, sodium, salt
Cosmetic Restriction
Other Restriction(s)

Functions HUMECTANT, SKIN CONDITIONING

SED = 0.026 mg/kg bw/ day

MOS information / References

MOS information
Hyaluronic acid is a carbohydrate polymer, distributed widely throughout the body in skin, connective tissues and synovial fluid. The level of this ingredient in this formulation indicates a SED that is significantly less than levels present typically in humans. As such, there is little potential for toxicity and NOAEL values are not established.

INCI Name CAPRYLYL GLYCOL

CAS # 1117-86-8
EC # 214-254-7
Chemical/IUPAC Name Octane-1,2-diol
Functions EMOLLIENT, HUMECTANT, SKIN CONDITIONING

SED = 0.257 mg/kg bw/ day

MOS information / References

In this formulation, this ingredient is present to support the function of the preservative phenoxyethanol. Aliphatic diols are generally well tolerated with regard to chronic exposure, with increasing chain length indicating decreasing toxicological potential.

Read across from Hexylene Glycol - The systemic NOAEL for this guideline study is considered to be 450 mg/kg/day, SIDS. Screening Information Data Set for High Production Volume Chemicals. (2003) 136 p

Assuming a minimum NOAEL value of 450 mg/kg/day

Calculated MOS = 450/0.257 = 1750

INCI Name CITRIC ACID
INN Name citric acid
Ph. Eur. Name acidum citricum
CAS # 77-92-9 / 5949-29-1
EINECS/ELINCS # 201-069-1
Chemical/IUPAC Name 2-Hydroxy-1,2,3-propanetricarboxylic acid
Functions BUFFERING, CHELATING, MASKING

SED = 0.026 mg/kg bw/ day

MOS information / References

Citric acid is a food grade ingredient, and occurs naturally in living organisms as part of the metabolic process – at this level of inclusion NOAEL data is not available, or required and no toxicological risks are apparent

Preservatives

The use of preservatives in cosmetic products is governed by Annex V of Regulation (EC) No 1223/2009

This formulation contains phenoxyethanol which is authorised by Annex V at a maximum concentration of 1%. The concentration at which this component is present in this formulation meets these specifications and the preservation system used in this product is compliant with Regulation (EC) No 1223/2009

Phenoxyethanol	Substance 2-Phenoxyethanol CAS # 122-99-6 EC # 204-589-7 Name of Common Ingredients Glossary PHENOXYETHANOL INN/ISO/AN	Regulation (EC) No 1223/2009 Regulated By 2007/17/EC Other Directives/Regulations Annex/Ref # V/29 Product Type, body parts Maximum concentration in ready for use preparation 1.0%

9.Undesirable effects and serious undesirable effects

None declared at the time of preparation of this document – a separate file must be made to record any declared incidences of undesirable effects – any serious undesirable effects must be notified to the competent authority and or local poison control agency

10. Information on the cosmetic product

The product is an established category of cosmetic products in current widespread use – no specific therapeutic claims are made. All constituents have been used widely in cosmetic preparations – no newly introduced or novel ingredients are used.

Cosmetic product safety Report Part B

CSC Reference –	**II151114TB20195A**
Product:	**Toner Base**
Manufacturer's Reference	**XXXXX**
Product Category -	**Toner - hydroalcoholic**
Manufacturer	**our supplier**

1. Assessment Conclusion

This product meets the criteria for safety specified by the requirements of Article 3 of REGULATION (EC) No 1223/2009

2. Labelled Warnings and Instruction for Use

No specific warnings required other than standard product usage instructions. If the product is used around the eye area, warning must be given to avoid direct eye contact.
No other specific instructions for use are prescribed.

Allergen declaration
In a rinse off product, any of the 26 allergens detailed in the European Commission Directive **2003/15/EC,** that are present in the final product at a concentration greater than or equal to 0.01% must be declared on the product labelling.

None present

3. Reasoning

Appropriate data were available for all components and a full review of this information has been made. The following information was reviewed as a minimum requirement

Relating to the final product -

Physical and Chemical Properties
Stability and Reactivity
Microbiological Purity
Packaging
Normal and reasonably foreseeable use
Target Population

And specifically

The general toxicological profile of each ingredient used:
The chemical structure of each ingredient:
The level of exposure of each ingredient;
The specific exposure characteristics of the areas on which the cosmetic product will be applied;
The specific exposure characteristics of the class of individuals for whom the cosmetic product is intended.

Margins of safety have been calculated for all components, with additional safety factors applied where appropriate due to the use of data from structurally related compounds.

CALCULATION OF THE MARGIN OF SAFETY

Maximum amount of ingredient applied (mg) **I**

Typical body weight of human (kg) **60**

Maximum absorption through the skin (%) **A**

Systemic Exposure Dose (mg/Kg/Bw) SED = **I x A / 60**

Margin of Safety **NOAEL / SED**

Where NOAEL equals no observed adverse effect level in mg/kg/bw from appropriate repeated dose studies.

MOS values for all toxicologically significant components (other than those whose presence is governed / prescribed specifically by the Annexes of Regulation (EC) No 1223/2009) have been calculated and are satisfactory (MOS >100)

Local toxicity – Phototoxic materials are not included in this formulation at levels of concern

CMRs – not included in this formulation

Nano materials – not included in this formulation

Dermal irritants / sensitizers – No significant exposure. Compatibility testing is generally advised if the product formulation uses ingredients at concentrations significantly greater than in previously well tolerated formulations. This formulation is very similar to other

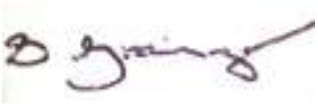
formulations that have been marketed previously, over a number of years without report of adverse reaction.

Interaction of substances

No significant interactions expected, based on a review of the chemical properties of the species included in this formulation. There are no components present that are likely to undergo spontaneous reaction – no species are present that have structural alerts with regard to carcinogenic activity.

4. Assessor's credentials and approval of part B

Approved - This product meets the criteria for safety specified by the requirements of Article 3 of REGULATION (EC) No 1223/2009



Scott Grainger BSc (Hons) MSc CSci CChem MRSC **15/11/14**

Chartered Chemist, Chartered Scientist

On behalf of Cosmetic Safety Consultants Ltd Reg. 07175899 DL14 6SX

England

Scott Grainger MSc BSc (Hons) CSci CChem MRSC

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7, Route de Rosnay Vendoeuvres 36500 France

Email info@cosmeticsafetyassessment.com

Qualifications

MSc Applied Chemistry

BSc (Hons) Combined Sciences 1st Class (Chemistry with Microbiology and Mathematics)

Chartered Chemist (CChem)

Chartered Scientist (CSci)

Full member of the Royal Society of Chemistry (MRSC)

Experience

20+ years in chemical and product safety of which cosmetic toxicology forms a minimum of 3 years

5+ years in small scale manufacturing of cosmetics

Member of the advisory panel of the GuildofCraftSoapandToiletryMakers

THIS IS TO CERTIFY THAT

SCOTT GRAINGER

HAS BEEN AWARDED THE DESIGNATION

CHARTERED CHEMIST

BY THE ROYAL SOCIETY OF CHEMISTRY

AND IS ENTITLED TO USE THE LETTERS CChem

President

Registrar

Date of Award

14 November 2008

RSC Membership Number

378846