



CERTIFICATE OF ANALYSIS

NIGHT CREAM

Batch No.: 4341201

Best Before End: November 2020

Analysis Description	Minimum Value	Maximum Value	Result	Compliance
Appearance			Viscous cream	Pass
Colour			White to off white	Pass
Odour			characteristic	Pass
pH @ 20 Degrees C	6.0	7.0	6.71	Pass
Viscosity RVT 20C SpindleC 10RPM	30000	60000	30000	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.

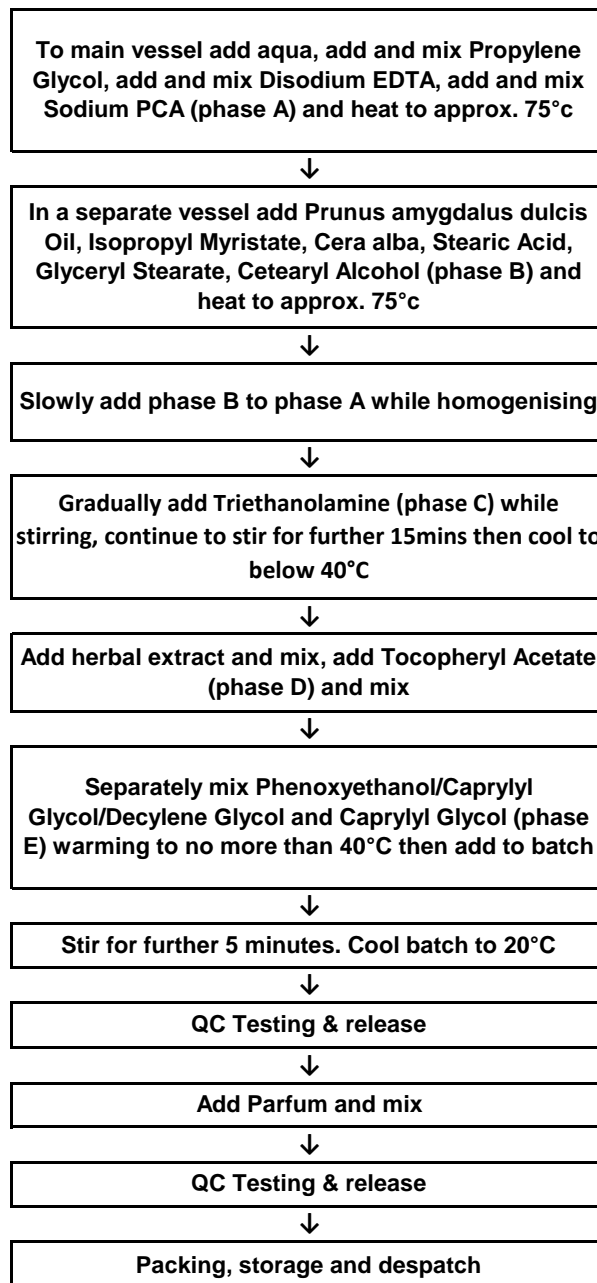
Due to the natural ingredients contained in many of our products, there may be a slight batch to batch variation in the colour, odour or consistency. However, we ensure that this does not affect the quality and efficacy of the products in any way.

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



PRODUCTION FLOW CHART

NIGHT CREAM



Date: 13/11/2019



INCI LISTINGS

1 Product

Night Cream

2 Product

TBNIGHCREA

3 INCI Listing

Banding (%)

>50.0 to ≤75.0

Aqua

>10.0 to ≤25.0

Isopropyl Myristate

>1.0 to ≤5.0

Stearic Acid

>1.0 to ≤5.0

Prunus amygdalus dulcis Oil

>1.0 to ≤5.0

Glyceryl Stearate

>1.0 to ≤5.0

Propylene Glycol

>1.0 to ≤5.0

Cera alba

>1.0 to ≤5.0

Cetearyl Alcohol

>0.1 to ≤1

Parfum

≤0.1

Chamomilla recutita Flower Extract

≤0.1

Lavandula angustifolia Flower Extract

≤0.1

Panax ginseng Root Extract

≤0.1

Symphytum officinale Leaf Extract

>0.1 to ≤1

Sodium PCA

≤0.1

Alcohol Denat.

≤0.1

Tocopheryl Acetate

>0.1 to ≤1

Triethanolamine

>0.1 to ≤1

Disodium EDTA

>0.1 to ≤1

Phenoxyethanol

>0.1 to ≤1

Ethylhexylglycerin

≤0.1

Methylisothiazolinone

4 Allergens Listing

≤0.1

Hexyl Cinnamal

≤0.1

Linalool

≤0.1

Hydroxycitronellal

≤0.1

Citronellol

≤0.1

Geraniol

≤0.1

Eugenol

5 Date

21/10/2013

Ingredients in grey area below 1%

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

PRODUCT INFORMATION FILE

Prepared according to EC 1223/2009

**Product Name:
Night Cream**

**Product Code:
TBNIGHCREA**

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

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A statement confirming the name and place of manufacture

A statement confirming compliance with good manufacturing practice (GMP) and referring to a description of the method of manufacturing

A statement confirming that no animal testing is performed by the manufacturer, his agents or suppliers, relating to the safety of this product

Composition of the Product

Physical / Chemical Characteristics

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VOLUME 1

Name and Place of Manufacture

The product is manufactured at:
A UK supplier's address.

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).

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 manufacturer's office.

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 manufacturer's office.

Physical/Chemical Characteristics

The raw material specifications and the finished product specification are held on file at our manufacturer's office.

Raw Material Quality/Purity

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

Stability

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.

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

Where there is a slight change in colour 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 manufacturer's office.

Packaging Information

Packaging Information is held on file at our manufacturer's office.

Allergens Declarations

Allergens Declarations are held on file at our manufacturer's office.

IFRA Statement

IFRA Statements are held on file at our manufacturer's office.

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

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

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 – II010415 CJNC 20059

Product: Night Cream

Manufacturer's Reference 20059

Product Category - Cosmetic Emulsion

Manufacturer XXXX

Safety Report Part A

1. Quantitative and qualitative composition of the product

INCI Name	INCI Banding (%)	CAS Number
Aqua	>50.0 to ≤75.0	7732-18-5
Isopropyl Myristate	>10.0 to ≤25.0	110-27-0
Stearic Acid	>1.0 to ≤5.0	57-11-4
Prunus amygdalus dulcis Oil	>1.0 to ≤5.0	8007-69-0 / 90320-37-9
Propylene Glycol	>1.0 to ≤5.0	57-55-6
Glyceryl Stearate	>1.0 to ≤5.0	31566-31-1
Cetearyl Alcohol	>1.0 to ≤5.0	67762-27-0 / 8005-44-5
Cera alba	>1.0 to ≤5.0	8012-89-3
Phenoxyethanol	>0.1 to ≤1	122-99-6
Triethanolamine	>0.1 to ≤1	102-71-6
Sodium PCA	>0.1 to ≤1	28874-51-3
Caprylyl Glycol	>0.1 to ≤1	1117-86-8
Disodium EDTA	>0.1 to ≤1	139-33-3 / 6381-92-6
Parfum	≤0.1	-
Decylene Glycol	≤0.1	1119-86-4
Tocopheryl Acetate	≤0.1	7695-91-2 / 58-95-7
Alcohol Denat.	≤0.1	-
Lavandula angustifolia Flower Extract	≤0.1	90063-37-9
Symphytum officinale Leaf Extract	≤0.1	84696-05-9
Panax ginseng Root Extract	≤0.1	84650-12-4
Chamomilla recutita Flower Extract	≤0.1	84082-60-0

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

Appearance:	Viscous cream
Colour:	White to off white
Odour:	Characteristic
Viscosity cps at 20°C: (Brookfield RVT, Spindle C, 10rpm)	30 000 – 60 000
pH:	6.0 – 7.0

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

Read-across from similar formulation Base Cream 20114A which makes up > 99%

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

Observation of retained product samples further validate the use of the above approach

See stability test report - Annex 1

3. Microbiological quality

The product base formulation (forming min 99% of this product) has successfully completed preservative efficacy testing according to British Pharmacopoeia criteria for topical products.

Read across from Donnington Laboratories Ltd test report M-4A352-1 formulation Base Cream 20114A

4. Impurities, traces, information about the packaging material

Ingredient Purity

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

Absence of nitrosating agents **Regulation (EC) No 1223/2009 due to presence of TEA.**

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 Annex 1

5. Normal and reasonably foreseeable use

The product is intended for use as moisturising emulsion for topical application in a number of potential exposure scenarios however principally, the product may be categorised as a general purpose product.

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

Several 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, however a 100% retention value has been used for all components, and a 100% value for dermal uptake / systemic availability – in the unlikely event of ingestion, the calculated total systemic availability value(100% retention and dermal uptake) would remain unchanged.

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 cm ³	Potential Systemic Exposure Dose (mg/kg) (based on 60kg average)	Specific Exposure mg/cm ²
Maximum component (%)	General Purpose cream / Lotion	1.2	2	1.2	100%	1.200	6725	40.00	0.3569
75	Aqua	0.900	2	1.800	100%	1.800	6725	30.000	0.2677
25	Isopropyl Myristate	0.300	2	0.600	100%	0.600	6725	10.000	0.0892
5	Stearic Acid	0.060	2	0.120	100%	0.120	6725	2.000	0.0178
5	Prunus amygdalus dulcis Oil	0.060	2	0.120	100%	0.120	6725	2.000	0.0178
5	Propylene Glycol	0.060	2	0.120	100%	0.120	6725	2.000	0.0178
5	Glyceryl Stearate	0.060	2	0.120	100%	0.120	6725	2.000	0.0178
5	Cetearyl Alcohol	0.060	2	0.120	100%	0.120	6725	2.000	0.0178
5	Cera alba	0.060	2	0.120	100%	0.120	6725	2.000	0.0178
1	Phenoxyethanol	0.012	2	0.024	100%	0.024	6725	0.400	0.0036
1	Triethanolamine	0.012	2	0.024	100%	0.024	6725	0.400	0.0036
1	Sodium PCA	0.012	2	0.024	100%	0.024	6725	0.400	0.0036
1	Caprylyl Glycol	0.012	2	0.024	100%	0.024	6725	0.400	0.0036
1	Disodium EDTA	0.012	2	0.024	100%	0.024	6725	0.400	0.0036
0.1	Parfum	0.001	2	0.002	100%	0.002	6725	0.040	0.0004
0.1	Decylene Glycol	0.001	2	0.002	100%	0.002	6725	0.040	0.0004
0.1	Tocopheryl Acetate	0.001	2	0.002	100%	0.002	6725	0.040	0.0004
0.1	Alcohol Denat.	0.001	2	0.002	100%	0.002	6725	0.040	0.0004
0.1	Lavandula angustifolia Flower Extract	0.001	2	0.002	100%	0.002	6725	0.040	0.0004
0.1	Symphytum officinale Leaf Extract	0.001	2	0.002	100%	0.002	6725	0.040	0.0004
0.1	Panax ginseng Root Extract	0.001	2	0.002	100%	0.002	6725	0.040	0.0004
0.1	Chamomilla recutita Flower Extract	0.001	2	0.002	100%	0.002	6725	0.040	0.0004

8. Toxicological profile of the substances

Margins of safety are based on maximum Systemic Exposure Doses derived from the exposure characteristics detailed above.

INCI Name STEARIC ACID

INN Name stearic acid

CAS # 57-11-4

EINECS/ELINCS # 200-313-4

Chemical/IUPAC Name Stearic acid

Functions CLEANSING, EMULSIFYING

SED 2.00 mg/kg bw/ day

MOS information / References

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Read across from the following data

Oleic Acid (C18:1)

NOAEL >7,500 mg/kg body weight per day (24 week oral study in Wister Rats)

IUCLID, 2000e

Lauric Acid NOEL >6000mg/kg was reported for lauric acid (18 week oral study, male rats)

Palmitic acid NOEL >5000mg/kg 150 days oral study in wister Rats)

Burdock GA, Carabin IG. Food Chem Toxicol. 2007 Apr;45(4):517-29.Safety assessment of myristic acid as a food ingredient.

Caprenin, (mixture of caprylic (C8), capric (C10), and behenic (C22) acids)

NOAEL 15% w/w i.e. 150000 mg/kg body weight per day

Webb, D.R., Wood, F.E., Bertram, T.A., and Fortier, N.E. (1993) A 91-day feeding study in rats with caprenin. Food and Chemical Toxicology, 31(12): 935-946.

Calculated MOS > 1000

INCI Name GLYCERYL STEARATE

Description Stearic acid, monoester with glycerol

INN Name glyceryl monostearate

Ph. Eur. Name glyceroli monostearas

CAS # 31566-31-1

EINECS/ELINCS # 250-705-4/286-490-9

Functions EMOLLIENT, EMULSIFYING

SED 2.00 mg/kg bw/ day

MOS information / References

Glyceryl mono-ester of stearic acid - This component is essentially a metabolic product of naturally occurring edible tri-glycerides, found in edible oils/fats – there are no significant toxicological issues with this ingredient and NOAEL data do not exist for this reason WHO - Unlimited ADI

CIR – safe at 6%

JACT 1(2):1-11, 1982 confirmed 09/01 IJT 22(S1):1-35, 2003

INCI Name PRUNUS AMYGDALUS DULCIS OIL

Description Prunus Amygdalus Dulcis Oil is the fixed oil obtained from the ripe seed kernel of the Sweet Almond Tree, Prunus amygdalus var. dulcis, Rosaceae

CAS # 8007-69-0 / 90320-37-9

EINECS/ELINCS # - / 291-063-5

Functions SKIN CONDITIONING

SED 2.00 mg/kg bw/ day

MOS information / References

Plant-Derived Fatty Acid Oils as Used in Cosmetics (CIR December 2010)

Draft Report of the Plant-derived edible oil group (CIR November 2010)

MOS information – No toxicological significance

INCI Name CETEARYL ALCOHOL

Description Alcohols, C16-18

Ph. Eur. Name alcohol cetylicus et stearylicus

CAS # 67762-27-0 / 8005-44-5

EINECS/ELINCS # 267-008-6 / -

Functions EMOLLIENT, EMULSIFYING, EMULSION STABILISING, OPACIFYING
VISCOSITY CONTROLLING

SED 2.00 mg/kg bw/ day

MOS information / References

There are no significant toxicological issues with this ingredient and NOAEL data do not exist for this reason.

Read across from the following data

Oleic Acid (C18:1)

NOAEL >7,500 mg/kg body weight per day (24 week oral study in Wister Rats)

IUCLID, 2000e

Lauric Acid NOEL >6000mg/kg was reported for lauric acid (18 week oral study, male rats)

Palmitic acid NOEL >5000mg/kg 150 days oral study in wister Rats)

Burdock GA, Carabin IG. Food Chem Toxicol. 2007 Apr;45(4):517-29.Safety assessment of myristic acid as a food ingredient.

Caprenin, (mixture of caprylic (C8), capric (C10), and behenic (C22) acids)

NOAEL 15% w/w i.e. 150000 mg/kg body weight per day

Webb, D.R., Wood, F.E., Bertram, T.A., and Fortier, N.E. (1993) A 91-day feeding study in rats with caprenin. Food and Chemical Toxicology, 31(12): 935-946.

Calculated MOS > 1000

INCI Name TRIETHANOLAMINE

Description

INN Name trolamine

Ph. Eur. Name

CAS # 102-71-6

EINECS/ELINCS # 203-049-8

Chemical/IUPAC Name 2,2',2''-Nitrilotriethanol

Cosmetic Restriction III/62

Functions BUFFERING, EMULSIFYING, MASKING, SURFACTANT

Annex/Part, Ref # III/1,62

Field of application and/or use

(a) Non-rinse-off products

(b) Other products

Maximum authorized concentration in the finished cosmetic product (a) 2.5%

Other limitations and requirements (a) (b)

- Do not use with nitrosating systems

- Minimum purity: 99%

- Maximum secondary amine content: 0.5% (applies to raw materials)

- Maximum nitrosamine content: 50 microgram/kg

- Keep in nitrite-free containers

SED = 0.40 mg/kg bw/ day

MOS information

Quality and concentration comply with Annex III / 1,62 as verified by certificates of analysis / supplier specification – see Annex 1

INCI Name LAVANDULA ANGUSTIFOLIA FLOWER EXTRACT

Description Lavandula Angustifolia Extract is the extract of the flowers of the Lavender, Lavandula angustifolia, Labiatae

INN Name

Ph. Eur. Name

CAS # 90063-37-9

EINECS/ELINCS # 289-995-2

Chemical/IUPAC Name

Cosmetic Restriction

Other Restriction(s)

Functions SKIN CONDITIONING

SED = 0.04 mg/kg bw/ day

MOS information / References

Based on linalool / linalyl acetate model – OECD SIDS Lowest NOAEL (several endpoints considered including reproductive, maternal , mutagenicity and immunotoxicity) is 160mg/kg (based on liver and kidney weight increase) Linalyl acetate is metabolised to linalool, producing a total linalool equivalent content of $45 + (25 \times .78) = 65\%$ $0.67 \times 0.65 =$ SED of 0.43 linalool $MOS = 160/0.43 = 372$

Read Across from Lavender essential oil - MOS for 1% oil (SED 0.67) =372

Oil present in lavender at <10% - $MOS = 372 \times 10 = 3720 * (0.67/0.04)$

Calculated MOS for extract >138000

INCI Name SYMPHYTUM OFFICINALE LEAF EXTRACT

Description Symphytum Officinale leaf Extract is an extract of the leaves of the Comfrey, Symphytum officinale L., Boraginaceae

CAS # 84696-05-9

EINECS/ELINCS # 283-625-3

Functions SKIN CONDITIONING

SED = 0.04 mg/kg bw/ day (to extract)

MOS information / References – based on Pyrrolizidine alkaloid content

PA (Pyrrolizidine alkaloid) content in leaf 8g /kg = 0.8% PA (Maximum potential value)

20% extraction efficiency of PAs into extract = 0.16% PA in extract

Used at 0.1% (extract) in final formulation, the concentration of PA in the final product is

$0.16 \times 0.001 = 0.00016\%$

8g per day usage of the final product equates to exposure to PAs of

$0.0000128 \text{ g PA} = 0.00128 \text{ mg PA} = 0.128 \text{ } \mu\text{g PA}$

SED = 0.002 $\mu\text{g /kg b.w./day}$

Adjusted SED (10% dermal uptake)

SED = 0.0002 $\mu\text{g /kg b.w./day}$

COMMITTEE ON TOXICITY OF CHEMICALS IN FOOD, CONSUMER PRODUCTS AND THE ENVIRONMENT

COT Statement on Pyrrolizidine Alkaloids in Food

COT Statement 2008/06

October 2008

In line with COC65 and EFSA66 opinions, the Committee considered that MOEs of 10,000 and above, corresponding to doses of up to 0.007 $\mu\text{g /kg b.w./day}$, would be unlikely to be of concern.

Reducing SED from full body to general purpose product –

$\text{SED} = 0.0002 \times 0.04 / 0.13 = 0.00006 \text{ } \mu\text{g /kg b.w./day}$

INCI Name PANAX GINSENG ROOT EXTRACT

Description

Panax Ginseng Root Extract is an extract of the roots of the Ginseng, Panax ginseng, Araliaceae

INN Name

Ph. Eur. Name

CAS # 84650-12-4

EC # 283-493-7

Chemical/IUPAC Name

Cosmetic Restriction

Other Restriction(s)

Functions EMOLLIENT, SKIN PROTECTING, TONIC

SED = 0.04 mg/kg bw/ day (to extract)

MOS information / References

NOAEL >100 mg/kg bw / day

MOS =100/0.04 = >2500

Read across from The American Journal of Chinese Medicine, January 2011, Vol. 39, No. 04 : pp. 779-788 Two-Year Toxicity and Carcinogenicity Studies of Panax ginseng in Fischer 344 Rats and B6C3F1 Mice Po-Chuen Chan, John C. Peckham, David E. Malarkey, Grace E. Kissling, Gregory S. Travlos, and Peter P. Fu

J Acupunct Meridian Stud 2008;1(2):121-127 - Toxicological Study on MUNOPHIL, Water Extract of Panax ginseng and Hericium erinaceum in Rats
Il-Dong Park, Hwa-Seung Yoo, Yeon-Weol Lee, Chang-Gue Son, Min Kwon, Ha-Jung Sung, Chong-Kwan Cho

INCI Name CHAMOMILLA RECUTITA FLOWER EXTRACT

Description

Chamomilla Recutita Flower Extract is an extract of the flowerheads of the matricaria, Chamomilla recutita (L.), Compositae

CAS # 84082-60-0

EC # 282-006-5

Functions MASKING, SKIN CONDITIONING

SED = 0.04 mg/kg bw/ day (to extract)

MOS information

Taken widely as an infusion (chamomile tea) - Intake from diet is likely to be greater than from cosmetic use in this context - no safety concerns.

Extraction of essential oil component is likely to a small degree (based on max 5% EO component in starting material) leading to SED for essential oil component of <0.01 mg/kg bw/ day which is below the level of toxicological concern for this category of substance

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 = 0.40 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 = $450/0.40 = 1125$

INCI Name SODIUM PCA

CAS # 28874-51-3

EINECS/ELINCS # 249-277-1

Chemical/IUPAC Name Sodium 5-oxo-2-pyrrolidinecarboxylate

Functions HUMECTANT, SKIN CONDITIONING

SED = 0.40 mg/kg bw/ day

MOS information / References

Cosmetic Ingredient Review Expert Panel. Final Report on the Safety Assessment for PCA and Sodium PCA. International Journal of Toxicology. 1999;18(Supplement 2).

These ingredients are recommended to be used in a concentration range of 0.2-4%.

Specific note - Should not be used in formulations that contain N-nitrosating agents – this formulation does not contain nitrosating agents.

INCI Name TOCOPHERYL ACETATE

CAS # 7695-91-2 / 58-95-7

EC # 231-710-0 / 200-405-4

Chemical/IUPAC Name 3,4-Dihydro-2,5,7,8-tetramethyl-2-(4,8,12-trimethyltridecyl)-2H-benzopyran-6-yl acetate

Functions ANTIOXIDANT, SKIN CONDITIONING

SCCS opinions •0494/01 - Opinion concerning The Use of alpha-Tocopherol Acetate in Cosmetic Products

SED = 0.04 mg/kg bw/ day

MOS information / References

NOAEL: 800-1600 IU/day (540 – 970 mg d- α -tocopherol equivalents/day)

Key studies: Gillilan et al. (1977); Meydani et al. (1996); Stephens et al. (1996)

MOS = 540/0.04 = >13500

INCI Name DECYLENE GLYCOL

CAS # 1119-86-4

EC # 214-288-2

Chemical/IUPAC Name 1,2-Decanediol

Cosmetic Restriction

Other Restriction(s)

Functions SKIN CONDITIONING

SED = 0.04 mg/kg bw/ day

MOS information / References

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 = $450/0.04 = 11250$

INCI Name ALCOHOL DENAT.

Description Ethanol denatured in accordance with Customs and Excise regulations

Functions ANTIFOAMING, ANTIMICROBIAL, ASTRINGENT, MASKING, SOLVENT, VISCOSITY CONTROLLING

SED = 0.04 mg/kg bw/ day

MOS information

At 0.04 mg/kg bw ethanol exposure is significantly lower than widespread EU published values for safe levels of consumption. No toxicological significance in this context

INCI Name DISODIUM EDTA

INN Name edetate disodium

Ph. Eur. Name natrii edetas

CAS # 139-33-3 --- 6381-92-6

EC # 205-358-3

Chemical/IUPAC Name Disodium dihydrogen ethylenediaminetetraacetate

Cosmetic Restriction

Other Restriction(s)

Functions CHELATING, VISCOSITY CONTROLLING

SED = 0.40 mg/kg bw/ day

MOS information / References

NOAEL of 500 mg/kg/day is derived for Na₃EDTA (Scientific Committee On Toxicity, Ecotoxicity and the Environment (CSTEE) opinion on the results of the risk assessment of: tetrasodium ethylenediamine tetraacetate (Na₄EDTA) CAS n°: 64-02-8 and edetic acid (EDTA) cas no. 60-00-4

Calculated MOS = 500/0.40 = 1250

INCI Name ISOPROPYL MYRISTATE

INN Name isopropyl myristate

Ph. Eur. Name isopropylis myristas

CAS # 110-27-0

EINECS/ELINCS # 203-751-4

Chemical/IUPAC Name Tetradecanoic acid, isopropyl ester

SED 10.00 mg/kg bw/ day

MOS information / References

Isopropyl Myristate is the iso-propyl ester of myristic acid . Myristic acid is a common component of edible tri-glycerides and the iso-propyl ester has a similar toxicological profile.

CIR approved to 82% (JACT 1(4):55-80, 1982 confirmed 06/02 IJT 24(S1):63-67, 2005)

Present in this formulation at max 25%, and assuming CIR MOS of Minimum 100

MOS = 82 / 25 * 100 = 328

Note - European Union (EU) ADI of 2.4 mg/kg for Isopropyl alcohol

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 2.00 mg/kg bw/ day

MOS information / References

MOS – based on lowest value of 1200mg / kg/bw /2.00 = >600

Reduction factor from oral route to dermal = 10. MOS = 6000

SIDS Initial Assessment Report for Chemical Name :Propylene glycol

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

INCI Name CERA ALBA

Description Beeswax. The wax obtained from the honeycomb of the bee. It consists primarily of myricyl palmitate, cerotic acid and esters and some high-carbon paraffins

Ph. Eur. Name cera alba / cera flava

CAS # 8012-89-3

EINECS/ELINCS # 232-383-7

Functions EMOLLIENT, EMULSIFYING, FILM FORMING, PERFUMING

SED = 2.00 mg/kg bw/ day

MOS information / References

Beeswax is essentially inert - it is used as a food additive without restriction and is eaten (honeycomb) widely without report of toxicological concern - beeswax must be refined appropriately before use in cosmetic formulations in order to minimise potential for microbial growth – supplier specification indicates this is acceptable – see Annex 1

Parfum

Chemical / ingredient classification - Perfume and aromatic compositions and their raw materials

With regard to the use of commercial fragrance preparations, the approach generally taken with regard to safety in use determination is the review of supporting documentation provided by the ingredient supplier. Specifically a review of International Fragrance Association (IFRA) certification which is based on the IFRA compliance program and is derived from information for individual fragrance components as follows -

The exposure (usage concentration, variety of use, volume of use) and chemical composition which is used in the preparation of a comprehensive dossier on the material including all available safety data . This dossier is reviewed by a panel of independent experts (RIFM), to make sure that there is no risk/danger for the consumer; if the safety assessment does not support the current use, the Panel instructs IFRA to issue a Standard, prepared in accordance with the Expert Panel's instructions and conclusions. Standards are used to set safe levels of use in 13 specific categories of consumer product

A review of the IFRA certification for the fragrance indicates that usage at 15.4% is tolerated in this category of product (Class 5 – fragrance is present well below this level, at 0.1%, indicating acceptable margins of safety in use

Women's Facial Creams/Facial Make-up/Facial Wipes. Facial Masks, Hand Cream, Baby Powder &Talc Hair permanent & other hair chemical treatments (e.g. relaxers) but not hair dyes Wipes or refreshing tissues for Face, Neck, Hands, Body Dry shampoo or waterless shampoo	Class 5
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Product Sensitisation potential due to fragrance components

IFRA standard recommendations for the limits of potentially allergenic materials are based on established No Expected Sensitization Induction Level (NESIL) – at 0.1%, this fragrance is unlikely to cause sensitisation.

Phototoxicity potential

IFRA standard recommendations for the limits of potentially allergenic materials based on established No Expected Sensitization Induction Level (NESIL) – at 0.1% phototoxicity is unlikely.

The fragrance manufacturer has declared the presence of the following substances governed by REGULATION (EC) No 1223/2009, specifically **Annex III – List of substances which cosmetic products must not contain except subject to the restrictions laid down – In the case of the following, declaration of the presence of these substances, if present above 0.001% in the final product must be included on product ingredient labelling.**

Hexyl Cinnamal
Hydroxycitronellal
Linalool
Citronellol
Geraniol
Eugenol

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%
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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 – II010415 CJNC 20059

Product: Night Cream

Manufacturer's Reference 20059

Product Category - Cosmetic Emulsion

Manufacturer XXXX

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 leave on 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 0.001% must be declared on the product labelling.

Hexyl Cinnamal
Hydroxycitronellal
Linalool
Citronellol
Geraniol
Eugenol

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) $SED = I \times A / 60$

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

01/04/15

Chartered Chemist, Chartered Scientist

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

England

Scott Grainger MSc BSc (Hons) CSci CChem MRSC

22, Rosemount Road, Bishop Auckland, County Durham DL14 6SX United Kingdom
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



Royal Society of Chemistry
Incorporated in England 1847
Incorporated by Royal Charter 1880
Pursue the Matter the Queen

President

A handwritten signature in cursive script, likely belonging to the President of the Royal Society of Chemistry.

Registrar

A handwritten signature in cursive script, likely belonging to the Registrar of the Royal Society of Chemistry.

Date of Award

14 November 2008

RSC Membership Number

378846

The certificate is issued subject to the provisions of the Charter and By-Laws
Registered Charity Number 207880



SAFETY DATA SHEET NIGHT CREAM

This SDS is not mandated under REACH Regulation (EC) No 1907/2006 and is provided for information only.

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

1.1. Product identifier

Product name NIGHT CREAM
Product number TBNIGHCREA

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

Contact person +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

Comment This product does not meet the criteria for classification in any hazard class according to Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures.

Physical hazards Not Classified

Health hazards Not Classified

Environmental hazards Not Classified

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

2.2. Label elements

Hazard statements NC Not Classified

2.3. Other hazards

NIGHT CREAM

SECTION 3: Composition/information on ingredients

3.2. Mixtures

PROPYLENE GLYCOL	1-5%
CAS number: 57-55-6	EC number: 200-338-0
Classification	
Not Classified	

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

SECTION 4: First aid measures

4.1. Description of first aid measures

General information	No specific recommendations.
Inhalation	Move affected person to fresh air at once. Get medical attention if any discomfort continues.
Ingestion	If necessary, rinse mouth and provide fresh air. Get medical attention if any discomfort continues.
Skin contact	Wash skin thoroughly with soap and water.
Eye contact	Rinse immediately with plenty of water. Remove any contact lenses and open eyelids wide apart. 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

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

Notes for the doctor	No specific recommendations.
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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

Hazardous combustion products Oxides of carbon.

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. In case of spills, beware of slippery floors and surfaces.

6.2. Environmental precautions

Environmental precautions No negative effects on the aquatic environment are known.

NIGHT CREAM

6.3. Methods and material for containment and cleaning up

Methods for cleaning up Contain and absorb spillage with sand, earth or other non-combustible 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

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Usage precautions Handle all packages and containers carefully to minimise spills.

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.

Storage class Unspecified storage.

7.3. Specific end use(s)

SECTION 8: Exposure Controls/personal protection

8.1. Control parameters

Occupational exposure limits

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

WEL = Workplace Exposure Limit

8.2. Exposure controls

Protective equipment



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.

NIGHT CREAM

SECTION 9: Physical and Chemical Properties

9.1. Information on basic physical and chemical properties

Appearance	Liquid.
Colour	White/off-white.
Odour	Characteristic.
pH	pH (concentrated solution): ~ 6.5 @ 20°C

9.2. Other information

SECTION 10: Stability and reactivity

10.1. Reactivity

10.2. Chemical stability

Stability	Stable at normal ambient temperatures.
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10.3. Possibility of hazardous reactions

Possibility of hazardous reactions	Will not polymerise.
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10.4. Conditions to avoid

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

Materials to avoid	Strong oxidising agents. Strong acids. Strong alkalis.
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10.6. Hazardous decomposition products

Hazardous decomposition products	Thermal decomposition or combustion products may include the following substances: Oxides of carbon. Oxides of nitrogen.
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SECTION 11: Toxicological information

11.1. Information on toxicological effects

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

NIGHT CREAM

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

General information Waste is suitable for incineration.

Disposal methods Dispose of waste to licensed waste disposal site in accordance with the requirements of the local Waste Disposal Authority.

SECTION 14: Transport information

General The product is not covered by international regulations on the transport of dangerous goods (IMDG, IATA, ADR/RID).

14.1. UN number

Not applicable.

14.2. UN proper shipping name

Not applicable.

14.3. Transport hazard class(es)

No transport warning sign required.

14.4. Packing group

Not applicable.

14.5. Environmental hazards

Environmentally hazardous substance/marine pollutant
No.

14.6. Special precautions for user

Not applicable.

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.

NIGHT CREAM

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

SECTION 16: Other information

Key literature references and sources for data	European Chemicals Agency, http://echa.europa.eu/
Issued by	Regulatory Manager
Revision date	15/07/2015
Revision	0

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

NIGHT CREAM

Analysis Description	Minimum Value	Maximum Value	Description
Appearance			Viscous cream
Colour			White to off white
Odour			characteristic
pH @ 20 Degrees C	6.0	7.0	
Viscosity RVT 20C SpindleC 10RPM	30000	60000	
Total Viable Count cfu/g		100	<100
Gram Negative Bacteria			Absent

Issue Date: 03/03/15

Revision: 1

Revision Date: 10/11/14

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 VEGAN SUITABILITY

NIGHT CREAM

The above product **does contain** an animal substance: Beeswax

During production, storage and transport there is no contact with any other extracts of animal origin.

We therefore declare that the product is **NOT** suitable for vegans but is suitable for Vegetarians.