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| COSMETIC PRODUCT SAFETY REPORT (Compliance with EU Regulation 1223/2009) |
|  |
| Blue Stratos Pre Electric Shave Lotion |

Authored by Kostas Kyriakides BSc CChem MRSC

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**Cosmetics Safety Assessor**

**COSMETIC PRODUCT SAFETY REPORT (Compliance with EU Regulation1223/2009)**

**Company (‘Responsible Person’): Jonarve Ltd.**

John Peace, Managing Director

**Address: Unit 10, Castle Park Industrial Estate, Flint, Clwyd, CH6 5XA, UK**

**Company Telephone No.:**  **01352 730026**

**Product Name:** Blue Stratos Pre Electric Shave Lotion

**Category (application of product):** Pre Electric Shave Lotion

**Our Reference No.:** KK30-28/1

**Formula Code: FF 701/1**

**Date of Report: 25 October 2013**

**PART A: Cosmetic product safety information**

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

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **INCI Name** | **% Conc.** | **% Active** | **Final %** | **CAS No.** | **Einecs No.** | **Cosmetic**  **Restriction** |
| Alcohol Denat. | 77.716 | 100 | 77.716 | 64-17-5 | 200-578-6 | - |
| Isopropyl Myristate | 15.000 | 100 | 15.000 | 110-27-0 | 203-751-4 | - |
| Parfum | 0.540 | 100 | 0.540 | - | - | - |
| Aqua (Water) | 6.544 | 100 | 6.544 | 231-791-2 | 231-791-2 | - |
| Benzophenone-2 | 0.200 | 100 | 0.200 | 131-55-5 | 205-028-9 | - |

INCI LISTING:

Alcohol Denat., Isopropyl Myristate, Aqua, Parfum, Benzophenone-2, Linalool, Limonene.

Coumarin, Evernia Furfuracea (Treemoss) Extract, Geraniol, Citral, Hydroxycitronellal,

Benzyl Salicylate.

**Allergens specified in the 7th Amendment to the EU Cosmetics Directive 76/678 present in the fragrance which must to be declared on the pack are listed below:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **INCI Name** | **% Conc.** | **CAS No.** | **Einecs No.** | **Cosmetic**  **Restriction** |
| Linalool | 0.042363 | 78-70-6 | 201-134-4 | III/84 |
| Limonene | 0.030429 | 5989-27-5 | 227-813-5 | III/88 |
| Coumarin | 0.009823 | 91-64-5 | 202-086-7 | III/77 |
| Evernia Furfuracea (Treemoss) Extract | 0.008640 | 90028-67-4 | 289-860-8 | III/92 |
| Geraniol | 0.005962 | 106 - 24 -1 | 203-377-1 | III/78 |
| Citral | 0.004930 | 5392-40-5 | 226-394-6 | III/70 |
| Hydroxycitronellal | 0.004909 | 107-75-5 | 203-518-7 | III/72 |
| Benzyl Salicylate | 0.003434 | 118-58-1 | 204-262-9 | III/75 |

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

**SPECIFICATION**

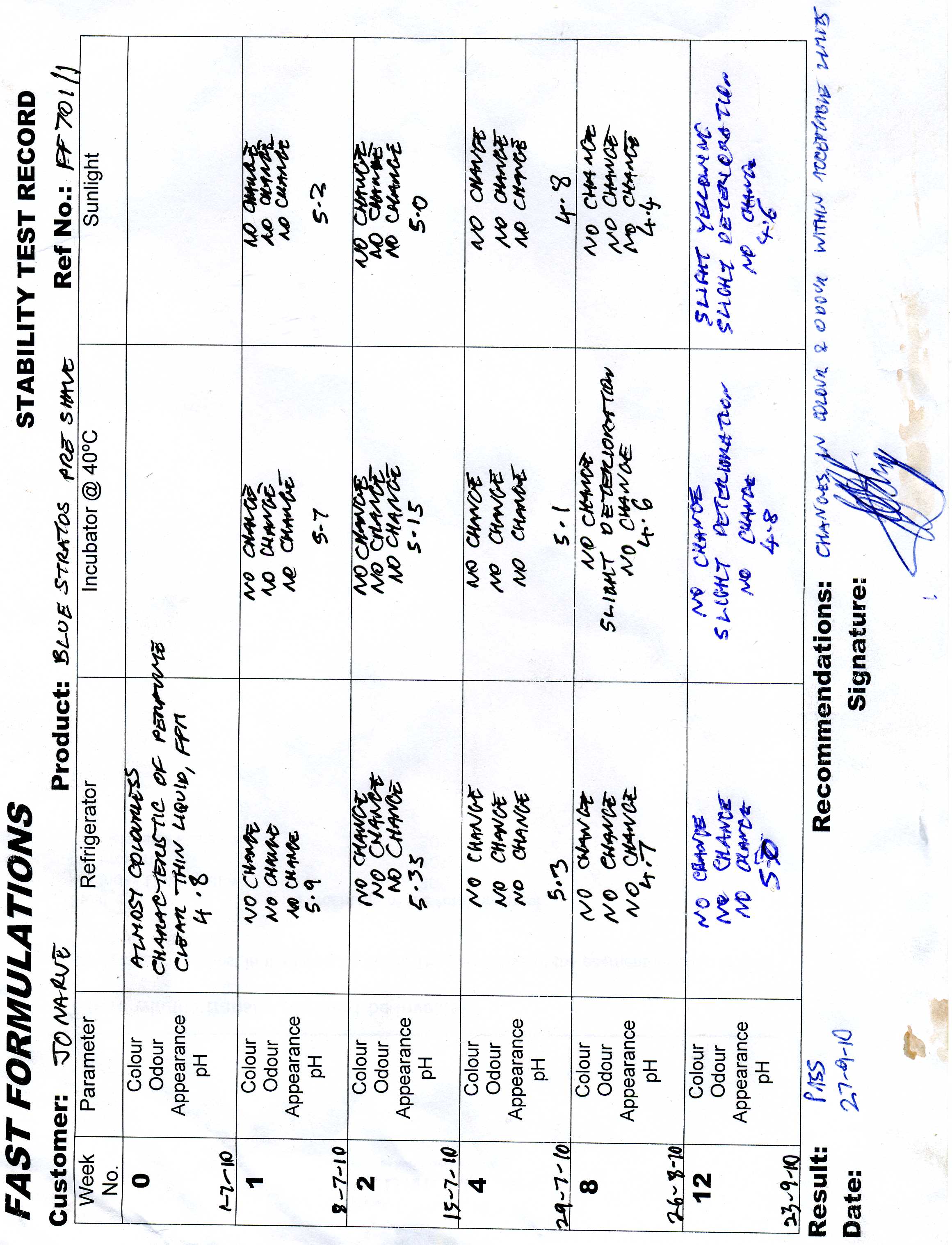
**JONARVE BLUE STRATOS PRE-ELECTRIC SHAVE LOTION**

**LAB REFERENCE: FF701.1**

|  |  |
| --- | --- |
| **COLOUR** | CLEAR, COLOURLESS TO YELLOW LIQUID |
| **ODOUR** | AS STANDARD |
| **pH** | NOT APPLICABLE |
| **VISCOSITY** | NOT APPLICABLE |
| **SPECIFIC GRAVITY** | 0.815 – 0.825 |

**The product has competed 12 weeks stability testing at 5’ C, 30’C,**

**40’ C, Day Light and Room temperature with satisfactory results.**

****

**3. Microbiological quality** **of the cosmetic product**

Not applicable as product is not susceptible to bacterial contamination due to the high level of ethanol content of 77.716%

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

The product is packed in a Cosmetic grade glass bottle with a sprinkler neck and a screw cap. There are not expected to be any issues of stability or interaction between the packaging and the product.

**5. Normal and reasonably foreseeable use**

Product will be used by adult males to lubricate the skin and soften facial hair before shaving.

The product is applied to the face and neck using the hands.

A small quantity of the product is unavoidably inhaled during applications but this is minimal as the application process is complete in a matter of seconds.

**6. The targeted (or exposed) population(s).**

Adult Male (aged 16+)

**7. Exposure to the substances and Margins of Safety**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **INCI Name** | **% Conc.** | **SED mg/kg/Day** | **NOAEL**  mg/kg/BW | **Critical toxicity Effect** | **Margin of Safety** |
| Alcohol Denat. | 77.716 | 16.8379 | 10,600 | hazardous under OSHA regulations | 629 |
| Isopropyl Myristate | 15.000 | 3.2499 | 5,000 | - | 1,538 |
| Benzophenone-2 | 0.200 | 0.0433 | 1,225 | Acute toxicity, Oral (Category 4) | 28,290 |

**The fragrance has been certified by its manufacturer as being compliant with IFRA code of practice and was not assessed independently by the safety assessor.**

**Calculation of Margin of Safety**

Assume skin absorption A % under in use conditions (if no data assume 100 % dermal absorption is assumed). For Ethanol a conservative estimate of 20% dermal absorption is assumed.

Calculated Daily exposure mg/kg/day: 21.666 mg/kg/bw/day (Based on SCCP calculation)

Retention factor 1 Typical body weight of human (kg) **60**

SED (mg/kg.bw/day) = Daily Exposure to product mg/kg bw/day X % Ingredient/100 X % Max Absorption through the skin/100

Margin of Safety MOS= NOAEL (should be>100)

SED

The NOAEL used for calculation is generally derived from a 90 oral day study in the

rat, but the whole toxicological profile is also be taken into account.

Schaefer and Redelmeier [6] estimated the percutaneously absorbed dose of ethanol from a topical application. Using Scheuplein and Blank's [54] permeability coefficient, a skin exposure area of 1000 cm2, and assuming a maximum exposure period after topical application of significantly less than 1 hr., they estimated that the percutaneous absorption of ethanol from a 70% solution would be approximately 100 mg. Schaefer and Redelmeier equated this amount of ethanol to that present in 1.5 ml of wine containing 10% (v/v) ethanol, and therefore concluded that "skin exposure to ethanol in cosmetics is not a safety concern".

Hence on 200 sq.cm exposed skin it is estimated that there would be 20 mg of ethanol absorbed in a single application and 80 mg per day (assuming 4 applications/day).

[6] Schaefer H, Redelmeier TE. Safety assessment of cosmetics. In: Schaefer H, Redelmeier TE, editor. Skin Barrier: Principles of Percutaneous Absorption. Basel: Karger; 1996. pp. 237–249.

[54] Scheuplein RJ, Blank IH. Mechanism of percutaneous absorption. IV. Penetration of nonelectrolytes (alcohols) from aqueous solutions and from pure liquids. J Invest Dermatol. 1973;60:286–296. [PubMed]

**8. Toxicological profile of the substances**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  | ***INGREDIENT TOXICOLOGICAL ASSESSMENT*** |  |  |
| **INCI name** | **% Conc.in product** | **Toxicological Summaries** | **Classification**  **\*\*** | **Rest-riction \*\*\*** |
| Aqua | 6.544 | Aqua (Water). 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. Oral Rat LD50: >90 mL/kg. [CAS: 7732-18-5; EINECS: 231-791-2]. Function: Solvent. The actual or estimated LD50 value: 100,000 mg/kg bodyweight. AICS status (NICNAS Australia): AICS Compliant.**\***  A ubiquitous chemical substance that is the basis for all known forms of life. Use in consumer products is not expected to result in any acute or chronic toxicity following typical exposure. | Unclassified | - |
| Alcohol Denat. | 77.716 | Alcohol Denat. Ethanol is used in our cleaning products as a solvent to keep in  solution some ingredients. It is a clear, colourless alcohol, produced by fermentation of sugars when used for alcoholic beverage. Ethanol is not harmful to aquatic organisms. Acute toxicity (i.e., L(E)C50) for several algae, invertebrates and fish species tested was greater than approximately 1000 mg/ l. Chronic toxicity (i.e., NOEC) for algae, invertebrates and fish was greater than 280 mg/ l. Ethanol is widely recognized as being readily biodegradable in the environment as it is both a metabolite of and nutrient for microbes. There are no persistent metabolites formed during biodegradation. Ethanol does not pose much of a threat when applied topically. Coming in contact with the skin will do nothing but dry it out and sterilize it. Spilt on a cut, it will hurt, but it will also prevent infection. [CAS: 64-17-5; EINECS: 200-578-6]. Function: Ethanol denatured in accordance with Customs and Excise regulations. The actual or estimated LD50 value: 10,600 mg/kg body weight. AICS status (NICNAS Australia): AICS Compliant. Oral LD50 value (rat): 10,600 and 7,060 mg/kg; (mouse): 3,450 mg/kg; (rabbit): 6,300 mg/kg. Comedogenic value: 0. CIR: Maximum "as used" concentration for safe as used conclusion: up to 99%. Concentration or other limitation on use for safe with qualifications conclusion: denatured with t-Butyl Alcohol, Denatonium Benzoate, Diethyl Phthalate, or Methyl Alcohol. **\***  Dermal: No acute dermal toxicity was reported in a study in rabbits, LDL0=20,000 mg/kg (Monick, 1968) and although this study is not experimentally robust, the result is consistent with the finding that ethanol uptake through intact skin is poor.  The half-life for the evaporation of ethanol from skin is 11.7 seconds (Pendlington, 2001) which implies that continuous immersion would be required for there to be any potential for dermal absorption. OECD SIDS (UNEP PUBLICATIONS) | F;R11 | - |
| Isopropyl Myristate | 15.000 | Isopropyl Myristate (IPM) has produced slight irritation of human skin, mild irritation of the rabbit eye and moderate irritation of rabbit skin. Other local effects have included nasal and lung irritation during inhalation of aerosols in monkeys and rats, acne development after application to rabbit skin, and increased permeability of human skin to certain other substances. Skin sensitization reactions have only rarely been reported, and no sensitizing potential has been detected in studies involving a large number of volunteers with normal skin. IPM was of low acute toxicity to laboratory animals by the oral and dermal routes. Repeated administration produced slight effects on the liver and blood in rats treated orally and in rabbits given skin applications. No evidence of skin carcinogenicity was seen in mice or a small number of rabbits, but one brief report suggested that IPM can promote the action of a known skin carcinogen in mice. An Ames bacterial test gave no evidence of mutagenicity. [CAS: 110-27-0; EINECS: 203-751-4].Function: Binding/ emollient/ solvent/ skin conditioning. The actual or estimated LD50 value: 5,000 mg/kg body weight. AICS status (NICNAS Australia): AICS Compliant. Oral LD50 value (rat):5,000 mg/kg; (mouse): 49,700 mg/kg. Comedogenic value: 5 (at 5% dilution value 3).Isopropyl Myristate. CIR: Maximum "as used" concentration for safe as used conclusion: up to 78%**\*** |  |  |
| Parfum | 0.540 | Parfum (Fragrance). All Fragrance allergens have been be calculated and compared to the limits imposed by the IFRA QRA category for the product. All values fall below the IFRA limit. The fragrance is used at 0.540 and has been assessed by the supplier as suitable for this type of formulation at this level and conforms to the 46th Amendment of the International Fragrance Association (IFRA) guidelines. The IFRA guidelines are guidelines for the safe use of fragrance ingredients and are based on an evaluation by independent experts of all toxicological and dermatological data relating to the ingredient concentrations and exposure to the final product. The Fragrance Material, which as supplied is classified as irritating to the skin and eyes and may cause sensitisation by skin contact. Resultantly prolonged, repeated exposure to this material may result in localised adverse reactions on certain individuals. Available information suggests the material is unlikely to cause significant System Toxicity following exposure.    See allergen declaration and IFRA Certificate below. | R38  R43,  R50/53  R65 | - |
| Benzophenone-2 | 0.200 | Benzophenone-2. The Food and Drug Administration (FDA) has approved the use of Benzophenone-8 as a safe and effective, Over-the-Counter (OTC) drug sunscreen ingredient at concentrations up to 3%. When used as a sunscreen ingredient in the United States, Benzophenone-8 must be called Dioxybenzone. The safety of Benzophenone-2, -6 and -8 has been assessed by the Cosmetic Ingredient Review (CIR) Expert Panel. The CIR Expert Panel evaluated the scientific data and concluded that these ingredients were safe for use in cosmetics and personal care products. In 2002, the CIR Expert Panel considered available new data on Benzophenones and reaffirmed the above conclusion. [CAS: 131-55-5; EINECS: 205-028-9]. Function: UV absorber. The actual or estimated LD50 value: 1,220 mg/kg body weight. AICS status (NICNAS Australia): AICS Compliant. Oral LD50 value (rat): 1,225 and 1,220 mg/kg. CIR: Maximum "as used" concentration for safe as used conclusion: up to 6%.**\***   |  |  | | --- | --- | | |  | | --- | | **Biocidal Products Directive (Directive 98/8/EC)  Information:** | |  |  |  | | --- | --- | | |  | | --- | | There is no information in ESIS for this substance with respect to the BPD. | |  |  |  | | --- | --- | | |  | | --- | | **Classification and Labelling  Information:** | |  |  |  | | --- | --- | | |  | | --- | | This substance is not classified in the Annex I of Directive 67/548/EEC as such, but it may be included in one of the group entries. An example of a group entry is 033-002-00-5 'arsenic compounds with the exception of those specified elsewhere in this Annex'. Substances not listed either individually or in group entries must be self classified.. | |  |  |  | | --- | --- | | |  | | --- | | **Export and Import of Dangerous Chemicals (Regulation (EC) No 689/2008)  Information:** | |  |  |  | | --- | --- | | |  | | --- | | Benzophenone-2 | |  |  |  | | --- | --- | | |  | | --- | | **HPV-LPV (High and Low Production Volume) Information:** | |  |  |  | | --- | --- | | |  | | --- | | **LPV Chemical** | |  |  |  | | --- | --- | | |  | | --- | | **IUCLID & OECD Chemical Data Sheets and Export Files  Information:** | |  |  |  | | --- | --- | | |  | | --- | | Not available for this substance. | |  |  |  | | --- | --- | | |  | | --- | | **European Priority Lists and Risk Assessment (Council Regulation (EEC) No 793/93)  Information:** | |  |  |  | | --- | --- | | |  | | --- | | This substance is not listed in a priority list (as foreseen under Council Regulation (EEC) No 793/93 on the evaluation and control of the risks of existing substances.). | |  |  | | --- | |  | | R22  R36/37/38  S-phrase(s)  S26  S36 |  |

**\****Dweck, Anthony (2011-09-03). Handbook of Cosmetic Ingredients - their use, safety and toxicology (Kindle Locations 495-508). Dweck Data. Kindle Edition.*

*\*Classification listed is from TABLE3.1 of Regulation (EC) No 1272/2008 and classification (67/548/EEC)*

*\*\*Restrictions(s) listed (Annexe No. / Ref No.) of Regulation (EC) No. 1223/2009 Cosmetic Products*

**9. Purity of Ingredients**

We have considered impurities in the ingredients that may affect safety, and are satisfied that the ingredients specified to be used in this product are of Cosmetic or Pharmaceutical grade from established cosmetic ingredient suppliers to satisfy Annex III limits. The process water used is purified and suitable for toiletries and cosmetic manufacture according to industry standards.

The fragrance has been assessed and is certified as suitable for this product according to IFRA Regulations.



**Alcohol:**

Alcohol Denat. (Ethyl alcohol) is a straight chain alcohol which is volatile, flammable, colorless liquid.

Molecular formula: C2H6O

Molar mass 46.07 g mol−1

Exact mass 46.041864814 g mol−1

Density 0.789 g cm−3

Melting point −114 °C, 159 K, -173 °F

Boiling point 78 °C, 351 K, 172 °F

Vapor pressure 5.95 kPa (at 20 °C)

Acidity (p*K*a) 15.9[2]

Basicity (p*K*b) -1.9

Refractive index (*n*D) 1.36

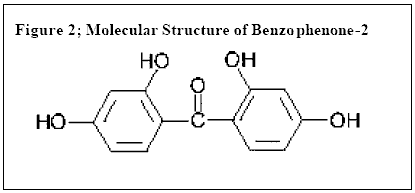
Viscosity 0.0012 Pa s (at 20 °C)

The alcohol is synthetic and controlled for use in the cosmetics industry. It is denatured in accordance with Customs and Excise requirements. Impurities present according to the manufacturers specifications are 100 ppm of Aldehydes & Ketones as Acetaldehyde. Specifications attached. The purity specification for this grade is 0.02% maximum Acetaldehyde, and complies with the CTPA requirements for cosmetic use.



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**Benzophenone-2**

[](http://www.google.co.uk/url?sa=i&rct=j&q=&esrc=s&frm=1&source=images&cd=&cad=rja&docid=jqgeAu6HfyoABM&tbnid=5Kc3kPhUYOZKhM:&ved=0CAUQjRw&url=http://www.connock.co.uk/articles_uv.htm&ei=176oUdn7Aci7O83tgJAF&bvm=bv.47244034,d.ZWU&psig=AFQjCNFhMbayGxf27mZHuti6riLHSgCCzw&ust=1370099789709623)

**1.1**

**IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING**

**Product identifiers**

Product name

Product Number T16403

Brand

CAS-No. 131-55-5

2,2 ′ ,4,4 ′ -Tetrahydroxybenzophenone

**1.2**

**Relevant identified uses of the substance or mixture and uses advised against**

**2.2**

**HAZARDS IDENTIFICATION**

**Classification of the substance or mixture**

**Classification according to Regulation (EC) No 1272/2008 [EU-GHS/CLP]**

Acute toxicity, Oral (Category 4)

Skin irritation (Category 2)

Eye irritation (Category 2)

Specific target organ toxicity - single exposure (Category 3)

**Classification according to EU Directives 67/548/EEC or 1999/45/EC**

Harmful if swallowed. Irritating to eyes, respiratory system and skin.

**Label elements**

**Labelling according Regulation (EC) No 1272/2008 [CLP]**

Pictogram http://img.guidechem.com/msdsimg/1358216557750.jpg

Hazard statement(s): H302 ,H315, H319, H335

Precautionary statement(s) : P261, P305 + P351 + P338

Warning : Harmful if swallowed. Causes skin irritation. Causes serious eye irritation.

May cause respiratory irritation. Avoid breathing dust/ fume/ gas/ mist/ vapours/ spray.

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

**According to European Directive 67/548/EEC as amended.**

Hazard symbol(s) http://img.guidechem.com/msdsimg/1358216557765.jpg

R-phrase(s) R22 R36/37/38

S-phrase(s) S26 S36

**Other hazards** - none

**COMPOSITION/INFORMATION ON INGREDIENTS**

**Substances**

Formula C13H10O5

Molecular Weight 246,22 g/mol

Component

**2,2',4,4'-tetrahydroxybenzophenone**

CAS-No. 131-55-5

EC-No. 205-028-9

**FIRST AID MEASURES**

**Description of first aid measures**

**General advice**

Consult a physician. Show this safety data sheet to the doctor in attendance.

**If inhaled**

If breathed in, move person into fresh air. If not breathing, give artificial respiration. Consult a physician.

**In case of skin contact**

Wash off with soap and plenty of water. Consult a physician.

**In case of eye contact**

Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.

**If swallowed**

Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.

**Most important symptoms and effects, both acute and delayed**

To the best of our knowledge, the chemical, physical, and toxicological properties have not been

thoroughly investigated.

**Indication of any immediate medical attention and special treatment needed**

no data available

**FIREFIGHTING MEASURES**

**Extinguishing media**

**Suitable extinguishing media**

Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

**Special hazards arising from the substance or mixture**

Carbon oxides

**Advice for firefighters**

Wear self contained breathing apparatus for fire fighting if necessary.

**Further information**

no data available

**ACCIDENTAL RELEASE MEASURES**

**Personal precautions, protective equipment and emergency procedures**

Use personal protective equipment. Avoid dust formation. Avoid breathing vapors, mist or gas. Ensure

adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust.

**Environmental precautions :**Do not let product enter drains.

**Methods and materials for containment and cleaning up :**Pick up and arrange disposal without creating dust. Sweep up and shovel. Keep in suitable, closed containers for disposal.

**HANDLING AND STORAGE**

**Precautions for safe handling :**Avoid contact with skin and eyes. Avoid formation of dust and aerosols.

Provide appropriate exhaust ventilation at places where dust is formed. Normal measures for preventive fire

protection.

**Conditions for safe storage, including any incompatibilities:** Store in cool place. Keep container tightly closed in a dry and well-ventilated place.

**EXPOSURE CONTROLS/PERSONAL PROTECTION :** Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.

**Personal protective equipment**

**Eye/face protection:** Safety glasses with side-shields conforming to EN166 Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

**Skin protection :**Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices.

Wash and dry hands.

The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it.

**Body Protection :**Complete suit protecting against chemicals, The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

**Respiratory protection :**For nuisance exposures use type P95 (US) or type P1 (EU EN 143) particle respirator.For higher level protection use type OV/AG/P99 (US) or type ABEK-P2 (EU EN 143) respirator cartridges. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

**PHYSICAL AND CHEMICAL PROPERTIES**

**Information on basic physical and chemical properties**

Form: solid

Melting point/range: 198 - 200 °C - lit.

Water solubility

Partition coefficient: n- octanol/water

**Possibility of hazardous reactions ;**no data available

**Incompatible materials ;**Strong oxidizing agents, Strong bases

**Hazardous decomposition products**

Other decomposition products - no data available

**TOXICOLOGICAL INFORMATION**

**Information on toxicological effects**

**Acute toxicity** LD50 Oral - rat - 1.220 mg/kg

**Skin corrosion/irritation**

**Serious eye damage/eye irritation**

Eyes - rabbit - Moderate eye irritation

**Respiratory or skin sensitization** no data available

**Germ cell mutagenicity**

Genotoxicity in vitro - mouse - lymphocyte

Cytogenetic analysis

Genotoxicity in vitro - mouse - lymphocyte

Sister chromatid exchange

**Carcinogenicity**

IARC: No component 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**

Inhalation - May cause respiratory irritation.

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

**Aspiration hazard** no data available

**Potential health effects**

**Inhalation:** **May be harmful if inhaled. Causes respiratory tract irritation.**

**Ingestion: Harmful if swallowed:**

**Skin: May be harmful if absorbed through skin. Causes skin irritation.:**

**Eyes:** Causes serious eye irritation

**Signs and Symptoms of Exposure :**To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

**Additional Information**

RTECS: DJ1892000

**ECOLOGICAL INFORMATION**

**Toxicity :**no data available

**Persistence and degradability :**no data available

**Bioaccumulative potential :**no data available

**Other adverse effects:**no data available

**DISPOSAL CONSIDERATIONS**

**Waste treatment methods**

**Product :**Offer surplus and non-recyclable solutions to a licensed disposal company. Contact a licensed professional waste disposal service to dispose of this material. Dissolve or mix the material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber.

**Contaminated packaging:** Dispose of as unused product.

**10. Undesirable effects and serious undesirable effects of cosmetic product**

On request, the suppliers have not provided information or reports known to them of Serious Undesirable Effects or Undesirable effects on this cosmetic product. If the supplier is aware of an abnormally high level of customer complaints the supplier must bring this to the attention of the Safety Assessor and submit this formulation for reassessment and notify the competent authorities of corrective actions taken.

**Effects of the product as applied on the skin**

The formulation may cause only minimal skin irritation even if exposure is prolonged and /or repeated. The product is unlikely to produce phototoxic reactions. Prolonged contact may cause skin dryness. There is unlikely to be any systemic reaction caused by absorption through the skin. We have calculated the margin of safety for all ingredients and found the safety factor to be acceptable. Our calculations had considered the total exposure of raw materials used in this product.

**Effect of the product on the eye**

The formulation may cause eye irritation during use of this product but it is not expected that this will last.

**Effect of ingestion**

The formulation as supplied is unlikely to cause any problems if ingested, especially as it is sold in small bottles. However, should it occur there is very little likelihood of any adverse effects due to the nature of the ingredients. The most probable outcome would be mild intoxication with possible stomach upset.

**Effect of Inhalation**

The risk of inhalation is considered unlikely. Any inhalation hazard will be due to the vapours of ethanol. Exposure to high concentrations may lead to symptoms such as nausea, dizziness, vomiting and uncoordinated behaviour similar to drunkenness. However it is not likely that the normal use of this product could lead to the inhalation of sufficient ethanol to cause these symptoms.

**11. Manufacturing Method**

1. All manufacturing equipment, mixing vessel and utensils are cleaned, sanitised and visually inspected.
2. This is a cold mix but using purified water at about 25/30C. All ingredients are accurately weighed using calibrated scales.
3. The Ethanol is added to the mixing vessel followed by Fragrance then Water and mixed until uniform. The SG is tested to ensure it is within the specification of 0.81 – 0.85
4. The product is aged for a specified period, chilled and for one day at 0’C-5’C and filtered.
5. Samples are taken to the Quality Control Laboratory for testing and approval.
6. The approved batch of product is transferred into suitable clean, labelled containers for filling into retail packs.

**12. Good Manufacturing Practice**

The product is produced by a reputable manufacturer, Jonarve Ltd UK who follow specific written cleaning, sanitation and control GMP procedures. Procedures also include microbiological control of raw materials, bulk and finished products, packaging material, personnel, equipment and preparation and storage rooms. GMP Statement from the managing Director attached:



**12. Information on the cosmetic product**

**Consumer Exposure**

Product will be used by adult males to lubricate the skin and soften facial hair before shaving.

The product is a liquid which is applied to the face and neck using the hands.

A small quantity of the product is unavoidably inhaled during applications but this is minimal as the application process is complete in a matter of seconds.Product Class: Pre Electric Shave Lotion

Period After Opening (PAO): 12 Months

IFRA Category: 4A

Frame Formulation Number: N/A

Targeted Population: Adult Male (Aged 16+) Mean Value 60 Kg

Amount per application: 0.65g (SCCP) No. Applications/day:1,

Skin surface area of application /sq.cm: 305 sq.cm Physical form: Liquid

Total amount applied per day:1300 mg

Part of body exposed to undiluted product: Neck, face, hands

Part of body exposed to diluted product: not diluted

Estimated Daily exposure mg/kg/day: 21.666 mg/kg/bw/day Dilution factor: N/A

Amount per unit area of skin per day mg/sq.cm/day: 0.0010

Retention Factor: 1

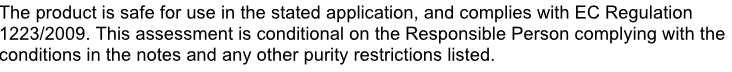
Exposure time Dilute: N/A Exposure time solvent inhalation: 1 min/day

Product pH: N/A

Specific Gravity 0.815-0.825

**PART B - Cosmetic product safety assessment**

1. **Assessment conclusion**

 The 26 potential allergens present in the perfume and essential oils have been calculated and declared where required.

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

Suggested warnings

Keep out of reach of children.

Flammable. Keep away from sources of ignition.

Use only as directed. For external use only

Not to be used on sore or damaged skin.

In the unlikely event of rash or irritation, discontinue use

Avoid contact with eyes

In the event of contact with the eye wash with copious quantity of water.

**3. Reasoning**

This type of formulation has been in common use in cosmetics over many years without any particular concerns. The Margin of Safety has been calculated and is 100 or over for all ingredients used and are hence considered safe.

The only potential skin sensitisers are contained in the fragrance. The total quantity of fragrance used is 0.540%, which is below the maximum safe limit stated in the IFRA certificate.

**The product does not contain any Nano materials**. The raw materials used to formulate this product are all well-known ingredients with a long history of safe use. They are used at levels that have been seen and assessed in similar products with no reports of irritation. The formulation is typical of its type and formulated by a company with a long history of safety and quality.

**4. Assessor’s credentials and approval of part B**

Kostas Kyriakides

Tel: 023922 40158

Mobile: 07913075262

Email: [kostasafe@gmail.com](mailto:kostasafe@gmail.com)

Cosmetics Safety Assessor

**Qualifications of the Safety Assessor**

The author of the report does not have a qualification in the theoretical and practical study of pharmacy, toxicology, medicine, but relevant qualifications and experience are given below.

Kostas Kyriakides BSc CChem MRSC Chartered Chemist, Member Royal Society of Chemistry, Member Society of Cosmetic Scientists. Worked in the personal care industry since 1970 as a QC chemist, R&D chemist, Laboratory Manager, Qualified Person (MHRA approved QP), Technical Manager, Head of Technical and Technical Consultant/ Cosmetics Safety Assessor.

**SAFETY ASSESSMENT FOR A COSMETIC PRODUCT**

**Our Reference No.: KK30-27**

**Product Name:** Blue Stratos Pre Electric 100ml

**Category (application of product):** Pre Electric Shave Lotion

**Our Reference No.:** KK30-28/1

**Formula Code: FF 701/1**

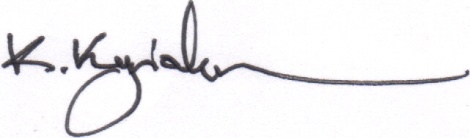
**Date of Report: 25 October 2013**

I, Kostas D. Kyriakides, a Chartered Chemist duly authorised according to the

Regulation of the European Parliament and of the Council on Cosmetic Products

2008/0035 (COD) dated 10 November 2009 (finally as 1223/2009),having taken into consideration the available information including formulation, the general toxicological profile of each ingredient used, the chemical structure, the CIR panel evaluation where available, the level of exposure and a total daily exposure calculated along with the margins of safety for each ingredient according to current state of scientific knowledge concludes that the product is not expected to cause damage to human health and can be marketed for the intended and foreseeable use as **Pre Electric Shave Lotion.** As a result of our evaluation the product has been classified as: **SAFE** for the proposed use without restrictions.

The product fully complies with the legislation listed above and complies with the various Annexes relating to banned, CMRs, and restricted ingredients; colours, preservatives and sunscreens. The product has been produced by a company certified to have good proven GMP and tested to ensure good microbiological quality.

**Signature of safety assessor**: ****

**Date:** 25 October 2013

**EU REGISTRATION ADVICE**

Before you place the product on the UK market please ensure your Responsible Person is registered with the European Commission Authentication Service ( https://webgate.ec.europa.eu/aida/selfreg ) .Once you have registered with ECAS you must go to the Cosmetic Products Notification Portal (<https://webgate.ec.europa.eu/aida/cpnp>) and follow the instructions given in the CPNP User Manual to register your product.

**Sources of data:**

Safety and quality data from the suppliers of the raw materials in the formulation.

SCCS opinion. Data obtained from publicly available databases or literature.

Studies performed or obtained by the manufacturer of the product.

CSR (chemical safety report). HERA reports. IUCLID database. RIVM reports.

ChemIDPlus Light - <http://chem.sis.nlm.nih.gov/chemidplus/chemidlite.jsp>

ChemIDPlus Advanced - <http://chem.sis.nlm.nih.gov/chemidplus/>

COLIPA Recommandations - <http://www.colipa.eu/publications-colipa-the-european-cosmetic-cosmetics-association/recommendations.html>

IPCS Inchem - <http://www.inchem.org/pages/jecfa.html>

PubMed - <http://www.ncbi.nlm.nih.gov/pubmed>

ToxNet - <http://toxnet.nlm.nih.gov/>

Handbook Of cosmetic Ingredients-their use, safety and toxicology (A.C.Dweck)

<http://echa.europa.eu/web/guest/information-on-chemicals/registered-substances>

<http://www.cdc.gov/niosh/ipcsneng/neng0087.html>

<http://www.cosmeticsinfo.org/ingredient_details.php?ingredient_id=1046>

**End of Report**