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| COSMETIC PRODUCT SAFETY REPORT (Compliance with EU Regulation 1223/2009) |
|  |
| Blue Stratos Eau de Toilette |

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’)**

**Tim Foley**

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**Product Name:** **Blue Stratos** **EDT**

**Category (application of product):** Eau De Toilette Spray

**Our Reference No.:** KK30-34

**Formula Code:** JON100002A

**Date of Report:** 23 January 2014

**PART A: Cosmetic product safety information**

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

BLUE STRATOS EDT JON100002A

MATERIAL %

DEB 100 76.078%

FRAGRANCE 3.490%

ROBERTET K36461

DEIONISED WATER 20.432%

**Product Composition**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **INCI Name** | **% Conc.** | **% Active** | **Final %** | **CAS No.** | **Einecs No.** | **Cosmetic****Restriction** |
| Alcohol Denat. | 76.078 | 100 | 76.078 | 64-17-5 | 200-578-6 | - |
| Parfum | 3.490 | 100 | 3.490 | - | - | - |
| Aqua (Water) | 20.432 | 100  | 16.415 | 231-791-2 | 231-791-2  | - |

INCI LISTING WHICH MUST BE DECLARED ON THE LABEL:

***Alcohol Denat., Aqua, Parfum,* *Linalool, Limonene, Coumarin, Geraniol, Citral,***

***Hydroxycitronellal, Benzyl Salicylate, Citronellol, Hexyl Cinnamal, Evernia Furfuracea (Treemoss) Extract***

**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 | 0.273791 | 78-70-6 | 201-134-4 | III/84 |
| Limonene | 0.196662 | 5989-27-5 | 227-813-5 | III/88 |
| Coumarin | 0.063483 | 91-64-5 | 202-086-7 | III/77 |
| Geraniol | 0.038529 | 106 - 24 -1 | 203-377-1 | III/78 |
| Citral | 0.031864 | 5392-40-5 | 226-394-6 | III/70 |
| Hydroxycitronellal | 0.031724 | 107-75-5 | 203-518-7 | III/72 |
| Benzyl Salicylate | 0.022196 | 118-58-1 | 204-262-9 | III/75 |
| Citronellol | 0.006038 | 106- 22 -9 | 203-375-1 | III/86 |
| Hexyl Cinnamal | 0.003385 | 101-86-0 | 202-983-3 | III/87 |
| Evernia Furfuracea (Treemoss) Extract | 0.002548 | 90028-67-4 | 289-860-8 | III/92 |

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

*General Description:*

*A clear, light yellow hydro - alcoholic liquid with a characteristic odour of the Blue Stratos fragrance. Free from foreign and suspended matter. The ethanol content is 80.0% by volume and 73.9% by weight.*

*Specifications*

*Required Tests Specification Method*

*Appearance Must be equivalent to approved standards.*

*Odour Must be equivalent to approved standards.*

*pH (10% aque.dispersion) 4.0 - 5.0 1*

*Benzophenone-2 (Qualitative) Positive 18*

*Supplementary Tests*

*Specific Gravity 0.8587 - 0.8611 21*

*(15.6o/15.6o C) Procedure D*

*Microbial Content Less than 100 microorganisms per gram (ml) 24*

 *and the population is static or decreasing.Free*

 *of Gram - negative bacteria and coagulase staphylococci*

 *and all other pathogens.*

**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**

Microbial Content: Less than 100 microorganisms per gram (ml) and the population is static or decreasing. Free of Gram - negative bacteria and coagulase staphylococci and all other pathogens

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

Packaging Data Blue Stratos Eau de Toilette

Section 6 Manual Number 445311

Bottle Rectangular glass bottle sprayed light blue, facetted

(various 50ml&100ml codes) shoulders and edges. Crimp neck S20 spray finish. Printed one pass white.

Code 50/100SPSL.022 Silver overcap for spray finish.

Carton (50 & 100ml) 505 micron Scancote A board. Printed one colour plus sealer face side, then one colour reverse.

The product is packed in a Cosmetic grade glass bottle with a polypropylene pump dispenser. There are not expected to be any issues of stability or interaction between the packaging and the product. Pack consists of: Glass bottle (50 ml &100 ml) with Crimped pump.

1. **Normal and reasonably foreseeable use**

Product will be used by members of the public usually adults to perfume the skin.

The product is applied to the skin, mainly neck, face, hands, arms and general body possibly using a manual pump spray dispenser- this produces a fine spray of product which is applied to the desired area.

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

**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.  | 76.078 | 1.16658 | 10,600 | - | 9,086 |

**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: 7.667 mg/kg/bw/day (Based on SCCNFP/0321/02)

 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.

**8. Toxicological profile of the substances**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  | ***INGREDIENT TOXICOLOGICAL ASSESSMENT*** |  |  |
| **INCI name** | **% Conc.in product** |  **Toxicological Summaries** | **Classification****\*\*** | **Rest-riction \*\*\*** |
| Aqua | 20.432 | 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. | 76.078 | Alcohol Denat. Ethanol is used in our cleaning products as a solvent to keep insolution 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 | - |
| Parfum  | 3.490 | 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 3.49 % 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. | R38R43,R50/53R65 | - |

**\****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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 **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 crimped 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 as the product is marketed in 50 ml and 100 ml containers with a pump dispenser. 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**

Equipment

 Equipment parts and pipe connections coming into contact with the product must be clean and dry, and must be constructed of 316 stainless steel or other suitable non-corrosive material EQUIPMENT MUST BE EXPLOSION PROOF.

 Batch tank with cover:propeller agitator: heat exchanger equipment capable of cooling the product to 0 – 5 o C :filter press fitted with suitable filter pads and any back up paper as required to achieve specified results.

Manufacturing Procedure

1 Dissolve all the ingredients (except any colour solutions) in Alcohol in the order listed

 Note It is advisable to add slightly less than the specified quantity of water to allow easy adjustment of the density after first evaluation.

2 Agitate the batch thoroughly. Avoid splashing. Keep tank covered to avoid Alcohol loss.

3 Take Baume' gravity reading.

4 Adjust the gravity by making successive increments of water until the reading on the Baume 'Hydrometer corresponds to the value indicated in the standard gravity chart for the specific batch temperature.

 The reading should be within the range + 0.4 Baume' from the specified value.

 a) If the Baume' reading is high add water.

 b) If the Baume' reading is low add alcohol.

5 Age the batch for the specified aging period in a well closed storage vessel.

6 (Optional) At the end of the aging period add filter aid and disperse thoroughly.

7 Cool the batch to 0 - 5 o C. This temperature should be the temperature of the product entering the filter press unless otherwise specified.

8 Filter through the appropriate filter pads until a sparkling clear solution is obtained. If necessary, recirculate at the specified temperature to obtain a clear liquid. In order to ensure complete removal of stray filter fibres from the effluent ,one or both of the following, should be done.

 a) Recirculate the first 100 litres back to the mixing tank, or

 b) Use optional backup paper or other to achieve the clarity required.

 Continuously examine the effluent prior to transfer to the holding tank.

9 Allow the filtered batch to return to room temperature

10 Add colour solution(s), if any, and mix thoroughly.

11 Submit a sample for Quality Assurance approval.

SIGNED Mr S. Foley – Technical Director

|  |  |  |
| --- | --- | --- |
| CHECK S.G. IS 0.83 - 0.89 ……………….. OBSERVED S.G. |  |  |
|  |  |  |  |  |  |  |
| PRODUCT TO STAND FOR 2 DAYS BEFORE FILTRATION |  |  |
|  |  |  |  |  |  |  |
| CHILL TO BETWEEN 0 - 5 DEGREES C BEFORE FILTERING………….... FILTRATION TEMP |
|  |  |  |  |  |  |  |
| DATE FILTERED:……………………….. |  | FILTERED BY:……………………… |
|  |  |  |  |  |  |  |
| PASSED FOR FILLING:………………… |  |  |  |  |

**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:



**13. Information on the cosmetic product**

**Consumer Exposure**

 The product is a liquid which is applied to the skin using a manual pump, for its fragrance. The product is left on the skin. The dosage is likely to be around 0.15g to 0.25g and possibly used two times daily.

Product Class: Eau De Toilette

Period After Opening (PAO): 12 Months

IFRA Category: 4A

Frame Formulation Number: 5.1-2000

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

Amount per application: 0.23 g No. Applications/day: 2

Skin surface area of application /sq.cm: 200 sq.cm Physical form: Liquid

Total amount applied per day: 460 mg

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

Part of body exposed to diluted product: not diluted

Estimated Daily exposure mg/kg/day: 7.667 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 (15.6 C): 0.83 - 0.89

**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 3.49 %, 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. The amount inhaled is considered negligible especially considering the large margins of safety of all the ingredients in this formulation

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

Kostas Kyriakides BSc CChem MRSC

Tel: 023922 40158

Mobile: 07913075262

Email: 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**

**Product Name:** **Blue Stratos** **EDT**

**Category (application of product):** Eau De Toilette Spray

**Our Reference No.:** KK30-34

**Formula Code:** JON100002A

**Date of Report:** 23 January 2014

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 **Eau De Toilette**.

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:** 17 January 2012

 **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**