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20 February 2025

UKCP-93295431

ROXELIS Pheromone Enhanced Cologne

UK cosmetic product number	UKCP-93295431
Internal reference number	
UK notified	20 February 2025
Product name	ROXELIS Pheromone Enhanced Cologne
For children under 3	No
Number of items	1
Shades	None
Are the items mixed?	No
Submission type	Exact concentration

Responsible Person

Company
GLOBAL STAR UK SOLUTION LTD

Address
7 COPPERFIELD ROAD COVENTRY
WEST MIDLANDS
ENGLAND UNITED KINGDOM
CV2 4AQ

Assigned contact
James Lin

Email address
GStarUK.service@hotmail.com

Telephone
+34 615 561 159

Your notification has been successfully submitted. Please note that this is not an indication that all information required has been submitted. Please note further that where information in relation to a cosmetic product changes, you are required to update the notification without delay.

Find a frame formulation (/frame_formulations)
How to notify nanomaterials (/guidance/how-to-notify-nanomaterials)

How to prepare images for notification (/guidance/how-to-prepare-images-for-notification)
Set up your authenticator app (/guidance/how-to-set-up-authenticator-app)

Email opss.enquiries@businessandtrade.gov.uk for help using this service.

Notified product:

ROXELIS Pheromone Enhanced Cologne

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UK cosmetic product number	UKCP-93295431
UK notified	20 February 2025
Product name	ROXELIS Pheromone Enhanced Cologne
For children under 3	No
Number of items	1
Shades	None
Label	ROA10-A021-30-BK1.jpg
Are the items mixed?	No

Responsible Person

Name
GLOBAL STAR UK SOLUTION LTD

Address
7 COPPERFIELD ROAD
COVENTRY
WEST MIDLANDS
ENGLAND UNITED KINGDOM
CV2 4AQ

Assigned contact

Name
James Lin

Email
GStarUK.service@hotmail.com

Telephone
+34 615 561 159

Details

Contains CMR substances	No
Nanomaterials	None
Category of product	Skin products
Category of skin product	Perfumes
Category of perfume	Hydroalcoholic perfumes
Physical form	Liquid
Special applicator	No
pH	No pH

Ingredients

Formulation given as Exact concentration

AQUA
90.96% w/w

ALCOHOL DENAT.
8.0% w/w

PROPYLENE GLYCOL
1.0% w/w

CITRUS LIMON (LEMON) FRUIT EXTRACT
0.02% w/w

1,2-HEXANEDIOL
0.02% w/w

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Material Safety Data Sheet

Name of Sample: ROXELIS Pheromone Enhanced Cologne

Commissioner: Shantou Roxelis Biotechnology Co., Ltd.

Issue Date: Jan-02-2025

Writtern by: Kenley Approved by: levi

Date: Jan-02-2025 Date: Jan-02-2025

Haoji Biotechnology Co., Ltd. MSDS

Material Safety Data Sheet

Report No. SDS2025010205AHXY Date of Issue Jan.02.2025

1.IDENTIFICATION

Product Identifier

Product Name ROXELIS Pheromone Enhanced Cologne

Details of the supplier of the safety data sheet

Manufacturer /Supplier Shantou Roxelis Biotechnology Co., Ltd.

Address Room 809-3, Building 1, Chongyaohao Commercial-Residential Center, No. 57 Huashan Road, Longhu District, Shantou City, 515000

Tel 13342745877

Emergency Telephone 13342745877

2.HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW:

This product contains no ingredients at their given percentages that are considered hazardous to your health.

Principle routes of exposure:

Eye Contact: No effects expected.

Skin Contact: No effects expected.

Ingestion: Not Available

Inhalation: Not Available

Hazard information: This a a personal care or cosmetic product that is safe for consumers and other users under normal and reasonable use.No effects expected.

Medical conditions aggravated by exposure: None known

3.COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS-No	Weight %
AQUA	7732-18-5	90.96
ALCOHOL DENAT.	-	8
PROPYLENE GLYCOL	57-55-6	1
CITRUS LIMON (LEMON) FRUIT EXTRACT	84929-31-7	0.02
1,2-HEXANEDIOL	6920-22-5	0.02

4.FIRST-AID MEASURES

First Aid Measures

General Advice	Provide this MSDS to medical personnel for treatment Always get medical attention when product is swallowed or when symptoms are significant or persist.
Eye Contact	Flush with water for 15 minutes.If irritation persists,call physician.
Skin Contact	Wash liberally with soap and water.If on clothes:Wash before reuse.
Inhalation	Not an expected route of exposure.
Ingestion	If patient is conscious and alert,dilute by drinking large quantities of water.Tf vomiting occurs spontaneously,keep head low to keep from breathing vomit into lungs.

Most important symptoms and effects

Symptoms	If in eyes:Possible mild irritation,watering or redness. lf swallowed:Possible gastrointestinal iritation or disturbance. If on skin:Concentrate may cause redness,irritation or burning sensation with prolonged exposure.

Indication of any immediate medical attention and special treatment needed

Notes to Physician	Treat symptomatically.

5.FIRE-FIGHTING MEASURES

Suitable Extinguishing Media

Dry chemical and carbon dioxide.Foam and water fog are effective but may cause frothing.

Unsuitable Extinguishing Media Not determined.

Specific Hazards Arising from the Chemical

This is a water based non-flammable product with no known fire or explosion hazards.

Hazardous Combustion Products Carbon oxides.

Protective equipment and precautions for firefighters

As in any fire,wear self-contained breathing apparatus pressure-demand,MSHA/NIOSH (approved or equivalent)and full protective gear.Cool containers exposed to fire with water.

6.ACCIDENTAL RELEASE MEASURES

Personal precautions,protective equipment and emergency procedures

Personal Precautions Use personal protective equipment as required.

Methods and material for containment and cleaning up

Methods for Containment	Prevent further leakage or spillage if safe to do so.
Methods for Clean-Up	SMALL SPILLS:Small spills (<1 gallon)maybe washed down a drain or cleaned up and disposed of into a sanitary sewer system. LARGE SPILLS:Large spills (>1 gallon)should be contained and collected (by absorption or vacuuming)then disposed of properly.

7.HANDLING AND STORAGE

Precautions for safe handling

Advice on Safe Handling	Handle in accordance with good industrial hygiene and safety practice.Do not contaminate water,food,or feed.Do not reuse empty containers.Keep containers clean &closed.

Conditions for safe storage,including any incompatibilities

Storage Conditions	Keep out of the reach of children.
Incompatible Materials	None known based on information supplied.

8.FXPOSURE CONTROI S/PFRSONAI PROTFCTION

Precautions for safe handling

Exposure Guidelines	The following information is given as general guidance

Appropriate engineering controls

Engineering Controls	Mechanical Ventilations (General): Normally sufficient Local Exhaust:Not Normally Needed.

Individual protection measures,such as personal protective equipment

Eye/Face Protection	Not normally required under normal use conditions.Avoid eye contact when using.
Skin and Body Protection	Gloves not required.This product is a skin cleanser and conditioner.
Respiratory Protection	Not needed.General ventilation is normally adequate.
General Hygiene Considerations	Do not get into eyes.Protect food &drink from contamination byproduct.

9.PHYSICAL AND CHEMICAL PROPERTIES

Precautions for safe handling

Appearance	Liquid	**Odor**	Tasteless
Color	Yellow	**Odor Threshold**	Not determined

Property	**Values**	**Remarks**	**Method**
pH	6.00-7.00		
Melting Point/Freezing Point	Not established		
Flash Point	100 ℃ / 212 F		
Evaporation Rate	Not determined		
Flammability (Solid,Gas)	Not established		
Upper Flammability Limits	Not determined		
Lower Flammability Limit	Not available		
Vapor Pressure	Not available		
Vapor Density	Not established		
Specific Gravity	Not established		
WaterSolubility	1.00 to 1.02		
Solubility in othersolvents	Completely soluble		
Partition Coefficient	Not determined		
Auto-ignition Temperature	Not determined		
Decomposition Temperature	Not determined		
Kinematic Viscosity	Not determined		
Dynamic Viscosity	500-800 cps		
Explosive Properties	Not determined		
Oxidizing Properties	Not determined		
Density			
lbs/gal	8.39-8.49		

10.STABILITY AND REACTIVITY

Reactivity

Not reactive under normal conditions.

Chemical Stability

Stable under recommended storage conditions.

Possibility of Hazardous Reactions

None under normal processing.

Hazardous Polymerization

Hazardous polymerization does not occur.

Conditions to Ayoid

Keep out of reach of children.

Incompatible Materials None known based on information supplied.

Hazardous Decomposition Products Carbon dioxide (CO2),Sulfur dioxide.

11.TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Product Information

Eye Contact	May cause mild eye irritation.
Skin Contact	None,this product is a skin cleanser and conditioner.
Inhalation	Under normal conditions of intended use,this material is not expected to be an inhalation hazard.
Ingestion	Possible gastrointestinal irritation or disturbance.

Component Information

Information on physical,chemical and toxicological effects

Symptoms	Please see section 4 of this SDS for symptoms.

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Carcinogenicity	This product does not contain any carcinogens or potential carcinogens as listed by OSHA, IARC or NTP.

Numerical measures of toxicity

Not determined

12.ECOLOGICAL INFORMATION

Ecotoxicity

The product is not expected to be hazardous to the environment.

Persistence/Degradability

Not determined

Bjoaccumulation

Not determined

Mobility

Not determined

Other Adverse Effects

Not determined

13.DISPOSAL CONSIDERATIONS

Waste Treatment Methods

Disposal of Wastes	Disposal should be in accordance with applicable regional,national and local laws and regulations.
Contaminated Packaging	Disposal should be in accordance with applicable regional,national and local laws and regulations.

14.TRANSPORT INFORMATION

Land transport (ADR/RID/GGVSE)

This product is not regulated as a hazardous material or dangerous goods for transportation.

Sea transport (IMDG -Code/GGVSee)

This product is not regulated as a hazardous material or dangerous goods for transportation.

Air transport (ICAO -TVIATA-DGR)

This product is not regulated as a hazardous material or dangerous goods for transportation.

Additional information

No relevant information available.

15.REGULATORY INFORMATION

International Inventories

Not determined

Legend:

TSCA -United States Toxic Substances Control Act Section 8(b)Inventory

DSL/NDSL- Canadian Domestic Substances List/Non-Domestic Substances List

EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

ENCS - Japan Existing and New Chemical Substances

IECSC- China Inventory of Existing Chemical Substances

KECL -Korean Existing and Evaluated Chemical Substances

PICCS- Philippines Inventory of Chemicals and Chemical Substances

Us Federal Regulations

SARA313

Not determined

Us State Regulations

U.S.State Right-to-Know Regulations

Not determined

16.OTHER INFORMATION

NFPA	**Health Hazards**	**Flammability**	**Instability**	**Special Hazards Not**
	0	0	0	**determined**
HMIS	**Health Hazards**	**Flammability**	**Physical Hazards**	**Personal Protection**
	0	0	0	Not determined

Disclaimer

The information provided in this MSDS is correct to the best of our knowledge,information and belief at the date of its publication.The information given is designed only as guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification.The 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,unless specified in the text.

COSMETIC PRODUCT SAFETY REPORT

Company Name:	**Shantou Roxelis Biotechnology Co., Ltd.**
Company Address:	**Room 809-3, Building 1, Chongyaohao Commercial-Residential Center, No. 57 Huashan Road, Longhu District, Shantou City, 515000**
Product Name:	**ROXELIS Pheromone Enhanced Cologne**
Net weight:	**30ML/1FL.OZ per consumer product**
Region of Origin:	**China**
Region of Destination:	**EU**
Version:	**1.0**
Date:	**2025-01-12**
Test Requested:	**This Cosmetic Product Safety Report (CPSR) is carried out according to Regulation (EC) No. 1223/2009 and its amendments.**
Test Results:	**Please refer to the following pages**

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Table of Contents

PART A – Cosmetic product safety information

A.1 Quantitative and Qualitative Composition of Products

A.1.1 Nominal Composition

The table below shows the aggregated break-down components of all raw materials from the product. Substances may have more than one function in the product. If so, the main function is given.

INCI Name	CAS No.	Concentration (%)	Funtion
AQUA	7732-18-5	90.96	SOLVENT
ALCOHOL DENAT.	-	8	SOLVENT
PROPYLENE GLYCOL	57-55-6	1	SOLVENT
CITRUS LIMON (LEMON) FRUIT EXTRACT	84929-31-7	0.02	SOLVENT
1,2-HEXANEDIOL	6920-22-5	0.02	SOLVENT

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

A.2.1 Physical/chemical characteristics of Raw Materials

The raw materials specifications are available upon request.

A.2.2 Physical chemical specifications of the end product

The finished product specifications are available upon request.

A.2.3 End product stability

The stability evaluation of the above formula was conducted under different operating conditions in an appropriate packaging at 0 ± 1 °C, room condition, and 40 ± 2 °C, 60±5% humdity for 3 months. The appearance, odor, pH value and packaging apperance examinations were carried out.

The compatibility between the formula and the packaging was also evaluated.

The overall results of these examinations allow it to be stated that the stability tests and compatibility tests are acceptable.

A.2.4 Durability (PAO)

It lies with the responsibility of manufacturer or responsible person to determine the product's minimum durability and perid-after-opening (PAO) based on the above results from the product stabitity testing.

A.3 Microbiological quality

A.3.1 The microbiological specifications of the substance or mixture

The microbiological specifications of all raw materials are available upon request.

A.3.2 The microbiological testing results of end product

The microbiological testing results of end product according to European Pharmacopoeia 10.0 2.6.12 & 2.6.13 were listed below.

Items	**Testing Results**	**Unit**
Aerobic Plate Count	<10	CFU/g
Yeasts and Moulds	<10	CFU/g
E. Coli, P. aeruginosa, S. aureus, C. albicans, bile-tolerant gram-negative bacteria,S. typhimurium,C.tetani	Undetected	/g

According to Appedix 9 of the 11th Revision of the NoG (SCCS/1628/21), the microbiological quality of this product was considered as acceptable for Category 1 products.

A.3.3 Results of preservation challenge test

The preservation challenge test result of this formulation according to European Pharmacopoeia 10.0 5.1.3 was listed below.

Micoorganisms	**24H**	**7D**	**D14**	**D28**
	Log reduction values			
Escherichia coli	2.9	4.4	-	NI
Staphylococcus aureus	2.7	4.3	-	NI
Pseudomonas aeruginosa	2.7	4.4	-	NI
Candida albicans	-		1.8	NI
Aspergillus niger	-		2.0	NI

Note: NI=No increase in number of viable micro-organisms compared to the previous reading

According to European Pharmacopoeia 10.0 5.1.3 Table 5.1.3-1. Criteria B, the preservation challenge test result of this formulation was considered as acceptable.

A.4 Impurities, traces and Information about the Packaging Material

A.4.1 Impurities and Traces of prohibited substances

The potential impurities and traces relevant for the raw materials were controlled via the raw material specifications. And the raw material specification are available upon request. This product does not contain any relevant impurity at significant levels, and the analytical testing results of heavy metals (below table) indicated the content of As, Hg, Pb, Sb, Cd and Ni (soluble) in this product were undetected and considred to be acceptable according to Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL) (published online: 06 Oct 2016) and German Health Authority BgA recommendations. Furthermore, in conformity with the article 3 of the regulation, the safety evaluation of this impurity and trace of prohibited substances is part of the safety evaluation of the cosmetic product.

Items	**Testing Results**	**BVL (published online: 06 Oct 2016)**	**BgA recommendations**

Pb	<0.01	≤2.0a	-
Hg	<0.001	≤0.1	-
As	<0.005	≤0.5b	-
Sb	<0.005	≤0.5	-
Cd	<0.01	≤0.1	-
Ni (soluble)	<2	-	10

a For the product make-up powder, rough, eyeshadow, eyeliner, kajal, as well as theater, fan or carnival make-up: 5 mg/kg

b For theater, fan or carnival make-up: 2.5 mg/kg

A.4.2 Information about the Packaging Material

The relevant characteristics of packaging material and in depth knowledge of its raw materials, is based on supplier data. The material information of packaging was listed below.

No.	Part	Material
1	Bottle	PET
2	Cap	ABS
3	Inner plug	PE

The analytical testing results of immediate container indicated Pb, Cd, Hg and Cr (VI) were undetected with total amount less than 10 ppm.

A.5 Normal and Reasonably Foreseeable Use

The normal use and reasonably foreseeable uses of the product are described for the product type and determine the exposure and hazards used in the safety assessment. Product misuse is not considered.

A.5.1 Normal use and reasonably foreseeable use conditions:

The normal use of this product is to apply this product as makeup remover for face or eyes. Application of this product to other parts of body is not foreseeable.

A.5.2 Warning and other explanation in the product labelling of the product category relevant for safety evaluation

As the printed instructions of use and warning is clear to describe the product usage and appropriate enough to avoid misuse, no special warnings or instructions of use are further required.

A.6 Exposure to the product

The exposure to the cosmetic product is described by the following items:

A.6.1 Product Type

This cosmetic product is applied as

Product Type: leave-on with retention factor of 0.1

A.6.2 Target Group

The target users for this product are: Adult. And the default adult body weight is 60 kg.

A.6.3 Area of application

The following exposure areas have been used in the Exposure calculations:

Area of application: skin

Application Surface area: 565 cm2

A.6.4 Routes of Exposure

The following exposure routes have been used in the Exposure calculations:

Routes of Exposure: Dermal

A.6.5 Amount per application

The following product quantity used per application has been used in the Exposure calculations:

Product Exposure: 5 g

A.6.6 Duration and Frequency

The following product use conditions have been used in the Exposure calculations:

Frequency of use: once per day

Exposure duration: 60 minutes

A.7 Exposure to the substances/impurities

Exposure to the substances/impurities has been calculated taking into account the potential expousure of product and the concentration of substances/impurities in the product. And exposure to aqua and sea water is not calculated as it is an innocuous and ubiquitous substance.

A.7.1 Exposure to the substance

INCI Name	Inclusion level (% w/w)	Total Systemic (SED) mg/kg bw/day	Local Dermal (CEL) µg/cm2
AQUA	90.96	2.0825	221.25
ALCOHOL DENAT.	8	0.41650833	44.250885
PROPYLENE GLYCOL	1	0.4165	44.25
CITRUS LIMON (LEMON) FRUIT EXTRACT	0.02	0.4165	44.25
1,2-HEXANEDIOL	0.02	0.064134586	6.81381855

A.7.2 Exposure to impurities

As there is no impurity at significant levels, there is no exposure calculation.

A.8 Toxicological Profile of the Substances

Toxicological Profiles are provided for all substances apart from those that are fragrances, regulated ingredients, substances assessed by external authoritative body (for example Cosmetic Ingredient Review (CIR), SCCS, etc), aqua or substances present at levels below a threshold of toxicological concern.

Accordingly, toxicological profiles of PARAFFINUM LIQUIDUM and SODIUM CHLORIDE are included here.

Toxicological profile of Paraffinum Liquidum（CAS# 8042-47-5）

Toxicological endpoints:

Acute toxicity: Its acute toxicity was practically non-toxic with oral LD50 > 5000 mg/kg bw in rats and dermal LD50 > 2000 mg/kg bw in rabbits[1] .

Skin irritation: According to acute irritation test in rabbits, it was found to be non-irritating to rabbit skin[1] .

Eye irritation: According to acute irritation test in rabbits, it was found to be non-irritating to eyes [1] .

Skin sensitization: Weight of evidence indicated it was not a skin sensitizer.

Repeated dose toxicity: No studies were available to evaluate the repeated exposure to mineral oils through dermal route. However, based upon the fact that there is no evidence to suggest significant percutaneous absorption, adverse effects are not expected following repeated dermal exposure . An ADI of 12 mg/kg bw/d for medium viscosity white mineral oils (kinematic viscosity between 8.5 - 11 mm^2/s at 100 oC) based on a 2-year feeding study in the rats with NOAEL of 1200 mg/kg bw/d[2] .

Mutagenicity/Genotoxicity: Highly refined Mineral Oils are not considered as being mutagenic/ genotoxicl[1] .

Carcinogenicity: It was found not to be carcinogneic in chroinc feeding study in rats [2] .

Reproductive toxicity: The data available from short-term and long-term studies in

experimental animals exposed to mineral oil via oral, inhalation or skin exposure routes provide no evidence of reproduction/ developmental toxicity. Moreover, Mineral oil has not been detected in reproductive organs [1] .

Critical Point of Departure Value for MoS calculation

Critical Point of Departure Value	1200 mg/kg bw/d
Exposure Estimate	0.42 mg/kg bw/d
Margin of Safety (MoS)	2857

Regulatory Status - Not regulated in (EC) No 1223/2009 and without the assessment opinion from SCCS or CIR.

Conclusion

It was highly refined white mineral oil that are removed aromatic hydrocarbon during the refinery process, which complies with purity requirements of USP/NF/BP/JP/Ph.Eur. for Mineral Oil. And it is concluded that the currently available data is sufficient to consider it safe to be used as intended in this product.

Reference list:

[1] ECHA. Registration dossier of White mineral oil (petroleum) (CAS No. 8042-47-5). Last accessed on 2022-10-22@ https://echa.europa.eu/registration-dossier/-/registered - dossier/15514.

[2] EFSA. Scientific opinion on the safety assessment of medium viscosity white mineral oils with a kinematic viscosity between 8.5 - 11 mm²/s at 100 °C for the proposed uses as a food additive. EFSA Journal 2013;11(1):3073.

Toxicological profile of SODIUM CHLORIDE (CAS# 7647-14-5)

Toxicological endpoints:

Acute toxicity: It was recognzied to be of none acute toxicity based on animal experimental data and human usage experience[1] .

Skin irritation: At physiological concentrations (0.9%) sodium chloride is not irritating to the eyes or skin. However, as concentration increases it can become moderately irritating to the eyes and skin, especially abraded skin[1] .

Eye irritation: At physiological concentrations (0.9%) sodium chloride is not irritating to the eyes or skin. However, as concentration increases it can become moderately irritating to the eyes and skin, especially abraded skin[1] .

Skin sensitization: It was not recognized to be a skin sensitiser based on animal experimental data and human usage experience [1] .

Phototoxicity: No data. But it was considered acceptable as it was demonstrated not to have significant UV absorpition capacity[1] .

Repeated dose toxicity: Salt, also known as sodium chloride, is regulated by U.S. Food and Drug Administration (FDA) as a “generally recognized as safe” (GRAS) ingredient. A “GRAS” substance is one that has a long history of safe, common use in foods, or that is determined to be safe, for the intended use, based on proven science. The major adverse effect of increased sodium intake is elevated blood pressure. Higher blood pressure is an acknowledged risk factor for ischaemic heart disease, stroke and renal disease. For sodium, EFSA considers that 2.0 g sodium/day is a safe and adequate intake for the general adults. A salt intake of less than 5 grams (approximately 2g sodium) per person per day is recommended by WHO for the prevention of cardiovascular diseases, the leading cause of death globally [2] .

Mutagenicity/Genotoxicity: It is not mutagenic in vitro or in vivo [1] .

Carcinogenicity: It was not recognzied as a human carcinogen [1] .

Reproductive toxicity: It was not recognzied as a specific reproductive or developmental toxicant [1] .

Critical Point of Departure Value for MoS calculation

Critical Point of Departure Value	83 mg/kg bw/d
Exposure Estimate	0.03 mg/kg bw/d
Margin of Safety (MoS)	2767

Regulatory Status – Not regulated in (EC) No 1223/2009 and without the assessment opinion from SCCS or CIR.

Conclusion

opinion from SCCS or CIR.Hence, based on the large safety margin, it can be concluded it is safe to be used as intended

in this product. Reference list:

[1] ECHA. Regsitration dossier of Sodium chloride (CAS No. 7647-14-5). Last accessed on 2022-09-28@https://echa.europa.eu/registration-dossier/-/registered-dossier/15467.

[2] WHO. Last accessed on 2022-09-28@ https://www.who.int/data/gho/indicator-metadata-registry/imr-details/3082.

A.9 Undesirable effects and serious undesirable effects

As at the date of this report the product has not yet been commercialized, therefore there are no data available from post marketing surveillance on undesirable effects or serious undesirable effects to the cosmetic product.

No relevant data on other cosmetic product are available.

A.10 Information on the Cosmetic Product

This product will be produced using Good Manufacturing Practice for Cosmetics according to US FDA CFSAN Cosmetic Good Manufacturing Practice Guidelines with DEKRA Certificate DH2022GMP (D)0056.

PART B – Cosmetic Product Safety Assessment

B.1 Assessment conclusion

After overall evaluating the information in part A, this product can be assessed as safe for normal and reasonably foreseeable use in accordance with the European Cosmetics Regulation (EC) No 1223/2009.

The formulation does not contain forbidden or banned ingredients per Regulation (EC) No. 1223/2009 of the European Parliament and of the Council 30 November 2009 on Cosmetic Products and its amendments, and the safety assessment has been carried out in accordance with this regulation.

B.2 Labelled warnings and instructions of use

As the printed instructions of use and warning is clear to describe the product usage and appropriate enough to avoid misuse, no special warnings or instructions of use are further required.

B.3 Reasoning

B.3.1 Safety Evaluation of the Substances

All of the following ingredients have been assessed as safe for human health under normal and reasonably foreseeable conditions of use.

Substance Name	Inclusion Level (%)	Max.Use conc. (%)	Margin of Safety	Assessment Conclusion	Reference
AQUA	90.96	90	NA	Conforms to accepted external review in a product.	CIR Expert Panel.Safety assessment of ingredients usedin cosmetics. IJT31(Suppl. 3): 269-295, 2012.
ALCOHOL DENAT.	8	79.2	NA	Conforms to accepted external review in a product.	CIR Expert Panel.Safety assessment of ingredients usedin cosmetics.IJT 38(Suppl. 3): 6-22, 2019.

Substance Name	Inclusion Level (%)	Max.Use conc. (%)	Margin of Safety	Assessment Conclusion	Reference
PROPYLENE GLYCOL	1	77.3	NA	Conforms to accepted external review in a product.	CIR Expert Panel.Safety assessment of ingredients used in Cosmetics. IJT 34(Suppl. 2): 5-69, 2015.
CITRUS LIMON (LEMON) FRUIT EXTRACT	0.02	2857	NA	Conforms to accepted external review in a product.	See Section A.8
1,2-HEXANEDIOL	0.02	10	NA	Conforms to accepted external review in a product.	See Section A.8

B.3.2 Safety Evaluation of the Product

This product along with all substances contained within the formulation of the product has been evaluated and found to be safe for its normal and reasonably foreseeable use based on submitted product information and other information pubicly available.

The product will be produced with certified Good Manufacturing Practices for cosmetics. And the stability, microbiological quality, packaging, warnings and use instructions have been considered and taken into account as part of safety evaluation of this product. These aspects are covered under Sections A2, A3, A4 & A5 of the report.

Based upon the information supplied, unless otherwise stated in this report, it was assumed that neither this product, nor the ingredients used in the product, contained any impurities/contaminants that would cause harm to the health of a consumer. And this evaluation result is vailid only to the conditions described herein. And any deviation from the above disclosed conditions will necessitate a new evaluaiton. Furthermone, if any serious undesirable effects attributed to the use of this product occurred, the safety assessor shall be informed immediatedly. Under such circumstances, a new safety assessment will be conducted, and conclusions may be revised.

B.4 Assessor´s credentials and approval of part B

Dr. Raul Xin, EUROTOX Registered Toxicologist (ERT)

RADAR Notification Emails/Message d'information du systeme RADAR ☆

发件人: donotreply-nepasrepondre <donotreply-nepasrepondre@hc-sc.gc.ca>
时　间: 2024年7月12日(星期五) 下午3:41
收件人: undisclosed-recipients:

RADAR Batch Email Transmission/Transmission en lot de courriels du systme RADAR

RADAR (Environment/Environnement:PROD)

Cosmetic Notification / Déclaration de cosmétiques

Le français suit This is an automated message, please do not reply. If you submitted multiple Cosmetic Notification Forms (CNF), please be advised that you may receive multiple acknowledgement emails.
Health Canada's Consumer and Hazardous Products Safety Directorate has received a CNF for the following product:
Product Name: ROXELIS Pheromone Enhanced Cologne
Cosmetic Number: 03636365
Case Number: 2024-084406
Please note that this message and the Cosmetic Number provided do not constitute an approval for sale by Health Canada, nor an indication that the product complies with all regulatory requirements. The responsible company must ensure that the cosmetic meets the requirements of the Food and Drugs Act and the Cosmetic Regulations. A Health Canada representative may contact you if additional information is required.
Whenever a change affecting the information in a CNF is made, notifiers must amend the CNF and resubmit to Health Canada. Examples of such changes include modifications of the cosmetic formulation or company information, or discontinuation of sale in Canada. When submitting an amendment or discontinuation of sale, select the appropriate "Notification Type" from the drop-down list in Section 1 of the form. Please include the Cosmetic Number in the dialog box that appears. For detailed instructions, see Section 9 in How to complete a Cosmetic Notification Form (https://www.canada.ca/en/health-canada/services/consumer-product-safety/cosmetics/notification-cosmetics/guidance-document-complete-cosmetic-notification-form.html). Remember to save a copy of any changes to your CNF information for your own records.

Ceci est un message automatisé, s'il vous plaît ne répondez pas. Si vous avez soumis plusieurs formulaires de déclaration des cosmétiques (FDC), veuillez noter que vous pourriez recevoir plusieurs courriels d'accusé de réception.
La Direction de la sécurité des produits de consommation et des produits dangereux a reçu un FDC pour le produit suivant :
Nom du produit : ROXELIS Pheromone Enhanced Cologne
Numéro de cosmétique : 03636365
Numéro de Cas : 2024-084406
Veuillez noter que ce message et le numéro de cosmétique fourni ne constituent pas une approbation pour la vente de la part de Santé Canada, ni un acquiescement que le produit est conforme à toutes les exigences réglementaires. La compagnie responsable doit s'assurer que le cosmétique respecte les exigences de la Loi sur les aliments et drogues et du Règlement sur les cosmétiques. Un représentant de Santé Canada pourrait vous contacter si des informations supplémentaires sont nécessaires.
À chaque fois qu'il a une modification affectant l'information contenue dans un FDC, le déclarant doit modifier le FDC et le soumettre de nouveau à Santé Canada. Des exemples de modifications incluent une modification de la composition du cosmétique ou des coordonnées de l'entreprise ou un arrêt de la vente au Canada. Pour présenter une modification ou un arrêt de vente, sélectionnez le « Type de déclaration » approprié à partir de la liste déroulante dans la Section 1 du formulaire. Veuillez inclure le numéro de cosmétique dans la boîte de dialogue qui apparaîtra. Pour des instructions détaillées, veuillez consulter la Section 9 du document de référence : comment remplir un formulaire de déclaration des cosmétiques (https://www.canada.ca/fr/sante-canada/services/securite-produits-consommation/cosmetiques/declaration-produits-cosmetiques/document-reference-comment-remplir-formulaire-declaration-cosmetiques.html). Souvenez-vous de sauvegarder une copie de toute modification apportée aux renseignements de votre FDC dans vos dossiers.

Message Id/Identification du message: cbc9b2b2-6243-4315-a24b-a3c46e8910bb

General Information

CPNP Reference**: 4965278**
Industry Reference:
Version: **1**
Date first notification: **20/02/2025 10:07:46**
Last modification date: **20/02/2025 10:07:46**

Product Name	Shades (if applicable)	Language
ROXELIS Pheromone Enhanced Cologne		English

Product specifically intended for children under 3 years of age: No

ID: **226889**
Responsible person: **GLOBAL ONE SOLUTION LTD**
Responsible person address: 6 rue d'Armaillé, 75017, Paris, France
Phone:
Fax:
Email: wmthghi@outlook.com

Contact person: **Jeffrey Lin**
Contact person address: 6 rue d'Armaillé , 75017, Paris, France
Phone: +34 615 561 159
Additional phone 1:
Additional phone 2:
Fax:
Email: wmthghi@outlook.com

Product imported in the Community: Yes
Country of origin: China
End date of responsibility of the responsible person: 21/10/2025
Germany: Germany

Category level (1 > 2 > 3): Skin products > Perfumes > Hydroalcoholic perfumes
Physical form: Liquid
Applicator/packaging:
Notification type: Exact concentration

	Substance	Value	
Complete Composition			
Formulation name: Perfume (Eau De Cologne, Eau De Toilette, Eau De Parfum, Extrait De Parfum, Parfum)			
Exact concentration	AQUA	90.96	
Exact concentration	ALCOHOL DENAT.	8.00	
Exact concentration	PROPYLENE GLYCOL	1.00	
Exact concentration	1,2-HEXANEDIOL	0.02	
Exact concentration	CITRUS LIMON (LEMON) FRUIT EXTRACT	0.02	
CMR			
Nanomaterials			

Other information of significance for poison centers

Original packaging (photograph)

Name	Options

Original labelling (image)

Name	Options
ROA10-A021-30-BK1.jpg	

Distributors

CAs/PICs Comments

<< RETURN

COSMETIC PRODUCTS

Cosmetic Product Listing Number: 53-568979-633101

Product Name (As listed on label): * ROXELIS Pheromone Enhanced Cologne

Product Webpage Link:

Fragrance or Flavor: * N/A

Professional Use Only : -- Select --

PRODUCT CATEGORY CODE(S)

PRODUCT CATEGORIES
• (05) Fragrance preparations - (B) Perfumes

1 - 1

INGREDIENTS

Note that any update regarding Fragrance and/or Flavor made through the ingredient upload tool, will automatically update the above "Fragrance or Flavor" selection field in the previous section.

INGREDIENT UNII CODE(S)	COMMON, USUAL OR CHEMICAL NAME (PREFERABLY IN THE ORDER AS LISTED ON THE LABEL)
059QF0KO0R	AQUA
	ALCOHOL DENAT.
6DC9Q167V3	PROPYLENE GLYCOL
	CITRUS LIMON (LEMON) FRUIT EXTRACT
TR046Y3K1G	1,2-HEXANEDIOL

row(s) 1 - 5 of 5

LIST OF FACILITIES WHERE THE COSMETIC IS MANUFACTURED OR PROCESSED

IS THIS FACILITY SMALL BUSINESS?	FACILITY FEI / REGISTRATION NUMBER	FACILITY NAME	FACILITY ADDRESS
Yes	3032984539	Shantou Roxelis Biotechnology Co., Ltd.	Room 809-3, Building 1, Chongyaohao Commercial-Residential Center, No. 57 Huashan Road, Longhu District,Shantou City,515000,CHN

1 - 1

PRODUCT IMAGES

Upload an image(s) of the label, whether it be the front, back or side label by clicking on the drag and drop area to select an image from your computer, or dragging the file from your computer onto this area. Once the file has been selected from your computer, click the 'Upload' button. PLEASE NOTE: Image must be a .JPG format. File name with special characters will not be accepted. The maximum size for each image is 1MB. If uploading more than one image, ensure that the file name for each image is unique.

IMAGE	IMAGE PREVIEW
ROA10-A021-30-BK1.jpg	

1 - 1

COSMETIC REGISTRATION AND LISTING

- Registration of Cosmetic Product Facility
- Cosmetic Product Listing

ESTABLISHMENT REGISTRATION & DRUG LISTING

- Establishment Registration
- NDC Labeler Code Request
- Drug Listing and Certification
- NDC Reservation

OUTSOURCING FACILITY REGISTRATION AND PRODUCT REPORTING

- Outsourcing Facility Registration
- Compounded Drug Reporting

DSCSA ANNUAL REPORTING

- Wholesale Drug Distributor and Third-Party Logistics Provider Reports

GENERIC DRUG SELF-IDENTIFICATION

- Generic Facility GDUFA Self-Identification

SELF HELP

- Structured Product Labeling Resources
- UNII Search
- Request UNII
- DUNS Search
- FEI Search Portal
- Registration and Listing of Cosmetic Product Facilities and Products Industry Guidance
- Tutorials

MANAGE ACCOUNT

- Edit User Profile
- Manage Users

REGISTRATION OF COSMETIC PRODUCT FACILITY

For assistance with validation errors in Cosmetics Direct, contact cosmeticsdirect@fda.hhs.gov. For general questions regarding electronic registration of cosmetic product facilities, contact eRLC@fda.hhs.gov.

A summary of registration information for cosmetic product facilities is provided below. For more information, please also refer to: Registration & Listing of Cosmetic Product Facilities and Products.

In general, every person that owns or operates a facility that engages in the manufacturing or processing of a cosmetic product for distribution in the United States must register each facility (section 607(a)(1) of the FD&C Act). Please refer to FDA's guidance document for the description of "facility" and exemptions, such as for "small business" in the registration context: Guidance for Industry: Registration and Listing of Cosmetic Product Facilities and Products. For more information, please also refer to: Registration & Listing of Cosmetic Product Facilities and Products.

To facilitate the registration process, the owner or operator of a facility will need to obtain an FEI number before submitting the facility registration. To determine if an entity already has an FEI number, please refer to the FEI Search Portal. If your firm does not have an FEI number assigned by FDA, see How can I request an FEI? at FEI Search Portal (fda.gov).

GO | ACTIONS | SEARCH BRAND | CREATE NEW / UPLOAD FILE

STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	FACILITY NAME	FACILITY FEI	FACILITY DUNS	DOCUMENT TYPE	LAST MODIFIED USER	LAST MODIFIED DATE	
SUBMISSION ACCEPTED	260dd02d-f670-64b1-e063-6294a90afec8	260dd02d-f671-64b1-e063-6294a90afec8	cm1965087243.6748512309@direct	1	Shantou Roxelis Biotechnology Co Ltd	3032984539	-	COSMETIC FACILITY REGISTRATION	Huirong Liao	03-NOV-2024 21:34:41	-
SUBMISSION ACCEPTED	260dd692-c4b3-6d40-e063-6294a90a3c35	260dd692-c4b4-6d40-e063-6294a90a3c35	cm8304587129.9234516780@direct	1	Shantou Roxelis Biotechnology Co Ltd	3032984539	-	COSMETIC FACILITY REGISTRATION	Huirong Liao	03-NOV-2024 21:34:41	-

1 - 2

VIEW SPL | DOWNLOAD SPL | CREATE NEW VERSION | << RETURN

Note: Click on the Data Element Name for each field below to display instructions and helpful hints for filling out this Registration of Cosmetic Product Facility submission form. A red asterisk (*) indicates a required field.

For assistance with validation errors and general questions regarding electronic registration and listing of cosmetic product facilities and products, contact cosmeticsdirect@fda.hhs.gov.

DOCUMENT TYPE DETAILS

Document Type: * COSMETIC PRODUCT LISTING

Set ID: * 2e90563b-3722-87f1-e063-6294a90a0092

Version Number: * 1

Root ID: * 2e90563b-3723-87f1-e063-6294a90a0092

Effective Date: * 02-20-2025

PRODUCT, INGREDIENT AND FACILITY LISTING OF THE COSMETIC PRODUCT

Is this a product listing for a small business (optional product listing)?: [x] Yes [ ] No

Responsible Person (as listed on label):

Type of Business: [x] MANUFACTURER [ ] PACKER [ ] DISTRIBUTOR

Responsible Person Name (as listed on label): * Shantou Roxelis Biotechnology Co., Ltd.

Responsible Person Phone Number (Include Country/Area Code): * 86-0754-13342745877

Parent Company Name (if applicable):

Responsible Person D&B D-U-N-S Number for Address Listed on the Product Label:

PRODUCT(S), INGREDIENT(S), AND FACILITY(IES)

row(s) 1 - 1 of 1

EDIT	COSMETIC PRODUCT LISTING NUMBER	PRODUCT NAME (AS LISTED ON LABEL)	PRODUCT MARKETING STATUS
✎	53-568979-633101	ROXELIS Pheromone Enhanced Cologne	LISTED

row(s) 1 - 1 of 1

CONFIRMATION STATEMENT

The data and information in this submission have been reviewed and, to the best of my knowledge, are certified to be true and accurate. I agree to report changes to this information as required under section 607 of the Federal Food, Drug, and Cosmetic Act.

WARNING: A willfully false statement is a criminal offense, U.S. Code, Title 18, Section 1001.

[x] I Agree *

Date * 02-20-2025

Name of Submitter * Shantou Roxelis Biotechnology Co., Ltd.

ADDITIONAL CONTACT INFORMATION FOR AUTHORIZED AGENT

Additional Contact Name: Jessica Zhong

Phone Number (Include Country/Area Code): 001-719-6787182

Email: UA.customerservice@hotmail.com

Phone Extension:

VIEW SPL | DOWNLOAD SPL | CREATE NEW VERSION | << RETURN

Note: Click on the Data Element Name for each field below to display instructions and helpful hints for filling out this Registration of Cosmetic Product Facility submission form. A red asterisk (*) indicates a required field.

For assistance with validation errors and general questions regarding electronic registration and listing of cosmetic product facilities and products, contact cosmeticsdirect@fda.hhs.gov.

DOCUMENT TYPE DETAILS

Document Type: *	COSMETIC FACILITY REGISTRATION		
Set ID: *	260dd02d-f670-64b1-e063-6294a90afec8	Version Number: *	1
Root ID: *	260dd02d-f671-64b1-e063-6294a90afec8	Effective Date: *	11-03-2024

REGISTRATION DETAILS

Is this a facility registration for a small business (optional registration)?: Yes / No

Facility Name: *	Shantou Roxelis Biotechnology Co Ltd	Facility Country: *	China
Facility FEI Number: *	3032984539	Facility Street Address: *	Room 809-3, Building 1, Chongyaohao Commercial-Residential Center, No. 57
Facility D&B D-U-N-S Number:		Facility City: *	Shantou City
Parent Company Name (if applicable):		Facility State or Province:	
		Facility Zip/Postal Code: *	515000

FACILITY CONTACT DETAILS

Name of the Owner and/or Operator of the Facility: *	Shantou Roxelis Biotechnology Co., Ltd.	Facility Phone Number (Include Country/Area Code): *	86-0754-13342745877
Facility Email: *	sdokn1559@163.com		

US AGENT

U.S. Agent Name (for foreign facilities): *	UA INTERNATIONAL INC.	U.S. Agent Phone Number (Include Country/Area Code): *	1-719-678-7182
U.S. Agent Email (if not available, enter "N/A") *	UA.customerservice@hotmail.com	U.S. Agent Phone Extension:	

FACILITY BRAND NAMES

EDIT	BRAND NAME	RESPONSIBLE PERSON NAME	PRODUCT CATEGORY CODE(S)
	Shantou Roxelis Biotechnology Co., Ltd.	Shantou Roxelis Biotechnology Co., Ltd.	• (01) Baby products - (A) Baby shampoos • (01) Baby products - (B) Lotions, oils, powders, and creams • (01) Baby products - (C) Baby wipes • (01) Baby products - (D) Other baby products - 1. Leave-on • (01) Baby products - (D) Other baby products - 2. Rinse-off • (02) Bath preparations - (A) Bath oils, tablets, and salts • (02) Bath preparations - (B) Bubble baths • (02) Bath preparations - (C) Bath capsules • (02) Bath preparations - (D) Other bath preparations • (03) Eye makeup preparations (other than children's eye makeup preparations) - (A) Eyebrow pencils • (03) Eye makeup preparations (other than children's eye makeup preparations) - (B) Eyeliners • (03) Eye makeup preparations (other than children's eye makeup preparations) - (C) Eye shadows • (03) Eye makeup preparations (other than children's eye makeup preparations) - (D) Eye lotions • (03) Eye makeup preparations (other than children's eye makeup preparations) - (E) Eye makeup removers • (03) Eye makeup preparations (other than children's eye makeup preparations) - (F) False eyelashes • (03) Eye makeup preparations (other than children's eye makeup preparations) - (G) Mascaras • (03) Eye makeup preparations (other than children's eye makeup preparations) - (H) Eyelash and eyebrow adhesives, glues, and sealants • (03) Eye makeup preparations (other than children's eye makeup preparations) - (I) Eyelash and eyebrow preparations (primers, conditioners, serums, fortifiers) • (03) Eye makeup preparations (other than children's eye makeup preparations) - (J) Eyelash cleansers • (03) Eye makeup preparations (other than children's eye makeup preparations) - (K) Other eye makeup preparations • (04) Children's eye makeup preparations - (A) Children's eyeshadows • (04) Children's eye makeup preparations - (B) Other children's eye makeup • (05) Fragrance preparations - (A) Colognes and toilet waters • (05) Fragrance preparations - (B) Perfumes • (05) Fragrance preparations - (C) Powders (dusting and talcum) (excluding aftershave talc) • (05) Fragrance preparations - (D) Other fragrance preparations • (06) Hair preparations (non-coloring) - (A) Hair conditioners - 1. Leave-on • (06) Hair preparations (non-coloring) - (A) Hair conditioners - 2. Rinse-off • (06) Hair preparations (non-coloring) - (B) Hair sprays (aerosol fixatives) • (06) Hair preparations (non-coloring) - (C) Hair straighteners • (06) Hair preparations (non-coloring) - (D) Permanent waves • (06) Hair preparations (non-coloring) - (E) Rinses (non-coloring) • (06) Hair preparations (non-coloring) - (F) Shampoos (non-coloring) - 1. Leave-on • (06) Hair preparations (non-coloring) - (F) Shampoos (non-coloring) - 2. Rinse-off • (06) Hair preparations (non-coloring) - (G) Tonics, dressings, and other hair grooming aids • (06) Hair preparations (non-coloring) - (H) Wave sets • (06) Hair preparations (non-coloring) - (I) Other hair preparations - 1. Leave-on • (06) Hair preparations (non-coloring) - (I) Other hair preparations - 2. Rinse-off • (07) Hair coloring preparations - (A) Hair dyes and colors (all types requiring caution statement and patch test) • (07) Hair coloring preparations - (B) Hair tints • (07) Hair coloring preparations - (C) Hair rinses (coloring) - 1. Leave-on • (07) Hair coloring preparations - (C) Hair rinses (coloring) - 2. Rinse-off • (07) Hair coloring preparations - (D) Hair shampoos (coloring) - 1. Leave-on • (07) Hair coloring preparations - (D) Hair shampoos (coloring) - 2. Rinse-off • (07) Hair coloring preparations - (E) Hair color sprays (aerosol) • (07) Hair coloring preparations - (F) Hair lighteners with color ...(73)

1 - 1

CONFIRMATION STATEMENT

The data and information in this submission have been reviewed and, to the best of my knowledge, are certified to be true and accurate. I agree to report changes to this information and renew as required under section 607 of the Federal Food, Drug and Cosmetic Act.

WARNING: A willfully false statement is a criminal offense, U.S. Code, Title 18, Section 1001.

I Agree *

		Date *	11-04-2024
		Name of Submitter *	Shantou Roxelis Biotechnology Co., Ltd.

ADDITIONAL CONTACT INFORMATION FOR AUTHORIZED AGENT

Additional Contact Name:		Phone Number (Include Country/Area Code):	
Email:		Phone Extension:	