

Sytenol® A Raw Material Information Profile

Trade Name:	Sytenol® A
Product Code:	BK 1023
INCI Name:	Bakuchiol
Supplier Name:	Sytheon
Country of Origin:	India
Field of application:	Cosmetics
Function of the product:	Active ingredient
Recommended use concentration:	0.5% - 1%
Use restrictions:	None

Composition

Chemical Name	CAS#	EC#
Phenol, 4-[(1E, 3S)-3-ethenyl-3, 7-dimethyl-1, 6-octadienyl]	10309-37-2	685-515-4
Compositional break down* (indicative values)	Bakuchiol content typically ranging from 99.5 to 99.9% with a moisture content of ≤0.6%	

*The compositional breakdown is given for indication. Only the information contained in the Certificate of Analysis are considered as specifications

Additives (intentionally added to maintain quality or stability...)

Chemical Name	CAS#	EC#	%
None			

By-products and impurities

Based on our production process, raw materials and equipment used, we expect that the material contains:

	Not Expected	Yes	Nature & max in ppm / Comments
Diethylene glycol	X	<input type="checkbox"/>	
Dioxane	X	<input type="checkbox"/>	
Dioxin	X	<input type="checkbox"/>	
Free Ethylene Oxide	X	<input type="checkbox"/>	
Glycol Ether	X	<input type="checkbox"/>	
Parabens	X	<input type="checkbox"/>	
Polyethylene glycols (PEG)	X	<input type="checkbox"/>	
Phthalates	X	<input type="checkbox"/>	
Polycyclic Aromatic Hydrocarbon	X	<input type="checkbox"/>	
Melamine	X	<input type="checkbox"/>	
Nitrosamines	X	<input type="checkbox"/>	
Residual solvents*	<input type="checkbox"/>	X	Methanol, Hexanes & Ethyl Acetate – ≤ 25 ppm, typically < 10 ppm
Silicone	X	<input type="checkbox"/>	
Other Impurities*			Psoralene & isopsoralene: Total ≤ 25 ppm, typically ≤ 5 ppm

*The residual solvents and impurities are given for indication. Only the information contained in the Certificate of Analysis are considered as specifications. These impurities are technically unavoidable in good manufacturing practices.

Sytenol®A Raw Material Information Profile

Global Chemical Regulation compliance

Global REACH-like Regulation Status

Country	Regulation	Chemical name	Identification number under specific regulation	Status under specific Regulation
Europe	REACH	Phenol, 4-[(1E, 3S)-3-ethenyl-3, 7-dimethyl-1, 6-octadienyl]	EC# 685-515-4	Registered # 01-2120113117-71-0000 1 to 10 tons
UK	UK REACH	Phenol, 4-[(1E,3S)-3-ethenyl-3,7-dimethyl-1,6-octadien-1-yl]-	CAS# 10309-37-2-	Under DUIN by our local distributor Registration deadline is of 6 years from October 27, 2021
Korea	K-REACH			Exemption for cosmetic use
Turkey	KKDIK			Exemption for < 1 ton/year importation

Global Inventory Status

Country	Inventory	Yes	No	Additional Information
USA	TSCA listed	<input type="checkbox"/>	X	Exemption for cosmetic use
Canada	DSL listed	<input type="checkbox"/>	X	
	NDSL listed	<input type="checkbox"/>	X	
	Schedule 4*	X	<input type="checkbox"/>	Approved for <1 ton/year importation
Australia	AICS listed	<input type="checkbox"/>	X	
	AICIS exempted or reported introduction*	X	<input type="checkbox"/>	Low risk ingredient - Approved with volume restriction and for cosmetic uses. Reported volume limit is managed by our local distributor
Philippines	PICCS listed	<input type="checkbox"/>	X	Exemption for cosmetic use
China	IECSC listed	<input type="checkbox"/>	X	
	Record notification*	X	<input type="checkbox"/>	Approved for < 1 ton/year importation
Japan	ENCS listed	<input type="checkbox"/>	X	Exemption for cosmetic use
	ISHL listed**	<input type="checkbox"/>	X	

*Low volume exemption or Chemical imported volume permit/notification is only based on the assumption that the ingredient is imported by Sytheon or its distributors.

**Exemption in case of importation of the cosmetic finished product

Sytenol®A Raw Material Information Profile

Global Cosmetic Regulation compliance

Country	Regulation	Yes	No	Comment
Australia	Classical cosmetic: Industrial Chemicals Act 1989 Schedules (Poisons Standard)	X		Compliant
	Therapeutic Goods Act 1989 - ARTG list	<input type="checkbox"/>	X	Non-Compliant
Canada	Classical cosmetic: The Food and Drug Act, Cosmetic Regulations (C.R.C., ch. 869) Cosmetic Ingredient Hotlist	X	<input type="checkbox"/>	Compliant
China	Cosmetic Supervision and Administration Regulation (CSAR) Safety and technical standard for cosmetics	X	<input type="checkbox"/>	Compliant NMPA submission code: 20230048
	IECIC list 2021		X	
Europe	EU Cosmetic Regulation 1223/2009	X	<input type="checkbox"/>	Compliant
Japan	Classical cosmetic: Japanese Standards of Cosmetics (Notification No.331 of 2000)	X	<input type="checkbox"/>	Compliant
	Quasi-drugs: Pharmaceutical Affairs Law of Japan (PAL)	<input type="checkbox"/>	X	Non-Compliant
Korea	Classical cosmetic: Cosmetic Act 17250	X	<input type="checkbox"/>	Compliant
	Microplastics: Notification 2017-3 amending Annex I (forbidden substances) of Safety and Technical Standard for Cosmetics	X	<input type="checkbox"/>	Not concerned
USA	Classical cosmetic: Federal Food, Drug and Cosmetic (FD&C) Act (21 CFR 700 to 740) California Safe Cosmetics Program (Proposition 65)	X	<input type="checkbox"/>	Compliant
	Microbead-Free Waters Act of 2015	X	<input type="checkbox"/>	Not concerned

To the best of our knowledge, Sytenol®A is also compliant with the local cosmetic regulations of the following countries / geographical areas:

Taiwan

New Zealand

Hong Kong

Asean

Gulf countries

Saudi Arabia

Morocco

Andean community - CAN

Mercosur

CACM

India

Russia

Sytenol® A Raw Material Information Profile

Product Specification

✓ Refer to attached Technical Data Sheet

Manufacturing and Ingredients

Manufacturing location

✓ India

Production Process

✓ Refer to attached Flow Chart

Origin

Product	Origin*	Country of Origin
Bakuchiol	Natural/ edible plant seeds of <i>Psoralea Corylifolia</i> Wild harvested	India

*Natural or Plant derivative or Synthetic

Natural raw material is defined as plant, animal, mineral, or microbiological origin and obtained by physical, enzymatic, or microbiological processes, or obtained by traditional production processes (e.g., extraction, distillation, heating, fermentation).

For plant origin: Wild or Cultivated.

Sytenol®A Raw Material Information Profile

Statements

Animal Testing

Animal means: a) Live non-human vertebrate animals, including: (i) independently feeding larval forms; and (ii) fetal forms of mammals as from the last third of their normal development (or earlier if the animal is to be allowed to live beyond that stage of development and, as a result of the testing procedures, is likely to experience pain, suffering, distress or lasting harm after it has reached that stage of development); b) Live cephalopods.

(Definition under EU Directive 2010/63)

✓ We certify that Sytheon has not sponsored any animal testing, as per above definition, after March 11, 2013, with the product. Please refer to Tox/Ecotoxicological summary document for detailed information.

Allergens (fragrance)

Allergens EU Regulation 2023/1545 (July 26, 2023)

EU Regulation 1223/2009 - Annex III

Linalool (CAS 78-70-6) and Caryophyllene Beta (CAS 87-44-5) are expected to be present at technically unavoidable traces levels, which are naturally occurring substances from the plant seed. Based on analytical evidence,

- Linalool content is ≤ 1000 ppm, typically is ≤ 550 ppm (15 analyzed samples)
- Caryophyllene beta content can exceed 1000 ppm, typically is ≤ 1900 ppm. (20 analyzed samples)

Allergens (food)

EU Regulation 1169/2011 - Annex II: Substances or products causing allergies and intolerances.

✓ Based on the information available on the raw materials, production process, and equipment used, we certify that the food allergens listed in annex II of Regulation 1169/2011 are not expected to be present.

BSE/TSE

✓ We certify that the Sytenol®A does not contain any ingredient of animal origin and has not been in contact with raw materials of animal origin during its manufacturing process. Consequently, the product is not exposed, and is not related to the risk of Bovine Spongiform Encephalopathy (BSE) Transmissible spongiform encephalopathy (TSE).

California Proposition 65

✓ Based on the information available on the raw materials, production process, and equipment used, we certify that the product is compliant to Prop 65 law of California, USA.

Sytenol®A Raw Material Information Profile

Statements

CITES and IUCN Red List

✓ We certify that we do not use CITES and IUCN Red regulated plant species as intentional components of the raw material.

CMR

CLP Regulation 1272/2008, Annex VI; EU Regulation 1223/2009 Article 15, Substances classified as CMR substances and Article (17), Traces of prohibited substances.

- ✓ Based on the information available on the raw materials, production process, and equipment used, substances related to the CMR are not expected to be present in Sytenol®A.
- ✓ The Product complies with the provision of Article 15 of EU Regulation 1223/2009 related to the CMR substances as amended.
- ✓ The potential presence of traces of CMR substances (Hexane / CAS 110-54-3) cannot be avoided and is covered by the provision of Article 17 of EU Regulation 1223/2009. Please refer to RMIP under «By-products and impurities» section for more information.

European Cosmetic Regulation (EC) n° 1223/2009

Including annexes II, III, IV, V and all amendments

- ✓ Based on the information available on the raw materials, production process and equipment used, and supported by extensive analytical data, we certify that Sytenol®A is compliant to the European Cosmetic Regulation
- ✓ The Product complies with the provisions of Article 15 and Article 17 (EU Regulation 1223/2009) related to the CMR substances (see above CMR statement)
- ✓ The Product complies with the provisions of Article 18 related to animal testing.
- ✓ The Product is not expected to contain any ingredient and any substance listed in the annex II.
- ✓ The Product is not expected to contain any ingredient and any substance listed in the annexes III, IV, However, Hexane (CAS 110-54-3) listed in Annex II/999 and Methanol (CAS 67-56-1) listed in Annex III/52 can be present at trace levels and are technically unavoidable under good manufacturing practices.

Gluten

- ✓ Based on the information available on the raw materials, production process and equipment used, we certify that the presence of gluten is not expected. Therefore, we do not perform any analysis for this substance.

Sytenol®A Raw Material Information Profile

Statements

GMO

✓ Based on the information available on the raw materials, production process and equipment used, we certify that the Sytenol®A is not obtained from Genetically Modified Raw Materials (GMO) and does not contain Genetically Modified Organisms (GMO).

Halal

✓ We certify that Sytenol®A is halal certified.

Heavy metals

✓ We certify that the heavy metals (Pb, Hg, As, Cd) present in Sytenol® A are ≤ 1 ppm each.
✓ Refer to attached Technical Data Sheet.

Irradiation

✓ We certify that Sytenol®A has not been exposed to ionizing radiation and does not contain any components resulting from ionizing radiation.

Latex

✓ Based on the information available on the raw materials, production process and equipment used, we certify that the presence of latex is not expected. Therefore, we do not perform any analysis for this substance.

Microplastics

European Union: (EU) 2023/2055 of 25 September 2023 amending ANNEX XVII to Regulation (EC) No 1907/2006

✓ At the European Union level, Commission Regulation (EU) 2023/2055 of 25 September 2023 amending ANNEX XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) as regards synthetic polymer microparticles entered into force on 17 October this year. The Regulation describes the criteria for the definition of “synthetic polymer microparticles”.

From the best of our knowledge about the starting materials, the process, and the structure of the product, we can certify that Sytenol® A is not considered as “synthetic polymer microparticles” according to this definition.

Therefore, it is outside the scope of the EU restriction (ANNEX XVII) proposal to ban intentionally added microplastics in certain products in the European Union

Sytenol®A Raw Material Information Profile

Statements

Nanomaterials

✓ We certify that Sytenol®A is not a nanomaterial as defined by the Cosmetic EU Regulation 1223/2009, the French Decree 2012-232, and the European Commission Recommendation 2011/696.

Natural labels and indexes

Ecocert/Cosmos

Sytenol®A does not comply with Ecocert/Cosmos Natural standard.

✓ Natrue

We certify that the Sytenol®A is 100% Natural by Natrue

✓ Natural Index/Natural Origin Index

We certify that Sytenol®A has a Natural Index (NI) 1 and a Natural Origin Index (NOI) 1 based on the definition of ISO 16128.

Palm Oil

✓ We certify that Sytenol®A does not contain palm oil or palm derived compounds.

Pesticides

✓ Based on the information available on the raw materials, production process and equipment used, we certify that pesticides are not expected to be present in Sytenol® A. Therefore, we do not perform routine analysis for this substance.

Preservatives

EU Regulation 1223/2009 - Annex V

✓ Based on the information available on the raw materials, production process, and equipment used, we certify that Sytenol®A does not contain any preservative.

Residual solvents

Guidelines ICH Q3C and USP General methods <467>

✓ We certify that Methanol (class 2), Hexane (class 2) and Ethyl Acetate (class 3) are likely to be present in Sytenol®A which are below the concentration limits of the guidelines as technically unavoidable traces under good manufacturing practices. Analyses are performed on each batch (please refer to CoA and RMIP under “By-products and impurities” section)

SVHC (Substances of Very High Concern)

✓ Based on the information available on the raw materials, production process, and equipment used, we certify that substances of very high concern (SVHC) as defined by REACH, are not likely to be present.

Sytenol®A Raw Material Information Profile

Statements

VEGAN

✓ We certify that Sytenol®A is obtained from vegetable raw materials and does not contain any animal based raw material. It has not been produced with raw materials from animal or human origin and has not encountered any animal or human material during its manufacturing process. The product is therefore suitable* for vegan and vegetarian.

**“suitable” means that no independent certification is available for the product and the suitability conclusion based on the assessment of SYTHEON as described above.*

VOC

Swiss Ordinance SR 814.018, Annex 1 (Art 2, a), exemption from tax (Article 8) and amendments

✓ Based on the information available on the raw materials, production process and equipment used, none of the substances listed in Annex 1 (Art 2, a) of SR 814.018 are expected to be present above the threshold of 3% (limit given in article 8)

Sytenol® A Raw Material Information Profile

Safety and Environment

Toxicological Information

- ✓ We certify that the product is compliant with the requirement of the EU Cosmetic Regulation (EC N°1223/2009) related to the ban on animal testing and its marketing in the EU of cosmetic products.
- ✓ Refer to Safety Assessment & ECHA link for accessing summary of the studies.
<https://echa.europa.eu/fr/registration-dossier/-/registered-dossier/17106>

Ecotoxicological Information

- ✓ Refer to the Safety Data Sheet & ECHA link for accessing summary of the studies.
<https://echa.europa.eu/fr/registration-dossier/-/registered-dossier/17106>

List of available documents

Documents	Yes	No	Comments
Process Flow chart	X		
Technical Data Sheet	X		
Tox/Ecotoxicological summary	X		Safety assessment also available - Not attached
Safety Data Sheet	X		

May 23, 2024

Disclaimer: The information given, and the recommendations made herein are based on our research and are believed to be accurate, but no guarantee of their accuracy is made. This information is intended to be helpful, but no warranty is expressed or implied as to the results obtained from use of the formulation, procedure or products suggested herein. Neither is any permission or recommendation to practice any invention covered by patent either expressed or implied.