

## REGULATORY DATA SHEET

|                      |                              |
|----------------------|------------------------------|
| <b>PRODUCT NAME:</b> | <b>Lipocol™ SC Pastilles</b> |
| <b>INCI NAME:</b>    | <b>Cetearyl Alcohol</b>      |

**REVISION DATE:** June 14, 2023  
**REVISION NUMBER:** 5

### COMPOSITION

| INCI NAME        | CAS#       | EC#       | Range % |
|------------------|------------|-----------|---------|
| Cetearyl Alcohol | 67762-27-0 | 267-008-6 | 100     |

Additionally, as per the current product specifications, the carbon chain distribution of this product is as follows:

C12: 2% Maximum  
 C14: 7% Maximum  
 C16: 25 – 35%  
 C18: 60 – 67%  
 C20: 2% Maximum  
 C22: 1% Maximum

### CERTIFICATIONS

| Certification Type | Details   |
|--------------------|---|
| Halal              | The product is not Halal certified by Vantage™. However, based on the review of the raw materials and manufacturing process, the product meets the following Halal requirements: <ol style="list-style-type: none"> <li>Does not contain any ingredient of animal origin.</li> <li>Does not contain or was manufactured with ethyl alcohol.</li> <li>Equipment used for manufacturing is not used for the manufacturing of products containing ingredients of animal origin.</li> <li>Does not come in contact with any products of animal origin or products containing such ingredients.</li> </ol> |
| Kosher             | The product is not Kosher certified by Vantage™. However, based on the review of the raw materials and manufacturing process, the product meets the following Kosher requirements: <ol style="list-style-type: none"> <li>Does not contain any ingredient of animal origin.</li> <li>Equipment used for manufacturing is not used for the manufacturing of products containing ingredients of animal origin.</li> <li>Does not come in contact with any products of animal origin or products containing such ingredients.</li> </ol>   |
| Organic            | N/A   |
| COSMOS             | N/A   |

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|      |  |
|------|--|
| RSPO | This product contains palm or palm oil derivatives. The manufacturing facility is RSPO certified according to the Mass Balance Supply Chain Model. RSPO Certification number will appear on the product COA if the version of this product is considered mass balance. |
|------|--|

## **SOURCE**

According to information provided by our current raw material supplier, and to its composition, **Lipocol™ SC Pastilles** contains the following raw material whose origin is as follows:

| INCI NAME        | ORIGIN  | COO   |
|------------------|---|-------|
| Cetearyl Alcohol | Plant - fatty alcohols C16-C18 distillation consisting predominantly of cetyl and stearyl alcohols derived from palm oil. | India |

## **COUNTRY OF MANUFACTURE**

India

## **MANUFACTURING PROCESS**

**Lipocol™ SC Pastilles** is produced starting with palm oil which is then hydrogenated into Alcohols and distilled. The crude fatty acid goes through hydrogenation and distillation to produce to crude alcohol which is fractionated. After pastillation, the product is packaged.

## **VEGAN / VEGETARIAN STATUS**

Please note that **Lipocol™ SC Pastilles** is dedicated to cosmetic use only. Vantage Specialty Ingredients, Inc. hereby certifies that to the best of our knowledge the **Lipocol™ SC Pastilles** is considered Vegan under the following conditions:

- Does not contain meat, fish, fowl, animal byproducts, eggs or egg products, milk or milk products
- Does not involve animal testing of ingredients or finished product by supplier, producer, manufacturer or independent party
- Does not contain animal-derived GMOs or genes used to manufacture ingredients or finished products

## **ALLERGENS**

### **EUROPEAN UNION (EU):**

**Lipocol™ SC Pastilles** is not expected to contain any of the 26 Allergens listed on the Fragrance Restrictions in Annex II and III of Regulation (EC) No. 1223/2009. However, since the detection of allergens does not form part of the product specification it is not routinely analyzed.

### **FOOD AND DRUG ADMINISTRATION (FDA):**

According to the Food Allergen Labelling and Consumer Protection Act of 2004 (FALCPA), the 8 food allergens identified by the law include: Milk, eggs, fish (e.g. bass, flounder, cod), crustacean shellfish (e.g. crab, lobster, shrimp), tree nuts (e.g. almonds, walnuts, pecans), peanuts, wheat and soybeans. **Lipocol™ SC Pastilles** does not contain and is not classified as a major food allergen indicating by the Food Allergen Labelling and Consumer

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Protection Act of 2004 (FALCPA). Vantage™ Specialty Ingredients, Inc. does not warrant the ingestion of the product indicated above. Lipocol™ SC Pastilles is intended to be used solely as a cosmetic ingredient.

### **CALIFORNIA PROPOSITION 65**

To the best of our knowledge, materials listed under Proposition 65 (as amended) are not intentionally introduced in the composition of Lipocol™ SC Pastilles therefore their presence is not expected except at extremely low trace levels for which we do not conduct any tests.

### **CALIFORNIA SAFE COSMETICS ACT**

To the best of our knowledge, substances indicated on the California Safe Cosmetics Act, are not intentionally introduced in the composition of Lipocol™ SC Pastilles, therefore their presence is not expected except at extremely low trace levels for which we do not conduct any tests.

### **COMPLIANCE WITH REGULATION (EC) N° 1223/2009 COSMETIC REGULATION**

Lipocol™ SC Pastilles is compliant with Regulation (EC) N° 1223/2009.

### **ANIMAL TESTING**

In accordance with Regulation (EC) N° 1223/2009, Chapter V; Article 18 of the European Parliament and of the Council of 30 November 2009 on Cosmetic Products, Vantage Specialty Ingredients has not performed animal testing on Lipocol™ SC Pastilles. Therefore, Vantage Specialty Ingredients certifies that Lipocol™ SC Pastilles has not been subject to animal testing by our company for cosmetic purpose. However, there may be historical data/testing available which helped to establish the toxicological profile for raw material under which this product is classified.

### **CARCINOGENIC, MUTAGENIC, REPROTOXIC (CMR) SUBSTANCES**

To the best of our knowledge, substances classified as CMR substances according to Article 15 of Regulation (EC) No. 1223/2009 are not intentionally introduced or contained in the composition of Lipocol™ SC Pastilles. However, since the detection of these substances does not form part of the specification, they are not routinely analyzed.

### **NANOMATERIALS**

Based on our findings and the information provided by the current raw material supplier, Lipocol™ SC Pastilles does not contain or fit under the definition of “nanomaterial” according to Regulation (EC) N° 1223/2009 or Commission Recommendation 2011/696/EU and therefore cannot be considered as a nanomaterial, nor contains any nanomaterials. Additionally, Lipocol™ SC Pastilles is a pastille.

### **SUBSTANCES OF VERY HIGH CONCERN (SVHC)**

To the best of our knowledge, Lipocol™ SC Pastilles, does not contain any of the Annex XIV candidate chemicals proposed to be SVHC (Substances of Very High Concern) or those substances listed on the SVHC Candidate List above the 0.1% threshold as stated in REACH (Article 57, Regulation No. 1907/2009) determined either through (i) non-use of the substance (ii) mass balance calculation or (iii) specific testing. The chemical materials listed are not used in the manufacture or the formulation of this product. However, this product has not been tested for these chemical materials.

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## **CONFLICT MINERALS**

Vantage Specialty Ingredients, Inc. is not required to disclose information under the Dodd-Frank Wall Street Reform and Consumer Financial Protection Act. In addition, conflict minerals or conflict mineral derivatives from the Democratic Republic of the Congo or any adjoining countries (as defined by the Act) are not purchased. Furthermore, conflict minerals are not expected to be used in the manufacture of our products.

## **CONVENTION ON INTERNATIONAL TRADE IN ENDANGERED SPECIES OF WILD FAUNA AND FLORA (CITES)**

In accordance with Regulation (EC) No 338/97 and its Annexes (and its adaptations) and under the terms of CITES & its Appendices (and its adaptations), Lipocol™ SC Pastilles is NOT derived from species listed respectively in Annexes A, B, C and D or Appendices I, II, or III.

## **GENETICALLY MODIFIED ORGANISMS (GMOs)**

To the best of our knowledge and based on information provided to us, Lipocol™ SC Pastilles does not contain, nor was processed using any ingredients that were derived from Genetically Modified Organisms.

## **GLOBAL CHEMICAL INVENTORIES**

Lipocol™ SC Pastilles has been evaluated to determine compliance with the following chemical inventories:

| <b>Ingredient</b> | <b>CAS #</b> | <b>Australia</b> | <b>Canada</b> | <b>China</b>              | <b>European Union</b> | <b>Japan</b>        | <b>Korea</b>            | <b>United States</b> |
|-------------------|--------------|------------------|---------------|---------------------------|-----------------------|---------------------|-------------------------|----------------------|
| Cetearyl Alcohol  | 67762-27-0   | AIIIC Listed     | DSL Listed    | IECSC/<br>IECIC<br>Listed | 267-008-6             | ENCS/ISHL<br>Listed | KECI/<br>KECL<br>Listed | TSCA<br>Listed       |

Please note that the above table is based off a preliminary search on each ingredient completed by our team; we recommend a more comprehensive review of the international regulatory status of this product in your final formulation.

## **GLUTEN**

To the best of our knowledge and based on information provided to us, Lipocol™ SC Pastilles, does not contain any gluten.

## **HEAVY METALS / ELEMENTAL IMPURITIES**

Please be advised that based on information available to us, Lipocol™ SC Pastilles does not contain heavy metals as intentional additives. Our current supplier has informed us that the product complies with ICH requirements. These substances may be present as impurities, but we do not specifically run any analysis on our raw materials or end-product to measure for these materials.

## **PHTHALATES**

No phthalates are intentionally added as ingredients or processing aids to Lipocol™ SC Pastilles during manufacturing.

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## **ISO 16128**

According to the composition and manufacturing process of **Lipocol™ SC Pastilles**, with respect to ISO norm 16128, please see below calculations for Naturality Index (NI), Naturality Origin Index (NOI), Organic Index (OI) and Organic Origin Index (OOI):

| INCI NAME        | NI | NOI | OI | OOI |
|------------------|----|-----|----|-----|
| Cetearyl Alcohol | 0  | 1   | 0  | 0   |

## **REACH**

Please be advised **Lipocol™ SC Pastilles** is in compliance with REACH regulations. The REACH registration covers our downstream users and the cosmetic use PC 39 according to the Cosmetic Europe (ex Colipa) mapping.

| INCI NAME        | CAS#       | EC#       | REACH Registration                              |
|------------------|------------|-----------|---|
| Cetearyl Alcohol | 67762-27-0 | 267-008-6 | 01-2120092297-47-XXXX<br>Under Alcohols, C16-18 |

## **RESIDUAL PESTICIDES**

Please be advised **Lipocol™ SC Pastilles** is not monitored for residual pesticides. However, to the best of our knowledge, a presence of pesticides in the finished product is not expected to be present, with respect to the used raw materials and the production process.

## **RESIDUAL SOLVENTS**

The European Pharmacopoeia and the United States Pharmacopeia have adopted the ICH (International Committee on Harmonization) Guideline Q3C Residual Solvents. Please be advised that **Lipocol™ SC Pastilles** is not manufactured with the use of any solvent listed as Class 1, Class 2, or Class 3 listed in the ICH Q3C Guideline for residual solvents. However, since residual solvent detection does not form part of the product specification it is not routinely analyzed.

## **SAFETY ASSESSMENT**

Please note that **Lipocol™ SC Pastilles** has not been independently tested for safety by Vantage™. However, the material has been CIR reviewed, as per the summary listed below:

| Ingredient       | Conclusion   |
|------------------|--|
| Cetearyl Alcohol | - In a safety assessment of Cetearyl Alcohol originally conducted in 1988, the CIR Expert Panel stated this cosmetic ingredient was safe in present practices of use and reviewed newly available studies/information regarding types/concentrations to reconfirm the safety [CTFA 2005: used at concentrations up to 15%]( <i>Annual Review of Cosmetic Ingredient Safety Assessments: 2005/2006, IJT 27(Suppl. 1):77-142, 2008</i> ) |

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## **TRANSMISSIBLE/BOVINE SPONGIFORM ENCEPHALOPATHY (TSE/BSE)**

Lipocol™ SC Pastilles does not contain any animal-derived material and therefore will not contain any Transmissible Spongiform Encephalopathy (TSE) agents likely to cause Bovine Spongiform Encephalopathy (BSE). Furthermore, Vantage Specialty Ingredients adheres to the Scientific Committee on Cosmetology guidelines on approved processing methods according to the current European directive on BSE and TSE.

## **VOLATILE ORGANIC COMPOUNDS (VOC)**

Lipocol™ SC Pastilles does not meet the definition as a volatile organic compound (VOC) under any of the following regulations:

- 40 CFR Part 51 Section 51.100
- California Air Resources Board's definition of reactive organic gas (ROG) or total organic gases (TOG)
- EC Directive 1999/13/EC (Solvent Emissions Directive)
- The Swiss Federal Council (based on 35a and 35c of the Environmental Protection Act).

## **NITROSAMINES**

Please be advised that nitrosamines are not intentionally added in the processing or raw materials for the manufacture of Lipocol™ SC Pastilles. Additionally, the product has not been in contact with nitrosamines and/or secondary amines containing materials during the manufacturing process, therefore we do not expect our product to contain any nitrosamines and/or secondary amines containing materials.

## **MICROBIOLOGICAL PARAMETERS**

Please be advised Lipocol™ SC Pastilles is not monitored on microbial parameters. High processing temperatures and/or very low water content of the final product decrease the risk of microbial contamination.

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