

REGULATORY DATA SHEET

(Representative Sample)

Lot #: Not Available Supplier: TKB Trading LLC

PRODUCT NAME:	Cellulose Blend
	Octyldodecanol (and) Ethylcellulose (and) Isostearyl Alcohol
	(and) Hydrogenated Dilinoleyl Alcohol

REVISION DATE: November 4, 2021 REVISION NUMBER: 7

COMPOSITION

	CAS#	EC#	Range %
Octyldodecanol	5333-42-6	226-242-9	65.0 – 75.0
Ethylcellulose	9004-57-3	N/A	8.00 - 14.0
Isostearyl Alcohol	27458-93-1	248-470-8	7.00 – 12.0
Hydrogenated Dilinoleyl Alcohol	68783-41-5	500-231-1	7.00 – 12.0

CERTIFICATIONS

Certification Type	Details						
Halal	The product is not Halal certified.						
	However, based on the review of the raw materials and manufacturing process, the product meets the						
	following Halal requirements:						
	a. Does not contain any ingredient of animal origin.						
	 Equipment used for manufacturing is not used for the manufacturing of products containing ingredients of animal origin. 						
	 Does not come in contact with any products of animal origin or products containing such ingredients. 						
Kosher	The product is not Kosher certified.						
	However, based on the review of the raw materials and manufacturing process, the product meets the						
	following Kosher requirements:						
	a. Does not contain any ingredient of animal origin.						
	 Equipment used for manufacturing is not used for the manufacturing of products containing ingredients of animal origin. 						
	c. Does not come in contact with any products of animal origin or products containing such ingredients.						
Organic	N/A						
COSMOS	N/A						
RSPO	N/A						

SOURCE

According to information provided by our current raw material suppliers, and to its composition, **Cellulose Blend** contains the following raw materials whose origins are as follows:

	ORIGIN	COO
Octyldodecanol	Plant/Synthetic – Guerbet reaction of decyl alcohol (of non- GMO vegetable origin: coconut and palm kernel oil sourced mainly from Indonesia/Malaysia)	EU
Ethylcellulose	Plant/Synthetic – synthetic polymer derived from plant origin (highly purified cellulose pulp made from soft wood tress, such as pine, and/or cotton linters)	USA
Isostearyl Alcohol	Plant – naturally derived from coconuts.	USA
Hydrogenated Dilinoleyl Alcohol	Plant/Synthetic – the end-product of the controlled hydrogenation of dilinoleyl alcohol (derived from rapeseed)	EU

COUNTRY OF MANUFACTURE

USA

MANUFACTURING PROCESS

Cellulose Blend is manufactured via heating and blending process.

VEGAN / VEGETARIAN STATUS

Please note that **Cellulose Blend** is dedicated to cosmetic use only. TKB TRADING LLC hereby certifies that to the best of our knowledge **Cellulose Blend** 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):

Cellulose Blend 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. **Cellulose Blend** does not contain and is not classified as a major food allergen indicated by the Food Allergen Labelling and Consumer Protection Act of 2004 (FALCPA). TKB TRADING LLC does not warrant the ingestion of the product indicated above. It 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 **Cellulose Blend**, 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 **Cellulose Blend**, 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

Cellulose Blend 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, TKB TRADING LLC has not performed animal testing on **Cellulose Blend** and its components. Therefore, TKB TRADING LLC certifies that **Cellulose Blend** 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 **Cellulose Blend**. 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 suppliers, this product 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, **Cellulose Blend** is a gel.

SUBSTANCES OF VERY HIGH CONCERN (SVHC)

To the best of our knowledge, **Cellulose Blend**, 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.

CONFLICT MINERALS

TKB TRADING LLC 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), **Cellulose Blend** 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 by the current raw material suppliers, **Cellulose Blend** does not contain, nor was processed using any ingredients that were derived from GMO material.

GLOBAL CHEMICAL INVENTORIES

Cellulose Blend has been evaluated to determine compliance with the following chemical inventories:

Ingredient	CAS #	Australia	Canada	China	European Union	Japan	Korea	United States
Octyldodecanol	5333-42-6	AIIC Listed	DSL Listed	IECSC/ IECIC Listed	226-242-9	ENCS/ISHL Listed	KECI/ KECL Listed	TSCA Listed
Ethylcellulose	9004-57-3	AIIC Listed	DSL Listed	IECSC/ IECIC Listed	-	ENCS/ISHL Listed	KECI/ KECL Listed	TSCA Listed
Isostearyl Alcohol	27458-93-1	AIIC Listed	DSL Listed	IECSC/ IECIC Listed	248-470-8	ENCS/ISHL Listed	KECI/ KECL Listed	TSCA Listed
Hydrogenated Dilinoleyl Alcohol	68783-41-5	AIIC Listed	Not Listed and/or Exempt	IECIC Listed	500-231-1	Not Listed and/or Exempt	KECI/ KECL Listed	TSCA 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 by the current raw material suppliers, **Cellulose Blend**, does not contain any gluten.

HEAVY METALS / ELEMENTAL IMPURITIES

Heavy metals are not intentionally added to **Cellulose Blend** as supplied by TKB TRADING LLC. TKB has performed outside testing using ICP-MS. Typical results are reported below:

Metals Analysis, ppm

Elemental Impurity	Class	Result
As	1	<0.5 ppm
Cd	1	<0.1 ppm
Hg	1	<0.05 ppm
Pb	1	<0.1 ppm

Please note that heavy metals do not form a part of the product specification, therefore are not routinely analyzed.

PHTHALATES

No phthalates are intentionally added as ingredients or processing aids to **Cellulose Blend** during manufacturing.

ISO 16128

According to the composition and manufacturing process of **Cellulose Blend** 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):

	NI	NOI	OI	001
Octyldodecanol	0	1	0	0
Ethylcellulose	0	0.92	0	0
Isostearyl Alcohol	0	1	0	0
Hydrogenated Dilinoleyl Alcohol	0	1	0	0

According to the composition listed above:

- The Natural Content is 0 %

- The Natural Origin Content is 99.93 – 99.99 %

REACH

Please be advised **Cellulose Blend** 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.

	CAS#	EC#	REACH Registration
Octyldodecanol	5333-42-6	226-242-9	Exempted, Quantity <1 T
Ethylcellulose	9004-57-3	N/A	Exempted, Quantity <1 T
Isostearyl Alcohol	27458-93-1	248-470-8	Exempted, Quantity <1 T
Hydrogenated Dilinoleyl Alcohol	68783-41-5	500-231-1	Exempted, Quantity <1 T

RESIDUAL PESTICIDES

Please be advised **Cellulose Blend** 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 **Cellulose Blend** 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. The only Class 3 solvents likely to be present at very low levels are ethyl alcohol (ethanol) and ethyl ether (diethyl ether or ethoxyethane), which are by-products generated during the manufacture of Ethylcellulose. According to information provided by our current supplier, the Ethylcellulose contains <500 ppm of either ethanol or ethyl ether, and therefore an even lower concentration is expected in **Cellulose Blend** based on the composition. However, since residual solvent detection does not form part of the product specification it is not routinely analyzed.

SAFETY ASSESSMENT

Please note that **Cellulose Blend** has not been independently tested for safety. However, most of the materials of the mixture have been CIR reviewed, as per the summaries listed below:

Ingredient	Conclusion
Octyldodecanol	- CIR Expert Panel concluded that Octyldodecanol was safe for use in cosmetics and personal care products as currently used [CTFA 2003: used up to 85%] and they considered new available data to reaffirm the conclusion (Original Report - <i>Final Report on the Safety Assessment of Stearyl Alcohol, Oleyl Alcohol and</i> <i>Octyl Dodecanol, JACT 4(5): 1-29, 1985</i>).
Ethylcellulose	 FDA includes Ethylcellulose on its list of multipurpose additives allowed to be directly added to food; as substances migrating to food from paper and paperboard products, FDA considers Ethycellulose to be GRAS. CIR Expert Panel assessed and reaffirmed the safety of Ethylcellulose and concluded it was safe as a cosmetic ingredient in the practices of use and concentration provided in the assessment [CTFA 2009: up to 8% in lipsticks] (<i>Final Report of the Cosmetic Ingredient Review Expert Panel – Amended Safety Assessment of Cellulose and Related Polymers as used in Cosmetics, March 23, 2009</i>).
Isostearyl Alcohol	- CIR Expert Panel noted that much is known about the biological activities of fatty acids and long-chain aliphatic alcohols and esters. They evaluated the scientific data and concluded that these fatty alcohols were safe for use as cosmetic ingredients. In 2005, they considered available new data and reaffirmed the conclusion from 1988 [CTFA 2005: reported to be used at levels up to 15%] (Original Report – <i>Final Report on the Safety Assessment of Cetearyl Alcohol, Cetyl Alcohol, Isostearyl Alcohol, Myristyl Alcohol, and Behenyl Alcohol, 1988</i>).
Hydrogenated Dilinoleyl Alcohol	 Not CIR reviewed According to the product SDS, Hydrogenated Dilinoleyl Alcohol is not dangerous classified. Irritation to skin or eyes and sensitization are not expected.

Please note the product mentioned above is dedicated to cosmetic use only. The data above is based on our current knowledge and are not claimed to be complete. This does not relieve the end-user from the responsibility to check the suitability of the product for the intended use and from a risk assessment of its own products.

TRANSMISSIBLE/BOVINE SPONGIFORM ENCEPHALOPATHY (TSE/BSE)

Cellulose Blend 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, TKB TRADING LLC 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)

Cellulose Blend does not contain any volatile organic compounds (VOCs) 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 **Cellulose Blend**. 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 **Cellulose Blend** 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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