

ALKEST® TW 80 K NR

Version: 02

Revision date: January, 2026

1. GENERAL PRODUCT INFORMATION

Chemical Description: Polyoxyethylene sorbitan monooleate

CAS Number: 9005-65-6

EC Number: 500-019-9

INCI Name: POLYSORBATE 80

INS number: 433

FEMA number: 2917

Average Molecular Weight: 1310 g/mol

Appearance, 25°C: Clear amber liquid

HLB: 15.0

Shelf Life: 730 days

Country of Manufacturing: United States

Functions: Surfactant, emulsifier, stabilizer.

2. GLOBAL CHEMICAL INVENTORY

COUNTRY	INVENTORY	STATUS
USA	TSCA	Active
EU	EINECS	Not Listed
CANADA	DSL	Listed
CANADA	NDSL	Not Listed
AUSTRALIA	AIC	Listed
CHINA	IECSC	Listed
PHILIPPINES	PICCS	Listed
JAPAN	ENCS	Listed
JAPAN	ISHL	Listed
NEW ZEALAND	NZIOC	Listed
SOUTH KOREA	KECI/KECL	Listed
TAIWAN	TCSI	Listed
THAILAND	TECI	Listed

EU REACH Regulation:

All Indovina products supplied from the European Economic Area* (EEA) are compliant with the REACH Regulation EC 1907/2006 as all components:

- have been registered by Indovina or an affiliate, and/or its suppliers, and/or

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- are excluded from the Regulation, and/or
- are exempted from registration.

Any customer purchasing our products from outside the EEA and subsequently importing these into the EEA have responsibility to comply with the REACH regulation and they should contact their Indovinya Representative for further information.

*European Member States + Iceland, Liechtenstein, Norway

UK REACH Regulation:

Please contact an Indovinya Representative for further information regarding this regulation.

KKDIK Regulation:

Please contact an Indovinya Representative for further information regarding this regulation.

3. SOURCING ORIGIN

	Origin	Raw material – Popular name / Species	Biodiversity Origin	Place of cultivation
Plant *	Yes	Fatty acid from Palm kernel oil (<i>Elaeis guineensis</i>)	Africa	Indonesia, Malaysia and Phillipines
		Sorbitol from Corn (<i>Zea mays</i>)	Mexico	Mexico and USA
Animal	No	-	-	-
Synthetic	Yes	Ethylene Oxide - Petrochemical	-	-
Mineral	No	-	-	-
Other	No	-	-	-

* Plant sources have been cultivated.

4. RENEWABLE SOURCE

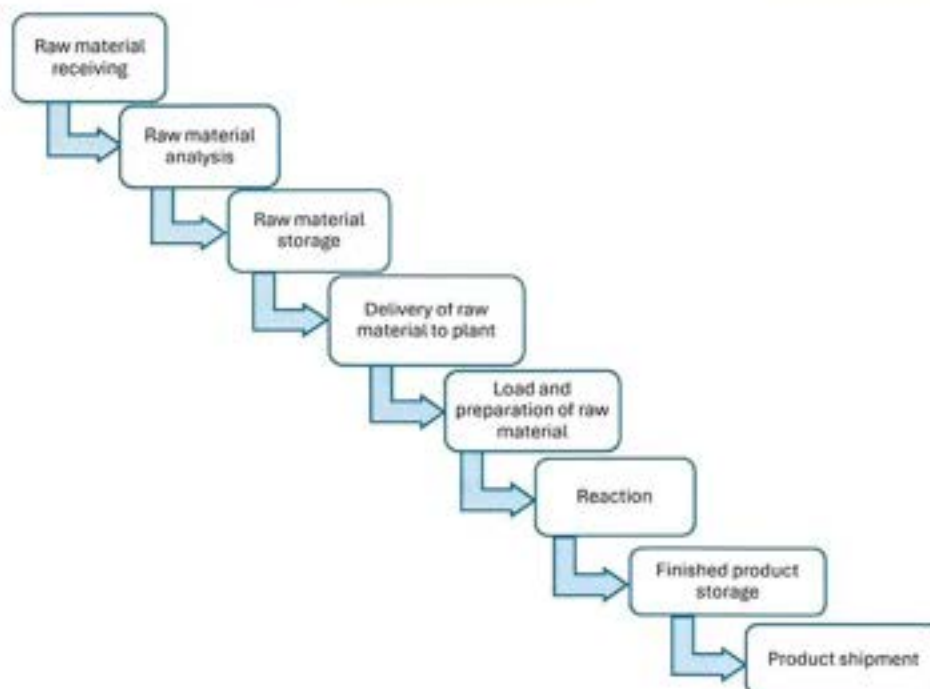
Based on the best knowledge of the raw materials, the percentage of the product that is derived from a renewable source is declared below:

% RENEWABLE MOLECULAR WEIGHT (RMw): 32%

5. ISO 16128

According to ISO 16128-2:2017, item 4.3.2, the product has a Natural Origin Index (INO) = 0.

6. PROCESS FLOWCHART



7. BIODIVERSITY

Based on the best knowledge of the manufacturing process and raw materials, the product does not contain any source of Brazilian Genetic Resources and/or Associated Traditional Knowledge according to the Brazilian Federal Law 13.123/2015, being exempt from registration in the National System of Management of Genetic Resource and Associated Traditional Knowledge (SisGen) and Benefit-Sharing.

8. CITES CONVENTION

Based on the best knowledge of the manufacturing process and raw materials, the product does not contain any ingredient coming from species included in the CITES Convention (Convention on International Trade in Endangered Species of Wild Fauna and Flora). The product is compliant with CITES Convention.

9. NAGOYA PROTOCOL

Based on the best knowledge of the manufacturing process and raw materials, the product is not subject to regulation under the Nagoya Protocol or any other Access and Benefit Sharing (ABS) legislation.

10. GENETICALLY MODIFIED ORGANISMS (GMO)

The raw materials used in the manufacturing of the product are derived from non-genetically modified and genetically modified sources (corn derivatives) and it cannot be segregated from one

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another in the current process. The production process follows a conventional chemical technology without the use of biotechnology methods.

The raw materials, as well as the final product, are manufactured—from synthesis, refining and purification—to the best of our knowledge, to leave no protein or DNA residues from the genetic modification of the original crops. Therefore, genetically modified DNA presence is not expected in the product.

11. ANIMAL DERIVED COMPONENTS

The product is not produced from raw materials of animal origin. There are no components derived from bovine, ovine, caprine, porcine or related ingredients of animal origin. The inputs used in production are from synthetic, petrochemical, plant and/or mineral origins. Products of animal origin or products containing ingredients of animal origin are produced in the same manufacturing facility. The production process seeks to exclude through a rigorous cleaning procedure, as far as possible and practicable, all forms of contamination by animal origin raw materials.

Based on the best knowledge, the product does not contain Transmissible Spongiform Encephalopathy (TSE) / Bovine Spongiform Encephalopathy (BSE) due to the origin of the raw materials.

12. VEGAN

The product complies with the vegan requirements described below:

1. Does not contain animal ingredients or animal byproducts (eggs, dairy, and other animals' byproducts) in the manufacturing process and final product.
2. Not tested on animals (cruelty free).

The production process seeks to exclude through a rigorous cleaning procedure, as far as possible and practicable, all forms of contamination by animal origin raw materials.

13. KOSHER

The product is Kosher certified for the following plants: Pasadena Plant.

14. HALAL

The product is Halal certified for the following plants: Pasadena Plant.

15. FOOD ALLERGENS

Based on the best knowledge of the manufacturing process and raw materials, food allergens are not intentionally added and not expected to be present in the product according to the Brazilian Regulation RDC Nº 727/2022, European Regulation (EU) Nº 1169/2011 and Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA – U.S. FDA).

The process has no potential of cross contamination with food allergens. The presence of food allergens is not tested or monitored in the final product.

16. COSMETIC ALLERGENS

Based on the best knowledge of the manufacturing process and raw materials, cosmetic allergens are not intentionally added and not expected to be present in the product according to the Brazilian Regulation RDC N° 530/2021 and European Regulation (EC) N° 1223/2009 (including the 81 fragrance allergens). The presence of cosmetic allergens is not tested or monitored in the final product.

17. COSMETIC USE

Brazil:

The product complies with the requirements laid down for substances (including impurities), ingredient and/or raw materials according to the Brazilian Cosmetic Regulation RDC N° 530/2021, RDC N° 528/2021, RDC N° 44/2012, RDC N° 69/2016, RDC N° 529/2021, and its amendments.

Details of the substances (including impurities) present in the regulation:

Substance	Concentration	Regulation
1,4-Dioxane	< 0.0001%	RDC N° 529/2021
Ethylene oxide	< 0.0001%	RDC N° 529/2021
Hydrogen peroxide	< 0.015%	RDC N° 530/2021

The presence of technically unavoidable impurities complies with the Brazilian cosmetic regulation.

Europe:

The product complies with the requirements laid down for substances (including impurities), ingredient and/or raw materials according to the consolidated European Cosmetic Regulation (EC) N° 1223/2009 - Annex II, III, IV, V and VI.

Details of the substances (including impurities) present in the Annex II, III, IV, V and VI:

Substance	Concentration	Annex Number
1,4-Dioxane	< 0.0001%	II
Ethylene oxide	< 0.0001%	II
Hydrogen peroxide	< 0.015%	III

The presence of technically unavoidable impurities described in Annex II complies with Article 17 of the Regulation. Therefore, this product complies with the Regulation (EC) N° 1223/2009 regarding Cosmetic Products.

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Mexico:

The product complies with the requirements laid down for substances (including impurities), ingredient and/or raw materials according to the Mexican Cosmetic Regulation 'ACUERDO por el que se determinan las sustancias prohibidas y restringidas en la elaboración de productos de perfumería y belleza (2010)', and its amendments.

Details of the substances (including impurities) present in the regulation:

Substance	Concentration	Article
1,4-Dioxane	< 0.0001%	SEGUNDO
Ethylene oxide	< 0.0001%	SEGUNDO
Hydrogen peroxide	< 0.015%	TERCERO

The presence of technically unavoidable impurities complies with the Mexican cosmetic regulation.

18. INTERNATIONAL FRAGRANCE ASSOCIATION (IFRA)

The components of the product are listed on the IFRA Transparency List. The product complies with the IFRA Standard 51st Amendment regarding restricted, prohibited and specification of substances.

19. CONFLICT MINERALS

Based on raw materials suppliers' information, the product does not contain any intentionally added metal (Tantalum, Tungsten, Tin, Gold, or Cobalt – termed as "Conflict Minerals") derived from Columbite-Tantalite/Coltan, Cassiterite, Gold, Wolframite or their derivatives originating from the Democratic Republic of the Congo and its adjoining countries. Conflict Minerals are not expected to be present and are not monitored in the final product.

This information regarding Conflict Minerals is as defined in Section 1502 of the United States Dodd-Frank Wall Street Reform and Consumer Protection Act.

20. RoHS

Note that the RoHS Directive applies to electrical and electronic equipment and the product does not fall within this scope. However, if the product is used as a raw material in the manufacture of any components of electrical and electronic equipment, see information below.

Based on the best knowledge of the manufacturing process and raw materials, the substances listed at European Directive 2011/65/EU (RoHS 2), as amended by Directive (EU) 2015/863 (RoHS 3), are not intentionally added to the product. The presence of these substances, no matter whether present intentionally or as an impurity, are not expected to exceed the defined threshold limits:

Cadmium (Cd): < 100 ppm

Lead (Pb): < 1000 ppm

Mercury (Hg): < 1000 ppm
Hexavalent Chromium (Cr VI): < 1000 ppm
Polybrominated Biphenyls (PBB): < 1000 ppm
Polybrominated Diphenyl Ethers (PBDE): < 1000 ppm
Bis(2-Ethylhexyl) phthalate (DEHP): < 1000 ppm
Benzyl butyl phthalate (BBP): < 1000 ppm
Dibutyl phthalate (DBP): < 1000 ppm
Diisobutyl phthalate (DIBP): < 1000 ppm

21. HEAVY METALS AND COALITION OF NORTHEASTERN GOVERNORS (CONEG)

Based on the best knowledge of the manufacturing process and raw materials, the heavy metals listed at European Parliament and Council Directive 94/62/EC on packaging and packaging waste and Toxics in Packaging Clearinghouse (TPCH) established by the Coalition of Northeastern Governors (CONEG), are not intentionally added to the product. The presence of these substances, no matter whether present intentionally or as an impurity, are not expected to exceed the defined threshold limits:

Lead + Cadmium + Hexavalent Chromium + Mercury: < 100 ppm total

22. PERSISTENT ORGANIC POLLUTANTS (POPS)

Based on the best knowledge of the manufacturing process and raw materials, the substances listed in the Annexes I, III or IV of the Regulation (EU) 2019/1021 on Persistent Organic Pollutants (POPs) and subsequent amendments are not intentionally added to the product.

23. OZONE DEPLETION

Based on the best knowledge of the manufacturing process and raw materials, the substances listed in Regulation (EU) 2024/590 on substances that deplete the ozone layer are not intentionally added to the product.

24. PHARMACOPEIA COMPLIANCE

The Product meets the United States Pharmacopeia monograph and methodologies (compendial procedures or validated according to USP or ICH guidelines).

25. ELEMENTAL IMPURITIES

According to USP (United States Pharmacopeia) General Chapters <232> Elemental Impurities – Limits and <233> Elemental Impurities – Procedures, the product was analyzed and meets USP limits for elemental impurities (inhalation use). Elemental impurities are not intentionally added to the product.

The "Elemental impurities" consists of the following metals: Cadmium, Lead, Inorganic Arsenic, Inorganic Mercury, Cobalt, Vanadium, Nickel, Thallium, Gold, Palladium, Iridium, Osmium, Rhodium, Ruthenium, Selenium, Silver, Platinum, Lithium, Antimony, Barium, Molybdenum, Copper, Tin and Chromium.

26. RESIDUAL SOLVENTS

According to USP (United States Pharmacopeia) General Chapter <467> Residual Solvents, the product was analyzed and meets USP limits for residual solvents.

The Residual Solvent 1,4-Dioxane (Class 2) may be present in the final product due the synthesis process (by-product). Present levels are below the limit tolerated in the USP-NF monograph. None of the other residual solvents are intentionally added during the manufacturing process.

27. VOLATILE ORGANIC COMPOUND (VOC)

Swiss Ordinance on the Incentive Tax on Volatile Organic Compounds:

According to Swiss Ordinance on the Incentive Tax on Volatile Organic Compounds, the product does not apply for any known VOC duties to be paid, or the VOC value is below the threshold of 3%.

European Union:

According to Directive 2010/75/EU on industrial emissions (integrated pollution prevention and control), VOC is defined as follows: 'volatile organic compound' means any organic compound as well as the fraction of creosote, having at 293,15K a vapour pressure of 0,01 kPa or more, or having a corresponding volatility under particular conditions of use. For vapour pressure, please refer to section 9 of the Safety Data Sheet (SDS).

United States:

According to CFR Title 40, Chapter I, Subchapter C, Part 59, Subpart D, § 59.401, volatile organic compound or VOC means any organic compound that participates in atmospheric photochemical reactions, that is, any organic compound other than those which the Administrator designates as having negligible photochemical reactivity. For a list of compounds that the Administrator has designated as having negligible photochemical reactivity, also referred to as exempt compounds, refer to 40 CFR 51.100(s).

VOC content means the weight of VOC per volume of coating, calculated according to the procedures in § 59.406(a) of this subpart.

28. HAZARDOUS AIR POLLUTANTS (HAP)

The product contains the following Hazardous Air Pollutants (HAP), according to US EPA (United States Environmental Protection Agency), no matter whether present intentionally or as an impurity:

1,4-Dioxane: < 0.0001%

Ethylene oxide: < 0.0001%

29. TEXTILE RESTRICTED SUBSTANCES LIST

The product complies with the following Restricted Substances List for textile and leather:

- Apparel & Footwear International RSL Management Group (AFIRM) - Restricted Substance List
- Bluesign® Restricted Substances List
- ZDHC Roadmap to Zero Programme - Manufacturing Restricted Substances List (ZDHC MRSL)

The product contains restricted substances according to the following:

- American Apparel & Footwear Association's (AAFA) - Restricted Substance List:
1,4-Dioxane: < 0.0001% (listed as Volatile organic compounds)
Ethylene oxide: < 0.0001% (listed as Volatile organic compounds)
- Standard 100 by OEKO-TEX (International Association for Research and Testing in the field of Textile and Leather Ecology):
1,4-Dioxane: < 0.0001% (listed as Volatile organic compounds)
Ethylene oxide: < 0.0001% (listed as Volatile organic compounds)

30. FOOD CONTACT

The product is listed in the following food contact regulations. It is recommended that the end-user make their own determination on the suitability of this product of their application.

Brazil:

RDC n° 326/2019 on plastic materials intended to come into contact with food: Present.

RDC n° 88/2016 on paper materials intended to come into contact with food: Present (max. 10 mg/dm²).

China:

GB 9685-2016 - National Food Safety Standard - Standard for the Uses of Additives in Food Contact Materials and Articles: Present – Adhesives, Coatings, Paper and Board, and Plastics (30 mg/kg SML(T) as Ethylene glycol; FCA0942).

European Union:

Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food: Present.

EuPIA (European Printing Ink Association) – Inventory List: Present.

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Germany:

BfR Recommendations on Food Contact Materials:

XXXVI - Paper and Board for Food Contact: Present (max. 10 mg/dm²).

Switzerland:

Food Contact Ordinance:

Annex 2, Permitted substances for the production of plastic articles: Present

Annex 9, Permitted substances for the production of silicone articles: Present (Additive, SML 60 mg/kg).

Annex 10, Permitted substances for the production of printing inks: Present (Additives, SML 60 mg/kg).

Japan:

Positive List of Food Contact Materials - Specifications and Standards for Foods, Food Additives, etc: Present.

United States:

Food and Drug Administration (FDA), Title 21 CFR:

21 CFR 175.105 Adhesives: Present.

21 CFR 176.170 Components of paper and paperboard in contact with aqueous and fatty foods: Present.

21 CFR 176.180 Components of paper and paperboard in contact with dry food: Present.

21 CFR 176.200 Defoaming agents used in coatings: Present.

21 CFR 176.210 Defoaming agents used in the manufacture of paper and paperboard: Present.

21 CFR 178.3400 Emulsifiers and/or surface-active agents: Present.

31. FOOD USE

The product complies with the following:

- Food Chemicals Codex (FCC): meets the monograph requirements on food additives.
- U.S. Code of Federal Regulation 21 CFR on food additives: meets the current requirements and complies with the uses allowed as follows: §172.515 Synthetic flavoring substances and adjuvants; §172.840 Polysorbate 80; §173.340 Defoaming agents.

32. NUTRITIONAL INFORMATION

The product has the following nutritional analysis based on 100 grams of product:

Nutritional Measure	Testing Units	Result
Calories	Kilocalorie	535.00
Total Fat	Grams	28.79
Saturated Fat	Grams	2.49
Polyunsaturated Fat	Grams	0.06
Monounsaturated Fat	Grams	26.24
Trans Fatty Acid	Grams	0.42
Cholesterol	Milligrams	< 0.01
Sodium	Milligrams	10.19
Carbohydrates	Grams	68.86
Dietetic Fiber	Grams	0.00
Potassium	Milligrams	< 0.50
Calcium	Milligrams	< 0.10
Vitamin A, C, D	Milligrams	0
Sugars	Grams	0
Proteins	Grams	0
Thiamine, Riboflavin, Niacin, Iron	Milligrams	0

33. ANIMAL TESTING

Indovinya is committed to the evolution of the world and its people through chemistry. Therefore, we have an obligation of utmost importance to ensure the safety of our products to people and the environment.

During product development, toxicological and ecological information are obtained through scientific literature to provide appropriate hazard communications to employees and customers and apply to authorities for registration.

On limited occasions, animal testing is conduct when data is not available to address safety assessment or government agencies requires specific studies. In all cases, our policy is guided by the "3R" Principles (reduction, replacement, and refinement) and does not allow the use of non-human primates.

Indovinya reaffirms its encouragement of actions that stimulate the development and validation of methodologies that are alternatives to testing live animals for educational and research purposes as well as the support in general of cruelty-free testing approaches.

Indovinya hereby confirms that animal testing was not performed on the product.

34. NANOMATERIALS

Nanomaterials have not been intentionally manufactured or added to the product, according to the EU Regulation (EC) N° 1223/2009 definition. Nanomaterials are not expected to be present in the product. However, these substances are not monitored in the final product. The information is based on supplier information and manufacturing process.

35. IRRADIATION

Based on the best knowledge of the production process, raw materials and sources of these ingredients, the product has not been treated with radiation, it does not contain irradiated ingredients and does not come in contact with materials containing radiological elements during manufacturing, packaging, storage and transportation. Under normal conditions, radiation process is not implemented in our facilities.

36. BIODEGRADABILITY

For biodegradability, please refer to section 12 of the Safety Data Sheet (SDS).

37. CMR (CARCINOGENIC, MUTAGENIC AND TOXIC TO REPRODUCTION) AND SVHC (SUBSTANCE OF VERY HIGH CONCERN)

The product is not classified as Carcinogenic, Mutagenic or Toxic to Reproduction (CMR) as defined by Regulation (EC) n° 1272/2008 (CLP Regulation).

Moreover, it does not contain any Substance of Very High Concern (SVHC) as defined in Article 57 of Regulation (EC) n° 1907/2006 at > 0.1% (w/w) no matter whether present intentionally or as an impurity.

38. CALIFORNIA PROPOSITION 65

The product contains the following substances known to the State of California to cause cancer or reproductive toxicity as listed under Proposition 65 State Drinking Water and Toxic Enforcement Act:

1,4-Dioxane: < 0.0001%

Ethylene oxide: < 0.0001%

It is important to emphasize that only the parameters guaranteed in the product specification are monitored as quality requirements and not all the substances listed under Proposition 65 are controlled in the final product.

39. PRESENCE AND ABSENCE OF SPECIFIC SUBSTANCES

The presence or absence of the following substances are declared below. Note, however, that routine analytical testing is not conducted for these substances, unless identified in the product specification.

PRESERVATIVES/ANTIOXIDANT:	Not intentionally added and not expected.
COLORANTS:	Not intentionally added and not expected.
PESTICIDES:	Not intentionally added and not expected. Based on supplier information.
SOLVENTS:	Please refer to the section RESIDUAL SOLVENTS in this document.
NITROSAMINES:	Not intentionally added and not expected. The product does not contain any source of nitrosamines formation (nitrosating agents and/or primary, secondary and tertiary amine and/or amides and/or ammonium salt). There are no potential sources of contamination or cross contamination with nitrosamines during the manufacturing process.
PHTHALATES:	Not intentionally added and not expected.
SULFATES:	Not intentionally added and not expected.
PER- AND POLYFLUOROALKYL SUBSTANCES (PFAS), including but not limited to PFOA, PFOS, PFHxS, PFNA, and HFPO-DA:	Not intentionally added and not expected.
PARABENS:	Not intentionally added and not expected.
ALKYL PHENOLS AND ALKYL PHENOL ETHOXYLATES:	Not intentionally added and not expected.
PHENOL, INCLUDING BISPHENOL:	Not intentionally added and not expected.
POLYHALOGEN-BIPHENYL / TERPHENYLS / DIPHENYLETHERS (PCB, PCT, PBB, PBDE):	Not intentionally added and not expected.
BENZENE, TOLUENE AND XYLENE:	Not intentionally added and not expected.
ETHANOL:	Not intentionally added and not expected.

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FORMALDEHYDE:	Not intentionally added and not expected.
DIOXIN:	Not intentionally added and not expected.
MESYLATES:	Not intentionally added and not expected.
MELAMINE:	Not intentionally added and not expected.
RUBBER OR LATEX:	Not intentionally added and not expected.
GLUTEN:	Not intentionally added and not expected. Based on supplier information.
MYCOTOXINS, INCLUDING AFLATOXINS:	Not intentionally added and not expected. Based on supplier information.

40. SUBSTANCES NOT CONTROLLED IN THE SPECIFICATION

Only the parameters described in the product specification are monitored as quality requirements. Substances not identified in the specification are not controlled batch-by-batch.

Under various environmental protection and product safety regulations, directives, standards and initiatives "intentionally added" means "deliberately utilized during the manufacture of the components and/or for the formulation of a material or component where its continued presence is desired in the final product to provide a specific property, appearance or quality." The substances identified as not intentionally added are not used as additives or in the manufacturing process of the product. The substances may only be present as adventitious trace impurities (not intentionally added to the product). Analyses for trace impurities in the products are not conducted as part of routine lot certification procedures, unless identified in the certification of analysis.

41. BIOENGINEERED FOODS

The product is produced from sorbitol and fatty acids, using conventional chemical technology without the use of biotechnological means. However, the chemical raw material sorbitol, used in the manufacturing process, is made by hydrogenation of starch hydrolysates from corn.

The corn is listed as one of the crops of concern under the Bioengineered Foods of the United States Department of Agriculture (USDA). However, it is important to emphasize that both the process for the production of our raw materials and final product are manufactured (from synthesis, refining, and to purification), to the best of our knowledge, do not leave residues of protein or DNA from the genetic modification of the original crops. For this reason and following the guidelines declared by the United States Department of Agriculture (USDA), the product is not considered a Bioengineered Foods.

42. RSPO (ROUNDTABLE ON SUSTAINABLE PALM OIL)

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The product is not Mass Balance Certified. For a certified product, please contact your technical service representative to check availability.

Disclaimer

This information is given to you in good faith to the best of our current reasonable knowledge, taking into consideration current status of technology as generally applied in the industry and assuming that you will use our Products for industrial purposes only. It does not constitute any guarantee or warranty, express or implied, all of which are hereby expressly disclaimed. Under no circumstances shall Indorama Ventures Oxides LLC or any of its affiliates be liable for any consequential, incidental or special damages or loss of profit incurred by you, regardless of whether the possibility of such damages or loss was disclosed to or reasonably foreseeable by you. Any future sales of the Products shall be governed by and controlled by Sales Terms and Conditions accompanying this form. With reference to the safety data sheets of each of the above Products, you have full responsibility to use the Products consistent with such information, including but not limited to any restrictions on use of the Products. Once any Product sold to you leaves our custody or control, you shall have full responsibility for and liability arising out of the storage, handling, transportation, sale, use, reuse, recycling and/or disposal of any such Product, and of any derivative product, co-product, by-product or waste product therefrom, including the use of any such product alone or in combination with other substances, and compliance with any laws or regulations relating thereto, including but not limited to those affecting testing for uses of such products.

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