

Primient Covation Zemea® Product Overview

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Dear Valued Customer:

Primient Covation is excited about growing our business relationship with you. This overview pertains to the following Products, each a different grade of 1,3-propanediol under the Zemea® brand. In response to your information request regarding Zemea® Propanediol:

Commercial Names

Zemea® Propanediol
Zemea® Select Propanediol
Zemea® USP-NF Propanediol
Zemea® USP-FCC Propanediol

Supplier and Manufacturer

Primient Covation LLC
Primient Covation has one manufacturing site in Loudon, TN USA.

Product Information and Composition

Chemical Name	INCI Name	CAS #	EINECS #	Purity
1,3-Propanediol	Propanediol	504-63-2	207-997-3	≥ 99.8 %

Product Properties

Primient Covation 1,3-propanediol is a clear, colorless, slightly sweet odor glycol derived from a sustainable and renewable corn sugar fermentation process. It is soluble in water, has a viscosity of 52cP at 20°C, a specific gravity of 1.053 at 20°C, and a neutral pH. Propanediol does not support the growth or survival of pathogens and in fact, when above a 20% concentration, inhibits the growth of microorganisms. It is known to have a low water activity (below 0.6aW) but this is not routinely analyzed.

Product Intentions

Under the Zemea® brand, product intention is for cosmetics, household goods, and other applications where the intended customers are reasonably assumed to use the material as an ingredient for their formulations of products meant to contact human skin or animals. Material meant for food goods is not claimed as ready to eat or for direct use by customers and is assumed to undergo further processing.

Grades of Zemea®

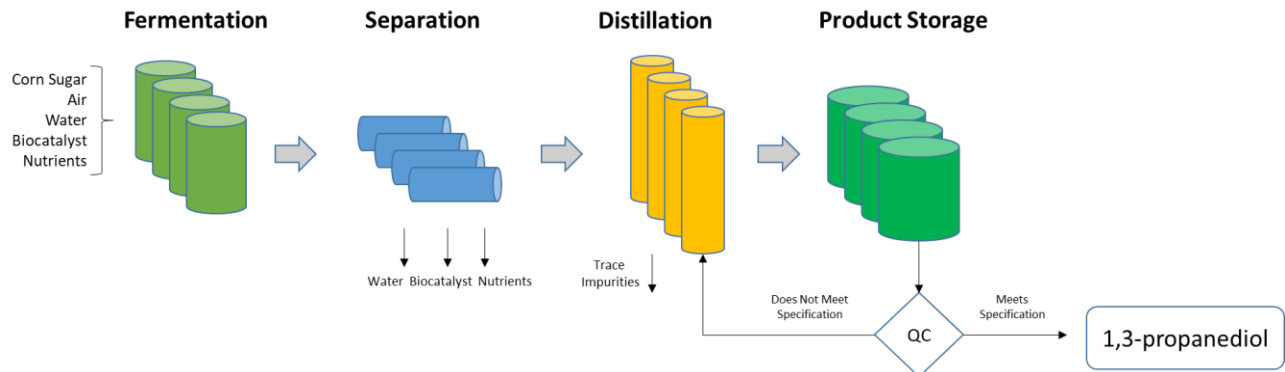
Zemea® Propanediol is at least 99.80% pure and is tested for and meets specifications set forth in ASTM International monographs associated with biobased 1,3-propanediol.

Zemea® Select Propanediol is at least 99.80% pure and receives an extra processing step to minimize the impacts of color and odor, in addition to being tested for and meeting specifications set forth in ASTM International monographs associated with biobased 1,3-propanediol.

Zemea® USP-NF Propanediol is at least 99.90% pure and is tested for and meets specifications set forth in ASTM International and the United States Pharmacopeia-National Formulary monographs associated with biobased 1,3-propanediol.

Zemea® USP-FCC Propanediol is at least 99.90% pure and is tested for and meets specifications set forth in ASTM International and the United States Pharmacopeia-Food Chemical Codex monographs associated with biobased 1,3-propanediol. 1,3-Propanediol is generally recognized as safe by the FDA (GRN No. 302) for its defined intended uses. These Products are collectively referred to as **Zemea®** or **Products** below.

Process Flow Diagram



Aflatoxin/Mycotoxin

These Products are not specifically tested for aflatoxins or mycotoxins but are not expected to contain them. Aflatoxins and mycotoxins are not present as an intentional component in the raw materials used in the manufacture of these Products. The corn used to produce the dextrose feedstock is monitored for these components by our supplier. The supplier only accepts corn that meets U.S. Food and Drug Administration requirements for food products. There are no other known sources for aflatoxins and mycotoxins in the fermentation process. Therefore, a risk of the presence of these in the finished Products is very unlikely to exist.

Allergens

Primient Covation does not use any allergens, including but not limited to: milk, eggs, fish, shellfish, tree nuts, peanuts, wheat, soybeans, or sesame (the nine most common food allergens in the United States as found in the Food Allergy Safety, Treatment, Education, and Research (FASTER) Act of 2021). The 81 allergens listed in the EU 2023/1545 of July 2023 are also not intentionally added to our process or product. To the best of our knowledge, these substances are not present in our finished Products or as an intentional component in the raw materials used in the manufacture of this Product. Primient Covation LLC also enforces an Allergen Control Policy that reduces the risk of unintentional allergen contamination. We do not routinely analyze these Products for the substances listed above but do verify our Allergen Control Program via swabbing and third-party ISO certified laboratory testing.

Animal Ingredients, BSE/TSE Claims, Vegetarian, and Vegan

All grades of Zemea® Propanediol (CAS # 504-63-2) contain no animal products or animal flesh. They are suitable for use by vegetarians. Primient Covation LLC elected to have analyzed final product samples over a year of production on a skip-lot basis by an ISO certified laboratory for a "Vegan Screen" analysis in August of 2023. This screen included PCR analyses for meat, dairy, and egg markers; Primient Covation's propanediol did not result in detectable levels for any of these things.

As no animal products or flesh are utilized in their production, these Products should not be considered a vector for BSE or TSE.

Animal Testing for Non-food Use

Primient Covation has not conducted nor commissioned animal tests on these Products for non-food use. Animal tests have been conducted on petrochemical based 1,3-propanediol (CAS #: 504-63-2). However, petrochemical based 1,3-propanediol is not manufactured by the Primient Covation company.

Bio-based Content

Primient Covation's Products are 100% bio-based.

Biodegradation

Zemea® was predicted to rapidly biodegrade aerobically and anaerobically. OECD 301B test guideline data for aerobic biodegradation demonstrated that Zemea® was readily biodegradable and supports the use of these models. These predictions are based on the chemical structure of 1,3-propanediol and anaerobic biodegradation potential for similar molecules.

Zemea® (CASNR 504-63-2) has not been tested using the OECD 311 test guideline; however, we can predict with relative certainty that Zemea® will anaerobically biodegrade using the US Environmental Protection Agency EPI Suite (v4.10) environmental fate models created for 1,3-propanediol.

Business Continuity

Details of Primient Covation's business continuity are proprietary, but the following can be shared:

- Primient Covation has approved/qualified alternate raw material suppliers to ensure an uninterrupted raw material supply.
- Primient Covation cross-trains employees, ensuring continuation of employee coverage in the event of unforeseen workforce disruptions.
- Inventory stock at distributors and other global facilities may be made available.

Carcinogenic, Mutagenic, & Reproductive Toxicity Certification

We hereby confirm that 1,3-propanediol is not classified as a carcinogen according to the following internationally recognized regulations and classifications:

- Regulation (EC) No. 1272/2008 on Classification, Labelling and Packaging (CLP)
- Regulation (EC) No. 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)
- Globally Harmonized System of Classification and Labelling of Chemicals (GHS)
- U.S. OSHA Hazard Communication Standard (29 CFR 1910.1200)

1,3-Propanediol is not listed by:

- IARC (International Agency for Research on Cancer)
- NTP (National Toxicology Program)
- OSHA as a regulated carcinogen

Based on current toxicological data and regulatory reviews, 1,3-propanediol does not contain and is not produced with any substances classified as carcinogenic, mutagenic, or reprotoxic (CMR categories 1A, 1B, or 2). Accordingly, 1,3-Propanediol is considered carcinogen-free under applicable global chemical safety regulations.

Certifications Available



cGMP Quality System

Quality is important to our business because we value our customers. We strive to provide our customers with products which meet and even exceed their expectations. The processes used to produce our products are based on Primient Covation's procedures, quality guidelines, HARPC/HACCP program, and current Good Manufacturing Practices (cGMP). Our Loudon, TN operation complies with applicable FDA regulations detailed in 21 CFR Chapter I for Food Manufacturers and is Kosher and Halal certified. Our plant is periodically audited by third parties, including customers, and those audit results are kept confidential per the respective disclosure agreement. Our plant has been audited against a variety of standards, including but not limited to FDA 21 CFR 110, 117, and 120, EFfCI, IPEC-PQC, Halal, Kosher, and ELC Quality Systems.

Primient Covation is randomly audited by the Tennessee Department of Agriculture on behalf of the FDA, as determined by their risk assessment which defines Primient Covation LLC as a Moderate Risk Facility.

Complaint Handling

Customer Complaints are taken very seriously by Primient Covation. Contact your Regional Sales Representative or the Product Director to receive a Complaint Investigation Form. This is to be returned to the Sales Representative or Product Director or can be submitted directly to our Customer Service Representative. Complaints are handled within 30 days of the complaint submission, or 30 days from receipt of a sample from the customer (if required). Investigations for complaints include root cause analysis and corrective actions that are to be completed within reasonable time. Results of investigations and root cause analyses are reviewed during monthly Operations Reviews and HARPC/HACCP meetings as well as the annual Quality Management Review for focus on improvements in that area.

Continuing Guarantee

Primient Covation LLC hereby states that each and every article containing and comprising each shipment or other delivery of food grade Zemea® products manufactured by Primient Covation LLC, to or on the order of a "buyer", are hereby guaranteed by Primient Covation LLC, as of the date of each shipment or delivery, to be not adulterated or misbranded within the meaning of the U.S. Federal Food, Drug, and Cosmetic Act (FFDCA), as amended, and to be not an article that may not, under provisions of Sections 404, 505, and 512 of the FFDCA, be introduced into interstate commerce, and to be subject to policies and procedures implemented by Primient Covation LLC to meet requirements set forth by the FFDCA, as amended, or any applicable state or municipal law containing definitions of adulteration or misbranding substantially the same as those found in the FFDCA.

Additionally, Zemea® Products are further guaranteed, within the responsibilities set forth for facilities by the FFDCA, to be produced in accordance with applicable current Good Manufacturing Practices, and any buyer requirements communicated in writing by the buyer to Primient Covation LLC, including without limitation requirements relating to quality assurance, quality control, and food safety. Primient Covation LLC products listed above comply with the FFDCA and all applicable regulations promulgated thereunder, including the Preventive Controls for Human Food rule (21 CFR 117) and any other applicable federal, state, and local laws and regulations relating to food safety, and are not articles that cannot be legally transported, imported, or sold under the provisions of any other U.S. federal, state or local law, rule, regulation, ordinance, or order.

All Food Contact packaging utilized by Primient Covation LLC is certified to meet FDA standards for food contact materials.

Furthermore, Primient Covation hereby states that the 1,3-propanediol it manufactures is produced and distributed in compliance with the applicable requirements of the U.S. Federal Food, Drug, and Cosmetic Act (21 U.S.C. §301 et seq.) and the regulations promulgated thereunder. We guarantee the products are not adulterated or misbranded within the meaning of the Act and that they meet the identity, purity, and safety expectations for use as a cosmetic raw material.

This guarantee is continuing and shall be in full force and effect until revoked in writing by Primient Covation LLC.

Cosmetic Regulation EC 1223/2009

Based on our current knowledge and review of Regulation (EC) No. 1223/2009 on cosmetic products, as amended up to and including Commission Regulation (EU) 2025/877, Primient Covation LLC confirms that Zemea® Propanediol (CAS No. 504-63-2) is not listed in Annex II, and where applicable, complies with the conditions of Annexes III, IV, V, and VI. Therefore, when used according to these restrictions, Zemea® Propanediol can be used in cosmetic products placed on the EU market.

In addition, we confirm the following with respect to Regulation (EC) No. 1272/2008 on Classification, Labelling and Packaging (CLP), as amended:

- Zemea® Propanediol is not classified as a carcinogenic, mutagenic, or toxic to reproduction (CMR) substance.
- Zemea® Propanediol is not intentionally manufactured with, and does not contain as an impurity, any substances classified as CMR of categories 1A, 1B, or 2 under CLP above relevant thresholds.
- Consequently, Zemea® Propanediol is not subject to the prohibitions of Article 15 of Regulation (EC) No. 1223/2009 on cosmetic products, as amended.

This statement is based on the most recent consolidated versions of Regulations (EC) No. 1272/2008 and (EC) No. 1223/2009, including amendments published up to and including Commission Regulation (EU) 2025/877.

Disclaimer:

This statement is provided for regulatory support purposes only. Responsibility for ensuring compliance of finished cosmetic products remains with the Responsible Person (RP) as defined under Regulation (EC) No. 1223/2009.

Deforestation, Regulation PE-Cons 82/22 and EU Regulation 2023/115

Our Products are not and were not responsible for deforestation and forest degradation. Our products are bio-based and we are a sustainably goal driven business. These practices do not fall under our principles.

Dyes and Fragrances

Primient Covation does not utilize dyes or fragrances in its production of 1,3-propanediol.

FDA Audit Status and Registration

The Primient Covation LLC Loudon, TN facility is U.S. FDA registered as a Food Manufacturing Facility following 21 CFR Part 1 - *Registration of Food Facilities, and Maintenance and Inspection of Records for Foods*, under the Public Health Security and Bioterrorism Preparedness and Response Act of 2022. Primient Covation is subject to unannounced FDA current Good Manufacturing Practices (cGMP) compliance inspections on a regular basis. For information concerning the most recent audit results, contact the Product Director.

Food Defense

Primient Covation LLC has assembled a multidisciplinary team as its Food Defense Team under the direction of a Qualified Individual trained in FSPCA courses appropriate for Vulnerability Assessments, Mitigation Strategies, and Food Defense Plan Preparation and Reanalysis. This team meets at least annually or before major production changes, if required. This team has analyzed all process steps to determine vulnerabilities utilizing the KAT methodology and appropriate mitigation strategies are applied.

Global Regulatory Status

Regulatory Listing	Number/Reference
Australia (AICS)	Listed
Canada (DSL)	Listed
China (IECSC)	Listed
Denmark (BEK)	302 & 783
European Union (EINECS)	207-997-3
Germany (WGK)	1677
Indonesia	Listed
Japan (ENCS)	(2)-234
Japan (ISHL)	(2)-234
Korea (KECI)	KE-29268
Mexico (INSQ)	Listed
New Zealand (HSNO)	HSR006355
Philippines (PICCS)	Listed
Taiwan (TCSI)	Listed
Thailand (TECI)	55-1-03966
USA (TSCA)	504-63-2
Vietnam	Listed

Gluten Free

These Products do not contain as an ingredient and is not manufactured on processing equipment that comes in contact with gluten or products containing gluten.

HACCP/HARPC and Food Safety

Primient Covation LLC has assembled a cross-functional HACCP/HARPC Team that assembles monthly or sooner if changes in manufacture occur. The team comprising qualified members reviews prerequisite programs, input hazard analyses, the process flow chart, and process step hazard analyses utilizing the knowledge, training, and education of each member to help determine potential hazards and risks associated with different areas and functions of the facility. From these hazard analyses, critical control points were determined. Subsequently, critical limits, monitoring procedures, corrective actions, verification procedures, and documenting and record-keeping procedures were included in the HACCP/HARPC Plan. The entirety of the HACCP/HARPC Plan is reviewed annually by the HACCP/HARPC Team.

Heat Treated Pallets

Pallets purchased by Primient Covation are heat-treated (HT) pallets bearing the IPPC logo. The IPPC heat-treatment or "HT" designation is clearly visible on the exterior of the pallets and are ISPM 15 Compliant. The pallet supplier also treats the pallets with PQ-80® to ensure pallets do not mold over time.

Pallets are purchased new and are stored indoors. The pallets are manufactured in the USA from USA hardwoods.

Heavy Metals Analysis

Given the manufacturing process Primient Covation uses for the manufacture of these Products, the presence of heavy metals is not anticipated, nor is there historical record of the presence of heavy metals, as confirmed by inductively coupled plasma (ICP) analysis. Primient Covation analyzes all final product on a skip-lot basis with a frequency of three samples per week for the following inorganic impurities:

Metals	Detection Limit, ppm	Method	Typical Result, ppm
Chromium	< 1.0	ICP	None detected
Cobalt	< 1.0	ICP	None detected
Iron	< 1.0	ICP	None detected
Manganese	< 1.0	ICP	None detected
Nickel	< 1.0	ICP	None detected
Titanium	< 1.0	ICP	None detected
Vanadium	< 1.0	ICP	None detected

Primient Covation analyzes every Zemea® Select lot for these same inorganic impurities and achieves the same typical results as above.

Primient Covation analyzes every Zemea® USP-FCC lot for the inorganic impurities listed for compliance to the USP Food Chemicals Codex with the following typical results:

Metals	Detection Limit, ppm	Method	Typical Result, ppm
Lead	< 1.0	ICP	None detected
Nickel	< 1.0	ICP	None detected
Cobalt	< 1.0	ICP	None detected

In addition, Primient Covation has elected to have third-party analysis performed by a certified laboratory for metals outlined in the ICH Guideline Q3D (R1) on a skip-lot basis with a frequency of six samples per year (based on a hazard analysis and historical record of results). Typical results for this analysis are as follows:

Metal	Detection Limit, ppm	Method	Typical Result, ppm	Metal	Detection Limit, ppm	Method	Typical Result, ppm
Silver	< 1.0	ICP	Not Detected	Nickel	< 1.0	ICP	Not Detected
Arsenic	< 1.0	ICP	Not Detected	Osmium	< 1.0	ICP	Not Detected
Gold	< 1.0	ICP	Not Detected	Lead	< 1.0	ICP	Not Detected
Barium	< 1.0	ICP	Not Detected	Palladium	< 1.0	ICP	Not Detected
Cadmium	< 1.0	ICP	Not Detected	Platinum	< 1.0	ICP	Not Detected
Cobalt	< 1.0	ICP	Not Detected	Rhodium	< 1.0	ICP	Not Detected
Chromium	< 2.0	ICP	Not Detected	Ruthenium	< 1.0	ICP	Not Detected
Copper	< 1.0	ICP	Not Detected	Antimony	< 2.0	ICP	Not Detected
Mercury	< 1.0	ICP	Not Detected	Selenium	< 2.0	ICP	Not Detected
Iridium	< 1.0	ICP	Not Detected	Tin	< 1.0	ICP	Not Detected
Lithium	< 1.0	ICP	Not Detected	Thallium	< 1.0	ICP	Not Detected
Molybdenum	< 1.0	ICP	Not Detected	Vanadium	< 1.0	ICP	Not Detected

Historical Risk

Primient Covation has never been involved in a product recall and has not been the victim in any instances of known economic adulteration. As these Products are intended for further processing and are, in general, niche in nature, risk of economic adulteration is considered low.

Human Trafficking

Primient Covation has a zero-tolerance policy for human trafficking and forced labor. We are committed to upholding human rights by integrating anti-trafficking efforts into our operations and supply chains.

Kosher and Halal Status

All grades of Zemea® Propanediol have been certified as Kosher and Halal by the appropriate authorities. For current certificates, please contact the Product Director or your Regional Sales Contact.

Labeling

Labels for Zemea® brand propanediol include a blue background for the brand name. The label includes the chemical name (1,3-propanediol) as well as the INCI name (Propanediol) as part of the grade. CAS#, manufacturing date, net weight, and lot number are included. Safety instructions including the use of the SDS, product information, and medical emergency phone numbers for multiple regions internationally are apparent. Shelf life and appropriate storage conditions are indicated. Certification indications for USDA Certified Biobased Product, Orthodox Union Pareve Kosher status, IFANCA Halal status, and NF status are also included.

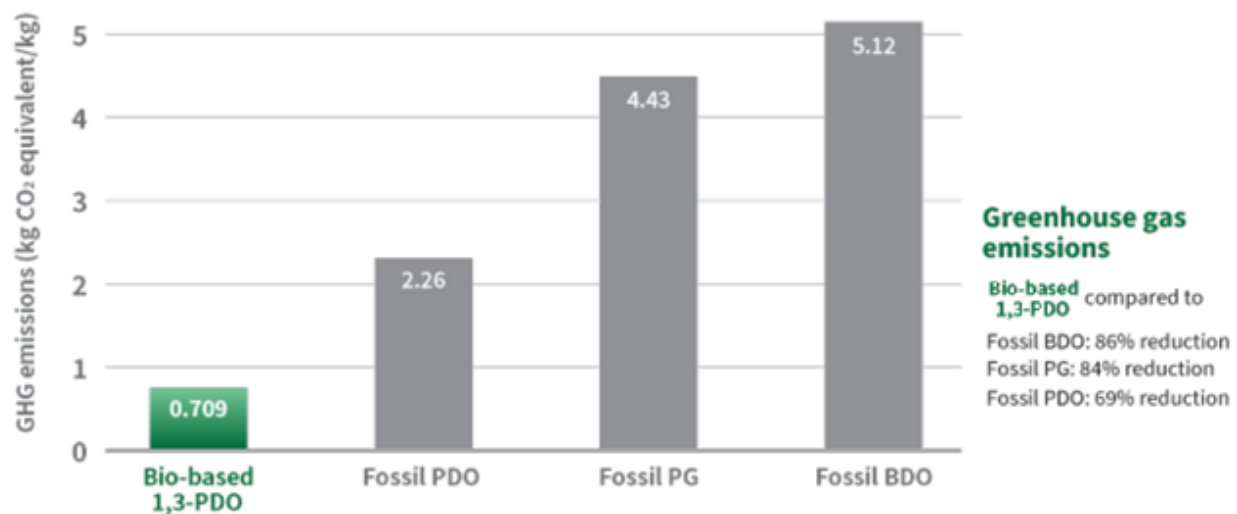
Life Cycle Impact Analysis

In 2023 Primient Covation conducted a life cycle assessment (LCA) for BioPDO compliant with ISO 14040 standards. The LCA is a cradle-to-gate study covering all steps of production starting with corn grain production, corn wet milling, and production of BioPDO and was performed by the TrueNorth Collective. The study is also compliant with the EU product environmental footprint (PEF) standards. The Susterra® and Zemea® PDO LCA study is based on 2022 primary manufacturing data from our Loudon, Tennessee PDO manufacturing site; 2017 primary manufacturing data from the corn wet milling facility Primient in Loudon, Tennessee, and primary data from Primient's corn supply chain, plus ecoinvent 3.9.1 datasets for terephthalic acid (TPA) monomer and corn grain production, modified to be representative of CovationBio's corn supply from the US Midwest. The LCA models were created in SimaPro software. The LCA indicated the following Life Cycle Impact Assessment (LCIA) results for 1kg of Susterra® or Zemea® PDO on a cradle-to-gate basis, calculated using EF 3.1 impact assessment methodology:

Impact category	Unit	Bio-PDO
Acidification (EF)	mol H ⁺ eq	0.01
Ecotoxicity, freshwater (EF)	CTUe	12.30
Particulate matter (EF)	disease inc.	0.00
Eutrophication, marine (EF)	kg N eq	0.01
Eutrophication, freshwater (EF)	kg P eq	0.00
Eutrophication, terrestrial (EF)	mol N eq	0.02
Human toxicity, cancer (EF)	CTUh	0.00
Human toxicity, non-cancer (EF)	CTUh	0.00
Ionising radiation (EF)	kBq U-235 eq	0.04
Land use (EF)	Pt	70.70
Ozone depletion (EF)	kg CFC11 eq	0.00
Photochemical ozone formation (EF)	kg NMVOC eq	0.01
Resource use, fossils (EF)	MJ	23.90
Resource use, minerals and metals (EF)	kg Sb eq	0.00
Water use (EF)	m3 depriv.	-0.186
Climate Change-Fossil (IPCC)	kg CO2 eq	1.77
Climate Change-Biogenic (IPCC)	kg CO2 eq	1.32
Climate Change-Uptake (IPCC)	kg CO2 eq	-2.38
Climate Change-Land transformation (IPCC)	kg CO2 eq	0.00
Climate Change- Total	kg CO2 eq.	0.709

Table 1: LCIA indicators for cradle-to-gate production of 1 kg Bio-PDO

The climate change potential, often referred to as Greenhouse Gas emissions for Susterra® or Zemea® 1,3-propanediol, is 0.709Kg CO₂eq. A third-party review of the Susterra® and Zemea® PDO LCA study was completed in 2024. It must be noted that the third-party panel review has the following limitations per ISO: 1. A critical review can neither verify nor validate the goals that are chosen for an LCA, nor the ways the results are used. 2. In no way does the review imply endorsement of any comparative assertion that is based on the LCA by members of the review panel. Because the Susterra® and Zemea® PDO LCA is cradle-to-gate, and PDO is often converted or used alongside other materials in the final product, comparing potential environmental impacts at the raw material level provides an incomplete picture for decision-making. We strongly recommend considering the potential impacts in a cradle-to-final product LCA — or better, a cradle-to-cradle LCA — in order to assess the benefits and trade-offs of design choices for the final product.



Lot Code Explanation

Primient Covation LLC designates product in the following manner:

LPYYMXXXXX

The components of the lot code are as follows:

LP: Designated code of the Primient Covation facility within the Primient global system.

YY: The last two digits of the year of production. Ex: Product produced in 2023 would receive a "23".

M: A letter indicating the month of production. Letters are assigned to months in alphabetical order from A to L. Ex: Product produced in July would receive a "G".

XXXXX: A sequential number assigned to each lot per month. Ex: The one hundred eightieth lot produced for the month would receive "00180".

For further clarity through example, the 173rd lot produced at the Primient Covation LLC facility in Loudon, TN, in the year 2021, in the month of August, would receive lot designation "LP21H00173". This lot is used as an example; it does not represent an existing lot produced by Primient Covation.

A lot number is assigned to each shipment of bulk material; one truck/rail container has a unique lot and originates from one final product land tank with a unique identifier.

A lot number is assigned to a campaign of small packaging (totes, drums, pails). A campaign is an amount of packaging filled at the same time with the same brand and grade of material, from the same final product land tank with a unique identifier. Each campaign has a unique lot number.

Melamine

1,3-Propanediol is not a source for protein, thus it is not considered “at risk” for intentional adulteration with melamine.

Nagoya Protocol

We, Primient Covation LLC, declare that all brands and grades of Primient Covation’s bio-based 1,3-propanediol were developed via the utilization of a genetic resource and/or of an associated traditional knowledge, as defined in the above-mentioned regulation.

We, Primient Covation LLC, declare that our utilization of the genetic resource is compliant with the EU regulation regarding measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union, which entered into force on 12 October 2014, and with the relevant national legislation in place when this genetic resource was accessed after this date.

We, Primient Covation LLC, confirm that we apply the Best Practice for Cosmetics Industry, jointly developed by Cosmetics Europe, EFfCI, IFRA, and UNITIS.

One aim of this protocol is to ensure that countries in which genetic resources and traditional knowledge originate should have the option of retaining some right over those resources or knowledge.

The bio-manufacturing processes and specific genetic elements of the *Escherichia coli* K12 (ATCC 53911) biocatalyst that is utilized by Primient Covation to produce 1,3-propanediol have been patented by DuPont in 28 nations under 19 technical subject areas, or core technologies, and over 100 granted patents. Expiration of the patents in this estate cover a date range from 2012 to 2037. Through this patent process, DuPont has been granted sole knowledge ownership and/or inventorship for technology that is practiced for production of 1,3-propanediol. The national origin of the bacterial production host, and genetic elements utilized in the recombinant microorganism have been shown to originate from DuPont laboratories or Universities/Institutions in the United States of America (USA). If further detail is needed, please schedule an approved remote appointment with the Primient Covation Product Director.

Nanotechnology

These Products do not contain nanomaterials nor are they produced using nanotechnology following the definitions in EU regulation 1223/2009/EC and in the European Commission Recommendation on the Definition of Nanomaterial 2011/696/EU.

Natural Status

ISO 16128 for the definition of the grade of naturalness of raw materials has been evaluated carefully, and we came to the following conclusion for our Zemea® Propanediol product: Zemea® Propanediol under the INCI name “Propanediol” utilizes dextrose from #2 Dent Industrial Corn as the carbohydrate source for fermentation.

As applied, the ISO 16128 Standard is understood to define Propanediol as a natural ingredient according to ISO 16128-1:2016 since this ingredient is obtained through a fermentation process followed by traditional processes without intentional chemical modification.

Based on Table 1 in ISO 16128-2:2017, the following indices apply for Zemea® Propanediol:

Natural Index: 1

Natural Origin Index: 1

Nutrition Statement

1,3-Propanediol is listed as “generally recognized as safe” (GRAS) for use as a direct food additive by the US Food and Drug Administration (21CFR184.1666) when used in accordance with its intended use.

1,3-Propanediol has the general structure of carbohydrates; for food labeling purposes it should be included with the grams of carbohydrates per serving declaration.

If a claim is made as to sugar alcohol content, 1,3-propanediol should also be included as a sugar alcohol.

Primient Covation LLC provided samples to an accredited and ISO Certified third party laboratory to determine the Gross Calorific Values using bomb calorimetry. This information was used to determine the total carbohydrates (per 100 grams) and generate a table reflecting the true Gross Calorific Energy for our material (see below table).

Nutritional Content	
Nutrition Information Reported as is on a per 100g Basis	
Material	Primient Covation Propanediol
Total Calories*	420 ¹
Moisture, %	0.014
Ash, %**	<0.0681
Total Carbohydrates***	100
Protein	0
Fat	0
Fiber	0
Sodium & Potassium	0
Vitamins & Minerals	0
*Determined by Parr Bomb Calorimetry, ASTM D5865-10a	
**Determined USP 41/NF 36 Supplement 1, Propylene Glycol Monograph	
***Determined by US FDA 21CFR 101.9(c)(6)	

Reference 1: Merrill, A.E. and Watt, B.K., “Energy Value of Foods – Basis and Derivation” USDA Handbook 1974, pp2-3.

Organizational Chart

An up-to-date Organizational Chart is available upon request from the Product Director.

Packaging

Packaging is available in 5-gallon lined steel or HDPE pails (40lbs.), 55-gallon lined steel or HDPE drums (440lbs.), 275-gallon IBCs (2200lbs.), bulk trailers, bulk railcars, and isotainers. Zemea® USP-NF grade material is not to be packaged in plastic packaging.

The packaging used is manufactured from FDA-approved polyethylene that does not contain slip additives. They are not ethylene oxide treated. Per 21 CFR 177.1520, (c), 2.1, these liners are approved for use in the United States as an article or component of an article intended for use in contact with food, subject to the specific limitation that it may contact food only at temperatures of 212 °F and below. The primary packaging used complies with Regulations (EC) No. 1935/2004 of the European Parliament and of the council of 27 October 2004 on materials

and articles intended to come into contact with food, Commission Regulation (EU) No. 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food, and Commission Regulation (EC) No. 2023/2006 of 22 December 2006 on good manufacturing practice for materials and articles intended to come into contact with food.

Packaging Tolerances

Primient Covation LLC guarantees that all packaged 1,3-Propanediol (CAS No. 504-63-2) is filled to the declared net weight, subject to a standard weight tolerance of $\pm 0.75\%$, consistent with industry practices and regulatory guidelines for packaged chemical materials. This tolerance takes into account the packaging weight tolerances as well.

Our standard fill tolerances are as follows:

- 5-gallon pails (40 lbs nominal fill): ± 0.3 lbs (0.14 kg)
- 55-gallon drums (440 lbs nominal fill): ± 3.3 lbs (1.5 kg)
- Intermediate Bulk Containers (IBCs, 2200 lbs nominal fill): ± 16.5 lbs (7.5 kg)

This tolerance ensures that packaged product complies with applicable requirements for net quantity declarations, while accounting for normal process variation in bulk chemical filling operations.

Primient Covation LLC targets fill weights such that net contents consistently meet or exceed the declared values, and in practice containers are generally filled slightly above nominal weights to avoid any risk of underfill.

This tolerance statement shall remain in effect until superseded or withdrawn in writing by Primient Covation LLC.

Palm Oil

Primient Covation does not utilize Palm Oil as an ingredient.

Pesticide and Herbicide Residue

These Products are produced at the Primient Covation manufacturing facility in Loudon, Tennessee and have been tested by Eurofins (third-party) for the presence of a wide range of pesticide and herbicide residues (over 500) including glyphosate. None of the residues included in the analysis were detectable in a concentration above the calibrated detection limit (Reporting Limit).

Pesticide and herbicide are applied at our facility by licensed and certified third-party contractors. Records of applications, event reports, certifications, chemicals used, and trends of areas are reviewed monthly by the Quality Manager.

PFAS

Primient Covation LLC does not intentionally add PFAS to its process or product, including both Zemea® and Susterra® brands. These substances are not anticipated to be within our product; therefore, Primient Covation does not regularly test for them. Primient Covation LLC acknowledges that components of packaging (Teflon gaskets in IBC packaging only) have been discovered as having possibility of containing PFAS depending on the scope of chemicals included in the definition. All packaging meets FDA requirements. This information is provided in good faith and is believed to be accurate but is intended for informational purposes only and not as a recommendation or endorsement. Primient Covation LLC cannot anticipate or control how this information could be used. Therefore, you should not rely on it for any legal position or regulatory aspect, but you should conduct independent inquiry, research, and testing before using the information, including, without limitation, the designation of product claims. All

warranties are hereby disclaimed, including the implied warranties of fitness for a particular purpose and of merchantability.

Phosphates and Phosphonates

To the best of our knowledge, these substances are not present in our finished Products. We do not routinely analyze these Products for the substances listed above.

Preservatives, pH adjusters, Ethoxylates, Bisphenols, 1,4-Dioxane, DEG, Phthalates, Parabens, Cyclotetra/hexa/pentasiloxane, Latex, Residual Solvents, Irradiation, Dioxin, & Polychlorinated Biphenyl (PCB), Nitrosamines

Primient Covation does not use any of the chemicals listed below in the manufacturing of these Products in accordance with the following quality criteria: preservatives, ethoxylates, bisphenols, 1,4-dioxane, DEG, phthalates, parabens, latex, and cyclotetra/hexa/pentasiloxane as intentional components of these Products. Primient Covation does not use any solvents in our process, including those classified as Class 1, Class 2, or Class 3 Residual Solvents listed in USP General Chapter <467> *Residual Solvents*, or as intentional components. Routine analytical verification confirms that residual solvents are not present above the limits specified in that chapter. Accordingly, 1,3-propanediol is considered to be compliant with USP <467> requirements for residual solvents.

Primient Covation does not routinely analyze these Products for nitrosamine impurities but does not anticipate their presence.

We do not add pH adjusters to our finished Product.

These Products are not irradiated during production. Ingredients for fermentation broth are irradiated using ultraviolet light in compliance with 21 CFR 179.39 – *Ultraviolet Radiation* for the purposes of reducing microbial load to fermenters, but is not used as a preventive control for product.

Primient Covation's Products are not treated with ETO (ethylene oxide) nor any other chemical sterilizing agent.

These Products are not routinely tested for dioxins or PCBs. However, based on a detailed knowledge of the raw materials and processing conditions, dioxins and PCBs contamination is not considered a significant risk.

Product Origin

Zemea® under the INCI name "Propanediol" utilizes dextrose from #2 Dent Industrial Corn sourced primarily from Illinois and Indiana, U.S. as the carbohydrate source for fermentation. In 2019, approximately 90% of all corn produced in the U.S. contains genetically modified (GM) traits according to the USDA. We do not test the corn or the dextrose for GMO content, but this is a control measure implemented by the supplier. Zemea® produced at the Primient Covation manufacturing facility in Loudon, Tennessee tested negative for the presence of genetically modified corn traits as certified by Eurofins GeneScan, Inc. using a qualitative PCR test. In addition, a PCR analysis of these Products conducted by E. I. DuPont de Nemours and Company, Inc. was negative for the presence of genetic material from the fermentation-based bioprocess. No animal ingredients are used in the manufacture of these Products, and they are certified BSE/TSE free.

Prop 65 Ingredients and CITES, Convention on International Trade in Endangered Species of Wild Fauna and Flora

Primient Covation does not use any of the chemicals listed in CA Proposition 65 as intentional components of these Products. Primient Covation does not use material from species listed in CITES as intentional components of these Products.

REACH and TSCA

We confirm that 1,3-Propanediol (CAS 504-63-2) manufactured and/or supplied by Primient Covation LLC is registered under REACH in accordance with Regulation (EC) No. 1907/2006. The substance is in full compliance with the requirements of REACH, including registration, evaluation, and communication of safety data as applicable.

TSCA (Toxic Substances Control Act, U.S.)

We confirm that 1,3-Propanediol (CAS 504-63-2) is listed on the U.S. EPA TSCA Inventory and is manufactured and/or imported in compliance with the Toxic Substances Control Act (15 U.S.C. 2601 et seq.).

This confirmation is provided for regulatory compliance purposes only and does not constitute a warranty of product performance or suitability for specific applications.

Safety Data Sheets and Specification Sheets

Current Safety Data Sheets and Specification Sheets are available through the Product Director or your Regional Sales contact.

Site Security

The Primient Covation facility in Loudon, TN USA is a facility with an inspected exterior perimeter fence to prevent entry by unauthorized personnel. Company personnel are required to have a Primient issued swipe card for entry. Visitors are checked in and must remain with trusted employees to which they are assigned. Adequate lighting is made available throughout the site and cameras are utilized at entrances and locking turnstile gates. A guard shack intercepts any person or vehicle attempting to gain access to the facility.

Storage Conditions and Expiration Date

Sealed containers should be stored within a temperature range of 0 °C – 50 °C (32 °F – 122 °F). Containers can be resealed and stored within the same temperature range. Avoid prolonged exposure to oxygen and water. The use of nitrogen during storage is encouraged. If the seal is unbroken and the material has been stored according to the manufacturer's recommendations, a 2-year shelf life can be expected.

Substances of Very High Concern

Primient Covation confirms that Zemea® does not contain any of the substances listed in the Candidate List of Substances of Very High Concern (up until and including substances added on 25th June 2025) above a concentration of 0.1% weight by weight (w/w). The Candidate List now contains 250 substances.

Primient Covation confirms there are no substances intended to be released from Zemea® Propanediol as defined by Article 7(2) under normal or reasonably foreseeable conditions of use. Article 7(2) states that any producer or importer of articles shall notify the European Chemicals Agency (ECHA) if a substance listed on the REACH SVHC list is present in a concentration over 0.1% w/w in any article it produces.

Primient Covation confirms that we do not add to the above product any of the substances subject to authorization in Annex XIV to Regulation (EC) N° 2022/586 as last amended on 11 April 2022 (Commission Regulation (EU) 2022/586 of 11 April 2022). REACH Annex XIV now contains 59 substances.

Supplier Approval

Primient Covation utilizes a supplier approval program to ensure a consistent supply chain of appropriate and approved materials and services. Review of a manufacturer, its location, its history, its facility, and its products foster a full risk analysis and determination of appropriateness for use. Full documentation of agreements, expectations, and requirements are maintained.

Primient Covation does not import food materials from outside the United States and therefore does not require a Foreign Supplier Verification Program.

Tariff Code

Harmonized Tariff Schedule 2905.39.9000

Traceability

Primient Covation LLC maintains full traceability of 1,3-Propanediol (CAS No. 504-63-2) throughout our manufacturing and distribution processes. Each lot is assigned a unique identifying number that links to:

- Production records, including processing conditions and quality control data
- Raw material sources and suppliers used in the manufacturing process
- Distribution records, including customer shipment details.

This system ensures that every container of 1,3-Propanediol can be traced back to its point of manufacture and forward to the customer, in compliance with applicable current Good Manufacturing Practice (cGMP) standards.

All traceability records are maintained for a minimum of 3 years and are available for regulatory inspection upon request.

Mock Recalls are performed every other year to ensure the Traceability Program is effective.

Volatile Organic Compounds

1,3-Propanediol (propanediol), CAS No. 504-63-2, produced at our facility is a highly pure, liquid product with a release specification of at least 99.8%.

Propanediol is considered to be a VOC under the accepted definition in most literature: "Volatile organic compounds, or VOCs, are organic chemical compounds whose composition makes it possible for them to evaporate under normal indoor atmospheric conditions of temperature and pressure. VOCs have a high vapor pressure and low water solubility."¹ The European Union uses the boiling point, rather than its volatility, in its definition of VOCs: "A VOC is any organic compound having an initial boiling point less than or equal to 250°C measured at the standard atmospheric pressure of 101.3 kPa."² For all definitions, the VOC content of propanediol is stated to be 100%; however, due to its low vapor pressure (required to be <0.1mmHg under the California Air Resource Board (CARB)) and high solubility in water, it may be eligible for a Low Vapor Pressure Volatile Organic Compound (LVP-VOC) exemption under CARB.

Boiling Point of Propanediol: 214.22°C (Range: 211-217°C)

Vapor Pressure of Propanediol at 20°C: 0.0159hPa or 0.0119 mmHg

1. www.epa.gov 2. "Directive 2004/42/CE of the European Parliament and the Council" EUR-Lex. European Union Publications Office. Retrieved 2007-09-27.

Water Source

These Products do not come into contact with sewage sludge per the requirements of 7 CFR 205.105(g).



Primient Covation LLC
198 Blair Bend Road
Loudon, TN 37774

Production utilizes, when required, potable city water supplied by the Loudon Utilities Board of Loudon County Tennessee, USA. Verification of its safety is completed quarterly by third party analysis.

Contact Information

Documents pertaining to our products are available on TraceGains. Our products are listed under our parent company, Primary Products Ingredients Americas LLC, under location "Loudon - Bio PDO". Requests for documents can be made through this program if your company is also registered there. Some of our distributors have accounts in TraceGains and are able to easily retrieve documents on customers' behalf. If access is not possible in this system, contact your Regional Sales Representative or the Product Director, listed below.

Please contact Primient Covation if you have any questions or require additional information.
Colton Reid, Product Director:
colton.reid@covapdo.com

Sincerely,

A handwritten signature in black ink that reads "Colton Reid".

Colton Reid
Product Director
colton.reid@covapdo.com
Primient Covation LLC

The information provided herein is based on data Primient Covation believes to be reliable, to the best of its knowledge, applies only to the specific material designated herein as sold by Primient Covation and does not apply to use of the material in any process or in combination with any other material. It is provided at the request of and without charge to our customers. Accordingly, Primient Covation cannot guarantee or warrant such information and assumes no liability for its use. Other than as set forth in a contract of sale, Primient Covation makes no warranty, express or implied, as to the material set forth herein, including the warranty of merchantability or fitness for a particular use.