

Dear Valued Customer,

Peter Cremer North America, LP ("Cremer North America" or "Cremer") regularly receive a substantial number of surveys and requests regarding our products. To manage these efficiently and respond in a timely manner, we have developed a standardized information package designed to streamline the exchange of regulatory, quality, and sustainability-related information.

By using this format to respond to surveys, questionnaires, and similar inquiries, we are able to ensure greater consistency, accuracy, and efficiency in our communications. This approach enables us to better support all requests while maintaining the high standards of service our customers expect.

The information contained within this document, provided by our supplier, is accurate to the best of our knowledge at the time of publication.

Thank you for your continued interest in our products and services.

Approved:

Amanda Clements Reason: Approved Date: 08/01/2025 16:29:57 EDT

Electronically signed by: Amanda Clements Reason: Approved

Corporate Quality Assurance Cremer North America

Updated: 08/01/2025

IMPORTANT: The information on specifications provided herein, while believed to be accurate and reliable, is given without guarantee or warranty of any kind expressed or implied. Any implied warranties of merchantability and fitness for purposes are expressly disclaimed. Purchaser assumes all risk in acting on this information or any information provided by Peter Cremer N.A. representatives. Individual requirements may vary, and each purchaser is urged to perform its own tests, experiments, and investigations in the use of Peter Cremer N.A. products for purposes of determining efficacy for the intended use and for purposes of determining compliance with applicable Federal, State, and local laws and regulations. Nothing contained herein shall be construed as a recommendation to use any product in connection with existing patents covering any material or its use. Moreover, no license is to be implied under any patents relating to uses of the above-described chemicals other than those uses specifically referenced herein.

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## Section 1: Supplier Code/Manufacturing Location(s) and Address(es)

Supplier Code: S-01

Manufacturing Location: 8201 Fruitridge Road

Sacramento, California 95826

**United States** 

## **Section 2: General Product Information**

The information contained in this document relates to the following Cremer products:

CO-1214 Kosher (bulk)	6275431	TA-1618K MB (bulk)
CO-1214 Kosher (drum)	6275432	TA-1618K (bulk)
CO-1695.5 K MB Cetyl Alcohol, NF (bulk)	6248234	TA-1618 Pastilles (bag)
CO-1695 NF MB Pastilles (bag) – Private	6247040	C-899 K (bulk)
CO-1695.5 K Cetyl Alcohol, NF (bulk)	6270082	C-899 K Fatty Acid (drum)
CO-1695 NF Pastilles (supersack)	6226268	CE-1270 RSPO MB (bulk)
CO-1695 NF Pastilles (bag)	6201276	CE-1270 RSPO MB (tote)
CO-1695 NF Pastilles (bag) – Private	6201271	CE-1270 RSPO MB (drum)
CO-1898 K NF (bulk)	6226267	CE-1270 (bulk)
CO-1897 NF Pastilles (bag)	6201275	CE-1270 (tote)
CO-1650 K MB (bulk)	6201270	CE-1270 (drum)
CO-1650 K MB Pastilles (bag)	6245127	CE-1295 (bulk)
CO-1650 K MB Pastilles (bag) – <i>Private</i>	6201295	CE-1295 (drum)
CO-1650 K (bulk)		
CO-1650 K Pastilles (bag)		
CO-1650 K Pastilles (bag)		
	CO-1214 Kosher (drum) CO-1695.5 K MB Cetyl Alcohol, NF (bulk) CO-1695 NF MB Pastilles (bag) – <i>Private</i> CO-1695.5 K Cetyl Alcohol, NF (bulk) CO-1695 NF Pastilles (supersack) CO-1695 NF Pastilles (bag) CO-1695 NF Pastilles (bag) – <i>Private</i> CO-1898 K NF (bulk) CO-1897 NF Pastilles (bag) CO-1650 K MB (bulk) CO-1650 K MB Pastilles (bag) CO-1650 K MB Pastilles (bag) – <i>Private</i> CO-1650 K MB Pastilles (bag)	CO-1214 Kosher (drum) 6275432 CO-1695.5 K MB Cetyl Alcohol, NF (bulk) 6248234 CO-1695 NF MB Pastilles (bag) — Private 6247040 CO-1695.5 K Cetyl Alcohol, NF (bulk) 6270082 CO-1695 NF Pastilles (supersack) 6226268 CO-1695 NF Pastilles (bag) 6201276 CO-1695 NF Pastilles (bag) 6201271 CO-1898 K NF (bulk) 6226267 CO-1897 NF Pastilles (bag) 6201275 CO-1650 K MB (bulk) 6201270 CO-1650 K MB Pastilles (bag) 6245127 CO-1650 K MB Pastilles (bag) 6201295 CO-1650 K MB Pastilles (bag) 6201295 CO-1650 K MB Pastilles (bag) 6201295

### **Section 3: Physiochemical Information**

#### CAS registration numbers and chemical name

This is a separate document that can be requested by contacting your supply chain specialist. Please refer to the Safety Data Sheet for your specific product.

## **Product Specifications**

This is a separate document that can be requested by contacting your supply chain specialist. Please refer to the Product Specifications Sheet for your specific product.

### **Composition Statement**

This is a separate document that can be requested by contacting your supply chain specialist. Please refer to the Safety Data Sheet for your specific product.

## **Origin Statement**

Our manufacturer's alcohols and related products are derived from vegetable origin. Tropical tree nut sources (palm/palm kernel/coconut) which are typically sourced as a commodity from Malaysia, Indonesia, and the Philippines.



#### **Feedstock**

Our manufacturer's feedstock raw materials include coconut and palm kernel oils. These refined vegetable oils are first converted to a methyl ester which also generates crude glycerin. The intermediate methyl esters are then fractionated into the final products or used as raw materials to produce the other products.

#### **Supplier Flowchart**

Our manufacturer's process is as follows:

The distilled methyl esters are saponified and acidulated to produce fatty acids.

The distilled methyl esters are hydrogenated to produce fatty alcohols. Alcohols are often distilled and fractionated to achieve the chain length distribution that meets our customers' needs.

## **Section 4: Product Quality Information**

## **Monograph Compliance**

National Formulary: Only Cetyl Alcohol and Stearyl Alcohol NF brands, manufactured in the Sacramento, California plant, currently meet the National Formulary (NF) specification. Other Fatty Alcohols, including Cetyl Alcohol and Stearyl Alcohol without NF grade in the brand names are not designed to meet the National Formulation specification.

Non-monograph specification: Other Cetyl Alcohol, Stearyl Alcohol, and Cetearyl Alcohol are made under the manufacturer's quality controls; hence, in conformance with the manufacturer's Quality Assurance Program requirements will be supplied according to the current specification.

#### Bovine Spongiform Encephalopathy/Transmissible Spongiform Encephalopathy (BSE/TSE) Statement

BSE/TSE are not applicable to our manufacturer's alcohols and related products as they are derived from plant oils only.

## Vegan/Vegetarian Statement

Our manufacturer's alcohols and related products are manufactured from raw materials not of animal origin. These products do not come in contact with any animal parts or byproducts during the manufacturing process.

## Genetically Modified Organisms (GMO)/Bioengineered Statement

Our manufacturer's alcohols and related products do not contain genetically modified organisms (GMO), nor are they derived from non-GMO sources. The feedstocks are made from natural sources such as palm, palm kernel, and coconut, which have not been genetically modified commercially.

## Nanomaterial/Nanotechnology Statement

Our manufacturer's alcohols and related products are not considered to meet the definition of a reportable nanomaterial as defined by the US EPA's TSCA nano-reporting rule.

#### **Non-Irradiation Statement**

Our manufacturer's alcohols and related products are not irradiated. To the best of their knowledge, raw materials are not sourced from areas after nuclear accidents or incidents.



## **Microbiological Statement**

Based on the manufacturing process and low moisture content, our manufacturer's alcohols and related products are not micro-susceptible.

#### **Allergens Statement**

While our manufacturer's alcohols and related products are derived from vegetable oils, which may themselves contain residual protein and therefore be of some allergenic concern, the final products are not expected to contain allergens due to the rigorous processing of the oils used to create the products. The rigorous processing steps include feedstock processing, extreme alkaline conditions, and thermal stress conditions applied during the manufacturing process. Any residual proteins (i.e., potential allergens) in the crude oils are expected to be removed through these extreme processing steps. Our manufacturer does not explicitly analyze for the absence or presence of the listed chemicals or materials below. Allergens identified in the US, Canada, Mexico, or EU regulations include: milk, egg, fish, crustacean, shellfish, crab, shrimp/prawn, tree nuts, peanuts, wheat, buckwheat, sulfites, sesame seeds, sunflower seeds, aspartame, gluten source, monosodium glutamate, corn, starch, rye, cherry, barley, rice, celery, soybean, mustard seeds, lupin, mollusks, and other allergen sources listed in EU regulations. Other allergens that are not present include: lactose, galactose, mannose, hydrolyzed proteins, modified starch, semolina, testacea, oat, triticum, spelt, kamut products, yeast, cotton seed, poppy seed, artificial colors, and carmine.

#### **Latex Statement**

Our manufacturer's alcohols and related products are processed and refined in a closed system and are not expected to contain nor to have come in contact with latex. Our manufacturer does not explicitly analyze for the presence or absence of latex in their products.

#### **Pesticides Statement**

Our manufacturer's alcohols and related products go through several purification steps including water washing and fractionation before becoming a final product. These purification steps remove any potential pesticide residues from the products. Our manufacturer does not explicitly analyze for the presence or absence of pesticides in their products.

### **Chemical Impurities and Contaminants Statement**

Chemicals listed below are expected to not be present in our manufacturer's alcohols and related products based on the feedstock and the manufacturing process currently employed. Our manufacturer does not explicitly analyze for the presence or absence of the listed chemical substances in their products. Current 20 high priority chemicals designated by US EPA including Asbestos, 1,4-Dioxane, Phthalates, Formaldehyde, and Chlorobenzenes; organic halogens including Polychlorinated Biphenyl, and Chlorinated Phenols; all 34 Nonfunctional Constituents (NFC) under CA Right to Know Act (SB 258) such as Benzene, Parabens, Nitrosamines, Ethylene Oxide, etc.; polymers such as Polyvinyl chloride (PVC), Polyvinylidene chloride (PVDC), and Styrene; Acrylamide, Cyanuric Acid, Fluorescent Whitening Agents (Optical Brighteners), Epichlorohydrin, Bisphenol A, Melamine, Metal organic compounds, Oleonitrile, and Oleamide.

#### **Methanol Statement**

Please consult the Safety Data Sheet, section 15, for your specific product to determine if it contains methanol as an impurity at or above 1%.



#### **Residual Solvents Statement**

Our manufacturer's alcohols and related products do not contain residual solvents of class 1, 2, or 3 that would meet the criteria for those classifications described in General Chater <467> of the USP and the Appendix 1 list of solvents in ICH Guideline Q3C: Guideline for Residual Solvents. These products also comply with the VICH guideline GL18: Impurities: Residual Solvents in New Veterinary Medicinal Products, Active Substances and Excipients issued by the European Medicines Agency. Residual Solvents are not used or produced in the manufacture of our manufacturer's alcohols or related products.

#### **Heavy Metals Statement**

Heavy metals are not expected to be in our manufacturer's alcohols and related products, which have gone through a distillation process. Heavy metals are not expected to be able to be vaporized through distillation and are not expected to be in their final product. Our manufacturer does not explicitly analyze for the presence or absence of the listed materials in their products.

#### Per- and Polyfluoroalkyl Substances (PFAS) Statement

Our manufacturer is aware of new and forthcoming regulations on Per- and Polyfluoroalkyl Substances (PFAS). They abide by all applicable laws and regulations. Their products and ingredients meet high levels of safety and quality standards. They do not formulate their products with PFAS.

#### **Ethanol Statement**

Our manufacturer's alcohols and related products are not expected to contain ethanol based on their raw materials, manufacturing process, handling, and storage. Our manufacturer does not explicitly analyze for the presence or absence of ethanol.

#### **Ethynol Statement**

Our manufacturer's alcohols and related products are not expected to contain ethynol based on their raw materials, manufacturing process, handling, and storage. Our manufacturer does not explicitly analyze for the presence or absence of ethynol.

#### **Dioxin Statement**

Our manufacturer's alcohols and related products are not expected to contain dioxin based on their raw materials, manufacturing process, handling, and storage. Our manufacturer does not explicitly analyze for the presence or absence of dioxin.

## Polyaromatic Hydrocarbons (PAH) Statement

Our manufacturer's alcohols and related products are not expected to contain polyaromatic hydrocarbons (PAH) based on their raw materials, manufacturing process, handling, and storage. Our manufacturer does not analyze for the presence or absence of PAH.



## **Microplastics Statement**

Our manufacturer's alcohols and related products are processed and refined in a closed system and are not expected to contain microplastics based on their manufacturing process, handling, and storage. Our manufacturer does not analyze for the presence or absence of microplastics.

#### **Biocidal Product Regulation (BPR) Statement**

With reference to Regulation (EU) No. 528/2012, regarding placing on the market and use of biocidal products, our manufacturer certifies their alcohols and related products are not subject to the labeling requirements specified in the regulation noted above. Preservatives are expected to not be present in these products based on the feedstock and manufacturing process currently employed. Our manufacturer's products are not considered as "treated articles" according to Article 3 of the regulation noted above.

#### **Preservatives Statement**

Preservatives are not added to our manufacturer's alcohols and related products. Their products are processed and refined in a closed system and are not expected to contain or to have come in contact with any preservatives/additives.

#### **Colorants Statement**

Colorants are not added to our manufacturer's alcohols and related products. Their products are processed and refined in a closed system and are not expected to contain or to have come in contact with any colorants. Our manufacturer does not explicitly analyze for the presence or absence of colorants in their products.

#### Jatropha Statement

Our manufacturer's alcohols and related products are in compliance with the FDA Notification to Industry issued July 6, 2012\*. None of our manufacturer's supply chains for these products are sourced from the Jatropha plant or any of its derivatives.

\*Source: FDA Notification to Industry, Products using oils, glycerin, or proteins that were derived from the Jatropha plant may have toxic effects, July 6, 2012.

# Section 5: Environmental, Health, Safety, and Sustainability Information ISO 14001/RC 14001 Status

Cremer North America has defined its EHS&S management system including its processes and interaction in accordance with the requirements of RC 14001:2023 and ISO 14001:2015 in the areas of pastillization, flaking, blending, packaging, product transfer and storage, distribution of specialty chemicals, and supporting functions. Cremer North America actively involves various levels of employees in EHS&S program development and implementation, including the development, review, and revision of the EHS&S management system.

#### **Sustainable Procurement Policy**

At Cremer North America sustainable procurement is about leveraging our existing policies within our supply chain to address social, economic, and environmental considerations over the life cycle of our products. Sustainability also means creating continuously improving policies which will drive sustainable results and personal accountability throughout the organization. This begins with sustainable strategic sourcing of our raw materials and flows through to our waste management systems.



## Proposition 65 - Safe Drinking Water and Toxic Enforcement Act of 1986

Please refer to the Safety Data Sheet for your specific product for Proposition 65 status. If the Safety Data Sheet is without Proposition 65 information, the product is not expected to contain Proposition 65 chemicals based on our manufacturer's knowledge in feedstock, manufacturing, storage, and handling information. Our manufacturer does not explicitly analyze for the presence or absence of substances listed in Proposition 65.

#### **EU REACH Compliance Statement**

EU REACH registration is only applicable to products supplied by our manufacturer from their EU division. Our manufacturer's alcohols and related products, supplied by Cremer North America, are not sourced from our manufacturer's EU division and therefore EU REACH registration is not applicable.

#### **EPA FIFRA Inert Registration Status Statement**

If a product's EPA FIFRA inert registration status is needed, please contact your supply chain specialist.

## Cosmetic Use/Regulation (EC) No 1223/2009 Statement

No animal testing has been conducted on our manufacturer's alcohols or related products pertaining to cosmetic ingredient use, which complies with the EU Cosmetics Directive 1223/2009.

#### **TSCA Inventory Status Statement**

Our manufacturer has verified that all their alcohols and related products are on the active TSCA inventory.

#### **Substances of Very High Concern (SVHC) Statement**

Our manufacturer's alcohols and related products are not expected to contain SVHC (Substances of Very High Concern) based on their knowledge in feedstock, manufacturing, storing, and handling information. Our manufacturer does not analyze for the presence or absence of SVHC.

#### Carcinogenic, Mutagenic, or Toxic for Reproduction (CMR) Statement

Our manufacturer's alcohols and related products are not expected to contain CMR (Carcinogenic, Mutagenic, and toxic to Reproductivity) substances based on their knowledge in feedstock, manufacturing, storing, and handling information. Our manufacturer does not analyze for the presence or absence of CMR materials.

#### **Conflict Minerals Statement**

Our manufacturer's alcohols and related products do not contain tin, tantalum, tungsten, or gold which are considered "Conflict Minerals."



## **Volatile Organic Compounds (VOC) Statement**

Our manufacturer's alcohols and related products would be considered as Volatile Organic Compounds (VOCs) for the purposes of the Clean Air Act under EPA's broad definition in 40 CFR Part 51.100 where a VOC is defined as: "Any compound of carbon, excluding carbon monoxide, carbon dioxide, carbonic acid, metallic carbides or carbonates, and ammonium carbonate, which participates in atmospheric photochemical reactions." For the California Air Resources board (CARB) VOC regulation, depending on different consumer product categories, fatty alcohols and related products can be qualified as low vapor pressure compounds that do not count against the VOC content limit per CARB regulation. Our manufacturer encourages the customer to check the CARB website and make their own regulatory assessment to ensure regulatory compliance according to their product type.

## Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) Statement

Our manufacturer's alcohols and related products are not derived from species listed in Appendices I, II, or III of the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES).

### **Restriction of Hazardous Substances (RoHS) Conformance**

Our manufacturer's alcohols and related products are in conformity with the European Union Directive 2011/65/EC on the restriction of the use of certain hazardous substances, including Lead (Pb), Mercury (Hg), Cadmium (Cd), Hexavalent Chromium (Cr VI), Polybrominated Biphenyls (PBB), and Polybrominated Diphenyl Ethers (PBDE), Bis(2-ethyhexyl) phthalate (DEHP), Butyl benzyl phthalate (BBP), Dibutyl phthalate (DBP), and Diisobutyl phthalate (DIBP), in electrical and electronic equipment.

#### **Section 6: Site Quality Information**

#### ISO 9001 Status

Our manufacturer's alcohols and related products are manufactured in compliance with ISO 9001:2015 Quality Management Systems.

The quality management system of Cremer North America is certified and in compliance with the ISO 9001:2015 Standard, within the scope of Marketing, Lab Testing, and Processing of Chemical Products.

#### **GMP Compliance Statement**

Our manufacturer's NF alcohols brands are manufactured in compliance with Excipient GMPs.

Cremer North America is registered with the FDA as a food facility and is inspected by the FDA and/or the Ohio Department of Agriculture to verify that Good Manufacturing Practices (GMP) are being met.

#### **HACCP Program**

Cremer North America has an established HACCP program for our human food, animal food, cosmetic, or excipient materials. Through a multi-discipline team, risks are identified and controlled through prerequisite programs, preventive controls program, risk assessments, process flow areas of impact, and critical control points.



#### **Lot Derivation**

Our manufacturer assigns a unique identifier, lot number, to each finished product shipment to allow for the traceability of the product back to the incoming raw materials according to written procedures.

Cremer North America also has a procedure for assigning unique identifiers, lot numbers, to the products we supply. This allows for traceability from the time of arrival at CNA, through each stage of production, and release of the product for shipment.

#### **Kosher and Halal Status**

Our manufacturer's Sacramento plant is Kosher certified, however not Halal certified at this time. For more information on the Kosher status of your specific product, please reach out to your supply chain specialist.

#### **Shelf Life Statement**

Cremer North America does not provide shelf life or expiry dates. Shelf life is affected by how a product is stored, packaged, and handled. Specific recommendations for shelf life can be found on the material's COA if required.

#### Significant Changes/Management of Change

Our manufacturer, and Cremer North America, each have a process to evaluate any changes made to the manufacturing site, scale, equipment, manufacturing process, starting material, packaging, or product specifications of any of our products to determine whether the change is considered significant. The customer will be notified of any changes that are determined to be significant.

## **Section 7: Miscellaneous Information**

None.



# **Change Control**

	Issue #	Reason for Change	Initiated by:
ĺ	1	New product packet	A. Clements