Excipient Information Packet for P&G Chemicals Star KPO Kosher Glycerin

Effective date: January 31, 2023

I. Product Regulatory Datasheet

Section 1 – General Product Information

Product Name: Star KPO Kosher Glycerin (for excipient use only)
Product Code: 95711091
Scope of document: Pharmaceutical excipient, food additive, cosmetics

Section 2 – Manufacturing, Packaging, Release Site and Supplier Information

Manufacturer: Peter Cremer North America
South Terminal
3117 Southside Avenue
Cincinnati, OH 45204
GMP: PCNA South Terminal is compliant with The Joint IPEC – PQG Good Manufacturing Practices Guide for Pharmaceutical Excipients

Section 3 – Physicochemical Information

CAS #: 56-81-5
Origin information: Tropical tree nut sources (palm kernel/coconut/palm)
Synonyms: Glycerol
Morphological form: Clear liquid with a slightly sweet taste
Brief description of manufacture:
Star KPO Kosher Glycerin is derived from tropical tree nut sources (palm kernel/coconut/palm). Crude oil is extracted or extruded from seeds or fruits of plants, followed by a degumming process to remove phosphatides and slimes water mixed with oil. After that, the oil goes through a refining, bleaching and deodorizing (RBD) process to remove organic and inorganic impurities and reduce colors, odors, and flavors. The triglyceride component in RBD grade oil undergoes an esterification reaction to form crude glycerine and methyl esters. Crude glycerine is manufactured by cleaving the glycerine off of the triglyceride fat backbone during the transesterification reaction with methanol and further refined to produce refined glycerin in a series of purification steps (concentration, distillation, condensation, and carbon bleaching). Star KPO Kosher Glycerin (96%) is produced by combining Superol KPO Kosher Glycerin and USP purified water.

Section 4 – Regulatory Information

Generally Recognized As Safe (GRAS) for human foods and animal feeds (21 CFR §182.1320 and §582.1320), Food Safety Modernization Act (FSMA) food facility registered.

Chemical Inventory Status
Refer to the assigned Safety Data Sheet Section 15 for the relevant country Existing Chemical Inventory Status.

EU REACH Compliance
PGC's glycerin brands are exempted under Annex V for purposes of EU REACH registration.

Drug Master File (DMF)
Star KPO Kosher Glycerin is for excipient use only and DMF management is not applied.

Residual Solvents Information
Star KPO Kosher Glycerin is a blend of Superol KPO Kosher Glycerin and purified water. P&G Chemicals Superol KPO Kosher Glycerin is for excipient use only and does not contain residual solvents of class 1, 2 or 3 that would meet the criteria for those classifications described in General Chapter <467> of the USP or Section 5.4 Residual Solvents in the current European Pharmacopoeia. This glycerin product also complies with the EMA/VICH guideline GL18 ®: Impurities: Residual solvents in new veterinary medicinal products, active substances and excipients issued by European Medicines Agency. Residual Solvents are not used or produced in the manufacture of Superol KPO Kosher Glycerin, and we do not expect these solvents to be present in the refined glycerin.

ICH Q3C (R8) - P&G Chemicals does not use any of the 3 listed residual solvents added in the ICH Q3C (Revision 8) guidance regarding residual solvents in our refining process and would not expect them to be present in our raw materials – consequently they are not expected to be present, but we do not analyze for them. The added solvents to Revision 8 include: 2-Methyltetrahydrofuran (2-MTHF), Cyclopentyl Methyl Ether (CPME), and Tertiary Butyl Alcohol (TBA).

Metal Catalyst and Metal Reagent Residues
Star KPO Kosher Glycerin is refined without the use of a metal catalyst or reagent and complies with the EMEA Guideline on the Specification Limits for Residues of Metal Catalysts or Metal Reagents (EMEA/CHMP/SWP/4446/2000).

California Proposition 65

Star KPO Kosher Glycerin complies with California's Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65). A Proposition 65 warning is not required. This product contains no listed substances known to the state of California to cause cancer, birth defects, or other reproductive harm at levels which require a warning under the statute.

Elemental Impurities

In the framework of the ICH Q3D Elemental Impurities guidelines and per USP General Chapter <232> Elemental Impurities, P&G Chemicals provides the elemental impurity profile of the Star KPO Kosher Glycerin products in the table below. None of the elements listed below are intentionally added during the production process nor are any metal catalysts used in the glycerin manufacturing process.

Sr. No	Name of Element	Class	Intentionally added? Yes / No	Potentially present Yes / No	Typical Result Less Than (ppm or ug/g)	Frequency of testing/ test performed in-house or externally
1	Cadmium	1	No	No	0.01	Yearly / in-house
2	Nickel	2A	No	No	0.02	Yearly / in-house
3	Lead	A	No	No	0.01	Yearly / in-house
4	Arsenic	A	No	No	0.02	Yearly / in-house
5	Mercury	A	No	No	0.01	Yearly / in-house
6	Iridium	2B	No	No	N/A	N/A
7	Osmium	2B	No	No	N/A	N/A
8	Palladium	2B	No	No	N/A	N/A
9	Platinum	2B	No	No	N/A	N/A
10	Rhodium	2B	No	No	N/A	N/A
11	Ruthenium	2B	No	No	N/A	N/A
12	Chromium	3	No	No	0.01	Yearly / in-house
13	Molybdenum	2A	No	No	N/A	N/A
14	Vanadium	2A	No	No	0.01	Yearly / in-house
15	Copper	3	No	No	0.01	Yearly / in-house
16	Selenium	2A	No	No	N/A	N/A
17	Barium	3	No	No	N/A	N/A
18	Cobalt	2A	No	No	0.01	Yearly / in-house
19	Titanium	3	No	No	N/A	N/A
20	Silver	2B	No	No	N/A	N/A
21	Gold	2B	No	No	N/A	N/A
22	Lithium	3	No	No	N/A	N/A
23	Tin	2B	No	No	N/A	N/A
24	Antimony	3	No	No	N/A	N/A

California SB 484 Certification

Star KPO Kosher Glycerin is compliant with the California Safe Cosmetics Act of 2005 (Senate Bill 484) regarding the protection of cosmetic products from containing ingredients with chronic health effects. Glycerin is not in the list of chemicals known or suspected to cause cancer, birth defects, or other reproductive toxicity from California Department of Public Health. Additionally, this product does not contain any of the listed chemicals. Further labeling and health-related information release are not required.

Restriction of Hazardous Substances (RoHS) Certificate
Star KPO Kosher Glycerin is compliant 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.

EU Cosmetic Regulation
Star KPO Kosher Glycerin complies with the EU Cosmetic Directive including EU Cosmetic Regulation 1223/2009 and its amendments for use as a cosmetic ingredient.

Kosher/Halal Status
Star KPO Kosher Glycerin product manufactured and stored by Peter Cremer North America, South Terminal and distributed by The Procter & Gamble Company is Kosher Passover certified with Rabbi's signature under the supervision of the Orthodox Union (OU).

Star KPO Kosher Glycerin product manufactured and stored by Peter Cremer North America, South Terminal and distributed by The Procter & Gamble Company is Halal certified with the Crescent M Halal logo by The Islamic Food and Nutrition Council of America (IFANCA).

Allergens/Hypersensitivities, Preservatives, Antioxidants, Latex, and Other Information
P&G Chemicals Star KPO Kosher Glycerin is processed and refined in a closed system and does **NOT** contain or have contact with following substances based on our raw materials, manufacturing process, handling and storage. P&G Chemicals does not analyze for presence or absence of those substances.

- Allergens identified in the US, Canada, Mexico, or EU regulations. These 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, barley, rice, celery, soybean, mustard seeds, celery, lupin, mollusks, and other allergen sources listed in EU regulation. 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, carmine.
- Preservatives, additives including latex, antioxidants such as Butylated Hydroxytoluene (BHT), Butylated Hydroxyanisole (BHA), and *tert*-Butylhydroquinone (TBHQ).
- Asbestos, Iodine, Magnesium, Sewage Sludge.

- All 34 Nonfunctional constituents (NFC) under CA Right to Know Act (SB 258) such as Benzene, Parabens, Nitrosamines, Ethylene Oxide etc.
- Phthalates such as DEHP (Di(2-ethylhexyl) phthalate, DINP (Diisononyl phthalate), Glycol Ethers, Nanoparticles, Aflatoxins, Silicones, ethylene oxide, 1,4-dioxane, and melamine.
- Agricultural chemical residues from pesticides, feed additives, or veterinary drugs.
- Trans Fats or Partially Hydrogenated Oils
- Polyaromatic Hydrocarbons (PAHs), dioxin.
- Polychlorinated Biphenyls (PCBs).
- Organic halogens including Polychlorinated biphenyl, Chlorinated phenol
- Other chemical contaminates such as Acrylamide, Cyanuric Acid, Fluorescent Whitening Agents (Optical Brighteners), Epichlorohydrin, BisPhenol A, Metal organic compounds, Oleonitrile and Oleamide, artificial colorants.

Micro Statement

Star KPO Kosher Glycerin does not contain microorganisms or their toxins or metabolites in quantities that present an unacceptable risk for human and animal health safety. The manufacturing process includes a distillation step with high temperature that would destroy potential microbes and low available moisture in a concentrated glycerin solution offers the inherent environment that cannot accommodate the growth of microorganisms. PGC glycerin is made according to IPEC-PQG GMP Guide for Pharmaceutical Excipients and is compliant with EU Directive 2005/2073 for Micro-Purity.

Irradiation Treatment

Star KPO Kosher Glycerin is not irradiated. To the best of our knowledge, the raw materials are not sourced from areas after nuclear accidents or incidents.

Animal Testing Statement

No animal testing has been conducted on this product pertaining to the cosmetic ingredient use, which complies with the EU Cosmetics Directive 1223/2009.

BSE/TSE Information

BSE/TSE concerns do not apply because this product is derived from plant oils only.

CITES Statement

This product is 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).

Conflict Minerals Statement
Star KPO Kosher Glycerin does not contain tin, tantalum, tungsten, or gold which are considered "Conflict Minerals".

GMO Information
According to National Bioengineered (BE) Food Disclosure Standard Disclosure by the United States Department of Agriculture (USDA), under 7 C.F.R. § 66.9(a), Star KPO Kosher Glycerin is not subject to BE labeling because it is obtained from non-genetically engineered sources (palm kernel/coconut/palm), which are non-BE crops.

Jatropha Statement
This product is compliant with the FDA Notification to Industry issued July 6th, 2012 on the prevention of products using glycerin derived from the Jatropha plant. Star KPO Kosher Glycerin products are not sourced from the Jatropha plant or any of its derivatives.

Nagoya Protocol Statement
The oil feedstock of Star KPO Kosher Glycerin are derived from tropical tree nut sources (palm/palm kernel/coconut), typically sourced as commodity from Malaysia, Indonesia and the Philippines. Long existing agricultural commodities used as oleochemical feedstock, such as palm oil, palm kernel oil, and coconut oil, are not in scope for the Nagoya Protocol.

Natural Statement
This product does not meet the definition of "natural" by The Association of American Feed Control Officials (AAFCO). Given the lack of guidance by the FDA and other regulatory bodies, this product is not supported to be labeled as "Natural".

According to ISO 16128, Guidelines on technical definitions and criteria for natural and organic cosmetic ingredients and products, this product has Natural Origin Index of 0.97 and Natural Index of 0.

Organic Certification
Star KPO Kosher Glycerin cannot be certified organic per the guidance from National Organic Standards Board, USDA National Organic Program (NOP).

The World Anti-Doping Agency (WADA) Statement
Star KPO Kosher Glycerin does not contain banned substances listed in WADA based on our raw materials, manufacturing process, handling and storage. P&G Chemicals does not analyze for presence or absence of those banned substances.

Nutritional Information
According to the 21CFR 101.9 - NUTRITION LABELING OF FOOD, Glycerin is not exempted under 21CFR 101(j)(4). Glycerin is considered a carbohydrate by US FDA and should be considered in the total carbohydrate amount stated in the nutritional declaration if 1 gm or greater per serving. If any claim is made regarding sugar content, also as a sugar alcohol.

Nutritional Information per 100g

Attribute	Limits
Food-Energy Value	4.32 Kcal/g
Protein	0
Cholesterol	0
Fat	0
Carbohydrate	100 g
Total Sugars	0
Added Sugars	0
Dietary Fiber	0
Minerals	0
Vitamins	0
Preservatives	0
Additives	0

Section 5 – Miscellaneous Product Information

Lot Derivation
Each finished product tank and shipment in is given a unique identification number. The lot number allows traceability of the product back to the incoming raw materials according to written procedures.

Re-test Period Statement
The retest period for Procter & Gamble Chemicals' Glycerin brands is 24 months at ambient temperature conditions (25 °C/77 °F) in unopened containers (railcars and tanker trucks). After this period, it is recommended to retest the product for critical parameters prior to usage.

Storage and Handling
The storage temperature range is set to ensure high quality glycerin stability. A sufficient temperature is required to ensure all stability indicating criteria are met to support a 24-month re-test interval. The optimal storage conditions would be as near to 25 ºC as possible; however,

for operational needs (pumping) or for short storage durations (<3 months), the temperature can be increased to temperatures not exceeding 52 ºC (approximately 125 ºF).

Significant Changes
P&G Chemicals has a process to address significant changes according to the IPEC guidelines on Significant Change. We will notify our customers of any changes that are determined to be significant. This notification will be in writing and sufficiently ahead of the implementation of such change as to allow the customer time to evaluate the likely effects of the change and respond to P&G Chemicals if necessary.

Section 6 – Effective Date

This document is effective from January 24, 2022 and is valid until being suspended. This version supersedes any previous version that P&G Chemicals has issued on this brand. This document is based on The International Pharmaceutical Excipients Council Excipient Information Package User Guide 2020.

Section 7 – Contact Information

If you have any additional question on EIP regulatory part, please contact:
Neha Patel
P&G Chemicals Global Product Stewardship Manager
The Procter & Gamble Company,
5201 Spring Grove Avenue
Cincinnati, OH 45217
Email: patel.n@pg.com

II. Site Quality Overview

Star KPO Kosher Glycerin is produced by Superol KPO Kosher Glycerin and purified water, therefore please refer to EIP for Superol KPO Kosher Glycerin if any question on Site Quality of Superol KPO Kosher Glycerin.

Section 1 – Site Overview

Scope:

- Site Name: Peter Cremer North America (Contract Manufacture For P&G Chemicals)
- Address: 3117 Southside Ave, Cincinnati, OH, 45204
- Excipients Covered: Star KPO Kosher Glycerin (for excipient use only)

Customer Audit Policy: It is preferred that customers use the information within the EIP as evidence in lieu of an onsite audit. However, this is not always feasible. The contract manufacturing site does host customer audits, based on the IPEC-PQG GMP Guide with some food safety topics included (should food customer be present) such as HACCP. To schedule an audit, please contact Customer Development Manager, per contact information below in EIP Title Page.

Site Details:

- Site Information: Approximately 150 employees on site. Approximately 20 support manufacture of Star KPO Kosher Glycerin. Total site is approximately 27 acres. For the Star process, production employees work first shift (Monday – Friday).
- Site Activities: Blend USP Glycerin and purified water to make Star KPO Kosher Glycerin. Other site activities include: drumming, flaking and pastillating other products.
- Primary Applications: Pharmaceutical excipient (not to be used as an API), food additive, cosmetics.
- Organizational chart: QA has an independent reporting structure outside of operations.

Section 2 – Compliance Evidence

The site follows the Joint IPEC-PQG Good Manufacturing Practices Guide for Pharmaceutical Excipients. The contract manufacturing site also maintains an SQF certification as part of the Global Food Safety Initiative (GFSI).

Section 3 – IPEC-PQG GMP Compliance Details

Below are details on a significant portion of the IPEC-PQG GMP Guide, to level 3 detail. Fourth level details have been omitted due to complexity and document length.

Documentation Requirements

- Quality Manual: The site has a quality manual in place, which meets requirements of the GMP guide, such as quality management standards.
- Control of Documents: P&G has a corporate system for creating, approving and distributing standards & specifications. Approved documents are provided to Peter Cremer electronically via a user access-controlled system. Approved documents have a footer which contains the effective date of the standard. Control of Records: Records are maintained per site procedure. Good Documentation Practices are followed, including ink only, with error correction being a single line, with initials, date, and reason for correction.

Change Control: There is a company change control system, for items such raw material specifications, approved suppliers, analytical test methods, and finished product specifications. The site has a comprehensive change control system, to cover site specific changes such as analytical equipment and process equipment. Changes are communicated to customers as defined in the IPEC Significant Change Guide.

Management Commitment: The site has documented quality objectives. These are reviewed with management, per the site management review policy.
Customer Focus: Star KPO Kosher Glycerin is produced and sold to meet internal specifications. The site has a customer audit policy, as discussed in Section 1.

Quality Policy:
Planning

- Quality Objectives: The site has quality objectives that are reviewed monthly and annually.
- Quality Management System Planning: The site completes annual internal audits. Findings from internal audits are reviewed with site management and tracked for completion.
- Responsibility, Authority, and Communication
- Responsibility and Authority: Peter Cremer has defined responsibility and authority both corporately and within the site. This is included in various locations such as role descriptions, organization charts, policies and procedures.

- Management Representative: The site has defined resources to meet the requirement of the IPEC-PQG GMP Guide and other applicable standards and industry guidance documents. Voluntary standards are at the discretion of the site.
- Internal Communication: The site has an established management communication system.

Management Review

- General: The site has various levels of management review, both internal and external to the manufacturing site.
- Review Input: Items within scope of the IPEC-PQG GMP Guide are reviewed at least annually.
- Review Output: Items within scope of the IPEC-PQG GMP Guide are reviewed at least annually.

Provision of Resources: See below

Human Resources

- General: All personnel have training appropriate to the tasks they must perform.
- Competence, Awareness and Training: All personnel have training appropriate to the tasks they must perform. Training is provided on a variety of topics, in multiple settings, and delivered in multiple ways, which vary based on the training required. This includes classroom training, web based training, hands on training, and 1:1 coaching. Training is documented via certificates, training records and completed knowledge checks. Training topics are both general, such as GMP and hygiene, and specific task oriented training. Personnel do not complete tasks they are not qualified for without direct supervision.
- Personnel Hygiene: The site has a hygiene GMP policy in which all staff is trained on. This policy includes (but is not limited to) personal health, clothing, hand washing, protective clothing, food, drink, allergens, tobacco, and personal medication.

Infrastructure

- Building and Facilities: Buildings and facilities are adequate for the intended use. Tanks are stored outside in a secured location. There are dedicated areas for raw material receiving, finished product shipping, production, breakrooms, bathrooms, laboratories, maintenance actives, material storage, and samples retains.
- Equipment: Equipment is fit for service, based on the material being held or processed at that stage of the process. Finished product is stored and transferred using either stainless steel or aluminum. Finished product is transported via food grade trailers.
- Utilities: Utilities are primarily non-contact with the finished product surfaces. Utilities include steam (with Kosher food grade treatment chemicals), potable water

(from local municipality), nitrogen, and compressed air. Each utility has a risk assessment and appropriate mitigation steps to prevent contamination.

- Water: Water is potable from local municipality. Water is primarily used for washouts, and is heated. For Star KPO Kosher Glycerin, purified water is used from a dedicated reverse osmosis water system unit.

Work Environment

- Air Handling: Air handling is not required, as the production of Star KPO Kosher Glycerin is in an enclosed system.
- Controlled Environment: Controlled Environment is not required, as the production of Star KPO Kosher Glycerin is in an enclosed system.
- Cleaning and Sanitary Conditions: Production areas are kept clean and orderly. Waste is segregated and removed in a timely manner.
- Pest Control: Pest control is completed be a service provider, and pesticides are not applied by site personnel. Traditional pest control methods are used. Insect lights are used on site.
- Lighting: Lighting is adequate.
- Drainage: The excipient is not open to the environment.
- Washing and Toilet Facilities: There are adequate personal washing facilities and changing rooms. Handwashing includes potable water (hot and cold), soap, and single use paper towels.

Planning of Product Realization: Peter Cremer has been producing Star KPO Kosher Glycerin since 1999. There is a depth and breadth of knowledge in Star KPO Kosher Glycerin production. Technical resources (engineering, analytical, etc.) as well as operations and QA are a part of product development, design, installation and validation, following corporate and IPEC-PQG GMP Guide requirements. There are few changes in production of Star KPO Kosher Glycerin.

Customer-related Processes

- Determination of Requirements Related to the Product: Peter Cremer has a controlled specification for the glycerin in the scope of this EIP. There is a database of shipping requirements by Customer location to meet customer specific requirements for transportation and unloading.
- Review of Requirements Related to the Product: Specifications are defined by P&G. For shipping requirements to the customer, a P&G central transportation group reviews those requirements to determine availability of transportation.
- Customer Communication: P&G has a customer complaint system, which all complaints can be filled. This is available through the customer's P&G contact.

Customer inquiries are also made via the customer's P&G contact. P&G communication of change to the customer follows IPEC Significant Change Guide.

Design and Development: Technical resources (engineering, R&D, analytical, etc.) as well as operations and QA are a part of product development, design, installation and validation, following corporate and IPEC-PQG GMP Guide requirements. There are few changes in production of Star KPO Kosher Glycerin.

Purchasing

- Purchasing Process: Peter Cremer does not purchase raw materials for the production of Star KPO Kosher Glycerin. Raw materials are received from the P&G Cincinnati Plant and municipal water department. The water used as a raw material is then purified on site. The water is then tested in accordance to P&G specifications (reference USP Purified Water monograph).
- Purchasing Information: N/A.

Verification of Purchased Product: Quality critical materials are tested when they arrive on site, and then released for material unloading. There is additional testing of materials prior to use in production. Sampling and testing is defined. The incoming Superol that is qualified at the P&G Cincinnati Plan is again tested in accordance to P&G Specifications as defined in the incoming raw material testing scheme.

Production and Service Provision

- Control of Production and Service Provision: Production of Star KPO Kosher Glycerin is a batch process. Batches of raw material are made per pre-defined parameters. During processing, many parameters are constantly measured. Quality critical parameters are defined, and monitored. These records are verified as a part of the batch record release.
- Validation of Processes for Production and Service Provision: The site has a validation master plan, which defined the validation overview and requirements. Validation is maintained through maintenance and change control. The glycerin process is validated.
- Identification and Traceability: Traceability is maintained throughout processing. Batches are defined by the blending tank.
- Customer Property: N/A.
- Preservation of product: Refined Star KPO Kosher Glycerin is stored in line with the technical data sheet generated by P&G.
- Control of Measuring Devices and Monitoring Devices: Instruments are calibrated to instruments that are traceable to NIST or equivalent standard.
- Monitoring and Measurement

- Customer Satisfaction: Customer complaints are reviewed and investigated.
- Internal Audit: An internal audit program is in place. This is used to meet the requirements of the IPEC-PQG GMP Guide, P&G, SQF and PCNA internal requirements.
- Monitoring and Measurement of Processes: During processing, many parameters are constantly measured. Quality critical parameters are defined, and monitored. These records are verified as a part of the batch record release. Analytical testing is completed on in process samples as a part of the process control strategy.
- Monitoring and Measurement of Product: Product testing is defined by specifications. Testing is completed with P&G developed and validated test methods. Data from these test methods are used to make CofAs. This is done in a computer system, and has a manual analytical review. The site has an Out of Specification (OOS) procedure defined. This procedure includes investigation of analytical as well as manufacturing, and has retesting requirements defined, when required. Stability is completed for glycerin, following The IPEC Excipient Stability Program Guide. P&G glycerin has a retest period of 2 years. This information is captured on the CofA.
- Control on Nonconforming Product
- Reprocessing: The site does not reprocess finished product.
- Reworking: The site does not rework product.
- Returned Excipients: Returned excipients may be downgraded to a non-regulated application.

Analysis of Data: Data is integral as a part of the continuous improvement process. Data is reviewed in different forums, on various frequencies, including daily, weekly, monthly, quarterly, and annually.

Improvement

- Continual Improvement: The site has a continuous improvement program. Data is reviewed in different forums, on various frequencies, including daily, weekly, monthly, quarterly, and annually.
- Corrective Actions: The site has a defined corrective actions program.
- Preventative Actions: The site has a defined preventative actions program.

Section 4 – Miscellaneous Site Information

Not Applicable.

Section 5 – Revisions

This is the 2nd version of Quality Section of the Excipient Information Package for P&G Chemicals Star KPO Kosher Glycerin based on The International Pharmaceutical Excipients Council Excipient Information Package User Guide 2020.

Section 6 – Contact Information

If you have any additional question on EIP quality part, please contact:
Christopher Monteparo
Site Quality Assurance Manager of P&G Chemicals
The Procter & Gamble Company, Cincinnati Chemicals Plant
5201 Spring Grove Avenue, Cincinnati, OH 45217, USA
Email: monteparo.cn@pg.com

III. Site and Supply Chain Security Overview

Section 1 – Scope

- This section provides a high level overview of Peter Cremer North America's (PCNA) Site and Supply Chain Security measures in place for the facility and excipients described below:
- Star KPO Kosher Glycerin is made from Superol KPO Kosher Glycerin refined at the *Cincinnati Glycerin Refinery* and blended with purified water at Peter Cremer North America, South Terminal.
    - Address:Peter Cremer North America
      3117 Southside Avenue
      Cincinnati, OH 45204
- The Excipient Product covered by this document include:
    - Star KPO Kosher Glycerin
- The Parent Corporation of PCNA is Peter Cremer Holding GmbH & Co. KG, Glockengiesserwall 3, 20095 Hamburg, Deutschland.

Section 2 – Supply Chain Security

- Carriers who transport PGC's Star KPO Kosher Glycerin must be rated for "Food Grade" material only (this means stainless steel containers, non-contact pumps/gears during trans-loading, etc.).
- All tank truck shipments to customers must undergo a "Kosher Wash", at a kosher wash facility with wash certificate, between each load. After the kosher wash, the vessel is sealed and the seal identification codes are listed on the wash certificate.
- Prior to loading the vessels 3 prior cargos are verified via a "Prior Cargo List" validated by Central PGC.
- The seals on all incoming vessels are verified prior to loading to ensure transportation vessels have not been compromised during transit to the plant.
- All vessels containing Star KPO Kosher Glycerin are sealed after loud out. Unique seal codes are recorded on the Bill of Lading (BOL) as well as the Certificate of Analysis (CoA) which the customer receives and uses to ensure the integrity of the vessel/contents have not been compromised.
- Peter Cremer North America takes a retain sample of each lot and shipping container for traceability which is kept per site retention procedure.
- Finished Product is released by Quality Assurance to operations. Operations then gives the material handlers permission to the tank via the control system.
- PGC only guarantees the quality and security of refined glycerin products shipped bulk from a P&G ship site to a receiving customer site (end use/consuming customer

or distributor/reseller). PGC does not guarantee our products if they have been re-packed or altered.

- Cincinnati Chemicals Plant is registered under FSMA as food facility.

Section 3 – Security Information

- A comprehensive security plan exists at Peter Cremer North America site. As this facility is located along the Ohio River, the site is regulated under Homeland Security and the U. S. Coast Guard. As per regulation, any details relating to our plans are strictly confidential.
- The site is secured and access is controlled by an independent security vendor 24 hours a day/7 days a week, 365 days a year.
- Employee access is through a key card system. Each employee must have a Transportation Workers Identification Credentials (TWIC) Card through Homeland Security. All visitors and contractors access the Plant through the Guard House. Security personnel have specific post-orders which outline access, badges, camera monitoring, etc.
- Data and computer system protection is maintained via a site controlled access system. Only plant personnel and select management have access. Upon termination the employees' access to the plant as well as to computer systems (intranet, etc.) are revoked.
- Training is provided to all employees and contractors for security/data and computer system protection.
- Background checks are completed on all prospective employees prior to hiring and are managed by Human Resources.
- The U.S. Food and Drug Administration Food Defense Self Assessment Tool is reviewed annually as a part of continuous improvement.

Section 4 – Safety & Environmental Information

- A documented Health and Safety Program exists for Peter Cremer. This program follows HS&E guidelines to ensure compliance with national and local OSHA and EPA regulations.
- Sufficient resources have been committed to implementing, maintaining and improving the HS&E management system.
- HS&E management system is periodically evaluated by internal resources and continually improved.
- PCNA's Health and Safety program also includes Fire Protection, Process Safety, and Industrial Hygiene and Environmental.

- Peter Cremer is a registered member of the American Chemistry Council's *Responsible Care* program.

Section 5 – Business Continuity Plan

- A comprehensive Business Continuity Plan exists for Peter Cremer North America. This plan is approved by executive leadership.
- The plan covers contingencies for a variety of events including, but not limited to; fire/explosion, civil unrest, product recall, loss of IT, loss of people, damaging weather and other risks.
- This document also contains a list of key resources in the event the BCP needs to be activated. The plant leadership team is required to maintain a copy at their home as well as at work to ensure it is available.
- A test is conducted each year on a mock BCP situation and resulting areas of opportunity for improvements are documented. Any outages are addressed and an action plan is put in place to remediate them.

Section 6 – Miscellaneous Site Information

Not Applicable.

Section 7 – Revisions

This is the 2nd[t] version of Manufacturing Section of Excipient Information Package for P&G Chemicals Star KPO Kosher Glycerin based on The International Pharmaceutical Excipients Council Excipient Information Package User Guide 2020.

Section 8 – Contact Information

If you have any additional question on EIP manufacturing part, please contact:
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