Excipient Information Packet for P&G Chemicals Moon OU Kosher Glycerin USP/FCC

Effective date: January 31, 2023

I. Product Regulatory Datasheet

Section 1 – General Product Information

Product Name: Moon OU Kosher Glycerin, USP/FCC (for excipient use only)
Product Code: 10275531
Scope of document: Pharmaceutical excipient, food additive, cosmetics

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

Manufacturer: The Procter & Gamble Company
Procter & Gamble Chemicals
Cincinnati Chemicals Plant
5201 Spring Grove Avenue
Cincinnati, OH 45217
GMP: PGC Cincinnati Plant is compliant with The Joint IPEC – PQG Good Manufacturing Practices Guide for Pharmaceutical Excipients

Section 3 – Physicochemical Information

CAS #: 56-81-5
Origin information: vegetable sources (soybean/canola/palm kernel/coconut/palm)
Synonyms: Glycerol
Morphological form: Clear liquid with a slightly sweet taste
Brief description of manufacture:
The crude glycerin used in our manufacture process to make Moon OU Kosher Glycerin USP/FCC brand is derived from commodity vegetable sources (soybean/canola/palm kernel/coconut/palm), typically sourced as commodity from USA, Malaysia, Indonesia and the Philippines. Crude glycerine is further refined to produce refined glycerin in a series of purification steps (concentration, distillation, condensation, and carbon bleaching).

Section 4 – Regulatory Information

Moon OU Kosher Glycerin, USP/FCC is intended only for excipient use in pharmaceutical applications. It complies with United States Pharmacopeia (USP) requirements for excipients. Additionally, it complies with Food Chemicals Codex (FCC) compendial requirements for food

ingredient use and is Generally Recognized As Safe (GRAS) for human foods and animal feeds (21 CFR §182.1320 and §582.1320) by the US Food and Drug Administration (FDA).

PGC Cincinnati Chemicals Plant is registered with US FDA as a food facility and it complies with the Food Safety Modernization Act (FSMA), including food GMP's. PGC Cincinnati Chemicals Plant is also accredited as AA rating for Brand Reputation Compliance (BRC) food safety certification as a scheme of Global Food Safety Initiative (GFSI).

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)
An excipient DMF is not required by law or US FDA regulations. PGC does not file a Type IV DMF for Moon OU Kosher Glycerin, USP/FCC.

EU Food Additives: E422 Glycerol Monograph
Moon OU Kosher Glycerin, USP/FCC complies with the Commission Regulation (EU) No 231/2012 for glycerol as a food additive as contained in E422 Glycerol Monograph. Compliance includes meeting the requirement for 3-monochloropropane-1,2-diol (3-MCPD) with a maximum limit of 0.1 mg/kg, for butanetriols, which have consistent results of "not detected" using a method detection limit of 0.02%.

Residual Solvents Information
Moon OU Kosher Glycerin, USP/FCC products do 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 and The Appendix 1 list of solvents in ICH Guideline Q3C: Guideline for Residual Solvents. 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 Moon OU Kosher Glycerin, USP/FCC.

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).

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 Moon OU Kosher Glycerin, USP/FCC. We have extensively evaluated the in-process and finished products and found no detectable levels of residual solvents.

Iron and the Alkali Elements
Iron and the Alkali elements (Lithium, Sodium, Potassium, Rubidium, Cesium and Francium) have not been detected in Moon OU Kosher Glycerin, USP/FCC with the general limit of detection as 0.5 ppm by ICP. Based on the testing results, these elements, if present, would be at levels less than 0.5 ppm.

Metal Catalyst and Metal Reagent Residues
Moon OU Kosher Glycerin, USP/FCC 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).

EU Cosmetic Regulation
This product complies with the EU Cosmetic Directive including EU Cosmetic Regulation 1223/2009 and its amendments for use as a cosmetic ingredient.

California Proposition 65
Moon OU Kosher Glycerin, USP/FCC 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.

Residual Pesticides
Moon OU Kosher Glycerin, USP/FCC does not contain any of 70 pesticides listed under USP general chapter 561, articles of botanical origin.

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 Moon OU Kosher Glycerin, USP/FCC 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

Moon OU Kosher Glycerin, USP/FCC 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

Moon OU Kosher Glycerin, USP/FCC is compliant with the European Union Directive 2002/95/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) in electrical and electronic equipment.

Kosher/Halal Status

Moon OU Kosher Glycerin, USP/FCC is Kosher certified under the supervision of the Orthodox Union (OU).

Allergens/Hypersensitivities, Preservatives, Antioxidants, Latex, and Other Information

Moon OU Kosher Glycerin, USP/FCC 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.

Nitrosamine Statement

Moon OU Kosher Glycerin, USP/FCC product is processed and refined in a closed system and do(es) NOT contain or have contact with Nitrosamines based on our raw materials, manufacturing process, handling and storage. P&G Chemicals does not analyze for presence or absence of those substances. Based on IPEC Europe guideline, detailed excipient nitrosamines risk evaluation has been performed and the document is available upon request.

Micro Statement

Moon OU Kosher Glycerin, USP/FCC 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

Moon OU Kosher Glycerin, USP/FCC is not irradiated. To the best of our knowledge, the raw materials are not sourced from areas after nuclear accidents or incidents.

Ethylene Oxide Statement

Moon OU Kosher Glycerin, USP/FCC complies with the Commission Regulation (EU) No 2022/1396 regarding the presence of ethylene oxide in food additives. Compliance includes meeting the requirement for Ethylene Oxide (sum of Etylene Oxide and 2-chloro-ethanol) with a maximum limit of 0.01 mg/kg.

DEG/EG Statement

Moon OU Kosher Glycerin, USP/FCC complies with all USP Compendia requirements, including Identification B: limit test for diethylene glycol and ethylene glycol. As such, Moon OU Kosher Glycerin, USP/FCC complies with the USP IBD&C calculation for China Pharmacopeia DEG/EG requirements, NMT 0.025% DEG/EG.

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
Moon OU Kosher Glycerin, USP/FCC 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), Moon OU Kosher Glycerin USP/FCC is not subject to BE labeling because it has been subjected to a refinement process validated to make the modified genetic material in the food undetectable.

Glyphosate Statement
According to testing conducted, no glyphosate residue was detected in Moon OU.

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. Moon OU Kosher Glycerin, USP/FCC products are not sourced from the Jatropha plant or any of its derivatives.

Nagoya Protocol Statement
The crude glycerin used in our manufacture process to make Moon OU Kosher Glycerin USP/FCC brand is derived from commodity vegetable sources (soybean/canola/palm kernel/coconut/palm), typically sourced as commodity from USA, Malaysia, Indonesia and the Philippines. P&G Chemicals has no knowledge on the original soybean source nor the soybean residues in the crude glycerin feedstock. Long existing agricultural commodities used as oleochemical feedstock, such as soybean oil, 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

Moon OU Kosher Glycerin, USP/FCC cannot be certified organic per the guidance from National Organic Standards Board, USDA National Organic Program (NOP).

The World Anti-Doping Agency (WADA) Statement

Moon OU Kosher Glycerin, USP/FCC 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.

Vegan statement

Moon OU Kosher Glycerin, USP/FCC is strictly from vegetable sources and does not contain, nor was it processed with or sourced from anything animal derived including from eggs or dairy. Consequently, it should be suitable for food ingredient use in Vegan food products.

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

Section 1 – Site Overview

Scope

- Site Name: P&G Cincinnati Plant
- Address: 5201 Spring Grove Ave
  Cincinnati, OH, 45217
- Excipients Covered: Moon OU Kosher Glycerin, USP/FCC (for excipient use only)

Customer Audit Policy

It is preferred that customers use the information within the EIP or the BRC audit as evidence in lieu of an onsite audit. However, this is not always feasible. The site does host group customer audits, with a pre-defined agenda, based on 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 shown in EIP Title Page.

Site Details

- Site Information: Approximately 100 employees on site. Approximately 50 support manufacture of glycerin. Total site is approximately 27 acres. Union employees work a rotating shifts.
- Site Activities: Refining (vapor-phase distillation) and bulk shipment of glycerin. The site also produces surfactants on dedicated equipment for P&G internal use.
- 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, and outside of the plant to P&G Chemicals Global QA.

Section 2 – Compliance Evidence

The site follows The Joint IPEC-PQG Good Manufacturing Practices Guide for Pharmaceutical Excipients and maintains BRC certification (since 2011). The BRC audit standard is part of Global Food Safety Initiative (GFSI). The BRC audit standard has requirements beyond food safety, including quality and legality. Requirements for certification include an annual onsite audit with approximate 3 day duration. Within the BRC standard, there are 7 sections which are audited (Senior Management Commitment, The Food Safety Plan – HACCP, Food Safety and Quality Management System, Site Standards, Product Control, Process Control, and Personnel) . The audit spends approximately 50% of the time on the manufacturing floor, and the balance reviewing records and procedures. For more information, please see the BRC website (http://www.brcglobalstandards.com/).

The site also completes the SMETA (Sedex Members Ethical Trade Audit). For more details please see the Sedex website (http://www.sedexglobal.com/ethical-audits/smeta/).

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 corporate documents. The site maintains an electronic database for access of site controlled documents, accessible to all site employees. Site documents have a footer with expiration valid for 1 day from the date printed. Site owned (versus corporately owned) documents are approved and retained per site procedure.
- 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. IPEC-PQG GMP does not have a requirement to line through blank spaces on documents.

Change Control: There is a corporate 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: Glycerin is produced and sold to meet internal specifications, as well as USP, FCC specifications. The site has a customer audit policy, as discussed in Section 1.

Quality Policy: The site has a documented Quality Policy which is shared with the site annually.

Planning

- Quality Objectives: The site has quality objectives that are reviewed monthly, quarterly, and annually.

- Quality Management System Planning: The Planning team completes internal audits. Findings from internal audits go into the site CAPA system. CAPA are reviewed regularly with management.

Responsibility, Authority, and Communication

- Responsibility and Authority: P&G 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, BRC Food Safety Standard, 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. There are various levels of review which happen daily, weekly, monthly, quarterly, and annually.
- Review Input: Items within scope of the IPEC-PQG GMP Guide are reviewed at a minimum quarterly.
- Review Output: Items within scope of the IPEC-PQG GMP Guide are reviewed at a minimum quarterly.

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, Step-Up Cards, 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 staffs are 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. The process, while enclosed, is primarily indoors. There are dedicated areas for raw material receiving, finished product shipping, production, breaks, bathrooms, laboratories, maintenance actives, material storage, and samples retains. The site also produces surfactants for internal P&G use. This is produced with dedicated equipment that is segregated from glycerin production.
- 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 railcars or 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.

Work Environment

- Air Handling: Air handling is not required, as the production of glycerin is in an enclosed system.
- Controlled Environment: Controlled Environment is not required, as the production of 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 P&G personnel. Traditional pest control methods are used. Insect lights are not used on site.
- Lighting: Lighting is adequate. Due to the nature of the operation, many lights are on motion detectors to only light when needed.
- Drainage: Not required as the production of glycerin is in an enclosed system.
- 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

P&G has been producing glycerin since the 1850's, and producing at the P&G Cincinnati Plant since 1890. There is a depth and breadth of knowledge in glycerin production. 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 glycerin.

Customer-Related Processes

- Determination of Requirements Related to the Product: P&G has a controlled specification. In addition, 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, and the requirements of the USP monographs. 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 glycerin.

Purchasing

- Purchasing Process: P&G Cincinnati Plant only purchases raw materials and process aids from approved suppliers. There is a corporate supplier qualification procedure, which includes (but not limited to) a questionnaire, on site visit, lab scale distillation, analytical analysis, and qualification. Service providers are approved via corporate purchasing group, following a defined work process.
- Purchasing Information: These requirements are met.
- 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.

Production and Service Provision

- Control of Production and Service Provision: Production of glycerin is a continuous process which has batches of raw materials. 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 raw material tank. Lots are defined as finished product tank. Multiple lots may be made from one batch of raw material.
- Customer Property: Not applicable.
- Preservation of product: Refined 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, BRC Food Safety Standard, and P&G 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 and monographs. Where there is testing as required by the monograph (such as USP, FCC or EP) tests methods are Compendial or equivalent, with equivalency validation. Non monograph 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 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 of Nonconforming Product

- Reprocessing: The site can reprocess material. The glycerin process is a distillation process. As is inherent in any distillation process, reflux is generated and reprocessed. Reflux is segregated into a tank, analyzed, and made a part of a batch.
- Reworking: The site does not rework product that has left the site and is out of P&G control.

- Returned Excipients: Returned excipients may be reprocessed, based on risk assessment, or 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 – Contact Information

If you have any additional question on EIP quality part, please contact:
Christopher Monteparo
Site Quality Assurance Manager of P&G Chemicals
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III. Site and Supply Chain Security Overview

Section 1 – Scope

- This section provides a high-level overview of P&G Chemicals (PGC) Site and Supply Chain Security measures in place for the facility and excipients described below:
- Glycerin produced and sold by PGC is Refined at the *Cincinnati Glycerin Refinery*
  - Address: 5201 Spring Grove Ave
    Cincinnati, OH 45217
- The Excipients Product covered by this document include:
  - Moon OU Kosher Glycerin, USP/FCC
- The Parent Corporation of P&G Chemicals is The Procter and Gamble Company, located at 1 Procter and Gamble Plaza, Cincinnati, OH 45202

Section 2 – Supply Chain Security

- Carriers who transport PGC's refined 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.
- All railcar shipments are made via a dedicated Kosher Glycerin rail fleet.
- 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 at the Cincinnati Glycerin Refinery. This ensures transportation vessels have not been compromised during transit to the plant.
- All vessels loaded at the Cincinnati Plant 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.
- PGC 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. Controls and logic will only allow the material handlers to move product out of the tank after this has been completed.

- 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 the Cincinnati Glycerin Plant with regular assessments completed and approved by the Facility Security Officer (FSO) as well as PGC leadership and in compliance with corporate guidelines.
- The Cincinnati Glycerin Plant is secured and access is controlled via the June Street Guard House which is staffed 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 and all visitors and contractors access the Plant through the June Street 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 selected Central R&D personnel have access. Upon termination the employees' access to the plant as well as to computer systems (intranet, etc.) are revoked.
- Training is provided on both a Corporate Level and Site Specific Level for security/data and computer system protection.
- Background checks are completed on all prospective employees prior to hiring and are managed by Human Resources along with Talent Supply personnel.
- 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 the Cincinnati Glycerin Plant. This program follows corporate HS&E guidelines to ensure compliance with OSHA and P&G's own, more stringent, requirements.
- Independent reviews of the Health, Safety and Environmental (HS&E) system at P&G Cincinnati Plant have been conducted with the following conclusions:
    - HS&E policies and procedures were comparable in scope and effectiveness to the ISO 14001:2004 and the 29CFR 1910 (OSHA) standards.

- Sufficient resources have been committed to implementing, maintaining and improving the HS&E management system at the corporate, Business Unit and facility levels.
- P&G's HS&E management system is periodically evaluated by internal resources and continually improved.
- P&G Cincinnati Plant Health and Safety program also includes Fire Protection, Process Safety, and Industrial Hygiene and Environmental.
- P&G Cincinnati Plant 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 the Cincinnati Chemicals Plant. This plan is approved by executive leadership at P&G and follows corporate guidelines.
- The plan covers contingencies for a variety of events including, but not limited to; pandemic flu, fire/explosion, civil unrest, raw material shortages, product recall, loss of IT, loss of people, damaging weather and other risks.
- The document lists out the crisis management plan and the business interruption limits as well as any single point of failure items.
- 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 – Contact Information

If you have any additional question on EIP manufacturing part, please contact:
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P&G Chemicals
Delivering solutions, creating value

1 IMPORTANT NOTE This technical product information, while believed to be accurate and reliable, is given without guarantee or warranty of any kind expressed or implied. Purchaser assumes all risk in acting on this information provided by Procter & Gamble representatives. Individual requirements vary, and each purchaser is urged to perform their own tests, experiments and investigations in the use of Procter and Gamble products 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 Procter & Gamble patents relating to uses of the above described chemicals other than those uses specifically mentioned herein