Dear Valued Customer:

In order to meet our customers' needs, P&G Chemicals North America, is upgrading its glycerin brand portfolio. These improvements include producing all of our glycerin brands domestically at our Cincinnati Glycerin plant, enhancing our best in class quality standards, and simplifying our current product portfolio. Effective October 1, 2011, PGC North America will no longer be offering SUPEROL KNP, SUPEROL VEG, Moon KPO, or Moon NK. Our new brand Moon OU will be replacing SUPEROL VEG and SUPEROL KNP.

Beginning October 1, 2011 the brands of glycerin that we will offer are

- SUPEROL KPO
- Moon OU
- SUPEROL NK
- STAR KPO
- STAR NK

*Tech Grade and CP Grade will be available on a limited basis.

We are providing the following information to assist in qualifying our new brand Moon OU. Please do not hesitate to contact your P&G representative with any questions.

P&G Chemicals 1-800-477-8999

PGCHEMICALS.COM

Updated Maggie Del Presto, Glycerin CDM, June 2013

P&G Chemicals

Contents

General Information

Corporate Address
P&G Chemicals
11530 Reed Hartman Highway
Cincinnati, OH 45241

Main Contact:
Maggie Del Presto
Customer Development Manager
Info Line: 1-800-477-8899
Office: 513-627-0471
Email: delpresto.m@pg.com

Manufacturing Site and Personnel

Plant Address
P&G Cincinnati Plant
5201 Spring Grove Ave
Cincinnati, OH 45217

General Plant Information

Ownership history:	Procter & Gamble since 1837
Built:	1886
Years operating at current location:	120
Main Plant:	10 Acres
Facilities:	20,000 sq ft
Original Use:	Glycerin refinery
Building Materials:	Brick, metal siding, steel, concrete
Total employees:	85
Within manufacturing process	40
Employees in QA/QC	2

Union:	Employees' Representation Association Union
Security:	Fenced with ID security gates
Operation Hours:	24/7
Shifts:	4 teams working 12 hr rotations
Sub Contractors:	None

Personnel

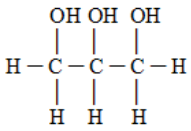
Cincinnati Plant Site Manager	John Collins
QA Manager	Kitty Fields

Material Produced at Site

- Superol KPO, Glycerin 99.7%, USP*/FCC/EP
- Superol NK, Glycerin 99.7%, USP*/FCC
- MOON OU, Glycerin 99.7%, USP*/FCC
- HDL – MSAS, AES Paste for liquid laundry products (housed in a different location)

*For excipient use only

General Physical/Chemical Information

Material name:	Glycerin 99.7%
Synonyms/Trade names:	Glycerol, Glycerine
Chemical name:	1, 2, 3-Propanetriol
Molecular Structure:	
Formula:	$CH_2OHCHOHCH_2OH$

Chemical Abstract Number (CAS):	56-81-5
Physical State:	Liquid
Specific Gravity:	1.2613 min
Boiling Point:	290°C
Taste:	Tangy sweet
Viscosity:	71 cp @ 25°C
Flash Point:	>198.9°C
Color:	Water white

Nutritional Information

Food Energy value	4.32 Kcal/g
Protein	0
Cholesterol	0
Fat	0
Minerals	0
Vitamins	0
Preservatives	0
Additives	0

Glycerin is metabolized as a carbohydrate

Regulatory Information

Regulatory Items/Standards	Details
International Nomenclature for Cosmetic Ingredient (INCI) Name	Glycerin
Chemical Abstracts Number(CAS No.)	56-81-5
EINECS Number	200-289-5
US FDA Regulatory Status	GRAS - Generally recognized as safe when used according with good manufacturing practice.
FDA GRAS Clearance No.:	21 CFR 182.1320
Other Food Additive Clearance: FDA 21CFR	175.105; 175.300; 175.320; 175.380; 175.390; 176.179; 176.210; 177.1210; 177.2420; 178.3120; 182.90; 182.99
P&G's "National Drug Labelers Code" (NDC Number)	037000
GRAS F.E.M.A Number	2525
Harmonized Tariff Code Number	2905.45
Canadian Food and Drug Regulations, Part B	Division 16, Table XV, number 8 (glycerin) Division 16, Table VIII, G.3 (glycerol)
Quality Assurance	Manufactured in accordance with US Food & Drug Administration's requirements for current Good Manufacturing Practices (cGMPs) in 21 CFR Part 110 (Food) and 211 (drugs), consistent with IPEC's guidelines

Drug Master File (DMF) Number

This is not applicable to our line of glycerin.

A DMF is a means of submitting Confidential Business Information (CBI) data to US FDA for use in support of Investigational New Drug (IND) or New Drug Application (NDA) submissions, etc. A DMF is not required by law or FDA regulation, and submission is voluntary. Since P&G Chemicals' glycerin is for excipient use only, P&G Chemicals has not applied for a DMF.

Compendia Conformance

Our line of glycerin above meets the compendia requirement of the standards below

Brand	Meets Standard	Conformance Expected*
MOON OU™	US Pharmacopeia* Food Chemical Codex	European Pharmacopoeia British Pharmacopoeia Japanese Pharmacopoeia

*For excipient use only

AIB Audit	November 2011, Superior Rating of 935
BRC Audit (GFSI Approved Scheme)	October 2011, Grade A
	September 2012, Grade A

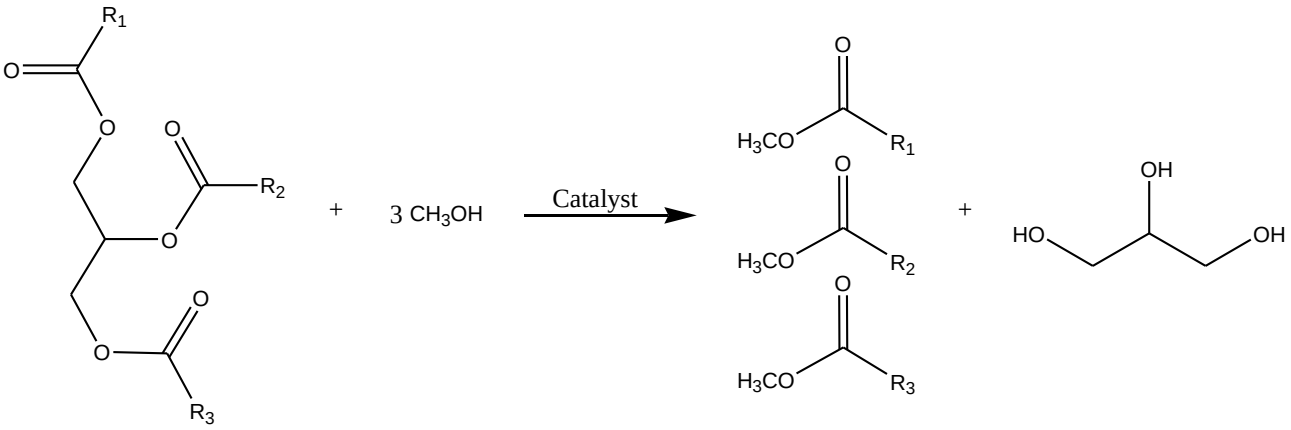
ISO vs QAKE

ISO 9000 certification is an excellent quality assessment program that examines the many systems important to delivering consistent high quality. Our own Quality Assurance Capability assessment builds off of the key aspects of not only ISO Certification, but also our own rigorous quality system standards. We feel our worldwide approach to quality assurance positions the Company to be among the best in the world in delivering our long-standing goal of products of superior quality and value for our consumers.

Process Chemistry

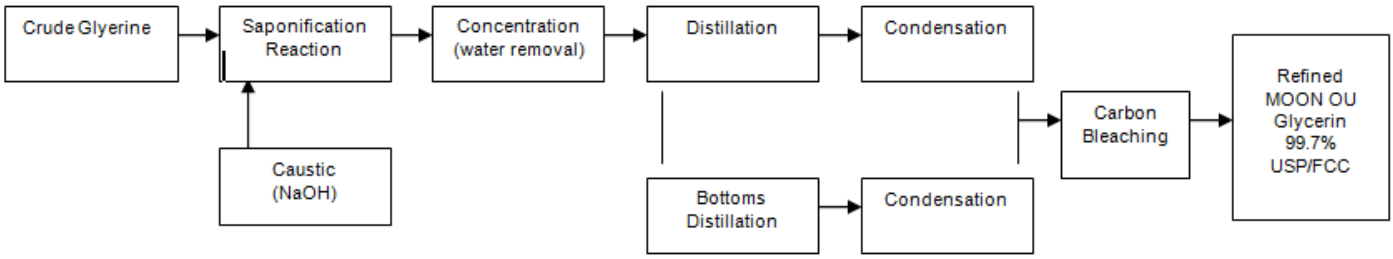
Crude glycerine is a co-product that is formed during methanolysis, hydrolysis, or saponification of triglycerides which results in the glycerin backbone being separated from the triglyceride.

Methanolysis



Triglycerides Methanol Methyl Esters Glycerin

Moon OU Process Flow



Raw Material/Feedstocks

P&G refined glycerin is made from a variety of crude sources, each qualified and audited against P&G's rigorous QA standards. Feed stocks for MOON OU are completely vegetable derived and are Kosher certified.

GMO

GMO Definition

A genetically modified organism is one whose genetic makeup has been altered using recumbent DNA or related techniques in genetics. From an agricultural point of view, crop science has developed methods to modify plants in order to improve yields, generate the desired meal-to-oil composition, etc.

Non-GMO Ingredients

Ingredients sourced from Non-GMO varieties of crops with identity preservation are certified as much as possible. This allows for adventitious contamination typically up to 1% from contamination in processing or storage.

GMO Free Claim

A proactive claim made by a manufacturer of a food product that represents all ingredients contained in the product are certified to be sourced from traditionally bred crops. Thresholds allowing for adventitious contamination are usually very stringent, typically <0.1%.

Moon OU Glycerin is solely sourced from vegetable oils. These sources can include oil from GMO oilseeds. GMO genetic materials are not expected to be present in the refined glycerin made from the highly refined oils.

Irradiation

P&G Glycerin has not been irradiated at any point during the production process.

Animal Testing

P&G Glycerin has GRAS status under FDA 21 CFR 182.1320 and consequently PGC does not perform any glycerin safety testing that involves animals. This has been the practice since 1969.

BSE/TSE

Bovine Spongiform Encephalopathy (BSE) and Transmissible Spongiform Encephalopathy (TSE) are not a concern with 100% vegetable based glycerin.

Microbial Growth

P&G Chemicals offers high purity line of Glycerin, namely Superol, Star and Moon. Our manufacturing process contains a distillation step (reaching temperatures of 300 - 345°F) which is self-sterilizing, destroying potential microbes. Moreover, glycerin contains low available moisture and as a concentrated solution, has the inherent environment that cannot accommodate the growth of microorganisms, which have been fully evaluated by P&G Chemicals. P&G Chemicals glycerin made according to IPEC-PQG GMP Guide for Pharmaceutical Excipients is compliant with EU Directive 2005/2073 for Micro-Purity1.

For more detailed description of glycerin's antimicrobial activity, please refer:

Mariani, E.J.; Libbey, C.J.; and Litsky,W."Antimicrobial Activity of Commercial Grade Glycerin." Developments in Industry Microbiology Vol. 14, Chapter 44, pp.356-360. American Institute of Biological Sciences, Washington D.C. 1973.

For the above reasons, we would not expect glycerin at these high concentrations to support the growth of microorganisms and thus consider microbial testing to be unnecessary.

Allergens

While the products above are derived from tropical oils (palm, palm kernel and/or coconut oils), vegetable oils, and/or animal derived feedstocks which may themselves be of allergenic concern, the products are highly processed, distilled and purified. Any protein residue in the crude oils is removed by this processing, thus removing the allergens.

No potential allergens identified in the US, Canada, or Mexico are present in the above brands of glycerin. These include milk, egg, fish, crustacean, shellfish, tree nuts, peanuts, wheat, sulfites, sesame seeds, aspartame, gluten source, monosodium glutamate, soybean and mustard seeds.

Additives and Preservatives

MOON OU is processed and refined in a closed system and is not expected to contain or to have come in contact with any of the following:

Asbestos
Artificial Color
Autolyzed Yeast Extract (AYE)
Cyanuric Acid
Heavy Metals
Hydrolyzed Vegetable Protein (HVP)
Iodine
Lodine
Melamine
Mustard
Preservatives/Additives
Polychlorinated Biphenyls (PCB's)
Povidone
Sesame Seeds
Sewage Sludge

Organic Status

According to regulatory standards, glycerin products manufactured and supplied by P&G Chemicals are manufactured entirely from naturally occurring substances such as vegetable oils or animal tallow, but they cannot be considered organic. Under the USDA's National Organic Program regulations, only glycerin produced strictly by hydrolysis of fats and oils can be used as an ingredient in products labeled as "organic" or "made with organic". This information can be found in 7 CFR 205.605. None of PGC's glycerin brands can currently be certified organic.

Residual Solvents

This is to confirm that our Glycerin products above are sold fully meeting all provision for Glycerin USP* included in the current USP* and its supplements.

Residual solvents are not used or produced in the manufacture of our Glycerin USP*.

Our Glycerin USP* products (for excipient use only) do not contain residual solvents of class 1, 2 or 3 that would meet the criteria for those classifications described in section <467> of the USP or section 5.4. Residual Solvents of the current European Pharmacopoeia. Additionally, no other solvents (non-ICH) are used in the finished product.

Based on our manufacturing process and handling/storage, we would not expect these solvents to be present in the refined glycerin.

Nonetheless, we have extensively evaluated our in-process and finished product and found no detectable levels of residual solvents. This will be reflected in all our Certificate of Analyses to demonstrate conformance with the latest specifications.

*For excipient use only

USP/FCC

P&G's USP*-labeled glycerin (for excipient use only) products fully meet the provisions for "Glycerin" as defined in the current USP Monograph and Food Chemical Codex (FCC). Analytical tests are performed according to the methods described in the current USP/NF. Where applicable, equivalent validated procedures may be used, in accordance with

USP/NF General Notices, Test and Assays. All P&G product specifications limits meet or exceed the compendia outlined in the USP* Glycerin.

*For excipient use only

Systemic Toxicity Information

Glycerin occurs naturally in animals and vegetables, in combined form as glycerol in fats, oils, and lipids. Glycerol is widely distributed in food as a natural constituent, and it has undergone review and approval for use as both a direct and indirect food additive and is generally recognized as safe (GRAS). It is also used extensively in cosmetics, toiletries, and pharmaceutical products.[1]

Since glycerol is commonly present in foods, drugs, and consumer products such as drinks and toothpaste, oral exposure to glycerol occurs in all people. Glycerol is readily absorbed from the gastro-intestinal tract and completely metabolized via standard pathways in the body. In 1976, a joint FAO/WHO Expert Committee on Food Additives (JEFCA) placed glycerol in the category "Acceptable Daily Intake (ADI) not specified" which means that on the basis of available data, the total daily intake expected to arise from foods and other consumer uses does not represent a hazard to health.[2] In 2002, JECFA estimated that the total daily per capita intake of glycerol was up to approximately 2800 mg and confirmed that its use as a flavoring agent is not expected to be of safety concern.[3]

Animal studies involving single or repeated exposure to glycerol by various routes indicate that glycerol has a low order of toxicity. The acute oral LD50 value (a measure of lethality) in several animal species has been determined to be as follows:

Rat 12.6-28.8 g/kg bw

Mouse 15-38 g/kg bw

Guinea pig 7.75-11.5 g/kg bw

Rabbit 17.6-27.0 g/kg bw

*Note the values reflect the range found in published studies.[4]

As with other animals, glycerol appears to be of generally low oral toxicity in humans. In a number of limited studies conducted on a total of about 30 human subjects receiving

doses in the rage 100-1500 mg/kg bw, the only overt signs of toxicity reported were headache, nausea, and diuresis at doses of more than 700 mg/kg bw. A complete toxicity profile of Glycerol can be obtained from the sources referenced below.

References
1) OECD SIDS Report for Glycerol, CAS No. 56-81-5. UNEP Publications, SIDS Initial Assessment Report for SIAM 14, March 2002.
2) Evaluation of Certain Food Additives, 20th Report of the Joint FAO/WHO Expert Committee on Food Additives. WHO Technical Report Series No. 599, FAO Food and Nutrition Series No. 1. WHO Geneva 1976.
3) Evaluation of Certain Food Additives, 57th Report of the Joint FAO/WHO Expert Committee on Food Additives. WHO Technical Report Series No. 909. WHO Geneva 2002.
4) Toxicity Profile for Glycerol (1993). BIBRA Information Services Ltd.

Diethylene Glycol and Related Compounds

P&G USP* Glycerin (for excipient use only) complies with all USP compendia requirements, including limit test for diethylene glycol and related compounds.

The *diethylene glycol and related compounds* limit test is performed on all lots of USP Glycerin supplied by P&G Chemicals. Additionally, Identification tests A and B are performed on all lots as part of the USP* testing and reported on the Certificate of Analysis.

Diethylene glycol (DEG) and related compounds are neither degradation products nor process related impurities in P&G Chemicals USP* glycerin. DEG is not used in the manufacture of P&G glycerin, it is not expected to be present in any of the constituent raw materials, nor is P&G glycerin exposed to diethylene glycol during the drumming, storage, or transport procedures. P&G Chemicals utilizes a positive release process for all glycerin shipped directly to customers or to distributors that includes a Gas Chromatography (GC) test method for detecting DEG and related compounds. This process ensures all glycerin is shipped in compliance with all applicable USP* standards.

For more information please consult the Guidance for Industry on Testing of Glycerin for Diethylene Glycol which is available at the Food and Drug Administration (FDA) website.

*For excipient use only

Kosher Status

OU- Orthodox Union- Kosher Certified. See appendix B

Shelf Life

In a controlled study, Procter & Gamble stored glycerin in sealed containers in a controlled environment at 73±3°F (22.8±1.7°C) for 24 months. The glycerin was analyzed periodically throughout and at the end of the storage study. All intermediate and final samples maintained adherence to USP limits and odor/flavor requirements.

This validated P&G's prior experience, which was that glycerin is stable under normal storage conditions (ambient temperature) for at least two years. It is recommended to retest glycerin after a two year aging period to confirm fitness for use. No specific data has been collected for the shelf-life of opened containers of glycerin; it is hygroscopic and it can be expected that moisture content would increase upon extended exposure to air.

A normal recommended long-term storage temperature for glycerin is ambient conditions. To avoid possible color degradation, the optimal storage conditions would be as near to 73°F (22.8°C) as possible.

Storage and Handling Guidelines

Storage Temp Target	Ambient not to exceed 125°F (52°C)
Storage Temp Max	125°F (52°C)
Handling Temp	95 – 125°F (35 - 52°C)
Viscosity at handling Temps	130 – 230 cps
Sensitive property change in storage	Odor, Moisture, Color, FA7E, RCS
Max Steam, psig	For long term tank storage – hot water or glycerine/ water mix preferred. 10 psi steam is allowed. For Railcar heating – low pressure 30 psig preferred
Load Out Filter	5 Micron

Rail Car or Truck	Lithcote, stainless, aluminum or food grade lining
Agitation/Recirculation	Yes
Storage Tank	Stainless Steel, lined with Ceilcote 252, or Plasite 9570
Pumps and Lines	Stainless Steel, lined with Ceilcote 252, or Plasite 9570

Pest Control

Services are provided by Terminix every week and is owned by the area glycerin operator

Instrument Calibration Program

All instruments are tested against standards no less than once per year. Calibrations are owned by the PM team. Calibration testing equipment is sent out yearly for calibration by a certified facility. All calibrations are performed according to specific SOP's and records are kept on file.

Lot (Batch) Determination

The glycerin system is a semi-continuous system that allows for lot determination by starting with the blend tank which is analyzed, approved, and processed by specific formula cards. Each final material storage take is filled and material lots are assigned according to the material and tank. All lots are fully traceable back to raw materials, equipment, storage take, and process date.

Average batch size is 1.7M pounds.

Traceability

Retain samples are collected from every finished product shipment and stored for a minimum of three years. Each retain is given a unique identification number, (lot number). The lot number allows traceability of the product back to the incoming raw materials according to written procedures. Examples of the two types of Lot Numbers are below.

Example:

PN77775037, SO00335161 or HT-0805-5136

A	B	C
PN	7777	5037

Column A First two digits. PN stands for Peter Cremer, SO = Southside and HT = Hudson Tank.

Column B Next four digits. Vessel material is shipped from.

Column C Last four digits. Lot generation date (5=2005, 037=37th day of the year).

Example:

(Kosher) KGDCR05-306-2

(Kosher Not for Passover) PGDCR07-100-1

(Vegetable) VGDCR05-210-3

(Non-Kosher) GDCR04-137-1

A	B	C	D	E
KG	DCR	05	306	2

Column A KG=Kosher, PG = Kosher Not for Passover, VG=Vegetable, G=Non Kosher.

Column B DCR=Superol, Moon (99.7%) DCS=Star (96%)

Column C Year product was manufactured (05 = 2005)

Column D Batch number (306 = 306th produced since January 1).

Column E Shipment number from the batch (2 = 2nd shipment from the batch).

IMPORTANT NOTE Stringent quality procedures are use to approve the glycerin and each manufacturing facility is audited by P&G's qualified auditing staff. The glycerin is transported to P&G storage facilities accompanied with a Certificate of Analysis and Kosher Certificate if applicable. Upon receipt of the glycerin it is loaded into tanks and analyzed for full formula card specifications. When the analysis is complete and the material passes, a lot number is generated. Once material is added to this lot, the new lot must be analyzed for full formula card specification and a new lot number is assigned. Every month following the lot generation date key product analysis are performed and after three months all of the analysis are completed and a new CoA is generated for the material. It is recommended that stored glycerin be tested every 6 month to 1 year from the CoA date.

Proposition 65

In response to concerns regarding compliance of our products with California's Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65), please be advised of the following:

P&G has evaluated our glycerin brands for components appearing on the current Proposition 65 chemicals list. None of the listed substances are components of neither our finished products nor would they be expected to be present in the manufacturing processes or the raw materials used in manufacturing our products. For more information and a current list of Proposition 65 chemicals, please visit:
http://www.oehha.ca.gov/prop65/prop65_list/Newlist.html

Specifications for Moon OU Glycerin

Glycerol % (Bosart & Snoddy table)	99.7 min (99.9)
Specific Gravity (25°C)	1.2613 min (1.2618)
Assay (% glycerin on anhydrous basis)	99.0 – 101.0

Moisture %	0.3 max
Color APHA (PT-Co Hazen Scale)	10 Max
Residue on ignition, % / ppm	0.007 / 70 max
Chlorides, % / ppm (as Chlorine)	0.001 / 10 max
Sulfates, % / ppm	0.002 / 20 max
Heavy Metals (as Pb), % / ppm	0.0001 / 1 max
Chlorinated Compounds (as Cl), % / ppm	0.003 / 30 max
Fatty Acids & Esters	NMT 0.3 ml (0.13)
Identification by IR	Passes Test as Glycerin
Identification by GC	Passes test as Glycerin
Diethylene Glycol (DEG) & Related Compounds, %	NMT 0.10% each DEG & EG NMT0.1% individual impurity & NMT 1.0% total impurities
Readily Carbonizable Substances Test	Passes current FCC
Residual Solvents	Compliant

Product Release Procedure

Each finished product tank is sampled and analyzed as prescribed by Formula Cards and Manufacturing Standards. Formula Cards are specific to each product and outline the necessary tests that must be conducted. Test methods detail how to perform each test listed on a Formula Card. Analytical results are stored in Quality Windows and also entered into a computerized Certificate of Analysis program that will be used to print the Certificate of Analysis when the glycerin is shipped.

A standard generic CoA has been attached at the end of this packet. (See Attachment A)

Sampling, Testing, and Storage of Incoming Raw Materials

Crude glycerin – raw material - is received in dedicated railcars, inspected, and sampled upon receipt. Sampling is designed and conducted in am manner that prevents contamination. Storage of material follows guidelines to insure no adverse effects on quality and prevents cross contamination. Material is controlled and a FIFO (First–In-First-Out) system.

Documentation and Records

SOP's

- All SOP are periodically reviewed and updated
- All SOP's are given expiration dates and a revision number
- Quality Unit, site leadership, and product development share responsibility to approve all SOP's

Records

- Production, Control, and distribution records maintained for at least one year from expiry date of the batch
- Include listing of all raw materials and equipment being used
- Retains are maintained for three years after batch distribution
- Include production instructions including sequences, ranges, parameters, sampling instructions, in-process controls, and actual yields
- Specifications are established and documented for raw materials, intermediates
- QA Quality Unit, site leadership, and product development share responsibility to approve all records

Computer System/Process Control

The refining and transfer processes are monitored and controlled by trained Operators via the Honeywell Experion (a continuous process control computer). Process is validated and run according to:

- daily operation schedules
- manufacturing standards
- SOP's
- computer processed data systems
- documented control parameters

Maintenance

AM - Autonomous Maintenance - AM is a system designed to detect and eliminate small problems in operating equipment before they escalate into major breakdown events. AM progress and AM task completion is monitored weekly by all members of the business.

This is basically accomplished by doing 4 things:

- Eliminate equipment defects
- Eliminate sources of contamination that accelerate equipment wear
- Eliminate hard-to-reach areas on the equipment that make it more difficult to clean
- Inspect, and maintain

PM - Progressive Maintenance - PM is a system designed around time-based maintenance, predictive maintenance, breakdown elimination/failure analysis, and AM team Training. Deliver. This system is oriented towards 3 goals:

- Extend equipment service life
- Maximize the reliability of the equipment when it's running
- Perform cost-effective maintenance

Cleaning Procedures

Equipment is cleaned according to documented procedures when needed with hot water.

Laboratory

The Quality Assurance lab is independent of the daily operations (see Organization Chart above). The lab is operated by Peter Cremer North America (PCNA). The PCNA lab is responsible for analyzing samples including raw materials (crudes) and final product prior to release. In-process samples are tested internally. All data is maintained in Quality Window software. Hard copy data and retains are kept for three years. The Quality Window data is backlogged in laboratory notebooks.

Equipment

All laboratory equipment is qualified via an IQ/OQ (Installation & Operational Qualification) process. Any new or existing equipment goes through this process. It then is maintained through a daily, weekly or monthly calibration. All laboratory equipment is maintained according to the manufacturing specifications. Only trained and qualified analysts conduct repair and maintenance of equipment. Logbooks are maintained for each piece of equipment detailing all maintenance, repairs and replacements, calibration dates and results and responsible people.

Analytical Methods

All methods and procedures originate with the Product Development (R&D) organization, and are transferred to the plant. The methods go through a formal verification to establish documented evidence that consistent results are obtainable. For the method to be acceptable, the standard deviation of the results must match that supplied with the Product Development validation data. Current, approved copies of all applicable analytical methods and procedures are available in the lab. Master copies of all methods are maintained by Product Development and modified as necessary. Superseded methods are archived.

Raw Material Suppliers

Acceptable suppliers for each raw material are audited and reviewed by the Product Development Group and kept on a specific list of qualified and approved suppliers. The system does not allow material to be accepted from unapproved suppliers or unapproved materials. The Central Chemicals Group owns and maintains the Approved Supplier List.

Training

Onboarding Classes/Manuals

New-hires attend an onboarding class their first day that is led by their department training coordinator. They are instructed on:

- accessing computer based SOPs
- location of the SOPs
- the training manuals,
- qualification guidelines
- specific expectations for their department
- the activity sheet listing items on which they are expected to be qualified by specific weeks.

Skill Matrix

Individual performance is tracked on a skill matrix that references proficiency on specific skills to each person. On each matrix includes:

- base/general skills
- business specific unit operations
- business specific common skills
- functional expertise
- advanced leadership

Step-Up Cards

Step-up cards are tools for individual assessment. Cards are reviewed with their training coordinator. The coordinator asks questions and evaluates the individual. Each step up card receives a second and sometimes third evaluation until the individual has completed qualification on that card.

Ongoing Training

The training coordinator is responsible for seeing that training manuals get updated as changes or additions take place in the operation, and that people get qualified on these changes. Skills that require regular refresher classes, such as hot work and confined space entry permit signers, are listed on the skill matrix with the refresher due date displayed.

Complaints, Returns, and Investigations

All customer complaints and returns are handled through the SCDR – Supply Chain Defect Report system. These incidents are registered and tracked for resolution. Corrective actions as well as timeframes for responding are assigned and monitored from the SCDR system. Records of all complaints, returns, and investigations are filed and kept for future use and corrective actions effectiveness.

Significant Changes

P&G Chemicals has a process to evaluate any changes made to the manufacturing site, scale, equipment, manufacturing process, starting material, packaging or product specification of any of PGC's finished products to determine whether the change is considered significant. 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.

For additional information, statements, MSDS's, samples, or requests please visit
www.pgchemicals.com

Readily Carbonizable Substances	95119738		PASS

Signature	**Name**
Date	**Position**
Manufacturing Location: 5201 Spring Grove Avenue, Cincinnati Ohio 45217	

This analysis is not to be construed as a warranty. Customer is responsible to verify the lot and code numbers of product received with the numbers contained on this report and perform any other analyses necessary to determine suitability of the product described above for the use intended by the customer. No representations as to FDA regulated use are made for this product unless it is designated as meeting either USP, NF, Cosmetic grade or Food Grade Status. The foregoing statements are valid up to, but not beyond, delivery to our primary customer. Any subsequent handling, repackaging, storage, processing, etc. render these claims void and unsubstantiated by Procter & Gamble Chemicals.

Certifications and Compliance Statements Section

Residual Solvents:

Procter & Gamble's USP/FCC Glycerin products are for excipient use only and 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. Residual Solvents are not used or produced in the manufacture of our Glycerin USP products, and we do not expect these solvents to be present in the refined glycerin. We have evaluated our in-process and finished product and found no detectable levels of residual solvents.

GMP/IPEC:

Procter & Gamble's USP/FCC glycerin brands are for excipient use only and manufactured in accordance with IPEC Good Manufacturing Practices Guide for Bulk Pharmaceutical Excipients and FCC GMP's for food chemicals.

BSE/TSE (Bovine Spongiform Encephalopathy and Transmissible Spongiform Encephalopathy) Statement:

BSE/TSE are not applicable for this product as it is derived from plant oils only.

Shelf Life of Glycerin

In a controlled study, Procter & Gamble stored glycerin in sealed containers in a controlled environment at 25º C for 24 months. The glycerin was analyzed periodically and at the end of the storage study. All intermediate and final samples maintained adherence to USP limits and odor/flavor requirements. This validated P&G's prior experience, which was that glycerin is stable under normal storage conditions (ambient temperature 25° C) for at least two years. No specific data has been collected for the shelf-life of opened containers of glycerin; it is hygroscopic and it can be expected that moisture content would increase upon extended exposure to air. A normal recommended storage temperature is ambient, not to exceed 125 °F (approximately 52 °C). To avoid possible color degradation, the optimal storage conditions would be as near to 25° C as possible. The optimal temperature for pumping 96-100% glycerin is 100-125 °F (approximately 38 -52°C).

Appendix A: Moon OU C of A Template

P&G Chemicals

11530 Reed Hartman Hwy.; Cincinnati, OH 45241 USA
Questions? Call Customer Service: 800-477-8899 or 513-626-6882

MOON-OU USP/FCC

CERTIFICATE of ANALYSIS

(Customer or Consignee)	**P&G Invoice No.**
(Dept., if applicable)	**Customer P.O. No.**
(Attention)	**Customer Code**
(Delivery Address)	**Vessel No.** **(Method TC • , TT • , Ship • , Iso •)**
(City, State, Zip)	**P&G Lot No.**
(Approximate weight Lb. ☐ KG ☐ MT ☐	**Shipment Date**
GCAS No. (s): 99961024	**Seals**
P&G Material Code: 10275531	**Country of Origin** **USA**
Manufacture Date:	

Test	GCAS #	Result	Specification Limits
Identification A by IR: Glycerin	60065177		PASS – as glycerin
Identification B by GC: Limit of DEG & EG	98955124		PASS: USL. 0.10% each of DEG and EG
Identification C by GC: Glycerin	98955124		PASS – as glycerin
Residual Solvents	USP 467	Compliant	Meet Requirement
Specific Gravity	64012970		LSL: 1.2613 @ 25ºC/25ºC
Color (APHA)	60064681		USL: 10
Residue on Ignition, %	60064682		USL: 0.007%
Chlorides	60065128		PASS: USL: 10 ppm
Odor	60065271		PASS
Sulfate	60065131		PASS: USL: 20 ppm
Heavy Metals	60065174		PASS: USL: 1 ppm
Chlorinated Compounds	60065420		PASS: USL: 0.003% or 30 ppm of C1
% Glycerin (calc. from Specific Gravity)	64012970		LSL: 99.7%
Fatty Acids and Esters (USP)	60065134		USL: 0.3 mL of 0.5N NaOH
Fatty Acids and Esters (FCC)	60065134		LSL: 4 mL of 0.5N HCl
Assay anhydrous, % (USP)	60065183		LSL: 99.0%; USL: 101.0%
Assay, % (FCC)	60065183		LSL: 99.0% ; USL 101.0%
Water	60065135		USL: 0.3%
Related Compounds	95076103		PASS: (USL 0.1% individual impurity; USL 1.0% for total impurities)
Flavor	60065270		PASS
Appearance	60044625		PASS: (Clear colorless viscous liquid, free of foreign material)

Readily Carbonizable Substances	95119738		PASS

Signature	**Name**
Date	**Position**
Manufacturing Location: 5201 Spring Grove Avenue, Cincinnati Ohio 45217	

This analysis is not to be construed as a warranty. Customer is responsible to verify the lot and code numbers of product received with the numbers contained on this report and perform any other analyses necessary to determine suitability of the product described above for the use intended by the customer. No representations as to FDA regulated use are made for this product unless it is designated as meeting either USP, NF, Cosmetic grade or Food Grade Status. The foregoing statements are valid up to, but not beyond, delivery to our primary customer. Any subsequent handling, repackaging, storage, processing, etc. render these claims void and unsubstantiated by Procter & Gamble Chemicals.

Certifications and Compliance Statements Section

Residual Solvents:

Procter & Gamble's USP/FCC Glycerin products are for excipient use only and 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. Residual Solvents are not used or produced in the manufacture of our Glycerin USP products, and we do not expect these solvents to be present in the refined glycerin. We have evaluated our in-process and finished product and found no detectable levels of residual solvents.

GMP/IPEC:

Procter & Gamble's USP/FCC glycerin brands are for excipient use only and manufactured in accordance with IPEC Good Manufacturing Practices Guide for Bulk Pharmaceutical Excipients and FCC GMP's for food chemicals.

BSE/TSE (Bovine Spongiform Encephalopathy and Transmissible Spongiform Encephalopathy) Statement:

BSE/TSE are not applicable for this product as it is derived from plant oils only.

Shelf Life of Glycerin

In a controlled study, Procter & Gamble stored glycerin in sealed containers in a controlled environment at 25º C for 24 months. The glycerin was analyzed periodically and at the end of the storage study. All intermediate and final samples maintained adherence to USP limits and odor/flavor requirements. This validated P&G's prior experience, which was that glycerin is stable under normal storage conditions (ambient temperature 25° C) for at least two years. No specific data has been collected for the shelf-life of opened containers of glycerin; it is hygroscopic and it can be expected that moisture content would increase upon extended exposure to air. A normal recommended storage temperature is ambient, not to exceed 125 °F (approximately 52 °C). To avoid possible color degradation, the optimal storage conditions would be as near to 25° C as possible. The optimal temperature for pumping 96-100% glycerin is 100-125 °F (approximately 38 -52°C).

Appendix C: Equivalency Statements

MOON OU & SUPEROL KNP Equivalency

P&G's Product Moon OU Glycerin USP*, FCC is equivalent to Superol KNP, USP*, FCC. The name present on the MSDS is MOON OU Glycerin USP*, FCC.

MOON OU is manufactured using the same raw material supply and manufacturing process as Superol KNP. As a result, the stability profile of MOON OU is the same as Superol KNP.

*For excipient use only

MOON OU, SUPEROL KNP, and SUPEROL VEG

The above brands of glycerin produced by P&G Chemicals are derived from the same vegetable oil feedstocks. MOON OU and SUPEROL KNP are derived exclusively from Kosher vegetable oils. SUPEROL VEG may be derived from non-Kosher and/or Kosher vegetable oils.

These brands of P&G Chemicals glycerin are refined in the same plant through the same process.

Animal Statement

This statement is to certify that **all P&G Chemicals product brands** are manufactured from raw materials **not of animal origin**. Our product brands does not come into contact with any animal parts or by products during the manufacturing process.

All P&G Chemicals products are produced solely from vegetable raw materials, derived from vegetable oil feedstock (palm, palm kernel and/or coconut oils). No material used in the manufacture of our products is of any animal origin (either whole or part).

In addition, the equipment used to manufacture our products are not used to produce any products of animal origin. Also, our products do not contain any additives.

If you have any questions, please call 800-477-8899.

Pablo Uranga
Customer Development Manager
P&G Chemicals
May 15, 2015

Elemental Impurities

What is Changing?

United States Pharmacopeia (USP) has officially published the new General Chapter's <232> *Elemental Impurities - Limits* and <233> *Elemental Impurities - Procedures* which will be implemented on **January 1, 2018**. Compliance to the limits in <232> are applicable to drug products currently in the USP-NF compendia . However, elemental impurity levels present in drug substances and excipients need to be known and reported as part of the risk-based control strategy to assure compliance of drug products with these standards. .

What is P&G doing?

In anticipation of these changes, P&G Chemicals has conducted elemental impurities testing on our USP Glycerin and National Formulary (NF) Cetyl and Stearyl Alcohol brandsand found no detectable levels of each elemental impurity at 0.02 ppm (20 ppb).

Although the USP General Chapter <232> will be implemented for drug products and replace the current General Chapter <231> Heavy Metals on January 1, 2018, **P&G Chemicals is prepared for this new approach to be utilized by the industry now.**

What has P&G completed?

We have completed our product evaluation well ahead of the January 2018 implementation date, providing our customers with critical data for input to their drug products and end formulations to meet the USP requirements.

- Our customers may file Drug Master Files for their products..
- P&G's input for Elemental Impurities allows them plenty of time to meet all their requirements.
- The low levels of elemental impurities in PGC`s excipient products provides our pharmaceutical customers additional formulation flexibility for their drug products

Our P&G Elemental Group has used ICP-MS/MS technology to provide the lowest detection levels possible, allowing us to report at the "less than ppb" levels vs the USP default levels of "less than ppm" limits.

P&G Chemicals
Delivering solutions, creating value

SUPEROL KPO® GLYCERIN, USP*/FCC/EP*
SUPEROL NK® GLYCERIN, USP*/FCC
STAR KPO® GLYCERIN
STAR NK® GLYCERIN
MOON OU® GLYCERIN, USP*/FCC

**Excipient Use Only*

Diethylene Glycol and Ethylene Glycol

P&G USP Glycerin complies with all USP compendia requirements, including Identification B: limit test for diethylene glycol and ethylene glycol.

The Identification B limit test is performed on all lots of USP Glycerin supplied by P&G Chemicals. Additionally, Identification tests A and C are performed on all lots as part of the USP testing and reported on the Certificate of Analysis.

Diethylene glycol (DEG) and ethylene glycol are neither degradation products nor process related impurities in P&G Chemicals USP glycerin. DEG or EG is not used in the manufacture of P&G glycerin, it is not expected to be present in any of the constituent raw materials, nor is P&G glycerin exposed to diethylene glycol during the drumming, storage, or transport procedures.

For more information please consult the Guidance for Industry on Testing of Glycerin for Diethylene Glycol which is available at the Food and Drug Administration (FDA) website.

Pablo Uranga

02/03/2016

Excipient Information Package for P&G Chemicals Moon OU Kosher Glycerin

I. Product Regulatory Datasheet

Section 1 – General Product Information

Product Name: Moon OU Kosher Glycerin, USP/FCC (for excipient use only)
SDS #: GLYC345
Product Code: 99961024, 96478499
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: 100% vegetable oils, predominantly US grown soybeans
Synonyms: Glycerol
Morphological form: Clear liquid with a slightly sweet taste
Brief description of manufacture:
Moon OU Kosher Glycerin is derived from vegetable sources, predominantly US grown soybean. Crude oil is extracted or extruded from seeds or fruits of vegetables, followed by a degumming process to remove phosphatides and slimes water mixed with oil. After that, the oil goes through a refining, bleaching, 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).

Section 4 – Regulatory Information

Compendial Compliance and Other Regulatory Status:
USP-NF, FCC, 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, GFSI BRC certified.

Drug Master File (DMF):
Moon OU Kosher Glycerin is for excipient use only and DMF management is not applied.

BSE/TSE Information:
Moon OU Kosher Glycerin is derived from vegetable oils only, therefore, BSE/TSE concerns do not apply.

Allergens/Hypersensitivities Information:
P&G Chemicals Moon OU Kosher Glycerin does not contain allergens identified in the US, Canada, Mexico, or EU regulations. These include milk, egg, fish, crustacean, shellfish, tree nuts, peanuts, wheat, sulfites, sesame seeds, aspartame, gluten source, monosodium glutamate, soybean, mustard seeds, celery, lupin, mollusks, and other allergen sources listed in EU regulation.
Other allergens that are not present include: lactose, hydrolyzed proteins, modified starch, semolina, testacea, corn, rye, barley, rice, oat triticum, spelt, kamut products, yeast, cotton seed, poppy seed, FD&C artificial colors, carmine.
No allergen is used during manufacturing, handling, or storage of Moon OU Kosher glycerin.

GMO Information:
Moon OU Kosher Glycerin is solely sourced from vegetable oils. These sources can include oil from GMO oilseeds. GMO genetic materials are not present in the refined glycerin made from the highly refined oils, as confirmed by GMO testing, i.e. qualitative DNA analysis with PCR.

Residual Solvents Information:
P&G Chemicals Moon OU 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. Residual Solvents are not used or produced in the manufacture of Moon OU Kosher Glycerin, and we do not expect these solvents to be present in the refined glycerin. We have extensively evaluated our in-process and finished product and found no detectable levels of residual solvents.

Metal Catalyst and Metal Reagent Residues:
P&G Chemicals Moon OU 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).

Elemental Impurities:
P&G Chemicals' pharmaceutical excipient products, including Moon OU Kosher Glycerin do not contain elemental impurities listed in USP General Chapter <232> Elemental Impurities, at levels exceeding 0.02 ppm, well below default concentration limits for drug substances and excipients listed in Table 2. USP General Chapter <232> will be implemented for drug products and replace the current General Chapter <231> Heavy Metals on January 1st, 2018. P&G

Chemicals has tested these excipient products and found no detectable levels of each elemental impurity at 0.02 ppm (20 ppb).

Kosher Status:
Moon OU Kosher Glycerin product manufactured, stored, and distributed by The Procter & Gamble Company, Cincinnati Chemicals Plant is Kosher Not Passover certified with Rabbi's signature under the supervision of the Orthodox Union (OU).

Irradiation Treatment:
Moon OU Kosher Glycerin is not irradiated.

Phthalate, Glycol Ether, Nanoparticles, Aflatoxin, and Silicones Statement:
Moon OU Kosher Glycerin does not contain the following: Phthalates, Glycol Ethers, Nanoparticles, Aflatoxins, and Silicones.

Proposition 65:
P&G Chemicals certifies that Moon OU Kosher Glycerin is compliant with California's Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65). Moon OU Kosher Glycerin has been evaluated and this product, as supplied to you, does not require a Proposition 65 warning. 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.

Preservatives:
P&G Chemicals Moon OU Kosher Glycerin is processed and refined in a closed system and is not expected to contain or to have come in contact with any preservatives/additives.

Antioxidants:
P&G Chemicals Moon OU Kosher Glycerin is processed and refined in a closed system and are not expected to contain or to have come in contact with any antioxidants such as Butylated Hydroxytoluene (BHT), Butylated Hydroxyanisole (BHA), and *tert*-Butylhydroquinone (TBHQ).

Latex:
P&G Chemicals Moon OU Kosher Glycerin is processed and refined in a closed system and is not expected to contain or to have come in contact with latex.

Organic Certification:
Based on Moon OU Kosher Glycerin current manufacturing process, crude glycerine is formed in the methanolysis reaction of triglyceride in RBD oil with synthetic methanol, instead of hydrolysis with water. Furthermore, as a result of recent action by the National Organic Standards Board, USDA National Organic Program has removed glycerin produced by hydrolysis of fats and oils as a "synthetics allowed" nonagricultural substance labeled as organic specified ingredient. Moon OU Kosher Glycerin cannot be certified organic.

Mercury (Hg), Cadmium (Cd), Hexavalent Chromium (Cr VI), Polybrominated Biphenyls (PBB), and Polybrominated Diphenyl Ethers (PBDE) in electrical and electronic equipment.

Micro Statement:
P&G Chemicals certifies that Moon OU 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 PGC glycerin manufacturing process includes a distillation step with high temperature to destroy potential microbes and low available moisture in a concentrated glycerin solution offers the inherent environment that cannot accommodate the growth of microorganisms, which have been fully evaluated by PGC. PGC glycerin is made according to IPEC-PQG GMP Guide for Pharmaceutical Excipients and is compliant with EU Directive 2005/2073 for Micro-Purity.

Natural Statement:
P&G Chemicals Moon OU Kosher Glycerin is derived from vegetable sources. Crude oil is extracted or extruded from seeds or fruits of vegetables, then goes through a refining, bleaching, deodorizing (RBD) process, then undergoes an esterification reaction to form crude glycerine and methyl esters, followed by further refining to produce refined glycerin in a series of purification steps (concentration, distillation, condensation, and carbon bleaching). Moon OU Kosher Glycerin is not supported to be labeled "Natural" based on the current manufacturing process. It is recommended to position PGC's Moon OU Kosher Glycerin where applicable as: 1) derived from natural sources; 2) obtained from natural sources; 3) derived from vegetable oils; 4) vegetable glycerin; and 5) obtained from plant sources.

Conflict Minerals Statement:
P&G has determined that Moon OU Kosher Glycerin sold by P&G Chemicals does not contain tin, tantalum, tungsten, or gold which are considered "Conflict Minerals".

Partially Hydrogenated Oils or Trans Fats Statement:
Based on US FDA final notice on June 17th, 2015, partially hydrogenated oils (PHOs) are no longer considered Generally Recognized as Safe (GRAS) because PHOs are the primary source of industrially produced trans fatty acids which have been evaluated to increase risks of human health for consumers. Moon OU Kosher Glycerin does not contain any Trans Fats or Partially Hydrogenated Oils and our refined glycerin manufacturing process does not include any hydrogenation or partial hydrogenation process.

Agricultural Chemical Residues:
Moon OU Kosher Glycerin does not contain any agricultural chemical residues from pesticides, feed additives, or veterinary drugs.

Multiple High Risk Ingredients Statement:
P&G Chemicals Moon OU Kosher Glycerin does not contain any following high risk ingredients in final products or during the manufacturing and distribution processes: alfalfa, papaya, sugar beets, zucchini & yellow summer squash, honey, amino acids, ascorbic acid, sodium ascorbate, citric acid, sodium citrate, flavoring (natural and/or artificial), high-fructose

corn syrup, hydrolyzed or textured vegetable protein, lactic acid, maltodextrins, molasses, sucrose, xanthan gum, or vitamins.

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

Section 5 – Miscellaneous Product Information

Lot Derivation:
Retain samples are collected from every finished product shipment and stored for a minimum of three years. Each retain is given a unique identification number, lot 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 (i.e. color) and to prevent finished product from freezing which could possibly damage equipment and/or indirectly affect product quality. 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 evaluate any changes made to the manufacturing site, scale, equipment, manufacturing process, starting material, packaging or product specification of any of P&G Chemicals finished products to determine whether the change is considered significant. This process is consistent and meets 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.

Nutritional Information:
According to FDA's Office of Food Labeling, glycerin is labeled as carbohydrate and, 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
Minerals	0
Vitamins	0
Preservatives	0
Additives	0

Glycerin is metabolized as a carbohydrate.

Section 6 – Revisions

This is the 3rd version of Excipient Information Package for P&G Chemicals Moon OU Kosher Glycerin based on The International Pharmaceutical Excipients Council Excipient Information Package User Guide 2013. It is revised on October 1, 2015.

Section 7 – Contact Information

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

Peng He
Regulatory Manager of P&G Chemicals Glycerin Global Business
The Procter & Gamble Company, Sharon Woods Innovation Center
11530 Reed Hartman Highway, Cincinnati, OH 45241, USA
Phone: (513) 627-7996; Email: he.p.3@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 via paper copy. These records are 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 and EP 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, 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 weekly 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 and EP 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 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 on 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.
- 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 – Revisions

This is the 1st version of Quality Section of Excipient Information Package for P&G Chemicals Moon OU Kosher Glycerin based on The International Pharmaceutical Excipients Council Excipient Information Package User Guide 2013. It is generated on September 17, 2015.

Section 6 – Contact Information

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

Christopher del Campo Hartman
Site Quality Assurance Manager of P&G Chemicals
The Procter & Gamble Company, Cincinnati Chemicals Plant
5201 Spring Grove Avenue, Cincinnati, OH 45217, USA
Phone: (513) 276-3818; Email: delcampohartman.ci@pg.com

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 Excipient 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.

- Threat Assessment Critical Control Point (TACCP) team is used to determine threats across the supply chain, following the Campden BRI TACCP Guide.

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 OHSAS 18001 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 – Revisions

This is the 1st version of Manufacturing Section of Excipient Information Package for P&G Chemicals Moon OU Kosher Glycerin based on The International Pharmaceutical Excipients Council Excipient Information Package User Guide 2013. It is generated on October 1, 2015.

Section 8 – Contact Information

If you have any additional question on EIP manufacturing part, please contact:
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Global MPD (Materials, Process, and Delivery) Leader of P&G Chemicals Glycerin
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11530 Reed Hartman Highway, Cincinnati, OH 45241, USA
Phone: (513) 668-8544; Email: wood.rl@pg.com

P&G Chemicals
Delivering solutions, creating value

SUPEROL KPO® GLYCERIN, USP*/FCC/EP*
SUPEROL NK® GLYCERIN, USP*/FCC
STAR KPO® GLYCERIN
STAR NK® GLYCERIN
MOON OU® GLYCERIN, USP*/FCC

Excipient Use Only

Roundtable on Sustainable Palm Oil

P&G is a member of the Roundtable on Sustainable Palm Oil (RSPO) and a member of the Sustainable Palm Oil Coalition. P&G is committed to the sustainable sourcing of palm oil and palm kernel oil. We use a very small amount of the world wide production of palm oil (about 1%), although the derivatives and by products of it are used in a variety of food and pharmaceutical products.

By 2015, we intend to only purchase and use palm oil that we can confirm to have originated from responsible and sustainable sources. We will seek to accomplish this goal through the following key steps:

1. Supplier and Partner Coaching – We are already working with our suppliers to share and reinforce our expectations around the sustainable production of palm oil, and encouraging them to certify their operations according to RSPO criteria. From 2011 onwards we will be reporting our progress in ensuring confirmed sustainable palm oil sourcing in our annual sustainability report.

2. Stakeholder Partnerships – We will expand and strengthen relationships with trade associations, government agencies, non-governmental organizations (NGO's), and other critical external stakeholders to help influence positive changes and incremental sustainability improvements in the palm oil supply chain and industry. We will partner with third-party organizations to help confirm and validate our palm oil sourcing and use strategies. For example, P&G is working with WWF on palm oil sourcing as part of our joint work program.

3. Industry Influence -- We will continue to support industry efforts to eliminate irresponsible and/or illegal deforestation of land for use in the planting and harvesting of palm plantations, as well as efforts to help ensure the appropriate selection and designation of land for such uses.[i]

Commitment on Sustainable Palm Oil Sourcing

- ✓ Traceability to mills for Palm Oil (PO) and Palm Kernel Oil (PKO) by Dec. 2015 and Plantations by 2020
- ✓ P&G to work with supplier partners to develop "NO DEFORESTATION" Plans.
- ✓ Maintain 100% RSPO for PO, divert PKO certificate fund to advance efforts for small holders improvement

No Deforestation Commitment

By 2020, we will ensure our suppliers –

- *Meet the RSPO Principle & Criteria (issued in April, 2013)*
- *No development of High Conservation Value (HCV)* areas and High Carbon Stock (HCS) forests*
- *No new development of peat lands regardless of depth*
- *No burning to clear land for new development or replanting*
- *Meet expectations of P&G's existing Sustainability Guidelines*
- *Respect for human, labor, and land tenure rights*

P&G's Work with Small Farmers to Ensure Zero Deforestation

P&G is focused on creating **long-term solutions** for the Company, for the industry, and for the small farmers who depend on this crop.

While P&G's overall use of palm oil, palm kernel oil and derivatives of each represents < 1% of worldwide production, we recognize our responsibility to ensure our sourcing of palm derived materials does not contribute to deforestation or infringe upon the rights of workers and indigenous peoples.

Establishing full traceability means that P&G will know who is growing the Palm fruits from which the PKO we buy is derived. This is critical for the Company to be certain that it is not contributing to deforestation.

In-Field Work with Smallholders

- Partnered with **Malaysia Institute for Supply Chain Innovation**
- Two 6-month studies to understand the PKO supply chain and challenges of smallholders
- Report findings and best practices to the industry

For more information, visit www.PG.com/Sustainability

PCUDEUTSCHLAND

The Procter & Gamble Co.
Mr. Verma
Sharon Woods Technical Center, 11510 Reed Hartman Highway
OH45241 Cincinnati
UNITED STATES

Berlin, 19/12/14

Ref.: PRJ 834183 / RSPO SCCS

Concerns: certificate

Dear Sir/Madam,

Please find enclosed your Scope Certificate for your project. When Control Union Certifications does not receive any reaction within 21 days after sending (date of postmark), it is assumed that you agree with its contents.

Your valid scope certificate summarises and visualises your current achievements with regard to the certification of your production. Please feel free to use it for your public relation purposes.

Please be aware that:
- The Scope Certificate can not be used as an Import or Transaction Certificate for a certain product.
- Only your most recently issued Scope Certificate is valid.

We hope to have informed you sufficiently.

With kind regards,

Schmidt, Ms. (Carmen)
Control Union Certifications

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