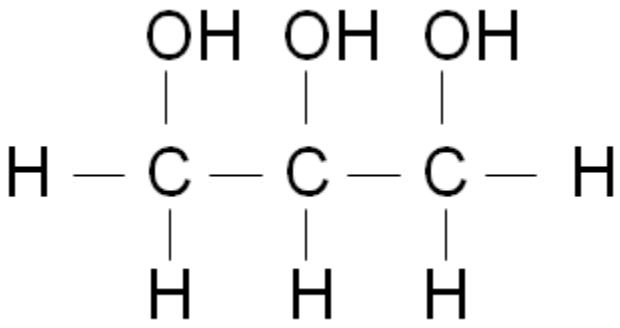
P&G Chemicals

Manufacturing Process, Quality, and Regulatory Packet

SUPEROL KPO



Dear Valued Customer:

We are providing the following information to assist in learning more about our SUPEROL KPO brand of glycerin. Please do not hesitate to contact your P&G representative with any questions.

P&G Chemicals 1-800-477-8999

PGCHEMICALS.COM

Updated Margaret DelPresto, Glycerin CDM, July 2013

P&G Chemicals

Contents

General Information

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

Main Contact:
Margaret 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

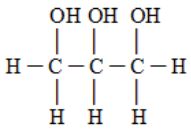
Cincinnati Plant Site Manager	John Collins
QA Manager	Kitty Fields

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*
SUPEROL KPO™	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

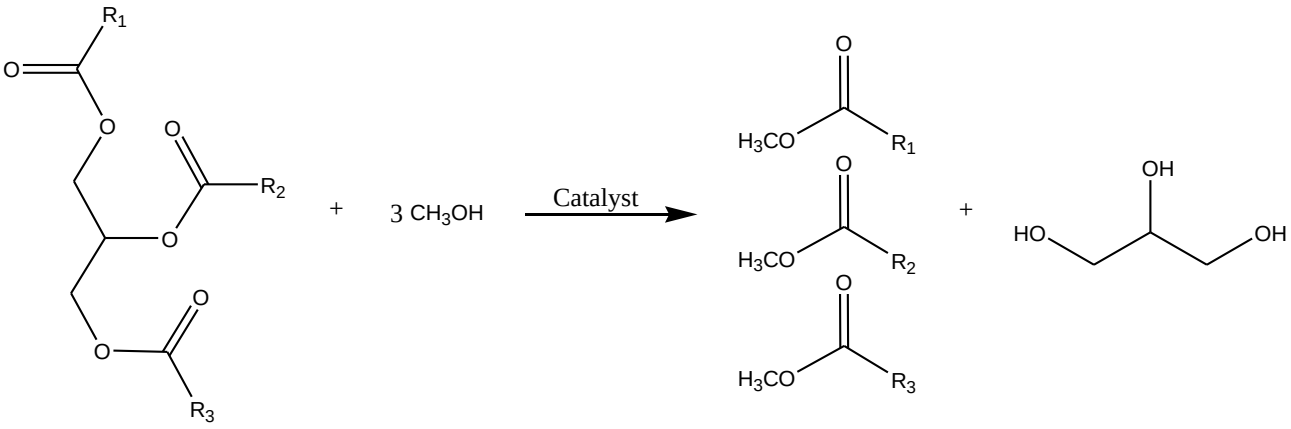
ISO vs QAKE

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

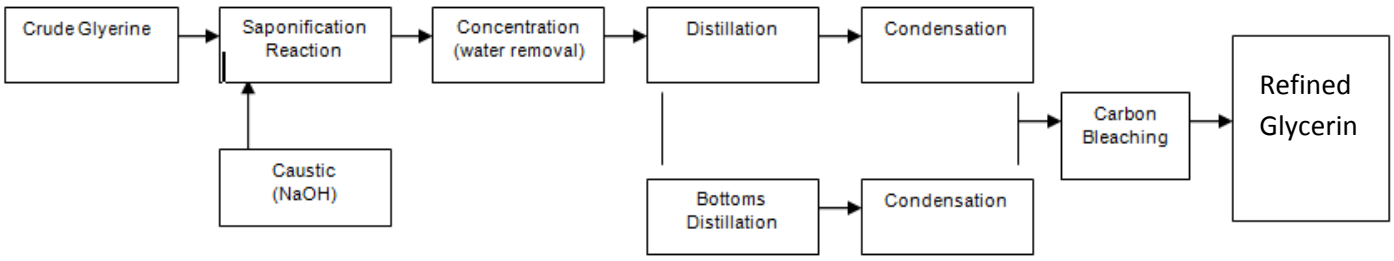
Crude glycerine is a co-product that is formed during methanolysis or hydrolysis of triglycerides which results in the glycerin backbone being separated from the triglyceride. The hydrolysis reaction is similar to the methanolysis reaction shown below.

Methanolysis



Triglycerides/Oils Methanol Methyl Esters Crude Glycerine

SUP KPO 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 SUP KPO are completely vegetable derived and are Kosher for Passover certified.

GMO

GMO Definition

Genetically modified organism, an organism 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 certified as much as possible. This allows for adventitious contamination typically up to 1% from commingling in processing or storage.

GMO Free Claim

Superol KPO Glycerin is refined glycerin from non-GMO sources. Superol KPO Glycerin is made from natural sources such as palm, palm kernel, and coconut, which have not been genetically modified commercially. The plant oil is highly refined and the triglyceride is cleaved to produce the glycerin, followed by a series of refining processes.

The above brands of glycerin marketed by P&G Chemicals are considered not genetically modified or not derived from a genetically modified organism as defined by EU Directive 1830/2003/EC on labeling and traceability and 1829/2003/EC on genetically modified food and feed and any amending legislation[1].

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 certifies that the above brands of glycerin do not contain microorganisms or their toxins or metabolites in quantities that present an unacceptable risk for human and animal safety. 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-Purity[1].

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[2]

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

SUP KPO 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)
Hydrolyzed Vegetable Protein (HVP)
DEHP (Di(2-ethylhexyl) phthalate
DINP (Diisononyl phthalate)
Iodine
Lodine
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, 3 or table 4 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 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 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 for Passover 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 SUP KPO 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 glycerine – 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

Appendix A: SUP KPO 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

SUPEROL KPO GLYCERIN, USP/FCC/EP

for excipient use only

CERTIFICATE of ANALYSIS

(Customer or Consignee)

(Dept., if applicable)

(Attention)

(Delivery Address)

(City, State, Zip)

(Approximate weight Lb. ☐ KG ☐ MT ☐

GCAS No. (s): 99318844

P&G Material Code: 10247141

Manufacture Date:

P&G Invoice No.

Customer P.O. No.

Customer Code

Vessel No.

(Method TC ☐, TT ☐, Ship ☐, Iso ☐)

P&G Lot No.

Shipment Date

Seals

Country of Origin USA

Test	GCAS #	Result	Specification Limits
Identification A by IR: Glycerin	60065177		PASS – as glycerin
Identification B by GC: Limit of DE	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 Gra	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%
USP 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
EP Identification A by RI: Glycerin	60065175		1.470-1.475
EP Sulphated Ash	95395280		USL: 0.01%
EP Halogenated Compounds	95410923		PASS (USL: 35 ppm)
EP Sugars	95341517		PASS
EP Aldehydes	95327474		PASS (USL: 10 ppm)
EP Acidity or Alkalinity	60065134		USL: 0.2 mL of 0.1M NaOH
EP Esters	60065134		LSL: 8.0 mL of 0.1M HCl
EP Impurity A and Related Substanc	95076103		PASS: (USL: 0.1% impurity A; USL: 0.1% for individual impurity with retention time less than glycerin, USL: 0.5% total impurities retention time greater than glycerin)

Signature	**Name**
Date	**Position**

Manufacturing Location: 5201 Spring Grove Avenue, Cincinnati Ohio 45217

Certifications and Compliance Statements Section

GMO:

This ingredient is considered NOT genetically modified or NOT derived from a genetically modified organism as defined by EU Directive 1830/2003/EC on labeling and traceability and 1829/2003/EC on genetically modified food and feed and any amending legislation.

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 or Section 5.4 Residual Solvents in the current European Pharmacopoeia. 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 extensively evaluated our in-process and finished product and found no detectable levels of residual solvents.

EP Compliance:

Superol KPO Glycerin, USP/FCC/EP meets the glycerin specification requirements of European Pharmacopoeia (EP).

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 with 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 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).

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

Dorotheastraße 30 10318 Berlin Germany
+49 30 509 69 88-0 +49 30 509 69 88-88 berlin@controlunion.com www.pcu-deutschland.de

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

Superol® KPO Glycerin, USP/FCC/EP
Moon® OU Glycerin, USP/FCC
Superol® NK Glycerin, USP/FCC
Star® KPO Glycerin
Star® NK Glycerin

Elemental Impurities

P&G Chemicals' pharmaceutical excipient products, including Superol Glycerin, USP/FCC, Moon Glycerin, USP/FCC, and Star* line of glycerin brands, 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).

P&G Chemicals Evaluation of Applicable USP General Chapter <232> Elemental Impurities

Element	Concentration Limits (µg/g) for Oral Drug Products with a Maximum Daily Dose of ≤10 g/day	Concentration Limits (µg/g) for Parenteral Drug Products with a Maximum Daily Dose of ≤10 g/day	Concentration Limits (µg/g) for Inhalational Drug Products with a Maximum Daily Dose of ≤10 g/day	Typical
				Result Less Than (ppm or µg/g)
Cadmium	0.5	0.2	0.2	0.01
Lead	0.5	0.5	0.5	0.01
Inorganic Arsenic	1.5	1.5	0.2	0.02
Inorganic Mercury	3	0.3	0.1	0.01
Chromium	1100	110	0.3	0.01
Nickel	20	2	0.5	0.02
Vanadium	10	1	0.1	0.01
Copper	300	30	3	0.01
Cobalt	5	0.5	0.3	0.01

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 brands. No levels of each elemental impurity were found at a 0.02 ppm (20 ppb) detection level (well below the USP concern levels).

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.