Lloyd's Register
LRQA

CERTIFICATE OF APPROVAL

This is to certify that the Management System of:

The Dow Chemical Company
Propylene Oxides and Propylene Glycols
2301 North Brazosport Boulevard
Freeport, Texas 77541, USA

has been approved by Lloyd's Register Quality Assurance
to the following Management System Standard:

ISO 9001:2008

The Management System is applicable to:

Manufacture of Propylene Oxide and Propylene Glycols.

This certificate is valid only in association with the certificate schedule bearing the same number on which the locations applicable to this approval are listed.

Approval
Certificate No: UQA 0112979

Original Approval: May 23, 2002

Current Certificate: January 1, 2016

Certificate Expiry: September 14, 2018

Issued by: Lloyd's Register Quality Assurance, Inc.

ANAB
ACCREDITED
ISO/IEC 17021
MANAGEMENT SYSTEMS
CERTIFICATION BODY

1330 Enclave Parkway, Suite 200, Houston, Texas 77077, USA

Lloyd's Register
LRQA

CERTIFICATE SCHEDULE

The Dow Chemical Company
Propylene Oxides and Propylene Glycols

Head Office:

2301 North Brazosport Boulevard
Freeport, Texas 77541, USA

Activities:

Headquarters Administration.

Locations:

2301 North Brazosport Boulevard
Freeport, Texas 77541, USA

Activities:

Manufacture of Propylene Oxides and Propylene Glycols.

21255 Highway 1 South, Building 1501
Plaquemine, Louisiana 70764, USA

Manufacture of Propylene Oxides and Propylene Glycols.

Approval
Certificate No: UQA 0112979

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Current Certificate: January 1, 2016

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ANAB
ACCREDITED
ISO/IEC 17021
MANAGEMENT SYSTEMS
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« Go Back to Search Results

Propylene Glycol USP/EP - HACCP Plan Compliance

Answer ID 7063 | Updated 03/09/2011 10:46 AM

What is the HACCP plan for PG USP/EP?

Compliance with Hazard Analysis and Critical Control Point or HACCP is a systematic approach to the identification, evaluation, and control of food safety hazards.

Dow has determined that a HACCP plan for PG USP/EP is not necessary due to its existing quality and regulatory compliance programs.

PG USP/EP is an excipient in pharmaceutical products and is manufactured according to the guidelines defined in “The IPEC-PQG Good Manufacturing Practices Guide for Bulk Pharmaceutical Excipients” © 2006 The International Excipients Pharmaceutical Council, which are more stringent than the principles of HACCP.

PG USP/EP is manufactured from hydrocarbon raw materials in a closed, continuously-operated process utilizing dedicated equipment. The process is not open to the environment at any time during normal operations, prior to loading it into shipping containers, so contamination by foreign materials is unlikely. The material is tested for compliance with the U.S., European, and Japanese Pharmacopoeia plus the U.S. Food Chemicals Codex, all of which require that the material not be contaminated or adulterated.

The Dow Chemical Company
Midland, MI 48674
U.S.A.

January 24, 2012

DOW PROPYLENE OXIDE AND PROPYLENE GLYCOL NOTIFICATION OF CHANGE TO LOT NUMBER FORMAT

Dear Valued Distributor:

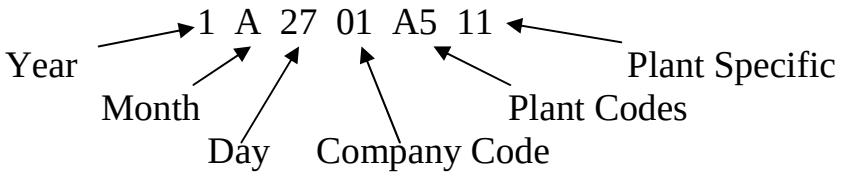
The purpose of this letter is to notify you of an upcoming minor change in the lot numbering format for Dow's Propylene Oxide and Propylene Glycol products.

In the current naming system, the first letter of the Dow lot number refers to the year of manufacture. For the year 2011, this letter was a "Z"; therefore, example lot number ZC0801S901 would have been produced in 2011. Since "Z" is the last letter in the alphabet, the lot numbering system will now use a number to designate the year of manufacture.

As a result, beginning **January, 1 2012**, the first digit in the Dow lot number system will be a "1" to designate the year 2012. The rest of the lot number format will remain unchanged. An example of a lot number using this new format would be 1A0101S901.

The following year, the number will change to a "2" to designate the year 2013, the number "3" will designate the year 2014, and so on.

The following is an illustration of the updated Dow lot number format:



As always, Dow is committed to providing quality products and innovative solutions to serve its customers. Please contact your sales representative if you have any questions.

Thank you for your continued business with Dow.

The Dow Chemical Company

Answer ID
3476

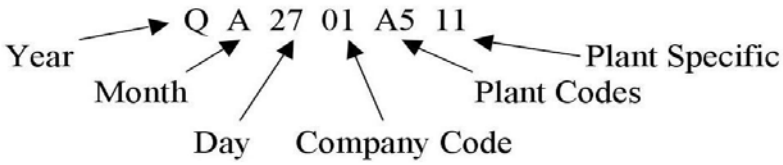
Propylene Glycols - Lot Numbering System

Question

What type of information is contained in the Lot (Batch) Number for Dow's Propylene Glycol produc

Answer

The following is a description of the information contained in the Lot (Batch) Number. This informat monitor the remaining shelf life of the product, identify the manufacturing location, or reference a un quantity of product. The Plant Specific code at the end can be in various formats, not just two digits



Year Code	Month Code		Company Codes
A = Pre 1987	A = January	01 = USA	02 = Canad
B = 1987	B = February	05 = England	08 = Nether
C = 1988	C = March	09 = Spain	19 = Germa
....	....	21 = Australia	24 = Colum
V = 2007	K = November	31 = Brazil	38 = Japan
W = 2008	L = December	43 = Argentina	72 = Taiwa
X = 2009		85 = Korea	

Plant Codes

North America

A5	Plaquemine, LA Manufacturing Site
N6	Freeport, TX Manufacturing Site
S9	Freeport, TX Marine Terminal
9G	Joliet, IL Terminal
FC	Carteret, NJ Terminal
DQ	Cincinnati, OH Terminal (Southside)
QN	Long Beach, CA Terminal
GJ	Chester, SC Terminal (SE Fleet)
74	Vopak Hamilton Terminal (Canada)
75	Vopak Montreal Terminal (Canada)

Europe

20	Stade, Germany; Manufacturing Site

TS	Teesside, UK; Terminal

Central and South America

A1	Aratu, Brazil Manufacturing Site
T8	Cartagena, Columbia Terminal
CT	Cartagena, Columbia Terminal
GT	Guaruja, Brazil Terminal

Pacific

35	Altona, Australia; Manufacturing Site
48	Tokyo Yuso Terminal, Japan
32	Riku-un Sangyo Terminal, Japan
59	Vopak Terminal, Singapore
90	Ulsan Terminal, Korea

The Dow Chemical Company
U.S.A.

May 18, 2010

Propylene Glycol USP/EP - Pharmacopeia and Current Good Manufacturing Practices (cGMP) Compliance

Dow's Propylene Glycol USP/EP is manufactured in Dow facilities in the U.S., Germany, Brazil and Australia according to current Good Manufacturing Practices as defined in the "The Joint IPEC-PQG Good Manufacturing Practices Guide for Pharmaceutical Excipients" © 2006_The International Pharmaceutical Excipients Council and Pharmaceutical Quality Group. The product is tested and complies with all items of the current USP, EP, JP and FCC as stated on the Sales Specification. The quality system for the Propylene Glycol business is also designed to conform to the requirements for ISO 9001:2008.

Dow's Propylene Glycol USP/EP is sold commercially on a global basis, including sales in Europe.

If you have any questions or require further information, please contact us via our web site at www.dow.com or call Customer Information Group (CIG) at the numbers below.

Sincerely,

Kim Bennett

Kim Bennett
Technical Service Specialist
The Dow Chemical Company
NA CIG Phone: (800) 447-4369 Fax: (989) 832-1465
E-mail: DowCIG@Dow.com

The Dow Chemical Company
U.S.A.

June 5, 2010

Propylene Glycol USP/EP (PG USP/EP)

Wood Pallet Treatment

Propylene Glycol USP/EP produced at our North America manufacturing sites is shipped in bulk quantities only. Wood pallets are not utilized at these facilities.

The pallets used in the packaging of the PG USP/EP product in Stade, Germany are heat treated according to ISPM-15 standards as established by International Plant Protection Committee (IPPC) Rules and Regulations. We have received confirmation from our pallet suppliers that none of these pallets have been chemically treated with tribromophenol (TBP) or any other bromine/ fungicide compounds.

If you have any questions or require further information, please contact us via our web site at www.dowpg.com.

Sincerely,

Kim Bennett
NA Technical Service
Performance Products
The Dow Chemical Company
NA CIG Phone: (800) 447-4369 Fax: (989) 832-1465
E-mail: DowCIG@Dow.com

Propylene Glycol USP/EP

Current Good Manufacturing Processes Questionnaire Response Document

The Dow Chemical Company supplies Propylene Glycol USP/EP to numerous customers and distributors, who in turn supply the product or products derived from PG USP/EP to their customers.

This document answers the questions many customers frequently ask regarding Dow's quality control system and is provided to customers in lieu of completing individual questionnaires.

Purpose

Propylene Glycol USP/EP, manufactured by Dow, is manufactured specifically for use in the pharmaceutical, food and cosmetics industries. The purpose of this document is to communicate the systems and procedures that Dow uses to comply with current Good Manufacturing Practices (cGMP) for the manufacture, storage and distribution of Propylene Glycol USP/EP, hereafter referred to as PG USP/EP, to customers.

Related Documents

1. *"Good Manufacturing Practices Guide for Bulk Pharmaceutical Excipients"*, © The International Pharmaceutical Excipients Council, 2001.
2. PG USP/EP Dow Global cGMP Practice Compliance Manual.
3. Purity Plus, Dow Propylene Glycol USP/EP, The Dow Chemical Company
4. *"Guidelines for Handling and Distribution of Propylene Glycol USP/EP"*, CEFIC (The European Chemical Industry Council), 1999,
5. Dow's propylene glycol website: www.dowpg.com
6. The Dow Chemical Company website: www.dow.com

Scope

This document refers only to **Propylene Glycol USP/EP (PG USP/EP)** produced by The Dow Chemical Company in the following locations:

Freeport, TX, USA
Plaquemine, LA, USA
Altona, Australia
Aratu, Brazil
Stade, Germany

Manufacturing Sites

Dow's PG USP/EP is manufactured in all Dow Propylene Glycol USP/EP facilities using the same production processes, and cGMP compliance programs. PG USP/EP quality from all Dow's manufacturing sites is statistically equivalent and meets or exceeds all the requirements listed in (see www.dowpg.com):

- The Dow Chemical Company PG USP/EP Sales Specification
- The United States, European and Japanese Pharmacopoeia
- The US Food Chemicals Codex

Sourcing

Dow makes an effort to source customers and terminals from the same location each time, but to avoid outages due to manufacturing and logistics considerations, customers in the U.S. may receive product from either of the Dow North American manufacturing locations.

Customers in Europe are exclusively sourced with PG USP/EP from Dow's facility in Stade, Germany.

Customers in Latin America may receive product from Aratu, Brazil or the TX or LA plants in the USA, depending on their location.

Customers in Australia / New Zealand receive material from Altona, Australia and other areas in the Pacific from Australia, Brazil, or the USA.

The date and lotting site of a specific lot is indicated in the Lot Number in accordance with system procedures (see Traceability).

Manufacturing Sites

PO/PG Freeport, Texas, U.S.A.

This ca. 90,000 sq. ft. facility is operated by ~35 employees.
Commissioned in 1951, it has been ISO 9002 certified since June 1995.

The Dow Freeport site does not have a FDA Registry number. The FDA issued an opinion in the April 5-8, 2004 audit write-up that FDA registration is not required since Active Pharmaceutical Ingredients are not manufactured at the Dow Freeport site.

PO/PG Plaquemine, Louisiana, U.S.A.

This ca. 90,000 sq. ft. facility is operated by ~35 employees.
Commissioned in 1958, it has been ISO 9002 certified since June 1997.

The most recent FDA audit was held in June 2003. No Form 483's were received. The FDA registry number for the Plaquemine site is 2312156.

PO/PG Stade, Germany

This facility is operated by ~70 employees and has been ISO certified (9001 and 14001) for many years. The U.S. FDA has not inspected the plant.

PO/PG Aratu, Brazil

This facility is operated by ~50 employees.
Commissioned in 1976 and is ISO 9001:2000 accredited.

PO/PG Altona, Australia

This facility is operated by ~20 employees and is AS/NZS ISO 9001:2000 accredited.

Product Information and GMP Programs

Propylene glycol is a nontoxic, low vapor pressure, practically odorless, slightly viscous, clear, colorless, hygroscopic liquid with over fifty years of use in food, pharmaceutical and cosmetic applications. It is recognized by the U.S. FDA as GRAS (generally recognized as safe) in 21 CFR 184.1666 and is approved for use as a direct and indirect additive for foods and pharmaceutical products, when manufactured and used in accordance with U.S. FDA requirements.

Dow's Propylene Glycol USP/EP, a high purity grade of propylene glycol is manufactured for use in foods, beverages, cosmetics, pharmaceuticals and a variety of other applications that specify adherence to quality standards. Dow's PG USP/EP is manufactured in Dow facilities worldwide under rigorous quality control and operational procedures utilizing GMP practices to provide the quality and product reliability that customers specify.

The USP/EP grade status indicates that the product is tested against the specified requirements of the United States, European and Japanese Pharmacopeia plus the U.S. Food Chemical Codex and Dow specific quality tests. Dow's PG USP/EP meets the requirements and standards of the Brazilian and other Pharmacopeias, U.S. Food and Drug Administration (FDA), Scientific Committee for Food (SCF), several European Community (EC) directives plus it complies with food, pharmaceutical and cosmetic regulations in markets where it is sold. The Cosmetic Toiletry and Fragrance Association (CTFA) lists propylene glycol as an approved ingredient in cosmetics and its safe use has been reviewed by the Cosmetic Ingredient Review (CIR). The Flavor Extract Manufacturing Association (FEMA) list propylene glycol as GRAS (FEMA GRAS number 2940).

Another prerequisite for PG USP/EP is the use of Good Manufacturing Practice (GMP) for its manufacture and distribution. GMP's are FDA, EC and compendial guidelines for ensuring that components used in food and pharmaceutical products are not adulterated or contaminated. Conformance to FDA or EC standards is a requirement in many countries worldwide.

Dow's Propylene Glycol USP/EP is manufactured according to Good Manufacturing Practices (GMP) as defined in the IPEC guide *"Good Manufacturing Practices Guide for Bulk Pharmaceutical Excipients"* © 2001 The International Pharmaceutical Excipients Council.

Dow has implemented its **Purity Plus** standards to fulfill GMP requirements. These standards include dedicated facilities for production and product handling, extensive quality assurance testing, dedicated bulk storage and transportation in stainless steel or lined equipment, color differentiated packaging, label management, distributor and terminal clean room programs, and personnel qualification and training programs. In support of distributors who are repackaging, Dow provides ongoing clean room drumming support, including start-up assistance and clean room inspections. ISO 9001/9002 certification (see www.dowpg.com for copies) has been achieved by all Dow's PG production facilities worldwide. All Dow production and most terminal locations are Kosher certified see www.dowpg.com for when stored below 40°C in closed containers away from sources of UV light.

Dow provides propylene certification documentation, and in accordance with GMP requirements, operates ongoing stability program on a global basis. PG USP/EP has a shelf life of two years, when stored under recommended conditions and is synthesized from hydrocarbon raw materials with no additives, including enzymes or process aids, being added during its manufacture. As manufactured by Dow PG USP/EP does not contain any animal or plant derived products and, therefore, no allergens, glutens, sulfites and genetically modified or BSE/TSE-risk materials.

For an American Chemistry Council (ACC) document on Propylene Glycol Nutritional content, download Propylene Glycol Information Update (109KB PDF)

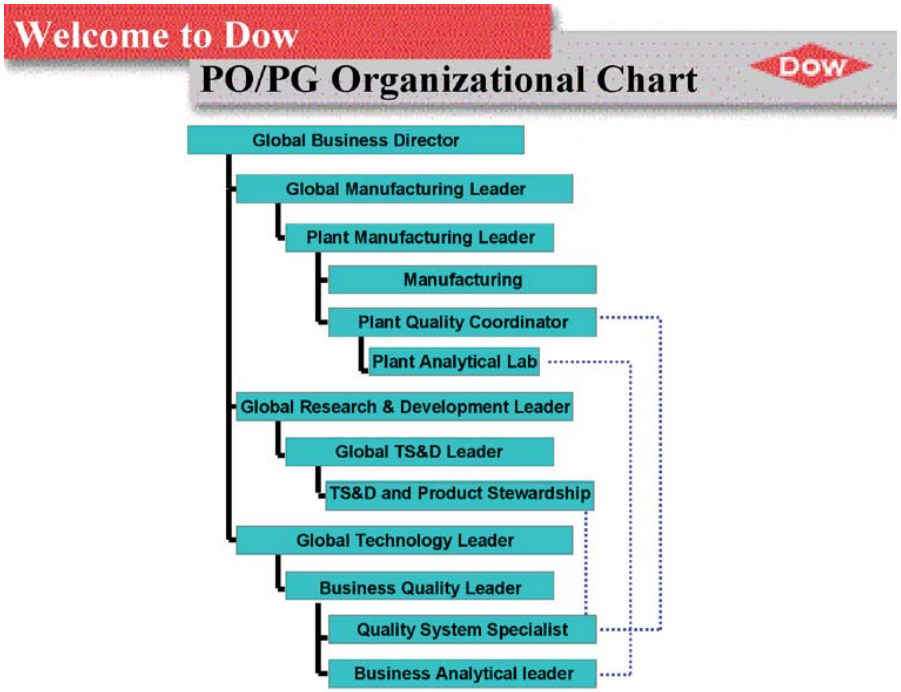
Additional product and regulatory compliance information is available on the Question and Answer document on www.dowpg.com.

Product Information: Physical Properties:

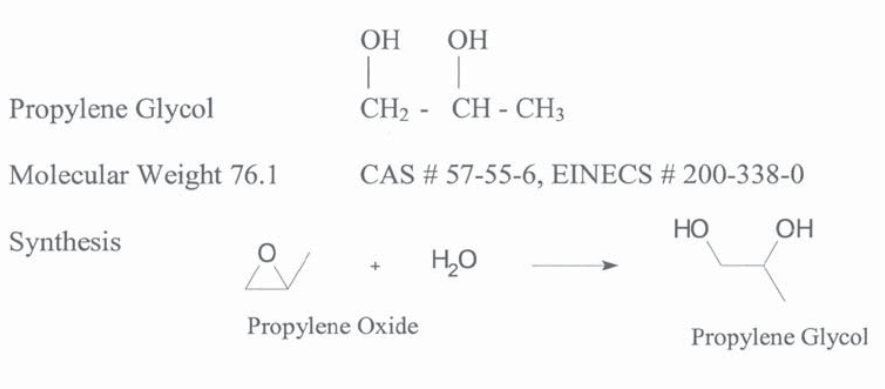
For a listing of Propylene Glycol USP/EP physical properties, download Dow Propylene Glycol USP/EP (114KB PDF)

Organization

As indicated in the following diagram, the quality function is independent of the production unit (see dotted blue lines) and is responsible for making decisions regarding raw material acceptance and product release, or process changes that might impact quality.



Process Description and Chemistry

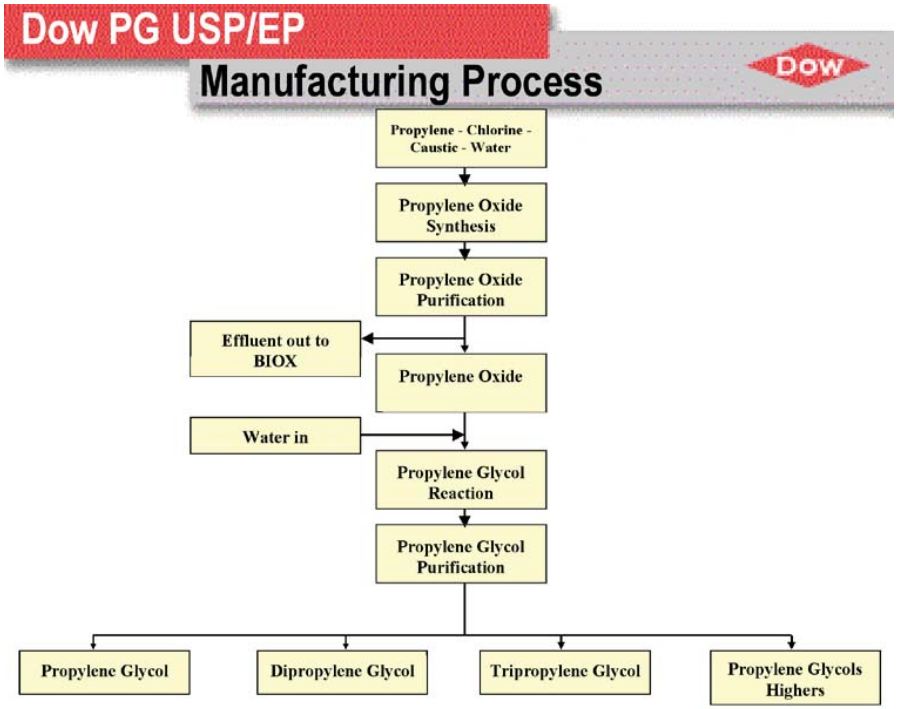


Raw Materials

Propylene oxide and water are the raw materials used for Propylene Glycol USP/EP production. Propylene oxide is produced internally by Dow using a continuous process, utilizing petroleum or inorganic derived raw materials. The water used is obtained from steam condensation.

The quality requirements for these raw materials are documented in raw material specifications. The propylene oxide and utilities distribution plants are responsible for monitoring and documenting the quality of these materials and for reporting any material non-conformance to the receiving plants.

Dow's Propylene Glycol USP/EP is not produced from, nor does it contain, any plant or animal products or by-products.



Process Control

PG USP/EP production is a continuous, computer-controlled process, carried out in a closed system isolated from the atmosphere. Process personnel control the production processes in accordance with daily operational schedules using computer process control (MOD V®) and process data systems with documented operating conditions.

Job procedures are documented and include procedures for startup, routine operation, shutdown, maintenance, cleaning and return to service.

Production records, such as transfer log sheets and logbooks, are maintained according to defined record control procedures and retention schedules.

Plant process data is maintained within the process control computer systems; defined procedures exist for retention, backup, change authorization, and verification of data. Production data and inventories are maintained using SAP software. The process systems, including computer control systems are routinely validated.

Critical equipment has a documented preventive maintenance program. Records of all repairs and scheduled activities such as lubrication and calibrations are maintained electronically within a global EMTS computer system. The maintenance group consists of trained craftsmen, reliability engineers, technicians, technical specialists, activity coordinators and planners who are responsible for repairs, preventive maintenance, and regulatory inspections.

Laboratory

Validated equipment and methods are used to analyze process and finished product samples. Calibration checks of critical lab equipment are routinely performed in accordance with written procedures. Equipment history and recommendations from the manufacturer determine the interval of these checks.

Out of calibration instruments are evaluated using a validity assessment program. Logbooks are maintained on each instrument to document performance, including maintenance and repairs.

Gas chromatograph results are computer processed and automatically transferred either into LIMS (Laboratory Information Management System) or a lot inspection binder.*

A re-sampling process is in place for handling out-of-spec results, which includes root cause determination.

Sampling and Testing

Qualified and appropriately trained individuals complete all in-process and finished product testing.

In-process testing is conducted at defined locations and times, to ensure the process is operating within established process parameters or acceptance tolerances.

Testing Protocols define what key variables are tested after each transfer of the product. Quarterly testing is conducted on all pharmacopoeia requirements, based on the original monograph test methods.

Note: Certificates of Analyses denote key point testing versus quarterly testing.

A Second Review Protocol is in place which, in accordance with the IPEC GMP Guide, allows for the second review to be conducted by a validated computer system. In the event that an individual performs the second review, they must be qualified and can not be the same individual that initially performed the task and recorded the data.

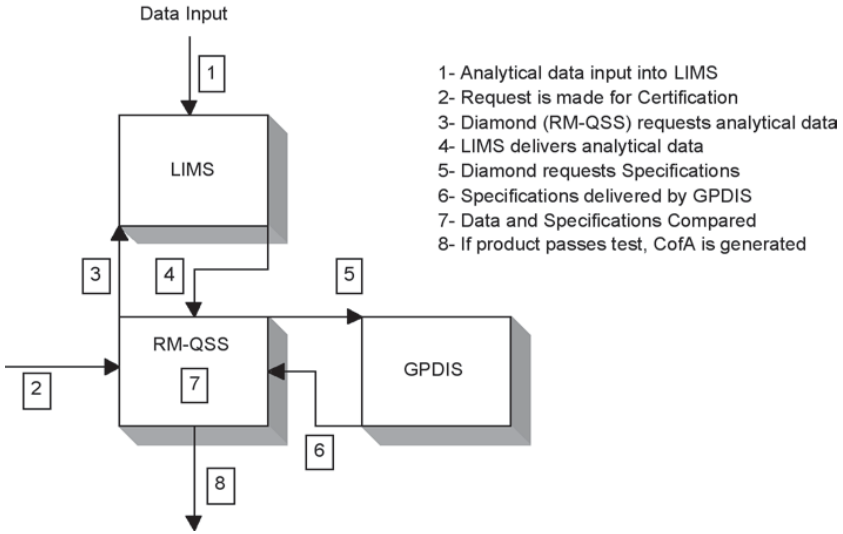
* The Altona, Australia facility personnel manually transfer the gas chromatograph results to a final lot inspection binder, along with all other analytical results into the SAP Quality Service System from which the certificates of analysis is generated.

Retained samples, representative of every specific product lot, are maintained for the length of the product shelf life plus current year (total three years). Additional samples are taken from every transport load, analyzed for key point control parameters and maintained, as well.

Organic Volatile Impurities (OVI) are tested on a quarterly basis to monitor whether analytical results meet the requirements of current USP.

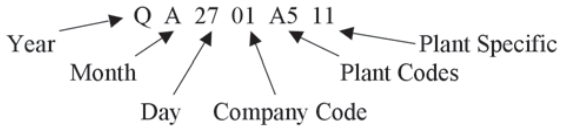
Product Release Procedures

Product specifications are stored in the Global Product Data Information System (GPDIS). Analytical results from LIMS are automatically compared to specifications through a computer interface (see diagram below). Product is released as available for sale only when each test item is within specification. Only the quality function has the authority to manually override the system. This overall system has been validated.*



Traceability

The lot naming system allows tracing of the product back to incoming raw materials, according to written procedures. Lot assignment is based on isolated sales tank quantities, with a numbering system as follows:



Year Code	Month Code	Company Codes	
A = pre-1987	A = January	01 = USA	02 = Canada
B = 1987	B = February	05 = England	08 = Netherlands
C = 1988	C = March	09 = Spain	19 = Germany
…	…	21 = Australia	24 = Columbia
T = 2005	K = November	31 = Brazil	38 = Japan
U = 2006	L = December	43 = Argentina	72 = Taiwan
		85 = Korea	

*Altona, Australia does not have a LIMS, so the analytical data is manually entered into QSS.

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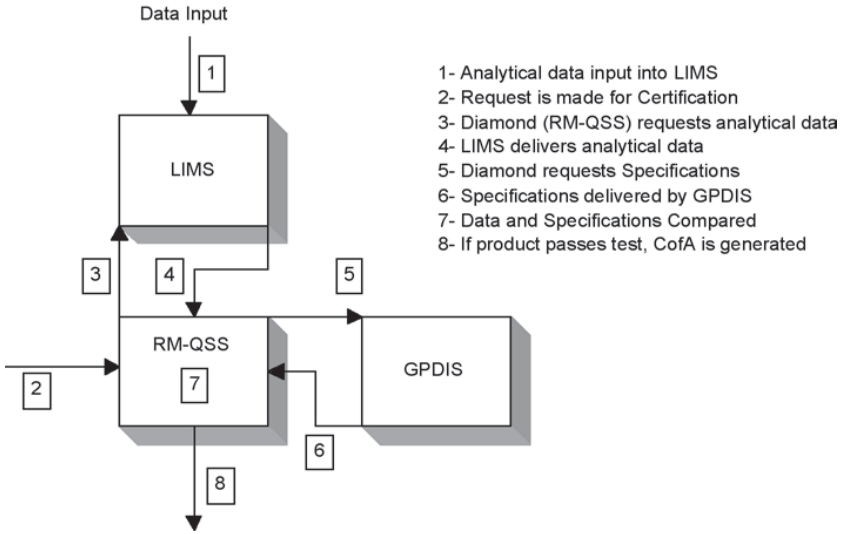

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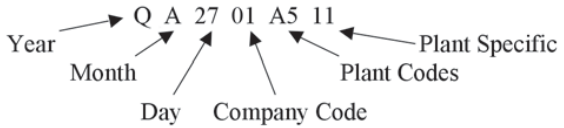

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CT	Cartagena, Columbia Terminal
GT	Guaruja, Brazil Terminal
Pacific	
35	Altona, Australia; Manufacturing Site
90	Ulsan Terminal, Korea
59	Vopak, Singapore
32	Riku-un Sangyo Terminal, Japan
48	Tokyo Yuso Terminal, Japan

Change Control

Dow's global **Management of Change** process establishes the minimum requirements for change control. An electronic tool (eMOC) is used to facilitate the process. A change is defined as "any alteration, whether temporary or permanent, that could affect the control or integrity of a process/system that goes beyond the established safe operating range, recipe, or proven raw material supplier."

Proposed changes are reviewed by appropriate multiple functions. If it is determined that there is potential impact on quality or cGMP issues, then the Business Quality Leader (BQL) or his designee must approve any changes. The BQL role is independent of manufacturing.

Together with Management of Change, a **Notification of Change** protocol has been established, which defines whether a change is significant and the person responsible for customer notification.

Training

Training is a vital part of the Operate Plant Work Process. Needs assessments are performed for each employee and a training matrix is developed based on the results. Course-work may include computer-aided training, In-Plant-Training (IPT) modules or formal classroom courses. GMP training is required once per year.

Customer Notice

Dow encourages its customers to review their applications of Dow products from the standpoint of human health and environmental quality. To help ensure that Dow products are used in ways for which they were intended or tested, Dow personnel are willing to assist in dealing with ecological and product safety considerations. Your Dow representative can arrange the proper contacts.

For Additional Information

For additional information, contact your Dow representative or the Dow Customer Information Group in your area:

U.S. and Canada: 1-800-441-4DOW (4369)
Mexico: 95-800-441-4369
Latin America: 989-832-1426
Europe: 32-3-450-2240
Pacific: 60-3-7958-3392
China: 800-600-0015
Brazil: 55-11-5188-9222

Published December 2003

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Form No. 117-01683-0205SI

SITE QUALITY OVERVIEW

According to the IPEC Standardized Excipient Information Package User Guide, 2013
The Site Quality Overview was designed as a means to assist in communicating to the user certain physical, manufacturing and regulatory information specific to the excipient. This information is intended to facilitate the use of the excipient in drug products.

Section 1 Facility Overview

EXCIPIENTS COVERED BY THIS DOCUMENT:
PROPYLENE GLYCOL USP/EP (PG USP/EP)
PURAGARD™ PROPYLENE GLYCOL USP/EP
PuraGard™ is currently only manufactured and available in the U.S.

Company/Site:
The Dow Chemical Company ("Dow") Propylene Oxide / Propylene Glycols Business has six manufacturing sites for PG USP/EP around the world as listed below. Please see Attachment 1 for site addresses.

- Freeport, Texas, USA
- Plaquemine, Louisiana, USA
- Altona, Australia
- Aratu, Brazil
- Stade, Germany
- Map Ta Phut, Thailand

Headquarter Address:

The Dow Chemical Company
Propylene Oxide/Propylene Glycols Business
2040 Dow Center
Midland, MI 48674
USA

Corporate Ownership
The Dow Chemical Company ("Dow") is a diversified, worldwide manufacturer and supplier of chemicals and performance products, plastics, hydrocarbons and consumer specialties, including agricultural products and pharmaceuticals. Founded in 1897 by Herbert H. Dow, it is one of the largest chemical companies in the world in terms of sales. In 2011 Dow had annual sales of $60 billion and employed approximately 52,000 people worldwide. The Company's more than 5,000 products are manufactured at 214 sites in 37 countries across the globe. The company's corporate and U.S.A. headquarters are located in Midland, Michigan. Dow is divided into global businesses and functions that are integrated at each site and geography.

Site Details
General Site Information:
Manufacturing sites for Propylene Oxide/Propylene Glycols (PO/PG) business:

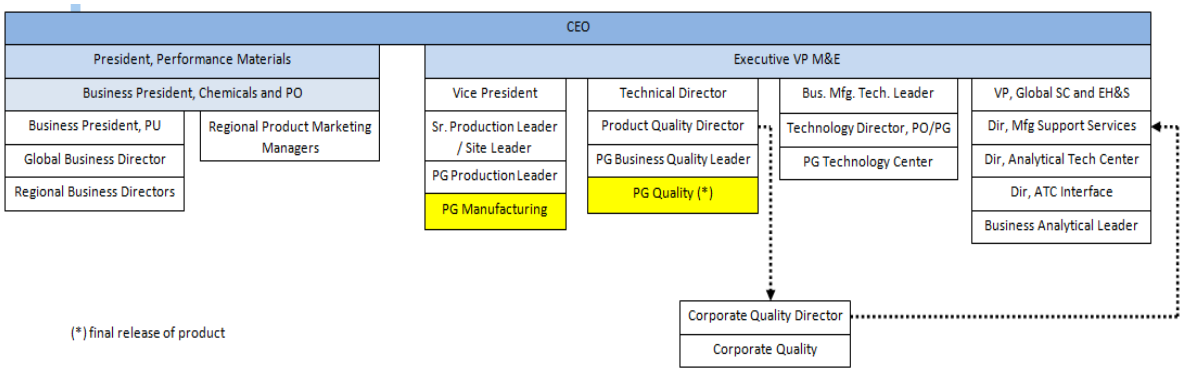
- PO/PG Freeport, Texas manufacturing site is about 90,000 square feet. The manufacturing site was commissioned in 1951.

- PO/PG Plaquemine, Louisiana manufacturing site is about 90,000 square feet. The manufacturing site was commissioned in 1958.
- PO/PG Aratu, Brazil manufacturing site was commissioned in 1976.
- PO/PG Stade, Germany manufacturing site was commissioned in 1972.
- PO/PG Altona, Australia manufacturing site was commissioned in 1978.
- PO/PG Map Ta Phut, Thailand, manufacturing site was commissioned in 2012.
- Employees working at these sites may include salaried, hourly and contract personnel.

Site activities:

- Activities include manufacturing, testing, storage, packaging, loading, R&D, and environmental monitoring.
- These facilities do not produce antibiotics, steroids or hormone type bulk pharmaceuticals

Organizational chart PO/PG Business



As indicated in the diagram, the quality function is independent of the production unit (dotted lines: administrative reporting only) and is responsible for making decisions regarding raw material acceptance and product release, or process changes that might impact quality.

Section 2 Evidence of Compliance

ISO 9001 Registration Information

- Texas facility has been ISO 9001:2008 certified since June 1995.
- Louisiana facility has been ISO 9001:2008 certified since June 1997.
- Stade facility is ISO certified (9001:2008 and 14001).
- Aratu facility is ISO 9001:2008 certified.
- Altona facility is AS/NZS ISO 9001: 2008 certified.
- Map Ta Phut is ISO9001:2008 certified.

LRQA Approval Certificate No. 0112979 and BGK0403005. ISO Certificates are available on www.dowpg.com

Other Certifications or External Audit Programs

The U.S. Food and Drug Administration (FDA) has specifically requested that Excipient Manufacturing locations not obtain FDA Registration as a Drug Establishment. Consequently, the

FDA Registration of all Dow North American PG USP/EP Manufacturing and Terminal Locations has been eliminated.

The compliance of Propylene Glycol USP/EP, produced in all global Dow locations, with the relevant government/pharmacopoeia requirements is given on the sales specification in the Government/Industry Standard section and on the certificate of analysis provided with each shipment. Additional audit programs include:

- Health Agency ANVISA in Brazil (National Health Agency) has audited Dow manufacturing site at Aratu and marine terminal at Guaruja – Brazil.
- Dow Stade PO/PG site is registered as an animal feed additive producer, based on EU regulation EC 153/2005, and corresponding German legislation, with audits carried out by local authorities on a regular basis. The site is FAMI-QS (Feed Additive Premixture Quality System) and food (FSSC 22000) certified; the certificate can be obtained at www.dowpg.com. This facility is also Halal certified.
- Dow Freeport, TX PG USP/EP manufacturing site was last audited by the FDA in April 2004. The Dow Plaquemine, LA PG USP/EP manufacturing site was last audited by the FDA in February 2013 and one form 483 was issued. These facilities also food (FSSC 22000) certified; the certificate can be obtained at www.dowpg.com. These facilities are also Halal certified.
- Dow Map Ta Phut PG site is audited by Thailand FDA and obtained the local Food Production License in December 2012. The site is also Halal certified.
- All PG USP/EP manufacturing facilities are Kosher certified. A full list of facilities and terminals with corresponding Kosher certificates can be found on the website at www.dowpg.com
- IPEA third-party IPEC GMP certification for Dow PG USP/EP has been received by Freeport and Plaquemine, and is currently commercially available as DOW PuraGuard™ only in North America.

Section 3 IPEC-PQG GMP Compliance Details:

Description of how the sites comply with the IPEC-PQG cGMPs for Pharmaceutical Excipients
Current Good Manufacturing Practices (cGMP) as outlined by FDA, European Commission (EC) and compendia guidelines seek to ensure that components used in food and pharmaceutical products are not adulterated or contaminated. Conformance to FDA or EC standards is a requirement in many countries worldwide.

Dow's Propylene Glycol USP/EP is manufactured according to current Good Manufacturing Practices as defined in the "The Joint IPEC-PQG Good Manufacturing Practices Guide for Pharmaceutical Excipients" © 2006_The International Pharmaceutical Excipients Council and Pharmaceutical Quality Group.

Dow has implemented its Purity Plus standards to fulfill cGMP requirements. These standards include dedicated facilities for production and product handling, extensive quality assurance testing, ongoing global stability program, dedicated bulk storage and transportation in stainless steel or lined equipment, color differentiated packaging, label management, distributor and terminal clean room programs, and personnel qualification and training programs. In support of Dow-authorized distributors who are repackaging Dow product, Dow provides ongoing clean room drumming support including start up assistance and GMP/GDP reviews.

Quality Management Systems-Excipient Quality Systems (4)

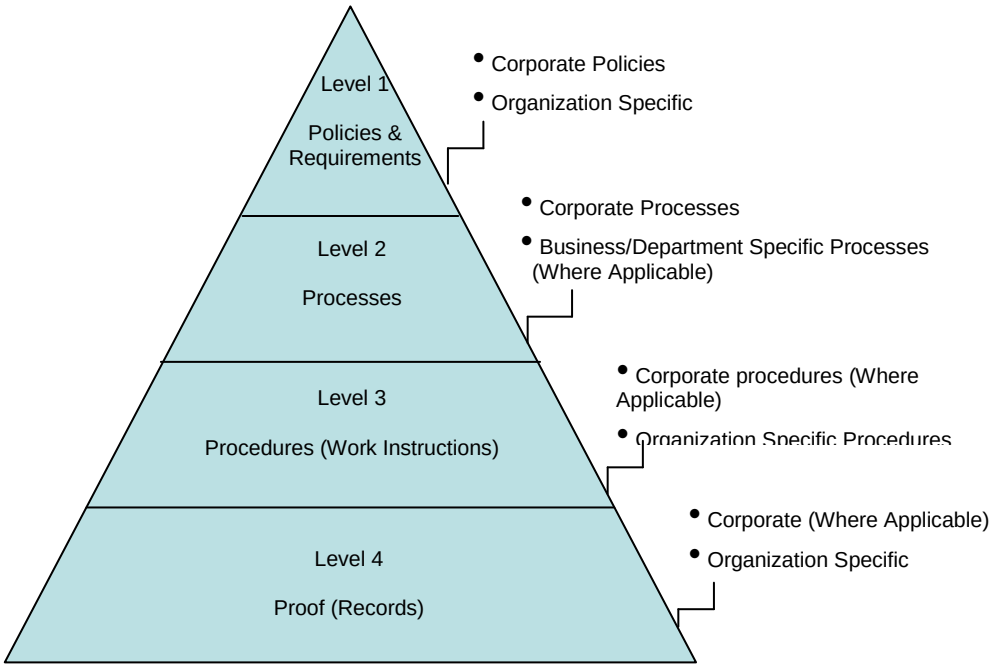
General Requirements (4.1)
Dow is organized around global businesses units designed to meet the changing needs of Dow's customers. The global businesses are responsible for selecting and implementing a quality management system that best fits the customer's respective needs, and the respective needs of their customers.

Dow's basic quality system requirements form part of the Operating Discipline Management System (ODMS), which is the company's comprehensive corporate management system that integrates the requirements of Operations, Quality, Environmental, Health and Safety, and Human Resource Management (People). Dow Corporate policy and requirements as well as current ISO 9001, Automotive Quality System requirements, Good Manufacturing Practices, ISO 14001 and Responsible Care requirements are included in the ODMS.

The quality system for the Propylene Glycol business is designed to conform to the following industry standard requirements:

- ISO 9001:2008
- Joint IPEC–PQG Current Good Manufacturing Practices Guide for Pharmaceutical Excipients, 2006

Documentation Requirements (4.2)
The following information summarizes the Dow ODMS document system model. The Propylene Glycol procedures are compliant with this model.



Controlled, electronic procedures are used wherever possible within the production facility. Changes to documents are maintained in a revision history and approvals of each document revision are clearly defined. Implementation of changes is conducted using Dow's global Management of Change work process which tracks completion of appropriate activities such as

training, document updates at the point of use, and integration with related documentation. All documents are managed by a web-based tool (EDMS).

Management Responsibility (5)

Management Commitment (5.1)
In each Dow business, leadership takes a visible and leading role in creating and sustaining core values, policies, strategies, directions, performance expectations, customer focus, continuous improvement and a management system that promotes performance excellence for business success.

Customer Focus (5.2)
The Dow Customer Service Center has developed strong customer relationships and additionally provides information regarding to products via http://www.dow.com/products/ In case of questions either contact the Answer Center at https://dow-answer.custhelp.com/app/home or Dow Customer Information Group.

Quality Policy (5.3)
The quality policy for the Propylene Glycol business is as follows:

"Quality Performance is a commitment to excellence by each Dow employee. It is achieved by teamwork and a process of continuous improvement.

We are dedicated to being the leader in providing quality products and services which meet or exceed the expectations of our customers."

Planning (5.4)
Dow's Propylene Glycol business maintains an improvement plan that includes clearly stated targets and objectives focused on People, Environmental, Health, & Safety (EH&S), Value Growth, and Operational Excellence. Quality objectives are clearly designated within the improvement plan and all are measurable and consistent with the business Quality Policy. Annual goals for each production facility are aligned with this business plan. Progress towards all targets, objectives, and goals are reviewed during the Management System Review and during other business meetings throughout the year.

Responsibility, Authority and Communication (5.5)
Responsibilities and authorities are clearly defined by Dow management through use of defined work processes and the roles and responsibilities required to ensure effectiveness. Each employee within the production facility has a written job description with defined responsibilities and has a training record to ensure they have the required skills, knowledge and experience to ensure success within the job.

The production facility has a defined Quality Unit, independent from manufacturing, which is led by the Business Quality Specialist. The Quality Unit has the responsibility and authority to approve or reject all raw materials, packaging components, intermediates and finished products. In addition, the Quality Unit participates in review and approval of changes within the facility's Notification of Change (NOC) and Management of Change (MOC) work processes.

Management Review (5.6)
Dow's Propylene Glycol business is part of Dow's Propylene Oxide/Propylene Glycol business within the Chemicals portfolio. The Business Quality Leader serves as the Management Representative for the global ISO 9001:2008 quality system. A Management System Review (MSR) is conducted at least once per year with the Management Representative and other business leadership. The objective of the MSR is to drive the PDCA (Plan, Do, Check and Act) cycle in an effective manner, for continuous improvement. The MSR is intended to complement other assessments and audits.

MSR review inputs include:

- Previous MSR Reports
- Audit Reports (Internal and External – especially systems)
- Self-Assessments (significant findings)
- Status of Corrective & Preventive Actions, MOC, Compliance Tasks
- Performance Results relative to Business Objectives and Targets
- Performance Results relative to Quality Objectives and Quality Policy
- Adequacy of current Measurements and Resources
- Work Process Performance and Product Conformity
- Concerns/Satisfaction from relevant interested parties (customers, clients, public)
- Data related to continuing suitability and effectiveness of all elements of the Management System in relation to changing conditions and the need or opportunity for improvement

MSR review outputs include:

- An assessment of the effectiveness of the quality system, quality objectives, and quality policy
- Resource determination for current and future activities
- Follow-up actions

Resource Management (6)

Provision of Resources (6.1)
Each Dow production facility utilizes established global work processes for all manufacturing, maintenance, testing, and quality activities. Within each of these work processes, roles and responsibilities are clearly defined. The work force includes sufficient salaried, hourly, and contract personnel to ensure the requirements of the work process and quality system are met. A portion of the work force are shared or leveraged across other facilities or businesses as appropriate.

Human Resources (6.2)
An Industrial hygiene policy is in place to ensure all personnel have proper protective equipment for the job they are performing. In addition, there are documented expectations regarding work attire and sanitation practices that must be followed.

The production facility has an established training program that is facilitated by the Training Coordinator. The responsibilities of the plant Training Coordinator include:

- Helping employees understand training requirements
- Assigning a Lead Trainer for job-specific training
- Assessing progress of people in job-specific training

- Notifying employees when licenses must be renewed
- Developing training programs and timelines
- Ensuring cGMP training is completed for all employees on an annual basis
- Maintaining records of training in the Dow training database, personnel files and/or the Plant Training Grid
- Ensuring compliance is achieved for all training policies and requirements

Infrastructure (Facilities and Equipment) (6.3)
Each Dow production facility has an adequate number of buildings, equipment, and raw materials to manufacture, process, package, test, and store products in accordance with quality system requirements. The buildings are in a good state of repair and all critical equipment has a preventative maintenance and cleaning schedule. Records of all repairs and scheduled activities such as lubrication and calibrations are maintained by Dow electronically within a global computer system.

Work Environment (6.4)
There is an active housekeeping and pest control program in place at Dow's PG USP/EP production facilities. The pest control program includes use of mechanical traps and bug lights.

Product Realization (7)

Planning of Product Realization (7.1)
PG USP/EP from Dow is produced synthetically from propylene oxide and water at high temperature and pressure without the use of catalysts or additives. Product requirements are documented within individual product specifications which are located in the Specification and Recipe Repository (SRR) portion of the SAP* architecture. In-process and final product sampling and testing plans are documented.

A production schedule is developed by the global Supply Chain group based on customer forecasting and order activities. Measurements are in place to monitor the effectiveness of the planning and scheduling work processes.

Customer-Related Processes (7.2)
Dow's PG USP/EP is supplied to customers globally based on a uniform, standardized sales specification which includes all items of the current USP, EP (Ph.Eur.), JP FCC monographs for propylene glycol, plus additional Dow specific test items. Any customer requirement that exceeds the standard offering is assessed following the Customer Specification Rule. If the value is supported and the requirement can be met, a customer specification will be put in place. The Technical Service & Development group works actively with strategic customers to develop meaningful specifications to ensure success of the Dow product in their application.

Changes considered within the business and production facility are evaluated using the IPEC Americas Significant Change Guideline for Bulk Pharmaceutical Excipients (2009). Documented guidelines for communication to customers are followed based on the significance of a level 1, 2, or 3

* SAP is a software application known as enterprise resource planning or ERP. Enterprise resource planning software is essentially a set of software applications that are intended to integrate and streamline business processes.

change. Changes are managed using Dow's web-based e-MOC tool (electronic Management of Change tool).

Design and Development (7.3)
New products and processes are developed using the Innovate Commercial Offering (ICO) global work process. As appropriate, trials will be conducted in a lab or pilot plant setting or within the main production facility using an experimental run plan.

Purchasing (7.4)
Each Dow production facility has specifications or service agreements in place to ensure suppliers of raw materials, packaging materials and services meet agreed upon requirements. Raw material specifications are documented within the SRR portion of the SAP architecture. Raw materials and packaging materials are evaluated and verified prior to approval for use by the Quality Unit. Supplier qualification and assessment procedures are in place and performance of each supplier is monitored.

Production and Service Operations (7.5)
The Propylene Glycol manufacturing process (Attachment 2) is a continuous, computer-controlled process, carried out in a closed system isolated from the atmosphere. Process personnel control the production process in accordance with daily operational schedules using computer process control (MODV® or ABB system) and process data system with documented operating conditions. There is traceability forward from the raw materials through to the final batch/lot and backward from final batches/lots through to the raw materials. Final batches/lots are assigned a unique batch/lot number which is assigned based on isolated, released sales tank quantities

Master production records are in place for each product family and detailed batch records are created for each final batch. In-process and final product sampling and testing plans are in place to ensure appropriate monitoring of defined critical process and product parameters occurs within each unit operations of the production process. Validated cleaning procedures are in place for use after maintenance and shutdown activities.

Control of Measuring and Monitoring Devices (7.6)
Quality critical equipments are defined within each Dow facility as those necessary to manufacture, test or ensure compliance with product specifications. Malfunction or improper operation of this equipment may result in an altered or suspect product that may be unacceptable for sale. A quality critical instrument is further defined as a system, including measuring device and hardware/software response, used to control the specific measured parameters.

All quality critical equipment and instrumentation are on a documented schedule for calibration and maintenance. The schedule is established by considering such things as manufacturer's recommendation, past experience, nature of the process, or other pertinent factors. Non-routine maintenance activities are also scheduled when specific problems such as leaks, known or suspected equipment failure, or visual inspections show a need.

Measurement, Analysis and Improvement (8)

Planning (8.1)
The performance of key process and product metrics throughout each Dow production facility are monitored and trended on a daily basis to determine if improvements are warranted. Most improvement projects are conducted using Six Sigma quality improvement methodology. This

methodology includes Measure-Analyze-Improve-Control phases and concludes with a period where effectiveness of the established control plan is verified.

Measurement and Monitoring (8.2)
Each Dow production facility conducts internal audits at planned intervals to ensure the quality management system conforms to the requirements of ISO 9001:2008 standard, current Good Manufacturing Practices (cGMPs), and is effectively implemented and maintained. The responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records are defined in a documented plant policy. Required elements to be audited include:

- All sections of the ISO 9001:2008 standard, and the ISO 14001:2004 standard (where applied)
- A tour of the facility
- Traceability assessment and batch record review
- Review of supplier audit program
- Review of product stability program
- Evaluate effectiveness of the housekeeping and pest control programs and documentation

Audit results are communicated to management on a routine basis as well as during the Management System Review. Corrective actions are entered in a tracking database to ensure documentation of root cause, closure of follow-up, and verification of effectiveness.

The facility has a comprehensive analytical sample and testing plan which includes the location and frequency of sampling as well as the tests to be conducted for each sample. The results of the in-process and final product testing are used to monitor processes and products in addition to supporting release of final batches into commerce. Test methods are either pharmacopoeia methods, industry standard or developed within Dow and validated to ensure adequate precision and accuracy for the intended use.

Control of Nonconforming Product (8.3)
Raw materials and packaging materials are taken through a documented acceptance evaluation upon receipt by Dow. Materials determined to be non-conforming are quarantined pending further evaluation and investigation with the supplier. If rejected, the materials are returned to the supplier. Records of non-conforming raw materials and packaging materials are maintained by the Quality Unit.

Intermediate and finished products are thoroughly assessed by the Quality Unit to determine final disposition. This assessment includes a review of batch records, maintenance activities, cleaning records, and testing records. Batches determined to be non-conforming are quarantined pending further evaluation and investigation to determine root cause. Disposition of non-conforming batches can include downgrading, or disposal. Non-conforming product is not reworked or reprocessed. Records of non-conforming raw materials and packaging materials are maintained by the Quality Unit.

Analysis of Data (8.4)
Dow's production facilities are focused on continuous improvement of products and work processes. Improvement projects are triggered from the following sources:

- Internal Audits and Self Assessments
- Customer Audits
- Third Party Audits

- Customer Complaints
- Product Reviews
- Management System Reviews

As mentioned previously, most improvement projects are conducted using Six Sigma quality improvement methodology. This methodology includes Measure-Analyze-Improve-Control phases and concludes with a period where effectiveness of the established control plan is verified.

Improvement (8.5)
A documented corrective and preventive action procedure is in place at each Dow production facility which ensures that issues such as product nonconformities, the manufacturing process and associated work processes, customer complaints, complaints to suppliers (subcontractors), and problems with the quality system itself are investigated in a timely manner to determine root cause and appropriate follow-up actions.

Section 4 Miscellaneous Site Information:

HACCP Program:
Compliance with Hazard Analysis and Critical Control Point or HACCP is a systematic approach to the identification, evaluation, and control of food safety hazards.

Propylene Glycol USP/EP (PG USP/EP) is used as an excipient in pharmaceutical products and as a direct food additive in accordance with the applicable sections of Title 21 Code of Federal Regulations and is regulated as E1520 in the European food additive register (an amendment of EU Directive 95/2/EC). Dow's PG USP/EP is manufactured according to the guidelines defined in "The IPEC-PQG Good Manufacturing Practices Guide for Bulk Pharmaceutical Excipients" © 2006 The International Pharmaceutical Excipients Council (IPEC). Dow's proven compliance with GMP requirements provides a very strong basis for meeting the prerequisite program (PRP) requirements of HACCP.

In addition, the Dow PG USP/EP business continues to work on assuring that supporting documentation is in place for meeting the requirements of the Global Food Safety Initiative (GFSI). The production plants in the US and Germany are food certified (FSSC 22000).

Dow PG USP/EP is manufactured from hydrocarbon raw materials in a closed, continuously-operated process utilizing dedicated equipment. The process is not open to the environment at any time during normal operations, prior to loading it into shipping containers, so contamination by foreign materials is unlikely. The material is tested for compliance with the U.S., European, and Japanese Pharmacopoeia plus the U.S. Food Chemicals Codex, all of which require that the material not be contaminated or adulterated.

Six Sigma Quality Improvement Methodology:
Most improvement projects within the production facility are conducted using Six Sigma quality improvement methodology. This methodology includes Measure-Analyze-Improve-Control phases and concludes with a period where effectiveness of the established control plan is verified.

Section 5 Revision History

Date	Changes
12 July 2006	Created document
04 May 2008	Reviewed and updated content
17 September 2010	Reviewed and updated Organization chart, added Customer Focus section and Manufacturing site addresses, updated Lot numbering information, Terminal information and certification information
May 2012	Updated certificates, info about HACCP and lot numbering system
July 2013	Added Map Ta Phut related information and new lot numbering system for LA an APA
August 2014	Revised. Certification and batch information updated.

Section 6 Contact Information

Information about Dow's product and quality system is readily available to all Propylene Glycol USP/EP customers on the business web site at www.dowpg.com.

Additional information about PG USP/EP is readily available at the ANSWER CENTER located on the PG business web site. The ANSWER CENTER is a dynamic knowledge database that provides answers to frequently-asked technical questions and other valuable information related to Dow's PG USP/EP and other products.

If you can't find what you're looking for, please contact your local Dow representative or the Dow Customer Information Group in your area:

U.S and Canada: 1-800-441-4DOW (4369)

Latin America: +55-11-5188-9000

Europe: +800-3-694-6367

Asia Pacific: +800-7776-7776

E-mail: dowcig@dow.com

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Attachment 1: Manufacturing Site addresses

North America Manufacturing sites:

The Dow Chemical Company
2301 N. Brazosport Blvd.
PO/PG Plant
Freeport, TX 77541

The Dow Chemical Company
21255 Hwy 1
PO/PG Plant
Plaquemine, LA 70764

Stade Manufacturing site:

Dow Deutschland Anlagengesellschaft mbH
POPG Facility
Buetzflethersand
21683 Stade, Germany

Altona Manufacturing site:

Altona POD Plant
541-583 Kororoit Creek Rd.
Altona, Victoria, Australia 3018

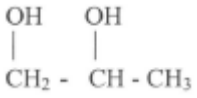
Aratu Manufacturing site:

Dow Brasil S.A.
Aratu Industrial Plant
Rodovia Matoim SN Rotula 3 St.2
Candeias, BA, Brazil 43813-000

Map Ta Phut Manufacturing site:

Dow Chemical Thailand Ltd.
No.10/4, Moo 2, Ban Chang Sub-district
Ban Chang District, Rayong,
Thailand.

Attachment 2: Propylene Glycol USP/EP Process Description

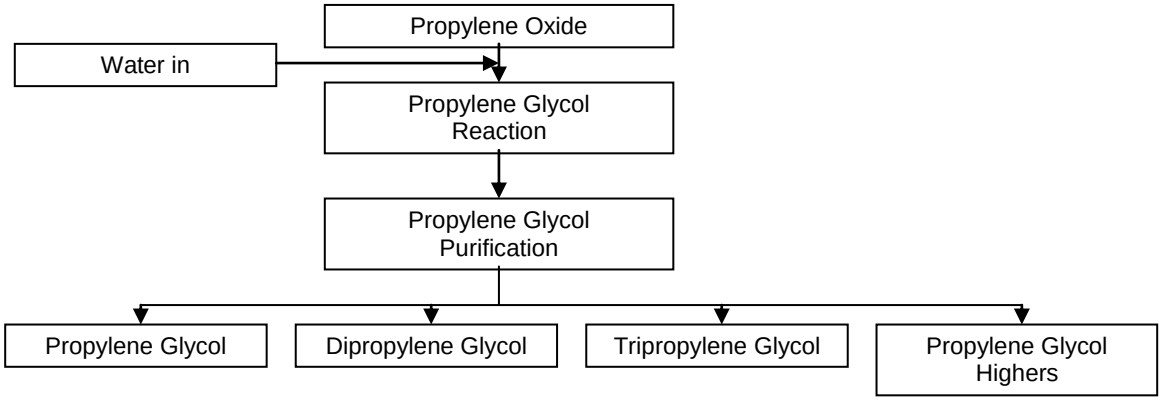
Propylene Glycol 

Molecular Weight 76.1

CAS # 57-55-6,
EINECS # 200-338-0

Synthesis 

Manufacturing Process



Attachment 3: Propylene Glycol USP/EP Batch Numbering Process

The Dow lot/batch naming system is based on a written Global procedure. The lot/batch number is a 10 digit alpha-numeric code, which Dow uses to ensure traceability of the PG USP/EP, back to the raw materials, and its movements. The batch/lot assignment for PG USP/EP is based on isolated, released tank quantities.

FOOD SAFETY MANAGEMENT SYSTEM OVERVIEW

Facility Overview

PRODUCTS COVERED BY THIS DOCUMENT:

PROPYLENE GLYCOL USP/EP (PG USP/EP)
PURAGUARD™ PROPYLENE GLYCOL USP/EP (PG USP/EP)

Company/Site:
The Dow Chemical Company ("Dow") Propylene Oxide / Propylene Glycols Business has five manufacturing sites for PG USP/EP around the world as listed below. Please see Attachment 1 for site addresses.

- Freeport, Texas, USA
- Plaquemine, Louisiana, USA
- Altona, Australia
- Aratu, Brazil
- Stade, Germany
- Map Ta Phut, Thailand

Headquarter Address:

The Dow Chemical Company
Propylene Oxide/Propylene Glycols Business
2040 Dow Center
Midland, MI 48674
USA

Corporate Ownership
The Dow Chemical Company ("Dow") is a diversified, worldwide manufacturer and supplier of chemicals and performance products, plastics, hydrocarbons and consumer specialties, including agricultural products and pharmaceuticals. Founded in 1897 by Herbert H. Dow, it is one of the largest chemical companies in the world in terms of sales. In 2011, Dow had annual sales of $60 billion and employed approximately 52,000 people worldwide. The Company's more than 5,000 products are manufactured at 197 sites in 36 countries across the globe. The company's corporate and U.S.A. headquarters are located in Midland, Michigan. Dow is divided into global businesses and functions that are integrated at each site and geography. More information is available at www.dow.com.

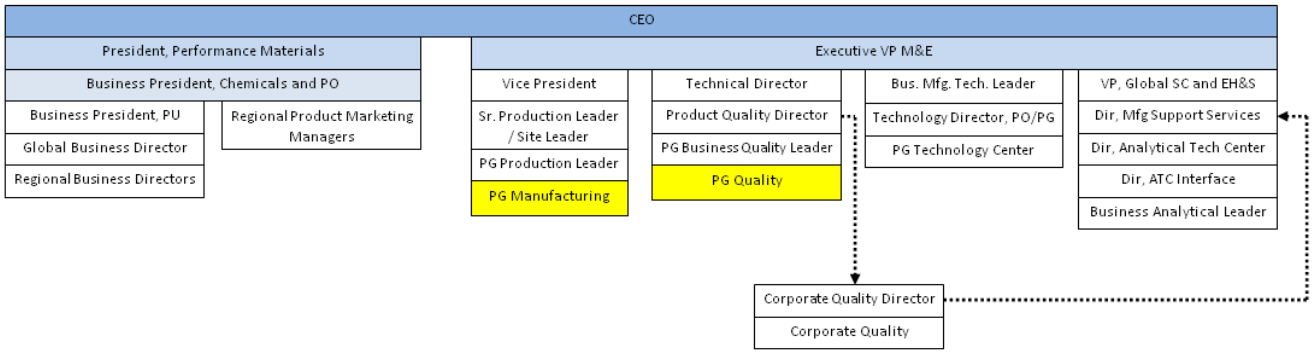
Manufacturing Process

Dow PG USP/EP is manufactured from hydrocarbon raw materials in a closed, continuously-operated process utilizing dedicated equipment. The process is not open to the environment at any time during normal operations, prior to loading it into shipping containers, so contamination by foreign materials is unlikely. The material is tested for compliance with the U.S., European, and Japanese

Pharmacopoeia plus the U.S. Food Chemicals Codex, all of which require that the material not be contaminated or adulterated. See Attachment 2 for Process Flow Diagram.

Organizational chart PO/PG Business

Per the organization diagram below, the quality function is independent of the production unit (dotted lines: administrative reporting only) and is responsible for making decisions regarding raw material acceptance and product release, or process changes that might impact quality.



External Certifications and Audit Programs

ISO 9001 Registration Information

- *Texas facility has been ISO 9001:2008 certified since June 1995.*
- *Louisiana facility has been ISO 9001:2008 certified since June 1997.*
- *Stade facility is ISO certified (9001:2008 and 14001).*
- *Aratu facility is ISO 9001:2008 certified.*
- *Altona facility is AS/NZS ISO 9001: 2008 certified.*

LRQA Approval Certificate No. 0112979. ISO Certificates are available on www.dowpg.com

Other Certifications or External Audit Programs

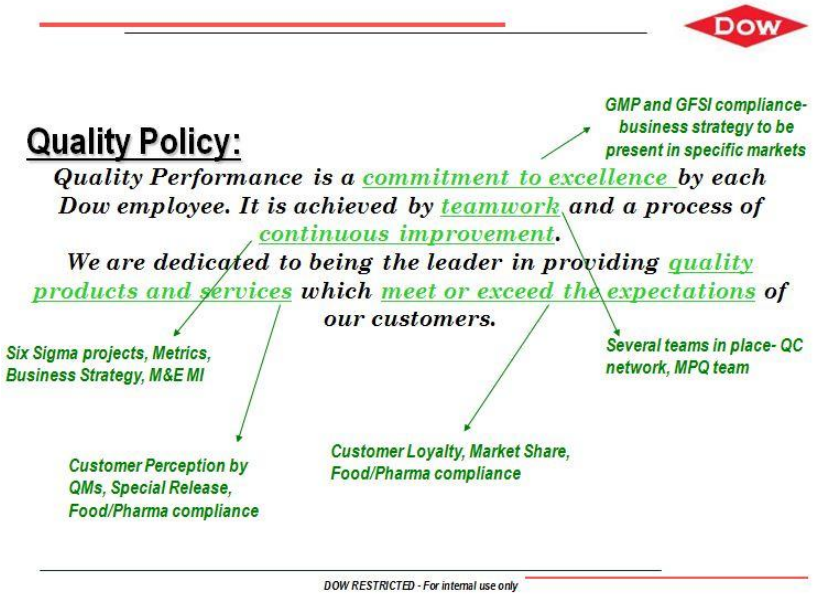
The compliance of Propylene Glycol USP/EP, produced in all global Dow locations, with the relevant government/pharmacopoeia requirements is given on the sales specification in the Government/Industry Standard section and on the certificate of analysis provided with each shipment. Additional audit programs include:

- Dow Stade PO/PG site is registered as an animal feed additive producer, based on EU regulation EC 153/2005, and corresponding German legislation, with audits carried out by local authorities on a regular basis. The site is also FAMI-QS (Feed Additive Premixture Quality System) certified; the certificate can be obtained at www.dowpg.com. This facility is also Halal certified.
- Dow Freeport, TX and Plaquemine, LA manufacturing sites were audited by International Pharmaceutical Excipients Auditing (IPEA) and achieved third party certification to current Good Manufacturing Practices as defined in the "The Joint IPEC-PQG Good Manufacturing Practices Guide for Pharmaceutical Excipients" and ANSI standard in March 2011. These facilities are also Halal certified.
- Health Agency ANVISA in Brazil (National Health Agency) has audited Dow manufacturing site at Aratu and Marine Terminal at Guaruja – Brazil.

- All PG USP/EP manufacturing facilities are Kosher certified. A full list of facilities and terminals with corresponding Kosher certificates can be found on the website at www.dowpg.com.

Quality and Food Safety Policy

The propylene glycol business follows the corporate Dow Chemical quality policy which is also applicable for food safety. The policy is explained below:



Food Safety Teams

Food Safety Team Leader (ISO 22000 Section 5.5)
The Propylene Glycol Business Quality Leader has appointed Food Safety Team Leaders for each of the global manufacturing locations. This role is filled by the Quality Coordinator at each plant and is shown on the organizational chart above. The team leader manages the food safety team, organizing its work and making sure that all members have relevant training and education. The team leader is responsible for making sure that the FSMS is maintained and updated and reports to top management on the effectiveness and suitability of the system.

Food Safety Team (ISO 22000 Section 7.3.2)
Top management has appointed Food Safety Teams and Team Leaders for each manufacturing plant. The teams are made up of qualified personnel representing each relevant function of the plants. The teams are carefully composed to provide multi-disciplinary experience and knowledge of the products, processes, equipment and food safety hazards.

Food Safety Training

Competence, Awareness, and Training (ISO 22000 Section 6.2.2)
All personnel are trained on applicable regulatory requirements, the principles of a food safety management system, and the relevance and importance of their activities on the safety of the

products, on their responsibility to report problems with the food safety management system, and on the requirements for effective communication. Records of training are maintained.

Prerequisite Program (PRP)

Prerequisite Programs (ISO/TS 22002-1; ISO 22000 Section 7.2)
Prerequisite program requirements are described in ISO/TS 22002-1. PRPs are established to provide a foundation for our FSMS program and have been fully implemented to help control the risk of introducing food safety hazards.

For the propylene glycol business, Good Manufacturing Practices (GMP) is the basis of the PRP program. Each plant follows the current version of the International Pharmaceutical Excipients Council (IPEC) Current Good Manufacturing Practices Guide for Bulk Pharmaceutical Excipients and has implemented remaining PRPs listed in ISO/TS 22002-1 which are not covered by the IPEC cGMPs.

Hazard Analysis

Hazard Analysis (ISO 22000 Section 7.4)
A Hazard Analysis (risk assessment) was performed with input from the Food Safety Teams and the Technology Center functions to determine which food safety hazards must be controlled, to what degree and in what combination they are needed to ensure the safety of the product. A generic hazard analysis was conducted on a global level for Manufacturing as well as Supply Chain and Packaging to identify common hazards that exist for all manufacturing plants.

Additionally, each manufacturing location performs a hazard analysis for their particular facility to identify if any additional hazards exist beyond those identified in the generic analysis.

Operational Prerequisite Programs (oPRPs)

Operational Prerequisite Programs (ISO 22000 Section 7.5)
A program is established and documented for each of the controls that have been identified as an operational PRP. The program includes the information detailed in the Propylene Glycol Food Safety Management System manual.

HACCP Plan

HACCP Plan (ISO 22000 Section 7.6.1)
The Propylene Glycol business has established and documented a global HACCP plan. The plan identifies the hazards, if any, to be controlled at each control point, the control measures used, critical limits, the monitoring procedures, the corrections and corrective actions to be taken if limits are exceeded. The HACCP procedure documents the responsibilities, authorities and records relating to the HACCP Plan.

Critical Control Points (ISO 22000 Section 7.6.2)
No Critical Control Points (CCPs) have been identified for current manufacturing process due to the closed, dedicated process. If any hazards are identified, they are controlled by the HACCP Plan.

Critical Limits (ISO 22000 Section 7.6.3)
For each CCP identified (if any), for each monitoring point, a critical limit is determined, and the rationale for that limit is documented. The critical limit is set to ensure that an acceptable level of the hazard is not exceeded.

Monitoring of Critical Control Points (ISO 22000 Section 7.6.4)
A monitoring system is designed and documented for each CCP (if any) to demonstrate that the CCP is in control. This system consists of procedures, work instructions and records defining the measurements or observations, timeframes, monitoring devices, calibration methods, frequency, responsibilities and authorities, and records. The monitoring systems identify when the critical limits have been exceeded in time for the product to be isolated before it is used or consumed.

Deviation (CAPA) Procedures (ISO 22000 Section 7.6.5)
The plant's HACCP Plan identifies what corrections or corrective actions must be taken when results exceed critical limits. The cause of the nonconformity is identified; the out of control parameter is brought back under control and preventive action taken to ensure that the nonconformity does not reoccur.

Verification Procedures (ISO 22000 Section 7.8 and Section 8)
Activities that are used to verify the effectiveness of the food safety management system include, but are not limited to:

- Internal audits of the food safety management system (including the PRP).
- Review of CCP measurements (if applicable) and compliance with established limits.
- Management System Review (MSR) that includes a review of food safety management system elements.

Attachment 1: Manufacturing Site addresses

North America Manufacturing sites:

The Dow Chemical Company
2301 N. Brazosport Blvd.
PO/PG Plant
Freeport, TX 77541

The Dow Chemical Company
21255 Hwy 1
PO/PG Plant
Plaquemine, LA 70764

Stade Manufacturing site:

Dow Deutschland Anlagengesellschaft mbH
POPG Facility
Buetzflethersand
21683 Stade, Germany

Altona Manufacturing site:

Altona POD Plant
541-583 Kororoit Creek Rd.
Altona, Victoria, Australia 3018

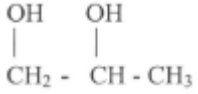
Aratu Manufacturing site:

Dow Brasil S.A.
Aratu Industrial Plant
Rodovia Matoim SN Rotula 3 St.2
Candeias, BA, Brazil 43813-000

Map Ta Phut Manufacturing site:

Dow Chemical Thailand. Ltd.
No. 8, I-4 Road
Map Ta Phut Industrial Estate
Muang, Rayong, Thailand 21150

Attachment 2: Propylene Glycol USP/EP Process Description



Propylene Glycol

Molecular Weight 76.1

CAS # 57-55-6,
EINECS # 200-338-0

Synthesis

Manufacturing Process