

 DOW CHEMICAL PACIFIC (SINGAPORE) PRIVATE LIMITED		PT.LANCAR JAYA GLOBALINDO JL.MENCENG RAYA NO.33 RT 009 JAKARTA JK 11820 ID Ship From: Yusen Laem Chabang Sub Mft Chonburi Thailand			
Certificate of Analysis Product Number 00000114877 Product Name Propylene Glycol USP/EP Delivery No. 824635640 / 000010 Order Number 114467695 Shipping Units 80.000 DR Date Shipped 2022-12-21 (YYYY-MM-DD) Shipment No. 41973890		Customer Information Customer Name PT.LANCAR JAYA GLOBALINDO Customer PO number 000250/LJG/2022 Container ID TCLU6183756 Specification Number 000000059518			
Batch Number Seal Number Expiration Date Manufacturing Date Quantity Net Weight Manufacturing Plant Manufacturer Address Manufacturer: Dow Chemical Thailand Ltd		C815MSTR41 ML-TH0059327 2024-11-29 (YYYY-MM-DD) 2022-11-29 (YYYY-MM-DD) 80.000 DR 17200.000 KG MTP AIE PG 10/4 Moo 2 ASIA IND EST BANCHANG Rayong 21130			
It is hereby certified that the material indicated above has been inspected and tested in accordance with the conditions and requirements of the contract or purchase order and, unless agreed otherwise conforms in all respects to the specification relevant thereto and it meets all requirements of the current United States Pharmacopoeia, current Food Chemical Codex, current European Pharmacopoeia and current Pharmacopoeia of Japan.					
Test	Unit	Lower Limit	Upper Limit	Value	Method
Assay	%	99.80	-	99.96	Current USP ✓
M Acidity	ml	-	0.20	0.02	Current USP ✓
M Chlorides	ppm	-	70	< 70	Current USP ✓
M Residue on Ignition per 50g	mg	-	3.50	2.48	Current USP ✓
M Specific Gravity @ 25/25degC		1.035	1.037	1.035	Current USP ✓
Spec. Grav. @ 20C		1.0376	1.0389	1.0379	ASTM D4052
M Sulfate	ppm	-	60	< 60	Current USP ✓

Butuh penyediaan terlampir

Date

2022-12-22 (YYYY-MM-DD)

Time 04:10:15 (Greenwich Mean Time) Page 2 of 4

DOW		PT.LANCAR JAYA GLOBALINDO			
DOW CHEMICAL PACIFIC (SINGAPORE) PRIVATE LIMITED		JL.MENCENG RAYA NO.33 RT 003 JAKARTA JK 11820			
		ID Ship From: Yusen Laem Chabang Sub Mft Chonburi Thailand			
Water Content	%	-	0.200	0.009	Current USP ✓
M ID Test A matches IR scan	-	-	-	Pass	Current USP ✓
ID Test B Limit of Ethylene Glycol	-	-	-	Pass	Current USP ✓
ID Test B Limit of Diethylene Glycol	-	-	-	Pass	Current USP ✓
ID Test C Matches GC Scan	-	-	-	Pass	Current USP ✓
M Acidity	ml	-	0.05	0.02	Current EP
A Boiling Point	°C	184	189	185	Current EP
M Clarity	-	-	-	Pass	Current EP
M Color	-	-	-	Pass	Current EP
O Melting Point	°C	121	128	126	Current EP
N Oxidizing Substances 0.05M sodium thiosulfate	ml	-	0.20	0.05	Current EP
M Reducing Substances	-	-	-	Pass	Current EP
M Refractive Index @ 20degC	-	1.431	1.433	1.433	Current EP
M Relative Density @ 20/20degC	-	1.035	1.040	1.038	Current EP
M Sulfated ash	%	-	0.0100	0.0024	Current EP
Water Content	%	-	0.200	-	Current EP
Assay	%	99.80	-	99.96	Current FCC
M Acidity	-	-	-	Pass	Current FCC
M Appearance clear & colorless	-	-	-	Pass	Current FCC
M Distillation, IBP	°C	185.0	-	187.0	Current FCC
M Distillation, DP	°C	-	189.0	188.0	Current FCC
Lead (Pb)	ppm	-	1.0	< 1.0	Current FCC
M Identification matches IR scan	-	-	-	Pass	Current FCC
M Residue on Ignition	%	-	0.0070	0.0018	Current FCC

Butuh pengesahan
terlampir

Date

2022-12-22 (YYYY-MM-DD)

Time 04:10:15 (Greenwich Mean Time) Page 3 of 4

DOW

DOW CHEMICAL PACIFIC
(SINGAPORE) PRIVATE LIMITED

PT. LANCAR JAYA GLOBALINDO

JL. MENCENG RAYA NO.33 RT 009

JAKARTA

JK

11820

ID

Ship From: Yusen Laem Chabang Sub Mft

Chonburi

Thailand

		1.035	1.037	1.035	Current FCC
M Specific Gravity @ 25/25degC		-	-	-	
Water Content	%	-	0.200	0.009	Current FCC
M Acidity	-	-	-	Pass	Current JP
M Arsenic	ppm	-	2.0	< 2.0	Current JP
M Chlorides	%	-	0.007	< 0.007	Current JP
M Distilling Range 184 - 189 degC	% vol	95	-	97	Current JP
M Glycerine (Odor)	-	-	-	Pass	Current JP
M Heavy Metals	ppm	-	5.0	< 5.0	Current JP
Melting Point	°C	174	178	176	Current JP
Odor	-	-	-	Pass	Current JP
M Residue on Ignition	%	-	0.0050	0.0016	Current JP
M Specific Gravity @ 20/20degC		1.035	1.040	1.038	Current JP
M Sulfate	%	-	0.002	< 0.002	Current JP
Water Content	%	-	0.500	0.009	Current JP
Acidity as acetic acid	%	-	0.0020	0.0003	DOWM 101370
Appearance clear, free of suspended matter	-	-	-	Pass	Visual
Chlorides	ppm	-	1.0	< 1.0	DOWM 101867
Color, Pt-Co	-	-	10	2	ASTM D5386
Dimer, Trimer & Higher Polymers	%	-	0.100	0.037	DOWM 100687
Ethylene Glycol ✓	%	-	0.0080	< 0.0080	DOWM 100687
Diethylene Glycol ✓	%	-	0.0080	< 0.0080	DOWM 100687
Odor	-	-	-	Pass	Olfactory
practically odorless	-	-	-	-	-
Iron	ppm	-	0.30	< 0.01	ASTM E394

Note 1:
values reported for Assay, Ethylene Glycol and Diethylene Glycol under USP and for Assay under FCC are obtained using the validated equivalent Dow GC Method DOWM 100687.

M: Quarterly Sample

Butuh penyesuaian
terlampir

Date 2022-12-22 (YYYY-MM-DD)

Time 04:10:15 (Greenwich Mean Time) Page 4 of 4

 DOW CHEMICAL PACIFIC (SINGAPORE) PRIVATE LIMITED	PT. LANCAR JAYA GLOBALINDO JL.MENCENG RAYA NO.33 RT 009 JAKARTA JK 11820 ID Ship From: Yusen Laem Chabang Sub Mft Chonburi Thailand
<u>Q:Annual Sample</u> Plant Quality Coordinator For inquiries please contact Customer Service or local sales ® = Trademark of The Dow Chemical Company ("Dow") or an affiliated company of Dow	

gms 16/12/22

Butuh pengesahan
terlampir

STANDARISASI CERTIFICATE OF ANALYSIS API PRODUK

No	Nama Bahan	Manufaktur	Referensi pada CoA Manufacturer saat ini	Referensi pada CoA yang diusulkan	Penyesuaian Parameter			Nomor SPBB	Keterangan
					Parameter yang Dihilangkan	Parameter yang Ditambah	Parameter yang direvisi		
1	Propylen Glycol	Dow	USP/EP	USP47/ FI VI	-	Pemerian menyesuaikan USP 47	Assay : $\geq 99.5\%$ sesuai USP 47	RD.02-SBC/019.03	Penyesuaian CoA dari Manufacturer
					-	Kelarutan menyesuaikan USP 47			

Diperiksa oleh,

 22/11/24

Koordinator QC

 22/11/24

Koordinator TS

 22/11/24

Koordinator QA

Disetujui oleh,

 22/11/24

Manager QA

Freely soluble in water; very slightly soluble in alcohol; insoluble in ether and in chloroform.

Prochlorperazine Maleate: White or pale yellow, practically odorless, crystalline powder. Its saturated solution is acid to litmus. Slightly soluble in warm chloroform; practically insoluble in water and in alcohol.

Procyclidine Hydrochloride: White, crystalline powder, having a moderate, characteristic odor. Melts at about 225°, with decomposition. Soluble in water and in alcohol; insoluble in ether and in acetone.

Progesterone: White or creamy white, odorless, crystalline powder. Is stable in air. Soluble in alcohol, in acetone, and in dioxane; sparingly soluble in vegetable oils; practically insoluble in water.

Proguanil Hydrochloride: White, crystalline powder. Sparingly soluble in alcohol; slightly soluble in water; practically insoluble in methylene chloride.

Proline: White, odorless crystals, having a slightly sweet taste. Freely soluble in water and in absolute alcohol; insoluble in ether, in butanol, and in isopropanol.

Promazine Hydrochloride: White to slightly yellow, practically odorless, crystalline powder. It oxidizes upon prolonged exposure to air and acquires a blue or pink color. Freely soluble in water and in chloroform.

Promethazine Hydrochloride: White to faint yellow, practically odorless, crystalline powder. Slowly oxidizes, and acquires a blue color, on prolonged exposure to air. Freely soluble in water, in hot dehydrated alcohol, and in chloroform; practically insoluble in ether, in acetone, and in ethyl acetate.

Propafenone Hydrochloride: White powder. Soluble in methanol and in hot water; slightly soluble in alcohol and in chloroform; very slightly soluble in acetone; insoluble in diethyl ether and in toluene.

Propane: Colorless, flammable gas (boiling temperature is about -42°). One hundred volumes of water dissolves 6.5 volumes at 17.8° and 753 mm pressure; 100 volumes of anhydrous alcohol dissolves 790 volumes at 16.6° and 754 mm pressure; 100 volumes of ether dissolves 926 volumes at 16.6° and 757 mm pressure; 100 volumes of chloroform dissolves 1299 volumes at 21.6° and 757 mm pressure. Vapor pressure at 21° is about 10290 mm of mercury (108 psi). *NF category:* Propellant.

Propanediol: Clear, colorless, hygroscopic liquid. *Specific Gravity* (841), *Method I*: 1.040–1.065. Soluble in water, in alcohol, in methyl alcohol, in isopropyl alcohol, in butyl alcohol, in acetone, in propylene glycol, and miscible with many polar solvents. *NF category:* Humectant; solvent; wetting and/or solubilizing agent.

Propantheline Bromide: White or practically white crystals. Is odorless and has a bitter taste. Melts at about 160°, with decomposition. Very soluble in water, in alcohol, and in chloroform; practically insoluble in ether and in benzene.

Proparacaine Hydrochloride: White to off-white, or faintly buff-colored, odorless, crystalline powder. Its solutions are neutral to litmus. Soluble in water, in warm alcohol, and in methanol; insoluble in ether and in benzene.

Proparacaine Hydrochloride Ophthalmic Solution: Colorless or faint yellow solution.

Propionic Acid: Oily liquid having a slight pungent, rancid odor. Miscible with water and with alcohol and various other organic solvents. *NF category:* pH modifier (acidifying agent/alkalizing agent/buffering agent); antimicrobial preservative; antioxidant.

Propofol: Clear, colorless to slightly yellowish liquid. Very soluble in methanol and in ethanol; slightly soluble in cyclohexane and in isopropyl alcohol; very slightly soluble in water.

Propranolol Hydrochloride: White to off-white, crystalline powder. Is odorless and has a bitter taste. Melts at

about 164°. Soluble in water and in alcohol; slightly soluble in chloroform; practically insoluble in ether.

Propyl Gallate: White, crystalline powder having a very slight, characteristic odor. Freely soluble in alcohol; slightly soluble in water. *NF category:* Antioxidant.

Propylene Glycol: Clear, colorless, viscous liquid having a slight, characteristic taste. Is practically odorless. Absorbs moisture when exposed to moist air. Miscible with water, with acetone, and with chloroform. Soluble in ether and will dissolve many essential oils, but is immiscible with fixed oils. *NF category:* Humectant; plasticizer; solvent; antimicrobial preservative.

Propylene Glycol Alginate: White to yellowish fibrous or granular powder. Practically odorless and tasteless. Soluble in water, in solutions of dilute organic acids, and, depending on the degree of esterification, in hydroalcoholic mixture containing up to 60% by weight of alcohol to form stable, viscous colloidal solutions at a pH of 3. *NF category:* Suspending and/or viscosity-increasing agent; emulsifying agent.

Propylene Glycol Diacetate: Clear, colorless liquid having a mild, fruity odor. Soluble in water. *NF category:* Emulsifying agent; solvent.

Propylene Glycol Dicaprylate/Dicaprate: Clear, colorless or slightly yellow oily liquid at 20°. Soluble in fatty oils and in light petroleum; slightly soluble in dehydrated alcohol; practically insoluble in water. *NF category:* Emulsifying agent; vehicle.

Propylene Glycol Dilaurate: Clear, oily liquid at 20°. Colorless or slightly yellow. Very soluble in alcohol, in methanol, and in methylene chloride; practically insoluble in water. *NF category:* Emollient; emulsifying agent.

Propylene Glycol Monocaprylate: Clear, colorless, or slightly yellow, oily liquid at 20°. Very soluble in alcohol, in chloroform, and in methylene chloride; practically insoluble in water. *NF category:* Vehicle; emulsifying agent; diluent.

Propylene Glycol Mono and Dicaprylate: Clear, colorless, or slightly yellow, oily liquid at 20°. Very soluble in alcohol, in chloroform, and in methylene chloride; practically insoluble in water. *NF category:* Vehicle (solid carrier); emulsifying agent; diluent.

Propylene Glycol Monolaurate: Clear, oily liquid at 20°. Colorless or slightly yellow. Very soluble in alcohol, in methanol, and in methylene chloride; practically insoluble in water. *NF category:* Emollient; emulsifying agent.

Propylene Glycol Monostearate: White, wax-like solid or as white, wax-like beads or flakes. Has a slight, agreeable, fatty odor and taste. Soluble in organic solvents such as alcohol, mineral or fixed oils, benzene, ether, and acetone; insoluble in water, but may be dispersed in hot water with the aid of a small amount of soap or other suitable surface-active agent. *NF category:* Emulsifying agent.

Propylhexedrine: Clear, colorless liquid, having a characteristic, amine-like odor. Volatilizes slowly at room temperature. Absorbs carbon dioxide from the air, and its solutions are alkaline to litmus. Boils at about 205°. Very slightly soluble in water. Miscible with alcohol, with chloroform, and with ether.

Propylparaben: Small, colorless crystals or white powder. Freely soluble in alcohol and in ether; slightly soluble in boiling water, very slightly soluble in water. *NF category:* Antimicrobial preservative.

Propylparaben Sodium: White powder. Is odorless and hygroscopic. Freely soluble in water; sparingly soluble in alcohol; insoluble in fixed oils. *NF category:* Antimicrobial preservative.

Propylthiouracil: White, powdery, crystalline substance. Is starch-like in appearance and to the touch, and has a bitter taste. Soluble in ammonium hydroxide and in alkali

Propylene Glycol



C₃H₈O₂

1,2-Propanediol;

Propane-1,2-diol CAS RN®: 57-55-6.

76.09

DEFINITION

Propylene Glycol contains NLT 99.5% of C₃H₈O₂.

IDENTIFICATION

[NOTE—Compliance is determined by meeting the requirements of Identification tests A, B, and C.]

Change to read:

- A. *SPECTROSCOPIC IDENTIFICATION TESTS** (197), *Infrared Spectroscopy*: 197F_A (CH 1-May-2020)
 [NOTE—Undried specimen.]

- B. LIMIT OF DIETHYLENE GLYCOL AND ETHYLENE GLYCOL**
 Diluent: Methanol

Standard solution: 2.0 mg/mL of USP Propylene Glycol RS, 0.050 mg/mL of USP Ethylene Glycol RS, 0.050 mg/mL of USP Diethylene Glycol RS, and 0.10 mg/mL of 2,2,2-trichloroethanol (internal standard) in methanol

Sample solution: 50 mg/mL of Propylene Glycol and 0.10 mg/mL of 2,2,2-trichloroethanol (internal standard) in methanol

Chromatographic system

(See Chromatography (621), System Suitability.)

Mode: GC

Detector: Flame ionization

Column: 0.53-mm × 30-m fused-silica coated with 3.0-μm G43 stationary phase, and a deactivated split liner with glass wool

Temperature

Injector: 220°

Detector: 250°

Column: See the temperature program table below.

Initial Temperature (°)	Temperature Ramp (°/min)	Final Temperature (°)	Hold Time at Final Temperature (min)
100	—	100	4
100	50	120	10
120	50	220	6

Carrier gas: Helium

Injection size: 1.0 μL

Flow rate: 4.5 mL/min

Injection type: The split flow ratio is about 10:1.

System suitability

Sample: Standard solution

[NOTE—For informational purposes only. See Impurity

Table 1 for relative retention times for ethylene glycol, internal standard, and diethylene glycol. The retention time for propylene glycol is 4 min.]

Impurity Table 1

Component	Relative Retention Time
Ethylene glycol	0.8
Propylene glycol	1.0

Impurity Table 1 (continued)

Component	Relative Retention Time
Internal standard	1.7
Diethylene glycol	2.4

Suitability requirements

Resolution: NLT 5 between ethylene glycol and propylene glycol

Analysis

Sample: Sample solution

Acceptance criteria

Diethylene glycol: If a peak at the retention time for diethylene glycol is present in the *Sample solution*, the peak response ratio relative to 2,2,2-trichloroethanol is NMT the peak response ratio for diethylene glycol relative to 2,2,2-trichloroethanol in the *Standard solution*: NMT 0.10% for diethylene glycol.

Ethylene glycol: If a peak at the retention times for ethylene glycol is present in the *Sample solution*, the peak response ratio relative to 2,2,2-trichloroethanol is not more than the peak response ratio for ethylene glycol relative to 2,2,2-trichloroethanol in the *Standard solution*: NMT 0.10% for ethylene glycol is found.

- C.** Examine the chromatograms obtained in Identification test B. The retention time of the propylene glycol peak of the *Sample solution* corresponds to that of the *Standard solution*.

ASSAY

PROCEDURE

Sample: Propylene Glycol

Chromatographic system

(See Chromatography (621), System Suitability.)

Mode: GC

Detector: Thermal conductivity

Column: 1-m × 4-mm; 5% phase G16; support S5

Temperature

Injector: 240°

Detector: 250°

Column: Increase from 120° to 200° at a rate of 5°/min.

Carrier gas: Helium

Injection size: 10 μL

[NOTE—The approximate retention time for propylene glycol is 5.7 min, and the approximate retention times for the three isomers of dipropylene glycol, when present, are 8.2, 9.0, and 10.2 min, respectively.]

Analysis: Calculate the percentage of C₃H₈O₂ in the *Sample* by dividing the area under the propylene glycol peak by the sum of the areas under all of the peaks, excluding those due to air and water, and multiplying by 100:

$$\text{Result} = [r_U / (r_U + \Sigma r_U)] \times 100$$

r_U = peak response for Propylene Glycol from the *Sample*

Σr_U = sum of individual impurity peak responses, excluding those due to air and water, from the *Sample*

Acceptance criteria: NLT 99.5%

IMPURITIES

INORGANIC IMPURITIES

- Residue on Ignition** (281)

Sample: 50 g

Analysis: Heat the *Sample* in a tared 100-mL shallow dish until it ignites, and allow it to burn without further application of heat in a place free from drafts. Cool, moisten the residue with 0.5 mL of sulfuric acid, and ignite to constant weight.

Acceptance criteria: The weight of the residue is NMT 3.5 mg.

- **Chloride and Sulfate, Chloride** (221): A 1-mL portion shows no more chloride than corresponds to 0.10 mL of 0.020 N hydrochloric acid (70 ppm).
- **Chloride and Sulfate, Sulfate** (221): A 5.0-mL portion shows no more sulfate than corresponds to 0.30 mL of 0.020 N sulfuric acid (60 ppm).

SPECIFIC TESTS

- **SPECIFIC GRAVITY** (841): 1.035–1.037

- **ACIDITY**

Sample: 10 mL of Propylene Glycol

Analysis: Add 1 mL of phenolphthalein TS to 50 mL of water, then add 0.1 N sodium hydroxide until the solution remains pink for 30 s. Add the *Sample*, and titrate with 0.10 N sodium hydroxide until the original pink color returns and remains for 30 s.

Acceptance criteria: NMT 0.20 mL of 0.10 N sodium hydroxide.

- **WATER DETERMINATION, Method I** (921): NMT 0.2%

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight containers.

- **USP REFERENCE STANDARDS** (11)

USP Diethylene Glycol RS

USP Ethylene Glycol RS

USP Propylene Glycol RS