

Date Printed: 2016-09-22

Effective Date: 2016-09-12 Supersedes Date: 2014-07-11

Name: Propylene Glycol USP/EP

Specification Number: 000000059518 **Previous Specified Material:** 00111814

Shelf Life

Container Type	Conditions of Handling	Conditions of Storage	Shelf Life	Deterioration Characteristics
Drum			24 Months	
Bulk			24 Months	

Government and Industry Standards

COMMISSION REGULATION (EU) No 231/2012 (food additives) EUROPEAN PHARMACOPOEIA (EP) FOOD CHEMICALS CODEX (FCC) THE JAPANESE PHARMACOPOEIA (JP) THE UNITED STATES PHARMACOPEIA (USP) 21CFR Part 117

Test and Test Condition	Limit	Unit	Method Note	
Assay	99.80 Min	%	Current USP	
Acidity Test Frequency:	0.20 Max quarterly	ml	Current USP	
Chlorides Test Frequency:	70 Max quarterly	ppm	Current USP	
Heavy Metals Test Frequency:	5.0 Max quarterly	ppm	Current USP	
Residue on Ignition, per 50g Test Frequency:	3.50 Max quarterly	mg	Current USP	

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Final Testing Requirements					
Test and Test Condition		Limit	Unit	Method	Note
Specific Gravity, @ 25/25degC		1.035 — 1.037		Current USP	
Test Frequency:	quarter	ly			
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Sulfate		60 Max	ppm	Current USP	
Test Frequency:	quarter	ly			
Water Content		0.200 Max	%	Current USP	
water content		0.200 Wax	70	carrent osi	
ID Test A, matches IR scan		Pass		Current USP	
Test Frequency:	quarter	ly			
ID Test B, Limit of Ethylene Glycol		Pass		Current USP	
ID Took D. Lincit of Diothyrlan a Chroni		Dana		Commont LICD	
ID Test B, Limit of Diethylene Glycol		Pass		Current USP	
ID Test C, Matches GC Scan		Pass		Current USP	
ib rest e, wateries de sean		1 433		carrent osi	
Acidity		0.05 Max	ml	Current EP	
Test Frequency:	quarter	ly			
Boiling Point		184 — 189	°C	Current EP	
Test Frequency:	quarter	ly			
Clarity		Pass		Current EP	
Test Frequency:	quarter			Carrent Er	
,	4	-1			
Color		Pass		Current EP	
Test Frequency:	quarter	ly			
				_	
Heavy Metals		5.0 Max	ppm	Current EP	
Test Frequency:	quarter	ıy			
Melting Point		121 — 128	°C	Current EP	
Test Frequency:	annually		Ü	odirene zi	
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Oxidizing Substances, 0.05M sodium	l	0.20 Max	ml	Current EP	
thiosulfate					
Test Frequency:	quarter	ly			

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Final Testing Requirements					
Test and Test Condition	Limit	Unit	Method Note	2	
Reducing Substances	Pass		Current EP		
Test Frequency:	quarterly				
Refractive Index, @ 20degC	1.431 — 1.433		Current EP		
Test Frequency:	quarterly				
	quaries,				
Relative Density, @ 20/20degC	1.035 - 1.040		Current EP		
Test Frequency:	quarterly				
Sulfated ash	0.0100 Max	%	Current EP		
Test Frequency:	quarterly				
Water Cantaint	0.200 May	0/	Current ED		
Water Content	0.200 Max	%	Current EP		
Assay	99.80 Min	%	Current FCC		
7.55d y	33.00 Will	70	Carrent r CC		
Acidity	Pass		Current FCC		
Test Frequency:	quarterly				
Appearance, clear & colorless	Pass		Current FCC		
Test Frequency:	quarterly				
Distillation IDD	405 O M:-	0.0	Comment FCC		
Distillation, IBP	185.0 Min	°C	Current FCC		
Test Frequency:	quarterly				
Distillation, DP	189.0 Max	°C	Current FCC		
Test Frequency:	quarterly	Č	Carreneree		
	quaries,				
Lead (Pb)	1.0 Max	ppm	Current FCC		
Test Frequency:	annually				
Identification, matches IR scan	Pass		Current FCC		
Test Frequency:	quarterly				
Residue on Ignition	0.0070 Max	%	Current FCC		
Test Frequency:	quarterly	/0	Current FCC		
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Specific Gravity, @ 25/25degC	1.035 — 1.037		Current FCC		
Test Frequency:	quarterly				
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Water Content	0.200 Max	%	Current FCC
Acidity Test Frequency:	Pass quarterly		Current JP
Arsenic Test Frequency:	2.0 Max quarterly	ppm	Current JP
Chlorides Test Frequency:	0.007 Max quarterly	%	Current JP
Distilling Range, 184 - 189 degC Test Frequency:	95 Min quarterly	% vol	Current JP
Glycerine (Odor) Test Frequency:	Pass quarterly		Current JP
Heavy Metals Test Frequency:	5.0 Max quarterly	ppm	Current JP
Melting Point Test Frequency:	174 — 178 annually	°C	Current JP
Odor Test Frequency:	Pass quarterly		Current JP
Residue on Ignition Test Frequency:	0.0050 Max quarterly	%	Current JP
Specific Gravity, @ 20/20degC Test Frequency:	1.035 — 1.040 quarterly		Current JP
Sulfate Test Frequency:	0.002 Max quarterly	%	Current JP
Water Content	0.500 Max	%	Current JP
Acidity, as acetic acid	0.0020 Max	%	DOWM 101370

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Test and Test Condition	Limit	Unit	Method	Note
Appearance, clear, free of suspended matter	Pass		Visual	
Chlorides	1.0 Max	ppm	DOWM 101867	
Color, Pt-Co	10 Max		ASTM D5386	
Dimer, Trimer, & Higher Polymers	0.100 Max	%	DOWM 100687	
Ethylene Glycol	0.0080 Max	%	DOWM 100687	
Diethylene Glycol	0.0080 Max	%	DOWM 100687	
Iron	0.30 Max	ppm	ASTM E394	
Odor, practically odorless	Pass		Olfactory	
Spec. Grav. @ 20C	1.0376 — 1.0389		ASTM	
Test Frequency: qu	arterly		D4052	

General Notes

- 1 Values reported for Assay, Ethylene Glycol and Diethylene Glycol under USP and for Assay under FCC are obtained using the validated Dow GC Method DOWM 100687.
- 2 Concerning Regulation (EU) No 231/2012: Distillation range of 185 189°C
 is covered by current FCC; Purity of 99.5% is covered by GC analysis (DOWM
 100687)

READ PRECAUTIONARY INFORMATION AND MATERIAL SAFETY SHEETS. THIS PRODUCT IS SHIPPED IN COMPLIANCE WITH APPLICABLE LAWS AND REGULATIONS REGARDING CLASSIFICATION, PACKAGING, SHIPPING AND LABELING.

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