DuPont de Nemours, Inc.
SALES SPECIFICATION

Date Printed: 2021-07-06

Effective Date: 2019-12-18
Supersedes Date: 2019-11-17

Name: ETHOCEL™ Standard 10 Premium Ethylcellulose

Specification Number: 000000029780
Previous Specified Material: 00029780

Government and Industry Standards

Current EP - European Pharmacopoeia
Current FCC - Food Chemicals Codex
Current JP - Japanese Pharmacopoeia
Current NF - National Formulary
U.S. FDA 21 CFR 172.868; 73.1; 73.1001; 573.420
US FDA GRAS Notification GRN 000470

Final Testing Requirements

Test and Test Condition	Limit	Unit	Method	Note
Viscosity	9.0 — 11.0	mPa.s	Current NF	1
Ethoxyl Content, assay	48.0 — 49.5	WT%	Current USP	
Loss on Drying, moisture	2.0 Max	WT%	Current USP	
Chloride (as NaCl)	0.05 Max	WT%	Current USP/EP/JP	
Residue on Ignition	0.40 Max	WT%	Current USP/EP/JP	
Aldehydes	100 Max	ppm	Current USP/EP/JP	
Test Frequency:	audit basis			
Arsenic	2 Max	ppm	Current ChP	
Test Frequency:	audit basis			
Lead	2 Max	ppm	Current FCC	
Test Frequency:	audit basis			

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Final Testing Requirements

Test and Test Condition	Limit	Unit	Method	Note
Heavy Metals, Test - JP	10 Max	ppm	Current JP	
Test Frequency:	audit basis			
Acidity or Alkalinity	Pass		Current USP/EP/JP	
Test Frequency:	audit basis			
Residual Solvents	Pass		Current USP/EP/JP	2
Test Frequency:	audit basis			
Identification, NF	Pass		Current NF	
Test Frequency:	audit basis			
Identification, Test A - EP	Pass		Current EP	
Test Frequency:	audit basis			
Identification, Test B - EP	Pass		Current EP	
Test Frequency:	audit basis			
Identification, Test - JP	Pass		Current JP	
Test Frequency:	audit basis			
Identification, FCC	Pass		Current FCC	
Test Frequency:	audit basis			
Microbial Count, Total Aerobic	100 Max	CFU/g	Current USP	3
Test Frequency:	audit basis			
Total Count, Combined Mold and Yeast	100 Max	CFU/g	Current USP	4
Test Frequency:	audit basis			
Staphylococcus Aureus, negative	Pass		Current USP	5
Test Frequency:	audit basis			
Pseudomonas Aeruginosa, negative	Pass		Current USP	6
Test Frequency:	audit basis			

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Test and Test Condition	Limit	Unit	Method	Note
Salmonella Species, negative	Pass		Current USP	7
Test Frequency:	audit basis			
Escherichia Coli, negative	Pass		Current USP	8
Test Frequency:	audit basis			

Final Testing Requirements Notes:

1 5% solution in 80/20 Toluene/Alcohol Mixture at 25 degC.
2 Current USP, General Chapter <467>.
3 Microbiological, see General Notes
4 Microbiological, see General Notes
5 Microbiological, see General Notes
6 Microbiological, see General Notes
7 Microbiological, see General Notes
8 Microbiological, see General Notes

General Notes

1 Current versions of all cited methods will be used. Updates to the methods will be documented within the controlled document system and communicated through the Management of Change process within the Ethylcellulose facility.

Specification limits apply to material as packaged in the original containers. They do not apply if the material has been repackaged, improperly stored, or if the package has been opened in an uncontrolled environment.

2 Current versions of all cited methods will be used.

Specification limits apply to material as packaged in the original containers. They do not apply if the material has been repackaged, improperly stored, or if the package has been opened in an uncontrolled environment.

Samples returned for analysis must have been obtained under conditions which prohibit the introduction of microbial contamination. Sterile containers and sampling equipment must be used.

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General Notes

3 All test labeled as Microbiological the use the current versions of all cited methods

Specification limits apply to material as packaged in the original containers. They do not apply if the material has been repackaged, improperly stored, or if the package has been opened in an been obtained under conditions which prohibit the introduction of microbial contamination. Sterile containers and sampling equipment must be used.

External Notes

1 This product meets the requirements outlined in 21 CFR 172.868; 73.1; 73.1001; 573.420, NF, EP, JP, and FCC.

2 The manufacturing facility and this product have been Kosher certified.

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