

Dow Cellulosics

ETHOCEL

Ethylcellulose Polymers Technical Handbook







Table of Contents

1	Intro	duction	
	1.1	General Properties	4
2	ETH	OCEL Polymers	6
	2.1	Structures	6
	2.2	Products	
	2.3	Nomenclature	
3	App	lications	8
4	Form	ulating with ETHOCEL	10
	4.1	Choice of Solvents	
	4.1	Aromatic Hydrocarbon-Alcohol Mixtures	11
	4.2	Viscosity vs Concentration	
	4.3	Blending for Intermediate Viscosities	
	4.4	Polymers	
	4.5	Pigments and Dyes	
	4.6	Heat and Light Stabilizers	
	4.7	Film Properties	
	4.8 4.9	Plasticizers Solvent-Free Emulsions	10
_			
5		maceutical Applications	
	5.1 5.2	Granulation	
	5.3	Coating Tablet Binding	
c			
6	Spe 6.1	cialty Applications Personal Care	
	6.2	Food Applications	
	6.3	Animal Feed	
	6.4	Conductive Pastes	
	6.5	Ceramics	
	6.6	Printing Inks	23
		Gravure Ink	24
		Heat-Transfer Printing	
		Solvent-Free Hot Melt Inks	
	6.7	Hot Melt Strippable Coatings	
	6.8	Room-Temperature Lacquers	25
	6.8 6.9	Room-Temperature Lacquers Gel Lacquers	25 25
7	6.8 6.9 Safe	Room-Temperature Lacquers Gel Lacquers Handling of ETHOCEL Products	25 25 26
7	6.8 6.9 Safe 7.1	Room-Temperature Lacquers Gel Lacquers Handling of ETHOCEL Products Health Considerations	25 25 26 26
7	6.8 6.9 Safe 7.1 7.2	Room-Temperature Lacquers Gel Lacquers Handling of ETHOCEL Products Health Considerations Combustibility	25 25 26 26 26
7	6.8 6.9 Safe 7.1 7.2 7.3	Room-Temperature Lacquers Gel Lacquers Handling of ETHOCEL Products Health Considerations Combustibility Dust Explosion	25 25 26 26 26 26
7	6.8 6.9 Safe 7.1 7.2	Room-Temperature Lacquers Gel Lacquers Handling of ETHOCEL Products Health Considerations Combustibility	25 25 26 26 26 26 26

 7.6
 Storage/Handling
 26

Table of Tables

Table 1.	Physical properties of ETHOCEL Standard polymers4
Table 2.	ETHOCEL polymers7
Table 3.	Typical use map for ETHOCEL polymers9
Table 4.	Viscosity and film properties of ETHOCEL Std. 10 polymer in single solvents (15 g polymer in 100 mL solvent)10
Table 5.	Solvent compositions for minimum solution viscosity for ETHOCEL polymers in common binary solvents10
Table 6.	Solvents for ETHOCEL polymers14–16
Table 7.	Film coverage with ETHOCEL polymers and other cellulose products18
Table 8.	Plasticizers with varying softening effects on ETHOCEL polymers19
Table 9.	Selection of ETHOCEL polymers for pharmaceutical applications20
Table 10.	Viscosity of ETHOCEL Std. 10 Premium solutions in ethanol20
Table 11.	Diphenhydramine HCI release rates in deionized water21
Table 12.	Selection of ETHOCEL polymers for specialty applications

Table of Figures

Figure 1.	Softening point and melting point temperatures as a function of ethoxyl content of ETHOCEL polymers	5
Figure 2.	Chemical structure of cellulose	6
Figure 3.	Chemical structure of ethylcellulose	6
Figure 4.	Example of nomenclature for an ETHOCEL Standard polymer	7
Figure 5.	Viscosity of 5% solutions of ETHOCEL Std. 100 polymer in toluene with various alcohols	11
Figure 6.	Viscosity-concentration chart for ETHOCEL Standard polymers	12
Figure 7.	Blending chart for intermediate viscosities of ETHOCEL polymers	13
Figure 8.	Load-elongation curves for ETHOCEL polymers	19
Figure 9.	Drug dissolution of ETHOCEL Std. 10 Premium granular vs. fine particle	21

Introduction



THOCEL* is a trademark of The Dow Chemical Company for its family of thermoplastic cellulose ethers. These polymers have provided excellent service to industry since their commercial introduction by Dow in the mid-1930s.

These multifunctional, water-insoluble, organosoluble polymers are used in many pharmaceutical and specialty applications. They function as binders; tough, flexible film formers; masking and time-release agents; water barriers; and rheology modifiers, to name a few.

For additional information, see **www.ETHOCEL.com.**

Table 1. Physical properties of ETHOCEL Standard polymers

Appearance	white powder
Odor	none
Taste	none
Density (bulk), g/cm ³ , ETHOCEL Std. 4, 7, 10, 20, 45, 100	0.4
Density (bulk), g/cm ³ , ETHOCEL Std. 200 & 300	0.3
Specific gravity, g/cm ³	1.12–1.15
Glass transition temperature, °C (°F)	129–133 (264–271)
Softening point, °C (°F), see Figure 1	133–138 (271–280)
Melting point, °C (°F), see Figure 1	165–173 (329–343)
Film properties	
Refractive index	1.47
Tensile strength	See Figure 8, pg. 19
Electrical properties	
Dielectric constant at 25°C, 1 MHz	2.8–3.9
Dielectric constant at 25°C, 1 kHz	3.0–4.1
Dielectric constant at 25°C, 60 Hz	2.5–4.0
Power factor at 25°C, 1 kHz	0.002-0.02
Power factor at 25°C, 60 Hz	0.005–0.02
Volume resistivity, ohm·cm	10 ¹² -10 ¹⁴
Dielectric strength, V/0.0254 mm	1500

1.1 General Properties

ETHOCEL ethylcellulose polymers are colorless, odorless, tasteless, and noncaloric. They have outstanding chemical and physical properties (Table 1). These properties make them useful in many applications—from pharmaceutical, food, and personal care applications to specialty applications, including some of the most sophisticated electronic devices.¹

Flammability Once ignited, ETHOCEL will support combustion. However, ETHOCEL offers no greater fire hazard on storage and handling than does paper or cellulose in the same physical form.

Thermal Stability ETHOCEL is stable up to its melting point (~160°C, 320°F). The viscosity of ETHOCEL polymers is stable to high temperatures. It has good outdoor durability and toughness at both high and low temperatures.

Low Ash Content ETHOCEL has a very low ash content, making it useful in applications such as conductive inks and pastes, dielectrics, ceramics, and fluorescent lighting.

Stability to Light ETHOCEL does not discolor on exposure to strong sunlight nor does it promote the discoloration of plasticizers or polymers.

Chemical Stability/Resistance

ETHOCEL is a stable, slightly hygroscopic material. It is inert to attack by aqueous alkalies, even when hot and highly concentrated. It is resistant to salt solutions and resists oxidation below its softening temperature.

¹ All applications may not be suitable for all regions.

Ref: Majewicz, T.G., et al., eds., "Cellulose Ethers," Encyclopedia of Polymer Science and Technology, John Wiley & Sons, Inc., New York, 2002.

Figure 1. Softening point and melting point temperatures as a function of ethoxyl content of ETHOCEL polymers

Thermoplasticity ETHOCEL possesses excellent thermoplasticity. Unplasticized ETHOCEL softens and becomes plastic at 135°C to 160°C (Figure 1). It can be compounded with plasticizers, waxes, and polymers while in a plastic condition. Plasticized ETHOCEL softens at much lower temperatures than unplasticized ETHOCEL and forms the basis of compositions for molding, extruding, and laminating uses.

Flexibility Films made from ETHOCEL polymers are highly flexible and retain their flexibility at temperatures well below freezing.

Film Formation ETHOCEL is an excellent film former. Films made from ETHOCEL are tough, with high tensile strength and an unusual degree of flexibility even at low temperatures. ETHOCEL polymers yield a greater volume of film-forming solids than any other cellulose derivative.

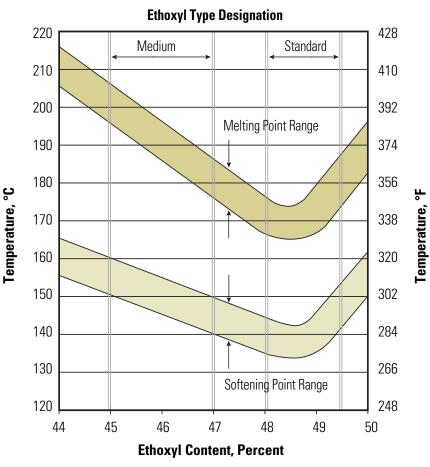
Compatibility ETHOCEL is compatible with most common plasticizers and polymers. It yields clear films with a wider variety of plasticizers and polymers than any other cellulose derivative.

Water Resistance ETHOCEL is an excellent water barrier. Films of ETHOCEL absorb little moisture either on exposure to the atmosphere or after long immersion in water.

Binding The good binding qualities of ETHOCEL are useful in applications such as tableting and microencapsulation.

Controlled Release ETHOCEL allows control of the release of active ingredients from solid dosage forms.

Solubility ETHOCEL dissolves in a wide range of solvents such as aliphatic alcohols, chlorinated solvents, and natural oils. It is practically insoluble in glycerin, propylene glycol, and water.



Note: ETHOCEL ethylcellulose polymers are produced in two ethoxyl types (Medium and Standard). See Section 2.2, pg. 6.



ETHOCEL Polymers



2.1 Structures

ETHOCEL ethylcellulose polymers are derived from and have the polymeric "backbone" of cellulose, which is a naturally occurring polymer. The molecule has a structure of repeating anhydroglucose units (Figure 2). Note that each anhydroglucose unit (ring) has three reactive -OH (hydroxyl) sites.

Cellulose is treated with an alkaline solution to produce alkali cellulose, which is subsequently reacted with ethyl chloride, yielding crude ethylcellulose. (Figure 3).

2.2 Products

The Dow Chemical Company manufactures and markets many different ETHOCEL products to accommodate the needs of customers for different physical properties, uses, viscosities, and solubilities.

Figure 2. Chemical structure of cellulose

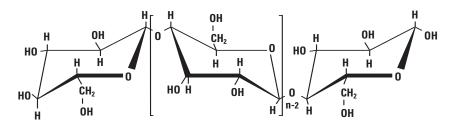
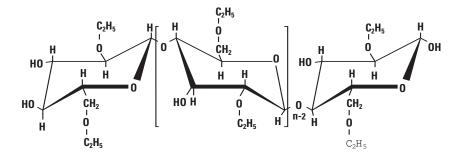


Figure 3. Chemical structure of ethylcellulose



ETHOCEL polymers are white granular powders with a bulk density of approximately 0.4 g/cm³. The differences in physical properties of ETHOCEL polymers result largely from variation in ethoxyl content.

ETHOCEL polymers are produced in two ethoxyl types (Standard and Medium) that cover the range of the most useful ethoxyl content. "Standard" polymers have an ethoxyl content of 48.0 to 49.5%; and "Medium" polymers have an ethoxyl content of 45.0 to 47.0%. **Medium polymers are supplied on a very restricted, made-to-order basis only.**

ETHOCEL polymers are also produced and marketed in a number of different viscosities. Viscosity increases as the length of the polymer molecule increases.

Standard and Medium ethoxyl types are available in Premium grades, useful in regulated applications, and Industrial grades (Table 2). Premium grades are designed to meet the requirements of pharmaceutical applications. *However, the physical and chemical properties of ETHOCEL polymers apply to both Premium and Industrial grades.*

ETHOCEL Std. 7, 10, and 100 Premium polymers are also available in a fine particle size. These products are designated ETHOCEL Std. 7 Premium FP, Std. 10 Premium FP, and Std. 100 Premium FP. They were designed for pharmaceutical formulations but are useful in other applications such as personal care or applications that require high surface area polymers.

Table 2. ETHOCEL polymers

Product	Viscosity	Ethoxyl	Content, %
Viscosity	Range,	Standard	Medium ^c
Designation	mPa⋅s (cP)	48.0-49.5	45.0-46.5
4	3-5.5	ETHOCEL Std. 4 ^a	—
7	6—8	ETHOCEL Std. 7 ^{a,b}	—
10	9-11	ETHOCEL Std. 10 ^{a,b}	—
14	12.6-15.4	ETHOCEL Std. 14 ^{a,c}	—
20	18–22	ETHOCEL Std. 20 ^a	—
45	41-49	ETHOCEL Std. 45 ^a	—
50	45–55	—	ETHOCEL Med. 50 ^{a,c}
70	63-77	—	ETHOCEL Med. 70 ^{a,c}
100	90-110	ETHOCEL Std. 100 ^{a,b}	ETHOCEL Med. 100 ^C
200	180-220	ETHOCEL Std. 200	—
300	270–330	ETHOCEL Std. 300	
350	250–385		_

^a Premium in addition to Industrial grades are available.

^b Fine particle forms are available.

^C Supplied on a restricted, made-to-order basis only.

Note: Viscosities are for a 5% solution measured at 25°C in an Ubbelohde viscometer. For Medium products, solvent is 60% toluene and 40% ethanol. For all other ETHOCEL products, solvent is 80% toluene and 20% ethanol.

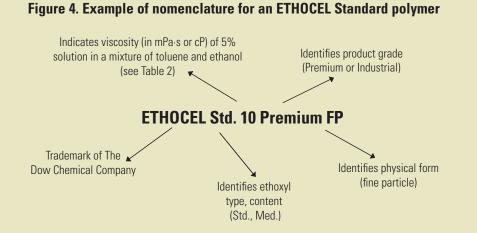
2.3 Nomenclature

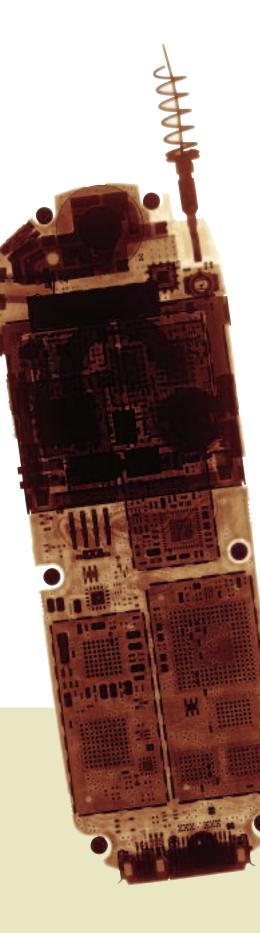
ETHOCEL is a trademark of The Dow Chemical Company for a line of cellulose ether products. The letters following (Std., Med.) identify the ethoxyl type and ethoxyl content (the chemistry designation).

The number that follows the chemistry designation identifies the viscosity of that product in millipascal-seconds (mPa·s). Viscosity of a 5% solution is measured at 25°C in an Ubbelohde viscometer. For Medium products, solvent is 60% toluene and 40% ethanol. For all other ETHOCEL products, solvent is 80% toluene and 20% ethanol. Note: millipascal-seconds (mPa·s) is equivalent to centipoise (cP).

ETHOCEL products are correctly specified by listing the ethoxyl content (as Standard or Medium), the nominal viscosity, and the grade (Premium or Industrial). For example, ETHOCEL Std. 20 Premium polymer correctly describes a Dow ethylcellulose product with:

- "Standard" ethoxyl content (48.0-49.5%).
- Nominal Ubbelohde viscosity of 20 mPa·s for a 5% solution (in 80% toluene and 20% ethanol) measured at 25°C. (See Table 2 for ranges.)
- Intended use in pharmaceuticals or other regulated applications.





7



THOCEL ethylcellulose polymers have provided excellent functionality in many pharmaceutical and specialty applications for more than 60 years. ETHOCEL polymers are essentially tasteless, odorless, noncaloric, and physiologically inert. They offer an attractive range of physical properties and can be blended with other materials to achieve intermediate characteristics.

Pharmaceuticals ETHOCEL Premium products are among a very small number of water-insoluble excipient polymers that are approved and accepted globally for pharmaceutical applications. They are proven organosoluble polymers for tablet coatings, controlled-release coatings, microencapsulation, granulation, and taste masking. **Personal Care** ETHOCEL polymers are approved for use in cosmetics. Ethylcellulose is listed in the International Cosmetic Ingredient Dictionary and Handbook. It is also listed in the Japanese Standards of Cosmetic Ingredients.

ETHOCEL is soluble in many organic solvents, including ethanol and natural oils. It yields strong, flexible films at low concentration. It provides excellent water resistance and can be used to protect water-sensitive ingredients. It can be used to mask or control the release of active ingredients.

ETHOCEL has been used in lipsticks and nail polishes (gives long-lasting brilliance), as a fragrance stabilizer, and as a thickener for perfumes and body creams (waterproof sunscreens).

Applications

Food/Feed ETHOCEL is used as a flavor fixative in encapsulation and as a vitamin coating. It is approved for and used in inks for marking fruits and vegetables, as a component of paper and paperboard in contact with aqueous and fatty foods, and for certain uses in animal feed. ETHOCEL polymers are approved for use in animal feed in Europe per Directive 70/524/EEC for all species or categories of animals. International Feed Name and International Feed Number (IFN): ethyl cellulose 4-08-045. The IFN will assist feed producers in having their feed products approved by regulators such as the U.S. Department of Agriculture, the Canadian Food Inspection Agency, and the UN Food and Agriculture Organization (FAO).

Ceramics ETHOCEL is used in ceramic applications as a rheology modifier and binder. It provides green strength to the unfired ceramic and burns out cleanly, leaving no residue after firing.

Conductive Pastes ETHOCEL is used in conductive pastes and inks. It functions as a rheology modifier and as a binder and stabilizer for metal pigments. It burns out cleanly, leaving no residue after firing.

Printing Inks ETHOCEL is used in gravure, flexographic, and screen printing inks. It is soluble in common solvent systems and is compatible with plasticizers, waxes, and other polymers commonly used. It functions as a rheology modifier, dispersant, and binder for pigments and as a polymeric binder for pigment chips. It contributes to the formation of tough, abrasion-resistant films. It reduces tack of ink films and improves printability on difficult substrates. Ink films dry quickly because of the permeability of films of ETHOCEL polymers. **Specialty Coatings** ETHOCEL brings an unusual combination of properties to specialty coatings applications.

Hot Melts ETHOCEL dissolves readily in many hot polymers, plasticizers, and oil and wax mixtures. It has excellent thermoplasticity.

Adhesives Hot melts using ETHOCEL can be easily heat-sealed. ETHOCEL contributes added strength especially where stresses may be applied to a freshly sealed joint.

Paper Coatings ETHOCEL provides remarkable toughness (resistance to scuffing) and flexibility at room temperature and low temperatures. The coating has good gloss and block resistance and retains a low rate of water vapor transmission. Fluorescent Lighting ETHOCEL acts as a rheology modifier and binder for coating fluorescent lighting tubes. ETHOCEL is removed by heating. It burns cleanly, leaving no residues, which allows the triphosphor coating to adhere to the glass tube.

Other Applications ETHOCEL is also used in waterproofing coatings, hightemperature/maintenance coatings, enameling, lacquers, varnishes, and marine coatings.

Table 3. Typical use map for ETHOCEL polymers

				Fu	nctio	nalit	v				ETH(Prod) CE
	Binder	Controlled release	Film former	Low ash	Microencapsulation	Protective coating	Rheology modifier	Tack	Taste masking	Water barrier	Premium grades	Industrial grades
Adhesives	•		•				•	•		•		•
Ceramics	•			•			•				•	•
Conductive pastes	•			•			•	•			•	•
Electronics	•		•	•			•	•			•	•
Fluorescent lighting	•			•			•	•				•
Food/Feed	•	•	•		•				•	•	•	•
Food packaging	•		•			•		•		•	•	•
Hot melts			•			•	•			•		•
Personal care	•	•	•		•	•	•			•	•	•
Pharmaceutical	•	•	•	•	•	•			•	•	•	
Printing inks	•		•			•	•	•		•		•
Varnishes/lacquers			•			•	•			•		•

Formulating With ETHOCEL

4.1 Choice of Solvents

Any given application usually employs several different solvent combinations. Solutions of ETHOCEL ethylcellulose polymers in aromatic hydrocarbons are highly viscous; consequently, only low-solids solutions are possible when these solvents are used singly. Ethanol and methanol yield solutions of ETHOCEL polymers having lower viscosity than do aromatic hydrocarbons, but the properties of the films are affected. There are mixtures of aromatic hydrocarbons with methanol or ethanol that yield solutions of ETHOCEL polymers having a lower viscosity than is obtainable with either solvent type used singly. These mixtures also deposit films having good strength. This is shown by the data on the 80-20 toluene-ethanol solvent included in Table 4 for comparison.

Table 4. Viscosity and film properties of ETHOCEL Std. 10 polymer in single solvents (15 g polymer in 100 mL solvent)

	Solution Pro	perties @ 25°C	Film Pr	operties
Solvent	Viscosity, mPa⋅s (cP)	Specific Gravity	Yield Point, kg/cm²	Elongation %
n-Butanol	1900	0.848	425	6
Butyl acetate, 90%	590	0.901	430	7
Ethanol, Formula 30	560	0.850	a	a
Ethyl acetate, 99%	360	0.924	440	9
Ethylene dichloride	470	1.238	420	5
Methyl ethyl ketone	320	0.845	428 ^b	7b
Toluene	1930	0.890	440	12
80-20 Toluene-ethanol	260	0.887	440	7

The lower molecular weight aliphatic esters and ketones produce solutions of ETHOCEL polymers that have comparatively low viscosities and that yield films of good strength and extensibility. However, it is preferable in most cases to use these solvents with a small proportion of one of the lower molecular weight alcohols because of the lower viscosities obtainable for such mixtures (Table 5).

Solutions of ETHOCEL polymers will tolerate dilution with petroleum thinners to an unusually high degree for cellulose derivatives. However, the resultant polymer solution will have a higher viscosity than if it had been prepared with an aromatic solvent.

The most practical solvents for ETHOCEL polymers are mixtures that have been formulated to yield solutions having the lowest viscosity consistent with good film properties and that have a suitable evaporation rate.

^a Too brittle to test properly.

^b Films showed "orange peel."

Table 5. Solvent compositions forminimum solution viscosity for ETHOCELpolymers in common binary solvents

Solvent Mixture	Solvent Composition			
Aromatic/ethanol	20% ethanol			
Aromatic/ester	No change by varying ester			
Esters/ethanol	20% ethanol			
Ketones/ethanol	20% ethanol			
Aromatic naphthas/ethanol	30% ethanol			
Aliphatic naphthas/ethanol	30% ethanol			

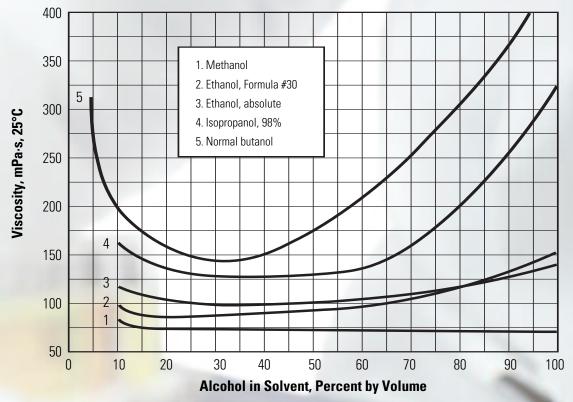
4.1. Aromatic Hydrocarbon-Alcohol Mixtures

Solvent mixtures may be formulated from aromatic hydrocarbons and the lower molecular weight aliphatic alcohols to yield solutions of ETHOCEL polymers having low viscosity. Figure 5 shows the effect of alcohol content on the viscosity of a solution of an ETHOCEL polymer in a mixture with an aromatic hydrocarbon. The curves show the viscosities of a 5% solution of ETHOCEL Std. 100 polymer in mixtures of toluene with four low molecular weight aliphatic alcohols. The viscosity is extremely high in toluene alone; it decreases rapidly with the addition of small percentages of alcohol. As the alcohol content increases significantly the viscosity rises with all alcohols except methanol. This increase

is greater with higher molecular weight alcohols. Figure 5 also shows that a lower minimum viscosity can be obtained with ethanol or methanol than with butanol.

The shape and relative position of the viscosity curves of Figure 5 change only slightly when the concentration of ETHOCEL polymer is increased. Substitution of xylene or ethylbenzene for the toluene has little effect on the alcohol content at which the minimum viscosity is obtained, the actual viscosity at the minimum with any one alcohol, or the shape of the curves. Therefore, the viscosity of a solution of ETHOCEL polymers will be dependent primarily on the kind of alcohol used, and on its percentage in the solvent.

Figure 5. Viscosity of 5% solutions of ETHOCEL Std. 100 polymer in toluene with various alcohols



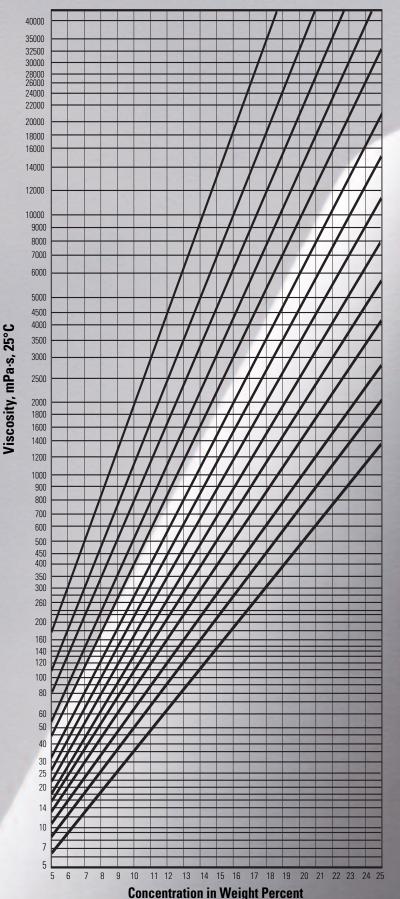


Figure 6. Viscosity-concentration chart for ETHOCEL Standard polymers

(Solutions in 80-20 Toluene-Ethanol by Weight)

4.2 Viscosity vs Concentration

The relationship between solution viscosity and concentration for a series of product viscosities is shown in Figure 6. Viscosity determinations were made at 25°C in 80-20 toluene-ethanol. From Figure 6, it is possible to select the viscosity of the ETHOCEL polymer required to obtain a solution of desired viscosity and concentration; it also permits the solids content at a given solution viscosity to be determined. The amount of dilution required to obtain a given solution viscosity can also be estimated from Figure 6. The data suggest the possibility of using high-viscosity ETHOCEL polymers as efficient thickeners for organic solvent-based formulations.



NOTE: Viscosity grade is indicated on vertical axis (5% solutions)

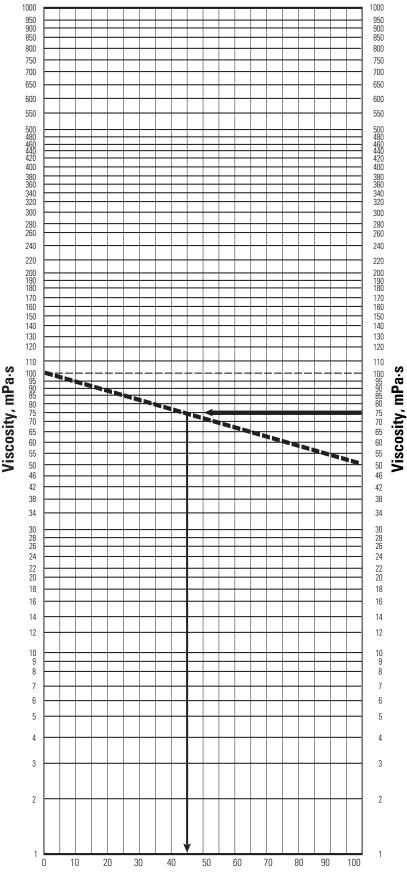
Figure 7. Blending chart for intermediate viscosities of ETHOCEL polymers

4.3 Blending for Intermediate Viscosities

If viscosities intermediate to those listed are required, refer to the blend chart (Figure 7). On the vertical axes are the viscosities for two different ETHOCEL products measured in any given set of units at the same conditions. On the horizontal axis is shown the percentage of one of the viscosity types of ETHOCEL in the blend.

For example, to produce a 5% solution of ETHOCEL polymers having a viscosity of 75 mPa·s by blending 100 mPa·s material with 50 mPa·s material: A line is drawn connecting these two viscosities as indicated by the dashed line on the chart. The point of intersection of this line with the 75 mPa·s line shows that 45% of the 50 mPa·s material is required in the blend.

Figure 7 can be used for blending viscosity types of ETHOCEL polymers with each other, and with nitrocellulose as well. For accurate results, the viscosities of ETHOCEL polymers and nitrocellulose should be measured in the same solvent under the same conditions of temperature and concentration.



Percent in Blend of Resin of Viscosity on Right Hand Scale

Table 6 shows the solubility of ETHOCEL polymers in a number of common single solvents. The table does not list concentrations or viscosities, or all solvents for ETHOCEL polymers-it is only intended as a general guide. Again, ETHOCEL polymers are most soluble in blends of aromatic hydrocarbons and aliphatic alcohol.

Table 6. Solvents for ETHOCEL polymers

Solvent		Solubility ^a of ET	HOCEL Polymers
Туре	Name	Standard ethoxyl	Medium ethoxy
Aromatic hydrocarbons	Toluene	Sol clear	Gels
	Xylene	Sol clear	Gels
	Ethylbenzene	Sol clear	Sol gels
	Isopropyl benzene	Sol clear	Swells
	Diethylbenzene	Sol gels	Swells
	Diphenylethane	Sol gels	Swells
Cycloaliphatic	Cyclohexane	Swells	Insol
hydrocarbons	Cyclohexene	Sol clear	Sol clear
	Methyl cyclohexane	Swells	Insol
Aromatic naphthas	_	Swells	Swells
Aliphatic naphthas	Petrobenzol	Swells	Swells
	Troluoil	Swells	Swells
	Aliphatic petroleum thinner	Swells	Swells
	Benzosol	Swells	Swells
	Tolusol	Swells	Swells
	V.M. & P. ^b	Swells	Swells
Naval stores	Dipentene	Sol clear	Swells
	Turpentine, gum spirits	Sol hazy	Swells
Chlorinated aliphatic	Chloroform	Sol clear	Sol clear
hydrocarbons	Carbon tetrachloride	Sol clear	Gels
	Ethylene dichloride	Sol clear	Sol clear
	Trichloroethylene	Sol clear	Sol clear
	Propylene dichloride	Sol clear	Sol clear
	Trichloroethane	Sol clear	Sol clear
	Perchloroethylene	Sol hazy	Swells
	Tetrachloroethane	Sol clear	Sol clear
	Methylene chloride	Sol clear	Sol clear
Chlorinated aromatic	Monochlorobenzene	Sol clear	Sol hazy
hydrocarbons	o-Dichlorobenzene	Sol clear	Sol hazy
	Trichlorobenzene	Sol clear	Swells

^a Solubility rated on a mixture of 2 g ETHOCEL in 18 mL of solvent. The following abbreviations were used to indicate the six degrees of solubility observed: Sol clear—Soluble, solution clear of haze and free from gels

Sol hazy—Soluble, solution hazy and free from gels

Sol gels—Soluble, solution of granular nature due to presence of gels Gels—Completely gelatinized

Swells—Swollen or incompletely gelatinized

Insol—Insoluble

^b Varnish Makers and Painters



Table 6. Solvents for ETHOCEL polymers

B. ALCOHOLS AND ETHERS Solvent Solubility of ETHOCEL Polymers							
Туре	Name	Standard Ethoxyl	Medium Ethoxy				
Monohydric aliphatic alcohols	Methanol, anhydrous	Sol clear; Swells	Sol gels				
Mononyuric anphatic alconois	Ethanol, anhydrous	Sol clear; Swells	Gels				
	Ethanol, Formula 2B	Sol clear; Swells	Gels				
	Isopropanol, 91%	Sol clear; Swells	Swells				
	Isopropanol, 99%	Sol clear; Swells	Swells				
	sec-Butanol	Sol clear; Swells	Gels				
		Sol clear; Swells	Sol gels				
	<i>n</i> -Butanol	Sol clear; Swells	Sol gels				
	Octyl (2-ethylhexyl) alcohol	Sol clear; Swells	Gels				
Nonohydric cyclic alcohols	Cyclohexanol	Gels	Sol clear				
	Furfuryl alcohol	Sol clear	Gels				
	Methyl cyclohexanol	Sol clear	Gels				
	Tetrahydrofurfuryl alcohol	Sol clear	Gels				
	Benzyl alcohol	Sol clear	Sol clear				
	Phenyl ethyl alcohol	Sol clear	Sol clear				
	Pine oil	Sol clear	Sol gels				
Polyhydric alcohols	Ethylene glycol	Insol					
	Diethylene glycol	Insol	Insol				
	Glycerin	Insol	Insol				
	Triethanolamine	Swells	Insol				
ther alcohols	DOWANOL* PM glycol ether	Sol clear	Gels				
	DOWANOL DPM glycol ether	Sol clear	Gels				
	DOWANOL EP glycol ether	Sol clear	Gels				
	DOWANOL DB glycol ether	Sol clear	Gels				
Ethers	Ethyl ether	Sol hazy	Swells				
	Isopropyl ether	Sol hazy	Swells				
	Dioxane	Sol clear	Sol clear				
	Morpholine	Sol clear	Sol clear				
	<i>n</i> -Butyl ether	Swells	Swells				
	Phenyl ether	Swells	Sol hazy				
	Benzyl ether	Sol hazy	Swells				

^aSolubility rated on a mixture of 2 g ETHOCEL in 18 mL of solvent. The following abbreviations were used to indicate the six degrees of solubility observed: Sol clear—Soluble, solution clear of haze and free from gels

Sol blaze — Soluble, solution clear of haze and free from gets Sol hazy — Soluble, solution hazy and free from gets Sol gets — Soluble, solution of granular nature due to presence of gets Gets — Completely getatinized

Swells—Swollen or incompletely gelatinized Insol—Insoluble *Trademark of The Dow Chemical Company



Table 6. Solvents for ETHOCEL polymers

	C. ESTERS		
Solvent		Solubility ^a of ET	HOCEL Polymers
Туре	Name	Standard Ethoxyl	Medium Ethoxyl
Acetates	Methyl acetate, 99%	Sol clear	Sol clear
	Ethyl acetate, 85-88%	Sol clear	Sol clear
	Isopropyl acetate	Sol gels	Sol clear
	sec-Butyl acetate	Gels	Sol clear
	Isobutyl acetate	Gels	Sol clear
	n-Butyl acetate	Sol gels	Sol clear
	sec-Amyl acetate	Swells	Sol clear
	Cyclohexyl acetate	Sol gels	Sol clear
	Glycol diacetate	Gels	Sol clear
Esters of hydroxy acids	Ethyl lactate	Sol gels	Sol clear
	Isopropyl lactate	Sol gels	Sol clear
	n-Butyl lactate	Sol clear	Sol clear
	Methyl salicylate	Sol gels	Sol clear
	D. KETONES	5	
Solvent		Solubility ^a of ET	HOCEL Polymers
Туре	Name	Standard Ethoxyl	Medium Ethoxyl
Ketones	Acetone	Sol clear; Swells	Sol gels
	Methyl ethyl ketone	Sol clear; Swells	Sol gels
	Methyl isobutyl ketone	Sol clear; Swells	Swells
	Mesityl oxide	Sol clear	Sol gel
	Diacetone alcohol	Sol clear	Gels
	Cyclohexanone	Sol clear	Gels
	Methyl cyclohexanone	Sol clear	Gels
	Acetophenone	Sol clear	Sol gels

^aSolubility rated on a mixture of 2 g ETHOCEL in 18 mL of solvent. The following abbreviations were used to indicate the six degrees of solubility observed: Sol clear—Soluble, solution clear of haze and free from gels

Sol hazy—Soluble, solution of granular nature due to presence of gels Sol gels—Soluble, solution of granular nature due to presence of gels Gels—Completely gelatinized Swells—Swollen or incompletely gelatinized

Insol-Insoluble

4.4 Polymers

In formulating with ETHOCEL polymers, other polymers are used to improve gloss, rubbing properties, adhesion, and resistance to certain solvents. Generally, the percentage of modifying polymer is approximately equal to that of the ETHOCEL polymer, and the amount of plasticizer will be about one-half that of the polymer total. However, depending on the application, the ratio of ETHOCEL polymer, plasticizer, and modifying polymer can be varied greatly. ETHOCEL products are compatible in all proportions with the following modifying polymers:

- Most pure phenolics
- Modified phenolics
- Coumarone indenes
- Natural polymers
- · Processed natural polymers
- Rosin
- Rosin derivatives
- Long oil alkyds

There is limited compatibility with urea formaldehydes, alkyds of medium oil length, vinyl butyral polymers, and vinyl acetate polymers. Small percentages of ETHOCEL polymers can be added to these polymers, or small percentages of these polymers can be added to ETHOCEL products, usually without causing incompatibility or haze. Approximately equal ratios of such polymers and ETHOCEL polymer will, however, invariably produce hazy or incompatible films.

ETHOCEL polymers are incompatible with most of the short oil alkyds and vinyl chloride-type polymers. On curing, certain urea formaldehyde and melamine formaldehyde polymers react with ETHOCEL polymers to greatly improve the solvent resistance and softening point of the finished films. Such compositions have been used, for example, as top coats to protect a gellacquered surface that might come in contact with solvents that would attack the ETHOCEL polymer alone.

4.5 Pigments and Dyes

ETHOCEL polymers do not react with pigments and dyes. ETHOCEL products can be pigmented by any of the usual methods and can be dyed with any dyes soluble in the solvents being used.

ETHOCEL polymers are excellent pigment-dispersing media. Dispersions of this type have been made on a tworoll or three-roll mill, and the resultant chips may be used to pigment both lacquers and inks.

4.6 Heat and Light Stabilizers

Extended exposure to heat and/or ultraviolet light can lead to degradation. Therefore, heat and light stabilizers are often added, particularly in unpigmented formulations. Octylphenol and butylated hydroxyphenol have performed effectively as antioxidants in this use, and 2,4-dihydroxybenzophenone has been used effectively as an ultravioletlight absorber.

Generally, combinations of 1% to 2% antioxidant plus 0.5% to 1% ultraviolet light absorber (based on total solids) give adequate protection against both heat and light degradation. Pigmented formulations seldom require light stabilization.





ETHOCEL products yield a greater volume of film-forming solids per unit weight than do most other commercial cellulose derivatives, as shown in Table 7. Films of ETHOCEL polymers are completely transparent, colorless, flexible, and tough.

The tensile strength and elongation properties of films of ETHOCEL polymers bear a relationship to the intrinsic viscosity of the ETHOCEL product used in making the films. Films made with the higher viscosity types of Medium and Standard ETHOCEL products are stronger and tougher than those of low viscosity. This is shown in Figure 8.

> Figure 8 also shows that Medium ethoxyl ETHOCEL products possess greater hardness and toughness than do Standard ethoxyl ETHOCEL products of similar viscosity. Hardness is measured by resistance to deformation; the yield points of films shown in Figure 8 may be

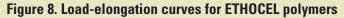
used to determine their relative hardness. An understanding of the differences between Medium and Standard ETHOCEL products is helpful in formulating coatings for maximum flexibility and toughness. At a comparable molecular weight (viscosity), the Medium ethoxyl ETHOCEL product is "tougher" than the Standard ethoxyl ETHOCEL product.

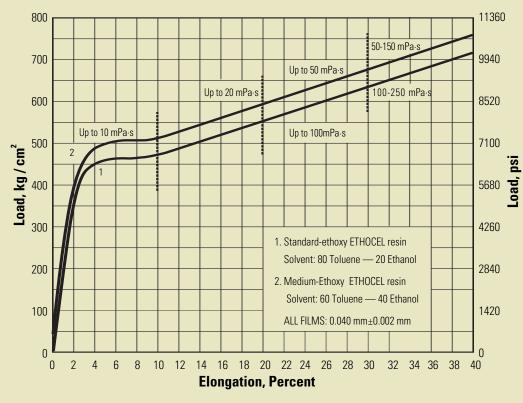
When mixtures of alcohols with aromatic hydrocarbons are used as solvents for ETHOCEL polymers without large proportions of plasticizers or other polymers, the mechanical properties of the deposited film are affected by the last solvent to evaporate. This is indicated by the data in Table 4, pg. 10, which show that brittle films were deposited from certain alcohol-type solvents, but that strong, flexible films resulted from aromatic hydrocarbon solvents. In general, when ethanol or methanol is used to reduce solution viscosity in mixtures with aromatic hydrocarbons, the solvent mixtures should be formulated so that the aromatic hydrocarbon is the last solvent to leave the film. For example, the proportion of ethanol in mixtures with toluene, which has a somewhat slower evaporation rate than ethanol, should not exceed 30%. With a slower evaporating hydrocarbon, such as xylene, the ethanol content can be increased to about 40%.

Table 7. Film coverage with ETHOCEL polymers and other cellulose products

Material	Specific Gravity of Film ^a	Area Covered, m²/kg (in²/lb)	Quantity to Cover Equal Area kg (Ib)
ETHOCEL Standard polymer	1.13	35 (24,500)	0.45 (1.00)
ETHOCEL Medium polymer	1.17	34 (23,700)	0.46 (1.03)
Cellulose acetate butyrate	1.22	32 (22,700)	0.49 (1.08)
Cellulose acetate	1.37	29 (20,200)	0.50 (1.10)
Cellulose nitrate	1.65	24 (16,800)	0.66 (1.48)

^aThickness = 0.25 mm (0.001 inch)





4.8 Plasticizers

ETHOCEL products are compatible with most common plasticizers. Plasticizers exert greater softening action on ETHOCEL polymers than on most other cellulose derivatives. The Medium ethoxyl type requires greater concentrations of plasticizers to produce a given degree of softness than does the Standard ethoxyl type. Table 8 lists plasticizers with high and low softening effect.

In many formulations using ETHOCEL polymers, 5 to 30% of plasticizer (based on the total solids) is sufficient to produce satisfactory flexibility. The choice of plasticizer depends on the other components and the temperature range or other application or use conditions, rather than on the particular ETHOCEL polymer. The most widely used plasticizers include phthalates, phosphates, glycerides, and esters of higher fatty acids and amides. For use in compositions that are resistant to low temperatures, long-chain, ester-type plasticizers are recommended. Examples include dibutyl sebacate, butyl stearate, glycol esters of coconut oil fatty acids, and butyl ricinoleate.

Plasticizers used with ETHOCEL polymers in pharmaceutical applications include dibutyl sebacate, triethyl citrate, triacetin, and acetylated monoglycerides.

4.9 Solvent-Free Emulsions

Solvent-free emulsions of ETHOCEL polymers may be customer-prepared by heating and melting a blend of an ETHOCEL polymer with a plasticizer. The resulting homogeneous, hot mixture is then emulsified with hot water to produce an emulsion of very finely divided particles of thermoplastic material in water. Clear, colorless films result when these emulsions are cast into films and dried. Film properties may be varied by altering:

- Plasticizer
- ETHOCEL product used
- Ratio of plasticizer to ETHOCEL polymers
- Drying time and temperature

Table 8. Plasticizers with varying softening effects on ETHOCEL polymers

Higher Softening Effect	Lower Softening Effect	
Dibutyl phthalate	Diphenyl phthalate	
Castor oil	Castor oil Dicyclohexyl phthalate	
Butyl phthalyl butyl glycolate	alyl butyl glycolate Cresyldiphenyl phosphate	
Butyl stearate	stearate Benzyl phthalate	

Pharmaceutical Applications



THOCEL Premium ethylcellulose polymers are recognized and used globally for many different functional purposes in pharmaceutical products. They are frequently used in controlled-release, solid-dosage formulations as well as for protective coatings for water-sensitive or reactive ingredients. They are also useful as granulation binders, as film formers, to improve tablet integrity and appearance, and to mask the taste of bitter active ingredients.

ETHOCEL Premium polymers meet the requirements of the Food Chemical Codex, the U.S. National Formulatory (NF), the Japanese Pharmaceutical Excipients (JPE) Monograph, and the European Pharmacopeia (EP). Refer to the product's Certificate of Analysis for a statement of compliance to the current version of each of these regulatory documents.

ETHOCEL FP polymers were developed specifically for use as excipients in controlled-release matrix formulations. As water-insoluble excipients, ETHOCEL polymers can effectively control the release of an active ingredient by modifying the size and length of the diffusion path. In this role, ETHOCEL polymer is typically used in combination with water-soluble excipients such as METHOCEL* cellulose ethers (hypromellose (HPMC) and methylcellulose). By varying the type and amount of the insoluble excipient ratio and the particle size, a wide variety of release rate profiles can be achieved.

Table 9 provides guidelines for selecting the right ETHOCEL polymer for pharmaceutical applications.

Table 9. Selection of ETHOCEL polymers for pharmaceutical applications

Application	ETHOCEL Polymer	
Controlled-release coatings	ETHOCEL Std. 7, 10, or 20 Premium	
	ETHOCEL blended with METHOCEL E5 or E15 Premium LV polymer	
Microencapsulation	ETHOCEL Std. 45 or 100 Premium	
Tablet coating	ETHOCEL Std. 7, 10, or 20 Premium	
Granulation	ETHOCEL Std. 10, 20, or 45 Premium	
Binder/direct compression	ETHOCEL Std. 7 Premium FP, 10 Premium FP, or 100 Premium FP	

* Trademark of The Dow Chemical Company

5.1 Granulation

Premium ETHOCEL polymers are often used for solvent granulation of water-sensitive materials. Tablets made with ethylcellulosegranulated materials are strong and have good dissolution properties. ETHOCEL polymers may also be used for extrusion granulation because of the thermoplastic nature of ethylcellulose. Dissolution times may be extended or modified by varying the amount of ETHOCEL polymer in a granulation or by adding water-soluble binders to the granulating fluid containing the ETHOCEL polymer.

5.2 Coating

ETHOCEL polymers have long been used as solvent-based tablet and bead coatings. They form strong films with good adhesion. Because ethylcellulose is water-insoluble, it is often used in conjunction with other water and organic-solvent soluble polymers such as METHOCEL cellulose ethers. Sustained or delayed release coatings can be achieved by varying the ratios of ETHOCEL and METHOCEL polymers. The viscosity of solutions of ethylcellulose prepared in ethanol with hypromellose (HPMC, METHOCEL E5 Premium LV), is listed in Table 10.

Table 10. Viscosity of ETHOCEL Std.10 Premium solutions in ethanol

ETHOCEL (%)	HPMC (%)	Viscosity (mPa·s)
15.0	0	454
15.0	0.4	480
15.0	1.5	577



Table 11. Diphenhydramine HCI release rates in deionized water

ETHOCEL	30% Drug Released	50% Drug Released	80% Drug Released
5% coating	10 min	20 min	150 min
10% coating	25 min	50 min	270 min
15% coating	45 min	75 min	360 min

The ETHOCEL and METHOCEL polymers should be dissolved in a solvent (or solvent blend) at approximately 10 to 15% solids. A plasticizer (e.g. glycerine) may be added to the mixture. The following solvents are recommended:

- Ethanol
- Methanol
- Acetone
- Chloroform and ethanol blend
- Ethyl lactate and ethanol blend
- Methyl salicylate and ethanol blend
- Methyl salicylate
- Toluene and ethanol blend
- Methylene chloride and ethanol blend

Spray coating can be used to apply a thin film coating of ETHOCEL to the surface of tablets or non-pareils. A solution of ETHOCEL is typically made with a solvent and a plasticizer. The solution is applied to the tablets or non-pareils using equipment such as a Wurster fluidized bed. The solvent evaporates, leaving a film coating of ETHOCEL polymer. Typical process temperatures include an inlet temperature of 55 to 60°C, product temperature of 35 to 45°C, and exhaust temperature of 30 to 40°C. These temperatures were used in a 9-inch Wurster fluidized bed with a 4 kg (8.8 lb) batch size. Different solvents and plasticizers have been used to make solutions of ETHOCEL for spray coating, for example:

Component	Weight Percent
ETHOCEL Std. 10 Premium	10
Triacetin USP	1
Acetone	89

The coating thickness, and thus release profile, can be varied by changing the number of passes through the fluidized bed. The above formulation was used to apply a controlled-release coating of

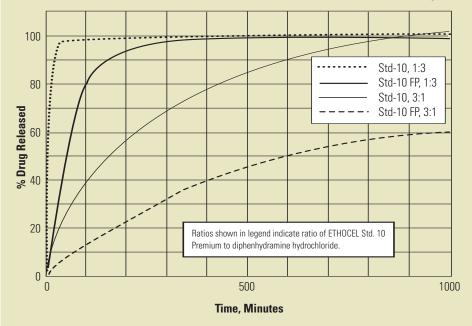


Figure 9. Drug dissolution of ETHOCEL Std. 10 Premium granular vs. fine particle

ETHOCEL to diphenhydramine, HClcoated, non-pareils using a Wurster fluidized bed. Coating levels of 5%, 10%, and 15% were tested for dissolution rates. Table 11 shows the time for 30%, 50%, and 80% drug release in deionized water.

Although it is not a true encapsulation process, time-release capsules are often manufactured by spraying solutions of METHOCEL and ETHOCEL polymers onto small beads of active ingredients. Wide variations of release rates or release patterns can be achieved by varying polymer ratios and coating weights.

ETHOCEL polymers also are used in a coacervation process to microencapsulate particles. The microencapsulation of particles in a boiling cyclohexane-ETHOCEL polymer mixture is described in the NCR process (U.S. Patent No. 3,567,650) and is used in some pharmaceutical applications.

The technology of making and spraying solvent-free emulsions of ETHOCEL polymers (as discussed on pg. 19) has been used in the pharmaceutical industry to coat tablets with ethylcellulose in the absence of volatile, flammable, organic solvents.

5.3 Tablet Binding

ETHOCEL products are used as tablet binders in dry granulation or direct compression formulations. Figure 9 illustrates the comparative dissolution of diphenhydramine hydrochloride from tablets prepared with granular and fine powder forms of ETHOCEL Standard Premium products at two different ethylcellulose to drug ratios at a constant compression force of 3600 kg (8000 lb). The drug release rates are significantly affected by the level of polymer in the tablet and the particle size. The higher the polymer concentration and the smaller the particle size, the slower the release rate.

Specialty Applications



THOCEL ethylcellulose polymers have provided excellent functionality in many specialty applications for more than 60 years. They have been used as viscosifiers, binders, and film formers in applications such as conductive pastes, printing inks, ceramics, and specialty coatings. Table 12 provides guidelines for selecting the right ETHOCEL polymer for specialty applications.

Table 12. Selection of ETHOCEL polymers for specialty applications

Application	ETHOCEL Polymer
Conductive pastes	ETHOCEL Std. 4, 7, 10, 45, 100, 200, 300 Premium and Industrial
Ceramics	ETHOCEL Std. 10, 45, 100 Premium and Industrial
Personal care	ETHOCEL Std. 7, 10, 20, 45, 100 Premium and Industrial
Rotogravure and flexo packaging inks	ETHOCEL Std. 4, 7, 10, 20 Industrial
Screen printing paste ink	ETHOCEL Std. 45, 100, 200, 300 Industrial
Low-solids coatings	ETHOCEL Std. 100, 200, 300 Industrial
Specialty coatings	ETHOCEL Std. 4, 7, 10, 20, 45, 100, 200 Industrial

6.1 Personal Care

ETHOCEL polymers are approved for use in cosmetics. Ethylcellulose is listed in the International Cosmetic Ingredient Dictionary and Handbook (INCI). The INCI name for ETHOCEL is ethylcellulose. It is also listed in the Japanese Standards of Cosmetic Ingredients.

ETHOCEL ethylcellulose polymers are naturally derived polymeric materials. ETHOCEL is not a skin sensitizer, it is not irritating to the skin, it is not mutagenic.

ETHOCEL is soluble in many organic solvents, including ethanol and natural oils. It yields strong, flexible films at low concentration. It provides excellent water resistance and can be used to protect water-sensitive ingredients.

ETHOCEL has been used in lipsticks and nail polishes (it gives long-lasting brilliance), as a fragrance stabilizer, and as a thickener for perfumes and body creams (waterproof sunscreens). It can be used to mask or control the release of active ingredients. Refer to Section 5 for more information on controlled release, granulation, coating, and tablet binding.

ETHOCEL FP polymers may broaden formulation options available in the area of personal care. ETHOCEL polymers have been used for decades in the hydrated state as water-resistant film formers in sunscreens, lipsticks, and ointments. The enhanced lipophilic and hydrophobic properties of ETHOCEL FP in the unhydrated state can be used to improve controlled release of oily actives, improve stability of an active, and in viscosity modification. Refer to **www.ETHOCEL.com** for the most recent information.

6.2 Food Applications

ETHOCEL polymers are odorless, tasteless, and film-forming and are therefore used in food applications such as flavor encapsulation, inks for marking fruits and vegetables, and as a component of paper and paperboard packaging in contact with aqueous and fatty foods. The specifications applicable to food uses are defined in the Food Chemicals Codex. ETHOCEL Premium polymers meet specifications of the Food Chemicals Codex. Refer to **www.ETHOCEL.com** for the most recent information.

6.3 Animal Feed

ETHOCEL polymers are organo-soluble film formers. These polymers can be used to control the release of nutrients in animal feed pellets or granules. They also protect nutrients or any other ingredient against external ingredient attacks—water in particular. In addition, moisture retention can also be achieved by coating the ingredient with ETHOCEL polymers.

6.4 Conductive Pastes

ETHOCEL polymers are used in conductive pastes. They function as a rheology modifier and as a binder and stabilizer for metal pigments. They burn out cleanly, leaving no residue after firing. An example of a solution for a conductive paste is given below.

Component	Weight Percent
ETHOCEL Std. 45 Industrial polymer	5–10
Butyl CELLOSOLVE™ acetate/terpineol blend	90–95
Dispersing agent	0.1

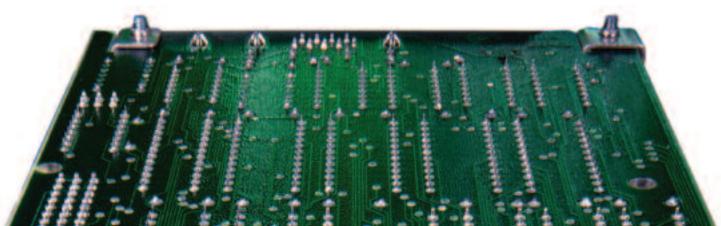
A final conductive paste might combine 20 to 40% of the solution described above with 60 to 80% metal powders.

6.5 Ceramics

ETHOCEL polymers are used in solventbased ceramics as rheology modifiers and binders. They provide green strength to the unfired ceramic and burn out easily, leaving no residue after firing.

6.6 Printing Inks

Generally, ETHOCEL polymers are used to enhance the quality of flexographic and gravure inks. However, they also can be used as a binder in these formulations. They favorably impact toughness and flexibility of the ink film, resulting in better folding resistance. They also improve printability on difficult substrates and contribute to the formation of tough, pinhole-free films even at low coating thickness. They show good compatibility with most of the resins and pigments used in these inks and show excellent solubility in common solvents such as toluene, ethyl acetate, and ethanol.



6.6 Gravure Ink

Gravure printing is used for relatively large-volume, high-quality, high-speed runs for printing high-quality publications, magazines, catalogues, and advertisements. It is also used in packaging for quality color printing on transparent and flexible films. ETHOCEL is soluble in solvents commonly used in gravure printing. It functions as a rheology modifier, improves printability on difficult substrates, and acts as a dispersant and binder for pigments. An example of a packaging gravure ink is given below:

Component	Parts
Magenta concentrated ink	100
Ink varnish	30
Toluene	40
ETHOCEL Std. 10 Industrial polymer	1

6.6 Heat-Transfer Printing

In heat-transfer printing, the ink is printed or deposited onto paper and then transferred with heat to fabrics (e.g. polyesters, triacetate, and acrylics). As an example, a heat-transfer ink formulation could contain:

Component	Parts
Буе	1–5
ETHOCEL Std. 10 Industrial polymer	12-20
Solvent	75–85
Thermoplastic binder (for tack)	0–10

6.6 Solvent-Free Hot Melt Inks

ETHOCEL products may also be used as the base polymer in formulating solventfree hot-melt inks, which are used to print textile fabrics, novelty designs and information on T-shirts, manufacturers' labels, and patterns for embroidery. A general composition is:

Component	Parts
Castor oil	6
Paraffin wax	40
ETHOCEL Std. 10 Industrial polymer	16
Pigments	20
Heat stabilizer	0–10

All ingredients except the ETHOCEL polymer are heated to 150°C (302°F). The ETHOCEL polymer is added slowly, with agitation. A homogeneous liquid ink results when the ETHOCEL polymer melts.

6.7 Hot Melt Strippable Coatings

Hot melt strippable coatings are 100% nonvolatile systems. These hot melts are used by industry primarily to protect metal parts against corrosion and damage during handling, shipment, and storage.

Room-temperature parts (or objects) are cleaned and then dipped into the hot melt. Within 5 seconds, a tight envelope 0.2 to 0.25 cm (0.07 to 0.10 inch) thick will gel around the part. The part is then lifted from the melt and cooled.

The materials used with ETHOCEL polymers in a transparent hot melt strippable coating must be carefully selected because of the high temperatures encountered in the dip tanks (177 to 191°C, 350–375°F) and because of the long heating periods involved. Heat-stable, nonvolatile mineral oils, polymers, and plasticizers must be chosen; antioxidants and heat stabilizers are recommended. If the coating is to be transparent, the ingredients must be compatible.

The materials in a typical strippable coating formulation could include:

Weight Percent
25
50
15
7
1
1
1
100

6.8 Room-Temperature Lacquers

Room-temperature lacquers are conventional lacquers in which the coating is applied at room temperature and the film is formed by evaporation of the solvent. ETHOCEL Standard polymers are recommended for this type of application because of greater solubility in typical organic solvents and greater compatibility with a wide range of modifying polymers.

ETHOCEL Std. 4, 7, and 10 products are typically used in lacquers where:

- Minimum viscosity development is desired at maximum lacquer nonvolatile (solids) content, or
- Somewhat reduced toughness can be accepted, or
- Compatibility with other lacquer ingredients is needed

ETHOCEL Std. 45 and 100 products are used in lacquers where greater toughness is desired combined with the greater solubility of Standard vs. Medium grades. These two ETHOCEL products are also used where maximum viscosity at minimum concentration is desirable. ETHOCEL Std. 20 ethylcellulose is a natural compromise.

ETHOCEL Medium products are used in lacquers where maximum toughness is desired and the somewhat lower solubility in particular solvents is not a problem.

6.9 Gel Lacquers

A gel lacquer of ETHOCEL polymer is hot lacquer composed primarily of ETHOCEL polymer, plasticizer, and solvents. The gel lacquer is a homogeneous liquid at or near the temperature of boiling water. When allowed to cool, the lacquer becomes a gelled mass resembling tough gelatin.

Dipping a cool (room temperature) object into a hot gel lacquer congeals a thick layer of lacquer onto the object's surface. While drying, the applied lacquer shrinks, resulting in a tight-fitting, uniform plastic coating. In a single dipping, a dry coating thickness ranging from 0.004 to 0.08 cm (0.0015 to 0.03 inch) is possible. The thickness of the coating is controlled by the temperature of the object being dipped and by the composition of the lacquer. The ability to obtain unusually heavy coatings with very few dips is a result of the phenomenon of gelation and is a primary advantage of these gel lacquers.

Safe Handling of ETHOCEL Products

Material Safety Data sheets on ETHOCEL ethylcellulose polymers are available to help customers further satisfy their own handling needs and those that may be imposed by regulatory agencies. This information should be requested and read PRIOR to handling or use of the product. Refer to **www.ETHOCEL.com** for the most recent information. The materials used in formulating with ETHOCEL polymers (solvents in particular) may constitute separate hazards from toxicity or flammability. Be certain to get handling and safety recommendations for each such product from its supplier.

7.1 Health Considerations

ETHOCEL polymers are thermoplastic polymers having a polymer "backbone" obtained from cellulose, a naturally occurring carbohydrate polymer.

Dusts from ETHOCEL polymers could conceivably cause temporary mechanical irritation to the eye under extreme conditions. They are considered as nuisance dusts when assessing workplace exposure and control. However, the products are considered to present no significant or unusual health hazard to personnel in normal industrial handling. As a result, no special precautions need be observed to handle the products safely other than the possible need for a local exhaust system to control dust during opening and dumping of bags.

7.2 Combustibility

Dusts or fine powders of ETHOCEL products in air can reach explosive levels, and care must be taken to prevent this.

ETHOCEL products are organic materials and will burn under the right conditions of heat and oxygen supply. ETHOCEL polymers will melt upon exposure to an open flame. Once melted and ignited, these polymers will support combustion. Fires can be extinguished by any available extinguishing agent.

7.3 Dust Explosion

Mechanical handling can cause formation of dusts. To reduce the potential for dust explosion, do not permit dust to accumulate. Material can be ignited by static discharge. Electrically ground all equipment. Do not permit dust to accumulate. Dust layers can be ignited by spontaneous combustion or other ignition sources. When suspended in air, dust can pose an explosion hazard.

7.4 Spills

To prevent accidents, good housekeeping requires that spills of ETHOCEL products should be thoroughly vacuumed or swept up. For small spills of liquid formulations of ETHOCEL polymers, a solid absorbent should be used to absorb the liquid. Any solvents should then be allowed to evaporate, and the absorbent containing the ETHOCEL polymer should be disposed of via approved landfill or incineration.

For large liquid spills, appropriate diking precautions should be taken until the solution can be collected for proper disposal. *In liquid solution spills, solvents may present significant health and fire hazards.*

7.5 Disposal

ETHOCEL polymers are not water-soluble and do not biodegrade in aquatic environments. The polymer should, therefore, present no ecological hazard to aquatic life.

ETHOCEL products present no significant ecological problems, and therefore can be disposed of by recycling, reclaiming, or burning in an adequate incinerator or by burial in an approved landfill. Incineration should be done under carefully controlled conditions to avoid the possibility of a dust explosion.

If it is necessary to dispose of a formulation that includes ETHOCEL products, it is recommended that the suppliers of all formulation ingredients be consulted before deciding on a suitable disposal method.

In disposal of any wastes, be certain all applicable federal, state, and local regulations are met.

7.6 Storage/Handling

The shelf life for ETHOCEL Standard grades is a nominal three years from date of manufacture. For ETHOCEL Medium grades, the shelf life is two years from date of manufacture. ETHOCEL products should be stored at temperatures not exceeding 32°C (90°F) in a dry area away from all sources of heat.

In storage or use, good housekeeping is required to prevent dusts or fine powders of ETHOCEL polymer from reaching explosive levels in air. When handling ETHOCEL polymers in large quantities or in bulk, refer to general precautions outlined in NFPA Code Nos. 68, 69 and 654.

As with any organic chemical material, ETHOCEL polymers should not be stored next to peroxides or other oxidizing agents.

Premium ETHOCEL products are subject to the "Good Manufacturing Practices" of the Food and Drug Administration. Materials in these applications should not be stored near hazardous or nonfood chemicals.

To prevent odor transference, ETHOCEL Premium polymers should not be stored adjacent to any foul-smelling material.

¹ National Fire Protection Association, Battery March Park, Quincy, MA 02269

Regulatory Status

Food and Pharmaceuticals

ETHOCEL Premium polymers meet the requirements of the following FDA regulations:

21CFR 73.1—Color additive for foods. Diluent in inks for marking food supplements in tablet form, gum and confectionery; inks for marking fruits and vegetables; and as diluent in color additive mixtures for coloring shell eggs.

21CFR 73.1001—Color additive for drugs. Diluent used in ink to mark ingested drugs and externally applied drugs.

21CFR 172.868—Certain direct food uses. As a binder and filler in dry vitamin preparations; as a component of protective coatings for vitamin preparations and mineral tablets; and as a flavor fixative in flavoring compounds.

21CFR 175.105—Adhesives. Generally recognized as safe. (Cross reference to 182.90).

21CFR 175.300—Resinous and polymeric coatings.

21CFR 176.170—Components of paper and paperboard in contact with aqueous and fatty food. Generally recognized as safe. (Cross reference to 182.90).

21CFR 176.180—Components of paper and paperboard in contact with dry food. Generally recognized as safe. (Cross reference to 182.90).

21CFR 177.1210—Closures with sealing gaskets for food containers. (Cross reference to 175.300).

21CFR 182.90—Substances generally recognized as safe-substances migrating to food from paper and paperboard products. Ethylcellulose.

ETHOCEL Premium ethylcellulose polymers meet the requirements of the Food Chemicals Codex, the International Codex Alimentarius, and the National Formulary (NF). They meet the requirements of the Japanese Pharmaceutical Excipients (JPE) Monograph as well as the requirements of the European Pharmacopoeia (EP).

ETHOCEL ethylcellulose polymers meet the requirements of Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with foodstuffs.

Cosmetics and Personal Care Products

ETHOCEL ethylcellulose polymers are allowed for use in cosmetics. Ethylcellulose is listed in the International Cosmetic Ingredient (INCI) Dictionary. The INCI name for ETHOCEL is ethylcellulose. Ethylcellulose is also listed in the Japanese Standards of Cosmetic Ingredients (JSCI).

ETHOCEL ethylcellulose polymers meet the requirements of Directive 96/335/EC establishing an inventory and a common nomenclature of ingredients employed in cosmetic products (INCI).

Animal Feed

International Feed Name and International Feed Number (IFN): *ethyl cellulose 4-08-045*. The IFN will assist feed producers in having their feed products approved by regulators such as the U.S. Department of Agriculture, the Canadian Food Inspection Agency, and the UN Food and Agriculture Organization (FAO).

United States FDA Regulation 21CFR 573.420—Certain uses in animal feed. As a binder or filler in dry vitamin preparation to be incorporated into animal food.

ETHOCEL industrial and Premium grade ethylcellulose polymers are approved in Europe for animal feed under Directive 70/524/EEC for all species or categories of animals.

For more information, complete literature, and product samples, you can reach a Dow representative at the following numbers:

From the United States and Canada:

call 1-800-447-4369 fax 1-989-832-1465

In Europe: toll-free +800 3 694 6367+ Phone: 32-3-450-2240 Fax: 32-3-450-2815

In Latin America:

Phone: 55-11-5188-9222 Fax: 55-11-5188-9749

In the Pacific:

Call 60 3 7958 3392 Fax 60 3 7958 5598

All Pacific countries except Indonesia & Vietnam:

Toll-free call 800 7776 7776 Toll-free fax 800 7779 7779

⁺Toll free from Austria (00), Belgium (00), Denmark (00), Finland (990), France (00), Germany (00), Hungary (00), Ireland (00), Italy (800 783825), The Netherlands (00), Norway (00), Portugal (00), Spain (00), Sweden (00), Switzerland (00) and the United Kingdom (00).

Or you can contact us on the Internet at:

www.ethocel.com

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