

paper.

### Product Information

### SOLUTION

### VISCOSITY

### Molecular Weight-Viscosity Relationship

METHOCEL cellulose ether products are linear poylmers consisting of anhydroglucose rings to which various substituent groups have been attached. The apparent viscosity is proportional to molecular weight or chain length of the METHOCEL cellulose ether products.

Commercial designations of METHOCEL cellulose ether products are based on viscosity values determined in water at 20°C and at a concentration of two percent cellulose derivative content. The methods are described in ASTM monographs D1347-72 and D2363-72.

### Molecular Weight | Viscosity Correlation 20°C



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ber of Average Molecular Weight for METHOCEL A cellulose ether and was obtained from osmotic pressures. The Number Average  $DP_n$  was obtained by dividing  $M_n$  by the unit molecular weight of 186. To obtain the Number Average Molecular Weights for the other

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METHOCEL cellulose ether products, the following Unit Molecular Weights must be used: METHOCEL "E", 201; METHOCEL "F", 195; METHOCEL "J", 222; METHOCEL "K", 192; and METHOCEL "HB", 195.

The table on page 6.4 provides further information

regarding correlation of number average molecular

weight with the commercial viscosity designation. To

interpret or to extend the table, plot the first column as

abscissa and the others as ordinates on bi-logarithmic

The date in the right-hand column represents the Num-

Intrinsic Viscosity is the limiting quotient of the specific viscosity divided by the concentration as infinite dilution is approached (that is, as the concentration approaches zero). The Number Average Molecular Weight is calculated from the limiting osmotic pressure of the solvent as the concentration of the solute approaches zero. The weight average molecular weight will be 3-10 times the  $M_n$  depending on the viscosity grade. Lower viscosity products require multiplying factors that are larger.

-Continued

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### Viscosities of Methylcellulose of Various Molecular Weights

Viscosity Grade 2%, 20°C, cP	Intrinsic Viscosity (n), dl / g at 20°C	Number Average DP <sub>n</sub>	Number Average Molecular Weight, M <sub>n</sub>
5	12	53	10 000
10	1.4	70	13.000
40	2.05	110	20,000
100	2.65	140	26,000
400	3.90	220	41,000
1,500	5.7	340	63,000
4,000	7.5	460	86,000
8,000	9.3	580	110,000
15,000	11.0	650	120,000
19,000	12.0	750	140,000
40,000	15.0	950	180,000
75,000	18.4	1,160	220,000

From Encyclopaedia of Polymer Science and Technology, 3, p. 504. Interscience, John Wiley & Sons, N.Y. and London, 1965.

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### Product Information

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### **Effect of Concentration on Viscosity**

An application or end product formulation usually requires a predetermined METHOCEL cellulose ether product viscosity. The following charts provide the concentrations of the various viscosity METHOCEL cellulose ether products that will produce the desired viscosity.

They illustrate the viscosity-concentration relationships for METHOCEL cellulose ether products at 20°C (68°F). The data in the graphs represent the average material found within a viscosity specification. The shaded areas indicate the range of viscosity that may be obtained for a given METHOCEL cellulose ether products.

The figures depict the viscosity-concentration relationships for solutions of low- and high-molecular-weight METHOCEL cellulose ether products. These graphs are prepared on 8th root, not on logarithmic paper. The 8th root of the viscosity is a roughly linear function of the concentration. To chart the line for any intermediate grade, locate the desired 2 percent viscosity above 2 percent on the abscissa and draw a straight line to the point of origin.

Blends of the METHOCEL E products also can be used to obtain a range of required viscosity and film properties. Examples of viscosity response with different blends of polymer at concentration of 5 and 10%, and related blending curves, are shown in the Figures under "Recommended Concentrations," page 6 • 13.

The data shown were measured in water as "solvent", at 20°C, using an Ubbelohde viscometer (ASTM D2363-72).

### Viscosity-Concentration Chart for Low Viscosity METHOCEL Products



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### 50,000 40.000 30,000 20.000 15,000 10,000 7,000 5,000 4.000 3,000 Viscosity, cP @20°C 2,000 1,000 700 500 400 300 200 100 70 40 10 6 8 10 12 14 **Concentration**, % of METHOCEL



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Viscosity-Concentration Chart for High-Viscosity METHOCEL

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### **Blending for Intermediate Viscosity**

METHOCEL cellulose ether products of the same substitution type but of different viscosity grades can be blended to obtain an intermediate viscosity grade. The figure following is a blending chart that can be used for this purpose. The points corresponding to the viscosities of the two starting materials are selected on the two vertical scales and connected with a line. The point corresponding to the desired final viscosity

Blending Chart for METHOCEL Cellulose Ether Products

is then located on one of the vertical scales and a horizontal line drawn from it to the first line. The percent of right-hand-scale material needed to make up the blend can then be read from the bottom scale. The example on the chart shows that 60 percent of 15,000 cps material and 40 percent of 400 cps material are needed to make a blend having a viscosity of 4,000 cps. Similarly, 50 percent of 25 cps material and 50 percent of 100 cps material yield a blend with a viscosity of 50 cps.





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### Effect of pH on Viscosity

Because METHOCEL methylcellulose and METHOCEL hydroxypropyl methylcellulose are nonionic, the viscosities of their solutions are generally stable over a wider pH range than are the viscosities of those gums which are ionic in nature. Outside the range of pH 3 to 11, however, there may be a gradual loss of viscosity at higher temperatures or after longer periods of standing, especially with high viscosity solutions. Solutions of METHOCEL cellulose ether products in strong acids or in strong caustic solutions will decrease in viscosity. This factor should be considered when determining the shelf life of products.

### **Effect of Additives on Viscosity**

In the preparation of formulations, viscosities may occasionally be considerably higher than expected. This phenomenon can be caused by interaction of the METHOCEL cellulose ether product with one or more of the formula ingredients. As a result, it may be possible to use less thickener and still have adequate thickening. This effect usually passes through a maximum which is dependent on the concentration of the interacting materials and on the presence of other ingredients such as pigments, latex particles, or preservatives. In systems having lower concentrations of additives,  $\sim 1\%$ , METHOCEL A or METHOCEL K products may be suitable. However, in systems where the concentration of additives are rather high,  $\sim 10\%$ , the more highly substituted products such as METHOCEL E or METHOCEL J

may be more compatible due to their increased organic compatibility. The effect will also vary with the purity of the specific reagent and with the manufacturing source. Effects of various additives on the viscosity of 1% solutions of METHOCEL is seen in the table on page 6•8.

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If a manufacturer wishes to minimize the increase in viscosity obtained from certain additives, the METHOCEL cellulose ether product or the additive should be blended separately into the formulation, preferably at a point where dilution of one of these ingredients takes place. It should be noted that certain surfactants at high concentration will precipitate METHOCEL cellulose ether product.

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%				Increase in Viscosity of METHOCEL Brands				
Irademark	Additiv	e Producer	Description	A	B	F	К	J
Conco AA5-35S	1	Continental Chemical Company	Sodium dodecyl benzene sulfonate	227	1863	908	36	-
Conco Sulfate EP	1	Continental Chemical Company	Diethanolamine lauryl sulfate	145	104	94	53	-
Miranol C2M Conc.	1	Miranol Chemical Co. Inc.	Dicarboxylated imidazoline derivative of coconut fatty acid	0	-5	1	-1	-8
	25			-80	75	-	-2	99
Miranol L2MSF	1	Miranol Chemical Co., Inc.	Dicarboxylated imidazoline derivative of tall oil fatty acid	11	6	11	8	
	10			-58	-81	-	-68	-9
Miranol 2MCT Modified	1	Miranol Chemical Co., Inc.	Polyoxyethylene (3)tridecyl sulfate salt of a dicarboxylated imidazoline derivative of coconut fatty acid	10	0	5	4	-1
	10			41	34	-	40	4
Wiranol HM Conc.	1	Miranol Chemical	Monocarboxylated imidazoline derivative of lauric acid	8	-1	5	4	!
	10			30	30	-	35	29
Polystep B-11	1	Stepan Chemical Co.	Ammonium lauryl ethoxylate (4) sulfate	36	50	57	42	:
luaternary 0	1	Geigy Chemical Corp.	Quaternary ammonium imidazoline derivative	26	22	22	18	1(
Span 60	1	ICI America, Inc.	Sorbitan monostearate	104	100	124	105	-
leepol 610	1	Shell Chemicals UK Ltd.	Secondary sodium alkyl sulfonate	184	36	122	132	-
riton CQ 400	1	Rohm & Hass Co.	Stearyl dimethyl benzyl ammonium chloride	109	71	149	168	-
lween 20	1	ICI United States, Inc.	Polyoxyethylene (20) sorbitan monolaurate	5	-8	-10	2	
Ultrawet 30 DS	1	ARCO Chemical Co.	Sodium linear alkylate sulfonate	2080	5845	2798	107	-

### 6.8 Effect of Additives on Viscosity of 1% Solutions of METHOCEL Cellulose Ether



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### SOLUTION **RHEOLOGY OF METHOCEL SOLUTIONS**

Rheology, defined as the "science of deformation and flow of matter," plays an important role in many practical applications, such as paint, cosmetics, food products, and many more, where modification of flow behavior is essential. A Newtonian fluid is one whose viscosity is independent of shear rate (or velocity gradient of flow). In actual practice many systems exhibit non-Newtonian flow behavior where apparent viscosity may decrease (pseudoplastic) or increase (dilatant) with increasing rate of shear. These behaviors differ from time dependent viscosity changes where viscosity may decrease (thixotropy) or increase (rheopexy) with time at a constant rate of shear.

Rheology of an aqueous solution of METHOCEL is affected by its molecular weight, concentration, temperature and by the presence of other solutes. In general, at a temperature below the incipient gelation temperature, aqueous solutions of METHOCEL exhibit pseudoplastic flow. Pseudoplasticity increases with increasing molecular weight or concentration. However at very low shear rates, all METHOCEL cellulose ether solutions appear to be Newtonian and the shear rate, below which the solution becomes Newtonian, increases with decreasing molecular weight or concentration. The two figures on this sheet demonstrate those properties (see also page 6.8).

### Apparent Viscosity vs. Shear Rate Curves for 2% Aqueous Solutions of METHOCEL at 20°C



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Apparent Viscosity vs. Shear Rate Curves for Aqueous Solutions of 4000 CPS Grade METHOCEL at Different Concentrations at 20°C



Below the incipient gelation temperature (for example at 20°C), the rheology of solutions of METHOCEL in water is not affected by the type or degree of substitutions, i.e. the same viscosity grade A, E, F, K, or J products will exhibit identical viscosity-shear rate curves as long as the concentration and temperatures are kept constant. Upon heating, a solution of METHOCEL forms three dimensional gel structure and exhibits highly thixotropic flow. At high concentrations, a low-viscosity type METHOCEL may also be thixotropic even below the gelation temperature.



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### SOLUTION

### **THERMAL GELATION** IN AQUEOUS MEDIA

METHOCEL cellulose ether products possess unique solubility properties in aqueous media. These products are insoluble and therefore dispersible in water that has been heated above a certain specific temperature. Below those temperatures the solvation and solubility of METHOCEL cellulose ether products increase as the temperature is lowered.

Aqueous solutions of METHOCEL cellulose ethers when heated will gel at temperatures that are specific for each type. These gels are completely reversible in that they are formed upon heating yet will liquify upon cooling. This unique thermal gelation of aqueous solution of METHOCEL cellulose ether is a valuable property for many end uses.

The gelation phenomenon of aqueous solution of METHOCEL cellulose ether has been postulated to be primarily caused by the hydrophobic interaction between molecules containing methoxyl groups. In a solution state at lower temperatures, molecules are hydrated and there is little polymer-polymer interaction other than simple entanglement. As the temperature is increased, the molecules gradually lose their water of hydration as reflected by decrease in viscosity. Eventually when a sufficient but not complete dehydration of the polymer occurs, a polymer-polymer association takes place and the system approaches an infinite network structure as reflected by a sharp rise in viscosity.

The behavior of a typical solution of METHOCEL cellulose ether, as the temperature is increased and subsequently cooled, is shown in the figure to the right. The upper figure on page 6+10 is a typical Arhenius plot of natural log viscosity vs reciprocal of absolute temperature showing deviation from linearity, indicating initiation of polymer association.

The specific thermal gelation temperature is governed by the nature and quantity of the substituent groups attached to the anhydroglucose ring and will thus vary with each type of cellulose ether. For a specific type of METHOCEL cellulose ether, there is little or no variation of gel temperature on changing viscosity of the grade. For all brands, increasing the concentration will result in lowering the thermal gelation temperature. Accurate measurement of gelation temperature is very difficult because it is a function of the rate of heating and the rate of shear during the viscosity measurement, and is also a function of temperature. A high rate of shear and fast heating rate will result in an apparently high gel temperature.

The Table shows the approximate gelation temperature

for 2% aqueous solution of each brand of METHOCEL cellulose ether products. The lower Figure on page 6.12 shows the relationship between gelation temperature and concentration for A, E and F type METHOCEL cellulose ethers.

### Approximate Gel Points of METHOCEL cellulose Ether Products (2% aqueous solution)

Brand	Gelation Temperature°C
А	48
HB	49
F	54
E	56
J	56
К	70

Gelation Of 2% Aqueous Solution Of METHOCEL A100 On Heating @ 0.25°C | min Rate



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### 6 • 12 Viscosity - Temperature Relationship for 2% Aqueous Solution of METHOCEL A100 at a Shear Rate of 86 sec<sup>1</sup>

Incipient Gelation Temperature Of Different METHOCEL Products As A Function Of Concentration



### **Gel Strength and Texture**

The texture and the stength of gel produced upon heating aqueous solutions of METHOCEL cellulose ether varies with the type, viscosity grade and the concentration of METHOCEL used. If a manufacturer wants a thermogelling substance to set with a slight elevation of temperature and give strong elastic gel, he uses METHOCEL A cellulose ether. If he wants a softer, non rubbery gel, he uses F or E type METHOCEL cellulose ethers. For applications in which only a mushy appearance is desirable on heating, METHOCEL K or METHOCEL J will be the product of choice.

In general the strength of the gel increases sharply on increasing molecular weight and gradually becomes constant at or above viscosity grade of 400 cP. Gel strength also increases with increasing concentration. The next table shows the typical gel strength of some of the METHOCEL cellulose ether products.

Agitation affects the strength and apparent temperature of gelation; continued rapid agitation during gelation -Continued may break down the gel structure and alter both the texture and strength of the gel. For the maximum development of gel strength under quiescent condition, heat the solution above the gelation temperature for about 3 hours.

### Gel Strength of Different METHOCEL Brand Cellulose Ethers as Measured by a Penetrometer.

METHOCEL A15400METHOCEL A251000METHOCEL A502000METHOCEL A1003500METHOCEL A4C5000METHOCEL A4M5000METHOCEL F4M1500METHOCEL E4M> 500METHOCEL E4MNot measurableMETHOCEL J4MNot measurable	METHOCEL Brand	Gel Strength, g/cm² of 2% Solution at 65°C
METHOCEL J4M Not measurable	METHOCEL A15 METHOCEL A25 METHOCEL A50 METHOCEL A100 METHOCEL A4C METHOCEL A4M METHOCEL F4M METHOCEL E4M METHOCEL K4M	400 1000 2000 3500 5000 5000 1500 > 500 Not measurable
	METHOCEL J4M	Not measurable

### Effect of Additives on Thermal Gelation

Additives may either increase or decrease the thermalgel temperature. A particular concentration of one additive may increase the gel temperature and the same concentration of a different additive may decrease it. Decrease in gel temperature is a function of the ions present: the higher the charge on the ion, the greater will be the decrease in the thermal gel temperature. If a manufacturer requires a high thermal gel temperature and plans to use additives that would reduce that temperature, he uses a METHOCEL cellulose ether product gelling at a temperature higher than the temperature he requires. As the concentration of a gel-causing additive increases, the thermal gel temperature decreases.

A list of representative additives and their effect on various METHOCEL cellulose ether products is shown in the following table.

Effect on Gelation Temperature Noted With Additives to 2 Percent Solutions of METHOCEL Cellulose Ether

Additiv	e	METH (1,	OCEL A15C 500 cps)	METH (1,	OCEL F15C* 500 cps)	MET (4	HOCEL K4M ,000 cps)	MET (5	HOCEL J5M ,000 cps)
Compound	%	°C	°F	°C	°F	°C	°F	°C	°F
CONTROL				( new an					
(no adr	litive)	50	122	63	145	85	185	62	143
NaCl	5	33	91	41	105	59	138	12	107
MaCI 1	5	12	107	52	125	67	153	50	107
FoCi	2	42	107	52	123	76	100	50	122
No CO	5	42	Coltor out	55	Calted out	10	Coltad aut	53	Caltad aut
	3		Salted out	45	Salted out	40	Salted out	44	Salteo out
AI2(504/3	2.5		Salted out	45	113	48	118	41	105
Na <sub>2</sub> CU <sub>3</sub> '	5		Salted out		Salted out		Salted out		Salted out
Na <sub>3</sub> PO <sub>4</sub>	2.0	32	89	42	107	52	125	43	109
Sucrose	5	51	124	66	151	84	183	60	140
Sucrose	20	44	111	59	138	61	142	53	127
Sorbitol	20	30	86	46	115	48	118	39	102
Glycerine <sup>1</sup>	20	34	93	60	140	65-70	149-158	55	131
Ethanol	20	>75	> 167	>75	> 167	>75	> 167	>78	>172
Polyethylene	20	52	126	>80	>176	>80	> 176	>78	> 172
Glycol 400									
Propylene	20	59	138	>80	> 176	>80	>176	>78	> 172
Glycol				I Charles					

\* a special viscosity grade made by blending

Of the compounds in the table, sucrose, ethanol, and the two polyglycols raise the gelation temperature. Unlisted additional compounds that raise the thermal gel temperature include Armac<sup>2</sup>, Armac HDT<sup>2</sup>, Hyamine 1622<sup>3</sup> alkali metal thiocyanates and urea.

<sup>1</sup> The Dow Chemical Company

<sup>2</sup> Armour and Company

<sup>3</sup> Rohm & Haas Company

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The effectiveness of a gel point raising additive on the thermal gel point will vary with the chemical nature of the additive and with the brand of METHOCEL cellulose ether product. For example, a particular additive, propylene glycol, that increases the thermal gel temperature of a solution of METHOCEL A or METHOCEL HB cellulose ether product by 4°C will increase the thermal-gel temperature of a solution of METHOCEL F cellulose ether product by 10°C, and that of a solution of METHOCEL K cellulose ether product by more than 20°C.

The increase in thermal gel point of a solution of METHOCEL is in direct proportion to the increase in concentration of the gel point raising additive. A 2 percent aqueous solution of METHOCEL A cellulose





ether product containing a 10 percent concentration by volume of ethanol will gel at a temperature 10°C higher than a pure aqueous solution of METHOCEL A. A 15 percent concentration of ethanol increases the gel temperature 15°C above the gel temperature of an aqueous solution of METHOCEL A.

A solution of METHOCEL F cellulose ether product containing a 10 percent concentration of propylene glycol gels 6°C higher than does a pure aqueous solution, whereas a solution of METHOCEL F cellulose ether product containing 15 percent concentration of propylene glycol gels 11°C higher than does a pure aqueous solution. The following figures show the relation between concentration of an additive and the thermal gel temperature of representative METHOCEL cellulose ether products.

### Effect of Propylene Glycol on Thermal Gel Temperature (2 Percent Solutions)



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### Product Information

### SOLUTION

### **Factors Affecting Use of Solutions**

### Recommended

### **Concentrations for Coating Solutions**

The concentration for METHOCEL E Premium (USP) products—for aqueous tablet coating—is dependent on the viscosity and equipment being used for spray application. For example: if desired viscosity of the complete coating solution is 150-200 centipoises, METHOCEL E products in water should provide that viscosity at the following concentrations:

Product	Concentration wt/wt
METHOCEL E5 Premium	7.5-10%
METHOCEL E15 Premium	4.5-6.5%
METHOCEL E50 Premium	2.3-3.5%

Note: With addition of other ingredients (pigments, lakes, dyes, plasticizer, etc.), viscosity may have to be adjusted accordingly.

The low viscosity of METHOCEL E5 Premium permits higher solids in the coating solution and consequently less water has to be removed. However, this lower viscosity product gives films having lower elongation. Higher viscosity METHOCEL E15 and METHOCEL E50 cellulose ethers result in tougher, stronger films. Use of blends of different viscosity METHOCEL E products can achieve desired balances of viscosity, solids content, and film strength that are not as readily achieved when one METHOCEL E product is employed.

### **Formulation Properties**

Properly formulated aqueous dispersions of METHOCEL

- E premium products should be:
- excellent film-formers
- noncaloric
- nonallergenic
- non-nutritive
- more resistant to microorganisms than are natural gums
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Blending Chart for METHOCEL E5 and E15 Pre- 6 • 15 mium (USP) (5% Concentration in Water)



### Blending Chart for METHOCEL E5 and E15 Premium (USP) (10% Concentration in Water)



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### 6-16 SOLUTION

### **Starting Point Formulations**

100% Aqueous Coating Systems for Tablets

Formulation	#1	·····#2 ······	#3
	METHOCEL E5	METHOCEL E15	METHOCEL E50
Polymer, % <sup>1</sup>	9.0	5.0	3.0
Plasticizer, %	2.0	1.1	0.66
Pigments, %	7.0	3.85	2.33
Potable Water, %	82.0	91.05	94.01
Solids, %	18.0	8.95	5.99

1% by weight

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Product Information

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### SOLUTION SURFACE ACTIVITY OF AQUEOUS SOLUTIONS

Solutions of METHOCEL cellulose ethers are nonionic surfactants that exhibit moderate surface tension and interfacial tension values, inducing effective emulsification in two-phase systems. Maximum surfactant properties are achieved through the use of METHOCEL E and METHOCEL J cellulose ether products.

The surfactancy of METHOCEL cellulose ether products contributes to their effectiveness as stabilizers and protective colloids. Since protective colloid effects can be specific both as to kind and viscosity, screening tests should be conducted on a range of viscosities and a variety of types of METHOCEL cellulose ether products. Operating temperatures must also be considered because thermal gelation of METHOCEL may occur and surface activity decreases just prior to gelation. Therefore a manufacturer will want to choose a METHOCEL cellulose ether product with a gel-point temperature high enough so he has the surface activity required in his operating temperature range.

### DEFOAMERS FOR AQUEOUS SOLUTIONS

The foaming of METHOCEL cellulose ether solutions is easily controlled by using foam stabilizers and defoamers. The defoamers listed in the table below have been efficient in use; other commercial defoamers could work as well but should be tested for performance. The concentration required for defoaming with any of these agents is 25-1000 ppm based on solution weights. Defoamer concentrations should be kept to the minimum required, because these materials are generally low in water solubility.

### Defoamers Used in Aqueous Solutions of METHOCEL Cellulose Ether

Application	Defoamer	Producer
General Use	Foamicide 581B	Colloids Inc.
	Nopco KFS	Nopco Chemical Company
	Antifoam A, F, B, C	Dow Corning Corporation
	Lauryl alcohol	Dow Corning Corporation
	tri-n-butyl phosphate	Eastman Chemical Corporation
	Polyglycol P1200	The Dow Chemical Company
Paper Sizings	Foamicide 581B	Colloids Inc.
Latex Paints	Hodag PV-22, PV-108	Hodag Chemical Company
	Colloids-581-B	Colloids Inc.
	Drew 475	Drew Chemical
Food	Dow Corning FG-10	Dow Corning Corporation

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# **METHOCEL**<sup>\*</sup>

### Product Information

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### SOLUTION

### EFFECT OF FREEZING ON SOLUTIONS

Solutions of METHOCEL cellulose ether products do not undergo separation into phases upon freezing. There is no separation of fluid layers (syneresis) or formation of insoluble precipitates or haze. This lack of phase separation on freezing is very important in frozen food items. As solutions of METHOCEL cellulose ether products are cooled, solubilization increases, as evidenced by increasing viscosity and improved clarity of solutions. When the solutions freeze, part of the water is held in the latent super-cooled state and does not freeze, and the heat normally released on freezing (heat of fusion) is decreased by the amount of this supercooling.

The figure below shows the relationship of the amount of heat liberated to the solids content of the solution being frozen.

### Heat of Fusion vs Concentration (of Aqueous Solutions)



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DESIGNED PRODUCTS DEPARTMENT

MIDLAND MICHIGAN 48640



Form No. 192-691-78

Mylan v. Qualicaps, IPR2017-00203 QUALICAPS EX. 2017 - 61/86





Product Information

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### SOLUTION

### PRESERVATIVES FOR AQUEOUS SOLUTIONS

METHOCEL cellulose ether products do not support the growth of microorganisms and normally do not require preservatives. They are not, however, antimicrobial agents; if contamination occurs, microorganism growth will not be inhibited. To preserve solutions of METHOCEL, addition of 0.05 to 0.1 percent of the following antimicrobial products is suggested: DOWICIDE\* A Preservative; DOWICIL\* 75 Preservative. Assistance on amounts and formulation requirements on use of the products is available on request. Regulated end users should utilize the appropriate permitted preservative.

### COMPATIBILITY OF AQUEOUS SOLUTIONS

The methylcellulose molecule is nonionic and is not precipitated as an insoluble salt by multivalent metal ions. However, METHOCEL cellulose ether products can be salted out of solution when the concentration

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of electrolytes or other dissolved materials exceeds certain limits. This is caused by competition of the electrolytes for water, which results in lessened hydration of the cellulose ether. Thus, as is true with gelation, an increase in the concentration of METHOCEL cellulose ether or an increase in the amount of additives can cause desolvation of molecules, resulting in salting out of the METHOCEL product. Because of the difference in the amounts of organic substitution, the tolerance for salts of solutions of METHOCEL hydroxypropyl methylcellulose products is generally higher than that of METHOCEL methylcellulose product. There is only slight variation in tolerance among the various METHOCEL hydroxypropyl methylcellulose products.

Water-insoluble materials such as pigments, fillers, etc. will not cause METHOCEL cellulose ether products to salt out of solution. Actually, solutions of METHOCEL often act as excellent dispersing mediums for such materials.

Other water-soluble substances such as starches, glues, and resins may or may not be compatible with METHOCEL cellulose ether products in solution. Tests should be run on these materials to determine compatibility. Often, when a METHOCEL cellulose ether product is not compatible with a substance, maintaining low concentration of the solute in the mixture may bring about compatibility.

Grams of Additive Tolerated by 100 cc 2% Solution without Salting Out							
Additive	METH A15	OCEL A4M	METHC F50	ICEL F4M	METHO K100	DCEL K4M	METHOCEL J5M
NaCl	11	7	17	11	19	12	10
MgCl <sub>2</sub>	11	8	35	25	40	39	22
Na <sub>2</sub> SO <sub>4</sub>	6	4	6	4	6	4	3
$Al_2(SO_4)_3$	3.1	2.5	4.1	3.6	4.1	3.6	2.7
Na <sub>2</sub> CO <sub>3</sub>	4	3	5	4	4	4	3
Na <sub>3</sub> PO <sub>4</sub>	2.9	2.6	3.9	3.5	4.7	4.3	2.5
Sucrose	100	65	120	80	160	115	100

### **Tolerance for Additives**

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### SECTION 7 PROPERTIES: FILM

Because you need quality, reliability and performance predictability in a thickener, protective colloid, film-former, emulsifier...that's why Dow designs, manufactures, and continues to improve METHOCEL water-soluble cellulose ether products.

GENERAL FILM PROPERTIES	7•1
EFFECT OF ADDITIVES	7•2
RESISTANCE TO SOLVENTS	7•2
THERMOPLASTIC FORMING	7•2

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### Product Information

### FILM

### **GENERAL FILM PROPERTIES**

High-strength water-soluble films, supported or unsupported, may be rolled, cast or extruded from formulations of METHOCEL cellulose ether products. These clear, smooth films or coatings, impervious to oils, greases and most solvents, are effective binders even when loaded with inert materials. Applications include paints and coatings.

### **Film Properties**

Tensile and elongation properties of typical films of METHOCEL—cast from water—are shown in the Table.

The need for a plasticizer may be more pertinent when using low viscosity 5cps METHOCEL because of lower film elongation properties. This can be more acute if drying temperatures are too hot.

	Typical Data			
Properties	METHOCEL A	METHOCEL E		
Specific Gravity	1.39	1.29		
Area Factor, in² / lb / mil	24,000	25,860		
Moisture-Vapor Transmission, Rate, 100°F, 90-100% R.H.	67.5g / 100 in² / 24 hr / mil	65		
Oxygen Transmission Rate, 75°F	25cc / 100 in² / 24 hr / mil	70cc / 100 in² / 24 hr / mil		
Tensile Strength, 75°F, 50% R.H.	8500-11,400 lb / in <sup>2</sup>	8500-8850		
Elongation 75°F, 50% R.H.	10-15%	5-10%		
Stability to Ultraviolet (500 hrs, Fadeometer Exposure)	Excellent	Excellent		
Resistance to Oils and Most Solvents	Excellent	Excellent		
Ultraviolet Transmission 400	55%	82%		
(2 mil film) 290	49%	34%		
210	26%	6%		
Refractive Index n <sub>D</sub> <sup>20°</sup>	1.49			
Softening Point	-	240°C		
Melting Point	290-305°C	260°C		
Charring Temperature	290-305°C	270°C		

### Unplasticized Films of METHOCEL Cellulose Ether Products

Note: Data apply to either standard or premium grades © 1974, 1978, The Dow Chemical Company

-Continued

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### 7•2 FILM

### Effect of Additives in Insolubilizing METHOCEL

Insolubilizing Agent	% in Film	Catalyst	Amount of Catalyst	Temp °C	Time Min	% •Insolub.	
Uformite 700 <sup>1</sup>	15	citric acid	pH 4.5	120	20	89	
Uformite 700 <sup>1</sup>	15	НСІ	pH 4.5	120	20	88	
Kymene 234 <sup>2</sup>	20	нсі	pH 2.0	120	20	96	
Rhonite R-21	15	NH4CI	0.75%	120	20	95	
Glyoxal	15	citric acid	4.0%	120	20	95	

Film of METHOCEL cellulose ether dipped for one minute in tannic acid at 95°C acquires 85% insolubility; film dipped for 30 minutes at 95°C becomes 100% insoluble.

<sup>1</sup>Rohm & Haas Company

<sup>2</sup>Hercules Powder Company

### **Resistance to Solvents**

Films and coatings of METHOCEL cellulose ether products are unaffected by animal and vegetable oils, greases, and petroleum hydrocarbons. Of the different types of products, METHOCEL A, METHOCEL F, and METHOCEL K brands are most resistant.

### **Thermoplastic Forming**

Procedures for preparing a dry-mix formulation of METHOCEL E cellulose ether and propylene glycol and other plasticizers are available for extruded sheeting and injection and compression moldings. Such mixes may be compounded in a ribbon-type blender at room temperature and satisfactorily handled by a feeder designed for powders. Most feeders perform better, however, if the dry mix is first densified by being passed through a set of press rolls or through a pelletmill. Flakes of METHOCEL E cellulose ether and propylene glycol and other plasticizers may be extruded or molded directly into a finished water-soluble product at temperatures ranging from 120 to 190°C (240 to 374°F). Properly plasticized sheet and tubing of METHOCEL cellulose ether products can be heat-sealed at about 130°C (266°F).

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### SECTION 8 REGULATED USES

Because you need quality, reliability and performance predictability in a thickener, protective colloid, film-former, emulsifier...that's why Dow designs, manufactures, and continues to improve METHOCEL water-soluble cellulose ether products.

FOODS	8•1
"A" Brand Products	8•1
"E", "F", "K", Brand Products	8•1
PESTICIDE USE	8•1
PHARMACEUTICALS, PARENTERAL INJECTIONS	8•2
COSMETICS	8•2

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FOODS	8•1
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"E", "F", "K", Brand Products	8•1
PESTICIDE USE	8•1
PHARMACEUTICALS, PARENTERAL INJECTIONS	8•2
COSMETICS	8•2

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### **REGULATED USES**

### FOODS

The unusual properties of METHOCEL cellulose ether products have long been used by the food industry. Both methycellulose and hydroxypropyl methylcellulose are recognized as acceptable food additives by the Food Chemicals Codex and the international Codex Alimentaries. Further, both are included in the United States Pharmacopoeia (U.S.P. XIX).

### **Products with "A" Designation**

All the premium grades of METHOCEL A brand meet the requirements of U.S.P XIX and Food Chemicals Codex II. They are generally recognized as safe (GRAS) and meet the requirements of Food Additive Regulation 182.1480 as multiple purpose food substances for non-standard-ized foods.

Besides finding application in non-standardized foods, *premium* METHOCEL A cellulose ether may be used in the following standardized foods<sup>1</sup>: French dressing, salad dressing, artificially sweetened fruit jelly, fruit preserves and jams, soda water, and certain frozen desserts.



<sup>1</sup> French dressing 169.115 Salad dressing 169.150 Artificially sweetened jelly 150.141 Artificially sweetened preserves & jams 150.161 Soda water 165.175 Non-fruit water ices 135.70 Water ices 135.90 Fruit sherbet 135.20 Non-fruit sherbet 135.65

*Premium* METHOCEL A cellulose ether product may likewise be used at a level of 0.15% as a binder to extend and stabilize meat and vegetable patties according to USDA regulation 9 CRF 318.7. *Premium* METHOCEL A may likewise be used at a level of 0.15% to extend and to stabilize (and as a carrier) poultry products under the following USDA regulation: 9 CFR 381.147.

By virture of its GRAS status, *premium* METHOCEL A methylcellulose may be employed as a component of containers or equipment coming in contact with food (indirect food additive). For these types of applications, *standard* METHOCEL A cellulose ether may be substituted for the premium product.

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Most indirect food additive regulations allow the use of GRAS substances. *Premium* METHOCEL A qualifies in all these cases. Where the word methylcellulose is specifically listed in the regulation, the standard grade of METHOCEL A may be used.

### Products with "E", "F", and "K" Designations

The *premium* grades of METHOCEL cellulose ether products designated "E", "F", and "K", meet the requirements of U.S.P. XIX, Food Chemicals Codex II, and Food Additives regulation 172.874 which allows the use of hydroxypropyl methycellulose in non-standardized foods as an emulsifier, film former, protective colloid, stabilizer, suspending agent, or thickener, except in confectionery. These same *premium* grades may also be used in the standardized foods: water ices, fruit and nonfruit sherbets, French dressing, salad dressing, and soda water.

In addition, either *premium* or *standard* grade METHOCEL "E", METHOCEL "F", and METHOCEL "K" brand products may, for a number of applications, be employed as components of containers or equipment coming in contact with food (indirect food additive).

More detailed information concerning the use of METHOCEL cellulose ether products in the food industry is available from Dow upon request.

The Dow Chemical Company, of course, does not recommend that any METHOCEL cellulose ethers be incorporated directly or indirectly into food products, except as such use accords with the provisions of the Federal Food, Drug and Cosmetic Act and applicable state and local laws and ordinances with which the user is cautioned to be familiar.

### **PESTICIDE USE**

Under 40 CFR 180.1001, certain inert ingredients used in pesticide formulations are exempt from the requirements of a tolerance. Methylcellulose and hydroxypropyl methylcellulose may be used in formulations applied to growing crops or raw agricultural commodities after harvest, and methylcellulose may be used in formulations applied to animals. Either standard or premium grade of METHOCEL cellulose ether products is appropriate.

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#### 8 • 2 REGULATED USES

### PHARMACEUTICALS, PARENTERAL INJECTIONS

*Premium* grades of METHOCEL A, METHOCEL E, METHOCEL F, and METHOCEL K are used for pharmaceutical and topical applications. These products are listed in U.S.P. XIX. In addition, METHOCEL A is generally recognized as safe (GRAS) by the Food and Drug Administration. Master files for these products are on file at the Bureau of Drugs of the Food and Drug Administration, to support new drug applications. Permission to open the master file can be obtained by writing The Dow Chemical Company, 2030 Dow Center, Midland, Michigan 48640, Att'n: Legal Department.

The Dow Chemical Company advises against the use of METHOCEL cellulose ether products in any form in the preparation of parenteral injections, because the material is not readily metabolized. Significant injury to the kidney may result from impurities in the blood stream, especially if the methylcellulose had not been properly dissolved.

A bibliography of pharmaceutical and medical references is available from The Dow Chemical Company, 2040 Dow Center, Midland, Michigan 48640, Att'n: Designed Products Sales.

### COSMETICS

METHOCEL cellulose ether products have established themselves in the cosmetics industry with a long history of safe industrial handling. The products have proven to be non-irritating and non-sensitizing in topical applications.

The CTFA names for the METHOCEL cellulose ethers are:

Methylcellulose for METHOCEL A products.

Hydroxypropyl methylcellulose for METHOCEL E, F, J and K products.

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### SECTION 9 ANALYSIS

Because you need quality, reliability and performance predictability in a thickener, protective colloid, film-former, emulsifier...that's why Dow designs, manufactures, and continues to improve METHOCEL water-soluble cellulose ether products.

MEASUREMENT OF VISCOSITY	9 <b>•</b> 1
Ubbelohde Tube Measurement	9•2
SUMMARY, OTHER METHODS	9•3
References	9•3

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### SECTION 9 ANALYSIS

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MEASUREMENT OF VISCOSITY	9•1
Ubbelohde Tube Measurement	9•2
SUMMARY, OTHER METHODS	9•3
References	9•3

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Product Information

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#### ANALYSIS

### **MEASUREMENT OF VISCOSITY**

Solutions of METHOCEL cellulose ether products are not strictly Newtonian, the shear-stress/rate-of-shear relationship is not often linear, and the viscosity behavior is pseudoplastic with increasing shear stress. Therefore, certain precautions must be observed for the accurate measurement of viscosity. Dow employs the A.S.T.M. reference method as its standard procedure. This method involves the use of Ubbelohde tubes, one type for low viscosity and one for high. The Ubbelohde tube is a precision device whose use requires only a small test sample.

For measuring low viscosity, the approximate capillary tube size for a given viscosity type is chosen in order to obtain a flow time of about 50 seconds:

	Viscosity, cps	Size of heavy wall tubing I.D. in mm.
	15	1.5
	25	2.8
7	100	2.4
	400	3.2

#### For measuring high viscosities:

Viscosity, cps	Size of heavy wall tubing I.D. in mm.			
1,500	5.0			
4,000	6.0			
8,000	7.5			
15,000	10.0			
50,000	15.0			
75,000	15.0			

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The viscometer is placed in a  $20^{\circ}C \pm 0.1^{\circ}C$  bath, and the length of time required to deliver a given volume between index marks through a tube of specified capillary size is measured. The time in seconds is then converted to centipoises. Detailed procedures are given in A.S.T.M. Standards D 1347-72 and D 2363-72<sup>1</sup>.

Surface treated powders require pH adjustments to assure complete solution. The ASTM methods are modified by adding 3-4 drops of concentrated reagent grade ammonium hydroxide after addition of the hot water.

Because solutions of METHOCEL cellulose ether are pseudoplastic, the most reproducible viscosities are obtained by cooling to  $5^{\circ}$ C ( $41^{\circ}$ F) and holding for at least one-half hour before testing.

The viscosity of a solution of METHOCEL may also be determined using a rotational viscometer, such as the Brookfield Model LVF<sup>2</sup> viscometer.

When the viscosity of a solution if less than 500 cps, the viscosity is independent of shear, and the solution may be regarded as Newtonian.

The apparent viscosity of a solution of higher viscosity will depend upon the rate of shear, and will decrease as the rate of shear is increased.

The Ubbelohde<sup>3</sup> viscosity (obtained using a capillary of diameter suitable to provide adequate shear) will be most closely approached by using the largest diameter Brookfield spindle that will give an on-scale reading at maximum speed. Thus, conditions are used that provide the highest shear, or lowest conversion factor. The rotational instrument should be calibrated against standard oils. The figure on page 9•2 diagrams an Ubbelohde tube set up.

Solutions with a viscosity of more than 500 cps are pseudoplastic; that is, their viscosity decreases with increased shear. At high concentrations, a low-viscositytype thickener may be thixotropic; that is, its viscosity is time-dependent under shear.

<sup>1</sup>Note: Revisions of these methods should be complete in early 1979

<sup>2</sup>Brookfield Synchro-lectric Viscometer, Brookfield Engineering Co., Stoughton, Massachusetts

<sup>3</sup>Ubbelohde suspended level viscometer is available from chemical supply houses.



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Ubbelohde Tubes for Measuring Viscosities



A.S.T.M. Standards D 1347 and D 2363, American Society for Testing and Materials, 1916 Race Street, Philadelphia, Pa. 19103.

- Continued

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Product Information

#### ANALYSIS

### SUMMARY OF OTHER METHODS

### **References to Methods of Analysis**

Procedures for the analysis of METHOCEL cellulose ether products have been standardized under ASTM D 1347 and ASTM D 2363. These and other information on analysis are listed in the following references:

> Aldrich, J. C., Samsel, E. P., "Application of Anthrone Test to Determination of Cellulose Derivatives in Non-aqueous Media," *Anal. Chem.* 29, 574-76 (1957).

> "Hydroxypropyl Methylcellulose," Food Chemicals Codex, Washington, D.C., National Academy of Sciences and National Research Council, Edition 2 (1972).

> "Hydroxypropyl Methylcellulose," The National Formulary, American Pharmaceutical Association, Washington D.C., Edition XIX (1970).

> Kanzaki, Grace, and Berger, Eugene Y., "Colorimetric Determination of Methylcellulose with Diphenylamine," *Anal. Chem.* 31, 1383-5 (1959).

> Dubois, M., Gilles, K. A., Hamilton, J. K., Repers, P. A., Smith, F., "Colorimetric Method for Determination of Sugars and Related Substances, *Anal. Chem.* 28, 350-356 (1956).

> "Methods of Testing Methylcellulose," ASTM D 1347-72, American Society for Testing and Materials, 1916 Race Street, Philadelphia, Pa., 19103.

"Methods of Testing Hydroxypropyl Methylcellulose," ASTM D 2363-72, American Society for Testing and Materials, 1916 Race St., Philadelphia, Pa., 19103.

"Methylcellulose," Food Chemicals Codex, Washington, D.C., National Academy of Sciences and National Research Council, Edition 2 (1972).

"Methylcellulose," U.S. Pharmacopoeia, Bethesda, Md., The United States Pharmacopoeial Convention, Inc. Edition XIX (1975).

Samsel, E. P., McHard, J. A., "Determination of Alkoxyl Groups in Cellulose Ethers," *Ind. Eng. Chem. Anal. Ed.* 14, 750-54 (1942).

Dow Method No. 211, "Determination of Methylcellulose in French Dressing and Salad Dressing," (1959).

Dow Method No. 212, "Determination of Hydroxypropyl Methylcellulose in French Dressing and Salad Dressing," (1959).

Dow Method No. 239, "The Determination of Methylcellulose in Aqueous Solution with Diphenylamine Reagent," (1962).

Dow Method No. MC-11A, "The Determination of Particle Size Distribution of METHOCEL Cellulose Ethers." (1973).

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### SECTION 10 HANDLING CONSIDERATIONS

Because you need quality, reliability and performance predictability in a thickener, protective colloid, film-former, emulsifier...that's why Dow designs, manufactures, and continues to improve METHOCEL water-soluble cellulose ether products.

HEALTH	10•1
STORAGE	10•1
SPILLS, HOUSEKEEPING	10•1
DISPOSAL	10•1
FACSIMILE MATERIAL SAFETY DATA SHEETS	
Methylcellulose	10.3
Hydroxypropyl Methylcellulose	10.5
Hydroxybutyl Methylcellulose	10•7

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### SECTION 10 HANDLING CONSIDERATIONS

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HEALTH	10•1
STORAGE	10•1
SPILLS, HOUSEKEEPING	10•1
DISPOSAL	10•1
FACSIMILE MATERIAL SAFETY DATA SHEETS	40.0
Methylcellulose	10.5
Hydroxybutyl Methylcellulose	10.5



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Product Information

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### HANDLING CONSIDERATIONS

### HEALTH

METHOCEL cellulose ether products resemble the naturally-occurring plant and seaweed gums in many of their chemical, physical, and functional properties, since all these materials possess a basic carbohydrate structure.

Gums have a long history of use in food and pharmaceutical products. METHOCEL cellulose ether products have had extensive evaluation and testing in both acute and long-term feeding studies in a number of species, including humans. Their use as food additives in a wide variety of food items attests to the safety of METHOCEL cellulose ether Premium products.

While dust from METHOCEL cellulose ether products could conceivably cause temporary mechanical irritation to the skin and eyes under extreme conditions and may be considered as nuisance dusts if breathed, the products are considered to present no significant health hazard in handling. As a result, no special precautions need to be observed in order to handle the products safely.

### STORAGE

METHOCEL products are organic polymers that will burn under the right conditions of heat and oxygen supply. Fires can be extinguished by conventional means.

In storage or use of any dusts or fine powders, good housekeeping is required to prevent dusts in air from reaching possibly explosive levels.

**Caution!** A fine dust of this material is capable of forming an explosive mixture with air. When handling in large quantities or in bulk, the general precautions outlined in NFPA 63, "Prevention of Dust Explosions in Industrial Plants," and in NFPA bulletins 68, 69, and 654 are recommended.

With METHOCEL cellulose ether products with particle sizes of  $74\mu$  or less (finer than 200 mesh) critical levels are reached at concentrations of 28 gm/m<sup>3</sup> (0.03g/ft<sup>3</sup>).

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As with any organic chemical material, METHOCEL cellulose ether products should not be stored next to peroxides or other oxidizing agents.

### **ACCIDENTAL SPILLS & HOUSEKEEPING**

Solutions of METHOCEL cellulose ethers are slippery. To prevent employee falls and injury, floor spills of dry powder should be thoroughly vacuumed or swept up. Any slight residual product on the walls or floor can then be flushed with water into a sewer. If the spill is a viscous solution, it should be further diluted with water before disposal. Likewise accumulation of dust should be avoided to control this hazard.

### DISPOSAL

While Dow studies using standard procedures showed no 5, 10, or 20 day BOD values, activated sludge studies with (<sup>14</sup>C) methylcellulose showed that methylcellulose was 96% degraded or otherwise removed from solution in 20 days. Thus the METHOCEL cellulose ethers should present no ecological hazard to aquatic life.

Since METHOCEL cellulose ether products and their formulations present no significant ecological problems, they can be disposed of by industrial incineration, or in approved landfill, *providing all federal, state, and local regulations are observed.* Dow recommends that the material be buried in an approved landfill; incineration should be done under carefully controlled conditions to avoid possibility of dust explosion.

### **CUSTOMER NOTICE**

Dow encourages its customers to review their applications of Dow products from the standpoint of human health and environmental quality. To help ensure that Dow products are not used in ways for which they are not intended or tested, Dow personnel will assist customers in dealing with ecological and product safety considerations. Your Dow salesman can arrange proper contacts.



NOTICE — This information is presented in good faith, but no warranty, express or implied, is given nor is freedom from any patent owned by The Dow Chemical Company or by others to be inferred. Inasmuch as any assistance furnished by Dow with reference to the proper use and disposal of its products is provided without charge, Dow assumes no obligation or liability therefor.

THE DOW CHEMICAL COMPANY • DESIGNED PRODUCTS DEPARTMENT • MIDLAND MICHIGAN 48640



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Form No. 192-698-78

Mylan v. Qualicaps, IPR2017-00203 QUALICAPS EX. 2017 - 79/86



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	M A T E R I A L DOW CHEMICAL U.S.A. MIDLAND MICH	SAFE IIGAN 4864	TY D O	ATA EMEI	SHE RGENCYF	E T HONE: 517	PAGE: 1 7-636-4400
	EFFECTIVE DATE: 30 MAY 78 DATE PRINTED: 6 JUL 78					PRODUCT C	ODE: 53925
	PRODUCT NAME: METHOCEL (R) A4C ME	ETHYCELLU	LOSE				MSD: 0054
	INGREDIENTS (TYPICAL VALUES - NOT	r specific	CATIONS)		;	: %	:
	METHOXYL				:	: 27.5- : 31.5	:
	SECTION 1		PHYSIC	AL DATA			
	BOILING POINT: NOT APPLICABLE VAP PRESS: NOT APPLICABLE VAP DENSITY (AIR = 1): NOT APPLIC APPEARANCE AND ODOR:	: : :	SOL. IN WA SP. GRAVI % VOLATIL	ATER: SE TY: NOT E BY VOL	E SECT. APPLIC. : NOT AP	7 PLICABLE	
	SECTION 2	FIRE	AND EXPLOS	ION HAZ	ARD DATA		
FLASH POINT:       : FLAMMABLE LIMITS (STP I)         METHOD USED:       : LFL: NOT APPL. UFL: NO'         EXTINGUISHING MEDIA: WATER FOG.       : SPECIAL FIRE FIGHTING EQUIPMENT AND HAZARDS: MINIMUM EXPLOSIVE         CONCENTRATION IS 0.03 OZ./CU. FT.					NAIR) CAPPL.		
	SECTION 3		REACTIV	ITY DATA			
	STABILITY: INCOMPATABILITY: OXIDIZING MATER HAZARDOUS DECOMPOSITION PRODUCT HAZARDOUS POLYMERIZATION: WILL N	RIAL. 'S: NOT OCCUR.					
	SECTION 4	SPILL, LE	EAK, AND DI	SPOSAL	PROCEDU	RES	
	ACTION TO TAKE FOR SPILLS (USE APPROPRIATE SAFETY EQUIPMENT): SWEEP UP- USE IF POSSIBLE, OR DISCARD. DISPOSAL METHOD: PREFERABLE METHOD WOULD BE TO BURY. CAN BE BURNED UNDER CAREFULLY CONTROL ED CONDITIONS TO FURMINATE DUST FYPLOSIONS						
	SECTION 5		HEALTH HA	ZARD DAT	'A		
	INGESTION: VERY LOW ACUTE AND CHE EYE CONTACT: MECHANICAL INJURY OF SKIN CONTACT: MECHANICAL INJURY OF SKIN ABSORPTION: NOT ABSORBED - L INHALATION: NUISANCE DUST. EFFECTS OF OVEREXPOSURE: NONE KNO (CONTINUED ON BACE 2)	RONIC ORAL NLY. ONLY. OW IN HAZA OWN.	NRD.	; LD50 =	>10G/K	G (RATS)	
	(R) INDICATES A REGISTERED OR TRA	DEMARK NA	ME OF THE I	DOW CHEM	ICAL CO	MPANY	

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SECTION 8 SPECIAL PRECAUTIONS AND ADDITIONAL INFORMATION

PRECAUTIONS TO BE TAKEN IN HANDLING AND STORAGE: USE REASONABLE CAUTION AND PERSONAL CLEANLINESS. CELLULOSE ETHERS ARE WATER-SOLUBLE POLYMERS WHICH FORM AQUEOUS DISPERSIONS BY SWELLING AND BY SUCCESSIVE HYDRATION OF THEIR STRUCTURAL LAYERS. THERE IS NO SHARP SOLUBILITY LIMIT.

ADDITIONAL INFORMATION : ----

LAST PAGE

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Mylan v. Qualicaps, IPR2017-00203 QUALICAPS EX. 2017 - 82/86

MATERIAL SAFETY DATA SHEET PAGE: 1 EMERGENCY PHONE: 517-636-4400 DOW CHEMICAL U.S.A. MIDLAND MICHIGAN 48640 PRODUCT CODE: 53938 EFFECTIVE DATE: 30 MAY 78 DATE PRINTED: 10 JUL 78 PRODUCT NAME: METHOCEL (R) F4M HYDROXYPROPYL MSD: 0056 METHYLCELLULOSE % INGREDIENTS (TYPICAL VALUES-NOT SPECIFICATIONS) 1 . : 27-30 : METHOXYL HYDROXYPROPYL : 4-7.5 : SECTION 1 PHYSICAL DATA BOILING POINT: NOT APPLICABLE : SOL. IN WATER: SEE SECT. 7 : SP. GRAVITY: NOT APPLICABLE VAP PRESS: NOT APPLICABLE : % VOLATILE BY VOL : NOT APPLICABLE VAP DENSITY (AIR=1): NOT APPLIC. APPEARANCE AND ODOR: ----FIRE AND EXPLOSION HAZARD DATA SECTION 2 FLASH POINT : ----: FLAMMABLE LIMITS (STP IN AIR) METHOD USED : ----: LFL: NOT APPL. UFL: NOT APPL. EXTINGUISHING MEDIA: WATER FOG. SPECIAL FIRE FIGHTING EQUIPMENT AND HAZARDS: MINIMUM EXPLOSIVE CONCENTRATION IS 0.03 OZ/CU. FT. SECTION 3 REACTIVITY DATA STABILITY: ----INCOMPATIBILITY: OXIDIZING MATERIAL. HAZARDOUS DECOMPOSITION PRODUCTS : ----HAZARDOUS POLYMERIZATION: WILL NOT OCCUR. SECTION 4 SPILL, LEAK, AND DISPOSAL PROCEDURES ACTION TO TAKE FOR SPILLS (USE APPROPRIATE SAFETY EQUIPMENT): SWEEP UP-USE IF POSSIBLE, OR DISCARD. DISPOSAL METHOD: PREFERABLE METHOD WOULD BE TO BURY. CAN BE BURNED UNDER CAREFULLY CONTROLLED CONDITIONS TO ELIMINATE DUST EXPLOSIONS. SECTION 5 HEALTH HAZARD DATA (CONTINUED ON PAGE 2) (R) INDICATES A REGISTERED OR TRADEMARK NAME OF THE DOW CHEMICAL COMPANY

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Mylan v. Qualicaps, IPR2017-00203 QUALICAPS EX. 2017 - 83/86

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# FACSIMILE



FACSIMILE 10 • 6 MATERIAL SAFETY DATA SHEET PAGE: 2 DOW CHEMICAL U.S.A. MIDLAND MICHIGAN 48640 EMERGENCY PHONE: 517-636-4400 PRODUCT CODE: 53938 PRODUCT (CONT D): METHOCEL (R) F4M HYDROXYPROPYL MSD: 0056 METHYLCELLULOSE SECTION 5 HEALTH HAZARD DATA (CONTINUED) INGESTION: VERY LOW ACUTE AND CHRONIC ORAL TOXICITY: LD50 > 10 G/KG (RATS).EYE CONTACT: MECHANICAL INJURY ONLY. SKIN CONTACT: MECHANICAL INJURY ONLY. SKIN ABSORPTION: NOT ABSORBED - LOW IN HAZARD. INHALATION: NUISANCE DUST. EFFECTS OF OVEREXPOSURE : NONE KNOWN SECTION 6 FIRST AID - NOTE TO PHYSICIAN FIRST AID PROCEDURES : CAUTION - NEVER GIVE FLUIDS OR INDUCE VOMITING IF PATIENT IS UNCONSCIOUS OR HAVING CONVULSIONS. EYES: FLUSH EYES. SKIN: FLUSH GROSSLY CONTAMINATED SKIN. INHALATION: REMOVE PATIENT TO FRESH AIR. INGESTION: NO PROBLEM. NOTE TO PHYSICIAN :----SECTION 7 SPECIAL HANDLING INFORMATION VENTILATION: CONTROL DUST TO COMFORT LEVEL. RESPIRATORY PROTECTION: USUALLY NONE. DUST RESPIRATOR IN VERY DUSTY ATMOSPHERES. PROTECTIVE CLOTHING : ----EYE PROTECTION: NOT NORMALLY NECESSARY, SAFETY GLASSES WITHOUT SIDE SHIELDS. SECTION 8 SPECIAL PRECAUTIONS AND ADDITIONAL INFORMATION PRECAUTIONS TO BE TAKEN IN HANDLING AND STORAGE: USE REASONABLE CAUTION AND PERSONAL CLEANLINESS. CELLULOSE ETHERS ARE WATER-SOLUBLE POLYMERS WHICH FORM AQUEOUS DISPERSIONS BY SWELLING AND BY SUCCESSIVE HYDRATION OF THEIR STRUCTURAL LAYERS. THERE IS NO SHARP SOLUBILITY LIMIT. ADDITION INFORMATION : ----

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10 • 7 MATERIAL SAFETY DATA SHEET PAGE: 1 EMERGENCY PHONE: 517-636-4400 DOW CHEMICAL U.S.A. MIDLAND MICHIGAN 48640 EFFECTIVE DATE: 30 MAY 78 DATE PRINTED: 10 JUL 78 PRODUCT CODE: 53960 PRODUCT NAME: METHOCEL (R) HB HYDROXYBUTYL METHYLCELLULOSE MSD: 0057 % INGREDIENTS (TYPICAL VALUES - NOT SPECIFICATIONS) : : : 29.5- : METHOXYL 33.5 2 1 2.0-: HYDROXYBUTOXYL 1 5.0 1 PHYSICAL DATA SECTION 1 BOILING POINT: NOT APPLICABLE : SOL. IN WATER: SEE SECT. 8 : SP. GRAVITY: NOT APPLICABLE

FACSIMILE

VAP PRESS: NOT APPLICABLE : SP. GRAVITY: NOT APPLICABLE VAP DENSITY (AIR=1): NOT APPLIC. : % VOLATILE BY VOL: NOT APPLICABLE APPEARANCE AND ODOR: WHITE, BLAND SOLID.

FLASH POINT: NONE:FLAMMABLE LIMITS (STP IN AIR)METHOD USED: ----:LFL: NOT APPLIC.EXTINGUISHING MEDIA: WATER FOG.:LFL: NOT APPLIC.

SPECIAL FIRE FIGHTING EQUIPMENT AND HAZARDS: MINIMUM EXPLOSIVE CONCENTRATION IS 0.03 OZ/CU. FT.

### SECTION 3

SECTION 2

REACTIVITY DATA

FIRE AND EXPLOSION HAZARD DATA

STABILITY:----INCOMPATIBILITY: OXIDIZING MATERIAL. HAZARDOUS DECOMPOSITION PRODUCTS: NONE. HAZARDOUS POLYMERIZATION: WILL NOT OCCUR.

### SECTION 4

SPILL, LEAK, AND DISPOSAL PROCEDURES

ACTION TO TAKE FOR SPILLS (USE APPROPRIATE SAFETY EQUIPMENT): SWEEP UP-USE IF POSSIBLE, OR DISCARD.

DISPOSAL METHOD: BURN UNDER CAREFULLY CONTROLLED CONDITIONS TO ELIMINATE DUST EXPLOSIONS. PREFERABLE METHOD WOULD BE TO BURY IN AN APPROVED LANDFILL. COMPLY WITH LOCAL, STATE, AND FEDERAL REGULATIONS.

(CONTINUED ON PAGE 2) (R) INDICATES A REGISTERED OR TRADEMARK NAME OF THE DOW CHEMICAL COMPANY

Form No. 192-701-78

Mylan v. Qualicaps, IPR2017-00203 QUALICAPS EX. 2017 - 85/86 

 10 • 8
 MATERIAL SAFETY DATA SHEET PAGE: 2

 DOW CHEMICAL U.S.A. MIDLAND MICHIGAN 48640
 EMERGENCY PHONE: 517-636-4400

 PRODUCT (CONTD): METHOCEL (R) HB HYDROXYBUTYL METHYCELLULOSE
 MSD: 0057

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SECTION 5

HEALTH HAZARD DATA (CONTINUED)

INGESTION: VERY LOW ACUTE AND CHRONIC TOXICITY. LD50 = >10G/KG (RATS). EYE CONTACT: MECHANICAL INJURY ONLY. SKIN CONTACT: MECHANICAL INJURY ONLY. SKIN ABSORPTION: NOT ABSORBED - LOW IN HAZARD. INHALATION: NUISANCE DUST. EFFECTS OF OVEREXPOSURE:----

SECTION 6

### FIRST AID-NOTE TO PHYSICIAN

FIRST AID PROCEDURES: CAUTION - NEVER GIVE FLUIDS OR INDUCE VOMITING IF PATIENT IS UNCONSCIOUS OR HAVING CONVULSIONS. EYES: FLUSH EYES WITH WATER. SKIN: FLUSH GROSSLY CONTAMINATED SKIN WITH WATER. INHALATION: REMOVE PATIENT TO FRESH AIR. INGESTION: NO PROBLEM. NOTE TO PHYSICIAN: ----

SECTION 7

SPECIAL HANDLING INFORMATION

VENTILATION: CONTROL DUST TO COMFORT LEVEL.

RESPIRATORY PROTECTION: USUALLY NONE. DUST RESPIRATOR IN

VERY DUSTY ATMOSPHERE.

PROTECTIVE CLOTHING: NONE.

EYE PROTECTION: NOT NORMALLY NECESSARY. SAFETY GLASSES WITHOUT SIDE SHIELDS.

SECTION 8 SPECIAL PRECAUTIONS AND ADDITIONAL INFORMATION

PRECAUTIONS TO BE TAKEN IN HANDLING AND STORAGE: USE REASONABLE CAUTION AND PERSONAL CLEANLINESS. CELLULOSE ETHERS ARE WATER-SOLUBLE POLYMERS WHICH FORM AQUEOUS DISPERSIONS BY SWELLING AND BY SUCCESSIVE HYDRATION OF THEIR STRUCTURAL LAYERS. THERE IS NO SHARP SOLUBILITY LIMIT.

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