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Polyethylene Glycols, Corresponding to the Japanese Pharmacopoeias  
and Japanese Pharmaceutical Excipients

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# MACROGOL Products

## Preface

MACROGOL products are polyethylene glycols which conform to the Japanese Pharmacopoeia (JP) and also the Japanese Pharmaceutical Excipients (JPE). They are addition polymers of ethylene oxide and water expressed in the following general formula:



The appearance of MACROGOL products varies depending on the average molecular weight. For example, MACROGOL 400 is a viscous liquid, while MACROGOL 1500 is a paste-like solid substance and MACROGOL 6000 is a wax-like solid substance (we provide two types: flakes and powder).

Each MACROGOL product is water-soluble, and has low toxicity (the LD<sub>50</sub> values for rats are shown on page 5).

Therefore, having these features, MACROGOL is used as a base material for ointments and suppositories, tablet coating agents, tablet binders, and other applications.

We offer a wide range of MACROGOL products as follows:

Product Name	Listing in JPE and JP
MACROGOL 200	Listed in JPE
MACROGOL 400	Listed in JP
MACROGOL 1500	Listed in JP
MACROGOL 4000	Listed in JP
MACROGOL 6000	Listed in JP
MACROGOL 20000	Listed in JP

Typical Property

1. Typical Properties

Table 1 shows the typical properties of MACROGOL products. The values are representative. These products are applicable for verification test and purity test standardized for either JPE or JP.

Table 1-a. Physical-chemical Properties

Product Name	Appearance (20±5 °C)	Physical-chemical Properties			
		Viscosity mm <sup>2</sup> /s (210 °F * <sup>1</sup> )	Specific Heat kJ·kg <sup>-1</sup> ·K <sup>-1</sup>	Heat of Fusion kJ·kg <sup>-1</sup>	Flash Point °C
MACROGOL 200	Colorless liquid	4.1	2.2 * <sup>2</sup>	—	196
MACROGOL 400	Colorless liquid	7.1	2.2 * <sup>2</sup>	150	230
MACROGOL 1500	White paste	16	2.3 * <sup>3</sup>	160	240
MACROGOL 4000	White flake or White powder	80	2.3 * <sup>3</sup>	180	270
MACROGOL 6000	White flake or White powder	800	2.3 * <sup>3</sup>	190	256
MACROGOL 20000	White flake	14,000	2.5 * <sup>3</sup>	190	296

\*<sup>1</sup> Measured at 98.9 °C (210 °F).

\*<sup>2</sup> Average value when heating between 30 and 60 °C.

\*<sup>3</sup> Average value when heating between freezing point and 100 °C.

Table 1-b. Properties standardized for either JPE or JP

Product Name	Listing in JPE and JP	Properties standardized for either JPE or JP					
		Freezing Point °C	Specific Gravity (20/20 °C)	pH * <sup>4</sup>	Average Molecular Weight	Water Content wt %	Ignition Residue wt %
MACROGOL 200	Listed in JPE	≤ 35	1.120	5.5	200	—	≤ 0.10
MACROGOL 400	Listed in JP	6	1.120	6.0	400	≤ 1.0	≤ 0.10
MACROGOL 1500	Listed in JP	40	—	5.5	540 * <sup>5</sup>	≤ 1.0	≤ 0.10
MACROGOL 4000	Listed in JP	55	—	7.0	3,100	≤ 1.0	≤ 0.25
MACROGOL 6000	Listed in JP	58	—	7.0	8,600	≤ 1.0	≤ 0.25
MACROGOL 20000	Listed in JP	60	—	7.0	20,000	≤ 1.0	≤ 0.25

\*<sup>4</sup> Measured as a 5 wt % aqueous solution.

\*<sup>5</sup> A mixture of equal amount of HOCH<sub>2</sub>(CH<sub>2</sub>OCH<sub>2</sub>)<sub>n</sub>CH<sub>2</sub>OH in which n is both 5 to 6 and 28 to 36.

Performance

1. Solubility

Table 2 shows the solubility of MACROGOL products. Their solubility decreases in accordance with the increase in their molecular weight.

Table 2. Solubility

Product Name		Water	Methanol	Ethanol	Diethyl Ether
MACROGOL 400	20 °C	A	A	A *	D
	50 °C	A	A	A *	D
MACROGOL 1500	20 °C	A	A	D **	D
	50 °C	A	A	A **	D
MACROGOL 4000	20 °C	B	C	D **	D
	50 °C	A	A	A **	D
MACROGOL 20000	20 °C	C	C	D *	D

\* Ethanol (95), \*\* Ethanol (99.5)

Value of Symbols A: More than 100 g of MACROGOL dissolves in 100 mL solvent.  
 B: From 50 g to 100 g of MACROGOL dissolves in 100 mL solvent.  
 C: From 1 g to 50 g of MACROGOL dissolves in 100 mL solvent.  
 D: Less than 1 g of MACROGOL dissolves in 100 mL solvent.

2. Hygroscopic Properties

MACROGOL products are hygroscopic, and their hygroscopic properties decrease in accordance with the increase in their molecular weight. For example, MACROGOL 200 has a high hygroscopic property similar to that of a propylene glycol, whereas MACROGOL 4000 and MACROGOL 20000 have very low hygroscopic properties. Figure 1 shows the equilibrium moisture regain of MACROGOL, and Figures 2 to 4 show the change of water content over time when the relative humidity (R.H.) varies.

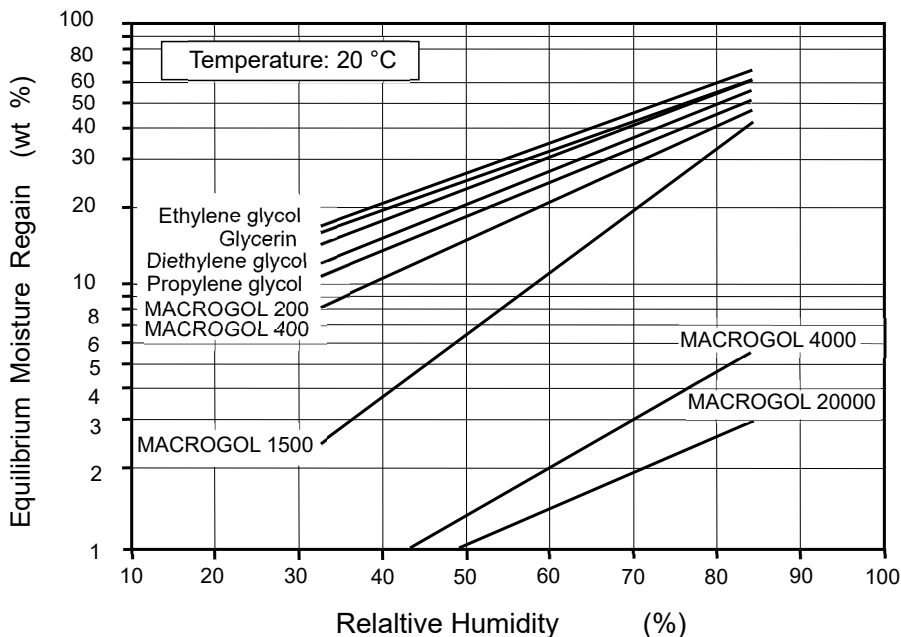


Figure 1. Relationship Between Relative Humidity and Equilibrium Moisture Regain

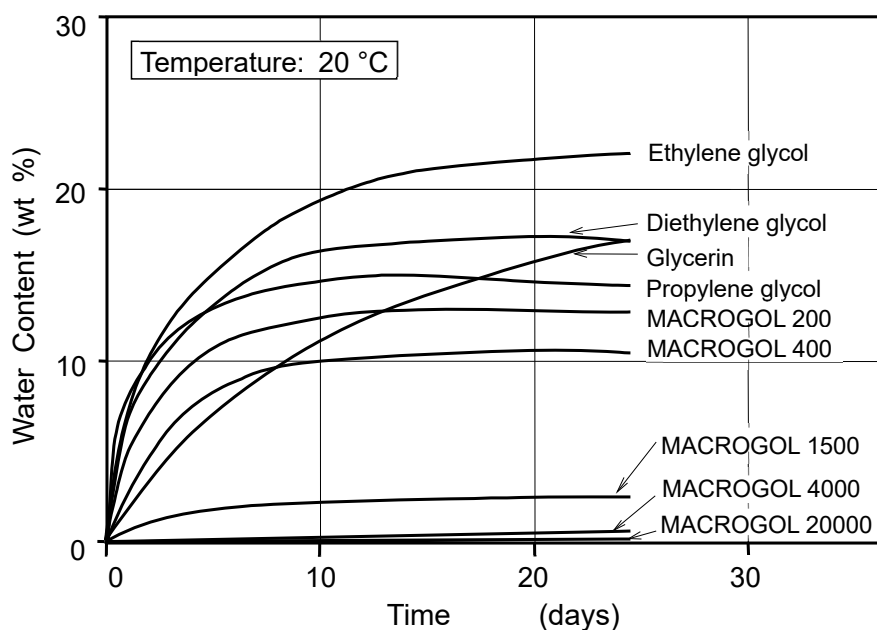


Figure 2. Change of Moisture Absorption Over Time (R.H.: 42%)

Method:

A 2 g sample was placed in a 20-mL beaker, which was allowed to stand in a sealed desiccator at a relative humidity of 42%, and then the moisture absorption was measured by investigating the variation in mass.

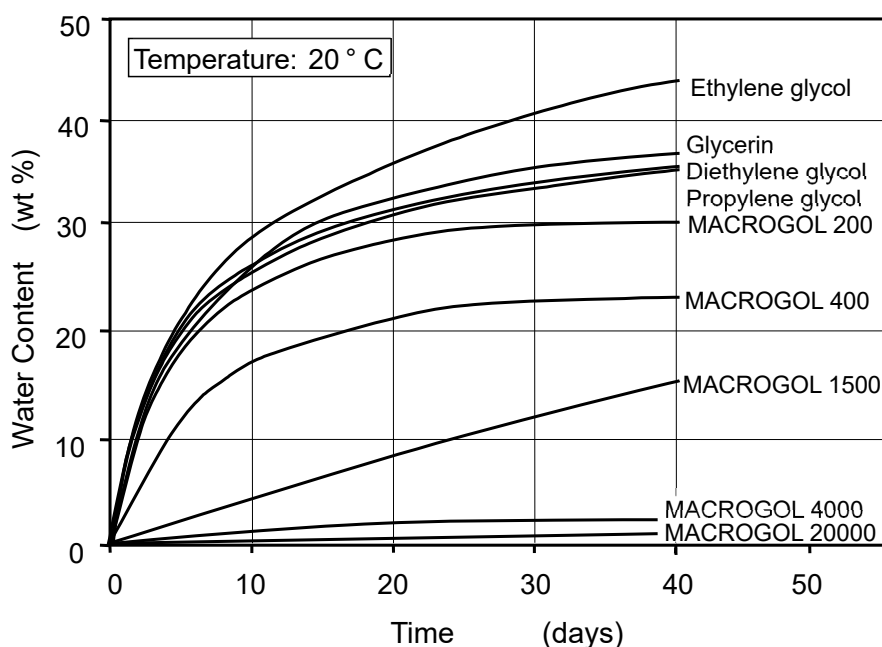


Figure 3. Change of Moisture Absorption Over Time (R.H.: 65%)

Method:

Same method as Figure 2 except that the test was conducted at a relative humidity of 65 %.

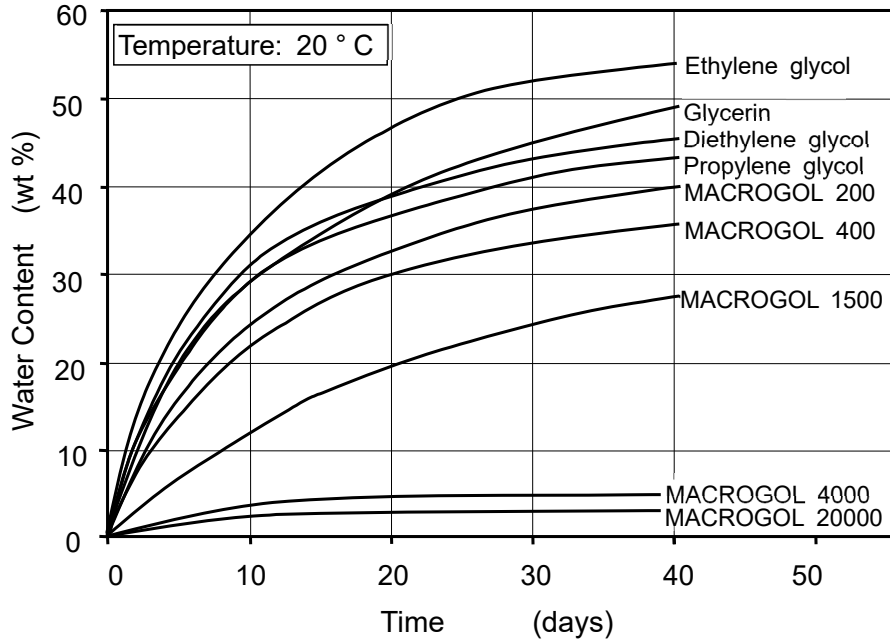


Figure 4. Change of Moisture Absorption Over Time (R.H.: 79%)

Method:

Same method as Figure 2 except that the test was conducted at a relative humidity of 79%.

### 3. Safety

MACROGOL products have low toxicity according to the following LD<sub>50</sub> values for rats.

Table 3. Toxicity

Product Name	LD <sub>50</sub> * g/kg (oral, rat)
MACROGOL 200	28
MACROGOL 400	30.2
MACROGOL 1500	44.2
MACROGOL 4000	50
MACROGOL 6000	50

\* Registry of Toxic Effects of Chemical Substances, Feb. 2003 (NIOSH)(CD-ROM).

#### 4. Other Performances

Figure 5 shows the temperature - kinematic viscosity curve of these products, and Figures 6 and 7 show the temperature - kinematic viscosity curve of these products and their aqueous solutions.

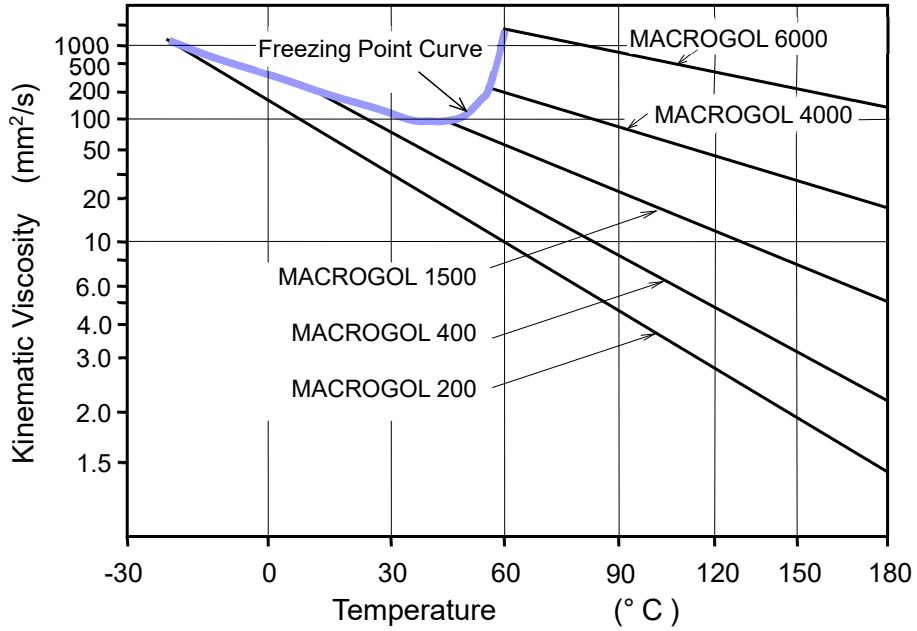


Figure 5. Temperature - Kinematic Viscosity Curve

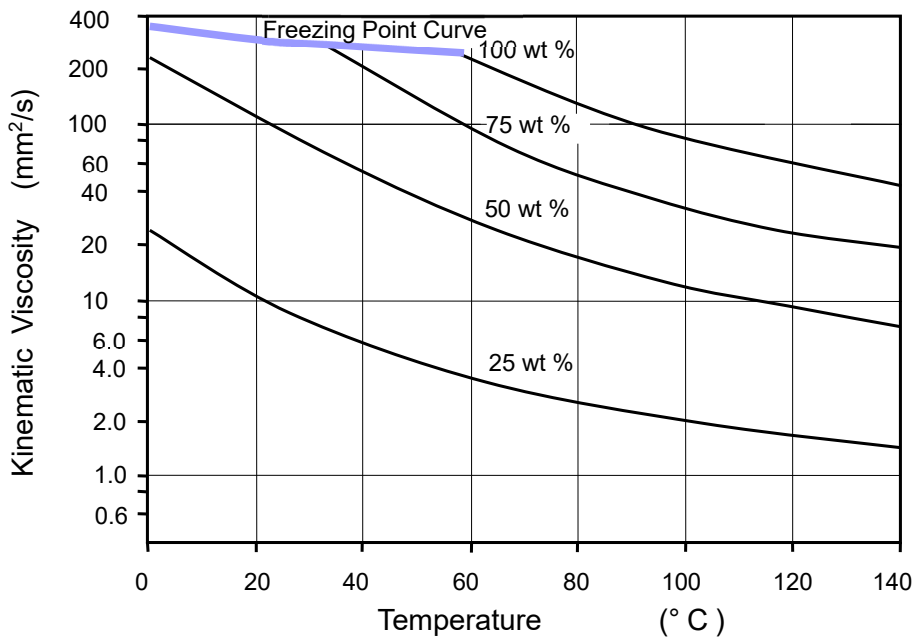


Figure 6. Temperature - Kinematic Viscosity Curve  
(MACROGOL 4000 and its Aqueous Solutions)

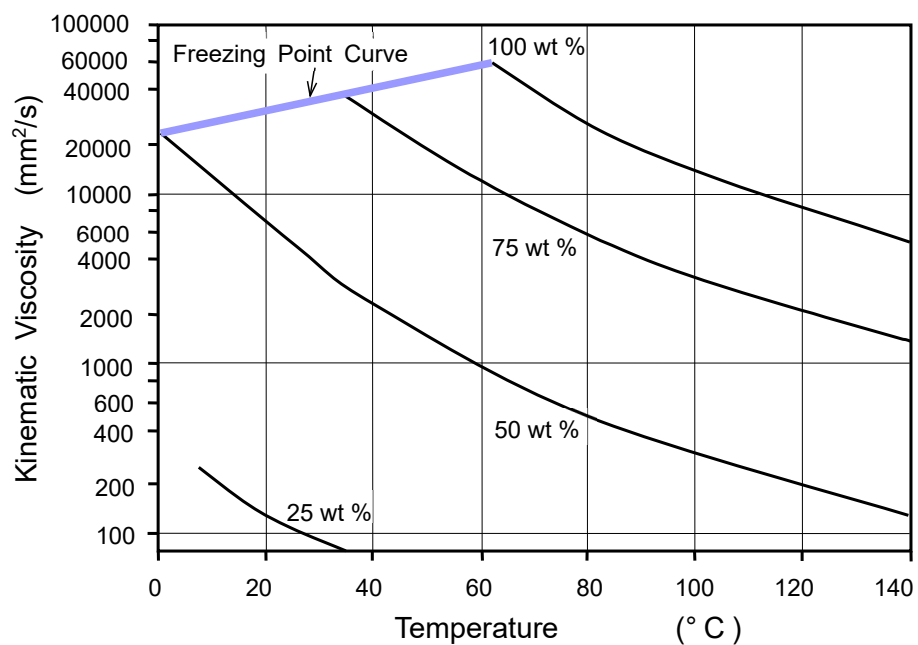


Figure 7. Temperature - Kinematic Viscosity Curve  
(MACROGOL 20000 and its Aqueous Solutions)

MACROGOL products can be used in the following applications as materials for pharmaceuticals:

### Base Material for Ointments

MACROGOL products are ideal as a base material for ointments (e.g. penicillin, Terramycin, streptomycin, and other antibiotics; antihistamine, benzocaine, and other narcotics; and for preservatives). These products can be used to adjust the concentration and viscosity of pharmaceuticals to be applied to the skin. These products assist in applying the pharmaceutical to the affected part evenly, and maintain the quantity of the pharmaceutical to be permeated into the affected part. These products also act to absorb body fluid oozing from the affected part.

<Example formula for base material of water-soluble ointment>

	wt %
MACROGOL 4000:	20
Stearyl alcohol:	37
Glycerin:	30
Water:	12
Sodium lauryl sulfate:	1
Total:	100

### Base Material for Suppositories

We offer a wide range of MACROGOL products, from MACROGOL 400 that has a freezing point of approximately 6 °C, to MACROGOL 20000 that has a freezing point of approximately 60 °C. It is possible to mix two or more MACROGOL products to produce a base material that has an ideal melting point and an ideal dissolving rate for suppositories.

In general, thermal stability (storage stability) is improved at ambient temperature (20±15 °C) by the use of MACROGOL products with a high average molecular weight.

### Binder for Tablets

MACROGOL products can also be used as a tablet surface smoother, coating agent, or binder.

MACROGOL 6000 has a shorter tablet coating time than the common sugar coating agent. With this product, you can obtain a tablet that has a fresh appearance and a hard surface. This product can also be used in tablets for diabetics.



**Important** :

Before handling these products, refer to the Safety Data Sheet for recommended protective equipment, and detailed precautionary and hazards information.

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