

# Ethylcellulose

## 1 Nonproprietary Names

BP: Ethylcellulose

PhEur: Ethylcellulose

USP-NF: Ethylcellulose

## 2 Synonyms

*Aquacoat ECD*; *Aqualon*; *Ashacel*; *BonuCel*; E462; *Ethocel*; ethylcellulosum; *Fetocel*; *Surelease*.

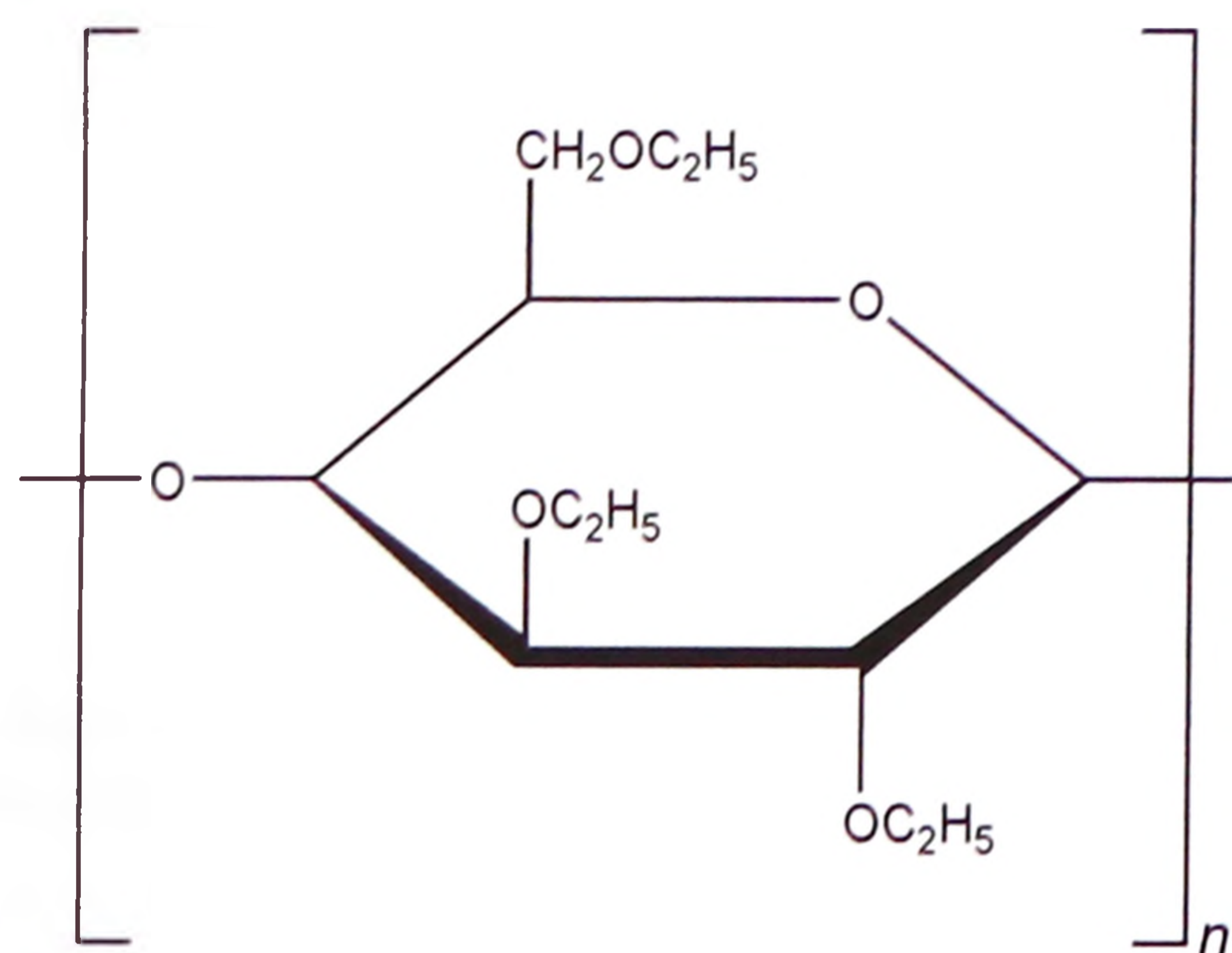
## 3 Chemical Name and CAS Registry Number

Cellulose ethyl ether [9004-57-3]

## 4 Empirical Formula and Molecular Weight

Ethylcellulose is partially ethoxylated. Ethylcellulose with complete ethoxyl substitution (DS = 3) is  $C_{12}H_{23}O_6(C_{12}H_{22}O_5)_n C_{12}H_{23}O_5$  where  $n$  can vary to provide a wide variety of molecular weights. Ethylcellulose, an ethyl ether of cellulose, is a long-chain polymer of  $\beta$ -anhydroglucose units joined together by acetal linkages.

## 5 Structural Formula



## 6 Functional Category

Coating agent; microencapsulating agent; tablet and capsule binder; tablet and capsule diluent; taste-masking agent; viscosity-increasing agent.

## 7 Applications in Pharmaceutical Formulation or Technology

Ethylcellulose is widely used in oral and topical pharmaceutical formulations; see Table I.

The main use of ethylcellulose in oral formulations is as a hydrophobic coating agent for tablets and granules.<sup>(1-8)</sup> Ethylcellulose coatings are used to modify the release of a drug,<sup>(7-10)</sup> to mask an unpleasant taste,<sup>(11,12)</sup> or to improve the stability of a formulation; for example, where granules are coated with ethylcellulose to inhibit oxidation. Modified-release tablet formulations may also be produced using ethylcellulose as a matrix former.<sup>(13-16)</sup>

Ethylcellulose, dissolved in an organic solvent or solvent mixture, can be used on its own to produce water-insoluble films. Higher-viscosity ethylcellulose grades tend to produce stronger and more durable films. Ethylcellulose films may be modified to alter their solubility<sup>(17)</sup> by the addition of hypromellose<sup>(18)</sup> or a plasticizer,<sup>(19-21)</sup> see Section 18. An aqueous polymer dispersion (or latex) of ethylcellulose such as *Aquacoat ECD* (FMC

Biopolymer) or *Surelease* (Colorcon) may also be used to produce ethylcellulose films without the need for organic solvents.

Drug release through ethylcellulose-coated dosage forms can be controlled by diffusion through the film coating. This can be a slow process unless a large surface area (e.g. pellets or granules compared with tablets) is utilized. In those instances, aqueous ethylcellulose dispersions are generally used to coat granules or pellets. Ethylcellulose-coated beads and granules have also demonstrated the ability to absorb pressure and hence protect the coating from fracture during compression.<sup>(21)</sup>

High-viscosity grades of ethylcellulose are used in drug microencapsulation.<sup>(10,22-24)</sup>

Release of a drug from an ethylcellulose microcapsule is a function of the microcapsule wall thickness and surface area.

In tablet formulations, ethylcellulose may additionally be employed as a binder, the ethylcellulose being blended dry or wet-granulated with a solvent such as ethanol (95%). Ethylcellulose produces hard tablets with low friability, although they may demonstrate poor dissolution.

Ethylcellulose has also been used as an agent for delivering therapeutic agents from oral (e.g. dental) appliances.<sup>(25)</sup>

In topical formulations, ethylcellulose is used as a thickening agent in creams, lotions, or gels, provided an appropriate solvent is used.<sup>(26)</sup> Ethylcellulose has been studied as a stabilizer for emulsions.<sup>(27)</sup>

Ethylcellulose is additionally used in cosmetics and food products.

**Table I:** Uses of ethylcellulose.

Use	Concentration (%)
Microencapsulation	10.0-20.0
Sustained-release tablet coating	3.0-20.0
Tablet coating	1.0-3.0
Tablet granulation	1.0-3.0
Taste-masking	5.0-50.0

## 8 Description

Ethylcellulose is a tasteless, free-flowing, white to light tan-colored powder.

## 9 Pharmacopeial Specifications

The pharmacopeial specifications for ethylcellulose have undergone harmonization of many attributes for PhEur, and USP-NF.

See Table II. See also Section 18.

## 10 Typical Properties

**Density (bulk)** 0.4 g/cm<sup>3</sup>

**Glass transition temperature** 129-133°C<sup>(28)</sup>

**Moisture content** Ethylcellulose absorbs very little water from humid air or during immersion, and that small amount evaporates readily.<sup>(29,30)</sup>

See also Figure 1.

**Particle size distribution** see Table III; see also Figures 2 and 3.

**Solubility** Ethylcellulose is practically insoluble in glycerin, propylene glycol, and water. Ethylcellulose that contains less than 46.5% of ethoxyl groups is freely soluble in chloroform, methyl acetate, and tetrahydrofuran, and in mixtures of aromatic hydrocarbons with ethanol (95%). Ethylcellulose