Product Safety Assessment

ETHOCEL™ Ethylcellulose Polymers

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Names

- CAS No. 9004-57-3
- ETHOCEL™ ethylcellulose polymer polymer
- ETHOCEL Standard 4 Industrial Grade ethylcellulose polymer
- ETHOCEL Standard 7 Premium ethylcellulose polymer
- ETHOCEL Standard 7 FP Premium ethylcellulose polymer
- ETHOCEL Standard 10 Industrial Grade ethylcellulose polymer
- ETHOCEL™ Standard 14 Premium ethylcellulose polymer
- ETHOCEL Standard 20 Premium ethylcellulose polymer
- ETHOCEL Standard 45 Premium ethylcellulose polymer
- ETHOCEL Standard 100 Premium ethylcellulose polymer
- ETHOCEL Standard 100 FP Premium ethylcellulose polymer
- ETHOCEL™ Standard 300 ethylcellulose polymer
- ETHOCEL Medium 70 ethylcellulose polymer
- ETHOCEL Standard 4 Premium ethylcellulose polymer
- ETHOCEL Standard 6 ethylcellulose polymer
- ETHOCEL Standard 7 Industrial Grade ethylcellulose polymer
- ETHOCEL™ Standard 10 Premium ethylcellulose polymer
- ETHOCEL Standard 10 FP Premium ethylcellulose polymer
- ETHOCEL Standard 14 Industrial Grade ethylcellulose polymer
- ETHOCEL Standard 20 Industrial Grade ethylcellulose polymer
- ETHOCEL Standard 45 Industrial Grade ethylcellulose polymer
- ETHOCEL™ Standard 100 Industrial Grade ethylcellulose polymer
- ETHOCEL Standard 200 ethylcellulose polymer
- ETHOCEL Medium 50 ethylcellulose polymer

Product Overview

- Ethylcellulose polymers are derived from and have the polymeric “backbone” of cellulose, a naturally occurring polymer. They are inert, high purity powders with no caloric value and are virtually colorless, odorless, and tasteless.¹ See Product Description.

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• Ethylcellulose polymers are used in a variety of pharmaceuticals, personal care products, foods, ceramics, pastes, inks, and specialty coatings.1 See Product Uses.
• Although consumers use products that contain ETHOCEL™ ethylcellulose polymers, workers in cellulose ether production facilities or in facilities that formulate products with cellulose ethers are most likely to have direct exposure to these materials. See Exposure Potential.
• Dust from ETHOCEL ethylcellulose polymers could cause temporary mechanical irritation to the skin or eyes under extreme conditions and may be considered a nuisance dust if inhaled. However, the products are low in toxicity and considered to present no significant health hazard.2 See Health Information.
• ETHOCEL ethylcellulose polymers are stable under recommended storage conditions. However, fine dusts of this material are capable of forming explosive mixtures with air.2 See Physical Hazard Information.

Manufacture of Product
• **Capacity** – ETHOCEL™ ethylcellulose products are manufactured by Dow at facilities in Midland, Michigan. The fine particle grade products are further processed and repackaged at a contract facility in Pennsylvania.3
• **Process**3 – These products are produced by treating cellulose with an alkaline solution to produce alkali cellulose, which is then reacted with ethyl chloride, yielding crude ethylcellulose polymers. The flow chart below is an overview of the production process:

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### Overview of Dow Ethylcellulose Production Process

1. **Cellulose**
2. **alkali Cellulose**
3. **Toluene**
4. **Ethyl Chloride**
5. **Caustic**
6. **Reactor**
7. **Filter**
8. **Granulation**
9. **Wash & Neutralize**
10. **Dewater & Dry**
11. **Density**
12. **Bulk Storage**
13. **Blend & Package**
14. **Micronize & Re-Package**

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![Flowchart of Dow Ethylcellulose Production Process](chart.png)
Product Description

ETHOCEL™ ethylcellulose polymers are inert, high purity powders with no caloric value and are virtually colorless, odorless, and tasteless. They are derived from and have the polymeric “backbone” of cellulose, a naturally occurring polymer.

Ethylcellulose polymers are produced in two ethoxyl types (standard and medium). Medium polymers are only supplied on a restricted, made-to-order basis. Ethylcellulose polymers are also produced and marketed in a number of different viscosities. Standard and medium ethoxyl types are available in premium grades and industrial grades. Premium grades are designed to meet the requirements of pharmaceutical applications and are useful in regulated applications. ETHOCEL Standard 7, 10, and 100 Premium polymers are also available in a fine particle size. Although designed for pharmaceutical formulations, these products are useful in other applications, such as personal care or applications that require high surface area polymers.

For indirect food use such as in paper and paperboard that might contact food, ethyl cellulose is considered “generally recognized as safe” (GRAS) by the U.S. FDA under 21 CFR § 182.90. Ethylcellulose polymers have been approved by the EU in food applications since the end of 2006.4

ETHOCEL Premium Grade ethylcellulose products are certified as Kosher and pareve for year-round and Passover use by the Union of Orthodox Congregations of America and conform to Halal requirements.

Product Uses

ETHOCEL™ ethylcellulose polymers have provided excellent functionality in many pharmaceutical and specialty polymer applications for more than 60 years. They offer an attractive range of physical properties and can be blended with other materials to achieve intermediate characteristics.

- **Pharmaceuticals** – Ethylcellulose polymers are among a very small number of water-insoluble excipient polymers that are approved and accepted globally for pharmaceutical applications. They are proven polymers for tablet coatings, controlled-release coatings, microencapsulation, granulation, and taste masking.
- **Personal care** – Ethylcellulose polymers are approved for use in cosmetics. Ethylcellulose polymers are listed in the *International Cosmetic Ingredient Dictionary and Handbook*. It is also listed in the *Japanese Standards of Cosmetic Ingredients*. These polymers have been used in lipsticks and nail polishes, as fragrance stabilizers, and as thickeners for perfumes and body creams (waterproof sunscreens).
- **Food** – In the United States, ethylcellulose polymers are used as flavor fixatives in encapsulation and as vitamin coatings. They are approved for and used in inks for marking fruits and vegetables, as components of paper and paperboard in contact with water-based and fatty foods, and for certain uses in animal feed. Ethylcellulose polymers have been approved by the EU in food applications since the end of 2006.4 They are also approved for use in animal feed in Europe.
• **Ceramics** – Ethylcellulose polymers are used in ceramic applications as a binder and to change the flow and slip characteristics of wet clay.

• **Conductive pastes** – Ethylcellulose polymers are used in conductive pastes. They function as binders and stabilizers for pigments and to change the flow characteristics of the pastes.

• **Printing inks** – Ethylcellulose polymers are used in gravure, flexographic, and screen printing inks. They are soluble in common solvent systems and are compatible with plasticizers, waxes, and other commonly used polymers. They contribute to the formation of tough, abrasion-resistant films.

• **Specialty coatings** – Ethylcellulose polymers bring an unusual combination of properties to specialty-coating applications such as hot melts, adhesives, paper coatings, fluorescent lighting, and other applications.

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**Exposure Potential**

ETHOCEL™ ethylcellulose polymers are used in the formulation of many consumer and industrial products. Based on the uses for these products, the public could be exposed through:

• **Workplace exposure** – Exposure can occur either in a cellulose ethers manufacturing facility or in the various industrial or manufacturing facilities that use cellulose ethers. Those working with cellulose ethers in manufacturing operations could be exposed during maintenance, sampling, testing, or other procedures. Each manufacturing facility should provide general and/or local exhaust ventilation to control airborne levels of cellulose ether dusts below exposure guidelines. Mechanical handling can cause formation of dusts. To reduce the potential for dust explosion, do not permit dust to accumulate. Keep areas swept up. See Health Information.

• **Consumer exposure to products containing ethylcellulose polymers** – Ethylcellulose polymers are formulated as components of many consumer products. See Health Information.

• **Environmental releases** – In the event of a spill, the focus is on containing the spill to prevent contamination of soil and surface or ground water. For small spills of liquid formulations containing ethylcellulose polymers, a solid absorbent should be used to absorb the liquid. Any solvents should then be allowed to evaporate, and the absorbent containing the ethylcellulose polymers should be disposed of by approved landfill or incineration. Water solutions of cellulosics are slippery. To prevent falls and injury, spills of dry powder should be thoroughly vacuumed or swept up immediately. Use care to minimize generation of airborne dust. 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 diluted with cold water before disposal. See Environmental, Health, and Physical Hazard Information.

• **Large release** – Industrial spills or releases are infrequent and generally contained. If a large spill does occur, the material should be captured, collected, and reprocessed or disposed of according to applicable governmental requirements. 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. If a large release does occur, do not permit dust to accumulate. When suspended in air, dusts can pose an explosion hazard. Eliminate all sources of ignition immediately.

• **In case of fire** – Deny any unnecessary entry into the area. Minimize any sources of ignition. Fires can be extinguished by conventional means. The use of water spray or fog, carbon-dioxide, or dry-chemical extinguishers is recommended when fighting a fire. Avoid strong water sprays that may raise dusts. Follow emergency procedures carefully. Firefighters should wear positive-pressure, self-contained breathing apparatus and protective clothing. See Environmental, Health, and Physical Hazard Information.

For more information, see the relevant Safety Data Sheet.

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Health Information$^{1,3,6}$

The single-dose oral toxicity of ethylcellulose polymers is low. Based on an examination of the ingredients and their sources, this product is free of known allergy-stimulating food substances. In addition, ethylcellulose polymers were not irritating to humans when applied in a 48-hour closed patch test and did not produce skin sensitization in human subjects. The potential for absorption through the skin in acutely toxic amounts is low. Exposure of humans to cellulosic dust in manufacturing operations has not led to any known adverse health effects.

Ethylcellulose polymers are listed in the current U.S. CFR and the Food Chemicals Codex and are considered “generally recognized as safe” (GRAS) by the U.S. FDA under 21 CFR § 182.90: Substances migrating to food from paper and paperboard products. Ethylcellulose polymers have been evaluated for safety by the European Food Safety Authority (EFSA). An EFSA scientific panel concluded that “ethyl cellulose will pass essentially unchanged through the gastrointestinal tract following oral ingestion and that adverse effects are unlikely.” As a result, ethylcellulose polymers have been approved by the EU in food applications since the end of 2006. Ethylcellulose polymers, with E-number E 462, are listed in Annex I of Directive 95/2 as a food additive generally permitted for use in food stuffs with an acceptable daily intake (ADI) of “not specified.”

Dusts from ethylcellulose polymers could cause temporary mechanical irritation to the eye under extreme conditions. They are considered as nuisance dusts when inhaled. 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, other than the possible need for a local exhaust system to control dust during opening and dumping of bags.

For more information, see the relevant Safety Data Sheet.

Environmental Information$^1$\(^2\)

Ethylcellulose polymers are not water soluble and of high molecular weight, which makes the potential to bioconcentrate (accumulate in the food chain) very low. For the same reasons, they do not biodegrade in aquatic environments. No significant ecological problems would be expected for ethylcellulose products, and they can be disposed of by recycling, reclaiming, burning in an adequate incinerator, or burying in an approved landfill. Incineration should be done under carefully controlled conditions to avoid the possibility of a dust explosion.

For more information, see the relevant Safety Data Sheet.

Physical Hazard Information$^1$\(^8\)

Dusts or fine powders of ethylcellulose polymers in air can reach explosive levels, and care must be taken to prevent this. Ethylcellulose polymers are organic materials and will burn under the right conditions of heat and oxygen supply. These polymers will melt upon exposure to an open flame. Burning behavior and explosiveness get worse as moisture content decreases.

Once ignited, ethylcellulose polymers will support combustion. However, they offer no greater fire hazard on storage and handling than does paper or cellulose in the same physical form. Ethylcellulose polymers are stable up to the softening point (~160°C (320°F)).

For more information, see the relevant Safety Data Sheet.
Regulatory Information

Regulations may exist that govern the manufacture, sale, transportation, use, and/or disposal of ETHOCEL™ ethylcellulose polymers. These regulations may vary by city, state, country, or geographic region. Information may be found by consulting the relevant Safety Data Sheet, ETHOCEL Ethylcellulose Polymers Technical Handbook, or the Dow Answer Center.

Additional Information

- Safety Data Sheet (http://www.dow.com/webapps/msds/msdssearch.aspx)
- The Dow Answer Center (http://www.ethocel.com)

For more business information about ETHOCEL ethylcellulose polymers, visit Dow's ETHOCEL ethylcellulose polymers web site: www.ethocel.com.

References

1. ETHOCEL™ Ethylcellulose Polymers Technical Handbook, Dow Cellulosics, The Dow Chemical Company, Form No. 192-00818-0905 X AMS
2. ETHOCEL Standard 4 Premium Ethylcellulose Material Safety Data Sheet, The Dow Chemical Company
5. Estimates provided by The Dow Chemical Company.
6. Dow Answer Center, Query No. 1191: ETHOCEL allergen (http://dow-answer.custhelp.com)
NOTICES:

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