

## Application Overview: Food Industry



### Direct Food Applications

Dow's Propylene Glycol USP/EP (PG USP/EP) is a versatile raw material, used widely as an additive in the food-processing industry, worldwide.

Globally approved and regulated for use in foodstuffs, Dow's PG USP/EP is an especially high-purity grade of monopropylene glycol. It is a clear, colorless, practically odorless, slightly viscous, hygroscopic liquid. The low toxicity and exceptional stability, high flash and boiling points, low vapor pressure and broad solvency power make Dow's PG USP/EP an ideal choice when selecting materials for use in food additive applications.

Due to its extremely low toxicity and long history of safe use, PG USP/EP is classified as "generally recognized as safe" (GRAS) by the U.S. Food and Drug Administration (U.S. FDA).

An overview of typical food applications for PG USP/EP follows, although it must be emphasized that it is the user's responsibility to consult area and country specific regulations for details of approved use (see section on Regulatory Status).

Dow PG USP/EP may reliably serve as:

- A solvent and carrier in many flavor formulations for the processed food and beverage industry. The solubility of various food flavoring materials in PG-water mixtures is shown in a chart on the last page. For additional solubility data of essential oils and aromatic chemicals, see the references.<sup>1</sup>
- A solvent and carrier for colors, antioxidants, enzymes and emulsifiers.
- A plasticizer and softening agent for food-contact items such as cork seals.
- A flavor extraction solvent and processing aid in the isolation of natural flavoring materials; extracting vanilla from vanilla beans is one such use.
- A humectant and stabilizer in prepared fruits, vegetables and bakery goods (except in Europe).

When employed as a direct food additive, the nutritional information of PG USP/EP is of importance for end-users. The caloric value of propylene glycol is defined as 4 calories per gram, according to the general definition for a carbohydrate given in the U.S. FDA 21 CFR 101.9(c)(1)(I)(B).





## Indirect Food Applications

Dow PG USP/EP is used in a number of important indirect food-contact applications.

It is extensively used as a heat-transfer fluid for food and beverage chilling and freezing applications. In the beverage industry, PG USP/EP is used to cool beer, wine, milk, juices and brewery fermentation tanks. In food processing, it may be used for the freezing of wrapped foods by their immersion in propylene glycol baths.

The heat transfer fluid is typically a formulation of an aqueous solution of PG USP/EP together with a food-safe corrosion inhibitor.<sup>2</sup>

Dow PG USP/EP is used as a printing-ink solvent for food packaging.

In cellophane film production, it serves as a plasticizer and processing aid.

PG USP/EP's inherent antimicrobial properties facilitate its use as a final rinse fluid following normal cleaning of food processing equipment. This helps inhibit spoilage of any residual traces of food which, if left untreated, could contaminate future production. Before the cleaned equipment is returned to service, any residual propylene glycol is easily removed by flushing with water.



## Regulatory Status

Dow PG USP/EP is tested against, and complies with the specific requirements of the current United States Pharmacopeia (USP), as well as those of the European (EP), and Japanese (JP) Pharmacopeias, plus the U.S. Food Chemicals Codex (FCC). It also meets the requirements of the Brazilian Pharmacopoeia (Farmacopéia Brasileira), and fulfills the purity criteria detailed in the European Council Directive 2000/63/EC for food additives, other than colors and sweeteners.



## U.S. Regulations

Propylene glycol, when manufactured according to current Good Manufacturing Practice (cGMP or GMP) per United States Food and Drug Administration guidelines, is cleared for various uses under Food Additive Regulations (Title 21, U.S. Code of Federal Regulations) promulgated in accordance with the U.S. Food, Drug and Cosmetic Act as amended. Since propylene glycol functions as an excipient, Dow follows the cGMP guidelines for excipients defined by the International Pharmaceutical Excipients Council (IPEC).<sup>3</sup> With cGMP, propylene glycol is “generally recognized as safe” according to 21CFR184.1666 and meets the specifications of the Food Chemicals Codex, 3d ED. (1981), p. 255. Dow supports only the use of its Propylene Glycol USP/EP product for all direct and indirect food applications of propylene glycol.

### Direct Food Applications

Propylene glycol is listed in the monographs of the Food Chemicals Codex and can, when of appropriate purity, be used for direct and indirect food additive applications. Also, propylene glycol is GRAS as a multiple purpose food substance under 21CFR184.6666. The use of propylene glycol to give foods specific physical or technical effects is defined in 21CFR170.3(o). Maximum use levels, in accordance with cGMP, are defined in 21CFR184.1(b)(1), and for some specific applications in 21CFR170.3(n). For applications where the level is not defined, the maximum allowable level of propylene glycol is two percent.

A number of standardized foods allow for the use of optional ingredients, which are “safe and suitable.” Propylene glycol will qualify where the use is suitable. These standardized foods are described in 21CFR sections 133, 135 and 169.

### Unreacted Indirect Food Applications

Propylene glycol is cleared for use in its unreacted form for indirect food contact under 21CFR sections 175, 176, 177, 178 and 182.

### Reacted Component Indirect Food Applications

Propylene glycol is cleared for use only as a reacted component under 21CFR sections 175, 176 and 177.

## European Regulations

### Direct Food Applications

Propylene glycol is classified as E1520 in an amendment to Directive 95/2/EC, which regulates human food additives, other than colors and sweeteners. It allows the use of propylene glycol as a carrier or carrier solvent for colors, emulsifiers, antioxidants and enzymes, up to a maximum of 1 gram per kilogram of final foodstuff. However, propylene glycol is not approved as a general-purpose direct-food additive in countries of the European Union.

### Indirect Food Applications

Propylene glycol is cleared for indirect food contact applications by Directive 90/128/EEC, and subsequent amendments, relating to plastic materials and articles intended to come into contact with foodstuffs. Of suitable quality, Dow PG USP/EP is authorized as a monomer and starting substance (1,2-propanediol, PM/Ref No 23740) for the manufacture of plastic materials and articles, without restriction or specific migration limits. 1,2-Propanediol (PM/Ref No 81840) is also recognized as an additive for the same purpose. Propylene glycol is included in the INS (International Numbering System) for food additives list, under the number “1520.”



## Purity Plus

Propylene Glycol USP/EP is a high-purity product that helps to provide the quality and performance demanded in food applications. The added PLUS, however, comes from knowing that it is backed by Dow – providing the extra purity, dependability and reliability that the food industry demands.

Dow Propylene Glycol USP/EP is certified as Kosher for all shipments, including for Passover (PESSACH). Dow's PG USP/EP also meets Halal requirements. All packaging is secured with specific tamper-evident seals.

Propylene Glycol USP/EP is manufactured in Dow facilities worldwide using rigorous quality-control procedures to provide exceptional product quality and application reliability. Dow PG USP/EP is synthesized from hydrocarbon raw materials. Materials of plant or animal origin, genetically-modified organisms, solvents, catalysts, additives or stabilizers are not used in the manufacturing process or added to the final product. This product is manufactured without known allergy-stimulating food substances.

Dow's production and handling of this food-grade additive is conducted according to current Good Manufacturing Practice (cGMP) guidelines, as issued by IPEC, to provide premium product purity (greater than 99.8%).

To meet these cGMP guidelines, Dow has implemented a number of stringent standards. They include the use of dedicated production, storage and handling facilities, extensive product testing, personnel training, color differentiated packaging and distributor clean-room programs.

# Solubility of Flavoring Materials in Propylene Glycol – Water Mixtures at 25°C\*

Flavoring	100%	80%	Percentage Propylene Glycol		
			60%	40%	20%
Solubility in ml per liter of solvent					
Alcohol C-10	x	x	4.1	0.5	0.2
Alcohol C-12	x	10.1	1.2	< 0.2	< 0.2
Aldehyde C 16	x	22.5	0.8	0.5	0.4
Allyl Butyrate	353.9	80.7	18.1	7.4	3.9
Allyl Caproate	162.8	23.4	3.8	0.5	0.3
Amyl Acetate	x	x	x	18.2	15.5
Amyl Butyrate	142.4	23.9	4.9	2.0	0.6
Iso Amyl Formate	x	65.1	56.2	20.3	19.9
Amyl Valerianate	93.9	19.5	3.3	0.9	0.5
Anethol	54.9	6.9	2.7	0.4	< 0.2
Benzaldehyde	x	232.8	47.5	18.1	7.8
Benzyl Acetate F.F.C.	x	83.9	19.9	4.1	2.7
Benzyl Propionate	x	41.3	8.0	2.4	1.1
Cinnamic Aldehyde (99-100% pure)	x	17.5	3.0	0.5	0.2
Citral	x	3.5	2.3	1.2	0.5
Diacetyl (100%)	x	x	x	x	209.0
Ethyl Butyrate	x	133.2	37.1	3.4	0.9
Ethyl Acetate	x	x	x	148.4	99.8
Ethyl Cinnamate	179.1	31.1	4.6	0.8	0.3
Ethyl Formate	x	x	x	x	234.1
Ethyl Oxyhydrate (Conc. Special Colorless)	x	x	x	x	34.8
Ethyl Valerate	298.7	86.6	27.4	8.3	8.1
Eucalyptol	278.5	55.8	19.7	4.5	3.4
Eugenol USP	x	-	383.8	1.2	0.5
Maltol	45.9	41.2	33.4	24.5	17.7
Methyl Anthranilate	x	240.2	32.3	4.4	3.5
Methyl Cyclopenteneolone	187.7	179.4	147.1	84.5	47.0
Methyl Salicylate	191.1	37.4	9.1	2.7	1.7
Nutmeg Oil	5.7	3.5	2.0	1.6	1.1
Ocotea Cymbarum	90.3	11.4	2.0	< 0.2	< 0.2
Oil Anise	29.7	6.2	2.0	0.5	0.2
Oil Bay	9.7	1.8	0.5	0.2	< 0.2
Oil Bay (Terpeneless)	x	34.0	1.3	0.5	0.2
Oil Caraway	28.0	5.5	0.5	0.3	0.3
Oil Cassia	x	31.7	7.9	6.9	2.0
Oil Cassia (Terpeneless)	x	52.7	9.0	1.0	0.5
Oil Cloves	x	11.9	3.0	2.0	0.9
Oil Cloves (Terpeneless)	x	64.7	0.3	0.4	0.3
Oil Dill Weed	13.3	0.5	0.3	< 0.2	< 0.2
Oil Ginger	< 0.2	-	-	-	-
Oil Lemon	9.8	6.1	3.7	2.2	0.4
Oil Lime (Distilled)	18.3	1.8	1.9	0.5	< 0.2
Oil Mace	12.5	3.3	0.5	0.3	0.2
(Distilled) (So Called)					
Oil Peppermint	x	3.1	0.5	0.2	< 0.2
Oil Peppermint (Terpeneless)x	5.6	0.5	0.3	0.3	-
Oil Petitgrain (Terpeneless)	< 0.2	7.6	1.3	0.5	0.2
Oil Pimento Leaf	x	9.7	1.6	0.6	0.3
Oil Sage (Spanish)	18.9	2.2	1.1	0.5	0.2
Oil Sassafras	19.5	12.2	2.0	1.2	0.8
Oil Spearmint (N.F XV)	8.3	0.5	0.4	0.2	0.2
Oil Thyme, White (High Test)	x	10.5	2.4	0.8	< 0.2
Oil Wormseed (AmericanChenopodium)	105.0	8.3	1.2	0.5	0.3
Oil Resin Celery	1.2	0.4	< 0.2	< 0.2	< 0.2
Oil Resin Ginger	Immisc.	-	-	-	-
Oil Resin Pepper	Immisc.	-	-	-	-
Orange Oil	1.6	1.6	1.0	0.7	0.4
Phenethyl Alcohol	x	x	x	240.2	32.0
Phenethyl Formate	204.4	34.9	5.5	1.4	0.3
Phenethyl Propionate	x	66.7	9.4	3.3	2.0

## Literature References

1. D.D. Lakritz, *American Perfumer* 48, No. 11,64,69 (1946)
2. *Dowcal N Heat Transfer Fluid*, Dow Europe Product Information, Form # CH-153-025-E-594
3. "The IPEC Good Manufacturing Practice Guide for Bulk Pharmaceutical Excipients" Copyright © The International Pharmaceutical Excipients Council, 2002



\* The solubilities of over 100 additional essential oils and aromatic chemicals are listed in D.D. Lakritz, *American Perfumer* 48, No11,64,69 (1946)

x = Miscible or soluble in all proportions  
 Immisc. = Immiscible or completely insoluble  
 < = less than

For more information, please visit our website or call:

United States & Canada: 1-800-447-4369

Europe: +32 3-450-2240

Pacific: +60 3-7958-3392

China: +800 600-0015

LAA: +989 832-1426

[www.dowpg.com](http://www.dowpg.com)

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Form # 117-01632 303EC