

CARBOWAX™ SENTRY™ Polyethylene Glycols

Innovation, Performance, Flexibility and Compliance from the Global Leader in PEGs



CARBOWAX™ SENTRY™ PEGs and MPEGs

A Leading Choice for Pharmaceutical, Personal Care and Food Products

CARBOWAX™ SENTRY™ Polyethylene Glycols (PEGs) and Methoxypolyethylene Glycols (MPEGs) are highly versatile excipients and Active Pharmaceutical Ingredients (API) produced to meet the exacting requirements of the pharmaceutical industry as well as the needs of personal care and food product formulators. But CARBOWAX™ SENTRY™ PEGs and MPEGs do more than meet requirements...they establish industry standards for innovation, performance, flexibility and compliance.

Innovation

Dow has been developing innovative solutions for more than 100 years and our innovation is evidenced in our quest for increased processing efficiency, in-depth support for quality requirements, and tailored supply chain solutions. You can depend on us for the science, technology and knowhow you need to support your own ability to innovate.



Performance

The performance of CARBOWAX™ SENTRY™ PEGs and MPEGs has been proven over decades of use in pharmaceutical, personal care and food product formulations. As Active Pharmaceutical Ingredients (API), their low toxicity is valuable in laxative and colonic lavage formulations. They are used widely as excipients in solid oral dosage forms, ointments and creams, gelatin capsules and liquid medications, and suppositories.

Flexibility

With CARBOWAX™ SENTRY™ PEGs and MPEGs, we can help you find the ideal product for your application. CARBOWAX™ SENTRY™ PEGs and MPEGs are available in a wide range of viscosities and melting points for formulating flexibility. Flexibility is further enhanced by multiple product forms including liquid, powder, granular and flake materials. By choosing a suitable product grade, or blending products, you can achieve the desired balance of water solubility, hygroscopicity, vapor pressure, melting or freezing range, and viscosity.

Compliance

CARBOWAX™ SENTRY™ PEGs and MPEGs comply with the stringent regulatory requirements for pharmaceutical, personal care, and food applications. They conform to the National Formulary (NF) monograph for polyethylene glycols. Additionally, CARBOWAX™ SENTRY™ grades meet the requirements of polyethylene glycols listed in the Food Chemicals Codex (FCC) monograph for polyethylene glycols. Selected liquid and solid CARBOWAX™ SENTRY™ PEGs and MPEGs have been certified to be compliant with the European Pharmacopoeia (Ph. Eur.) requirements for Macrogols.*

CARBOWAX™ SENTRY™ conforms to NF, FCC, select European Pharmacopoeia (EP) Macrogols and IPEC excipient cGMP guidelines. Solid Grades (MW 3350 and 4000) are fully compliant with ICH Q7A cGMP guidelines for API. Other solid grades (MW 1450 through MW 8000) are compliant with IPEC guidelines for excipients.

*Statements about the compliance status of CARBOWAX™ SENTRY™ PEGs and MPEGs are not intended as regulatory advice for any specific use nor are they an alternative to seeking regulatory advice for a user's particular intended use. It is the responsibility of the user of CARBOWAX™ SENTRY™ PEGs and MPEGs to read and understand all current applicable FDA regulations, as well as any other applicable regulations. See sidebar for additional information on Dow's commitment to Current Good Manufacturing Practice.



Commitment to cGMP on a World-Scale Production Platform

The manufacturing, handling and storage of all CARBOWAX™ SENTRY™ PEGs and MPEGs are conducted with all appropriate current Good Manufacturing Practice (cGMP) in our world-scale production facilities. Our solid grades plant (over MW 1450) meets IPEC guidelines for excipients. In addition, solid grades (MW 3350 and 4000) comply with ICH Q7A cGMP guidelines for APIs and the European Directive 2004/27/EC for active pharmaceutical ingredients.

For our lower molecular weight products (PEG 300 –1000 and MPEGs), cGMP compliance is in accord with the most current International Pharmaceutical Excipients Council (IPEC) Guide for Bulk Pharmaceutical Excipients.

CARBOWAX™ SENTRY™ PEGs and MPEGs are manufactured under the supervision of the Kashruth Division of the Union of Orthodox Jewish Congregations of America and are certified as kosher and pareve.

Our ability to supply PEGs and MPEGs meeting appropriate U.S. and European regulatory requirements globally is supported by Dow's inventory management solutions and a network of strategically located terminal facilities. We offer Product Stewardship assistance to ensure that CARBOWAX™ SENTRY™ products are properly handled throughout the supply chain.

CARBOWAX™ SENTRY™ PEGs and MPEGs

Chemistry and Product Line

CARBOWAX™ SENTRY™ PEGs and MPEGs are water soluble linear polymers formed by the addition reaction of ethylene oxide to an ethylene glycol equivalent. The general formula for polyethylene glycol is: $H-(OCH_2CH_2)_n-OH$ and for methoxypolyethylene glycol: $CH_3-(OCH_2CH_2)_n-OH$ where “n” is the average number of repeating oxyethylene groups.

CARBOWAX™ SENTRY™ PEGs and MPEGs are available in a wide range of viscosities and melting points to offer flexibility to help optimize formulations. Depending on molecular weight, CARBOWAX™ SENTRY™ products are available in liquid, solid, granular, powder, and flake forms.

CARBOWAX™ SENTRY™ PEGs are available in average molecular weights ranging from 300 to 8000. CARBOWAX™ SENTRY™ MPEGs are available in average molecular weights of 350 and 550. CARBOWAX™ SENTRY™ PEG 540 Blend, a mixture of PEG 300 and PEG 1450, completes the family of CARBOWAX™ SENTRY™ products.

CARBOWAX™ SENTRY™ PEG and MPEG Products

CARBOWAX™ SENTRY™ PEG	Supplied Form	CTFA/INCI Nomenclature ¹
300 NF, FCC Grade; Macrogol 300 Ph. Eur.	Liquid	PEG-6
400 NF, FCC Grade; Macrogol 400 Ph. Eur.	Liquid	PEG-8
540 Blend (PEG 300/PEG 1450)	Fused Solid	PEG 6 and PEG 32
600 NF, FCC Grade; Macrogol 600 Ph. Eur.	Semi Solid	PEG-12
1000 NF, FCC Grade	Fused Solid	PEG-20
1450 NF, FCC Grade	Flake	PEG-32
3350 NF, FCC Grade; Macrogol 3350 Ph. Eur.	Granular, Powder, Flake	PEG-75
4000 NF, FCC Grade; Macrogol 4000 Ph. Eur.	Granular, Powder, Flake	PEG-90
4600 NF, FCC Grade	Granular	PEG-100
8000 NF, FCC Grade; Macrogol 8000 Ph. Eur.	Granular, Powder, Flake	PEG-180
CARBOWAX™ SENTRY™ MPEG		
350 NF, FCC Grade	Liquid	PEG-6 Methyl Ether
550 NF, FCC Grade	Liquid	Methoxy PEG-10

¹CTFA/INCI = Personal Care Council (formerly known as Cosmetics, Toiletry and Fragrance Association) /International Nomenclature Cosmetic Ingredient





Compliance Information for Food Uses

Certain CARBOWAX™ SENTRY™ PEGs are permitted for use under the following Food Additive Regulations for direct and indirect food additives. This summary is not intended as an alternative to reading and understanding the full text of applicable current regulations for the user's intended use of CARBOWAX™ SENTRY™ PEGs and MPEGs, since additional restrictions and limitations may apply. It is the responsibility of the user of CARBOWAX™ SENTRY™ PEGs and MPEGs to read and understand all applicable FDA and EPA regulations in Titles 21 and 40 of the Code of Federal Regulations, as well as any other regulations applicable to the user's intended use. See sidebar for additional information on Dow's commitment to Current Good Manufacturing Practice.



FDA Food *FDA Regulation (21 CFR)*

Direct Additives Certain CARBOWAX™ SENTRY™ Polyethylene Glycols (Food Chemicals Codex Grade) are permitted for use under the following Food Additive Regulations for direct use in food other than milk, or preparations intended for addition to milk. There is no maximum limit on their use in these intended applications other than that the amount used shall not exceed the minimum amount needed to produce the intended technical effect.

Permitted Use	300	400	600	1000	540	1450	3350	4000	4600	8000
	Blend									
172.210 Defoamer and dispersing adjuvant in coatings applied to fresh citrus fruit for protection of the fruit.	x	x	x	x	x	x	x	x	x	x
172.820 1. Coating, binder, plasticizing agent and/or lubricant in tablets used for food. 2. Adjuvant to improve flavor and as a bodying agent in nonnutritive sweeteners. 3. Adjuvant in dispersing vitamin and/or mineral preparations 4. Coating on sodium nitrite to inhibit hygroscopic properties. Note: Not for use in milk or milk products.	x	x	x	x	x	x	x	x	x	x
173.310 Component of boiler water additives used in the preparation of steam that contacts food.	x	x	x	x	x	x	x	x	x	x
173.340 Component of defoaming agents used in the processing of food.	x	x	x	x	x	x	x	x	x	x

Indirect Additives Certain CARBOWAX™ SENTRY™ Polyethylene Glycols are permitted for use under the following Food Additive Regulations for indirect use as components of articles intended for use in contact with food. There is no maximum limit on their use in these intended applications other than that the amount used shall not exceed the minimum amount needed to produce the intended technical effect.

Permitted Use	300	400	600	1000	540 Blend	1450	3350	4000	4600	8000
175.105 Component of adhesives used in articles intended for packaging, transporting or holding food.	x	x	x	x	x	x	x	x	x	x
175.300 In reaction with triglycerides and fatty acids to produce reconstituted oils that are used in resinous and polymeric coatings.	x	x	x	x	x	x	x	x	x	x
176.170 As a component of paper and paperboard in contact with aqueous and fatty foods.	x	x	x	x	x	x	x	x	x	x
176.180 As a component of paper and paperboard in contact with dry food.	x	x	x	x	x	x	x	x	x	x
177.2600 As a component of rubber articles intended for repeated use.	x	x	x	x	x	x	x	x	x	x
178.3750 Component of articles intended for use in contact with food. Note: This regulation includes most uses in food-contact and food-packaging applications.	x	x	x	x	x	x	x	x	x	x
178.3910 Component of surface lubricants used in drawing, stamping and forming metallic articles from rolled foil or sheet by further processing.	x	x	x	x	x	x	x	x	x	x

EPA EPA Regulation (40 CFR)

Permitted Use	300	400	600	1000	540 Blend	1450	3350	4000	4600	8000
180.910 Inert ingredients used pre- and post harvest; exemptions from the requirement of a tolerance.	x	x	x	x	x	x	x	x	x	x
180.930 Inert ingredients applied to animals; exemptions from the requirement of a tolerance.	x	x	x	x	x	x	x	x	x	x



A World of Applications*

CARBOWAX™ SENTRY™ PEGs and MPEGs are recommended materials for pharmaceuticals and personal care, including...

Pharmaceuticals

	Application	Description	Recommended Product(s)
Excipients	Tablet Binding or Coating	CARBOWAX™ SENTRY™ PEGs act as binders and fillers offering internal and external lubrication. They are also effective plasticizers in tablet coating formulations, providing good hardness, water solubility and lubricity.	CARBOWAX™ SENTRY™ PEG 8000
	Gelatin Capsules	CARBOWAX™ SENTRY™ products are used extensively in soft gelatin capsules. They enhance solubility of the active substance as the primary water-soluble component in the liquid fill.	CARBOWAX™ SENTRY™ PEGs 300 – 1450
		For hard gelatin capsules, CARBOWAX™ SENTRY™ products effectively solubilize active ingredients in a melt-fill protocol. A suitable antioxidant additive such as Butylated Hydroxytoluene (BHT) may be beneficial in providing oxidative stability to the active ingredient and to the PEG under filling conditions.	Solid grade CARBOWAX™ SENTRY™ PEGs
Ointment Base	CARBOWAX™ SENTRY™ PEGs make excellent water-soluble ointment bases as they spread easily and evenly over the skin, even if moisture is present. Good water solubility can make it easy to incorporate aqueous ingredients. PEG ointment bases are preferred over traditional hydrophobic ointment bases as they effectively incorporate active ingredients but can be easily removed with water.	CARBOWAX™ SENTRY™ PEG 1000 and 540 Blend	
Liquid Medications	CARBOWAX™ SENTRY™ PEGs are ingredients in liquid oral-dose medications such as cough medicines and elixirs, where they function as solubilizers and non-alcohol diluents. Other ingredients include nose and ear drops and spray-on medicines.	CARBOWAX™ SENTRY™ Liquid PEGs	
Suppositories		CARBOWAX™ SENTRY™ PEGs serve as a formulation base to dissolve the active substance. They also allow enhanced bioavailability by facilitating effective and complete release of the active substance in the body.	CARBOWAX™ SENTRY™ PEG 1000 and 540 blend
		High molecular weight CARBOWAX™ SENTRY™ PEGs are also used to coat suppositories, providing elasticity and lubricity.	High molecular weight (MW) CARBOWAX™ SENTRY™ PEGs
Actives	Laxatives and Colonic Lavage	CARBOWAX™ SENTRY™ PEGs are well-known in the treatment of chronic constipation. Functioning as an osmotic laxative, they can provide a mild and effective treatment without common side effects seen in other laxative types. They are also widely used as colonic lavage to facilitate bowel cleansing prior to medical procedures such as colonoscopies, radiological exams, or gastrointestinal surgery.	CARBOWAX™ SENTRY™ PEGs 3350 and 4000
Chemical Intermediates		CARBOWAX™ SENTRY™ PEGs and MPEGs are used in the synthesis of pharmaceutical actives such as diesters, carbonates, carbamates, and PEG/protein conjugates ('PEGylation').	CARBOWAX™ SENTRY™ PEGs 300, 400, 600 – 8000; MPEGs 350 and 550
Processing Aids		CARBOWAX™ SENTRY™ PEGs have been in pharmaceutical granulation technology for decades. PEGs can offer control to achieve a more uniform particle size distribution, reduce fines concentration, enhance tablet hardness, and add lubricity.	CARBOWAX™ SENTRY™ PEGs with MW of 1450 and higher; high MW materials such as PEG 8000 preferred

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Personal Care

Application	Description	Recommended Product(s)
Creams and Lotions	CARBOWAX™ SENTRY™ PEGs and MPEGs are important ingredients in creams and lotions due to their affinity for water, inert nature, and ability to solubilize active ingredients. The humectant effect of PEGs increases the ability of these creams and lotions to retain water while also imparting a conditioning effect on the treated skin without producing the sensation of stickiness. The humectancy of CARBOWAX™ SENTRY™ PEGs and MPEGs also helps prevent creams and lotions from drying out.	Liquid CARBOWAX™ SENTRY™ PEGs. Use blends to tailor humectancy, viscosity or melting point.
Toothpastes	CARBOWAX™ SENTRY™ PEGs are non-toxic and non-irritant ingredients that are used widely in toothpastes because of their ability to affect water concentration, viscosity, consistency of application, and product stability. They are used successfully in transparent toothpastes containing large amounts of silicic acid. CARBOWAX™ SENTRY™ PEGs are tolerated by mucous membranes, enhancing their usefulness.	CARBOWAX™ SENTRY™ PEGs 600 – 3350
Bar and Liquid Soaps	CARBOWAX™ SENTRY™ PEGs help in plasticizing and sharpening the shape of bar soaps. Their humectancy also helps prevent soap bars from drying out and cracking. They contribute a conditioning property and pleasant “skin feel”. Soft hand-cleansing pastes can be formulated using CARBOWAX™ SENTRY™ PEGs with reduced viscosity and lower melting points.	Solid grades of CARBOWAX™ SENTRY™ PEGs Lower molecular weight CARBOWAX™ SENTRY™ PEGs
Hair Care Products	In shampoo formulations, CARBOWAX™ SENTRY™ PEGs act as wetting agents and are easily washed off with water. They have also been shown to be a non-greasy, non-toxic ingredient that can alter shampoo functionality and affect flowability and consistency. They are widely used in hair control products as an anti-static agent and as a plasticizer that will decrease the propensity of products to form a brittle film.	CARBOWAX™ SENTRY™ PEG 400, 600, 3350, 4000, 8000
Bath and Shower Gels	CARBOWAX™ SENTRY™ PEGs are well known to solubilize many organic compounds due to the organic backbone and hydrophilic hydroxyl end groups. These properties make them a good choice to solubilize bath oils and other insoluble ingredients. They are also known to leave a silky smooth feel after they are applied to the skin.	CARBOWAX™ SENTRY™ PEG 300 400, 600, 3350, 4000, 8000
Personal Care Sticks	The non-volatile nature of CARBOWAX™ SENTRY™ PEGs makes them suitable carriers for active ingredients in deodorants and insect repellent sticks. They are also used as solubilization aides in lipstick compositions. The physical form and consistency of sticks can be altered through the use of CARBOWAX™ SENTRY™ PEGs with solidification points ranging from 43°C to 63°C	CARBOWAX™ SENTRY™ PEGs 300 - 1450 CARBOWAX™ SENTRY™ PEGs 300, 400, 600 Solid grade CARBOWAX™ SENTRY™ PEGs
Effervescent Tablets	CARBOWAX™ SENTRY™ PEGs are excellent binders for bath salts or effervescent denture cleaners.	CARBOWAX™ SENTRY™ PEGs 3350 - 8000

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Product Stewardship

Dow has a fundamental concern for all who make, distribute and use its products, and for the environment in which we live. This concern is the basis of our product stewardship philosophy by which we assess the health and environmental information on our products and take appropriate steps to protect employee and public health and our environment. Our product stewardship program rests in each and every individual involved with Dow products – from the initial concept and research to manufacture, use, sale and disposal of each product.

Customer Notice

Dow strongly encourages its customers to review both their manufacturing processes and 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 environmental and product safety considerations. Dow product literature, including Material Safety Data Sheets, should be consulted prior to use of Dow products.

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Learn More...

For additional information regarding CARBOWAX™ SENTRY™ Polyethylene Glycol and Methoxypolyethylene Glycol products, and to obtain formulating samples, visit us online or contact us at the number listed for your area below.

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