



Dow Life Sciences

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## **CARBOWAX™ SENTRY™ Polyethylene Glycols**

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

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## A Leading Choice for Pharmaceuticals

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 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 pharmaceuticals. 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 applications. They conform to the US Pharmacopeia / National Formulary (USP/NF) monographs for polyethylene glycols and methoxypolyethylene glycols. Selected liquid and solid CARBOWAX™ SENTRY™ PEGs and MPEGs are compliant with the European Pharmacopoeia (Ph. Eur.) requirements for Macrogols.\*

### 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.

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 global 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.

\*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.



## 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 molecular weights 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. Low aldehyde grades of CARBOWAX™ SENTRY™ PEG 300, 400, and 600 are available.

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

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

### Compliance Information for Indirect Food Use

CARBOWAX™ SENTRY™ Polyethylene Glycols are permitted for use as components of articles intended to come in contact with food under FDA. This summary is not intended as an alternative to reading the full text of the applicable regulations, since additional restrictions and limitations may apply. It is the responsibility of the user of CARBOWAX™ SENTRY™ PEGs as an Indirect Food Additive to read and understand all applicable FDA regulations in Title 21 of the Code of Federal Regulations, as well as any other applicable regulations.

CARBOWAX™ SENTRY™ Polyethylene Glycols - FDA Clearances: 21 CFR																						
CARBOWAX™ SENTRY™ Polyethylene Glycol CAS# 25322-68-3	173.310(c)	173.340(a)(2)	175.105(c)(5)	175.300(b)(3)(ii)	175.300(b)(3)(xxxii)	175.300(b)(3)(xxxiii)	175.320(b)(2)	176.170(b)(1)	176.180(b)(1)	176.200(c)	176.210(d)(2)	177.1200(c)	177.1210(b)(3)	177.1390(c)(2)(fi)	177.1400(b)(4)	177.2600(c)(4)	177.2800(d)(5)	178.3120(d)(3)	178.3570(c)	178.3750(a)(b)(c)	178.3910(b)(2)	
300	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
400	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
600	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
1000	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
1450	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
3350	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
4000	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
4600	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
8000	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•

## A World of Applications\*

CARBOWAX™ SENTRY™ PEGs and MPEGs are recommended materials for pharmaceuticals including:

Pharmaceuticals			
	Application	Description	Recommended Product(s)
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
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. 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.	CARBOWAX™ SENTRY™ PEGs 300 – 1450  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 applications 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. High molecular weight CARBOWAX™ SENTRY™ PEGs are also used to coat suppositories, providing elasticity and lubricity.	CARBOWAX™ SENTRY™ PEG 1000 and 540 blend  High molecular weight (MW) CARBOWAX™ SENTRY™ PEGs
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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### 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.

## 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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