

# CARBOWAX<sup>TM</sup> SENTRY<sup>TM</sup> PEG 3350 & 4000

## Reliable APIs for safe digestive health

CARBOWAX™ SENTRY™ Polyethylene Glycols (PEGs) 3350 and 4000 (Uninhibited) are active pharmaceutical ingredients (APIs) that are highly water soluble and safe to use in multiple dosage forms.

These APIs are ideal for osmotic laxative formulations and offer mild and effective treatment to relieve constipation. They are also widely used in intestinal lavage formulations to facilitate bowel cleansing prior to medical procedures such as colonoscopies, radiological exams, or gastrointestinal surgery.

### A preferred API for laxative formulations

- CARBOWAX™ SENTRY™ Polyethylene Glycol 3350 USP Powder (Uninhibited); Macrogol 3350 Ph. Eur.
- CARBOWAX<sup>TM</sup> SENTRY<sup>TM</sup> Polyethylene Glycol 3350 USP Granular (Uninhibited); Macrogol 3350 Ph. Eur.
- CARBOWAX<sup>TM</sup> SENTRY<sup>TM</sup> Polyethylene Glycol 4000 NF Powder (Uninhibited); Macrogol 4000 Ph. Eur.



### **Best-in-Class Product Features**

- Mild and effective treatment to relieve constipation
- Consistency in taste and dissolution time
- Dependable fill properties due to flow characteristics
- Consistent bulk density, ensuring proper volume of product in your bottle or sachet

### **World Class Manufacturing**

- World scale production facility
- Dedicated manufacturing
- cGMP production, handling and storage
- Complies with ICH Q7 guidelines for APIs
- Polyethylene packaging available for quality preservation, durability, and handling ease

# CARBOWAX™ SENTRY™ PEG Active Pharmaceutical Ingredient Global Registrations

Country/Region	CARBOWAX™ SENTRY™ PEG 3350 (Uninhibited), Granular	CARBOWAX™ SENTRY™ PEG 3350 (Uninhibited), Powder	CARBOWAX™ SENTRY™ PEG 4000 (Uninhibited), Powder
United States	US DMF	US DMF	US DMF
Canada	CEP <sup>1</sup>	CEP <sup>1</sup>	CEP <sup>1</sup>
European Union	CEP <sup>2</sup>	CEP <sup>2</sup>	CEP <sup>2</sup>
China	DMF	DMF	DMF
Japan		DMF	
Korea		DMF	
Thailand			DMF
Technical Dossier: Chemistry, Manufacturing and Control (CMC)	CMC	CMC	CMC

<sup>&</sup>lt;sup>1</sup>Guidance Document: Use of Certificates of Suitability (CEP) as supporting information in Drug Submissions (11.1)

Please note that this is not an exhaustive list.

### **Product Details**

#### Brand / Trade name CARBOWAX™ SENTRY™

Packaging size 25 kg bag, 50 lb bag, 2000 lb supersack

UNII numbers 3WJQ0SDW1A, G2M7P15E5P

Physical form Granular & Powder

Chemical name Polyethylene glycol

Manufacturing Site St. Charles Operations,

St. Charles Operations, Hahnville, Louisiana, USA



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<sup>&</sup>lt;sup>2</sup>Based on information received from regulatory authorities and trade associations, the following countries accept CEPs, some with conditions: Albania, Algeria, Australia, Azerbaijan, Canada, Georgia, Ghana Israel, Kyrgyzstan, Malaysia, Moldova, Morocco, New Zealand, Saudi Arabia, Singapore, South Africa, Tunisia, and Uzbekistan.

CEPs are also accepted (with conditions) by the Taiwan Food and Drug Administration.