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FDA Status



**FDA General**

CARBOWAX™ SENTRY™ Polyethylene Glycols are produced to meet the requirements of the National Formulary (NF) monograph for drug applications and the Food Chemicals Codex (FCC) monograph for certain food and feed applications. CARBOWAX SENTRY Polyethylene Glycols meet the requirements of the Food Additive Regulations (21 CFR) listed below. Uses are subject to good manufacturing practices and any limitations which are part of the regulations.

FDA Food		CARBOWAX™ SENTRY™ Polyethylene Glycol													
FDA Regulation (21CFR)	Permitted Use	200	300	400	600	900	1000	540 BLEND	1450	3350	4000	4600	8000		
<b>Direct Additives:</b>	Certain CARBOWAX SENTRY Polyethylene Glycols (Food Chemicals Codex Grade) are cleared 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 applications other than the amount used shall not exceed the minimum amount needed to produce the intended technical effect.														
73.1(b)(2)	As a diluent in color additive mixtures for coloring shell eggs.													●	
172.210	Defoamer and dispersing adjuvant in coatings applied to fresh citrus fruit for protection of the fruit.		●	●	●	●	●	●	●	●	●	●	●	●	
172.820	1. Coating, binder, plasticizing agent and/or lubricant in tablets used for food. 2. Adjuvant to improve favor and as a bodying agent in saccharin 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.		●	●	●	●	●	●	●	●	●	●	●	●	
173.310	Component of boiler water additives used in the preparation of steam that contacts food.		●	●	●	●	●	●	●	●	●	●	●	●	
173.340	Component of defoaming agents used in the processing of food		●	●	●	●	●	●	●	●	●	●	●	●	
Note: Only CARBOWAX SENTRY PEGs 300-8000 meet the requirement of the above regulations that PEGs contain a maximum of 0.2 wt % of the sum of ethylene glycol and diethylene glycol.															

Indirect Additives:	Certain CARBOWAX and CARBOWAX SENTRY Polyethylene Glycols are cleared 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 applications other than that the amount used shall not exceed the minimum amount needed to produce the intended technical effect in the food-contact article.	CARBOWAX Polyethylene Glycol or CARBOWAX SENTRY Polyethylene Glycol											
		200 200E	300 300E	400 400E	600 600E	900	1000	540 BLEND	1450	3350	4000	4600	8000
175.105	Component of adhesives used in articles intended for packaging, transporting or holding food.	•	•	•	•	•	•	•	•	•	•	•	•
175.300	In reaction with triglycerides and fatty acids to produce reconstituted oils that are used in resinous and polymeric coatings (all PEGs except for PEG 200 and 200E, see footnote). <sup>1</sup>		•	•	•	•	•	•	•	•	•	•	•
176.170	As a component of paper and paperboard in contact with aqueous and fatty foods (all PEGs except for PEG 200 and PEG 200E, see footnote). <sup>1</sup>		•	•	•	•	•	•	•	•	•	•	•
176.180	As a component of paper and paperboard in contact with dry food (all PEGs except for PEG 200 and PEG 200E, see footnote). <sup>1</sup>		•	•	•	•	•	•	•	•	•	•	•
177.1200	As a component of cellophane used for packaging food (all PEGs except for PEG 200 and PEG 200E, see footnote). <sup>1</sup>		•	•	•	•	•	•	•	•	•	•	•
177.1400	Hydroxyethyl cellulose film components (all PEGs except for PEG 200 and PEG 200E, see footnote). <sup>1</sup>		•	•	•	•	•	•	•	•	•	•	•
177.2600	As a component of rubber articles intended for repeated use (all PEGs except for PEG 200 and PEG 200E, see footnote). <sup>1</sup>		•	•	•	•	•	•	•	•	•	•	•
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.		•	•	•	•	•	•	•	•	•	•	•
178.3910	Component of surface lubricants used in drawing, stamping and forming metallic articles from rolled foil or sheet by further processing. <sup>2,3</sup>		•	•	•	•	•	•	•	•	•	•	•

<sup>1</sup>The restriction for the use of PEGs in these applications requires an ethylene glycol + diethylene glycol content of 0.2 wt % (maximum) EG + DEG for a mole weight of below 350. Thus, PEG 200 and 200E are excluded from these applications.

<sup>2</sup>Total residual lubricant on the metal article in the form it contacts food does not exceed 0.2 milligram per square inch of food-contact surface.

<sup>3</sup>Mono- and diethylene glycol content not to exceed total of 0.2%

EPA Regulation (40 CFR)	Permitted Use	200 200E	300 300E	400 400E	600 600E	900	1000	540 BLEND	1450	3350	4000	4600	8000
180.1001(c) 180.1001(e)	Exempted from requirement of residue tolerance when used as inert ingredients in pesticide formulations applied to growing crops, to raw agricultural products after harvest or to animals used as food when used as a surfactant or adjuvants of surfactants. <sup>1</sup>		•	•	•	•	•	•	•	•	•	•	•

<sup>1</sup> The restriction for the use of PEGs in these applications requires an ethylene glycol + diethylene glycol content of 0.2 wt % (maximum) EG + DEG for a mole weight of below 350. Thus, PEG 200 and 200E are excluded from these applications.

The information given here is for use as a general guideline. The regulations should be consulted for complete details. Some uses may have been overlooked. Specific regulations will be reviewed on request.

The legal judgments expressed herein are felt to be accurate. The final responsibility is, however, up to the user, who should consult legal counsel.

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