

Guidance for Shell Egg Cleaners and Sanitizers

Compounds used to wash and destain shell eggs are potential food additives. Therefore, they are regulated by the Food and Drug Administration (FDA). Unfortunately, FDA does not have any published regulations dealing with shell egg cleaning and destaining compounds.

Since the end of the U.S. Department of Agriculture prior approval program for nonfood compounds, FDA has provided FSIS with some general guidelines we can give to companies inquiring about chemicals acceptable for use in formulating products for cleaning and destaining shell eggs.

- Substances that are Generally Recognized as Safe (GRAS) for use in food (Title 21 of the Code of Federal Regulations (CFR), Parts 182 and 184). They are not specifically limited when used to clean shell eggs. However, they should be used in accordance with Good Manufacturing Practices (GMP) as defined in 21 CFR, Section 182.1.
- Substances regulated for any purpose as food additives in 21 CFR, Parts 172-186. They may be used up to the maximum allowable concentration permitted by the food additive regulations.
- Dyes and pigments regulated as color additives for use in food may be > used provided they are used at levels not to exceed that specified in the > color additive regulations.

Any chemical that does not meet the criteria set forth above would need to be reviewed by FDA.

FDA regulates antimicrobial agents that are used on raw agricultural commodities, such as shell eggs, wherever food is prepared, packaged, or held for commercial purposes. The Environmental Protection Agency (EPA) regulates antimicrobial agents that are applied in the field, at treatment facilities where raw commodities are the only food treated and the treatment does not change the status of the food as a raw agricultural commodity, and during transportation between the field and such facility. Sanitizers formulated in compliance with 21 CFR, Section 178.1010 are acceptable for use in sanitizing shell eggs provided they are registered with EPA for this use. New sanitizers (i.e., not formulated in compliance with 21 CFR, Section 178.1010) intended for use on shell eggs that will be used for commercial purposes must be submitted to the FDA Center for Food Safety and Applied Nutrition for clearance. Questions regarding sanitizers applied to shell eggs in the field or at a treatment facility where raw commodities are the only food treated should be addressed to the Antimicrobial Division, Office of Pesticide Programs, EPA.

For further information, contact (202) 205-0279 or (202) 205-0623.