Monsanto

FROM (NAME & LOCATION) L. D. Press - St. Louis General Offices

DATE July 7, 1970 CC

SUBJECT SANTICIZER 409

REFERENCE

TO : REGIONAL MANAGERS/SALESMEN

Attached is a notice from the Federal Register that we have filed a petition requesting regulation of Santicizer 409 for use in PVC and other polymers in food contact use.

Favorable action on this petition would represent a significant contribution by Monsanto to the industry by offering plastics compounders a useful tool in formulating food contact articles. To our knowledge, this would represent the first polymeric plasticizer with broad approval in such applications in the U.S.

Santicizer 409 is significantly different from those plasticizers which currently are regulated for use in food contact applications because of the permanency it offers: resistance to plasticizer loss by extraction into oily foods, migration into other parts of a package (eg paper, styrene, styrofoam, etc.), or items for repeated or continual food contact such as tubing where extended service life is desired. The basis for requesting regulation of Santicizer 409 is not only the toxicity safety data that has been collected, but also the permanency characteristics of Santicizer 409.

Specifically, the portions of the Federal Register where we are seeking inclusion of Santicizer 409 are:

1. 121.2511 - Plasticizers for Polymeric Substances

   Limitations: None, provided that the polyester is free of phthalic radical and has a molecular weight between 1700 and 2200.

2. 121.2514 - Resinous and Polymeric Coatings

3. 121.2520 - Adhesives

   Limitations: None

4. 121.2526 - Resinous and Polymeric Coatings for Paper and Paperboard.

5. 121.2550 - Closures with sealing gaskets for Food Containers

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Within the matrix of types of food and conditions of use (See Table 1 and 2 - Pages 7-8 of PL 500), we would expect Santicizer 409 to be used as follows:

CONDITIONS OF USE	TYPES OF FOOD
A. High Temperature Heat Sterilized (e.g. over 212°F)	I, IV-B
B. Boiling Water Sterilized	II, III, VII
C. Hot Filled or Pasteurized above 150°F	II, IV-B, III, IV-A, V
D. Hot Filled or Pasteurized below 150°F	II, IV-B, VI-B, III, IV-A, V
E. Room Temperature Filled and Stored (no thermal treatment in the container)	I, II, IV-B, VI-B, III, IV-A, V, VII
F. Refrigerated Storage (no thermal treatment in the container)	I, II, III, IV-A, IV-B, VI-B, VII
G. Frozen Storage (no thermal treatment in the container)	I, II, III, IV-B, VII
H. Frozen Storage: Ready-prepared foods intended to be reheated in container at time of use:	
1. Aqueous or oil in water emulsion of high or low fat.	I, II, IV-B
2. Aqueous, high or low free oil or fat.	III, IV-A, VII

IMPORTANT! All that has happened so far is that we have filed a petition. This does not constitute "FDA Approval" by any means. The FDA has up to six months to accept or reject our petition - and one of their choices could be to reject it.

The point is that now is a time for formulation development and evaluation. Does your customer want to build a better mousetrap? Here is a new tool to consider.

L. D. PRESS

LDP/cs

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