

NOTIFICATION FOR A NEW FOOD CONTACT SUBSTANCE: ENVIRONMENTAL PHASE I REVIEW

DATE: July 11, 2000

FCN NO.: 000076

NOTIFIER: Technology Sciences Group Inc.

SUBSTANCE AND USE: Polydimethylhydrogen methylsiloxane for use as a crosslinker in silicone polymers for food packaging materials, in molds, and for the release of pressure sensitive labels.

1. Date: EA prepared July 11, 2000.

2. Name of sponsor: Wacker Silicones

3. Address: Wacker Silicones, 3301 Sutton Road, Adrian MI 49221

4. Description of the proposed action:

- a. Requested Action: Crosslinker V 06 is intended to be used as an ingredient in polymeric substrates (trade name, Dehesive) currently regulated for use in food packaging, molds, and pressure-sensitive adhesive labels. One square inch of surface treated with 2 micrometers of Dehesive release agent corresponds to a mass of 0.00125 g of Dehesive. The crosslinker is added to Dehesive at the rate of 100 g of crosslinker to 1000 g of Dehesive.
- b. Need for Action: The food contact substance will act as a crosslinker in release coatings that will come into contact with food. The crosslinker is completely immobilized within the structure of the release coating.
- c. Locations of use/disposal: The food contact substance, present in the precursor to the release coating, will be used at sites that manufacture food packaging materials, molds and pressure-sensitive labels. The treated articles will be disposed of in landfills and through incineration in municipal waste incinerators.
- 5. Identification of substances that are the subject of the proposed action:

Nomenclature. The crosslinker consists of modified, branched polydimethylhydrogen methylsiloxane(s). It is sold under various trade names: Crosslinker 443204 VP, SLM 443204, Vernetzer [Crosslinker] 443204 VP and Crosslinker V 06.

CAS registration number. None assigned

Molecular weight. The average mole weight of the crosslinker is 21,910; 92% of the product is greater than 1000 mole weight.

Molecular formula. See below.

Structural graphical formula

$$H-\overset{\dagger}{\text{Si-O}}(-\overset{\dagger}{\text{Si-O}})_{m}(-\overset{\dagger}{\text{Si-O}})_{m}-\overset{\dagger}{\text{Si-H}}$$

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$$\overset{\dagger}{\text{Si-O}}(-\overset{\dagger}{\text{Si-O}})_{m}(-\overset{\dagger}{\text{Si-O}})_{m}-\overset{\dagger}{\text{Si-H}}$$

$$\text{where } + = -\text{CH}_{3}$$

Physical description

The crosslinker is a colorless to yellow liquid with a vapor pressure of < 3 hPa at 20°C. It has a specific gravity of 0.97 /cm³ at 25°C. The crosslinker has negligible solubility in water.

- 6. Environmental consequences of the proposed action:
 - a. Production of the food-contact substance:

The crosslinker will be manufactured in Germany. No extraordinary circumstances apply to the manufacture of the food contact substance.

b. *Use and disposal of the food-contact substance*:

The basic polymer in which the crosslinker will be used is already regulated as a food-contact substance. The polymer is already disposed of in landfill sites or using incineration. Based on our analysis, use of the crosslinker will not introduce new substances into landfills or generate new combustion products. Therefore, we do not expect that incorporation of the crosslinker into the polymer will produce any violations of federal, state, or local regulations governing operation of landfills or combustion processes, or in fact have any adverse environmental effect.

The amount of crosslinker used in each food contact article will vary. However, the crosslinker will only be present at a concentration of less than 10% in the thin layer of Dehesive present at the surface of food contact articles. This layer will be present at a thickness of less than 2 microns. The anticipated market volume is described in an attachment to this document.

c. Use of resources and energy:

This product will replace other crosslinker compounds and will therefore not result in any increase in the use of energy or natural resources.

7. Alternatives to the proposed action:

Alternatives to the proposed action need not be considered, because no potential adverse effects have been identified.

8. List of preparers:

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9. Certification:

The undersigned official certifies that the information presented is true, accurate, and complete to the best knowledge of Wacker Silicones Corporation.

Signature of responsible official

Name and title of responsible official, printed or typed Sharronn E. Etter Director, Regulatory Affairs, Wacker Silicones