



**NOTIFICATION FOR A NEW FOOD CONTACT SUBSTANCE:
ENVIRONMENTAL ASSESSMENT**

DATE: April 24, 2000

FCN NO.: 00033

NOTIFIER: Dow Corning Corporation

SUBSTANCE AND USE: Silicone resins used in silicone paper coatings to adjust the force required to release pressure sensitive adhesive self stick labels and tapes.

1. Date: April 24, 2000

2. Name of sponsor: Dow Corning Corporation

3. Address: P.O. Box 994
Midland, Michigan 48686-0994

4. Description of the proposed action:

a. Requested action: Dow Corning would use silicone resins as components of silicone paper coatings to adjust the force required to release pressure sensitive self stick labels and tapes which are to be applied to food surfaces. The silicone coatings may contain silicone resin at up to 50% by weight of the total coating solids. These coatings are expected to remain with the paper backing upon removal of the self stick label.

b. Need for action: Silicone coatings provide easy release of self stick labels. In fact, the release force is often low enough that the self stick labels tend to prematurely separate from the release liner causing production upsets and slowdowns. Silicone resins added to silicone coating formulations modify the surface and adjust the release force so as to eliminate premature release yet still allow label removal in end-use applications.

c. Locations of use/disposal: Labels and tapes for food contact applications are used in a pattern corresponding to national population density, and are widely distributed throughout the country. Consequently, disposal of release liner, containing silicone resin, will

occur nationwide with the materials ultimately being deposited in landfills, incinerated, or recycled (where possible). Trends in U.S. solid waste management suggest that the proportion being landfilled will decrease, while the proportion being incinerated and recycled will increase. Environments potentially affected by disposal include watersheds or groundwater receiving leachate from land disposal sites and areas subject to air emissions from landfills and incineration sites.

5. Identification of substances that are the subject of the proposed action:

a. Complete nomenclature:

Silica, [(dimethylvinylsilyl)oxy] and [(trimethylsilyl)oxy]-modified

b. CAS Reg. No.:

68988-89-6

c. Molecular weight:

Number average (Mn) ~ 5000

Weight average (Mw) ~ 20,500

d. Molecular formula:

$(\text{SiO}_{4/2})_w(\text{Me}_3\text{SiO}_{1/2})_x(\text{Me}_2\text{ViSiO}_{1/2})_y(\text{OH})_z$

e. Structural formula:

A graphic structure is not available (see physical description)

f. Physical description:

Physically the resin is a silica structure which has been modified to contain dimethylvinylsilyloxy and trimethylsilyloxy groups in place of some of the hydroxy groups. It could be considered as a methylated silica. The approximate weight percents of the groups indicated by w, x, y and z in the molecular formula above is: w = 44%, x = 48%, y = 6% and z = 2%.

6. Environmental consequences of the proposed action:

- a. Production of the food contact substance:** There are no extraordinary circumstances that pertain to the manufacture of the food-contact substance which would require information on its production.

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b. Use and disposal of the food contact substance: The proposed action involves a food-contact substance that is a component of a paper coating. The principal routes of environmental introduction of the food-contact substance will result from its disposal in municipal solid waste combustors or in landfills. Based on the proposed use of the food contact substance, only extremely low levels of substances, if any, will enter the environment. The use level of the food-contact substance is a maximum of 1.25% of the finished coated paper. The estimated market volume of the food-contact substance for the proposed use is about 70,000 pounds/year. Migration data using food simulating solvents show that only a maximum of 0.3% of the food-contact substances in the coated paper can migrate from the coated paper, thus, the food-contact substance is substantive to the coated paper. The expected disposal routes for the coated paper are governed by Environmental Protection Agency (EPA) regulations in 40 CFR part 60 (for combustors) and part 258 (for landfills). Based on our analysis, the introduction of combustion products or substances at landfill sites are not environmentally significant. Therefore, we do not expect that any limited increase in environmental introductions resulting from the proposed action will threaten a violation of the EPA regulations governing combustors and landfills or have any other adverse environmental effect.

c. Use of resources and energy: The food-contact substance which is the subject of the proposed action is intended to compete with and replace similar substances currently used as release additives by competitors. Therefore, there will be little, if any, change in the use of natural resources and energy as a result of the proposed action. Release additive substances have been commercially used for many years in non food-contact applications. It is estimated that their use in food-contact applications is a relatively small amount, considerably less than 10%, of the total volume.

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:

Timothy H. Byers, Senior Product Market Specialist
John T. Woodard, Food and Drug Regulatory Specialist

9. Certification: The undersigned official certifies that the information presented is true, accurate, and complete to the best knowledge of Dow Corning Corporation.

April 24, 2000

Date

[Redacted signature box]

Signature of responsible official

John T. Woodard Food and Drug Regulatory Specialist

Name and title of responsible official