AUG 1 8 1987

Dow Corning Corporation 2200 West Salzburg Road Midland, NI 48640

34292-3 PM 31

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Attention: E.A. Abbott

Gentlemen:

Subject: Dow Corning Sylgard[®] Antimicrobial Treatment EPA Registration No. 34292-3 Your Amendment Dated April 15, 1987

The amendment referred to above, submitted in connection with registration under section 3(c)(7)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), is acceptable, provided that you:

- Submit/cite all data required for registration/reregistration of your product under FIFRA section 3(c)(5) when the Agency requires all registrants of similar products to submit such data.
- 2. Make the labeling changes listed below hefore you release the product for shipment bearing the amended labeling:
 - Add the following statement below the articles listed for treatment on the New Product Information Sheet.

After applying the antimicrobial treatment, the surface should then be allowed to dry. Open windows and use a fan or other active means of ventilation to remove the methanol vapors from the room.

3. Submit five (5) copies of your final printed labeling before you release the product for shipment.

			CONCURREN	CES		
SYMBOL	ORIGIONATOR					
SURNAME					 	
DATE		 			 	

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If these conditions are not complied with, the registration will be subject to cancellation in accordance with PIFRA section 6(e). Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records.

Sincerely yours,

John H. Le

Product Manager (31) Disinfectants Branch Registration Division (TS-767C)

Enclosure

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DOW CORNING

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new product information

SYLGARD[®] ANTIMICROBIAL TREATMENT

BACTERIOSTATIC AND FUNGISTATIC ACTIVITY ON TEXTILE SURFACES

Materials treated with SYLGARD® Antimicrobial Treatment are preserved by the bacteriostatic and fungistatic action imparted to the surfaces. Microbial contamination of surfaces may result in odor problems, discoloration, and deterioration. Application of SYLGARD[®] Antimicrobial Treatment* to the surfaces of materials inhibits the growth of microorganisms to aid in the control of these deleterious effects. SYLGARD[®] Antimicrobial Treatment forms a durable, wash resistant coating on non-food contact interior surfaces such as:

Carpet	Upholstery
Draperies	Ceilings
Walls	Floors, etc.

Antimicrobial Action is exhibited on contact in the presence of moisture. ACCEPTED with COMMENTS In DPA Letter Dated:

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*For Commercial Use Only

SYLGARD[®] ANTIMICROBIAL TREATMENT

EPA No. 34292-3 EPA Est. 34292-MI-01

Type....Brand of Silicone Quaternary Amine

Physical Form....42 percent active solids in methanol.

Typical Benefits....Broad spectrum bacteriostatic, fungistatic, algistatic activity on surfaces, durable attachment to a wide variety of surfaces. Compatible, efficient, easily diluted in water. Mold, mildew and fungi are inhibited by the SYLGARD[®] Antimicrobial Treatment.

Primary Use....Provide preservation for many types of materials against a wide variety of bacteria, fungi and yeasts.

Treat with SYLGARD[®] Antimicrobial Treatment: (1) for lasting freshness and to prevent deterioration and discoloration; (2) to to inhibit the growth of bacteria and mildew to prolong the life of the article; (3) to provide a durable, non-leachable antimicrobial treatment; (4) to provide hygienic freshness; (5) to provide a treatment that is not destroyed by repeated cleaning; (6) to inhibit the growth of odor-causing bacteria and mildew: (7) to retain its freshness by resisting the growth of odor-causing bacteria and mildew (fungus); (8) for chemical protection to resist odors; and (9) as an exclusive protective treatment that resists mildew and bacteria growth plus being odor resistant.

The information and data contained herein are based on information we believe reliable. You should thoroughly test any application, and independently conclude satisfactory performance before commercialization. Suggestions of uses should not be taken as inducements to infringe any particular patient.

DOW CORNING CORPORATION, MIDLAND, MICHIC IN 48640 TELEPHONE 517 496-4000

Information About Antimicrobial Agents

The exclusive SYLGARD^{**} Antimicrobial Treatment.

DESCRIPTION

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The SYLGARD^{**} Antimicrobial Treatment is 3 (Inmethoxysily!) propyloctadecyldimethyl ammonium chloride diluted to 42% active ingredients by weight with methanol. Alkoxysitanes of this nature have been shown to form durable bonded coatings to a number of materials (see references).

The SYLGARD Antimicrobial Treatment offers users the following features:

 Good durability – In the presence of moisture, the SYLGARD Antimicrobial Treatment is durable and imparts a broad spectrum, biostatic surface finish to a wide range of substrates. It is leach resistant, nonmigrating, and is not consumed by microorganisms.

 Broad spectrum activity – Effective against gram positive and negative bacteria, fungi, algae and yeasis

 Increased efficiency - Through proper application, durable bactenostatic, fungistatic and algistatic surfaces can be attained with a minimum amount of the SYLGARD Antimicrobial Treatment.

HOW TO USE

The SYLGARD Antimicrobial Treatment can be applied to organic or inorg hic surfaces as a ditute aqueous solution to give 0.1 to 1.0% by weight of active

SYLGARD" ANTIMICROBIAL TREATMENT

U.S. Environmental Protection Agency Number EPA Est 34292-MI-01 Type

Physical Form ... Special Properties Primary Use As a surface-durable antimicrobial treatment active against a wide vanety of bacteria, fung, algae and yeasts

ingredients. Aqueous solutions can be prepared by simply adding the antimicrobial agent to water with stirring.

Surfaces can be treated with the aqueous solution by dipping, padding or spraying until adequately wel, or applying by loaming techniques.

DOW CORNING

34292-3

After applying the antimicrobial treatment, the surface should then be allowed to dry. Open windows and use a fan or other active means of ventilation to remove the methanol wapors from the room.

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TYPICAL PROPERTIES

These values are not intended for use in preparing specifications.

		Сн,
	Structure	((CH,0), SKCH,), N.C. H, CI
		Сн
CTM 0208*	Concentration 42%	active ingredient in methanol
CTM 0176	Appearance	Light to dark amber liquid
CTM 0002	Refractive Index at 26 C (78.8 F)	1.390
CTM 0090A	Flash Point, degrees	11 C (52 F)
	Cloud Point, degrees.	
	Solubility Miscibl	e in all proportions with water,
	alcohols,	ketones, esters, hydrocarbons
		and chlorinated hydrocarbons
	Thermal Stability	. Stable to 125 C (257 F)
	Specific Gravity at 25 C (77 F)	
	Freeze-Thaw Stability	Stable through 10 cycles
		(-17 7 to 50 C/0 to 122 F)*

'in most cases. CTM's (Corporate Test Methods) correspond to ASTM standard tests

Specification Writers: Please contact Dow Corning Corporation, Aldiand, Michigan, before writing specifications on this product.

ACCEPTED with COMMENTS in 11A Letter Dated:

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Under the Federal Inserticide, Furnitistic, and Rodennicute Act as amended, for the posticide repriserved under EPA Reg. No. 342.92-3

FISH TOXICITY

The results of a four-day static lish loxicity study using rainbow trout and bluegills are summarized below:

	· 4 Day TL, Values			
Species	SYLGARD Antimicrobial Treatment	Toxaphenė		
Rainbow trout	0.56 ppm	~0.036 ppm		
Bluegills	0.51 ppm	0.024 ppm		

IMPORTANT INFORMATION ON STORAGE, HANDLING AND FLAMMABILITY

This product is "llammable" and "poisonous."

Storage and Shelf Life

Keep away from heat and open flame.

When slored in original unopened containers at or below 25 C (77 F), the SYLGARD Antimicrobial Treatment has a shelf life of 12 months from date of shipment. Since this material is moisture sensitive, keep the container tightly closed after each use.

Handling (Danger)

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Wear goggles or face shield and rubber gloves when handling the concentrated material. SYLGARD Antimicrobial Treatment, if ingested in amounts incidental to industriat handling, should pose no significant adverse health hazard. Direct contact of the undiluled material with eyes may cause serious injury. Special and particular care must be taken to prevent eye contact. In case of contact with eyes, immediately flush with large amounts of water for at least 15 minutes and get prompt medical attention. Single short-term skin exposure may cause slight irritation. Repeated or prolonged contact over

several days may cause blistering and a superficial burn. Precautions should be taken to avoid prolonged or repeated skin contact.

The SYLGARD Antimicrobial Treatment contains 50% methanol. Keep away from heat and open flame. Appropriate measures should be taken to prevent the accumulation of hazardous concentrations of methanol vapors in the work area.

Neutralization and Environmental Protection

The SYLGARD Antimicrobial Treatment, by standard BOD (biological oxygen demand) and TOD (total oxygen demand) determination, does not appear to be biodegradable. Potential harm to the environment is minimized, however, because of the minimum amount of chemical applied and its durable coupling to surfaces.

Inactivation of aqueous solutions of the SYLGARD Antimicrobial Treatment may be accomplished by initiation of one of the following:

(A.) Addition of an anionic surfactant or detergent in quantity equivalent to that of the SYLGARD Antimicrobial Treatment solution.

(B.) Addition of Triton X-100 nonionic delergent at a final concentration of

10,000 ppm (1.0% volume/volume) or greater to bath solutions up to 1.0% volume/volume of the SYLGARD Antimicrobial Treatment.

(C.) Heating the bath solution to a minimum temperature of 160 C (320 F) for 30 minutes.

Every effort should be made to contain accidental spills of the SYLGARD Antimicrobial Treatment. Many spills may be cleaned up with rags by wiping and mopping and allowing the liquid to absorb onto the fabric. These may then be disposed of by incineration.

Acute Oral Toxicity

The SYLGARD Antimicrobial Treatment has an extremely low acute oral toxicity of LD₁₀ = $:2.27 \pm 0.16$ g/kg body weigh, in albino rats.

Acute Skin Contact

Based on studies conducted on albino rabbits, undiluted SYLGARD Antimicrobial Treatment has a slight to moderate effect upon intact and abraded skin. A single exposure for several hours may cause slight erythema and edema. Prolonged or repeated contact, over a period of several days, may cause blistering and a superficial burn.

Repeated Skin Contact

A human repeated insult patch test has been conducted with a 2.0% aqueous solution of SYLGARD Antimicrobial Treatment on nonwoven polyester. The results of this study showed an overall incidence of skin irritation reactions to be 2/450 or 0.4%. Two subjects each reacted once to the applications of the test material; one with a very slight erythema and the other wilh very slight erythema and edema. There was no

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evidence of skin sensitization noted with any of the subjects.

Acute Dermal Absorption

The SYLGARD Antimicrobial Treatment has an extremely low acute dermal toxicity of $LD_{so} > 7.95$ g/kg body weight in albino rats. Therefore, this material does not appear to present a hazard from skin absorption under ordinary industrial handling conditions when good care and cleanliness are practiced.

Percutaneous Absorption

The SYLGARD Antimicrobial Treatment is not absorbed through the skin of rabbits. The potential hazard of the use of this material in contact with the skin is therefore considered to be insignificant.

Materials Safety Data Sheets

A Materials Safety Data Sheet, (Department of Labor, Form No. LSB-OOS-4), which gives OSHA data for this product, may be obtained by writing or calling Dew Corning Corporation, Midland, MI, 48640-0994; phone number (517) 496-4164.

Shipping Limitations

DOT Classification: Flammable.

PACKAGING

The SYLGARD Antimicrobial Treatment is supplied in 1-, 7-, 35- and 400-lb (0.454-, 3.2-, 15.9- and 181.4-kg) containers, net weight.

USERS PLEASE READ

The information and data contained herein are believed to be accurate and reliable; however, it is the user's responsibility to determine suitability of use. Since Dow Corning cannot know all of the uses to which its products may be put or the conditions of use, it makes no warranties concerning the fitness or suitability of its products for a particular use or purpose.

You should thoroughly test any proposed use of our products and independently conclude satisfactory performance in your application. Likewise, if the manner in which our products are used requires governmental approval or clearance, you must obtain it.

Dow Corning warrants only that its products will meet its specifications. There is no warranty of merchantability or fitness for use, nor any other express or implied warranty. The user's exclusive remedy and Dow Corning's sole ltability is limited to refund of the purchase price or replacement of any product shown to be otherwise than as warranted. Dow Corning will not be liable for incidental or consequential damages of any kind.

Suggestions of uses should not be taken as inducements to infringe any patents.

ADDITIONAL INFORMATION

Additional information on specific applications can be obtained by writing Dow Corning Corporation, New Ventures Business, Midland, MI, 48640-0994.

REFERENCES

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