

CASWELL FILE 19
107401

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OPP OFFICIAL RECORD
HEALTH EFFECTS DIVISION
SCIENTIFIC DATA REVIEWS
EPA SERIES 361

AUG 22 1989

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCESMEMORANDUM

SUBJECT: Evaluation of Proposed New Use for the Antimicrobial
DC5700 (Sylgard)

Record No.: 232575
TOX Chem No.: 892B
TOX Br. Proj. No.: 9-0803

FROM: Henry Spencer, Ph.D., Pharmacologist *sent 5/24/89*
Review Section II
Toxicology Branch I - Insecticide, Rodenticide Support
Health Effects Division (H7509C)

TO: John H. Lee, PM 31
Antimicrobial Program Branch
Registration Division (H7505C)

THRU: Marion P. Copley, D.V.M., Section Head *Marion Copley 7/18/89*
Review Section II *KB 8/22/89*
Toxicology Branch I - Insecticide, Rodenticide Support
Health Effects Division (H7509C)

The registrant, Dow Corning Corporation, has requested the addition of a registered new use on the label for the antimicrobial Sylgard (DC5700). The new use is for treatment of food storage areas.

Review

1. The use of Sylgard on food storage areas cannot be assessed without the submission of further information.

-2-

2. With regard to page 14A, "V. Sylgard Treatment for Hard Surfaces," no list of "precautions" is included in the data.
3. Treatment: Important prominent labeling on how to rid the treated room(s) of methanol fumes is required since the use as indicated provides an approximate air level of 1500 ppm, which is an unacceptable level for animal or human exposure. OSHA 8-hour limits are TWA = 200 ppm. For humans the TC_{10} = 300 ppm for CNS effects. A lethal level study in monkeys reported LC_{50} = 1000 ppm. The 1500 ppm values are based on a walk-in refrigerator of 8' x 10' x 12', with all surfaces treated.
4. The food storage area treatment label has no precautionary statements for use around food.
5. Proposed existing list of registered uses needs correction. Walls were specified in the earlier submission as "basement walls." The use of "etc." after floors is incorrect and must be deleted.

Conclusions

The proposed use in or on food storage areas implies to this reviewer a level of extremely low, if any, exposure if reasonable care is used in its (Sylgard) application. Only the applicator would be at minimal risk. Therefore, the use in food storage areas could be considered supportable following the submission of the required information with its review and acceptance.

The registrant is required to submit for review:

1. The list of precautions referenced on page 14A, paragraphs 6 and 7 under Treatment and Porous Surfaces.
2. Addition of a proposed statement in the requirement section of the label to actively ventilate the methanol fumes from the treatment area to the exterior of the building.
3. Addition of a proposed statement to not treat storage areas containing food stuffs unless the foods are protected (covered) to prevent contamination.
4. Add the word "basement" to walls and delete "etc." from "floors."
5. Submit the ingredients label for Zonyl FSN for review.

2

V. SYLGARD Treatment for Hard Surfaces

Hard surfaces are significantly different from soft (textile-related) surfaces when it comes to applying SYLGARD Treatment. Hard surfaces are typically ceramic tiles, smooth concrete, vinyl wall covering, paper wall covering, wood paneling, etc. The list is endless, but the two key parameters necessary for success are: 1) Have the surface as *clean* as possible, and 2) Have the surface treated as *uniformly* as possible with SYLGARD Treatment. If a surface does not appear to be heavily soiled, it is possible to treat without cleaning and achieve good results. Examine the surface closely by touching to detect any films that may be hard to see.



Vinyl wall covering on left was treated with SYLGARD Treatment; vinyl wall covering on right is untreated.

The only lasting protection available in the marketplace today is SYLGARD Treatment. SYLGARD Treatment applied to hard surfaces has shown effectiveness for more than a year in a variety of harsh southern Florida environments. This climate is known for its stressful conditions of high temperature, sun and humidity, which all accelerate mildew growth. The consumer must have realistic expectations about the performance of SYLGARD Treatment. They should be made aware that the treatment, when applied to a heavily used surface such as a counter top or shower, will lose effectiveness more quickly than when applied to a wall. Original cleanliness, uniformity of application, soiling rates and abrasive wear all influence the long-term effectiveness of SYLGARD Treatment.

Since SYLGARD Treatment inhibits the growth of microbes on contact, surfaces must be kept free of excessive dirt, and care must be taken when applying any coatings on the treated surface (insecticides,

waxes, etc.). These coatings may reduce the protection offered by SYLGARD Treatment as the active sites would be covered.

A. HARD-SURFACE TREATMENT PROCEDURE

More than 2 years of experience have shown that the following method provides the optimum SYLGARD Treatment application. The procedure is as follows:

Preparation of Surfaces: (If surfaces are not heavily soiled, go to Step 4.)

1. Add 1/2 - 1 cup of bleach (i.e., Clorox®) to a gallon of water.* Follow directions and handling precautions on the label.
2. Clean a small part of the hard surface in an inconspicuous place. Check to see if dye bleed or surface deterioration occurs. If not, continue to Step 3.
3. Clean the entire surface to be treated with the bleach solution made in Step 1.

Treatment:

4. Add 4.0 oz. of SYLGARD product to a gallon of water and mix.
5. Add 0.1 oz. of Zonyl® FSN to the mixture in Step 4 and mix. This will be enough SYLGARD solution to cover up to 600 sq. ft. The coverage will vary due to the different porosities of surfaces.
6. Spray or wipe the solution onto the surface. It is important to get the surface uniformly wet. (See precautions.)

Porous surfaces (cement, unfinished paneling or wood, unglazed ceramic tile, ceiling tiles) are treated more effectively by spraying twice, one pass after the other.

If spraying, a fine spray tip such as the TeeJet 800050 will help prevent streaks and supply a more even treatment to the surface. Avoid breathing vapor. (See precautions.)

7. Wipe the surface down with a soft cotton cloth or sponge which has been moistened in solution to prevent streaking. (See precautions.) Wipe glass or highly polished surfaces immediately to prevent spotting.

*Clorox is a registered trademark of Clorox Company

†Doing Battle with Mildew, "Better Homes and Gardens," August 1987, Vol. 65, No. 8, Pg. 39.

‡Zonyl is a registered trademark of E. I. du Pont de Nemours & Company.

1 cup 4 ounces
300 ppm

TC

10' x 10' x 8' = 800

2 1/2

2 1/2

2 1/2

2 1/2

2 1/2

3

DOW CORNING

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No.

4

FISH TOXICITY

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

<u>Species</u>	<u>4 Day TL_{50} Values</u>	
	<u>SYLGARD</u> <u>Antimicrobial Treatment</u>	<u>Toxaphene</u>
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 "flammable" and "poisonous."

Storage and Shelf Life

Keep away from heat and open flame.

When stored 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)

Wear goggles or face shield and rubber gloves when handling the concentrated material. SYLGARD Antimicrobial Treatment, if ingested in amounts incidental to industrial handling, should pose no significant adverse health hazard. Direct contact of the undiluted 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 detergent 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 $LD_{50} = 12.27 \pm 0.16$ g/kg body weight 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 with very slight erythema and edema. There was no

ACCEPTED
with COMMENTS
in EPA Letter Dated:

AUG 18 1987

34292-3

5

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 $LD_{50} > 7.95$ 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 heretofore considered to be insignificant.

Materials Safety Data Sheets

A Materials Safety Data Sheet, Department of Labor, Form No. LSB-205-4, which gives OSHA data for this product, may be obtained by writing or calling Dow 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 liability 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

1. Hough, J.S., and T.P. Lyons. 1972. Coupling of Enzymes onto Microorganisms. *Nature* (London) 235-389.
2. Johansson, O.K., F.O. Stark, G.E. Vogel, and R.M. Fleishmann. 1967.

Evidence for Chemical Bond Formation at Silane Coupling Agent Interfaces. *J. Compos. Mater.* 1:278-292.

3. Plueddemann, E.P. 1970. Adhesion Through Silane Coupling Agents. *J. Adhesion* 2:184-201.

4. Venter, J.E., J.E. Dixon, P.R. Maroko, and N.O. Kaplan. 1972. Biologically Active Catecholamines Covalently Bound to Glass Bead. *Proc. Nat. Acad. Sci. U.S.A.* 69:1141-1145.

5. Weetall, H.H. 1969. Trypsin and Papain Covalently Coupling to Porous Glass. *Science* 166:615-617.

6. Isquith, A.J., E.A. Abbott and P.A. Walters. 1972. Surface-Bonded Antimicrobial Activity of an Organosilicon Ammonium Chloride. *Appl. Micro.* 24:859-863.

7. Gettings, R.L., B.L. Triplett. 1978. New Durable Antimicrobial Finish for Textiles. *AATCC Book of Papers: 1978 Nat. Tech. Conf.* 259-261.

8. Isquith, A.J., C.J. McCallum. 1978. Surface Kinetic Test Method for Determining Rate of Kill by an Antimicrobial Solid. *App. & Envir. Micro.* 36:700-704.

9. Malek, J.R., J.L. Speier. 1982. Development of an Organosilicone Antimicrobial Agent for the Treatment of Surfaces. *J. Coated Fabrics* 12:38-45.

10. Speier, J.L., J.R. Malek. 1982. Destruction of Microorganisms by Contact With Solid Surfaces. *J. Coll Interface Science* 89:68-76.

11. Siddiqui, W.H., J.R. Malek, E. Stanton and E.J. Hobbs. 1983. Percutaneous Absorption of an Antimicrobial Organosilicon Quaternary Ammonium Chloride in Rabbits. *J. App. Tox.* 3:3:146-149.

ACCEPTED
with COMMENTS
In EPA Letter Dated:

AUG 18 1987

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No.

34292-3

6

DOW CORNING

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 interior surfaces such as:

Carpet Upholstery
Draperies *RD* Ceilings
RD Walls *RD* Floors, etc. *RD*
Food storage areas

Antimicrobial Action is exhibited on contact in the presence of moisture.

*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 fresh-
ness and to prevent deterioration
and discoloration; 2) to inhibit
the growth of bacteria and
mildew to prolong the life of the
article; 3) to provide a durable,
non-leachable antimicrobial treat-
ment; 4) to provide hygienic
freshness; 5) to provide a treat-
ment that is not destroyed by
repeated cleaning; 6) to inhibit
the growth of odor causing bacteri-
a and mildew; 7) to retain its
freshness by resisting the growth
of odor-causing bacteria and milde-
(fungus); 8) for chemical protect-
ion to resist odors; and 9) as an
exclusive protective treatment tha
resists mildew and bacteria growth
plus being odor resistant. 10) to
inhibit the growth of fungi that
produce spores associated with
many common allergies.



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 patent.

DOW CORNING CORPORATION, MIDLAND, MICHIGAN 48640 TELEPHONE 517 496-4000

7



13544

046815

Chemical: 1-Octadecanaminium, N,N-dimethyl-N-(3-(t

PC Code: 107401
HED File Code 13000 Tox Reviews
Memo Date: 08/22/89
File ID: 00000000
Accession Number: 412-03-0116

HED Records Reference Center
06/30/2003