

LAW OFFICES

HYMAN, PHELPS & MCNAMARA, P.C.

JAMES R. PHELPS  
PAUL M. HYMAN  
ROBERT A. DORMER  
STEPHEN H. MCNAMARA  
ROGER C. THIES  
THOMAS SCARLETT  
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JOHN A. GILBERT, JR.  
JOHN R. FLEDER  
MARC H. SHAPIRO  
FRANCES K. WU  
ROBERT T. ANGAROLA  
(1945-1996)

700 THIRTEENTH STREET, N.W.  
SUITE 1200  
WASHINGTON, D. C. 20005-5929  
(202) 737-5600  
FACSIMILE  
(202) 737-9329  
www.hpm.com

DIRECT DIAL  
(202) 737-4291

JENNIFER B. DAVIS  
OF COUNSEL

DAVID B. CLISSOLD  
CASSANDRA A. SOLTIS  
JOSEPHINE M. TORRENTE  
MICHELLE L. BUTLER  
ANNE MARIE MURPHY  
PAUL L. FERRARI  
JEFFREY N. WASSERSTEIN  
MICHAEL D. BERNSTEIN  
LARRY K. HOUCK  
DARA S. KATCHER\*  
KURT R. KARST  
MOLLY C. ANDRESEN  
SHAWN M. BROWN\*

\*NOT ADMITTED IN DC

June 22, 2004

By Facsimile/Confirmation by Mail

Mr. Christian Gimber  
Wacker Chemical Corporation  
3301 Sutton Road  
Adrian, Michigan 49221-9397

Dear Mr. Gimber:

You have asked whether the  $\alpha$ -cyclodextrin manufactured by Wacker Chemical Corporation (Wacker) may be legally marketed in the United States for food use. The answer is yes, Wacker's  $\alpha$ -cyclodextrin may be marketed immediately for use in foods.

As you know, many substances added to foods are not food additives and do not require approval by the Food and Drug Administration (FDA) prior to use. These substances, popularly known as "GRAS" substances, are considered to be "generally recognized as safe." As stated in the Federal Food, Drug, and Cosmetic Act (FDC Act), a GRAS substance is

generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use.

2803 MAIN STREET  
SUITE 760  
IRVINE, CALIFORNIA 92614  
(949) 553-7400  
FAX: (949) 553-7433

4819 EMPEROR BOULEVARD  
SUITE 400  
DURHAM, NORTH CAROLINA 27703  
(919) 313-4750  
FAX: (919) 313-4751

Mr. Christian Gimber  
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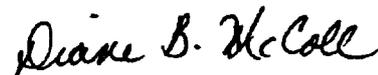
21 U.S.C. § 321(s). If a substance is found to be GRAS under the intended conditions of use, FDA approval or notification is not required prior to such use. FDA acknowledges that "under the 1958 amendment [to the FDC Act], a substance that is GRAS for a particular use may be marketed for that use without agency review and approval." 62 Fed. Reg. 18938, 18939 (April 17, 1997). FDA also recognizes that companies "have the right to make independent GRAS determinations on food substances." 53 Fed. Reg. 16544, 16545 (May 10, 1988).

A specially-convened independent panel of qualified scientific experts recently evaluated Wacker's  $\alpha$ -cyclodextrin for use in foods. After a critical review of the scientific evidence, including, e.g., physical and chemical identity information, Wacker's manufacturing process, publicly available safety data, corroborating unpublished safety data, the intended uses and consumption estimates, the Expert Panel concluded that, based on scientific procedures, Wacker's  $\alpha$ -cyclodextrin is GRAS under the conditions of its intended use in foods.

Accordingly, based on its GRAS status, Wacker's  $\alpha$ -cyclodextrin may be legally marketed for the conditions of use in foods that were evaluated by the Expert Panel.

We trust that these comments are responsive to your inquiry. If you have any further questions, please do not hesitate to contact us.

Sincerely,



Diane B. McColl

DBM/hfm