

Henkel

OCT 05 1992 AN-5891
dated
Henkel Corporation
Emery Group

October 1, 1992

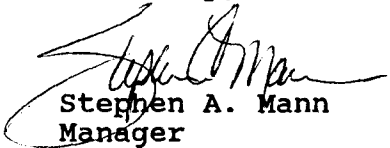
Mr. Bob Hinderer
The B.F. Goodrich Company
6100 Oaktree Blvd.
Cleveland, OH 44131

Dear Mr. Hinderer:

In reference to our telephone conversation, the Emersol 132 Stearic Acid would be suitable for uses which fall under the indirect or incidental food contact applications, Title 21 Parts 174-178, subject of course to any limitations which appear in the specific regulation for your intended use.

We trust this information will satisfy your request. If we can provide any additional information or assistance, please feel free to contact us.

Sincerely,


Stephen A. Mann
Manager
Technical Service
Oleochemicals Group
(513) 482-2257

SAM/alm

WPD0C\BOBH.BFGOOD

21589001

INTEROFFICE MEMORANDUM

Date: 01-Oct-1992 08:10am EDT
 From: KMA
 KMA@ALTC@MRGATE@CLE
 Dept:
 Tel No:

TO: DILLON, CONNIE@A1
 TO: hinderer, robert@A1
 TO: KOVAC, JOHN@A1
 TO: HORTON, BILL@A1

Subject: Stearic Acid Consolidation

Bob Hinderer contacted me today with regard to conversations he has had recently with Henkel and Keller and Heckman concerning the FDA status of Emersol 132.

You will remember that we had asked Henkel to write us a letter that would allow us to use Emersol 132 as our Food Grade stearic acid. Henkel sells Emersol 132 as a USP grade, not a Food Grade stearic acid. However, the Henkel representative felt that the USP grade could be considered Food Grade as far as PVC usage was considered.

The Henkel Technical Service Manager did write us such a letter, however, the bottom line is that the language is not exactly what Bob would have ideally wanted. Bob indicated that, while we could probably "get by" with the use of Emersol 132 in Food Grade applications, based on this letter, the use of the actual Emersol Food Grade version, 6332, will give us "an added degree of security."

In light of this, I wonder if we want to pursue this any further. How much savings would we lose by not consolidating to Emersol 132 (What is the cost difference between L22 and Emersol 132, and what is our usage?) Will the savings be too small to trade for the peace of mind? Are inventory implications important? Your input on these questions will help us determine where we go from here.

Thanks,

Bud

ASP/kma

Henkel's stearic acid doesn't come with GRAS status, so it couldn't be used as a food grade; up to B. G. to determine if we can use it as a food grade. Cost implications? Notify NSF.

21569002

BFG15556

BFGoodrich

ANIZATION CORP.

AN5871

TO

TO: J. POWELL

FROM

FROM: C.V. PURKS

SUBJECT

ALTC

T. & BLDG. NO.

E

PT. & BLDG. NO.

DATE YOUR LETTER

DATE THIS LETTER

May 28, 1992

FDA ACCEPTABILITY OF EMERSOL 132 STEARIC ACID.

THERE IS A PROGRAM OF RAW MATERIAL CONSOLIDATION IN PROGRESS WHICH IS DESIGNED TO DEVELOP A NARROWER LINE OF RAW MATERIAL CODES WHICH WILL BE EASIER TO MANAGE, AND IN THE LONG TERM OFFER LOWER RAW MATERIAL COSTS. STEARIC ACID IS A RAW MATERIAL WHICH WAS IDENTIFIED AS A CANDIDATE FOR CONSOLIDATION SINCE THERE WERE THREE PRIMARY AND ONE SECONDARY STEARIC ACID CODES IN OUR SYSTEM. THE CODES IN USE PRIOR TO THE CONSOLIDATION EFFORT WERE AS FOLLOWS:

L-2	EMERSOL 410	SINGLE PRESSED RUBBER GRADE
L-21	EMERSOL 132	DOUBLE PRESSED USP GRADE
L-22	EMERSOL 6320	DOUBLE PRESSED FDA GRADE
630353	EMERSOL 120	STANDARD PLASTICS GRADE USED BY BFG CANADA

A STRATEGY DEVELOPED TO KEEP EMERSOL 132 AS THE ONLY STEARIC ACID IN OUR SYSTEM, ROLLING THE USES FOR EMERSOL 410, AND EMERSOL 120 INTO EMERSOL 132. THIS STRATEGY HAS BEEN IMPLIMENTED. THE BULK OF COMPOUND RECIPES USED CODE L-2, SO WE DISQUALIFIED EMERSOL 410 FROM CODE L-2, APPROVED EMERSOL 132 AS THE ONLY SOURCE OF CODE L-2, AND REISSUED ALL RECIPES CALLING FOR L-21 AND 630353 WITH L-2.

THIS LEFT CODE L-22, THE FDA GRADE STEARIC ACID. THE CHOICE OF EMERSOL 132 WAS MOTIVATED BY CONVERSATIONS I HAD WITH HENKEL CORP., THE MANUFACTURER OF ALL FOUR OF THE STEARIC ACIDS IDENTIFIED ABOVE. THE HENKEL SALES REPRESENTATIVE FRANK VILALLI HAD TOLD ME THAT IN THE OPINION OF HIS COMPANY EMERSOL 132 COULD BE USED FOR APPLICATIONS IN WHICH THE CONTACT OF THE PACKAGING PRODUCT WITH FOOD WAS INDIRECT; THAT IS, WHEN THE STEARIC ACID WAS NOT BEING ADDED TO FOOD. I ASKED FOR A LETTER FROM HENKEL STATING THEIR POSITION, AND INCLUDE A COPY OF THE RESPONSE I RECEIVED.

PLEASE EXAMINE THE CONTENTS OF THIS LETTER AND TELL US WHETHER YOU FEEL THE ASSURANCES GIVEN BY HENKEL SUPPORT OUR USE OF EMERSOL 132 IN FOOD CONTACT APPLICATIONS SUCH AS PVC BLOWN BOTTLES AND FOOD WRAP.

THANK YOU,

C.V. PURKS

DISTRIBUTION:

R.HINDERER
C.A.DANIELS
A.S.PAZUR
S.J.MATHER
S.A.KLEIN

BFG15557

21.589003

MAY 18 1992

Henkel

Henkel Corporation
Emery Group

May 11, 1992

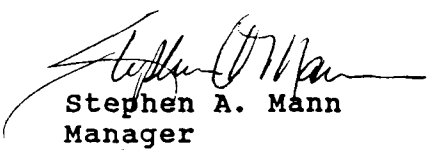
Mr. C.V. Purks
The B.F. Goodrich Company
6100 Oaktree Blvd.
Cleveland, OH 44131

Dear Mr. Purks:

In reference to your recent request, the Emersol 132 Stearic Acid would be suitable for use in indirect or incidental food contact applications where either Stearic Acids or Fatty Acids are mentioned, subject to any limitations in the specific regulation which covers the intended in use.

We trust this information will satisfy your request, if we can provide any additional information or assistance, please feel free to contact us.

Sincerely,



Stephen A. Mann
Manager
Technical Service
Oleochemicals Group
(513) 482-2401

SAM/alm

BFG15558

21569004

C614D011
C614F011

MATERIALS CATALOG
GEON PROD

USERID: N50CND1A
PTERMID: PV120099

PAGE 0001 NEXT PAGE 000

13 00 L002 STEARIC ACID-USP / NF GRADE---EMERSOL 132

L-2 STEARIC ACID

SPEC DT 03/30/92 PROD NO

PRM 481754 HENKEL CORPORATION

No FDA clearance per label

EMERSOL 132

943 00 L020 STEARYL AMIDE

L-20 ARMOSLIP 18

SPEC DT 07/29/86 PROD NO

943 00 L021 STEARIC ACID TRIPLE PRESSED-USP GRADE-FLAKES

L-21 STEARIC ACID USP GR SPEC DT 11/30/89 PROD NO

PRM 481754 HENKEL CORPORATION

No FDA clearance (Henkel) EMERSOL 132

943 00 L022 STEARIC ACID FOOD GRADE-FLAKES

L-22 STEARIC ACID-FDA

SPEC DT 08/06/90 PROD NO

PRM 481754 HENKEL CORPORATION

EMERSOL 6320DP

943 00 L023 REFER TO RAW MATERIAL NUMBER - 94300L042

OBSOLETE L-23 ERUCYL AMIDE

SPEC DT 05/22/84 PROD NO

943 00 L024 TRIGLYCERIDE OF OCTADECADIENOIC ACID

NEXT RESPONSE:

NEXT KEY:

*489T
587T
4068*

BFG15559

21589005

BFGoodrich

M E M O

TO: <i>Bob Connie</i>	
DATE: <i>9/17</i>	TIME: <i>1:50</i> MESSAGE BY: <i>jm</i>
MR. <i>Roman Wypart</i>	
MRS. <i>Roman Wypart</i>	
MS. <i>Roman Wypart</i>	
COMPANY: <i>AZLCO</i>	
ADDRESS: <i>8-221</i>	
TELEPHONE NO: <i>1150</i>	
Telephoned ☐	Please Call ☒
Returned Your Call ☐	Will Call ☐
Wants To See You ☐	Came To See You ☐
SPECIAL ATTENTION ☐	URGENT ☐
MESSAGE: <i>Re: FDA Status</i>	
<i>of the Estetic Acid</i>	
<i>acid is L-2</i>	

Stearic acid (Hendel)
94300L002 mm

BFG15560

21589005 A

BFGoodrich

INTER-ORGANIZATION CORRESPONDENCE

TO Distribution FIELD POINT OR DEPT. & BLDG. NO. DATE YOUR LETTER
FROM A.S. Pazur 8-22-11/11/92 FIELD POINT OR DEPT. & BLDG. NO. DATE THIS LETTER 2/5/92
SUBJECT Stearic Acid

The Raw Materials Council is proposing the consolidation of L2, L21 and L22 - the goal is to use only one stearic acid, Emersol 132 (now L21), in all compounds. This would be accomplished as follows:

1. All current stearic acids approved under code L2 would be disqualified.
2. Emersol 132, currently approved under L21 would be qualified under L2.

This would have the effect of utilizing what is currently L21 (Emersol 132) in all recipes currently calling for L2. This avoids having to change the hundred of recipes which currently specify L2.

3. Manually changing L21 to L2 in all recipes which currently specify L21. This would result in no change in stearic acid utilization for those recipes, since what used to be L21 will now be L2. This is manageable as the number of recipes containing L21 is reasonably small.
4. I will be pursuing with Bob Hinderer, Divisional Toxicologist, and Joe Powell, Legal Department, the possibility of using Emersol 132 in those food grade recipes now specifying L22. Our L22 source, Emersol 6320, is listed as "food grade" by the supplier, however, this designation for stearic acid means it is suitable as a food additive for direct addition to food. [Our feeling is that Emersol 132, a USP grade, should be acceptable as a "food grade" plastic additive.] L21 is suitable for ingestion, in small amounts, as it is used as a USP tablet coating. The amount which would be extracted from a plastic used for food packaging would be much smaller than the amounts ingested in the tablet application. If we can get this clarified, we will change those recipes now specifying L22 to an L2 specification also.

This memo is for the purpose of soliciting your comments on these proposed changes. Please see me or C.V. Purks for copies of the supplier and BFG specifications for these stearic acids. Please submit any questions or issues you have with these proposals in writing to me by February 21st. I would like to implement the L21/L2 change by March 15th.

Thanks for your cooperation.

Bud
Bud Pazur

BFG15561

21589006

Distribution via email message 2/5/92:

Managers and Scientists in Departments 5050, 5052, 5054, and 2376

cc: C.V. Purks
W. Horton/J. Kovac
D. Marshall
C.A. Daniels
L.M. Maresca
B. Hinderer
J. Powell

[rhs]stearicacidioc.asp

BFG15562

21589007

Stearic Acid

L-22

L-21

~~EMERY ~~then~~ Industries Inc~~

~~1300 CAREW Tower~~

~~Cinci, Ohio 45202~~

~~(513) 762-6200 530-7300~~

Ford Code

plus CFR

Check to see date on Stearic Acid (FDA Sec. 184.1090 pg 420)
if any changes
to Ford Code

need to contact Emery
i see if they will
submit pertinent data
to FDA for us as a
customer

Mark Lucke 708/450-74
akron # 986

Humboldt Chem Div

Witco Chem Corp

P.O. Box 125

~~Wilmington, DE 19380~~

2701 Lake St

Melrose Park, Ill 60160

CC: Norman Wygart

BFGoodrich

MEMO

TO: <u>Ber</u>	MESSAGE BY <u>TE</u>	
DATE <u>1/8</u>	TIME <u>11:30</u>	
MR. <u>Roman</u>		
MRS. <u>Norman Wygart</u>		
MS. <u>Norman Wygart</u>		
COMPANY:		
ADDRESS:		
TELEPHONE NO: <u>8-221-1150</u>		
Telephoned ☐	Please Call ☐	
Returned Your Call ☐	Will Call ☐	
Wants To See You ☐	Came To See You ☐	
SPECIAL ATTENTION ☐	URGENT ☐	
MESSAGE:		

L-21 Witco & Hydrone 5016 FG
take appropriate action
to ~~get~~ approved supplier

21589008

BFG15563

October 10, 1990

K. B. Srail
ALTC, B/416

SUBJECT: CODE L-21-FDA STATUS

Stearic acid that meets the specifications of the Food Chemicals Code, 3rd Edition and the requirements of 21CFR 172.860(b)(2) (i.e., free of chick edema factor), has been affirmed as generally recognized as safe (GRAS) as a direct food additive (21CFR 184.1090). Those substances that are GRAS as direct food additives are also GRAS as indirect food additives. Consequently, if Code L-22 is food grade stearic acid, it can be used in food contact articles with no specific restrictions. *Dependent on the impurity level.*

W.C. Bachtel
W. C. Bachtel

if it meets usual GMP

1010-3/jp

cc: C. V. Purks - ALTC

21589009

BFG15564