



74-422-21

July 5, 1974

CORROSIVITY STUDY ON A SERIES  
OF NINE MATERIALS

For Fatty Acid Producers' Council.

PURPOSE

This study was conducted to evaluate the corrosivity potential of the test materials in accordance with the procedure described in Section 173.240 under Title 49 of the Code of Federal Regulations, (Federal Register, February 12, 1973).

TEST MATERIALS

The samples were received from Fatty Acid Producers' Council on November 30, 1973 for use in this study as follows:

| <u>Sample</u>             |         | <u>Description</u>                                |
|---------------------------|---------|---|
| Caprylic Acid             | 1922-62 | Very pale, clear yellow liquid with a slight odor |
| Capric Acid               | 1922-63 | White crystal powder with a slight odor           |
| Lauric Acid               | 1922-64 | White crystal powder with a slight odor           |
| Myristic Acid             | 1922-65 | White crystal powder with a slight odor           |
| Palmitic Acid             | 1922-66 | White powder with a slight odor                   |
| Stearic Acid              | 1922-67 | White waxy powder with a slight odor              |
| Stearic Acid<br>(Eutetic) | 1922-68 | White waxy powder with a slight odor              |
| Oleic Acid                | 1922-69 | Clear gold light liquid with a slight odor        |
| Soya Fatty Acids          | 1922-70 | White waxy liquid with a slight odor              |

## PROCEDURE

Five-tenths gram or five-tenths milliliter of each undiluted test material was applied under a 1.5 by 1.5 inch, 12-ply surgical gauze patch, to two intact skin areas on each of six albino rabbits. The application sites were prepared by clipping the hair from the saddle area of the rabbits. Each patch was held in place with two strips of 1/2 x 4 inch strips of adhesive tape. After application of the patches, the trunk of each rabbit was wrapped with rubber dental damming which was secured with staples. The animals were immobilized in wooden restraining stocks for 4 hours.

At the end of the 4-hour exposure period, the patches were removed and any residual sample was gently sponged from the skin with a moistened towel. The reactions were scored immediately after removal of the patches (4-hour reading), and again at 24 and 48 hours after initial application, according to the scale reproduced in Tables 1 through 9 accompanying this report.

## RESULTS

The results following patch application of Caprylic Acid 1922-62, Capric Acid 1922-63, Lauric Acid 1922-64, Myristic Acid 1922-65, Palmitic Acid 1922-66, Stearic Acid 1922-67, Stearic Acid (Eutetic) 1922-68, Oleic Acid 1922-69, and Soya Fatty Acids 1922-70 to the skin of albino rabbits are shown in Tables 1 through 9, respectively.

No corrosive effects were noted at any site in any animal tested with Lauric Acid 1922-64, Myristic Acid 1922-65, Palmitic Acid 1922-66, Stearic Acid 1922-67, Stearic Acid (Eutetic) 1922-68, Oleic Acid 1922-69 and Soya Fatty Acids 1922-70 at any time during the study.

Caprylic Acid 1922-62 produced entire necrosis or spotted or entire blanching of each site at the 4-hour reading. At the 24 and 48-hour readings, entire or spotted coriaceousness was noted at each site.

Capric Acid 1922-63 produced entire blanching of one site and entire necrosis of one site at the 4-hour reading. The remaining sites exhibited no corrosive effects at the 4-hour reading. At the 24 and 48-hour readings six sites exhibited entire coriaceousness while the remaining six sites exhibited no corrosive effects.

## SUMMARY

The corrosive potential of Caprylic Acid 1922-62, Capric Acid 1922-63, Lauric Acid 1922-64, Myristic Acid 1922-65, Palmitic Acid 1922-66, Stearic Acid 1922-67, Stearic Acid (Eutetic) 1922-68, Oleic Acid 1922-69 and Soya Fatty Acids 1922-70 was evaluated in accordance with the procedure described in Section 173.240 under Title 49 of the Code of Federal Regulations (Federal Register, February 12, 1973).

Caprylic Acid 1922-62 and Capric Acid 1922-63 produced blanching, necrosis and coriaceousness.

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No corrosive effects were noted in any animal at any time during the study which were tested with Lauric Acid 1922-64, Myristic Acid 1922-65, Palmitic Acid 1922-66, Stearic Acid 1922-67, Stearic Acid (Eutetic) 1922-68, Oleic Acid 1922-69 and Soya Fatty Acids 1922-70.

Based on these results Lauric Acid 1922-64, Myristic Acid 1922-65, Palmitic Acid 1922-66, Stearic Acid 1922-67, Stearic Acid (Eutetic) 1922-68, Oleic Acid 1922-69 and Soya Fatty Acids 1922-70 are not classified as corrosive materials; Caprylic Acid 1922-62 and Capric Acid 1922-63 are classified as corrosive as these terms are defined in the above-cited Regulations.

IBR-U.S.  
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TABLE 1. Corrosive scores in rabbits following a 4-hour patch application of Caprylic Acid 1922-62.

| Rabbit<br>Number | Skin   | Eschar<br>Observation |        |        |
|------------------|--------|-----------------------|--------|--------|
|                  |        | 4 hr.                 | 24 hr. | 48 hr. |
| 1                | Intact | 4A                    | 4C     | 4C     |
|                  | Intact | 4B                    | 4C     | 4C     |
| 2                | Intact | 4B                    | 4D     | 4D     |
|                  | Intact | 4B                    | 4D     | 4D     |
| 3                | Intact | 4B                    | 4C     | 4C     |
|                  | Intact | 4B                    | 4C     | 4C     |
| 4                | Intact | 4B                    | 4C     | 4C     |
|                  | Intact | 4B                    | 4C     | 4C     |
| 5                | Intact | 4B                    | 4C     | 4C     |
|                  | Intact | 4B                    | 4C     | 4C     |
| 6                | Intact | 4B                    | 4C     | 4C     |
|                  | Intact | 4B                    | 4C     | 4C     |

A = Entire site necrotic  
 B = Spotted to entire site blanched  
 C = Entire site coriaceous  
 D = Spotted coriaceousness of site

#### SCORING KEY

| Evaluation of skin reactions  | Value* |
|---|--------|
| <b>Erythema and eschar formation:</b>   |        |
| No erythema.....  | 0      |
| Very slight erythema (barely perceptible).....  | 1      |
| Well-defined erythema.....  | 2      |
| Moderate to severe erythema.....  | 3      |
| Severe erythema (beet redness) to slight eschar formation (injuries in depth).....          | 4      |
| <b>Edema formation:</b>   |        |
| No edema.....   | 0      |
| Very slight edema (barely perceptible).....   | 1      |
| Slight edema (edges of area well defined by definite raising).....                          | 2      |
| Moderate edema (raised approximately 1 millimeter).....                                     | 3      |
| Severe edema (raised more than 1 millimeter and extending beyond the area of exposure)..... | 4      |

\* § 191.11 of the Regulations under the Federal Hazardous Substances Act.

TABLE 2. Corrosive scores in rabbits following a 4-hour patch application of Capric Acid 1922-63.

| Rabbit<br>Number | Skin   | Eschar<br>Observation |        |        |
|------------------|--------|-----------------------|--------|--------|
|                  |        | 4 hr.                 | 24 hr. | 48 hr. |
| 7                | Intact | 0                     | 0      | 0      |
|                  | Intact | 0                     | 0      | 0      |
| 8                | Intact | 0                     | 0      | 0      |
|                  | Intact | 0                     | 0      | 0      |
| 9                | Intact | 0                     | 4C     | 4C     |
|                  | Intact | 0                     | 4C     | 4C     |
| 10               | Intact | 0                     | 4C     | 4C     |
|                  | Intact | 0                     | 4C     | 4C     |
| 11               | Intact | 4B                    | 4C     | 4C     |
|                  | Intact | 4A                    | 4C     | 4C     |
| 12               | Intact | 0                     | 0      | 0      |
|                  | Intact | 0                     | 0      | 0      |

A = Entire site necrotic  
 B = Entire site blanched  
 C = Entire site coriaceousness

#### SCORING KEY

| <i>Evaluation of skin reactions</i>   | <i>Value*</i> |
|---|---------------|
| <b>Erythema and eschar formation:</b>   |               |
| No erythema.....  | 0             |
| Very slight erythema (barely perceptible).....  | 1             |
| Well-defined erythema.....  | 2             |
| Moderate to severe erythema.....  | 3             |
| Severe erythema (beet redness) to slight eschar formation (injuries in depth).....          | 4             |
| <b>Edema formation:</b>   |               |
| No edema.....   | 0             |
| Very slight edema (barely perceptible).....   | 1             |
| Slight edema (edges of area well defined by definite raising).....                          | 2             |
| Moderate edema (raised approximately 1 millimeter).....                                     | 3             |
| Severe edema (raised more than 1 millimeter and extending beyond the area of exposure)..... | 4             |

\* § 191.11 of the Regulations under the Federal Hazardous Substances Act.

TABLE 3. Corrosive scores in rabbits following a 4-hour patch application of Lauric Acid 1922-64.

| Rabbit<br>Number | Skin   | Eschar<br>Observation |        |        |
|------------------|--------|-----------------------|--------|--------|
|                  |        | 4 hr.                 | 24 hr. | 48 hr. |
| 13               | Intact | 0                     | 0      | 0      |
|                  | Intact | 0                     | 0      | 0      |
| 14               | Intact | 0                     | 0      | 0      |
|                  | Intact | 0                     | 0      | 0      |
| 15               | Intact | 0                     | 0      | 0      |
|                  | Intact | 0                     | 0      | 0      |
| 16               | Intact | 0                     | 0      | 0      |
|                  | Intact | 0                     | 0      | 0      |
| 17               | Intact | 0                     | 0      | 0      |
|                  | Intact | 0                     | 0      | 0      |
| 18               | Intact | 0                     | 0      | 0      |
|                  | Intact | 0                     | 0      | 0      |

SCORING KEY

| Evaluation of skin reactions  | Value* |
|---|--------|
| <b>Erythema and eschar formation:</b>   |        |
| No erythema.....  | 0      |
| Very slight erythema (barely perceptible).....  | 1      |
| Well-defined erythema.....  | 2      |
| Moderate to severe erythema.....  | 3      |
| Severe erythema (beet redness) to slight eschar formation (injuries in depth).....          | 4      |
| <b>Edema formation:</b>   |        |
| No edema.....   | 0      |
| Very slight edema (barely perceptible).....   | 1      |
| Slight edema (edges of area well defined by definite raising).....                          | 2      |
| Moderate edema (raised approximately 1 millimeter).....                                     | 3      |
| Severe edema (raised more than 1 millimeter and extending beyond the area of exposure)..... | 4      |

\* § 191.11 of the Regulations under the Federal Hazardous Substances Act.

TABLE 4. Corrosive scores in rabbits following a 4-hour patch application of Myristic Acid 1922-65.

| Rabbit<br>Number | Skin   | Eschar<br>Observation |        |        |
|------------------|--------|-----------------------|--------|--------|
|                  |        | 4 hr.                 | 24 hr. | 48 hr. |
| 19               | Intact | 0                     | 0      | 0      |
|                  | Intact | 0                     | 0      | 0      |
| 20               | Intact | 0                     | 0      | 0      |
|                  | Intact | 0                     | 0      | 0      |
| 21               | Intact | 0                     | 0      | 0      |
|                  | Intact | 0                     | 0      | 0      |
| 22               | Intact | 0                     | 0      | 0      |
|                  | Intact | 0                     | 0      | 0      |
| 23               | Intact | 0                     | 0      | 0      |
|                  | Intact | 0                     | 0      | 0      |
| 24               | Intact | 0                     | 0      | 0      |
|                  | Intact | 0                     | 0      | 0      |

#### SCORING KEY

| <i>Evaluation of skin reactions</i>   | <i>Value*</i> |
|---|---------------|
| <b>Erythema and eschar formation:</b>   |               |
| No erythema.....  | 0             |
| Very slight erythema (barely perceptible).....  | 1             |
| Well-defined erythema.....  | 2             |
| Moderate to severe erythema.....  | 3             |
| Severe erythema (beet redness) to slight eschar formation (injuries in depth).....          | 4             |
| <b>Edema formation:</b>   |               |
| No edema.....   | 0             |
| Very slight edema (barely perceptible).....   | 1             |
| Slight edema (edges of area well defined by definite raising).....                          | 2             |
| Moderate edema (raised approximately 1 millimeter).....                                     | 3             |
| Severe edema (raised more than 1 millimeter and extending beyond the area of exposure)..... | 4             |

\* § 191.11 of the Regulations under the Federal Hazardous Substances Act.

TABLE 5. Corrosive scores in rabbits following a 4-hour patch application of Palmitic Acid 1922-66.

| Rabbit<br>Number | Skin   | Eschar<br>Observation |        |        |
|------------------|--------|-----------------------|--------|--------|
|                  |        | 4 hr.                 | 24 hr. | 48 hr. |
| 25               | Intact | 0                     | 0      | 0      |
|                  | Intact | 0                     | 0      | 0      |
| 26               | Intact | 0                     | 0      | 0      |
|                  | Intact | 0                     | 0      | 0      |
| 27               | Intact | 0                     | 0      | 0      |
|                  | Intact | 0                     | 0      | 0      |
| 28               | Intact | 0                     | 0      | 0      |
|                  | Intact | 0                     | 0      | 0      |
| 29               | Intact | 0                     | 0      | 0      |
|                  | Intact | 0                     | 0      | 0      |
| 30               | Intact | 0                     | 0      | 0      |
|                  | Intact | 0                     | 0      | 0      |

SCORING KEY

| Evaluation of skin reactions  | Value* |
|---|--------|
| <b>Erythema and eschar formation:</b>   |        |
| No erythema.....  | 0      |
| Very slight erythema (barely perceptible).....  | 1      |
| Well-defined erythema.....  | 2      |
| Moderate to severe erythema.....  | 3      |
| Severe erythema (beet redness) to slight eschar formation (injuries in depth).....          | 4      |
| <b>Edema formation:</b>   |        |
| No edema.....   | 0      |
| Very slight edema (barely perceptible).....   | 1      |
| Slight edema (edges of area well defined by definite raising).....                          | 2      |
| Moderate edema (raised approximately 1 millimeter).....                                     | 3      |
| Severe edema (raised more than 1 millimeter and extending beyond the area of exposure)..... | 4      |

\* § 191.11 of the Regulations under the Federal Hazardous Substances Act.



TABLE 6. Corrosive scores in rabbits following a 4-hour patch application of Stearic Acid 1922-67.

| Rabbit<br>Number | Skin   | Eschar<br>Observation |        |        |
|------------------|--------|-----------------------|--------|--------|
|                  |        | 4 hr.                 | 24 hr. | 48 hr. |
| 31               | Intact | 0                     | 0      | 0      |
|                  | Intact | 0                     | 0      | 0      |
| 32               | Intact | 0                     | 0      | 0      |
|                  | Intact | 0                     | 0      | 0      |
| 33               | Intact | 0                     | 0      | 0      |
|                  | Intact | 0                     | 0      | 0      |
| 34               | Intact | 0                     | 0      | 0      |
|                  | Intact | 0                     | 0      | 0      |
| 35               | Intact | 0                     | 0      | 0      |
|                  | Intact | 0                     | 0      | 0      |
| 36               | Intact | 0                     | 0      | 0      |
|                  | Intact | 0                     | 0      | 0      |

SCORING KEY

| Evaluation of skin reactions  | Value* |
|---|--------|
| <b>Erythema and eschar formation:</b>   |        |
| No erythema.....  | 0      |
| Very slight erythema (barely perceptible).....  | 1      |
| Well-defined erythema.....  | 2      |
| Moderate to severe erythema.....  | 3      |
| Severe erythema (beet redness) to slight eschar formation (injuries in depth).....          | 4      |
| <b>Edema formation:</b>   |        |
| No edema.....   | 0      |
| Very slight edema (barely perceptible).....   | 1      |
| Slight edema (edges of area well defined by definite raising).....                          | 2      |
| Moderate edema (raised approximately 1 millimeter).....                                     | 3      |
| Severe edema (raised more than 1 millimeter and extending beyond the area of exposure)..... | 4      |

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TABLE 7. Corrosive scores in rabbits following a 4-hour patch application of Stearic Acid (Eutetic) 1922-68.

| Rabbit<br>Number | Skin   | Eschar<br>Observation |        |        |
|------------------|--------|-----------------------|--------|--------|
|                  |        | 4 hr.                 | 24 hr. | 48 hr. |
| 37               | Intact | 0                     | 0      | 0      |
|                  | Intact | 0                     | 0      | 0      |
| 38               | Intact | 0                     | 0      | 0      |
|                  | Intact | 0                     | 0      | 0      |
| 39               | Intact | 0                     | 0      | 0      |
|                  | Intact | 0                     | 0      | 0      |
| 40               | Intact | 0                     | 0      | 0      |
|                  | Intact | 0                     | 0      | 0      |
| 41               | Intact | 0                     | 0      | 0      |
|                  | Intact | 0                     | 0      | 0      |
| 42               | Intact | 0                     | 0      | 0      |
|                  | Intact | 0                     | 0      | 0      |

#### SCORING KEY

| Evaluation of skin reactions  | Value* |
|---|--------|
| <b>Erythema and eschar formation:</b>   |        |
| No erythema.....  | 0      |
| Very slight erythema (barely perceptible; .....   | 1      |
| Well-defined erythema.....  | 2      |
| Moderate to severe erythema.....  | 3      |
| Severe erythema (beet redness) to slight eschar formation (injuries in depth) .....         | 4      |
| <b>Edema formation:</b>   |        |
| No edema.....   | 0      |
| Very slight edema (barely perceptible) ..   | 1      |
| Slight edema (edges of area well defined by definite raising).....                          | 2      |
| Moderate edema (raised approximately 1 millimeter).....                                     | 3      |
| Severe edema (raised more than 1 millimeter and extending beyond the area of exposure)..... | 4      |

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TABLE 8. Corrosive scores in rabbits following a 4-hour patch application of Oleic Acid 1922-69.

| Rabbit<br>Number | Skin   | Eschar<br>Observation |        |        |
|------------------|--------|-----------------------|--------|--------|
|                  |        | 4 hr.                 | 24 hr. | 48 hr. |
| 43               | Intact | 0                     | 0      | 0      |
|                  | Intact | 0                     | 0      | 0      |
| 44               | Intact | 0                     | 0      | 0      |
|                  | Intact | 0                     | 0      | 0      |
| 45               | Intact | 0                     | 0      | 0      |
|                  | Intact | 0                     | 0      | 0      |
| 46               | Intact | 0                     | 0      | 0      |
|                  | Intact | 0                     | 0      | 0      |
| 47               | Intact | 0                     | 0      | 0      |
|                  | Intact | 0                     | 0      | 0      |
| 48               | Intact | 0                     | 0      | 0      |
|                  | Intact | 0                     | 0      | 0      |

SCORING KEY

| <i>Evaluation of skin reactions</i>   | <i>Value*</i> |
|---|---------------|
| <b>Erythema and eschar formation:</b>   |               |
| No erythema.....  | 0             |
| Very slight erythema (barely perceptible).....  | 1             |
| Well-defined erythema.....  | 2             |
| Moderate to severe erythema.....  | 3             |
| Severe erythema (best redness) to slight eschar formation (injuries in depth).....          | 4             |
| <b>Edema formation:</b>   |               |
| No edema.....   | 0             |
| Very slight edema (barely perceptible).....   | 1             |
| Slight edema (edges of area well defined by definite raising).....                          | 2             |
| Moderate edema (raised approximately 1 millimeter).....                                     | 3             |
| Severe edema (raised more than 1 millimeter and extending beyond the area of exposure)..... | 4             |

\* § 191.11 of the Regulations under the Federal Hazardous Substances Act.

TABLE 9. Corrosive scores in rabbits following a 4-hour patch application of Soya Fatty Acids 1922-70.

| Rabbit<br>Number | Skin   | Eschar<br>Observation |        |        |
|------------------|--------|-----------------------|--------|--------|
|                  |        | 4 hr.                 | 24 hr. | 48 hr. |
| 49               | Intact | 0                     | 0      | 0      |
|                  | Intact | 0                     | 0      | 0      |
| 50               | Intact | 0                     | 0      | 0      |
|                  | Intact | 0                     | 0      | 0      |
| 51               | Intact | 0                     | 0      | 0      |
|                  | Intact | 0                     | 0      | 0      |
| 52               | Intact | 0                     | 0      | 0      |
|                  | Intact | 0                     | 0      | 0      |
| 53               | Intact | 0                     | 0      | 0      |
|                  | Intact | 0                     | 0      | 0      |
| 54               | Intact | 0                     | 0      | 0      |
|                  | Intact | 0                     | 0      | 0      |

### SCORING KEY

| Evaluation of skin reactions  | Value* |
|---|--------|
| <b>Erythema and eschar formation:</b>   |        |
| No erythema.....  | 0      |
| Very slight erythema (barely perceptible; .....   | 1      |
| Well-defined erythema.....  | 2      |
| Moderate to severe erythema.....  | 3      |
| Severe erythema (beet redness) to slight eschar formation (injuries in depth) .....         | 4      |
| <b>Edema formation:</b>   |        |
| No edema.....   | 0      |
| Very slight edema (barely perceptible).....   | 1      |
| Slight edema (edges of area well defined by definite raising).....                          | 2      |
| Moderate edema (raised approximately 1 millimeter).....                                     | 3      |
| Severe edema (raised more than 1 millimeter and extending beyond the area of exposure)..... | 4      |

\* § 191.11 of the Regulations under the Federal Hazardous Substances Act.

HILL TOP RESEARCH, INC.  
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IMPORTANT NOTICE

SAMPLE DISPOSAL  
PROCEDURE

At the conclusion of a test program, two units of each sample used will be stored and remaining samples will be destroyed. No materials will be maintained longer than six months after the completion of the study unless the client notifies Hill Top Research, Inc.

New drugs are exempt from the above procedure. They will be retained or returned to the client.