## SIDS INITIAL ASSESSMENT PROFILE

| Category name                                     | Glycerides Category                              |   |                    |  |  |  |
|---|--|---|--------------------|--|--|--|
| CAS No(s), Chemical                               | CAS No [Class <sup>2</sup>                       | IUPAC or CAS Name   | Structural Formula |  |  |  |
| CAS No(s), Chemical                               | Monoglycerides                                   |   |                    |  |  |  |
| name(s) and structural<br>formula(s) <sup>1</sup> | 25496-72-4<br>[2]                                | Olein, mono-<br>Octadecenoic acid, 1,2,3-<br>propanetriol |                    |  |  |  |
|   |  |   | HO OH              |  |  |  |
|   |  |   | CH <sub>3</sub>    |  |  |  |
|   | 37220-82-9<br>[2]                                | Glycerol oleate   |                    |  |  |  |
|   |  |   | н.с                |  |  |  |
|   | 68309-32-0 and<br>61790-12-3 <sup>3</sup><br>[2] | Glycerides,tall-oil                                       | HO OH              |  |  |  |

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<sup>&</sup>lt;sup>1</sup> Glycerides are commonly identified by industry and regulatory authorities as mono-, di-, tri, etc. and therefore the logical way to group the information in a manner that makes sense to the reader/reviewer is to provide subcategories (monoglycerides, diglycerides, triglycerides and mixtures of mono-, di- and triglycerides) and is consistent with the way these compounds are referenced in literature and regulatory references.

 $<sup>^2</sup>$  Class 1 = single compounds composed of molecules with particular atoms arranged in a definite, known structure. Class 2 = CHEMICAL SUBSTANCES OF UNKNOWN OR VARIABLE COMPOSITION, COMPLEX REACTION PRODUCTS AND BIOLOGICAL MATERIALS (UVCB)

<sup>&</sup>lt;sup>3</sup> The substances are analogues (the two CAS numbers describe the same substance).

| <br>   |   |   |
|--|---|---|
| 31566-31-1                                       | Octadecanoic acid,                          |   |
| [2]  | monoester with 1,2,3-<br>propanetriol       |   |
|  | propanetriol                                |   |
|  |   | 0                                       |
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|  |   | CH <sub>3</sub>                         |
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| 61789-09-1                                       | Monoglycerides                              |   |
| [2]  | Monoglycerides,<br>hydrogenated tallow      |   |
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|  |   | HO                                      |
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| 11099-07-3 and<br>67701-27-3 <sup>3</sup><br>[2] | Glyceryl stearate                           |   |
| 67701-27-3 <sup>3</sup>                          |   |   |
| [2]  |   |   |
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|  |   | <del>/</del>                            |
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| 91744-73-9                                       | Glycerides, palm-oil                        |   |
| [2]  | Glycerides, palm-oil<br>mono-, hydrogenated |   |
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|  |   | Cfi <sub>3</sub>                        |
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|                   |   | HO OH O CH <sub>3</sub>  |
|-------------------|---|--|
|                   |   | Diglycerides   |
| 1323-39-3<br> 2   | Octadecanoic acid, 1,2-<br>propanediol monoester                            | Diglycerides  HO CH;  OC CH;  CH;                                |
| 65381-09-1<br>[2] | Decanoic acid, ester with 1,2,3-propanetriol octanoate                      | н.с.   |
|                   |   | Triglycerides  |
| 538-23-8<br>[1]   | Octanoin, tri- (Octanoic<br>acid, 1,2,3-propanetriyl<br>ester; Tricaprylin) |  |
| 7360-38-5<br>[1]  | Hexanoic acid, 2-ethyl-,<br>1,2,3-propanetriyl ester                        | H <sub>1</sub> C CH <sub>1</sub> CH <sub>1</sub> CH <sub>1</sub> |

| 85409-09-2        | Glycerides, C8-10                       |  |
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| [2]               |   | 0  |
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|                   |   | H <sub>1</sub> C   |
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|                   |   | H <sub>1</sub> C   |
|                   |   | )<br>Inc   |
|                   |   | н;C  |
| 73398-61-5        | Glycerides mixed                        |  |
| [2]               | Glycerides, mixed decanoyl and octanoyl |  |
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|                   |   | H.C-/ 0 0-0-4  |
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| 8023-79-8         | Oils glyceridic nalm                    |  |
| [2]               | Oils, glyceridic, palm<br>kernel        | CH <sub>1</sub>  |
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|                   |   | н/C  |
| (7701 20 4        | Chyparidae C0 10 and                    |  |
| 67701-28-4<br>[2] | Glycerides, C8-18 and C18-unsatd.       |  |
| [4]               | C10-unsatu.                             |  |
|                   |   | CH <sub>1</sub>  |
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|                   |   | $_{\rm H_3C}$ CH <sub>3</sub>  |
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| 68334-28-1        | Oils, vegetable,<br>hydrogenated        |  |
| [2]               | hydrogenated                            |  |
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|                   |   | H <sub>i</sub> C —   |
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|                   |   | CH <sub>1</sub>  |
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| 67701-26-2        | Glycerides, C12-18<br>(C14:C14:C18)     |  |
| [2]               | (C14:C14:C18)                           |  |
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|                   |   | H <sub>i</sub> C/ CH <sub>i</sub>  |
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| 67701-30-8 | Glycerides, C16-18 and C18-unsatd.           |   |
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| [2]        | (C18:C18:C18)                                |   |
|            | (C10.C10.C10)                                | <b>,</b>                                  |
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|            |  | H <del>/</del> C                          |
| 8030-12-4  | Tallow, hydrogenated                         |   |
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| 8001-78-3  | Castor oil, hydrogenated                     |   |
| [2]        |  |   |
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| 122-32-7   | Olein, tri - (Octadecenoic                   | H₁C<br>₹                                  |
| [2]        | acid, 1,2,3-propanetriyl)                    | <b>}</b>                                  |
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|            |  | H <sub>i</sub> C'                         |
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|            | Mixtures of m                                | nono-, di- and triglycerides <sup>1</sup> |
| 67701-33-1 | Glycerides, C14-18                           | ,   |
| [2]        | mono- and di-                                |   |
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|            |  | CH <sub>3</sub>                           |
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| 68606-18-8 | Glycerides, mixed coco,                      | UVCB                                      |
| [2]        | decanoyl and octanoyl Glycerides, C16-18 and |   |
| 68424-61-3 | Glycerides, C16-18 and                       | UVCB                                      |
| [2]        | C18-unsatd. mono- and                        |   |
|            | di-  |   |

| 85251-77-0        | Glycerides, C16-18<br>mono- and di-                  |   |
|-------------------|--|---|
| [2]               | mono- and di-  |   |
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| 97722-02-6        | Glycerides, tall-oil mono-,<br>di-, and tri-         |   |
| [2]               | di-, and tri-  |   |
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| 01744 20 6        | Glyparidae C16 10 and                                |   |
| 91744-20-6<br>[2] | Glycerides, C16-18 and C18-unsatd. mono-, diand tri- |   |
| [ <del>*</del> ]  | and tri-   |   |
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| 68991-68-4 and<br>91052-53-8 <sup>3</sup><br>[2] | Coconut oil,<br>transesterification<br>products with decanoic<br>acid mixed ester with<br>glyceryl octanoate | и.с. |
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#### SUMMARY CONCLUSIONS OF THE SIAR

## **Category Rationale**

The Glyceride Category contains thirty-one (31) sponsored glyceride substances which are defined as esters of monocarboxylic acids and glycerol bearing one (monoglycerides), two (diglycerides) or three (triglycerides) aliphatic chains, or, a mixture of mono-, di- and triglycerides, each ranging in number of carbons from 8 to 18. The C18 members of the group may be saturated or unsaturated with one carbon-carbon double bond. The glycerides grouping consists of both discrete chemicals with an incremental and constant change across its members (carbon chain length) and commercial mixtures that are composed of glycerides with a range of carbon chain lengths in its aliphatic side groups. The carbon chains do not contain any branching (they are all straight chains).

The chemical structure of the triglyceride members of this Glyceride Category is:

R, R1, and R2 are aliphatic chains containing from 8-18 carbon atoms, and two or three chains may be identical. The monoglycerides and diglycerides in this Glyceride Category have a similar structure except that glycerol is bonded to one and two aliphatic (fatty acid) chains, respectively, and have two and one free hydroxyl groups, respectively.

Glycerides are a group of lipids commonly called fats (solid at room temperature) and oils (liquid at room temperature). Due to the structural similarities of the glycerides, their physico-chemical properties are similar and

a clear correlation with chain length is observed. Melting point and boiling point increase with increasing chain length. The vapor pressures of the glycerides decrease with increasing carbon number and generally are low. Water solubility decreases and partition coefficient between octanol and water increase with increasing carbon number.

Fatty acids are generally ingested as triglycerides, which cannot be absorbed by the small intestine. When ingested, monoglycerides are readily absorbed through the duodenal mucosa and converted to triglycerides. In the small intestine, most triglycerides are split by pancreatic lipases into monoglycerides, free fatty acids, and glycerol, which can be absorbed by the intestinal mucosa. A small fraction of triglycerides are absorbed as free glycerol and as diglycerides. Once across the intestinal barrier, triglycerides are reformed. These resynthesized triglycerides collect into globules along with cholesterol and phospholipids and are encased in a protein coat as chylomicrons. Chylomicrons are transported in the lymph to the thoracic duct and eventually to the venous system. The chylomicrons are removed from the blood as they pass through the capillaries of adipose tissue. Fat is stored in adipose cells until it is transported to other tissues as free fatty acids which are used for cellular energy or incorporated into cell membranes.

Based on similarities in structural, physical chemical and toxicokinetic properties, read across among the sponsored substances is reasonable. The following table presents a summary of the read across approach (**bold text** indicates data are available; Read across is designated as "RA"). Read across results were selected based on the lowest available effects value or most conservative result.

| Substance<br>CAS#   | Acute<br>toxicity<br>(oral and<br>inhalation) | Repeated<br>dose (oral)             | Gene<br>mutation<br>in vitro | Chromosome<br>aberration in vitro | Chromosome<br>aberration<br>in vivo | Effects on fertility<br>and reproductive<br>organs | Developmental<br>toxicity (oral) |
|---|---|-------------------------------------|------------------------------|-----------------------------------|-------------------------------------|--|----------------------------------|
|   | ,   |                                     |                              | Monoglycerides                    |                                     |  | 1                                |
| Olein, mono-<br>Octadecenoic<br>acid, 1,2,3-<br>propanetriol<br>25496-72-4      | LD50 oral<br>>2,000 (Read<br>across (RA)      | NOAEL = 2500<br>(90 day)<br>(RA)    | Negative<br>(RA)             | Negative (RA)                     | Negative (RA)                       | NOAEL = 5000<br>(M/F) (RA)                         | NOAEL = 5000<br>(RA)             |
| Glycerol oleate <b>37220-82-9</b>   | LD50 oral<br>>2,000 (RA)                      | NOAEL =<br>2500<br>(90 day)<br>(RA) | Negative<br>(RA)             | Negative (RA)                     | Negative (RA)                       | NOAEL = 5000<br>(M/F) (RA)                         | NOAEL = 5000<br>(RA)             |
| Glycerides,tall-<br>oil<br><b>68309-32-0</b> and<br><b>61790-12-3</b>           | LD50 oral<br>>10,000                          | NOAEL =<br>12,500<br>(90 day)       | Negative                     | Negative                          | Negative (RA)                       | NOAEL = 5000<br>(M/F)                              | NOAEL = 5000                     |
| Octadecanoic<br>acid, monoester<br>with 1,2,3-<br>propanetriol<br>31566-31-1    | LD50 oral<br>>2,000 (RA)                      | NOAEL =<br>2500<br>(90 day)<br>(RA) | Negative                     | Negative (RA)                     | Negative (RA)                       | NOAEL = 5000<br>(M/F) (RA)                         | NOAEL = 5000<br>(RA)             |
| Monoglycerides<br>, hydrogenated<br>tallow 61789-<br>09-1                       | LD50 oral<br>>2,000 (RA)                      | NOAEL =<br>2500<br>(90 day)<br>(RA) | Negative<br>(RA)             | Negative (RA)                     | Negative (RA)                       | NOAEL = 5000<br>(M/F) (RA)                         | NOAEL = 5000<br>(RA)             |
| Glyceryl<br>stearate<br>11099-07-3 and<br>67701-27-3                            | LD50 oral<br>>5,000                           | NOAEL =<br>2500<br>(90 day)<br>(RA) | Negative<br>(RA)             | Negative (RA)                     | Negative (RA)                       | NOAEL = 5000<br>(M/F) (RA)                         | NOAEL = 5000<br>(RA)             |
|   |   |                                     |                              | Diglycerides                      |                                     |  |                                  |
| Octadecanoic<br>acid, 1,2-<br>propanediol<br>monoester<br>1323-39-3             | LD50 oral<br>>5,000                           | NOAEL = 3760<br>(13 week)           | Negative<br>(RA)             | Negative (RA)                     | Negative (RA)                       | NOAEL = 3760<br>(M/F)                              | NOAEL = 5000<br>(RA)             |
| Decanoic acid,<br>ester with 1,2,3-<br>propanetriol<br>octanoate<br>65381-09-1  | LD50 oral<br>>5,000                           | NOAEL =<br>2500<br>(90 day)         | Negative<br>(RA)             | Negative (RA)                     | Negative (RA)                       | NOAEL = 9800<br>(M/F)                              | NOAEL = 5000<br>(RA)             |
| Triglycerides   |   |                                     |                              |                                   |                                     |  |                                  |
| Octanoin, tri- (Octanoic acid, 1,2,3- propanetriyl ester; Tricaprylin) 538-23-8 | LD50 oral<br>>5,000                           | NOAEL =<br>9500<br>(26 week)        | Negative                     | Negative (RA)                     | Negative                            | NOAEL = 5000<br>(M/F) (RA)                         | NOAEL = 9500<br>(M/F)            |

| Hexanoic acid,<br>2-ethyl-, 1,2,3-<br>propanetriyl<br>ester <b>7360-38-5</b>   | LD50 oral<br>>48,000     | NOAEL =<br>2500<br>(90 day)<br>(RA) | Positive         | Negative (RA)            | Negative      | NOAEL = 5000<br>(M/F) (RA) | NOAEL = 5000<br>(RA)  |
|--|--------------------------|-------------------------------------|------------------|--------------------------|---------------|----------------------------|-----------------------|
| Glycerides, C8-<br>10<br><b>85409-09-2</b>   | LD50 oral >2,500         | NOAEL =<br>2500<br>(90 day)         | Negative<br>(RA) | Negative (RA)            | Negative (RA) | NOAEL = 9800<br>(M/F)      | NOAEL = 5000<br>(RA)  |
| Glycerides,<br>mixed decanoyl<br>and octanoyl<br>73398-61-5  | LD50 oral<br>>5,000      | NOAEL = 2500<br>(90 day)            | Negative         | Negative (RA)            | Negative (RA) | NOAEL = 9800<br>(M/F)      | NOAEL = 5000<br>(RA)  |
| Oils, glyceridic,<br>palm kernel<br>8023-79-8  | LD50 oral<br>>5,000      | NOAEL =<br>2500<br>(90 day)<br>(RA) | Negative<br>(RA) | Negative (RA)            | Negative (RA) | NOAEL = 5000<br>(M/F)      | NOAEL = 5000<br>(M/F) |
| Glycerides, C8-<br>18 and C18-<br>unsatd.<br>67701-28-4  | LD50 oral<br>>2,000 (RA) | NOAEL =<br>2500<br>(90 day)<br>(RA) | Negative<br>(RA) | Negative (RA)            | Negative (RA) | NOAEL = 5000<br>(M/F) (RA) | NOAEL = 5000<br>(RA)  |
| Oils, vegetable,<br>hydrogenated<br>68334-28-1   | LD50 oral<br>>2,000 (RA) | NOAEL =<br>2500<br>(90 day)<br>(RA) | Negative<br>(RA) | Negative (RA)            | Negative (RA) | NOAEL = 5000<br>(M/F) (RA) | NOAEL = 5000<br>(RA)  |
| Glycerides,<br>C12-18<br><b>67701-26-2</b>   | LD50 oral<br>>10,000     | NOAEL =<br>2500<br>(90 day)<br>(RA) | Negative<br>(RA) | Negative (RA)            | Negative (RA) | NOAEL = 5000<br>(M/F) (RA) | NOAEL = 5000<br>(RA)  |
| Glycerides,<br>C16-18 and<br>C18-unsatd.<br>67701-30-8   | LD50 oral<br>>2,000 (RA) | NOAEL =<br>2500<br>(90 day)<br>(RA) | Negative<br>(RA) | Negative (RA)            | Negative (RA) | NOAEL = 5000<br>(M/F) (RA) | NOAEL = 5000<br>(RA)  |
| Tallow,<br>hydrogenated<br>8030-12-4   | LD50 oral<br>>2,000 (RA) | NOAEL =<br>2500<br>(90 day)<br>(RA) | Negative<br>(RA) | Negative (RA)            | Negative (RA) | NOAEL = 5000<br>(M/F) (RA) | NOAEL = 5000<br>(RA)  |
| Castor oil,<br>hydrogenated<br>8001-78-3   | LD50 oral<br>>2,000 (RA) | NOAEL =<br>2500<br>(90 day)<br>(RA) | Negative         | Negative (RA)            | Negative (RA) | NOAEL = 5000<br>(M/F) (RA) | NOAEL = 5000<br>(RA)  |
| Olein, tri -<br>(Octadecenoic<br>acid, 1,2,3-<br>propanetriyl)<br>122-32-7   | LD50 oral >2,000         | NOAEL = 2500<br>(90 day)<br>(RA)    | Negative         | Negative (RA)            | Negative (RA) | NOAEL = 5000<br>(M/F) (RA) | NOAEL = 5000<br>(RA)  |
| 122 02 /   |                          |                                     | Mixtures         | of mono-, di- and trigly | ycerides      |                            |                       |
| Glycerides,<br>C14-18 mono-<br>and di-<br>67701-33-1   | LD50 oral<br>>2,000 (RA) | NOAEL =<br>2500<br>(90 day)<br>(RA) | Negative<br>(RA) | Negative (RA)            | Negative (RA) | NOAEL = 5000<br>(M/F) (RA) | NOAEL = 5000<br>(RA)  |
| Glycerides,<br>mixed coco,<br>decanoyl and<br>octanoyl 68606-<br>18-8  | LD50 oral<br>>2,000 (RA) | NOAEL =<br>2500<br>(90 day)<br>(RA) | Negative<br>(RA) | Negative (RA)            | Negative (RA) | NOAEL = 5000<br>(M/F) (RA) | NOAEL = 5000<br>(RA)  |
| Glycerides,<br>C16-18 mono-<br>and di-<br>85251-77-0   | LD50 oral<br>>2,000 (RA) | NOAEL =<br>2500<br>(90 day)<br>(RA) | Negative<br>(RA) | Negative (RA)            | Negative (RA) | NOAEL = 5000<br>(M/F) (RA) | NOAEL = 5000<br>(RA)  |
| Glycerides, tall-<br>oil mono-, di-,<br>and tri-<br>97722-02-6   | LD50 oral<br>>2,000 (RA) | NOAEL =<br>2500<br>(90 day)<br>(RA) | Negative<br>(RA) | Negative (RA)            | Negative (RA) | NOAEL = 5000<br>(M/F) (RA) | NOAEL = 5000<br>(RA)  |
| Glycerides,<br>C16-18 and<br>C18-unsatd.<br>mono-, di- and<br>tri-<br>91744-20-6   | LD50 oral<br>>2,000      | NOAEL =<br>2500<br>(90 day)<br>(RA) | Negative         | Negative (RA)            | Negative (RA) | NOAEL = 5000<br>(M/F) (RA) | NOAEL = 5000<br>(RA)  |
| Coconut oil,transesterific ation products with decanoic acid mixed ester with glyceryl octanoate 68991-68-4 and 91052-53-8 | LD50 oral<br>>2,000 (RA) | NOAEL =<br>2500<br>(90 day)<br>(RA) | Negative<br>(RA) | Negative (RA)            | Negative (RA) | NOAEL = 5000<br>(M/F) (RA) | NOAEL = 5000<br>(RA)  |

|  |                               |  | Acute aquatic toxicity (mg/L)            |  |  |  |  |
|--|-------------------------------|--|--|--|--|--|--|
| Substance CAS#   | Biodegradation                | Fish 96 hr LC50                          | Aquatic invertebrate 48 hr<br>EC50       | Aquatic plants 72 hr EC50                              |  |  |  |
|  |                               | Monoglycerides                           | 1  | 1  |  |  |  |
| Olein, mono- Octadecenoic acid, 1,2,3-propanetriol 25496-72-4                  | Readily biodegradable (RA)    | >100 or exceeds water<br>solubility (RA) | >100 or exceeds water solubility (RA)    | >100 or exceeds water<br>solubility (RA)               |  |  |  |
| Glycerol oleate<br>37220-82-9  | Readily biodegradable (RA)    | >100 or exceeds water<br>solubility (RA) | >100 or exceeds water<br>solubility (RA) | >100 or exceeds water<br>solubility (RA)               |  |  |  |
| Glycerides,tall-oil<br>68309-32-0 and 61790-12-3                               | Readily biodegradable         | LL50* >1000 (nominal)                    | EL50* >1000 (nominal)                    | EbL50* = 854.9<br>(nominal), ErL50* >1000<br>(nominal) |  |  |  |
| Octadecanoic acid,<br>monoester with 1,2,3-<br>propanetriol<br>31566-31-1      | Readily biodegradable         | >100 or exceeds water<br>solubility (RA) | >100 or exceeds water solubility (RA)    | >100 or exceeds water<br>solubility (RA)               |  |  |  |
| Monoglycerides,<br>hydrogenated tallow <b>61789</b> -<br><b>09-1</b>           | Readily biodegradable (RA)    | >10,000 (nominal)                        | >100 or exceeds water solubility (RA)    | >100 or exceeds water<br>solubility (RA)               |  |  |  |
| Glyceryl stearate<br>11099-07-3 and 67701-27-3                                 | Readily biodegradable (RA)    | >100 or exceeds water<br>solubility (RA) | >100 or exceeds water<br>solubility (RA) | >100 or exceeds water<br>solubility (RA)               |  |  |  |
|  |                               | Diglycerides                             |  |  |  |  |  |
| Octadecanoic acid, 1,2-<br>propanediol monoester<br>1323-39-3                  | Readily biodegradable (RA)    | >100 or exceeds water<br>solubility (RA) | >100 or exceeds water<br>solubility (RA) | >100 or exceeds water solubility (RA)                  |  |  |  |
| Decanoic acid, ester with 1,2,3-propanetriol octanoate 65381-09-1              | Readily biodegradable         | >10,000 (nominal)                        | EL50 >100 (nominal; 21 d)                | EbL50, ErL50 >100<br>(nominal)                         |  |  |  |
|  |                               | Triglycerides                            | 1  | •  |  |  |  |
| Octanoin, tri- (Octanoic acid, 1,2,3-propanetriyl ester; Tricaprylin) 538-23-8 | Readily biodegradable (RA)    | >100 or exceeds water solubility (RA)    | >100 or exceeds water<br>solubility (RA) | >100 or exceeds water<br>solubility (RA)               |  |  |  |
| Hexanoic acid, 2-ethyl-,<br>1,2,3-propanetriyl ester<br>7360-38-5              | Readily biodegradable         | >100 or exceeds water<br>solubility (RA) | >100 or exceeds water<br>solubility (RA) | >100 or exceeds water solubility (RA)                  |  |  |  |
| Glycerides, C8-10<br><b>85409-09-2</b>   | Readily biodegradable         | >100 or exceeds water<br>solubility (RA) | >100 or exceeds water<br>solubility (RA) | >100 or exceeds water<br>solubility (RA)               |  |  |  |
| Glycerides, mixed decanoyl and octanoyl <b>73398-61-5</b>                      | Readily biodegradable         | >53 (measured)                           | EL50 >100 (nominal)                      | EbL50, LLr50 > 1000<br>(nominal)                       |  |  |  |
| Oils, glyceridic, palm<br>kernel<br>8023-79-8                                  | Readily biodegradable<br>(RA) | >100 or exceeds water<br>solubility (RA) | >100 or exceeds water<br>solubility (RA) | >100 or exceeds water solubility (RA)                  |  |  |  |
| Glycerides, C8-18 and C18-<br>unsatd.<br><b>67701-28-4</b>                     | Readily biodegradable (RA)    | >100 or exceeds water solubility (RA)    | >100 or exceeds water<br>solubility (RA) | >100 or exceeds water solubility (RA)                  |  |  |  |
| Oils, vegetable,<br>hydrogenated<br>68334-28-1                                 | Readily biodegradable (RA)    | >100 or exceeds water<br>solubility (RA) | >100 or exceeds water solubility (RA)    | >100 or exceeds water<br>solubility (RA)               |  |  |  |
| Glycerides, C12-18<br>67701-26-2   | Readily biodegradable (RA)    | >100 or exceeds water<br>solubility (RA) | >100 or exceeds water solubility (RA)    | >100 or exceeds water<br>solubility (RA)               |  |  |  |
| Glycerides, C16-18 and C18-unsatd. <b>67701-30-8</b>                           | Readily biodegradable         | >10,000 (nominal)                        | EL50 >100 (nominal; 21 d)                | EbL50, ErL50 >100<br>(nominal)                         |  |  |  |
| Tallow, hydrogenated 8030-12-4   | Readily biodegradable (RA)    | >100 or exceeds water<br>solubility (RA) | EL50 >100 (nominal)                      | EbL50, ErL50 >100<br>(nominal)                         |  |  |  |
| Castor oil, hydrogenated 8001-78-3   | Readily biodegradable         | >10,000 (nominal)                        | >100 or exceeds water<br>solubility (RA) | >100 or exceeds water<br>solubility (RA)               |  |  |  |
| Olein, tri - (Octadecenoic acid, 1,2,3-propanetriyl)                           | Readily biodegradable         | >100 or exceeds water<br>solubility (RA) | EL50 >100 (nominal)                      | >100 or exceeds water<br>solubility (RA)               |  |  |  |
| 122-32-7   | Mix                           | stures of mono-, di- and trigly          | cerides                                  | · · · · · · · · · · · · · · · · · · ·                  |  |  |  |
|  |                               |  |  |  |  |  |  |
| Glycerides, C14-18 mono-<br>and di-<br><b>67701-33-1</b>                       | Readily biodegradable         | >10,000 (nominal)                        | >100 or exceeds water<br>solubility (RA) | >100 or exceeds water<br>solubility (RA)               |  |  |  |
| Glycerides, mixed coco,<br>decanoyl and octanoyl<br>68606-18-8                 | Readily biodegradable (RA)    | >100 or exceeds water solubility (RA)    | >100 or exceeds water<br>solubility (RA) | >100 or exceeds water solubility (RA)                  |  |  |  |
| Glycerides, C16-18 mono-<br>and di-  | Readily biodegradable (RA)    | >100 or exceeds water<br>solubility (RA) | >100 or exceeds water<br>solubility (RA) | >100 or exceeds water<br>solubility (RA)               |  |  |  |

| Glycerides, tall-oil mono-,<br>di-, and tri-<br>97722-02-6  | Readily biodegradable      | 1700 (nominal)                           | EL50 >100 (nominal)                      | ECr50 = 13.88 (nominal;<br>exceeds the estimated water<br>solubility of the substance) |
|---|----------------------------|--|--|--|
| Glycerides, C16-18 and C18-unsatd. mono-, di- and tri-<br>91744-20-6  | Readily biodegradable      | >100 or exceeds water<br>solubility (RA) | >100 or exceeds water<br>solubility (RA) | >100 or exceeds water<br>solubility (RA)   |
| Coconut oil,transesterification products with decanoic acid mixed ester with glyceryl octanoate 68991-68-4 and 91052-53-8 | Readily biodegradable (RA) | >100 or exceeds water<br>solubility (RA) | >100 or exceeds water<br>solubility (RA) | >100 or exceeds water<br>solubility (RA)   |

<sup>\*</sup>WAF sample preparations are reported relative to a loading rate rather than a concentration [LL50 (fish); EL50 (daphnia); EbL50/ErL50 (algae)]

## **Physical-chemical Properties**

The thirty-one (31) sponsored substances are solid or liquid glycerides and include i) two (2) substances composed of molecules with particular atoms arranged in a definite, known structure (defined chain length), and ii) twenty-nine (29) substances that are mixtures with a range of components. It is not possible to estimate values for mixtures with confidence and for the purposes of this assessment have been characterized by a representative chain length.

A property of a mixture of glycerides is therefore a function of that property for each of the discrete chain length components in the mixture. Melting point and boiling point increase with increasing chain length. Measured melting point values range from -32°C (CAS 122-32-7; triglyceride) to 85.4 °C (CAS 8001-78-3, triglyceride); for glycerides without measured data, estimated melting points range from 57-74 °C monoglyceride) to 349.8 °C (CAS 67701-30-8, triglyceride). Measured boiling point values range from 233°C at 1013 hPa (CAS 538-23-8, triglyceride) to 360-410 °C at 1013-1021 hPa (CAS 7360-38-5, triglyceride); for glycerides without measured data, estimated boiling points range from 378.7 °C (CAS 68991-68-4 and 91052-53-8, Mixtures of mono-, di- and triglycerides) to 893.4 °C (CAS 8001-78-3, triglyceride). Vapor pressure decreases with increasing carbon number and generally are low (5.09E-10 hPa at 25°C for CAS 538-23-8, triglyceride, measured; for glycerides without measured data, estimated values are <1E-05 hPa. Water solubility increases with decreasing carbon number; measured values range from <0.05 mg/L at 20°C (CAS 8001-78-3) to 3020 mg/L at 20 °C (CAS 7360-38-5, triglyceride); for glycerides without measured data, estimated values range from 6.52E-21 mg/L (CAS 67701-30-8, triglyceride) to 12.7 mg/L (CAS 68991-68-4 and 91052-53-8, Mixtures of mono-, diand triglycerides). Measured partition coefficient values (log Kow) range from >3 at 20°C (CAS 73398-61-5, triglyceride) to >6.5 (CAS 7360-38-5, triglyceride); for glycerides without measured data, estimated values range from 3.7 (CAS 68991-68-4 and 91052-53-8, Mixtures of mono-, di- and triglycerides) to 23.9 (CAS 67701-30-8, triglyceride).

#### **Human Health**

Most of the available toxicokinetic data (animal and humans) relates to the absorption of triglycerides including CAS 122-32-7, CAS 7360-38-5, CAS 8023-79-8 and CAS 73398-61-5, following oral administration, with limited data on its absorption after intravenous and dermal dosing. Toxicokinetic data are also available for CAS 1323-39-3 (diglyceride), Data were not located for the inhalation route.

Glycerides are expected to be readily absorbed following ingestion, with rapid elimination from most tissues (possible exception of adipose, spleen). Glyceride metabolism and re-synthesis play a role in the absorption and distribution of ingested glycerides. Expiration is at least one route of elimination for ingested glycerides. These pathways are relevant for humans as well as other mammals.

Acute oral toxicity studies were located for twelve (12) Glyceride Category members (CAS 61790-12-3 and 11099-07-3 (monoglycerides), 1323-39-3 and 65381-09-1 (diglycerides), 538-23-8, 7360-38-5, 85409-09-2, 73398-61-5, 8023-79-8, 67701-26-2 and 122-32-7 (triglycerides) and, 91744-20-6 (mixtures of mono-, di- and triglycerides)). The oral LD50s for rats are > 2000 mg/kg bw (CAS 122-32-7 (triglycerides) and 91744-20-6 (mixtures of mono-, di- and triglycerides)), and range up to > 48,000 mg/kg bw (CAS 7360-38-5 (triglyceride) (OECD 401, Directive 84/449/EEC, B.1, or no guideline specified)). At doses consistent with recent testing standards (i.e., 2000 to 5000 mg/kg bw), there were no clinical signs, changes in body weight or findings at gross necropsy. Similar findings (LD50s and lack of toxicity) were reported for mice. Acute aerosol inhalation studies

were located for two glycerides (CAS 85409-09-2 and 73398-61-5, triglycerides); there were no adverse findings when rats or guinea pigs were exposed to 0.028 mg/L for six hours.

Skin and eye irritation studies were located for six (6) and five (5) members of the Glycerides Category, respectively. The Glycerides (CAS 11099-07-3 (monoglyceride), 1323-39-3 (diglyceride), 7360-38-5, 73398-61-5 and 8023-79-8 (triglycerides) and 91744-20-6 (mixtures of mono-, di- and triglycerides) are not irritating to slightly irritating to the skin in standard irritation (Draize, OECD 405, FHSLA, or DOT) studies using rabbits. When a single occlusive patch containing an undiluted glyceride (CAS 11099-07-3, monoglyceride) was applied to human volunteer skin for 24 hours, no to slight irritation was noted. The Glycerides (CAS 11099-07-3 (monoglyceride), 1323-39-3 (diglyceride), 73398-61-5 and 67701-26-2 (triglycerides) and 91744-20-6 (mixtures of mono-, di- and triglycerides)) are not irritating to slightly irritating to the eyes in standard eye irritation (Draize or similar) studies using rabbits. The untested members of the Glyceride Category are expected to be not or slightly irritating to the skin and eyes. Clinical signs of respiratory tract irritation were not observed following 6 hour inhalation exposures to aerosols of two Glyceride Category members (CAS 85409-09-2 and 73398-61-5, triglycerides) at 0.028 mg/L.

Skin sensitization studies with guinea pigs and/or human volunteers were located for four (4) members of the Glycerides Category. In standard Magnusson and Kligman guinea pig maximization tests, the Glyceride Category members were not skin sensitizers. **CAS 73398-61-5**, triglyceride) was tested only in a guinea pig maximization test). In patch (**CAS 11099-07-3**, monoglyceride, and **7360-38-5**, triglyceride) or chamber studies with human volunteers (**CAS 122-32-7**, triglyceride), the Glyceride Category members were not skin sensitizers. The untested members of the Glyceride Category are expected to also not be skin sensitizers.

Repeated dose oral (gavage or diet studies) have been located for six (6) of the Glyceride Category members (CAS 61790-12-3 (monoglyceride), 1323-39-3 and 65381-09-1 (diglycerides), 538-23-8, 85409-09-2 and 73398-61-5 (triglycerides). There were no adverse effects of treatment reported following repeated oral studies with rats, by either gavage or diet route. The NOAELs were =>2500 mg/kg bw, indicating the Glyceride Category members are not toxic. Although the studies do not conform to current, standard guidelines, the substances do not cause systemic toxicity. Similar results are expected for the Glyceride Category members that have not been tested.

In vitro and in vivo mutagenicity studies have been located for eight (8) and one (1) of the Glyceride Category members, respectively. The Glyceride Category members are negative for genotoxicity (in vitro bacterial reverse mutation assays (CAS 68309-32-0 and 61790-12-3 and 31566-31-1 (monoglycerides), 538-23-8, 73398-61-5, 8001-78-3 and 122-32-7 (triglycerides), and 91744-20-6 (mixtures of mono-, di- and triglycerides), in vivo host-mediated mutagenicity assay (CAS 538-23-8, triglyceride), in vitro (CAS 68309-32-0 and 61790-12-3, monoglycerides) or in vivo (CAS 538-23-8, triglyceride) chromosomal aberration, in vivo micronucleus assay (CAS 538-23-8, triglyceride), in vivo dominant lethal (CAS 538-23-8, triglyceride) and SCE (CAS 538-23-8, triglyceride and CAS 7360-38-5, triglyceride). One of the substances (CAS 7360-38-5, triglyceride), was positive in an in vivo mouse spot test; the weight of evidence suggests this is not representative of the Glyceride Category members. A lack of genotoxicity is expected for those Glyceride Category members that have not been tested.

A carcinogenicity study has been located for Glyceride Category member CAS 538-23-8 (triglyceride). In a two year gavage carcinogenicity study, there were significant dose-related increased incidences of pancreatic exocrine hyperplasia and adenoma, and proliferative lesions of the forestomach of rats administered CAS 538-23-8 (triglyceride). Nephropathy and related severity were significantly decreased in high dose rats, and the incidence of mononuclear cell leukemia was decreased. A level of evidence of carcinogenicity was not assigned by NTP. A carcinogenicity study with tobacco-specific nitrosamine 4-(methylnitrosamino)-1-(3-pyridyl)-1-butanone (NNK) was conducted to test the transplacental carcinogenicity of NNK. Groups of pregnant hamsters were given subcutaneous (s.c.) injections of single or multiple doses of NNK (cumulative dose range, 50–300 mg/kg), on day 15 (last day of gestation) or on days 13, 14, and 15 of gestation, three s.c. injections of CAS 7360-38-5 (triglyceride, 43 males, 40 females, last 3 days of gestation) and the offspring were evaluated for tumor development up to one year later. Within 1 year after treatment, up to 70% of the offspring developed tumors in various organs, including respiratory tract, nasal cavity, adrenal glands, pancreas, and liver. No tumors were found in the control hamsters treated with the vehicle (trioctanoin) alone. The overall tumor incidence was proportional to the cumulative dose. Females had a generally higher tumor incidence than males. CAS 7360-38-5 (triglyceride) was negative in this study for transplacental carcinogenicity.

Effects on fertility and developmental toxicity studies were located for six (6) and five (5) Glyceride Category members, respectively. There were no effects on fertility (CAS 61790-12-3 (monoglyceride), 1323-39-3 and 65381-09-1 (diglycerides), 85409-09-2, 73398-61-5 and 8023-79-8 (triglycerides) or developmental effects (CAS 61790-12-3, monoglyceride, 538-23-8, 7360-38-5 and 8023-79-8, triglycerides) in rats, mice or hamsters in studies similar to OECD 416, FDA/WHO/DGHS safety evaluation protocol, 90 day studies examining reproductive organs, three-generation study or developmental studies with no protocol specified. In a developmental toxicity study in rats in which CAS 538-23-8 was used as the vehicle control (9500 mg/kg bw) and water was used as the negative control, it was evident that the vehicle itself exerted a mild degree of developmental toxicity. There was a statistically significant 8% increase in total soft tissue malformations in the vehicle control group compared to 0% in the water control group. Maternal weight gain and fetal size were also lower in animals receiving CAS 538-23-8 compared to the water controls, but these were not statistically significant." In a 3-generation study with CAS 73398-61-5 (triglyceride), during lactation the volume of milk secreted by rats receiving the medium chain triglyceride in the diet at 9800 mg/kg bw was smaller and resulted in slower gain in body weight; after weaning, normal growth of the rats resumed. In this study, the LOAEL for developmental toxicity was 9800 mg/kg bw. Although the studies do not all conform to current, standard guidelines, the NOAELs were all greater than 2000 mg/kg bw. Similar results are expected for the Glyceride Category members which have not been tested.

The Glycerides Category members do not possess properties indicating a hazard for human health. Adequate screening-level data are available to characterize the hazard to human health for the purposes of the OECD Cooperative Chemicals Assessment Programme.

#### **Environment**

Hydrolysis (OECD TG 111) studies have not been conducted for the glycerides. The ester group on the glycerides can be hydrolyzed to generate glycerin and the corresponding fatty acid. However, hydrolysis is expected to be very slow (>1 year) at room temperature, and the limited water solubility and steric hindrance of many of these substances will contribute to the lack of hydrolysis. If hydrolysis were to occur, the expected hydrolysis products (glycerin and the fatty acid) would not further hydrolyze, as there are no additional hydrolyzable groups for these substances.

The glycerides are subject to indirect photodegradation in air. Modeled photodegradation rates (half-lives) were estimated using AopWin v1.92 (EPI Suite v4.11). Estimated half-lives (hours; based on 12 hours of light per day; 1.5E+6 OH/cm³) for hydroxyl radicals generally increase with decreasing chain length and range from ca. 0.5 hours (CAS 122-32-7, triglyceride) to 4.7 hours (CAS 7360-38-5, triglyceride). No ozone reaction was estimated for most of the glycerides (the model is only applicable to unsaturated molecules); for those Glyceride Category members for which an estimation was made, the half-lives (hours, 7E-11 mol/cm³) for ozone reaction range from 0.46 to 2.1 hours (CAS 25496-72-4, 37220-82-9, 68309-32-0 and 61790-12-3 (monoglycerides), 122-32-7 (triglyceride), 68424-61-3 and 97722-02-6 (mixtures of mono-, di- and triglycerides). Level III fugacity modelling using EPI Suite v4.11 indicates that the glycerides will distribute primarily to soil and water, with lesser amounts to air and sediment.

Biodegradation studies generally confirm that the extent of biodegradation observed in 28 days meets the ready biodegradability criterion (CAS 68309-32-0 and 61790-12-3 (monoglycerides, 56-84% in 28 days), 31566-31-1 (monoglyceride, 108% in 51 days), 65381-09-1 (monoglyceride, 73 - 88% in 30 days), 7360-38-5 (triglyceride, >= 70.2 — <= 73.8 in 28 days), 85409-09-2 (triglyceride, 91.2 - 99.6% in 28 days), 73398-61-5 (triglyceride, 93% in 28 days), 67701-30-8 (triglyceride, 73 - 109% in 30 days), 8001-78-3 (triglyceride, 64% in 28 days), 122-32-7 (triglyceride, 77% in 28 days), 67701-33-1 (69 - 95% in 28 days; 68 - 73% in 30 days), 97722-02-6 (79% in 28 days), and 91744-20-6 (mixtures of mono-, di- and triglycerides, 72% in 28 days)). In one study, biodegradation under anaerobic conditions was also demonstrated (CAS 122-32-7; triglyceride, 63-106% in 51 days). Glyceride Category members that have not been tested are expected to be readily biodegradable based on read across to other Glyceride Category members.

Measured bioconcentration (BCF) factor data were not located for the Glycerides Category members. Estimated BCF values are calculated using BCFBAF v3.01 (EPI Suite v4.11). The Glyceride Category members have BCF values less than 500, indicating a low potential for bioaccumulation with the exception of **CAS** 1323-39-3 (diglyceride), with estimated BCF value of 1574. However, this value is very likely an overestimate of the substance's bioaccumulation potential since the influence of metabolism (via the common mechanism of  $\beta$ -

oxidation), which will be very high for substances in this category, is not fully represented. Overall, substances in the category have a low potential for bioaccumulation.

Due to the poorly soluble nature of many category members, it was difficult to distinguish whether the toxicity observed was due to the chemical toxicity or the physical presence of the test substance (particulates floating in and on the surface of the water, suds or film on the surface of the water) during aquatic toxicity testing. Therefore, two general strategies were used for testing these substances: (1) the use of a Water Accommodated Fraction (WAF) prepared at a maximum loading rate (i.e. concentrations of the test substance is significantly above its solubility limit) or (2) the use of a direct addition method in which the test substance was added directly to the test vessels, followed by shaking/stirring/use of a homogenizer for an extended period of time to allow for equilibrium. For both of these methods, it is more appropriate to report the nominal loading rate rather than a measured concentration, since the values greatly exceed the water solubility of the test substance. Acute toxicity test results are presented for aquatic species.

Fish

| Name and<br>CAS Number   | Species/Test method                                       | LC50<br>(mg/L), 96<br>hr    |  |
|--|---|-----------------------------|--|
|  | Monoglycerides  | I I                         |  |
| Olein, mono- Octadecenoic acid, 1,2,3-propanetriol <b>25496-72-4</b>           | No data located   |                             |  |
| Glycerol oleate<br>37220-82-9  | No data located   |                             |  |
| Glycerides,tall-oil<br>68309-32-0 and 61790-12-3                               | Pimephales promelas/ OECD 203/static                      | LL50*<br>>1000<br>(nominal) |  |
| Octadecanoic acid, monoester with 1,2,3-propanetriol 31566-31-1                | No data located   |                             |  |
| Monoglycerides, hydrogenated tallow 61789-09-1                                 | No data located   |                             |  |
| Glyceryl stearate<br>11099-07-3 and 67701-27-3                                 | No data located   |                             |  |
| Glycerides, palm-oil mono-, hydrogenated 91744-73-9                            | No data located   |                             |  |
|  | Diglycerides  |                             |  |
| Octadecanoic acid, 1,2-propanediol monoester 1323-39-3                         | No data located   |                             |  |
| Decanoic acid, ester with 1,2,3-propanetriol octanoate 65381-09-1              | Danio rerio/Similar to OECD 203/semi-static               | >10,000<br>(nominal)        |  |
|  | Triglycerides   |                             |  |
| Octanoin, tri- (Octanoic acid, 1,2,3-propanetriyl ester; Tricaprylin) 538-23-8 | No data located   |                             |  |
| Hexanoic acid, 2-ethyl-, 1,2,3-propanetriyl ester 7360-38-5                    | No data located   |                             |  |
| Glycerides, C8-10<br><b>85409-09-2</b>   | No data located   |                             |  |
| Glycerides, mixed decanoyl and octanoyl 73398-61-5                             | Danio rerio/Directive<br>92/69/EEC, C.1/semi-static       | >53<br>(measured)           |  |
| Oils, glyceridic, palm kernel 8023-79-8  | No data located   |                             |  |
| Glycerides, C8-18 and C18-unsatd.<br>67701-28-4                                | No data located   |                             |  |
| Oils, vegetable, hydrogenated 68334-28-1                                       | No data located   |                             |  |
| Glycerides, C12-18<br>67701-26-2   | No data located   |                             |  |
| Glycerides, C16-18 and C18-unsatd.<br>67701-30-8                               | Danio rerio/Similar to OECD 203/semi-static daily renewal | >10,000<br>(nominal)        |  |
| Tallow, hydrogenated 8030-12-4   | No data located   |                             |  |
| Castor oil, hydrogenated 8001-78-3   | Danio rerio/ ISO 7346/2/semi-<br>static daily renewal     | >10,000<br>(nominal)        |  |

| Olein, tri - (Octadecenoic acid, 1,2,3-propanetriyl) 122-32-7   | No data located   |                      |  |
|---|---|----------------------|--|
| M   | ixtures of mono-, di- and triglyceri                      | des                  |  |
| Glycerides, C14-18 mono- and di-<br>67701-33-1  | Danio rerio/Similar to OECD 203/semi-static daily renewal | >10,000<br>(nominal) |  |
| Glycerides, mixed coco, decanoyl and octanoyl <b>68606-18-8</b>   | No data located   |                      |  |
| Glycerides, C16-18 and C18-unsatd. mono- and di-<br>68424-61-3  | No data located   |                      |  |
| Glycerides, C16-18 mono- and di-<br>85251-77-0  | No data located   |                      |  |
| Glycerides, tall-oil mono-, di-, and tri-<br>97722-02-6   | Danio rerio/Similar to OECD 203/semi-static daily renewal | 1700<br>(nominal)    |  |
| Glycerides, C16-18 and C18-unsatd. mono-, di- and tri-<br>91744-20-6  | No data located   |                      |  |
| Coconut oil,transesterification products with decanoic acid mixed ester with glyceryl octanoate 68991-68-4 and 91052-53-8 | No data located   |                      |  |

## Aquatic Invertebrates

| Name and<br>CAS Number   | Species/Test method   | EC50<br>(mg/L)                 |  |
|--|---|--------------------------------|--|
|  |   | 48 hr                          |  |
|  | Monoglycerides  |                                |  |
| Olein, mono- Octadecenoic acid, 1,2,3-propanetriol <b>25496-72-4</b>           | No data located   |                                |  |
| Glycerol oleate <b>37220-82-9</b>  | No data located   | No data located                |  |
| Glycerides,tall-oil<br>68309-32-0 and 61790-12-3                               | Daphnia magna/OECD 202/static                                   | EL50*>1000<br>(nominal)        |  |
| Octadecanoic acid, monoester with 1,2,3-propanetriol 31566-31-1                | No data located   |                                |  |
| Monoglycerides, hydrogenated tallow 61789-09-1                                 | No data located   |                                |  |
| Glyceryl stearate<br>11099-07-3 and 67701-27-3                                 | No data located   |                                |  |
| Glycerides, palm-oil mono-, hydrogenated 91744-73-9                            | No data located   |                                |  |
|  | Diglycerides  |                                |  |
| Octadecanoic acid, 1,2-propanediol monoester 1323-39-3                         | No data located   |                                |  |
| Decanoic acid, ester with 1,2,3-propanetriol octanoate <b>65381-09-1</b>       | Daphnia magna/OECD<br>202/semi-static renewal every 2-3<br>days | EL50>100<br>(nominal; 21<br>d) |  |
|  | Triglycerides   |                                |  |
| Octanoin, tri- (Octanoic acid, 1,2,3-propanetriyl ester; Tricaprylin) 538-23-8 | No data located   |                                |  |
| Hexanoic acid, 2-ethyl-, 1,2,3-propanetriyl ester 7360-38-5                    | No data located   |                                |  |
| Glycerides, C8-10<br><b>85409-09-2</b>   | No data located   |                                |  |
| Glycerides, mixed decanoyl and octanoyl 73398-61-5                             | Daphnia magna/EU Guideline<br>92/69/EWG/static                  | EL50>100<br>(nominal)          |  |
|  | Daphnia magna/EU Guideline<br>92/69/EWG/static                  | EL50>100<br>(nominal)          |  |
| Oils, glyceridic, palm kernel <b>8023-79-8</b>                                 | No data located   |                                |  |
| Glycerides, C8-18 and C18-unsatd.<br>67701-28-4                                | No data located   |                                |  |

| Oils, vegetable, hydrogenated 68334-28-1  | No data located  |                                |  |
|---|--|--------------------------------|--|
| Glycerides, C12-18<br>67701-26-2  | No data located  |                                |  |
| Glycerides, C16-18 and C18-unsatd.<br>67701-30-8  | Daphnia magna/similar to OECD 202/semi-static renewal every 2-3 days | EL50>100<br>(nominal; 21<br>d) |  |
| Tallow, hydrogenated 8030-12-4  | Daphnia magna/similar to OECD 202/static                             | EL50>100<br>(nominal)          |  |
| Castor oil, hydrogenated 8001-78-3  | No data located  |                                |  |
| Olein, tri - (Octadecenoic acid, 1,2,3-propanetriyl) 122-32-7   | Daphnia magna/EU Guideline<br>92/69/EWG/static                       | EL50>100<br>(nominal)          |  |
| M   | lixtures of mono-, di- and triglyceric                               | es                             |  |
| Glycerides, C14-18 mono- and di-<br>67701-33-1  | No data located  |                                |  |
| Glycerides, mixed coco, decanoyl and octanoyl 68606-18-8  | No data located  |                                |  |
| Glycerides, C16-18 and C18-unsatd. mono- and di-<br>68424-61-3  | No data located  |                                |  |
| Glycerides, C16-18 mono- and di-<br>85251-77-0  | No data located  |                                |  |
| Glycerides, tall-oil mono-, di-, and tri-<br>97722-02-6   | Daphnia magna/similar to<br>OECD 202/static                          | EL50>100<br>(nominal)          |  |
| Glycerides, C16-18 and C18-unsatd. mono-, di- and tri-<br>91744-20-6  | No data located  |                                |  |
| Coconut oil,transesterification products with decanoic acid mixed ester with glyceryl octanoate 68991-68-4 and 91052-53-8 | No data located  |                                |  |

# Aquatic plants

| Name and<br>CAS Number   | Species/Test method                                | EC50<br>(mg/L), 72<br>hr   |          |
|--|--|--|----------|
|  | Monoglycerides                                     |  |          |
| Olein, mono- Octadecenoic acid, 1,2,3-propanetriol <b>25496-72-4</b>           | No data located                                    |  |          |
| Glycerol oleate <b>37220-82-9</b>  | No data located                                    |  |          |
| Glycerides,tall-oil<br>68309-32-0 and 61790-12-3                               | Pseudokirchnerella subcapitata/<br>OECD 201/static | EbL50* =<br>854.9, ErL50<br>>1000<br>(nominal)<br>NOELr =<br>500 |          |
| Octadecanoic acid, monoester with 1,2,3-propanetriol <b>31566-31-1</b>         | No data located                                    |  |          |
| Monoglycerides, hydrogenated tallow 61789-09-1                                 | No data located                                    |  |          |
| Glyceryl stearate<br>11099-07-3 and 67701-27-3                                 | No data located                                    |  |          |
| Glycerides, palm-oil mono-, hydrogenated 91744-73-9                            | No data located                                    |  |          |
|  | Diglycerides                                       |  | <u> </u> |
| Octadecanoic acid, 1,2-propanediol monoester 1323-39-3                         | No data located                                    |  |          |
| Decanoic acid, ester with 1,2,3-propanetriol octanoate 65381-09-1              | Desmodesmus subspicatus/<br>OECD 201/static        | EbL50,<br>ErL50 > 100<br>(nominal),<br>NOEL = 100                |          |
|  | Triglycerides                                      | •  |          |
| Octanoin, tri- (Octanoic acid, 1,2,3-propanetriyl ester; Tricaprylin) 538-23-8 | No data located                                    |  |          |

| Hexanoic acid, 2-ethyl-, 1,2,3-propanetriyl ester 7360-38-5   | No data located  |  |  |
|---|--|--|--|
| Glycerides, C8-10<br><b>85409-09-2</b>  | No data located  |  |  |
| Glycerides, mixed decanoyl and octanoyl 73398-61-5  | Desmodesmus subspicatus/<br>OECD 201/static            | EbL50,<br>ErL50 >1000<br>(nominal<br>loading),<br>NOEC =<br>1000                                   |  |
| Oils, glyceridic, palm kernel 8023-79-8   | No data located  | 1000   |  |
| Glycerides, C8-18 and C18-unsatd.<br>67701-28-4   | No data located  |  |  |
| Oils, vegetable, hydrogenated 68334-28-1  | No data located  |  |  |
| Glycerides, C12-18<br>67701-26-2  | No data located  |  |  |
| Glycerides, C16-18 and C18-unsatd.<br>67701-30-8  | Desmodesmus subspicatus/<br>similar to OECD 201/static | EbL50,<br>ErL50 > 100<br>(nominal),<br>NOEL = 100  |  |
| Tallow, hydrogenated 8030-12-4  | Desmodesmus subspicatus/<br>similar to OECD 201/static | EbL50,<br>ErL50 > 100<br>(nominal),<br>NOEL = 100  |  |
| Castor oil, hydrogenated 8001-78-3  | No data located  |  |  |
| Olein, tri - (Octadecenoic acid, 1,2,3-propanetriyl) 122-32-7   | No data located  |  |  |
| M   | lixtures of mono-, di- and triglyco                    | erides   |  |
| Glycerides, C14-18 mono- and di-<br>67701-33-1  | No data located  |  |  |
| Glycerides, mixed coco, decanoyl and octanoyl <b>68606-18-8</b>   | No data located  |  |  |
| Glycerides, C16-18 and C18-unsatd. mono- and di-<br>68424-61-3  | No data located  |  |  |
| Glycerides, C16-18 mono- and di-<br>85251-77-0  | No data located  |  |  |
| Glycerides, tall-oil mono-, di-, and tri-<br>97722-02-6   | Skeletonema costatum/ ISO<br>10253 1995/static         | ECr50 = 13.88<br>(nominal;<br>exceeds the<br>estimated<br>water<br>solubility of<br>the substance) |  |
| Glycerides, C16-18 and C18-unsatd. mono-, di- and tri-<br>91744-20-6  | No data located  |  |  |
| Coconut oil,transesterification products with decanoic acid mixed ester with glyceryl octanoate 68991-68-4 and 91052-53-8 | No data located  |  |  |

<sup>\*</sup>WAF sample preparations are reported relative to a loading rate rather than a concentration [LL50 (fish); EL50 (daphnia); EbL50/ErL50 (daga)]

There were no acute effects of the Glycerides Category members on fish, aquatic invertebrates or algae with LC50/LL50 or EC50/EL50 values less than the water solubility of the substance or that were less than 100 mg/L; similar results are expected for the Glycerides Category members that have not been tested.

There were no chronic reproductive effects of **CAS 65381-09-1** (diglyceride) or **67701-30-8** (triglyceride) on *Daphnia magna* (OECD 202), with NOEL (for reproduction) values > 100 mg/L; a concentration which exceeds the water solubility of the substances. Similar results are expected for the Glyceride Category members that have not been tested.

The Glycerides Category members do not possess properties indicating a hazard for the environment. Category members are rapidly biodegradable and have a low potential for bioaccumulation. Adequate screening-level data are available to characterize the hazard for the environment for the purposes of the

#### **OECD Cooperative Chemicals Assessment Programme.**

## **Exposure**

The 2012 production volumes reported by the US EPA (Chemical Data Reporting (CDR)) for the sponsored Glycerides in the United States is as follows:

| Name and<br>CAS Number  | Production volume<br>(Tonnes/year) |
|---|------------------------------------|
| Monoglycerides  |                                    |
| Olein, mono- Octadecenoic acid, 1,2,3-propanetriol <b>25496-72-4</b>  | 454 – 4,536                        |
| Glycerol oleate 37220-82-9  | 454 – 4,536                        |
| Glycerides,tall-oil 68309-32-0 and 61790-12-3   | 1,076                              |
| Octadecanoic acid, monoester with 1,2,3-propanetriol 31566-31-1   | 454 – 4,536                        |
| Monoglycerides, hydrogenated tallow 61789-09-1  | 28                                 |
| Glyceryl stearate 11099-07-3 and 67701-27-3   | 31 and 423                         |
| Glycerides, palm-oil mono-, hydrogenated 91744-73-9   | (b)                                |
| Diglycerides  |                                    |
| Octadecanoic acid, 1,2-propanediol monoester 1323-39-3  | (b)                                |
| Decanoic acid, ester with 1,2,3-propanetriol octanoate 65381-09-1   | (c)                                |
| Triglycerides   |                                    |
| Octanoin, tri- (Octanoic acid, 1,2,3-propanetriyl ester; Tricaprylin) 538-23-8  | (b)                                |
| Hexanoic acid, 2-ethyl-, 1,2,3-propanetriyl ester <b>7360-38-5</b>  | 35                                 |
| Glycerides, C8-10 <b>85409-09-2</b>   | (b)                                |
| Glycerides, mixed decanoyl and octanoyl 73398-61-5  | 454 - 4,536                        |
| Oils, glyceridic, palm kernel 8023-79-8   | 22,680 -45,359                     |
| Glycerides, C8-18 and C18-unsatd. <b>67701-28-4</b>   | 113,398 - 226,796                  |
| Oils, vegetable, hydrogenated 68334-28-1  | 454 – 4,536                        |
| Glycerides, C12-18 <b>67701-26-2</b>  | Not listed on CDR                  |
| Glycerides, C16-18 and C18-unsatd. <b>67701-30-8</b>  | (c)                                |
| Tallow, hydrogenated 8030-12-4  | 17                                 |
| Castor oil, hydrogenated 8001-78-3  | 5885                               |
| Olein, tri - (Octadecenoic acid, 1,2,3-propanetriyl) <b>122-32-</b> 7   | 45-227                             |
| Mixtures of mono-, di- and triglycerides  |                                    |
| Glycerides, C14-18 mono- and di- <b>67701-33-1</b>  | 4,536 - 22,680                     |
| Glycerides, mixed coco, decanoyl and octanoyl 68606-18-8  | (b)                                |
| Glycerides, C16-18 and C18-unsatd. mono- and di- <b>68424-61-3</b>  | 454- 4536                          |
| Glycerides, C16-18 mono- and di- <b>85251-77-0</b>  | (c)                                |
| Glycerides, tall-oil mono-, di-, and tri- 97722-02-6  | 445                                |
| Glycerides, C16-18 and C18-unsatd. mono-, di- and tri- 91744-20-6   | (b)                                |
| Coconut oil,transesterification products with decanoic acid mixed ester with glyceryl octanoate 68991-68-4 and 91052-53-8 | (b)                                |

<sup>(</sup>b) No production volumes reported to the EPA either because the substance is not produced in the US or substance or manufacturers are exempt from reporting. (c) Production Information withheld in order to maintain Confidential Business Information (CBI)

In U.S., the main applications are in personal care products, cosmetics, cleaning products, industrial intermediates and in pharmaceuticals.

Glycerides are naturally occurring substances. Exposures to those used in industry could arise in association with production, formulation and industrial use of these substances.

Glycerides are manufactured in established chemical manufacturing facilities that have standard engineering controls and procedures in place to ensure safe handling and use of chemicals. The precautions used includes corrosion-resistant vessels and piping of the type used for any quality-controlled chemical reaction. Glycerides have a low volatility and as a rule engineering controls are available that prevent the need for respiratory protection. For routine operations, including those involving a breach of the closed system, goggles or safety glasses, gloves, safety boots and helmets are worn, and a higher level of respiratory protection is applied and extra measures may be taken to prevent breathing of vapours, if (local) ventilation is inadequate. Formulation of large volumes of product occurs in a continuous process using a closed system; for smaller volumes, a batch process is used. Closed reactors and/or mixing tanks with closed charging systems are typically used for the formulation of

## glycerides.

Exposure to glycerides through the use of formulated products in industry and commerce is mitigated by following the recommended use and precaution instructions detailed in the material safety data sheet (MSDS). MSDS' reflect the hazard potential of the chemical ingredients in the product and provide details on the precautions necessary when handling these products and the instructions for first aid in case of an accidental exposure. Major routes of consumer exposure to glycerides are from the use of glycerides in personal care products and cosmetics. Indirect consumer exposure to glycerides may occur from exposures to residual levels of down-the-drain products in receiving waters from effluents of sewage treatment plants.

Note: This document may only be reproduced integrally. The conclusions in this document are intended to be mutually supportive, and should be understood and interpreted together.