Glycerides (mono and di)

**Handling/Processing**

<table>
<thead>
<tr>
<th>Identification of Substance</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Chemical Names:</strong></td>
</tr>
<tr>
<td>Monoglycerides and diglycerides;</td>
</tr>
<tr>
<td>monoacylglycerol (MAG) and diacylglycerol (DAG); mono- and diglycerides of fatty acids</td>
</tr>
<tr>
<td><strong>Other Name:</strong></td>
</tr>
<tr>
<td>Fatty acids, edible, mono- and diglycerides;</td>
</tr>
<tr>
<td>Mixed mono- and diglycerides; Mono- and diglycerides of edible fat-forming acids; Mono- and diglycerides of edible fats and oils; Mono- and diglycerides of fat-forming fatty acids; Glyceryl mono and di-esters; glycerol monostearate, glyceryl distearate; glyceryl</td>
</tr>
<tr>
<td><strong>Trade Names:</strong></td>
</tr>
<tr>
<td>Mono and diglyceride; Mono and diglycerides;</td>
</tr>
<tr>
<td>Mono- and diglycerides of fatty acids</td>
</tr>
</tbody>
</table>

**Summary of Current Use**

Glycerides (mono and di) are currently allowed in organic food processing at 7 CFR §205.605(b) for use only in drum drying of food.

**Characterization of Substance**

**Composition of the Substance:**
Mono- and diglycerides are a class of substances which contain a mixture of mono- and diglyceryl esters of the long chain fatty acids, either saturated and unsaturated, that occur in fats in food. The FDA Generally Recognized As Safe (GRAS) listing notes that the substance also contains minor amounts of triesters, and is prepared from fats, oils, or fat-forming acids derived from edible sources. It defines the substance as having at least 90% by weight glycerides, along with free glycerin and free fatty acids (FDA 2014). The Joint FAO/WHO Expert Committee on Food Additives (JECFA) defines mono- and diglycerides as being made up of at least 30% alpha-monoglycerides, along with diglycerides and minor amounts of triglycerides, and may also contain other isomeric monoglycerides, as well as free glycerol (not more than 7%), free fatty acids, soap and moisture (JECFA 1973).

As with fats, mono- and diglycerides occur in three major crystalline forms: alpha, beta, and beta’ (beta prime). Of these, the beta forms are most stable and moderately functional, while the alpha form is the most highly functional. Over time, the alpha-crystalline forms can convert into the beta-crystalline forms (Frank 2014). These crystalline forms are not to be confused with the description of the various molecular isomers of mono- and diglycerides determined by the position of the fatty acid(s) on the glycerol’s hydroxyl groups, shown below in Figure 1.
Figure 1. Structural formulas for the different isomers of monoglycerides and diglycerides, taken from JECFA Monograph (1973), where -OCR represents the fatty acid moiety.

Source or Origin of the Substance:
Mono- and diglycerides occur naturally in food as minor constituents of fats, in combination with the major constituent of food fats: triglycerides. They are also metabolic intermediates of triglycerides. When manufactured, they are prepared by the glycerolysis of fats or oils, or from fatty acids derived from edible sources (FDA 2014). These edible sources are commonly animal fats or vegetable oils such as soybean, canola, sunflower, cottonseed, coconut or palm oil (Frank 2014), and their main fatty acids used to manufacture mono- and diglycerides include lauric, linoleic, myristic, oleic, palmitic, and stearic acid (FDA 2014). The glycerol component of mono- and diglycerides is also derived from these edible fats and oils.

Properties of the Substance:
The functional properties of mono- and diglycerides are determined by various factors, including the type of fat used as the base ingredient, and hence the type of fatty acid, the percent monoglycerides, whether the original fat is saturated or unsaturated, the hydrophilic-lipophilic balance, and the form of the crystal (alpha-, beta-, or beta’-). The hydrophilic-lipophilic balance (HLB) describes the balance between the hydrophilic (water loving) glycerol end of the monoglyceride molecule versus the lipophilic (oil loving) fatty acid tail. It is measured on a scale of 0 to 20 with low numbers (less than 6) indicating greater solubility in oil (favoring water-in-oil emulsions) and higher values (greater than 8) indicating greater solubility in water (favoring oil-in-water emulsions) (Frank 2014; Clark 2013). Campell-Timperman and Jiménez-Flores (1996) observe that crystallization properties of mono- and diglycerides are affected by their fatty acid composition, glyceride form, pH and temperature. Table 1 describes the chemical and physical properties of mono- and diglycerides.

Table 1. General properties of mono- and diglycerides (JECFA 1973; Campbell-Timperman, Choi and Jiminez-Flores 1996).

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Form</td>
<td>Varies from liquid to hard solid</td>
</tr>
<tr>
<td>Color</td>
<td>Varies from yellow to white</td>
</tr>
<tr>
<td>Odor</td>
<td>Bland</td>
</tr>
<tr>
<td>Melting point</td>
<td>Range: 35-62°C</td>
</tr>
<tr>
<td>Solubility</td>
<td>Insoluble in water</td>
</tr>
<tr>
<td></td>
<td>Soluble in ethanol, chloroform, benzene</td>
</tr>
<tr>
<td>Acid value</td>
<td>≤6</td>
</tr>
<tr>
<td>Water content</td>
<td>≤2</td>
</tr>
</tbody>
</table>

Specific Uses of the Substance:
Mono- and diglycerides have many applications as food processing aids. They are principally used as emulsifiers. This function also translates into stabilization, preventing food separation, stabilizing air pockets and extending shelf life (Frank 2014).

The specific use for which mono- and diglycerides are permitted in organic food processing is in the drum drying of food. In this application, mono- and diglycerides can have various functions, but most significantly they act as an emulsifier and release agent. When mixed with food, mono- and diglycerides
help prevent sticking during processing, and in drum drying they help to strip the food from the cylinder walls once dried. In drum drying, a puree or slurry of food is added to one or two heated cylinders at varying feed rates depending on the particular food’s viscosity. As the cylinders or drums rotate, the slurry dries. The process creates powder or very fine flakes that can serve as the basis for snacks, soups, baked chips, some bakery items and cereals (Fusaro 2012). These dryers can reduce the moisture content of food to 5-6%.

Drum drying is suitable for drying foods that are naturally viscous after concentration, for example milk, precooked cereals, fruit pulps, applesauce, mashed potatoes, gelatinized starch and honey (Pua, et al. 2007). Mono- and diglycerides are some of the most common emulsifiers used in the drum drying of food. The Food Chemicals Codex notes that carrageenan produced by drum roll drying may contain mono- and diglycerides (1978). The 1995 NOSB TAP Review for glycerides notes that the substance is critical for some processing operations such as drum dehydrating of vegetables. Formulations for infant rice cereal slurries that are dried on a drum roller often include glycerol monostearate as an emulsifier (Luh 1991). Starch slurries are commonly drum dried, yielding a dry flake, including those that have been pre-cooked known as pregelatinized starches. The starches can be from numerous sources, including potato, tapioca, etc. (Furia 1973). Emulsifiers such as mono- and diglycerides may be employed in drum drying to improve creaminess, smoothness and gloss of pregelatinized starch used in instant puddings (O’Rourke 1980). The use of mono- and diglycerides in dehydrated potatoes also aids in rehydration (O’Brien 2004).

One patent also reported that low levels of mono- and/or diglycerides (1,000 – 2,000 ppm) in a drum dried powdered gelatin dessert product successfully functioned as an antifoam agent when the final product was dissolved in cold water (Leshik, et al. 1985).

Other uses of the substance include applications in textile processing, plastics production, oil formulations for various types of machinery (Valerio, et al. 2010), and as a feedstock for biofuel production (Zong, Ramanthan and Chen 2013).

Approved Legal Uses of the Substance:
The direct-food uses for mono- and diglycerides under the FDA GRAS listing at 21 CFR 184.1505 include use as an emulsifier, dough strengthener, flavoring agent, adjuvant, lubricant, release agent, solvent, vehicle, thickener, active surface-agent and texturizer. The listing also stipulates that the ingredient must be used in food at levels not to exceed current good manufacturing practices. FDA regulation 21 CFR 184.1(b) explains that under good manufacturing practices, the quantity of the ingredient added to food should not exceed the amount reasonably required to accomplish the intended physical, nutritional, or other technical effect in food.

Action of the Substance:
The action of glycerides stems from natural lubricating, emulsifying, dispersing and water binding properties (Sasol 2010). Emulsions are combinations of immiscible fluids reduced to very small droplets, which then mix into a temporarily stable phase. Emulsifiers help achieve and stabilize emulsions. Mono- and diglycerides do this as their hydrophilic glyceride heads associate with water molecules, while their lipophilic tails associate with oil molecules, thus enabling water and oil to remain in close connection and preventing either from agglomerating with like molecules. Mono- and diglycerides also increase the interfacial area of the oil or water droplets dispersed in an emulsion, which therefore require more energy to coalesce with like molecules into larger droplets. Consequently, the coalescence of droplets in an emulsion is reduced (Clark 2013). Conversely, mono and diglycerides decrease the interfacial or surface tension between fat molecules and water, thus helping to stabilize the emulsion (Cropper, et al. 2013) (Campbell-Timperman, Choi and Jiminez-Flores 1996). Monoglycerides exhibit stronger surface activity than diglycerides due to their two free hydroxyl groups (Hasenhuttl and Hartel 2008). The long, non-polar linear chains of monoglycerides can also complex with starch, preventing gelatinized starch from recrystallizing during storage (Muhlenchemie 2006).

In drum drying, mono- and diglycerides may be added to the flour before liquid is added to make the dough or slurry. In the case of potato flakes, such an addition coats the flour and thereby limits moisture
absorption. It also creates a dispersion of fat and moisture droplets throughout the dough, thereby lubricating the system. This helps control damage to the dough that may result from excessive tearing and stretching. Both of these actions limit the adhesiveness of the starch contained in the flour and thereby prevent the dough from sticking to the drum roll during drying (Martinez-Serna Villagran and Beverly 2001).

**Combinations of the Substance:**

Mono- and diglycerides may or may not be used in combination with other substances when used as emulsifiers in the drum drying of food. In drum drying, the mono- and diglyceride emulsifier may be dissolved in a fat or in a polyol fatty acid polyester such as a sucrose fatty acid polyester (Martinez-Serna Villagran and Beverly 2001). However, literature does not suggest this is a requirement for the addition of mono- and diglyceride emulsifiers to slurries intended for drum drying. Potato starches are commonly drum dried and may contain other additives besides mono and diglycerides. These may include sodium bisulfite to inhibit browning, sodium and pyrophosphate to inhibit greying, citric acid for emulsion stability, BHA or BHT to inhibit oxidation and preserve flavor, along with colors, spices, vitamins or other ingredients according to customer specifications (Oregon Potato Co. 2014; Martinez-Serna Villagran, Wooten, et al. 2005).

In many food emulsifier applications mono and diglycerides are used in combination with lecithin (Hassenhuetl and Hartel 2008; Muhlenchemie 2006). One example is the use of both glycerides and lecithin in margarine (Linden and Lorient 1999).

**Status**

**Historic Use:**

Mono- and diglycerides were first added to the National List in 2002 after being recommended by the National Organic Standards Board (NOSB) at the April 1995 NOSB Meeting. Discussion at that meeting noted that the food industry was trying to move away from their use, but that the material was still necessary for potato flake products. Thus, the NOSB voted to recommend restricting its use to drum roll drying of food.

The substance was reassessed during the Sunset review process in 2010 and the NOSB voted unanimously to recommend relisting it on §205.605(b). At that time, the NOSB did not find any evidence suggesting that proposed organic alternatives were favorable replacements. In their review of original recommendations, historical documents and public comments, the NOSB did not identify any unacceptable risks to the environment, human, or animal health as a result of the use or manufacture of the substance.

Industrial production of mono- and diglycerides began in the 1930s, using interesterification of fats with glycerol. This resulted in a product containing tri-, di- and monoglycerides. Subsequent developments in high vacuum, thin film molecular distillation made available product with higher monoglyceride content (Als and Krog 1991).

Drum drying of food emerged in the U.S. in the mid 1950s. Research at the Eastern Regional Research Center (ERRC) found in making dehydrated mashed potato flakes that additives should be incorporated into the potato mash mixes before drum drying to improve texture and extend shelf life. A monoglyceride emulsifier was identified as one such additive which had the added benefit of containing antioxidants (American Chemical Society 2007).

**Organic Foods Production Act, USDA Final Rule:**

The substances, mono- and diglycerides, do not appear in the Organic Foods Production Act of 1990. They are listed in the USDA organic regulations at §205.605(b) as “Glycerides (mono and di)—for use only in drum drying of food.”

**International**

Canada - Canadian General Standards Board Permitted Substances List


Glycerides (mono and di) are not permitted for use in organic food processing under EU regulations. They are not listed in EC No. 834/2007 or in EC No. 889/2008 Annex VIII: Certain products and substance for use in production of processed organic food referred to in Article 27(1)(a).

Japan Agricultural Standard (JAS) for Organic Production


Glycerides (mono and di) are not permitted under JAS standards. They are not listed in the Japanese Agricultural Standard for Organic Processed Foods (Notification No. 1606 of the Ministry of Agriculture, Forestry and Fisheries of October 27, 2005).

International Federation of Organic Agriculture Movements (IFOAM)


Glycerides (mono and di) are not permitted under IFOAM standards. They do not appear in the IFOAM Norms for Organic Production and Processing, Appendix 4 - Table 1: List of Approved Additives and Processing/Post-Harvest Handling Aids.

Evaluation Questions for Substances to be used in Organic Handling

Evaluation Question #1: Describe the most prevalent processes used to manufacture or formulate the substance. Further, describe any chemical change that may occur during manufacture or formulation of the substance when this substance is extracted from naturally occurring plant, animal, or mineral sources (7 U.S.C. § 6502 (21)).

One of the most common methods for producing mono- and diglycerides is via glycerolysis of vegetable oils, whereby the oils undergo a transesterification reaction with glycerol (Noureddini and Medikonduru 1997). In this reaction, one or more of the glycerol’s hydroxyl groups is replaced by a corresponding number of alkyl chains or fatty acids from the triglyceride. The glycerolysis reaction has also been referred to as interesterification (Hasenhuettl and Hartel 2008). The term transesterification refers to a reaction between an ester (e.g., triglycerides, the esters of glycerol) and an alcohol (e.g., glycerol or methanol), whereas interesterification is a reaction between two different esters exchanging their alkyl groups (Schrive, et al. 2008). Thus, the application of the term interesterification to the glycerolysis reaction stems from the source of the glycerol being esters (triglycerides). See Figure 2.

Glycerolysis is usually done in the presence of an alkaline catalyst such as sodium, potassium, or calcium hydroxide, and under high temperatures to create a blend of mono-, di-, and triglycerides, and a small amount of glycerol (Frank 2014; Campbell-Timperman, Choi and Jiminez-Flores 1996). Animal fats may also be used as the starting material. The transesterification reactions may also be acid-catalyzed, auto-catalyzed or enzyme-catalyzed (Kombe, et al. 2013). The monoglycerides and diglycerides produced through glycerolysis can be further separated out via distillation and subsequent processing to produce...
refined products such as distilled monoglycerides, ethoxylated monoglycerides, citric acid-, lactic acid- or acetic acid esters of monoglycerides, and diacetyl tartaric esters of mono- and diglycerides (Frank 2014). Champbell-Timperman, Choi and Jiminez Flores (1996) found that the triglyceride composition of a fat greatly affects the glycerolysis reaction rate in the production of mono- and diglycerides. In their experiment, butterfat was mixed with glycerol under 200°C maximum heat. A model glycerolysis system progresses with continual transition from triglycerides to mono- and diglycerides until monoglyceride concentration reaches approximately 75%, after which the proportion of glycerides remains constant for 60 minutes. However, with butterfat the concentration changed rapidly to 50/50 triglycerides and diglycerides, then after 60 minutes the diglyceride concentration remained fairly constant while the monoglyceride concentration increased as triglycerides decreased, demonstrating different rates of reaction for the different glycerides based on the starting material.

The other prevalent method for producing mono- and diglycerides is through direct esterification of fatty acids or their alkyl esters with glycerol (Noureddini and Medikonduru 1997), or of glycerol with fatty acids (Hasenhuettl and Hartel 2008). See Figure 2. This process yields approximately the same proportion of mono-, di-, and triglycerides as glycerolysis and requires either an acid or base catalyst (Hasenhuettl and Hartel 2008). The process may also use organic solvents to increase the yield of monoglycerides (Noureddini and Medikonduru 1997). The ratio of glycerol to fatty acids used with this method determines the composition of the finished product.

**DIRECT ESTERIFICATION:**

\[
\begin{align*}
\text{H}_2\text{C} & - \text{OH} + \text{RCOOH} \\
\text{H}_2\text{C} & - \text{OH} \\
\text{Glycerol} & \\
\text{Fatty Acid} &
\end{align*}
\]

**INTERESTERIFICATION:**

\[
\begin{align*}
\text{H}_2\text{C} & - \text{OH} + \text{H}_2\text{C} - \text{OCOR} \\
\text{H}_2\text{C} & - \text{OH} \\
\text{Glycerol} & \\
\text{Fat or Oil} &
\end{align*}
\]

\[
\begin{align*}
\text{H}_2\text{C} & - \text{OH} + \text{H}_2\text{C} - \text{OCOR} + \text{H}_2\text{O} \\
\text{H}_2\text{C} & - \text{OH} \\
\text{Glycerol} & \\
\text{Monoglyceride} &
\end{align*}
\]

\[
\begin{align*}
\text{H}_2\text{C} & - \text{OH} + \text{H}_2\text{C} - \text{OCOR} + \text{H}_2\text{O} \\
\text{H}_2\text{C} & - \text{OH} \\
\text{Glycerol} & \\
\text{Monoglyceride} &
\end{align*}
\]

\[
\begin{align*}
\text{H}_2\text{C} & - \text{OH} + \text{H}_2\text{C} - \text{OCOR} + \text{H}_2\text{O} \\
\text{H}_2\text{C} & - \text{OH} \\
\text{Glycerol} & \\
\text{Monoglyceride} &
\end{align*}
\]

Another method for the production of mono- and diglycerides is the hydrolysis of triglycerides, which may be either enzymatic or non-enzymatic (Tangkam, Weber and Wiege 2008). One patented method describes how various animal fats or vegetable oils, containing a mixture of fatty acids of different length carbon chains, can be mixed with a small amount of boric acid and heated to 250°C for up to 24 hours. This preferentially liberates fatty acids with shorter carbon chains which are then separated out by vacuum distillation as the reaction proceeds until 10%-25% of the fatty acids present in the reacting mixture have been removed. The resulting products are freed fatty acids and the residual mono- and diglycerides with longer-chain fatty acids; the boric acid is removed from the glycerides by washing (Barsky 1950).

Enzymatic synthesis of mono- and diglycerides using various lipase catalysts has been described as a method with high potential for industrial-scale application, favored by lower energy requirements and selectivity of the catalyst. It also results in a lighter colored end product with fewer off-flavors. At the time of their report (1997), Noureddini and Medikonduru stated that current industrial processes are based on the physiochemical glycerolysis of fats and oils rather than enzymatic synthesis. However, numerous studies have reported on optimal conditions for producing mono- and diglycerides from oils using enzymatic glycerolysis, often in solvent-free systems (Valerio, et al. 2010; Singh and Mukhopadhyay 2014).
Evaluation Question #2: Discuss whether the substance is formulated or manufactured by a chemical process, or created by naturally occurring biological processes (7 U.S.C. § 6502 (21)). Discuss whether the substance is derived from an agricultural source.

While mono- and diglycerides are derived from agricultural fats and oils, they are traditionally manufactured via a chemical reaction: the glycerolysis of those fats and oils. As described above, glycerolysis involves a chemical reaction between an ester and an alcohol where one or more of the molecules’ functional groups are exchanged. Similarly, direct esterification is a chemical reaction in which fatty acids replace the hydroxyl groups of glycerol, with water as a byproduct. Both processes involve the use of a catalyst, commonly an alkaline material such as sodium hydroxide. One study on the manufacture of mono- and diglycerides from milk fat describes mixing dry glycerol (50% w/w) and NaOH (0.1% w/w) with solid, crystallizable fractions of butter. The reaction proceeds with constant stirring at controlled temperature (195°C - 200°C). To neutralize the catalyst, the mixture is cooled and diatomaceous earth added. The solid mono- and diglyceride reaction products are separated from unreacted liquid glycerol via the physical process of decantation. The glycerides are then further purified by vacuum filtration (Campbell-Timperman, Choi and Jiminez-Flores 1996). The authors also report that, in general, molecular distillation is used to remove impurities from mono- and diglycerides. Molecular distillation is a physical separation carried out under high vacuum (around 10⁻⁴ mmHg) and heat (Fregolente, et al. 2006). The low pressure created by the vacuum allows molecules to pass freely to the condenser, facilitating separation of substances at the molecular level.

Because fats and fatty acids are insoluble in glycerol, organic solvents may be used to force their reaction to proceed (Hasenhuettl and Hartel 2008). Valerio et al. (2010) used n-butane as a solvent and sodium (bis-2-ethyl-hexyl) sulfosuccinate (AOT) as a surfactant. They reported that propane is another compressed liquid that may be used as a solvent in the production of glycerides.

Monoglycerides occur in food fats in amounts on the order of one-half to one percent (National Research Council (U.S.) Food Protection Committee 1952). Lipase is an enzyme which breaks down fats into monoglycerides and fatty acids. Used in reverse, it can catalyze the esterification of glycerol with fatty acids (Hasenhuettl and Hartel 2008). A report from Japan looked at oils with a high proportion of diacetyl glycerols obtained using a regiospecific lipase catalyst (Hou 2005). The author noted that for industrial-scale production, an immobilized enzyme is ideal so that it can be reused, and stated that only a few commercially immobilized lipases are available. The organisms used to produce these lipases are genetically modified. As with the other methods of production, enzyme-catalyzed production of mono- and diglycerides may or may not involve the use of organic solvents. The literature reviewed for this report suggests that the mono- and diglycerides produced are separated from unreacted glycerol and presumably the solvent. However, there is little information available on solvent residues remaining in the glycerides.

Evaluation Question #3: If the substance is a synthetic substance, provide a list of nonsynthetic or natural source(s) of the substance (7 CFR § 205.600 (b) (1)).

Mono and diglycerides are classified as synthetic on at §205.605(b). The predominant methods for their commercial production are glycerolysis and direct esterification of fatty acids with glycerol, both of which involve chemical reactions. Enzymatically produced mono- and diglycerides could potentially be considered nonsynthetic; however, non-GMO versions are not available. None of the literature reviewed for this report suggests significant commercial availability of nonsynthetic mono- or diglycerides obtained by the enzymatic hydrolysis of triglycerides.

Evaluation Question #4: Specify whether the substance is categorized as generally recognized as safe (GRAS) when used according to FDA’s good manufacturing practices (7 CFR § 205.600 (b)(5)). If not categorized as GRAS, describe the regulatory status.

Mono- and diglycerides are listed at 21 CFR 184.1505 as Direct Food Substances Affirmed as Generally Recognized as Safe (GRAS). The GRAS listing states that the ingredient may be used in food with no limitation other than current good manufacturing practice. The good manufacturing practice conditions of
use are defined in subsection (c)(1) as follows. “The ingredient is used in food as a dough strengtheners as defined in 170.3(o)(6)\(^1\) of this chapter; an emulsifiers and emulsifier salt as defined in 170.3(o)(8)\(^2\) of this chapter; a flavoring agent and adjuvant as defined in 170.3(o)(12)\(^3\) of this chapter; a formulation aid as defined in 170.3(o)(14)\(^4\) of this chapter; a lubricant and release agent as defined in 170.3(o)(18)\(^5\) of this chapter; a solvent and vehicle as defined in 170.3(o)(27)\(^6\) of this chapter; a stabilizer and thickener as defined in 170.3(o)(28)\(^7\) of this chapter; a surface-active agent as defined in 170.3(o)(29)\(^8\) of this chapter; a surface-finishing agent as defined in 170.3(o)(30)\(^9\) of this chapter; and a texturizer as defined in 170.3(o)(32)\(^10\) of this chapter. Of these GRAS approved uses, those permitted in organic food processing are those that aid in the drum drying of food, namely, use as an emulsifier, lubricant and release agent.

**Evaluation Question #5:** Describe whether the primary technical function or purpose of the substance is a preservative. If so, provide a detailed description of its mechanism as a preservative (7 CFR § 205.600 (b)(4)).

Chemical food preservatives are defined under FDA regulations at 21 CFR 101.22(a) (5) as “any chemical that, when added to food, tends to prevent or retard deterioration thereof, but does not include common salt, sugars, vinegars, spices, or oils extracted from spices, substances added to food by direct exposure thereof to wood smoke, or chemicals applied for their insecticidal or herbicidal properties” (FDA 2013).

Mono- and diglycerides are primarily used as emulsifiers. The primary function of emulsifiers is to facilitate the dispersion of oil in water or water in oil. In many applications, this creates a shelf-stable product by preventing separation of oils from other liquids in products such as salad dressings (Hasenhuettl and Hartel 2008), peanut butter, and ice cream. It retards the deterioration of physical properties of the end product, but does not prevent or retard chemical or microbial contamination.

The use for which mono- and diglycerides are permitted in organic food processing, the drum drying of food, also employs them as an emulsifier. However, in this application, the purpose of the emulsifier is to reduce stickiness of slurries that are applied to drum roll dryers to facilitate removal once dried. This use would not be considered that of a preservative according to the FDA definition.

**Evaluation Question #6:** Describe whether the substance will be used primarily to recreate or improve flavors, colors, textures, or nutritive values lost in processing (except when required by law) and how the substance recreates or improves any of these food/feed characteristics (7 CFR § 205.600 (b)(4)).

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\(^1\) 21 CFR 170.3(o)(6) defines dough strengtheners as: Substances used to modify starch and gluten, thereby producing a more stable dough, including the applicable effects listed by the National Academy of Sciences/National Research Council under “dough conditioner.”

\(^2\) 21 CFR 170.3(o)(8) defines emulsifiers and emulsifier salts as: Substances which modify surface tension in the component phase of an emulsion to establish a uniform dispersion or emulsion.

\(^3\) 21 CFR 170.3(o)(12) defines flavoring agents and adjuvants as: Substances added to impart or help impart a taste or aroma in food.

\(^4\) 21 CFR 170.3(o)(14) defines formulation aids as: Substances used to promote or produce a desired physical state or texture in food, including carriers, binders, fillers, plasticizers, film-formers, and tableting aids, etc.

\(^5\) 21 CFR 170.3(o)(18) defines lubricants and release agents as: Substances added to food contact surfaces to prevent ingredients and finished products from sticking to them.

\(^6\) 21 CFR 170.3(o)(27) defines solvents and vehicles as: Substances used to extract or dissolve another substance.

\(^7\) 21 CFR 170.3(o)(28) defines stabilizers and thickeners as: Substances used to produce viscous solutions or dispersions, to impart body, improve consistency, or stabilize emulsions, including suspending and bodying agents, setting agents, jellying agents, and bulking agents, etc.

\(^8\) 21 CFR 170.3(o)(29) defines surface-active agents as: Substances used to modify surface properties of liquid food components for a variety of effects, other than emulsifiers, but including solubilizing agents, dispersants, detergents, wetting agents, rehydration enhancers, whipping agents, foaming agents, and defoaming agents, etc.

\(^9\) 21 CFR 170.3(o)(30) defines surface-finishing agents as: Substances used to increase palatability, preserve gloss, and inhibit discoloration of foods, including glazes, polishes, waxes, and protective coatings.

\(^10\) 21 CFR 170.3(o)(30) defines texturizers as: Substances which affect the appearance or feel of the food.
When used as an emulsifier in ice creams, mono- and diglycerides are said to improve texture by decreasing the tension between the fat molecules and the water, allowing the two components to coexist in the same system and thereby producing a smoother and drier texture (Cropper, et al. 2013). However, this is not a recreation of texture but rather an enhancement of the role played by the natural emulsifiers in milk, casein and whey proteins.

In drum drying of food, mono- and diglycerides do affect texture, adding lubrication to slurries and reducing stickiness. However, this is again not a recreation of lost texture but a modification of texture that develops during processing with the addition of water or other liquid to starch. The use of 0.1%-1% mono- and diglyceride emulsifier has been proposed to react with free amylose (a starch polysaccharide) in cooked potato slurry that has become too sticky due to overcooking, resulting in excessive cell rupture (Martinez-Serna Villagran, Wooten, et al. 2005). This is an example of correction of textural degradation due to over processing.

**Evaluation Question #7:** Describe any effect or potential effect on the nutritional quality of the food or feed when the substance is used (7 CFR § 205.600 (b)(3)).

Although mono- and diglycerides have similar properties and comparable calories to triglycerides, or ordinary fats, they have essentially no caloric impact on food because they are used as additives in small amounts (less than 1% of a food’s total weight) (Environmental Nutrition 1997).

One report evaluated the nutritional function of diglycerides produced using a lipase enzyme as compared to conventional triglyceride oil. The author reported that a Japanese cooking oil containing 80% or more diglycerides claims a lower elevation in postprandial triglyceride concentrations in the blood after diglyceride ingestion, as compared to ingestion of the triglyceride with the same fatty acid composition, as well as less body fat accumulation. However, clinical studies are said to be in progress to confirm the efficacy of diglyceride oil (Hou). Also, 1,3-diglycerides have been shown to have beneficial effects in preventing obesity and lipemia (Tangkam, Weber and Wiege 2008) despite having a similar energy value and digestibility as triglycerides (Valerio, et al. 2010).

The Joint FAO/WHO Expert Committee on Food Additives (1974) reported that the various fatty acids present in mono- and diglycerides are not necessarily absorbed and metabolized in the same way as those of natural food fats, and that their nutritional significance may also differ. The report cites that long-chain fatty acids are less digestible than those with unsaturated fatty acids if fed alone or in large quantities, and administration of many polyunsaturated fatty acids causes depression of blood cholesterol levels whereas the ingestion of saturated fatty acids tends to increase it (JECFA 1974). Thus, depending on the fatty acid composition of the mono- and diglycerides and the level at which they are used, some of the above effects could occur. However, the literature reviewed for this report indicates typical usage levels as a food processing aid of 0.1 – 1%, with 3% being a maximum (Martinez-Serna Villagran, Wooten, et al. 2005).

**Evaluation Question #8:** List any reported residues of heavy metals or other contaminants in excess of FDA tolerances that are present or have been reported in the substance (7 CFR § 205.600 (b)(5)).

The Joint FAO/WHO Expert Committee on Food Additives (JECFA) Monograph for mono- and diglycerides (1973) reports a lead level of not more than 2 mg/kg. The FDA’s Action Levels for lead ranges from 0.5 to 7 µg/ml. Lead levels are not listed for agricultural substances or additives intended for direct food use (FDA 2000). A review of several MSDSs for commercial mono- and diglycerides products found no report of heavy metals or other contaminants (Futura Ingredients 2011) (New Directions Laboratory 2013).

**Evaluation Question #9:** Discuss and summarize findings on whether the manufacture and use of the substance may be harmful to the environment or biodiversity (7 U.S.C. § 6517 (c) (1) (A) (i) and 7 U.S.C. § 6517 (c) (2) (A) (i)).
Carbon monoxide, carbon dioxide, and unidentified organic compounds may be formed during combustion of mono- and diglycerides. However, mono- and diglycerides have a low persistence level in the environment. They are readily biodegradable and have been shown to be non-toxic to fish and aquatic invertebrates (European Chemicals Agency 1991).

Various chemicals may be employed in the manufacture of mono- and diglycerides. The catalyst sodium hydroxide is the most common. Sodium hydroxide is released into the environment as sodium cations and hydroxide anions in water, which can decrease the acidity of water. Sodium hydroxide does not bioaccumulate.

The use of organic solvents during glyceride manufacturing is described in several studies, with n-butane and propane cited specifically. Organic solvents are carbon-based substances capable of dissolving or dispersing other substances, and while many are recognized by The National Institute for Occupational Safety and Health as carcinogens, neither propane nor n-butane has a carcinogenicity classification (NIOSH 2013). Both n-butane and propane are highly volatile and widely occurring atmospheric pollutants. Volatilization is their primary environmental fate; however, adsorption or biodegradation via microbial digestion may occur in soil and water (Howard 1997). The substance n-butane was found to be present in 6 of 12 human breast milk samples from the U.S. (Howard 1997). The potential effects of n-butane on animals include frostbite from contact with liquid n-butane and cardiac symptoms as reported in a study on anesthetized dogs exposed to n-butane (5,000-200,000 ppm) for 2 minutes (CDC 1992). Main sources of release into the atmosphere for both n-butane and propane include waste incinerators and the combustion of gasoline. While these solvents have adverse environmental effects, their release into the environment from the production of mono- and diglycerides is not covered in the literature.

**Evaluation Question #10:** Describe and summarize any reported effects upon human health from use of the substance (7 U.S.C. § 6517 (c) (1) (A) (i), 7 U.S.C. § 6517 (c) (2) (A) (i)) and 7 U.S.C. § 6518 (m) (4))

Toxicological studies on the consumption of mono- and diglycerides were summarized by the JECFA in 1974. The report suggests that mono- and diglycerides have no acute toxicity at practicable dosage levels. It also reports that in mice fed glyceryl monostearate as their sole fat source, weight gain was not adversely affected and lactation and reproduction performance were normal. In humans, the mono- and diglycerides that are most likely to cause undesirable health effects are those which contain long-chain saturated fatty acids, such as stearic acid. Long-term studies on these compounds have shown increased liver weight in animals given high fat intake. However, the effects were not considered to have toxicological significance (JECFA 1974).

Mono- and diglycerides are not limited by an Acceptable Daily Intake (ADI) level. They appear in Annex II of the Report from the Commission on Dietary Food Additive Intake in the European Union: “List of food additives with ADI (acceptable daily intake) not specified,” found acceptable for specified use as recommended by the SCF (Scientific Committee on Food), or new additives (EU Commission on Dietary Food Additive Intake 2000). As recently as 2003, the ADI for mono- and diglycerides was listed as “Not Limited” by the EU Commission (JECFA 2003).

**Evaluation Question #11:** Describe any alternative practices that would make the use of the substance unnecessary (7 U.S.C. § 6518 (m) (6)).

The scope of use for mono- and diglycerides under current organic regulations is limited to the drum drying of food. Different methods and machinery are available for drying food products, including spray drying, freeze drying, infrared drying, the use of fluidized bed dryers, air lift dryers, scraped wall heat exchangers, drum dryers, etc. Drum drying is said to be the preferred method for making dehydrated potato flakes (Martinez-Serna Villagran and Beverly 2001), whereas air lift drying and fluidized bed drying are preferred when making potato granules. Freeze drying has been suggested as an acceptable alternative to drum drying, and infrared drying is often used in combination with drum drying (Martinez-Serna Villagran, Wooten, et al. 2005).
One patent describes a method for drum drying mashed potatoes without the use of any emulsifier. The procedure involves the dilution of the potato slurry, normally 22%-26% solids, with water down to 18%-20% solids, prior to drying. This enables a nearly monolayered layer to be applied to the dryer with greater uniformity, resulting in improved heat transfer and ultimately lower moisture content of the dried product. Following drying, the potatoes are extruded in sheets that are broken, screened and packaged. The patent does not cite a need to use an emulsifier to prevent sticking to the drum dryer (Cording and Willard 1956).

A newer alternative to the traditional thin-film drying methods described above is the use of a water-vapor permeable drying surface. Trials of this method using modified corn, potato, and rice starch films showed much faster drying times and higher quality end product as compared to the traditional thin-film drying (Browser and Wilhelm 1996).

**Evaluation Question #12:** Describe all natural (non-synthetic) substances or products which may be used in place of a substance (7 U.S.C. § 6517 (c) (1) (A) (iii)). Provide a list of allowed substances that may be used in place of the substance (7 U.S.C. § 6518 (m) (6)).

Although mono- and diglycerides are the preferred emulsifiers for reducing stickiness of potato mashes before they are drum dried into flakes (Martinez-Serna Villagran and Beverly 2001), other emulsifiers such as lecithin are said to also be suitable in the production of potato flake products (Martinez-Serna Villagran, Wooten, et al. 2005). De-oiled lecithin appears at §205.606 of the National List and may be nonorganic when not commercially available in organic form. Gum arabic, discussed below in #13, also appears at §205.606 and may be used in nonorganic form if not commercially available as organic.

Other emulsifiers that have been suggested as alternatives to mono- and diglycerides in the drum drying of food are synthetic, such as lactylate esters, sorbitan esters, propylene glycol mono- and diesters, and polyglycerol (Martinez-Serna Villagran and Beverly 2001).

**Evaluation Question #13:** Provide a list of organic agricultural products that could be alternatives for the substance (7 CFR § 205.600 (b) (1)).

One commercial product, a certified organic rice bran extract called Nu-RICE by Ribus, is marketed as an emulsifier and drum release agent that can act as a replacement for mono- and diglycerides (Ribus, Inc. 2015). The producer carried out experiments to test the product’s efficacy as an emulsifier as compared to other emulsifiers in the marketplace. The results of their trial are shown in Table 2. Ribus concluded from the results that egg and their own product, rice bran extract (RBE), had the highest capacity for oil-in-water binding. The RBE showed more uniform dispersion of the oil droplets than did the soy lecithin or oil and water alone (Ribus, Inc. 2013). The hydrophilic-lipophilic balance (HLB) of RBE is narrower than that of mono- and diglycerides, which may make it less versatile as an emulsifier depending on the composition of the mix to which it is added.

Table 2. Oil & Water Binding Project (Ribus, Inc. 2013). Rice Bran Extract (RBE) was evaluated in terms of capacity and stability in oil and water binding, and hydrophilic-lipophilic balance (HLB) as compared to several other commercial ingredients: egg, mono- and diglycerides, and soy lecithin. The qualitative and visual documentation was assessed by an outside third-party lab.

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>Capacity</th>
<th>Stability</th>
<th>HLB</th>
</tr>
</thead>
<tbody>
<tr>
<td>Egg (1)</td>
<td>1.2</td>
<td>1.2</td>
<td>5 - 8</td>
</tr>
<tr>
<td>RBE (2.3)</td>
<td>1.12</td>
<td>1.12</td>
<td>14.5 - 15</td>
</tr>
<tr>
<td>Mono’s &amp; Di (1)</td>
<td>1.0</td>
<td>1.0</td>
<td>8 - 14</td>
</tr>
<tr>
<td>Soy Lecithin (2, 3)</td>
<td>0.96</td>
<td>0.88</td>
<td>4 - 12</td>
</tr>
<tr>
<td>Reference Measure</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oil + Water</td>
<td>0.08</td>
<td>0.08</td>
<td>NA</td>
</tr>
<tr>
<td>Water</td>
<td>0</td>
<td>0</td>
<td>NA</td>
</tr>
</tbody>
</table>
In addition to soy lecithin, gum arabic has been cited as an additive for producing drum-dried jackfruit powder (Nussinovitch 2009), used to counteract the stickiness of the fruit due to its high sugar content. Gum arabic is characterized by very high water solubility (as opposed to glycerides), low viscosity, and an absence of odor, color and flavor (De Vries, Semeijn and Buwalda 2010). However, its use in drum dried food is not widely reported. Lecithin, on the other hand, is a common emulsifier. As compared to mono- and diglycerides, lecithin provides less emulsion stability, much less starch interaction, more fat modification, and has a higher HLB (Brentagg Food & Nutrition Europe 2014). It is also a better dough conditioner, but provides much less aeration than mono- and diglycerides (O'Brien 2004). In general, each emulsifier (and its form) is selected based on specifications of the food and the processing application.

Both soy lecithin and gum arabic are available in organic form. At the time of this report, there are 8 sources of certified organic soy lecithin and 4 sources of certified organic gum arabic on the list of certified USDA organic operations (NOP 2014).

References


—. Guidance for Industry: Aciton Levels for Poisonous or Deleterious Substances in Human Food and Animal Feed. August 2000.
January 27, 2015