

# Glycerides (mono and di)

## Handling/Processing

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### Identification of Substance

3 **Chemical Names:**

4 Monoglycerides and diglycerides;  
5 monoacylglycerol (MAG) and diacylglycerol  
6 (DAG); mono- and diglycerides of fatty acids

8 **Other Name:**

9 Fatty acids, edible, mono- and diglycerides;  
10 Mixed mono- and diglycerides; Mono- and  
11 diglycerides of edible fat-forming acids; Mono-  
12 and diglycerides of edible fats and oils; Mono-  
13 and diglycerides of edible fatty acids; Mono- and  
14 diglycerides of fat-forming fatty acids;  
15 Glycerol mono and di-esters; glycerol  
16 monostearate, glyceryl distearate; glyceryl

17 monopalmitate, glyceryl monooleate, etc;  
18 monostearin, monopalmitin, monooliein.

20 **Trade Names:**

21 Mono and diglyceride; Mono and diglycerides;  
22 Mono- and diglycerides of fatty acids

**CAS Numbers:**

Various. E.g. 67254-73-3; 67701-32-0 (C14-18 and  
C16-18-unsat.); 85251-77-0; 67784-87-6 (mono and  
diglycerides of hydrogenated palm oil); 26402-22-  
2, 26402-26-6 (medium chain mono- and  
diglycerides); 31566-31-1 (Glycerol monostearate)

**Other Codes:**

INS No. 471; E471

23

24

### Summary of Current Use

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

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### Characterization of Substance

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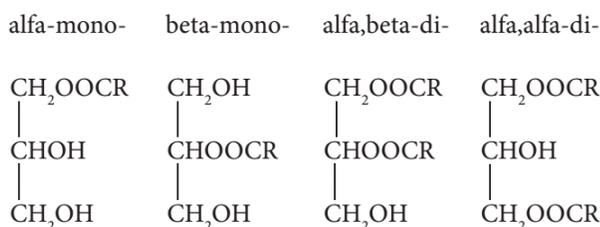
31 **Composition of the Substance:**

32 Mono- and diglycerides are a class of substances which contain a mixture of mono- and diglyceryl esters of the  
33 long chain fatty acids, either saturated and unsaturated, that occur in fats in food. The FDA Generally  
34 Recognized As Safe (GRAS) listing notes that the substance also contains minor amounts of triesters, and is  
35 prepared from fats, oils, or fat-forming acids derived from edible sources. It defines the substance as having at  
36 least 90% by weight glycerides, along with free glycerin and free fatty acids (FDA 2014). The Joint FAO/WHO  
37 Expert Committee on Food Additives (JECFA) defines mono- and diglycerides as being made up of at least 30%  
38 alpha-monoglycerides, along with diglycerides and minor amounts of triglycerides, and may also contain other  
39 isomeric monoglycerides, as well as free glycerol (not more than 7%), free fatty acids, soap and moisture (JECFA  
40 1973).

41

42 As with fats, mono- and diglycerides occur in three major crystalline forms: alpha, beta, and beta' (beta prime).  
43 Of these, the beta forms are most stable and moderately functional, while the alpha form is the most highly  
44 functional. Over time, the alpha-crystalline forms can convert into the beta-crystalline forms (Frank 2014). These  
45 crystalline forms are not to be confused with the description of the various molecular isomers of mono- and  
46 diglycerides determined by the position of the fatty acid(s) on the glycerol's hydroxyl groups, shown below in  
47 Figure 1.

48



49  
50

51 Figure 1. Structural formulas for the different isomers of monoglycerides and diglycerides, taken from JECFA  
52 Monograph (1973), where -OCR represents the fatty acid moiety.

53  
54

55 **Source or Origin of the Substance:**

56 Mono- and diglycerides occur naturally in food as minor constituents of fats, in combination with the  
57 major constituent of food fats: triglycerides. They are also metabolic intermediates of triglycerides. When  
58 manufactured, they are prepared by the glycerolysis of fats or oils, or from fatty acids derived from edible  
59 sources (FDA 2014). These edible sources are commonly animal fats or vegetable oils such as soybean,  
60 canola, sunflower, cottonseed, coconut or palm oil (Frank 2014), and their main fatty acids used to  
61 manufacture mono- and diglycerides include lauric, linoleic, myristic, oleic, palmitic, and stearic acid (FDA  
62 2014). The glycerol component of mono- and diglycerides is also derived from these edible fats and oils.

63

64 **Properties of the Substance:**

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

76

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

Property	
Form	Varies from liquid to hard solid
Color	Varies from yellow to white
Odor	Bland
Melting point	Range: 35-62°C
Solubility	Insoluble in water Soluble in ethanol, chloroform, benzene
Acid value	≤6
Water content	≤2

79

80 **Specific Uses of the Substance:**

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

84

85 The specific use for which mono- and diglycerides are permitted in organic food processing is in the drum  
86 drying of food. In this application, mono- and diglycerides can have various functions, but most  
87 significantly they act as an emulsifier and release agent. When mixed with food, mono- and diglycerides

88 help prevent sticking during processing, and in drum drying they help to strip the food from the cylinder  
89 walls once dried. In drum drying, a puree or slurry of food is added to one or two heated cylinders at  
90 varying feed rates depending on the particular food's viscosity. As the cylinders or drums rotate, the slurry  
91 dries. The process creates powder or very fine flakes that can serve as the basis for snacks, soups, baked  
92 chips, some bakery items and cereals (Fusaro 2012). These dryers can reduce the moisture content of food  
93 to 5-6%.

94  
95 Drum drying is suitable for drying foods that are naturally viscous after concentration, for example milk,  
96 precooked cereals, fruit pulps, applesauce, mashed potatoes, gelatinized starch and honey (Pua, et al. 2007).  
97 Mono- and diglycerides are some of the most common emulsifiers used in the drum drying of food. The  
98 Food Chemicals Codex notes that carrageenan produced by drum roll drying may contain mono- and  
99 diglycerides (1978). The 1995 NOSB TAP Review for glycerides notes that the substance is critical for some  
100 processing operations such as drum dehydrating of vegetables. Formulations for infant rice cereal slurries  
101 that are dried on a drum roller often include glycerol monostearate as an emulsifier (Luh 1991). Starch  
102 slurries are commonly drum dried, yielding a dry flake, including those that have been pre-cooked known  
103 as pregelatinized starches. The starches can be from numerous sources, including potato, tapioca, etc.  
104 (Furia 1973). Emulsifiers such as mono- and diglycerides may be employed in drum drying to improve  
105 creaminess, smoothness and gloss of pregelatinized starch used in instant puddings (O'Rourke 1980). The  
106 use of mono- and diglycerides in dehydrated potatoes also aids in rehydration (O'Brien 2004).

107  
108 One patent also reported that low levels of mono- and/or diglycerides (1,000 – 2,000 ppm) in a drum dried  
109 powdered gelatin dessert product successfully functioned as an antifoam agent when the final product was  
110 dissolved in cold water (Leshik, et al. 1985).

111  
112 Other uses of the substance include applications in textile processing, plastics production, oil formulations  
113 for various types of machinery (Valerio, et al. 2010), and as a feedstock for biofuel production (Zong,  
114 Ramanathan and Chen 2013).

#### 115 116 **Approved Legal Uses of the Substance:**

117 The direct-food uses for mono- and diglycerides under the FDA GRAS listing at 21 CFR 184.1505 include  
118 use as an emulsifier, dough strengthener, flavoring agent, adjuvant, lubricant, release agent, solvent,  
119 vehicle, thickener, active surface-agent and texturizer. The listing also stipulates that the ingredient must  
120 be used in food at levels not to exceed current good manufacturing practices. FDA regulation 21 CFR  
121 184.1(b) explains that under good manufacturing practices, the quantity of the ingredient added to food  
122 should not exceed the amount reasonably required to accomplish the intended physical, nutritional, or  
123 other technical effect in food.

#### 124 125 **Action of the Substance:**

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

140  
141 In drum drying, mono- and diglycerides may be added to the flour before liquid is added to make the  
142 dough or slurry. In the case of potato flakes, such an addition coats the flour and thereby limits moisture

143 absorption. It also creates a dispersion of fat and moisture droplets throughout the dough, thereby  
144 lubricating the system. This helps control damage to the dough that may result from excessive tearing and  
145 stretching. Both of these actions limit the adhesiveness of the starch contained in the flour and thereby  
146 prevent the dough from sticking to the drum roll during drying (Martinez-Serna Villagran and Beverly  
147 2001).

148  
149 **Combinations of the Substance:**

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

160  
161 In many food emulsifier applications mono and diglycerides are used in combination with lecithin  
162 (Hassenhuettl and Hartel 2008; Muhlenchemie 2006). One example is the use of both glycerides and  
163 lecithin in margarine (Linden and Lorient 1999) .  
164

<b>Status</b>
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166  
167 **Historic Use:**

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

173  
174 The substance was reassessed during the Sunset review process in 2010 and the NOSB voted unanimously  
175 to recommend relisting it on §205.605(b). At that time, the NOSB did not find any evidence suggesting that  
176 proposed organic alternatives were favorable replacements. In their review of original recommendations,  
177 historical documents and public comments, the NOSB did not identify any unacceptable risks to the  
178 environment, human, or animal health as a result of the use or manufacture of the substance.  
179

180 Industrial production of mono- and diglycerides began in the 1930s, using interesterification of fats with  
181 glycerol. This resulted in a product containing tri-, di- and monoglycerides. Subsequent developments in  
182 high vacuum, thin film molecular distillation made available product with higher monoglyceride content  
183 (Als and Krog 1991).  
184

185 Drum drying of food emerged in the U.S. in the mid 1950s. Research at the Eastern Regional Research  
186 Center (ERRC) found in making dehydrated mashed potato flakes that additives should be incorporated  
187 into the potato mash mixes before drum drying to improve texture and extend shelf life. A monoglyceride  
188 emulsifier was identified as one such additive which had the added benefit of containing antioxidants  
189 (American Chemical Society 2007).  
190

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

192 The substances, mono- and diglycerides, do not appear in the Organic Foods Production Act of 1990. They  
193 are listed in the USDA organic regulations at §205.605(b) as “Glycerides (mono and di) – for use only in  
194 drum drying of food.”  
195

196 **International**

197 **Canada - Canadian General Standards Board Permitted Substances List**

198 <http://www.tpsgc-pwgscc.gc.ca/ongc-cgsb/internet/bio-org/index-eng.html>  
199 Glycerides (mono and diglycerides) are permitted on the Canada Permitted Substances List, CAN/CGSB-  
200 32.311 Table 6.3 “Non-organic Ingredients Classified as Food Additives” with the following annotation:  
201 “For use only in drum drying of products. Organisms from genetic engineering are excluded.  
202 Documentation is required. Shall be produced from organic sources unless not commercially available.”  
203

204 **CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing**  
205 **of Organically Produced Foods (GL 32-1999)**

206 <ftp://ftp.fao.org/docrep/fao/005/Y2772e/Y2772e.pdf>  
207 Glycerides (mono and di) do not appear in the CODEX Alimentarius Commission Guidelines for the  
208 Production, Processing, Labeling, and Marketing of Organically Produced Food.  
209

210 **European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008**

211 <http://www.organic-world.net/news-eu-regulation.html>  
212 [http://eur-lex.europa.eu/LexUriServ/site/en/oj/2007/l\\_189/l\\_18920070720en00010023.pdf](http://eur-lex.europa.eu/LexUriServ/site/en/oj/2007/l_189/l_18920070720en00010023.pdf)  
213 Glycerides (mono and di) are not permitted for use in organic food processing under EU regulations. They  
214 are not listed in EC No. 834/2007 or in EC No. 889/2008 Annex VIII: Certain products and substance for  
215 use in production of processed organic food referred to in Article 27(1)(a).  
216

217 **Japan Agricultural Standard (JAS) for Organic Production**

218 [http://www.maff.go.jp/e/jas/specific/pdf/834\\_2012-3.pdf](http://www.maff.go.jp/e/jas/specific/pdf/834_2012-3.pdf)  
219 Glycerides (mono and di) are not permitted under JAS standards. They are not listed in the Japanese  
220 Agricultural Standard for Organic Processed Foods (Notification No. 1606 of the Ministry of Agriculture,  
221 Forestry and Fisheries of October 27, 2005).  
222

223 **International Federation of Organic Agriculture Movements (IFOAM)**

224 [http://www.ifoam.org/sites/default/files/page/files/ifoam\\_norms\\_version\\_august\\_2012\\_with\\_cover.pdf](http://www.ifoam.org/sites/default/files/page/files/ifoam_norms_version_august_2012_with_cover.pdf)  
225 Glycerides (mono and di) are not permitted under IFOAM standards. They do not appear in the IFOAM  
226 Norms for Organic Production and Processing, Appendix 4 – Table 1: List of Approved Additives and  
227 Processing/Post-Harvest Handling Aids.  
228

229 **Evaluation Questions for Substances to be used in Organic Handling**

230  
231 **Evaluation Question #1:** Describe the most prevalent processes used to manufacture or formulate the  
232 substance. Further, describe any chemical change that may occur during manufacture or formulation of  
233 the substance when this substance is extracted from naturally occurring plant, animal, or mineral  
234 sources (7 U.S.C. § 6502 (21)).  
235

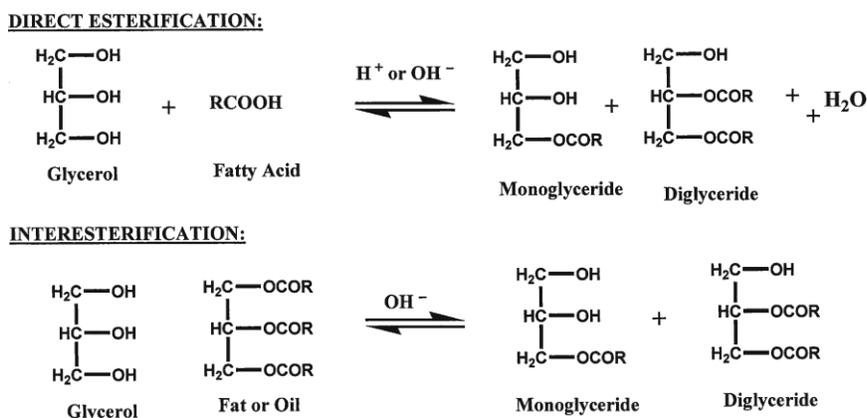
236 One of the most common methods for producing mono- and diglycerides is via glycerolysis of vegetable  
237 oils, whereby the oils undergo a transesterification reaction with glycerol (Noureddini and Medikonduru  
238 1997). In this reaction, one or more of the glycerol’s hydroxyl groups is replaced by a corresponding  
239 number of alkyl chains or fatty acids from the triglyceride. The glycerolysis reaction has also been referred  
240 to as interesterification (Hasenhuettl and Hartel 2008). The term transesterification refers to a reaction  
241 between an ester (e.g., triglycerides, the esters of glycerol) and an alcohol (e.g., glycerol or methanol),  
242 whereas interesterification is a reaction between two different esters exchanging their alkyl groups  
243 (Schrive, et al. 2008). Thus, the application of the term interesterification to the glycerolysis reaction stems  
244 from the source of the glycerol being esters (triglycerides). See Figure 2.  
245

246 Glycerolysis is usually done in the presence of an alkaline catalyst such as sodium, potassium, or calcium  
247 hydroxide, and under high temperatures to create a blend of mono-, di-, and triglycerides, and a small  
248 amount of glycerol (Frank 2014; Campbell-Timperman, Choi and Jiminez-Flores 1996). Animal fats may  
249 also be used as the starting material. The transesterification reactions may also be acid-catalyzed, auto-  
250 catalyzed or enzyme-catalyzed (Kombe, et al. 2013). The monoglycerides and diglycerides produced  
251 through glycerolysis can be further separated out via distillation and subsequent processing to produce

252 refined products such as distilled monoglycerides, ethoxylated monoglycerides, citric acid-, lactic acid- or  
 253 acetic acid esters of monoglycerides, and diacetyl tartaric esters of mono- and diglycerides (Frank 2014).  
 254

255 Campbell-Timperman, Choi and Jiminez Flores (1996) found that the triglyceride composition of a fat  
 256 greatly affects the glycerolysis reaction rate in the production of mono- and diglycerides. In their  
 257 experiment, butterfat was mixed with glycerol under 200°C maximum heat. A model glycerolysis system  
 258 progresses with continual transition from triglycerides to mono- and diglycerides until monoglyceride  
 259 concentration reaches approximately 75%, after which the proportion of glycerides remains constant for 60  
 260 minutes. However, with butterfat the concentration changed rapidly to 50/50 triglycerides and  
 261 diglycerides, then after 60 minutes the diglyceride concentration remained fairly constant while the  
 262 monoglyceride concentration increased as triglycerides decreased, demonstrating different rates of reaction  
 263 for the different glycerides based on the starting material.  
 264

265 The other prevalent method for producing mono- and diglycerides is through direct esterification of fatty  
 266 acids or their alkyl esters with glycerol (Noureddini and Medikonduru 1997), or of glycerol with fatty acids  
 267 (Hasenhuettl and Hartel 2008). See Figure 2. This process yields approximately the same proportion of  
 268 mono-, di-, and triglycerides as glycerolysis and requires either an acid or base catalyst (Hasenhuettl and  
 269 Hartel 2008). The process may also use organic solvents to increase the yield of monoglycerides  
 270 (Noureddini and Medikonduru 1997). The ratio of glycerol to fatty acids used with this method determines  
 271 the composition of the finished product.  
 272



273  
 274  
 275 Figure 2. Monoacylglycerol synthesis through direct esterification and interesterification (or  
 276 transesterification; Hasenhuettl and Hartel 2008).  
 277

278 Another method for the production of mono- and diglycerides is the hydrolysis of triglycerides, which  
 279 may be either enzymatic or non-enzymatic (Tangkam, Weber and Wiege 2008). One patented method  
 280 describes how various animal fats or vegetable oils, containing a mixture of fatty acids of different length  
 281 carbon chains, can be mixed with a small amount of boric acid and heated to 250°C for up to 24 hours. This  
 282 preferentially liberates fatty acids with shorter carbon chains which are then separated out by vacuum  
 283 distillation as the reaction proceeds until 10%-25% of the fatty acids present in the reacting mixture have  
 284 been removed. The resulting products are freed fatty acids and the residual mono- and diglycerides with  
 285 longer-chain fatty acids; the boric acid is removed from the glycerides by washing (Barsky 1950).  
 286

287 Enzymatic synthesis of mono- and diglycerides using various lipase catalysts has been described as a  
 288 method with high potential for industrial-scale application, favored by lower energy requirements and  
 289 selectivity of the catalyst. It also results in a lighter colored end product with fewer off-flavors. At the time  
 290 of their report (1997), Noureddini and Medikonduru stated that current industrial processes are based on  
 291 the physiochemical glycerolysis of fats and oils rather than enzymatic synthesis. However, numerous  
 292 studies have reported on optimal conditions for producing mono- and diglycerides from oils using  
 293 enzymatic glycerolysis, often in solvent-free systems (Valerio, et al. 2010; Singh and Mukhopadhyay 2014).  
 294

295 **Evaluation Question #2: Discuss whether the substance is formulated or manufactured by a chemical**  
296 **process, or created by naturally occurring biological processes (7 U.S.C. § 6502 (21)). Discuss whether the**  
297 **substance is derived from an agricultural source.**  
298

299 While mono- and diglycerides are derived from agricultural fats and oils, they are traditionally  
300 manufactured via a chemical reaction: the glycerolysis of those fats and oils. As described above,  
301 glycerolysis involves a chemical reaction between an ester and an alcohol where one or more of the  
302 molecules' functional groups are exchanged. Similarly, direct esterification is a chemical reaction in which  
303 fatty acids replace the hydroxyl groups of glycerol, with water as a byproduct. Both processes involve the  
304 use of a catalyst, commonly an alkaline material such as sodium hydroxide. One study on the manufacture  
305 of mono- and diglycerides from milk fat describes mixing dry glycerol (50% w/w) and NaOH (0.1% w/w)  
306 with solid, crystallizable fractions of butter. The reaction proceeds with constant stirring at controlled  
307 temperature (195°C - 200 °C). To neutralize the catalyst, the mixture is cooled and diatomaceous earth  
308 added. The solid mono- and diglyceride reaction products are separated from unreacted liquid glycerol via  
309 the physical process of decantation. The glycerides are then further purified by vacuum filtration  
310 (Campbell-Timperman, Choi and Jiminez-Flores 1996). The authors also report that, in general, molecular  
311 distillation is used to remove impurities from mono- and diglycerides. Molecular distillation is a physical  
312 separation carried out under high vacuum (around 10<sup>-4</sup> mmHg) and heat (Fregolente, et al. 2006). The low  
313 pressure created by the vacuum allows molecules to pass freely to the condenser, facilitating separation of  
314 substances at the molecular level.  
315

316 Because fats and fatty acids are insoluble in glycerol, organic solvents may be used to force their reaction to  
317 proceed (Hasenhuettl and Hartel 2008). Valerio et al. (2010) used n-butane as a solvent and sodium (bis-2-  
318 ethyl-hexyl) sulfosuccinate (AOT) as a surfactant. They reported that propane is another compressed liquid  
319 that may be used as a solvent in the production of glycerides.  
320

321 Monoglycerides occur in food fats in amounts on the order of one-half to one percent (National Research  
322 Council (U.S.) Food Protection Committee 1952). Lipase is an enzyme which breaks down fats into  
323 monoglycerides and fatty acids. Used in reverse, it can catalyze the esterification of glycerol with fatty  
324 acids (Hasenhuettl and Hartel 2008). A report from Japan looked at oils with a high proportion of diacetyl  
325 glycerols obtained using a regiospecific lipase catalyst (Hou 2005). The author noted that for industrial-  
326 scale production, an immobilized enzyme is ideal so that it can be reused, and stated that only a few  
327 commercially immobilized lipases are available. The organisms used to produce these lipases are  
328 genetically modified. As with the other methods of production, enzyme-catalyzed production of mono-  
329 and diglycerides may or may not involve the use of organic solvents. The literature reviewed for this report  
330 suggests that the mono- and diglycerides produced are separated from unreacted glycerol and presumably  
331 the solvent. However, there is little information available on solvent residues remaining in the glycerides.  
332

333 **Evaluation Question #3: If the substance is a synthetic substance, provide a list of nonsynthetic or**  
334 **natural source(s) of the substance (7 CFR § 205.600 (b) (1)).**  
335

336 Mono and diglycerides are classified as synthetic on at §205.605(b). The predominant methods for their  
337 commercial production are glycerolysis and direct esterification of fatty acids with glycerol, both of which  
338 involve chemical reactions. Enzymatically produced mono- and diglycerides could potentially be  
339 considered nonsynthetic; however, non-GMO versions are not available. None of the literature reviewed  
340 for this report suggests significant commercial availability of nonsynthetic mono- or diglycerides obtained  
341 by the enzymatic hydrolysis of triglycerides.  
342

343 **Evaluation Question #4: Specify whether the substance is categorized as generally recognized as safe**  
344 **(GRAS) when used according to FDA's good manufacturing practices (7 CFR § 205.600 (b)(5)). If not**  
345 **categorized as GRAS, describe the regulatory status.**  
346

347 Mono- and diglycerides are listed at 21 CFR 184.1505 as Direct Food Substances Affirmed as Generally  
348 Recognized as Safe (GRAS). The GRAS listing states that the ingredient may be used in food with no  
349 limitation other than current good manufacturing practice. The good manufacturing practice conditions of

350 use are defined in subsection (c)(1) as follows. "The ingredient is used in food as a dough strengthener as  
351 defined in 170.3(o)(6)<sup>1</sup> of this chapter; an emulsifier and emulsifier salt as defined in 170.3(o)(8)<sup>2</sup> of this  
352 chapter; a flavoring agent and adjuvant as defined in 170.3(o)(12)<sup>3</sup> of this chapter; a formulation aid as  
353 defined in 170.3(o)(14)<sup>4</sup> of this chapter; a lubricant and release agent as defined in 170.3(o)(18)<sup>5</sup> of this  
354 chapter; a solvent and vehicle as defined in 170.3(o)(27)<sup>6</sup> of this chapter; a stabilizer and thickener as  
355 defined in 170.3(o)(28)<sup>7</sup> of this chapter; a surface-active agent as defined in 170.3(o)(29)<sup>8</sup> of this chapter; a  
356 surface-finishing agent as defined in 170.3(o)(30)<sup>9</sup> of this chapter; and a texturizer as defined in  
357 170.3(o)(32)<sup>10</sup> of this chapter. Of these GRAS approved uses, those permitted in organic food processing are  
358 those that aid in the drum drying of food, namely, use as an emulsifier, lubricant and release agent.

359  
360 **Evaluation Question #5: Describe whether the primary technical function or purpose of the substance**  
361 **is a preservative. If so, provide a detailed description of its mechanism as a preservative (7 CFR §**  
362 **205.600 (b)(4)).**  
363

364 Chemical food preservatives are defined under FDA regulations at 21 CFR 101.22(a) (5) as "any chemical  
365 that, when added to food, tends to prevent or retard deterioration thereof, but does not include common  
366 salt, sugars, vinegars, spices, or oils extracted from spices, substances added to food by direct exposure  
367 thereof to wood smoke, or chemicals applied for their insecticidal or herbicidal properties" (FDA 2013).  
368 Mono- and diglycerides are primarily used as emulsifiers. The primary function of emulsifiers is to  
369 facilitate the dispersion of oil in water or water in oil. In many applications, this creates a shelf-stable  
370 product by preventing separation of oils from other liquids in products such as salad dressings  
371 (Hasenhuettl and Hartel 2008), peanut butter, and ice cream. It retards the deterioration of physical  
372 properties of the end product, but does not prevent or retard chemical or microbial contamination.

373  
374 The use for which mono- and diglycerides are permitted in organic food processing, the drum drying of  
375 food, also employs them as an emulsifier. However, in this application, the purpose of the emulsifier is to  
376 reduce stickiness of slurries that are applied to drum roll dryers to facilitate removal once dried. This use  
377 would not be considered that of a preservative according to the FDA definition.

378  
379 **Evaluation Question #6: Describe whether the substance will be used primarily to recreate or improve**  
380 **flavors, colors, textures, or nutritive values lost in processing (except when required by law) and how**  
381 **the substance recreates or improves any of these food/feed characteristics (7 CFR § 205.600 (b)(4)).**  
382

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<sup>1</sup> 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."

<sup>2</sup> 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.

<sup>3</sup> 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.

<sup>4</sup> 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.

<sup>5</sup> 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.

<sup>6</sup> 21 CFR 170.3(o)(27) defines solvents and vehicles as: Substances used to extract or dissolve another substance.

<sup>7</sup> 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.

<sup>8</sup> 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.

<sup>9</sup> 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.

<sup>10</sup> 21 CFR 170.3(o)(30) defines texturizers as: Substances which affect the appearance or feel of the food.

383 When used as an emulsifier in ice creams, mono- and diglycerides are said to improve texture by  
384 decreasing the tension between the fat molecules and the water, allowing the two components to coexist in  
385 the same system and thereby producing a smoother and drier texture (Cropper, et al. 2013). However, this  
386 is not a recreation of texture but rather an enhancement of the role played by the natural emulsifiers in  
387 milk, casein and whey proteins.

388  
389 In drum drying of food, mono- and diglycerides do affect texture, adding lubrication to slurries and  
390 reducing stickiness. However, this is again not a recreation of lost texture but a modification of texture that  
391 develops during processing with the addition of water or other liquid to starch. The use of 0.1%-1% mono-  
392 and diglyceride emulsifier has been proposed to react with free amylose (a starch polysaccharide) in  
393 cooked potato slurry that has become too sticky due to overcooking, resulting in excessive cell rupture  
394 (Martinez-Serna Villagran, Wooten, et al. 2005). This is an example of correction of textural degradation  
395 due to over processing.

396  
397 **Evaluation Question #7: Describe any effect or potential effect on the nutritional quality of the food or**  
398 **feed when the substance is used (7 CFR § 205.600 (b)(3)).**

399  
400 Although mono- and diglycerides have similar properties and comparable calories to triglycerides, or  
401 ordinary fats, they have essentially no caloric impact on food because they are used as additives in small  
402 amounts (less than 1% of a food's total weight) (Environmental Nutrition 1997).

403  
404 One report evaluated the nutritional function of diglycerides produced using a lipase enzyme as compared  
405 to conventional triglyceride oil. The author reported that a Japanese cooking oil containing 80% or more  
406 diglycerides claims a lower elevation in postprandial triglyceride concentrations in the blood after  
407 diglyceride ingestion, as compared to ingestion of the triglyceride with the same fatty acid composition, as  
408 well as less body fat accumulation. However, clinical studies are said to be in progress to confirm the  
409 efficacy of diglyceride oil (Hou). Also, 1,3-diglycerides have been shown to have beneficial effects in  
410 preventing obesity and lipemia (Tangkam, Weber and Wiege 2008) despite having a similar energy value  
411 and digestibility as triglycerides (Valerio, et al. 2010).

412  
413 The Joint FAO/WHO Expert Committee on Food Additives (1974) reported that the various fatty acids  
414 present in mono- and diglycerides are not necessarily absorbed and metabolized in the same way as those  
415 of natural food fats, and that their nutritional significance may also differ. The report cites that long-chain  
416 fatty acids are less digestible than those with unsaturated fatty acids if fed alone or in large quantities, and  
417 administration of many polyunsaturated fatty acids causes depression of blood cholesterol levels whereas  
418 the ingestion of saturated fatty acids tends to increase it (JECFA 1974). Thus, depending on the fatty acid  
419 composition of the mono- and diglycerides and the level at which they are used, some of the above effects  
420 could occur. However, the literature reviewed for this report indicates typical usage levels as a food  
421 processing aid of 0.1 - 1%, with 3% being a maximum (Martinez-Serna Villagran, Wooten, et al. 2005).

422  
423 **Evaluation Question #8: List any reported residues of heavy metals or other contaminants in excess of**  
424 **FDA tolerances that are present or have been reported in the substance (7 CFR § 205.600 (b)(5)).**

425  
426 The Joint FAO/WHO Expert Committee on Food Additives (JECFA) Monograph for mono- and  
427 diglycerides (1973) reports a lead level of not more than 2 mg/kg. The FDA's Action Levels for lead ranges  
428 from 0.5 to 7 µg/ml. Lead levels are not listed for agricultural substances or additives intended for direct  
429 food use (FDA 2000). A review of several MSDSs for commercial mono- and diglycerides products found  
430 no report of heavy metals or other contaminants (Futura Ingredients 2011) (New Directions Laboratory  
431 2013).

432  
433 **Evaluation Question #9: Discuss and summarize findings on whether the manufacture and use of the**  
434 **substance may be harmful to the environment or biodiversity (7 U.S.C. § 6517 (c) (1) (A) (i) and 7 U.S.C. §**  
435 **6517 (c) (2) (A) (i)).**

436

437 Carbon monoxide, carbon dioxide, and unidentified organic compounds may be formed during  
438 combustion of mono- and diglycerides. However, mono- and diglycerides have a low persistence level in  
439 the environment. They are readily biodegradable and have been shown to be non-toxic to fish and aquatic  
440 invertebrates (European Chemicals Agency 1991).

441  
442 Various chemicals may be employed in the manufacture of mono- and diglycerides. The catalyst sodium  
443 hydroxide is the most common. Sodium hydroxide is released into the environment as sodium cations and  
444 hydroxide anions in water, which can decrease the acidity of water. Sodium hydroxide does not  
445 bioaccumulate.

446  
447 The use of organic solvents during glyceride manufacturing is described in several studies, with n-butane  
448 and propane cited specifically. Organic solvents are carbon-based substances capable of dissolving or  
449 dispersing other substances, and while many are recognized by The National Institute for Occupational  
450 Safety and Health as carcinogens, neither propane nor n-butane has a carcinogenicity classification (NIOSH  
451 2013). Both n-butane and propane are highly volatile and widely occurring atmospheric pollutants.  
452 Volatilization is their primary environmental fate; however, adsorption or biodegradation via microbial  
453 digestion may occur in soil and water (Howard 1997). The substance n-butane was found to be present in 6  
454 of 12 human breast milk samples from the U.S. (Howard 1997). The potential effects of n-butane on animals  
455 include frostbite from contact with liquid n-butane and cardiac symptoms as reported in a study on  
456 anesthetized dogs exposed to n-butane (5,000-200,000 ppm) for 2 minutes (CDC 1992). Main sources of  
457 release into the atmosphere for both n-butane and propane include waste incinerators and the combustion  
458 of gasoline. While these solvents have adverse environmental effects, their release into the environment  
459 from the production of mono- and diglycerides is not covered in the literature.

460  
461 **Evaluation Question #10: Describe and summarize any reported effects upon human health from use of**  
462 **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)).**

463  
464 Toxicological studies on the consumption of mono- and diglycerides were summarized by the JEFCA in  
465 1974. The report suggests that mono- and diglycerides have no acute toxicity at practicable dosage levels. It  
466 also reports that in mice fed glyceryl monostearate as their sole fat source, weight gain was not adversely  
467 affected and lactation and reproduction performance were normal. In humans, the mono- and diglycerides  
468 that are most likely to cause undesirable health effects are those which contain long-chain saturated fatty  
469 acids, such as stearic acid. Long-term studies on these compounds have shown increased liver weight in  
470 animals given high fat intake. However, the effects were not considered to have toxicological significance  
471 (JECFA 1974).

472  
473 Mono- and diglycerides are not limited by an Acceptable Daily Intake (ADI) level. They appear in Annex II  
474 of the Report from the Commission on Dietary Food Additive Intake in the European Union: "List of food  
475 additives with ADI (acceptable daily intake) not specified," found acceptable for specified use as  
476 recommended by the SCF (Scientific Committee on Food), or new additives (EU Commission on Dietary  
477 Food Additive Intake 2000). As recently as 2003, the ADI for mono- and diglycerides was listed as "Not  
478 Limited" by the EU Commission (JECFA 2003).

479  
480 **Evaluation Question #11: Describe any alternative practices that would make the use of the substance**  
481 **unnecessary (7 U.S.C. § 6518 (m) (6)).**

482  
483 The scope of use for mono- and diglycerides under current organic regulations is limited to the drum  
484 drying of food. Different methods and machinery are available for drying food products, including spray  
485 drying, freeze drying, infrared drying, the use of fluidized bed dryers, air lift dryers, scraped wall heat  
486 exchangers, drum dryers, etc. Drum drying is said to be the preferred method for making dehydrated  
487 potato flakes (Martinez-Serna Villagran and Beverly 2001), whereas air lift drying and fluidized bed drying  
488 are preferred when making potato granules. Freeze drying has been suggested as an acceptable alternative  
489 to drum drying, and infrared drying is often used in combination with drum drying (Martinez-Serna  
490 Villagran, Wooten, et al. 2005).

491

492 One patent describes a method for drum drying mashed potatoes without the use of any emulsifier. The  
 493 procedure involves the dilution of the potato slurry, normally 22%-26% solids, with water down to 18%-  
 494 20% solids, prior to drying. This enables a nearly monocellular layer to be applied to the dryer with greater  
 495 uniformity, resulting in improved heat transfer and ultimately lower moisture content of the dried product.  
 496 Following drying, the potatoes are extruded in sheets that are broken, screened and packaged. The patent  
 497 does not cite a need to use an emulsifier to prevent sticking to the drum dryer (Cording and Willard 1956).  
 498

499 A newer alternative to the traditional thin-film drying methods described above is the use of a water-vapor  
 500 permeable drying surface. Trials of this method using modified corn, potato, and rice starch films showed  
 501 much faster drying times and higher quality end product as compared to the traditional thin-film drying  
 502 (Browser and Wilhelm 1996).  
 503

504 **Evaluation Question #12: Describe all natural (non-synthetic) substances or products which may be**  
 505 **used in place of a substance (7 U.S.C. § 6517 (c) (1) (A) (ii)). Provide a list of allowed substances that**  
 506 **may be used in place of the substance (7 U.S.C. § 6518 (m) (6)).**  
 507

508 Although mono- and diglycerides are the preferred emulsifiers for reducing stickiness of potato mashes  
 509 before they are drum dried into flakes (Martinez-Serna Villagran and Beverly 2001), other emulsifiers such  
 510 as lecithin are said to also be suitable in the production of potato flake products (Martinez-Serna Villagran,  
 511 Wooten, et al. 2005). De-oiled lecithin appears at §205.606 of the National List and may be nonorganic  
 512 when not commercially available in organic form. Gum arabic, discussed below in #13, also appears at  
 513 §205.606 and may be used in nonorganic form if not commercially available as organic.  
 514

515 Other emulsifiers that have been suggested as alternatives to mono- and diglycerides in the drum drying of  
 516 food are synthetic, such as lactylate esters, sorbitan esters, propylene glycol mono- and diesters, and  
 517 polyglycerol (Martinez-Serna Villagran and Beverly 2001).  
 518

519 **Evaluation Question #13: Provide a list of organic agricultural products that could be alternatives for**  
 520 **the substance (7 CFR § 205.600 (b) (1)).**  
 521

522 One commercial product, a certified organic rice bran extract called Nu-RICE by Ribus, is marketed as an  
 523 emulsifier and drum release agent that can act as a replacement for mono- and diglycerides (Ribus, Inc.  
 524 2015). The producer carried out experiments to test the product’s efficacy as an emulsifier as compared to  
 525 other emulsifiers in the marketplace. The results of their trial are shown in Table 2. Ribus concluded from  
 526 the results that egg and their own product, rice bran extract (RBE), had the highest capacity for oil-in-water  
 527 binding. The RBE showed more uniform dispersion of the oil droplets than did the soy lecithin or oil and  
 528 water alone (Ribus, Inc. 2013). The hydrophylic-lipophilic balance (HLB) of RBE is narrower than that of  
 529 mono- and diglycerides, which may make it less versatile as an emulsifier depending on the composition of  
 530 the mix to which it is added.  
 531  
 532  
 533

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

Ingredients	Capacity	Stability	HLB
Egg (1)	1.2	1.2	5 - 8
RBE (2,3)	1.12	1.12	14.5 - 15
Mono's & Di (1)	1.0	1.0	8 - 14
Soy Lecithin (2, 3)	0.96	0.88	4 - 12
Reference Measure			
Oil + Water	0.08	0.08	NA
Water	0	0	NA

538

539 In addition to soy lecithin, gum arabic has been cited as an additive for producing drum-dried jackfruit  
540 powder (Nussinovitch 2009), used to counteract the stickiness of the fruit due to its high sugar content.  
541 Gum arabic is characterized by very high water solubility (as opposed to glycerides), low viscosity, and an  
542 absence of odor, color and flavor (De Vries, Semeijn and Buwalda 2010). However, its use in drum dried  
543 food is not widely reported. Lecithin, on the other hand, is a common emulsifier. As compared to mono-  
544 and diglycerides, lecithin provides less emulsion stability, much less starch interaction, more fat  
545 modification, and has a higher HLB (Brentagg Food & Nutrition Europe 2014). It is also a better dough  
546 conditioner, but provides much less aeration than mono- and diglycerides (O'Brien 2004). In general, each  
547 emulsifier (and its form) is selected based on specifications of the food and the processing application.

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

552  
553

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