



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 175, 176, 177, and 178

[Docket No. FDA-2018-F-3757]

Indirect Food Additives: Adhesives and Components of Coatings; Paper and Paperboard Components; Polymers; Adjuvants, Production Aids, and Sanitizers

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA or we) is amending the food additive regulations to no longer provide for the use of 25 plasticizers in various food contact applications because these uses have been abandoned. We are taking this action in response to a food additive petition submitted by the Flexible Vinyl Alliance (FVA or petitioner).

DATES: This rule is effective [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. See section VIII for further information on the filing of objections. Submit either electronic or written objections and requests for a hearing on the final rule by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit objections and requests for a hearing as follows. Please note that late, untimely filed objections will not be considered. Electronic objections must be submitted on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Objections received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic objections in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Objections submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your objection will be made public, you are solely responsible for ensuring that your objection does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your objection, that information will be posted on <https://www.regulations.gov>.
- If you want to submit an objection with confidential information that you do not wish to be made available to the public, submit the objection as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper objections submitted to the Dockets Management Staff, FDA will post your objection, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2018-F-3757 for "Indirect Food Additives: Adhesives and Components of Coatings; Paper and Paperboard Components; Polymers; Adjuvants, Production Aids, and Sanitizers." Received objections, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for

those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit an objection with confidential information that you do not wish to be made publicly available, submit your objections only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” We will review this copy, including the claimed confidential information, in our consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

FOR FURTHER INFORMATION CONTACT: Stephen DiFranco, Office of Food Additive Safety (HFS-255), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740-3835, 240-402-2710; or Alexandra Jurewitz, Office of Regulations and Policy (HFS-024), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2378.

SUPPLEMENTARY INFORMATION:

I. Background

In the *Federal Register* of November 14, 2018 (83 FR 56750), we announced that we filed a food additive petition (FAP 8B4820), submitted by FVA, c/o Keller and Heckman LLP, 1001 G Street NW., Suite 500 West, Washington, DC 20001. The petition proposed that we amend our food additive regulations in parts 175, 176, 177, and 178 (21 CFR parts 175, 176, 177, and 178) to no longer provide for the use of 26 plasticizers that the petition identifies as *ortho*-phthalates because these food additive uses have been permanently abandoned. In some cases, these substances were approved for food additive uses more than four decades ago.

One of the 26 plasticizers identified in the petition was diallyl phthalate (Chemical Abstract Services number (CAS No.) 131-17-9). The filing notice indicated that this substance may be used as a food additive under §§ 175.105, 176.180, 176.300, and 177.1210 (see 83 FR 56750). However, upon further review, we determined that the use of diallyl phthalate is only authorized for use in these regulations as a monomer to produce polymers and not as a plasticizer. FVA makes no claims in their petition that the use of polymers produced with diallyl phthalate for food contact applications have been abandoned. Thus, after following up with the petitioner, diallyl phthalate is no longer subject to this petition, and diallyl phthalate will not be discussed further. In sum, there are 25 remaining substances that are the subject of this petition; their corresponding CAS numbers (when available) are listed in table 1.

Table 1.--*Ortho*-phthalates Affected by this Final Rule

Food Additive	CAS No.
---------------	---------

Dimethyl phthalate (dimethyl orthophthalate)	131-11-3
Diphenyl phthalate	84-62-8
Methyl phthalyl ethyl glycolate (1,2-Benzenedicarboxylic acid, 1-(2-ethoxy-2-oxoethyl) 2-methyl ester)	85-71-2
Diethyl phthalate	84-66-2
Diphenylguanidine phthalate ¹	17573-13-6
Ethyl phthalyl ethyl glycolate (Ethyl carbethoxymethyl phthalate)	84-72-0
Diisobutyl phthalate	84-69-5
Butyl benzyl phthalate ²	85-68-7
Di-n-butyl phthalate ³	84-74-2
Butyl phthalyl butyl glycolate ⁴ (Butyl carbobutoxymethyl phthalate)	85-70-1
Dihexyl phthalate (Di-n-hexyl phthalate)	84-75-3
Di(butoxyethyl) phthalate (Bis(2-n-butoxyethyl) phthalate)	117-83-9
Dimethylcyclohexyl phthalate	1322-94-7
Diisooctyl phthalate	27554-26-3
Dioctyl phthalate (Di-n-octyl phthalate)	117-84-0
Butyloctyl phthalate (n-butyl n-octyl phthalate)	84-78-6
Di(2-ethylhexyl) hexahydrophthalate ¹	84-71-9
Amyl decyl phthalate (n-amyl n-decyl phthalate)	7493-81-4
Butyl decyl phthalate ⁵ (n-butyl n-decyl phthalate)	89-19-0
Decyl octyl phthalate (Octyldecyl phthalate/n-octyl n-decyl phthalate)	119-07-3
Didecyl phthalate (Di-n-decyl phthalate)	84-77-5
Dodecyl phthalate	21577-80-0
Dihydroabietyl phthalate	26760-71-4
Castor oil phthalate, hydrogenated	None available (N/A)
Castor oil phthalate with adipic acid and fumaric acid-diethylene glycol ⁶	68650-73-7

¹ We note that while these substances are not chemically classified as *ortho*-phthalates, they are included in FAP 8B4820. The FAP describes all of the substances as *ortho*-phthalates, although for these substances that characterization is incorrect.

² The petitioner refers to this substance as butyl benzyl phthalate; it is listed in §§ 176.170 and 178.3740 as butylbenzyl phthalate. These terms are synonymous, referring to the same chemical substance.

³ The petitioner refers to this substance as di-n-butyl phthalate; it is listed in §§ 175.105, 175.300, 175.380, 176.170, 176.180, 176.300, 177.2420, and 177.2600 as dibutyl phthalate and in § 177.1200 as dibutylphthalate. These terms are synonymous, referring to the same chemical substance.

⁴ Substance is listed as butyl phthalate butyl glycolate in § 175.105. We believe this is a typographical error, and it should be listed as butyl phthalyl butyl glycolate.

⁵ The petitioner refers to this substance as butyl decyl phthalate; it is listed in § 175.105 as butyldecyl phthalate. These terms are synonymous, referring to the same chemical substance.

⁶ The petitioner refers to this substance as castor oil phthalate with adipic acid and fumaric acid-diethylene glycol; it is listed in § 177.1200 as castor oil phthalate with adipic acid and fumaric acid-diethylene glycol polyester. These terms are synonymous, referring to the same chemical substance.

The petitioner asserts that the currently authorized uses of the plasticizers identified in tables 2 through 19 have been abandoned. In addition to the uses of the 25 plasticizers that are approved for food additive uses as described in tables 2 through 19, certain plasticizers that are the subject of the petition are also authorized for prior sanctioned uses. Any such prior sanctioned use is beyond the scope of a food additive petition, which applies only to substances

that meet the definition of “food additive.” Accordingly, this final rule has no impact on any prior sanctioned uses.

Table 2.--*Ortho*-phthalates Authorized by § 175.105 Affected by this Final Rule (“Adhesives”)

Food Additive	CAS No.
Dimethyl phthalate (dimethyl orthophthalate)	131-11-3
Diphenyl phthalate	84-62-8
Methyl phthalyl ethyl glycolate (1,2-Benzenedicarboxylic acid, 1-(2-ethoxy-2-oxoethyl) 2-methyl ester)	85-71-2
Diethyl phthalate	84-66-2
Ethyl phthalyl ethyl glycolate (Ethyl carbethoxymethyl phthalate)	84-72-0
Diisobutyl phthalate	84-69-5
Butyl benzyl phthalate	85-68-7
Di-n-butyl phthalate ¹	84-74-2
Butyl phthalyl butyl glycolate ² (Butyl carbobutoxymethyl phthalate)	85-70-1
Dihexyl phthalate (Di-n-hexyl phthalate)	84-75-3
Di(butoxyethyl) phthalate (Bis(2-n-butoxyethyl) phthalate)	117-83-9
Diisooctyl phthalate	27554-26-3
Dioctyl phthalate (Di-n-octyl phthalate)	117-84-0
Butyloctyl phthalate (n-butyl n-octyl phthalate)	84-78-6
Di(2-ethylhexyl) hexahydrophthalate	84-71-9
Butyl decyl phthalate ³ (n-butyl n-decyl phthalate)	89-19-0
Decyl octyl phthalate (Octyldecyl phthalate/n-octyl n-decyl phthalate)	119-07-3
Dihydroabietyl phthalate	26760-71-4

¹ The petitioner refers to this substance as di-n-butyl phthalate; it is listed in § 175.105 as dibutyl phthalate. These terms are synonymous, referring to the same chemical substance.

² The petitioner refers to this substance as butyl phthalyl butyl glycolate; it is listed in § 175.105 as butyl phthalate butyl glycolate. We believe this is a typographical error, and it should be listed as butyl phthalyl butyl glycolate. These terms are synonymous, referring to the same chemical substance.

³ The petitioner refers to this substance as butyl decyl phthalate; it is listed in § 175.105 as butyldecyl phthalate. These terms are synonymous, referring to the same chemical substance.

Table 3.--*Ortho*-phthalates Authorized by § 175.300 Affected by this Final Rule (“Resinous and polymeric coatings”)

Food Additive	CAS No.
Diethyl phthalate	84-66-2
Ethyl phthalyl ethyl glycolate (Ethyl carbethoxymethyl phthalate)	84-72-0
Di-n-butyl phthalate ¹	84-74-2
Butyl phthalyl butyl glycolate (Butyl carbobutoxymethyl phthalate)	85-70-1
Diisooctyl phthalate	27554-26-3

¹ The petitioner refers to this substance as di-n-butyl phthalate; it is listed in § 175.300 as dibutyl phthalate. These terms are synonymous, referring to the same chemical substance.

Table 4.--*Ortho*-phthalates Authorized by § 175.320 Affected by this Final Rule (“Resinous and polymeric coatings for polyolefin films”).

Food Additive	CAS No.
Diethyl phthalate	84-66-2
Ethyl phthalyl ethyl glycolate (Ethyl carbethoxymethyl phthalate)	84-72-0
Butyl phthalyl butyl glycolate (Butyl carbobutoxymethyl phthalate)	85-70-1

Table 5.--*Ortho*-phthalates Authorized by § 175.380 Affected by this Final Rule (“Xylene-formaldehyde resins condensed with 4,4’-isopropylidenediphenol-epichlorohydrin epoxy resins”)

Food Additive	CAS No.
Diethyl phthalate ¹	84-66-2
Ethyl phthalyl ethyl glycolate ¹ (Ethyl carbethoxymethyl phthalate)	84-72-0
Di-n-butyl phthalate ^{1,2}	84-74-2
Butyl phthalyl butyl glycolate ¹ (Butyl carbobutoxymethyl phthalate)	85-70-1
Diisooctyl phthalate ¹	27554-26-3

¹ By cross-referencing § 175.300, § 175.380 authorizes use of this plasticizer.

² The petitioner refers to this substance as di-n-butyl phthalate; it is listed in § 175.300 as dibutyl phthalate. These terms are synonymous, referring to the same chemical substance.

Table 6.--*Ortho*-phthalates Authorized by § 175.390 Affected by this Final Rule (“Zinc-silicon dioxide matrix coatings”)

Food Additive	CAS No.
Diethyl phthalate ¹	84-66-2
Ethyl phthalyl ethyl glycolate ¹ (Ethyl carbethoxymethyl phthalate)	84-72-0
Di-n-butyl phthalate ^{1,2}	84-74-2
Butyl phthalyl butyl glycolate ¹ (Butyl carbobutoxymethyl phthalate)	85-70-1
Diisooctyl phthalate ¹	27554-26-3

¹ By cross-referencing § 175.300, § 175.390 authorizes use of this plasticizer.

² The petitioner refers to this substance as di-n-butyl phthalate; it is listed in § 175.300 as dibutyl phthalate. These terms are synonymous, referring to the same chemical substance.

Table 7.--*Ortho*-phthalates Authorized by § 176.170 Affected by this Final Rule (“Components of paper and paperboard in contact with aqueous and fatty foods”)

Food Additive	CAS No.
Butyl benzyl phthalate ¹	85-68-7
Di-n-butyl phthalate ²	84-74-2

¹ The petitioner refers to this substance as butyl benzyl phthalate; it is listed in § 176.170 as butylbenzyl phthalate. These terms are synonymous, referring to the same chemical substance.

² The petitioner refers to this substance as di-n-butyl phthalate; it is listed in § 176.170 as dibutyl phthalate. These terms are synonymous, referring to the same chemical substance.

Table 8.--*Ortho*-phthalates Authorized by § 176.180 Affected by this Final Rule (“Components of paper and paperboard in contact with dry food”)

Food Additive	CAS No.
Butyl benzyl phthalate ¹	85-68-7
Di-n-butyl phthalate ^{1,2}	84-74-2
Didecyl phthalate ¹ (Di-n-decyl phthalate)	84-77-5
Dodecyl phthalate ¹	21577-80-0

¹ By cross-referencing § 176.170, § 176.180 authorizes use of this plasticizer.

² The petitioner refers to this substance as di-n-butyl phthalate; it is listed in § 176.170 as dibutyl phthalate. These terms are synonymous, referring to the same chemical substance.

Table 9.--*Ortho*-phthalates Authorized by § 176.300 Affected by this Final Rule (“Slimicides”)

Food Additive	CAS No.
Butyl benzyl phthalate ¹	85-68-7
Di-n-butyl phthalate ²	84-74-2
Didecyl phthalate (Di-n-decyl phthalate)	84-77-5
Dodecyl phthalate	21577-80-0

¹ By cross-referencing §§ 176.170 and 176.180, § 176.300 authorizes use of this plasticizer.

² The petitioner refers to this substance as di-n-butyl phthalate; it is listed in § 176.300 as dibutyl phthalate. These terms are synonymous, referring to the same chemical substance.

Table 10.--*Ortho*-phthalates Authorized by § 177.1010 Affected by this Final Rule (“Acrylic and modified acrylic plastics, semirigid and rigid”)

Food Additive	CAS No.
Dimethyl phthalate (dimethyl orthophthalate)	131-11-3

Table 11.--*Ortho*-phthalates Authorized by § 177.1200 Affected by this Final Rule (“Cellophane”)

Food Additive	CAS No.
Diisobutyl phthalate	84-69-5
Di-n-butyl phthalate ¹	84-74-2
Dimethylcyclohexyl phthalate	1322-94-7
Castor oil phthalate, hydrogenated	N/A
Castor oil phthalate with adipic acid and fumaric acid-diethylene glycol ²	68650-73-7

¹ The petitioner refers to this substance as di-n-butyl phthalate; it is listed in § 177.1200 as dibutylphthalate. These terms are synonymous, referring to the same chemical substance.

² The petitioner refers to this substance as castor oil phthalate with adipic acid and fumaric acid-diethylene glycol; it is listed in § 177.1200 as castor oil phthalate with adipic acid and fumaric acid-diethylene glycol polyester. These terms are synonymous, referring to the same chemical substance.

Table 12.--*Ortho*-phthalates Authorized by § 177.1210 Affected by this Final Rule (“Closures with sealing gaskets for food containers”)

Food Additive	CAS No.
Diethyl phthalate ^{1,2}	84-66-2
Ethyl phthalyl ethyl glycolate ¹ (Ethyl carbethoxymethyl phthalate)	84-72-0
Di-n-butyl phthalate ^{1,3-5}	84-74-2
Butyl phthalyl butyl glycolate ¹ (Butyl carbobutoxymethyl phthalate)	85-70-1
Diisooctyl phthalate ¹	27554-26-3
Dimethyl phthalate ^{1,4} (dimethyl orthophthalate)	131-11-3
Diphenyl phthalate ^{1,2}	84-62-8
Methyl phthalyl ethyl glycolate ¹ (1,2-Benzenedicarboxylic acid, 1-(2-ethoxy-2-oxoethyl) 2-methyl ester)	85-71-2
Diphenylguanidine phthalate ⁴	17573-13-6
Diisobutyl phthalate ^{1,4}	84-69-5
Butyl benzyl phthalate ¹⁻⁴	85-68-7
Dihexyl phthalate (Di-n-hexyl phthalate) ^{1,2}	84-75-3
Di(butoxyethyl) phthalate ¹ (Bis(2-n-butoxyethyl) phthalate)	117-83-9
Dimethylcyclohexyl phthalate ⁴	1322-94-7
Diocetyl phthalate ^{1,4} (Di-n-octyl phthalate)	117-84-0
Butyloctyl phthalate ¹ (n-butyl n-octyl phthalate)	84-78-6
Di(2-ethylhexyl) hexahydrophthalate ¹	84-71-9
Amyl decyl phthalate ⁴ (n-amyl n-decyl phthalate)	7493-81-4
Butyl decyl phthalate ¹ (n-butyl n-decyl phthalate)	89-19-0
Decyl octyl phthalate ^{1,4} (Octyldecyl phthalate/n-octyl n-decyl phthalate)	119-07-3
Didecyl phthalate ^{3,4} (Di-n-decyl phthalate)	84-77-5
Dodecyl phthalate ³	21577-80-0
Dihydroabietyl phthalate ¹	26760-71-4
Castor oil phthalate, hydrogenated ⁴	N/A
Castor oil phthalate with adipic acid and fumaric acid-diethylene glycol ^{4,6}	68650-73-7

¹ By cross-referencing part 175, § 177.1210 authorizes use of this plasticizer.

² By cross-referencing part 178, § 177.1210 authorizes use of this plasticizer.

³ By cross-referencing part 176, § 177.1210 authorizes use of this plasticizer

⁴ By cross-referencing part 177, § 177.1210 authorizes use of this plasticizer.

⁵ The petitioner refers to this substance as di-n-butyl phthalate; it is listed in §§ 175.105, 175.300, 175.380, 176.170, 176.180, 176.300, 177.2420, and 177.2600 as dibutyl phthalate and in § 177.1200 as dibutylphthalate. These terms are synonymous, referring to the same chemical substance.

⁶ The petitioner refers to this substance as castor oil phthalate with adipic acid and fumaric acid-diethylene glycol; it is listed in § 177.1200 as castor oil phthalate with adipic acid and fumaric acid-diethylene glycol polyester. These terms are synonymous, referring to the same chemical substance.

Table 13.--*Ortho*-phthalates Authorized by § 177.1400 Affected by this Final Rule
("Hydroxyethyl cellulose film, water-insoluble")

Food Additive	CAS No.
Diisobutyl phthalate ¹	84-69-5
Di-n-butyl phthalate ^{1,2}	84-74-2
Dimethylcyclohexyl phthalate ¹	1322-94-7
Castor oil phthalate, hydrogenated ¹	N/A
Castor oil phthalate with adipic acid and fumaric acid-diethylene glycol ^{1,3}	68650-73-7

¹ By cross-referencing § 177.1200, § 177.1400 authorizes use of this plasticizer.

² The petitioner refers to this substance as di-n-butyl phthalate; it is listed in § 177.1200 as dibutylphthalate. These terms are synonymous, referring to the same chemical substance.

³ The petitioner refers to this substance as castor oil phthalate with adipic acid and fumaric acid-diethylene glycol; it is listed in § 177.1200 as castor oil phthalate with adipic acid and fumaric acid-diethylene glycol polyester. These terms are synonymous, referring to the same chemical substance.

Table 14.--*Ortho*-phthalates Authorized by § 177.1460 Affected by this Final Rule
("Melamine-formaldehyde resins in molded articles")

Food Additive	CAS No.
Dioctyl phthalate (Di-n-octyl phthalate)	117-84-0

Table 15.--*Ortho*-phthalates Authorized by § 177.1590 Affected by this Final Rule ("Polyester elastomers")

Food Additive	CAS No.
Dimethyl phthalate (dimethyl orthophthalate)	131-11-3

Table 16.--*Ortho*-phthalates Authorized by § 177.2420 Affected by this Final Rule ("Polyester resins, cross-linked")

Food Additive	CAS No.
Dimethyl phthalate (dimethyl orthophthalate)	131-11-3
Butyl benzyl phthalate	85-68-7
Di-n-butyl phthalate ¹	84-74-2

¹ The petitioner refers to this substance as di-n-butyl phthalate; it is listed in § 177.2420 as dibutyl phthalate. These terms are synonymous, referring to the same chemical substance.

Table 17.--*Ortho*-phthalates Authorized by § 177.2600 Affected by this Final Rule ("Rubber articles intended for repeated use")

Food Additive	CAS No.
Diphenylguanidine phthalate	17573-13-6
Di-n-butyl phthalate ¹	84-74-2
Dioctyl phthalate (Di-n-octyl phthalate)	117-84-0
Amyl decyl phthalate (n-amyl n-decyl phthalate)	7493-81-4
Decyl octyl phthalate (Octyldecyl phthalate/n-octyl n-decyl phthalate)	119-07-3

Didecyl phthalate (Di-n-decyl phthalate)	84-77-5
--	---------

¹ The petitioner refers to this substance as di-n-butyl phthalate; it is listed in § 177.2600 as dibutyl phthalate. These terms are synonymous, referring to the same chemical substance.

Table 18.--*Ortho*-phthalates Authorized by § 178.3740 Affected by this Final Rule (“Plasticizers in polymeric substances”)

Food Additive	CAS No.
Diphenyl phthalate	84-62-8
Butyl benzyl phthalate ¹	85-68-7
Dihexyl phthalate (Di-n-hexyl phthalate)	84-75-3

¹ The petitioner refers to this substance as Butyl benzyl phthalate; it is listed in § 178.3740 as butylbenzyl phthalate. These terms are synonymous, referring to the same chemical substance.

Table 19.--*Ortho*-phthalates Authorized by § 178.3910 Affected by this Final Rule (“Surface lubricants used in the manufacture of metallic articles”)

Food Additive	CAS No.
Diethyl phthalate	84-66-2

II. Evaluation of Abandonment

Section 409(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 348(i)) states that we must, by regulation, establish the procedure for amending or repealing a food additive regulation and that this procedure must conform to the procedure provided in section 409 of the FD&C Act for the promulgation of such regulations. Our regulations pertaining to administrative actions for food additives provide that the Commissioner of Food and Drugs, on his own initiative or on the petition of any interested person, under 21 CFR part 10, may propose the issuance of a regulation amending or repealing a regulation pertaining to a food additive or granting or repealing an exception for such additive (§ 171.130(a) (21 CFR 171.130(a))). The regulations further provide that any such petition must include an assertion of facts, supported by data, showing that new information exists with respect to the food additive or that new uses have been developed or old uses abandoned, that new data are available as to toxicity of the chemical, or that experience with the existing regulation or exemption may justify its amendment or repeal (§ 171.130(b)). New data must be furnished in the form specified in §§ 171.1 and 171.100 (21 CFR 171.1 and 171.100) for submitting petitions (§ 171.130(b)). Under these regulations, a petitioner may propose that we amend a food additive regulation if the petitioner can demonstrate that there are “old uses abandoned” for the relevant food additive (§

171.130(b)). Such abandonment must be complete and permanent for any intended uses in the United States market. While section 409 of the FD&C Act and § 171.130 also provide for amending or revoking a food additive regulation based on safety, an amendment or revocation based on abandonment is not based on safety but is based on the fact that regulatory authorization is no longer necessary because the use of that food additive has been completely and permanently abandoned.

Abandonment may be limited to certain authorized food additive uses for a substance (e.g., if a substance is no longer used in certain product categories), or abandonment may apply to all authorized food additive uses of a substance (e.g., if a substance is no longer being manufactured). If a petition seeks an amendment to a food additive regulation based on the abandonment of certain uses of the food additive, such uses should be adequately defined so that both the scope of the abandonment and any amendment to the food additive regulation are clear.

The petition states that FVA is a coalition that represents the plasticizer and vinyl products industry. Their membership consists of 11 plasticizer suppliers, 5 compounders, 5 non-profit industry groups, 4 manufacturers, 2 resin suppliers, 1 converter, and 11 other firms (Ref. 1).

As support for the claim that the plasticizers in table 1 are no longer manufactured, imported, or otherwise marketed for the identified food contact applications in the United States market and that the described uses are abandoned, the petition includes the results of a survey conducted on behalf of FVA. According to the petition, the survey was distributed to FVA's membership as well as other industry stakeholders. More specifically, FVA asked the survey recipients to sign letters that verify that they do not:

1. Currently manufacture the *ortho*-phthalates listed in table 1 for use in food contact applications in the United States;
2. Currently import the *ortho*-phthalates listed in table 1 for use in food contact applications in the United States;

3. Intend to manufacture or import the *ortho*-phthalates listed in table 1 for use in food contact applications in the United States in the future;
4. Currently maintain any inventory of the *ortho*-phthalates listed in table 1 for sale or distribution into commerce that is intended to be marketed for use in food contact applications in the United States; and
5. Possess any knowledge that the *ortho*-phthalates listed in table 1 are used in food contact applications in the United States.

There are 18 signed letters that are attached to the petition. These signed letters, some of which are directly from manufacturers of *ortho*-phthalates, assert that the survey recipients do not engage in any of the activities outlined in the five questions in the survey letters. The petition states that the survey letters collected include the substantial majority of phthalate and polyvinyl chloride manufacturers, as well as downstream compounders and users of these materials.

FVA also sought confirmation from the Plastics Industry Association's (PIA) Food, Drug and Cosmetic Packaging Materials Committee (FDCPMC) that no member company has any knowledge of the manufacturing or marketing of the plasticizers in table 1 for food contact applications. The FDCPMC is composed of PIA members with what the petition describes as particular interest and expertise in packaging for food, drugs, cosmetics, and related products. According to the petition, PIA's members represent entities in each sequence of the plastics industry supply chain, including processors, machinery and equipment manufacturers, and raw material suppliers.

The petition states that FVA also verified with other key industry stakeholders that they do not have any knowledge of the manufacturing or marketing of the substances in table 1 for food contact applications. These stakeholders included members of the Adhesives and Sealants Council, whose membership includes entities involved in the supply, manufacture, and distribution of adhesives and sealants in North America; the American Beverage Association,

which represents beverage producers, distributors, franchise companies and support industries; the American Forest and Paper Association, which the petition describes as having member companies that produce more than 75 percent of the pulp, paper, paper-based packaging, and wood building materials in the United States; the Grocery Manufacturers Association,¹ which the petition describes as representing more than 250 food, beverage, and consumer product companies globally; and the High Phthalates Panel of the American Chemistry Council (ACC). Specifically, the petition states that no member companies of these organizations have any knowledge of industry reliance on the subject food additive approvals. In followup correspondence with FDA, FVA stated these trade associations either contacted their entire memberships or the relevant portions of their memberships that would have knowledge regarding the use of *ortho*-phthalates (Ref. 2).

Furthermore, FDA identified the major manufacturers of *ortho*-phthalates in the United States (Ref. 3) and notes that these manufacturers are listed as member companies of the ACC (Ref. 4). FDA considers the totality of the parties surveyed to be representative of the entire supply-chain of food contact substances and end-use products which may rely on the authorizations in parts 175, 176, 177, and 178 for the use of plasticizers identified in tables 2 through 19.

In addition, when we publish a notice of filing of a food additive petition, stakeholders have an opportunity to provide information regarding whether any of the subject food additives are still being used. We received no comments that provided evidence of current use.

In light of the evidence submitted in the petition, as well as the absence of any evidence demonstrating lack of abandonment, we are granting the petition. We conclude that the plasticizers in table 1 have been completely and permanently abandoned with respect to the food additive uses listed in tables 2 through 19. Accordingly, FDA is removing the authorizations for

¹ The Grocery Manufacture's Association (GMA) became the Consumer Brands Association (CBA) in January 2020.

the food additive use of these substances in parts 175, 176, 177, and 178, as described in tables 2 through 19.

III. Comments on the Filing Notice

We provided 60 days for comment on the filing notice. We received less than 10 comments. No comments provided evidence that any of the 25 plasticizers that are the subject, and within the scope, of FVA's petition are currently being used in food contact applications. Most comments were general in nature and supported granting the petition. These comments expressed support for removing listings for substances that are no longer in use from the food additive regulations.

We summarize and respond to the comments in the following paragraphs. For ease of reading, we preface each comment discussion with a numbered "Comment," and the word "Response" appears before FDA's response. The number assigned is for organizational purposes only and does not signify any individual comment's value, importance, or order in which it was received.

(Comment 1) One comment expressed concern regarding the safety of diethyl phthalate.

(Response 1) Diethyl phthalate (CAS No. 84-66-2) is included in table 1 as a substance that has been abandoned as a food additive in food contact uses. As stated in the filing notice (83 FR 56750 at 56758), information on safety is not relevant to abandonment. To the extent that the comment suggests that FDA must make a safety determination as part of the review process for this abandonment petition, we disagree. Each year, we respond to hundreds of submissions under the various petition and notification programs we administer. Therefore, if use of a food additive is no longer authorized in response to an abandonment petition, we may determine that it is neither necessary nor an efficient use of our limited resources to address safety arguments related to an abandoned use.

(Comment 2) One comment encouraged FDA to abide by statutory timelines and suggested that we improperly delayed posting the filing notice in the *Federal Register*.

(Response 2) We acknowledge that there was a delay in the publication of the filing notice. We filed FVA's petition on July 3, 2018, and published the filing notice in the *Federal Register* on November 14, 2018. However, this delay did not affect the length of the 60-day comment period for the petition or the outcome of FDA's review of the petition.

(Comment 3) One comment sought clarity as to whether certain *ortho*-phthalates that were not the subject of this petition remain authorized for food contact use.

(Response 3) This final rule impacts only the specific *ortho*-phthalates that are the subject of the petition, for the uses identified in the petition. We acknowledge that some *ortho*-phthalates continue to be permitted for use in food contact applications, either as prior sanctioned ingredients or through food additive regulations.

(Comment 4) One comment stated that FDA did not explain how the petition affects installed food handling equipment containing "abandoned" *ortho*-phthalates. The comment expressed concern that the survey questions offered in support of the abandonment claim do not clearly capture the use of these substances in repeat use food contact substances such as conveyors, tubing, and other equipment currently installed in food manufacturing facilities. The comment asserted that for these uses to be abandoned, industry must not only cease to manufacture or sell items containing these plasticizers, but any remaining equipment containing the 26 plasticizers must not be used. The comment also requested that, if the petition is granted, we state that continued use of installed equipment containing the abandoned substances/plasticizers that come into contact with food is unlawful and that the food would be adulterated.

(Response 4) We disagree with the assertion that FVA's survey fails to address repeat-use items. Questions 1, 2, and 4 of FVA's survey encompass broad types of intended use. Specifically, these questions ask about current manufacturing, importing, and distribution of the subject *ortho*-phthalates for "food-contact applications," a broad term that arguably includes any food-contact use of the subject *ortho*-phthalates. Question 3 has the same scope but is specific to

the survey recipients' future plans. Regarding installed food processing equipment that may contain any of the substances in table 1, the comment did not provide any evidence showing that there is use of the subject substances in repeat-use food contact applications. We note that repeated-use food handling equipment typically has a finite lifetime. The petitioner provided information concerning the typical useful lifetime of some food handling equipment and noted that these lifetimes vary based on the operating conditions but are roughly 300 to 500 days for food handling conveyer belts, flexible tubing, and gaskets. This information is contained in Food Additive Master File No. 954, which was incorporated by reference into FAP 8B4820 by the petitioner. The petitioner characterized the approximate lifetimes provided as conservative estimates of the usable lifetimes of repeat-use articles subject to these regulations (Ref. 2).

In assessing other food additive uses, FDA has compiled representative exposure scenarios of repeat use food handling articles based on data collected through the Food Contact Notification Program (Ref. 5). We note that the estimated standardized lifetimes (i.e., the amount of time an article such as a conveyor belt can function before needing replacement) in these scenarios are 365 days for polymer conveyor belts (Ref. 6), flexible polymer tubing (Ref. 7), and polymer o-rings (Ref. 8). Likewise, estimates of dietary exposure from the use of lubricants, which may contain a plasticizer, used on food handling equipment (e.g., bearings, surfaces) assume that relubrication is required between 600 to 4000 machine operating hours. This is approximately 25 to 167 days, assuming nonstop operation (Ref. 8). Thus, lubricants are replaced on a relatively frequent basis.

As such, any of these types of repeat-use items that may have been in use as of July 2018, at the time this petition was filed, would be expected to be past the end of their usable life. Considering these estimated lifetimes and the evidence suggesting that there would not be replacement products containing the abandoned substances, we do not agree that there is reason to question the evidence supporting abandonment in the context of repeat-use food handling equipment.

With respect to the request that FDA state that continued use of installed equipment containing the abandoned substances/plasticizers that come into contact with food is unlawful and that the food would be adulterated, we decline. It would be premature for FDA to comment on the legal status of substances in response to an unproven concern that certain uses are not, in fact, abandoned.

(Comment 5) One comment stated that it is not clear what parts of industry were omitted from the petitioner's survey and questions whether the survey recipients possessed sufficient knowledge to accurately answer the survey in instances of repeat-use items.

(Response 5) As stated in section II of this final rule, we consider the totality of the parties surveyed in the FVA petition to be comprehensive and sufficient to determine that these uses are abandoned. FDA also considers question 5 of the survey, which asked about the recipients' general knowledge of the use of the substances in food contact applications in the United States, to encompass not only the activities of the survey recipients themselves, but also other firms which supply, purchase from, or otherwise interact with the survey recipients.

In their petition, FVA provided data from committees, panels, and industry associations composed of scientific and regulatory experts in the field of food contact materials, plasticizers, *ortho*-phthalates, and the plastics, paper and paperboard, and food industries in general. Individual companies that responded to the surveys were made aware of FVA's food additive petition based on abandonment and were notified that the scope of this petition included repeat-use items via publication in the *Federal Register* at 83 FR 56750.

(Comment 6) One comment stated that FDA should clarify that for any abandoned uses, all prior and future uses that have been or will be deemed "generally recognized as safe" (GRAS) are invalid. The comment asserted that if we decide to revoke food additive regulations in response to this petition, a company may seek to rely on a self-GRAS determination without agency knowledge to conclude that the use of one or more of these substances are GRAS.

(Response 6) With regard to the comment's concern that a manufacturer may conclude that use of one or more of these substances is GRAS without notifying us, we note that, for a substance to be GRAS based on scientific procedures, the scientific data and information about the use of a substance must be generally available and there must be general recognition among qualified experts that those data and information establish that the substance is safe under the conditions of its intended use (21 CFR 170.30). Prior approval as a food additive for one use does not mean that another use of the substance is GRAS (see 81 FR 54960 at 54976, August 17, 2016). FDA encourages firms to seek our evaluation of any conclusion of GRAS status before they introduce the substance into the market. In the future, if a manufacturer wishes to establish safe conditions of use for one or more of these substances in food contact applications, we expect the manufacturer to submit either a food additive petition or a food contact substance notification prior to market entry because these intended uses were previously authorized under section 409 of the FD&C Act.

IV. Conclusion

FDA reviewed the data and information in the petition and other available relevant material to evaluate whether the food contact uses listed in tables 2 through 19 have been permanently and completely abandoned. Based on the available information, we have determined that these food contact uses have been abandoned. Therefore, we are amending §§ 175.105, 175.300, 175.320, 176.170, 176.180, 176.300, 177.1010, 177.1200, 177.1460, 177.1590, 177.2420, 177.2600, 178.3740, and 178.3910 of the food additive regulations to no longer provide for the food additive uses of the substances listed in tables 2 through 19 because these uses have been abandoned. Although the regulatory text in §§ 175.380, 175.390, 177.1210, and 179.1400 will not be amended, these regulations are also affected because they authorize certain uses of substances listed in table 1 by cross-referencing other regulations.

V. Public Disclosure

In accordance with § 171.1(h), the petition and the documents that we considered and relied upon in reaching our decision to approve the petition will be made available for public disclosure (see FOR FURTHER INFORMATION CONTACT). As provided in § 171.1(h), we will delete from the documents any materials that are not available for public disclosure.

VI. Environmental Impact

We have determined under 21 CFR 25.32(m) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VII. Paperwork Reduction Act of 1995

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

VIII. Objections

If you will be adversely affected by one or more provisions of this regulation, you may file with the Dockets Management Staff (see ADDRESSES) either electronic or written objections. You must separately number each objection, and within each numbered objection you must specify with particularity the provision(s) to which you object, and the grounds for your objection. Within each numbered objection, you must specifically state whether you are requesting a hearing on the particular provision that you specify in that numbered objection. If you do not request a hearing for any particular objection, you waive the right to a hearing on that objection. If you request a hearing, your objection must include a detailed description and analysis of the specific factual information you intend to present in support of the objection in the event that a hearing is held. If you do not include such a description and analysis for any particular objection, you waive the right to a hearing on the objection.

Any objections received in response to the regulation may be seen in the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <https://www.regulations.gov>.

IX. References

The following references marked with an asterisk (*) are on display at the Dockets Management Staff (see ADDRESSES) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they also are available electronically at <https://www.regulations.gov>. References without asterisks are not on public display at <https://www.regulations.gov> because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. FDA has verified the website addresses, as of the date this document publishes in the *Federal Register*, but websites are subject to change over time.

*1. FVA 2017 Value Chain Survey Results.

<https://www.surveymonkey.com/results/SM-QMSNRGQQ8/> (last accessed December 17, 2021).

*2. Email correspondence between D. Hill, Keller and Heckman LLP and S. DiFranco, Division of Food Ingredients, Office of Food Additive Safety (OFAS), Center for Food Safety and Applied Nutrition (CFSAN), FDA, October 30, 2019.

3. Malveda, Michael P; Liu, Shirley; Passararat, Suchada; Sesto, Barbara. *Chemical Economics Handbook: Plasticizers*. IHS Chemical, 2015.

*4. American Chemistry Council Member Companies.

<https://www.americanchemistry.com/Membership/MemberCompanies/> (last accessed December 17, 2021.)

*5. Memorandum from A. Gonzalez-Bonet, Chemistry Review Group I, Division of Food Contact Notifications (DFCN), OFAS, CFSAN, to the file, November 8, 2017.

*6. Memorandum for FAP 8B4089 from L. Borodinsky, Food and Color Additives Review Section, OFAS, CFSAN, FDA to A. Laumbach, Indirect Additives Branch, OFAS, CFSAN, FDA, November 23, 1988.

*7. Memorandum for FCN 000109 from K. Arvidson, Chemistry Review Group I, Division of Product Manufacture and Use, Chemistry and Exposure Assessment Team, OFAS,

CFSAN, FDA to H. Macon, Division of Product Policy, OFAS, CFSAN, FDA, December 20, 2000.

*8. Memorandum for FAP 9B4644 from R. Costnatino, Special Project Team, Chemistry Review Team, Division of Manufacture and Use, OFAS, CFSAN, FDA to the file, April 21, 1999.

*9. Memorandum for FCN 001617 from A. Gonzalez-Bonet, Chemistry Review Group I, DFCN, OFAS, CFSAN, FDA to K. McAdams, DFCN, OFAS, CFSAN, FDA, February 23, 2016.

List of Subjects

21 CFR Part 175

Adhesives, Food additives, Food packaging.

21 CFR Parts 176, 177, and 178

Food additives, Food Packaging.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 175, 176, 177, and 178 are amended as follows:

PART 175--INDIRECT FOOD ADDITIVES: ADHESIVES AND COMPONENTS OF COATINGS

1. The authority citation for part 175 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348, 379e.

§ 175.105 [Amended]

2. Amend § 175.105 in the table in paragraph (c)(5) by removing the entries for “Butyl benzyl phthalate”, “Butyldecyl phthalate”, “Butyloctyl phthalate”, “Butyl phthalate butyl glycolate”, “Di(butoxyethyl) phthalate” “Dibutyl phthalate”, “Di(2-ethylhexyl) hexahydrophthalate”, “Diethyl phthalate”, “Dihexyl phthalate” “Dihydroabietylphthalate”, “Diisobutyl phthalate”, “Diisooctyl phthalate”, “Dimethyl phthalate”, “Dioctylphthalate”,

“Diphenyl phthalate”, “Ethyl phthalyl ethyl glycolate”, “Methyl phthalyl ethyl glycolate”, and “Octyldecyl phthalate”.

§ 175.300 [Amended]

3. Amend § 175.300 in paragraph (b)(3)(viii)(b) by removing the entry for “Dibutyl phthalate, for use only in coatings for containers having a capacity of 1,000 gallons or more when such containers are intended for repeated use in contact with alcoholic beverages containing up to 8 percent of alcohol by volume.” and in paragraph (b)(3)(xxiv) by removing the entries for “Butyl phthalyl butyl glycolate.”, “Diethyl phthalate.”, “Diisooctyl phthalate.”, and “Ethyl phthalyl ethyl glycolate.”.

§ 175.320 [Amended]

4. Amend § 175.320 in paragraph (b)(3)(ii) by removing the entries for “Butyl phthalyl butyl glycolate”, “Diethyl phthalate”, and “Ethyl phthalyl ethyl glycolate”.

PART 176--INDIRECT FOOD ADDITIVES: PAPER AND PAPERBOARD COMPONENTS

5. The authority citation for part 176 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 346, 348, 379e.

§ 176.170 [Amended]

6. Amend § 176.170 in the table in paragraph (b)(2) by removing the entries for “Butylbenzyl phthalate” and “Dibutyl phthalate”.

§ 176.180 [Amended]

7. Amend § 176.180 in the table in paragraph (b)(2) by removing in paragraph (b)(2) the entry for “Butyl benzyl phthalate”.

§ 176.300 [Amended]

8. Amend § 176.300 in paragraph (d) by removing the entries for “Dibutyl phthalate.”, “Didecyl phthalate.”, and “Dodecyl phthalate.”.

PART 177--INDIRECT FOOD ADDITIVES: POLYMERS

9. The authority citation for part 177 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348, 379e.

§ 177.1010 [Amended]

10. Amend § 177.1010 in paragraph (a)(8) by removing the entry for “Dimethyl phthalate.”.

§ 177.1200 [Amended]

11. Amend § 177.1200 in paragraph (c) by removing the entries for “Castor oil phthalate with adipic acid and fumaric acid-diethylene glycol polyester”, “Castor oil phthalate, hydrogenated”, “Dibutylphthalate”, “Diisobutyl phthalate”, and “Dimethylcyclohexyl phthalate”.

§ 177.1460 [Amended]

12. Amend § 177.1460 in paragraph (b) by removing the entry for “Dioctyl phthalate”.

§ 177.1590 [Amended]

13. Amend § 177.1590 in paragraph (a) by removing the entry for “Dimethyl orthophthalate.”.

§ 177.2420 [Amended]

14. Amend § 177.2420 in paragraph (b) by removing the entries for “Butyl benzyl phthalate (containing not more than 1.0 percent by weight of dibenzyl phthalate)”, “dibutyl phthalate”, and “Dimethyl phthalate”.

§ 177.2600 [Amended]

15. Amend § 177.2600 in paragraph (c)(4)(ii)(b) by removing the entry for “Diphenylguanidine phthalate.” and in paragraph (c)(4)(iv) by removing the entries for “*n*-Amyl *n*-decyl phthalate.”, “Dibutyl phthalate.”, “Didecyl phthalate.”, “Dioctyl phthalate.”, and “*n*-Octyl *n*-decyl phthalate.”

PART 178--INDIRECT FOOD ADDITIVES: ADJUVANTS, PRODUCTION AIDS, AND SANITIZERS

16. The authority citation for part 178 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348, 379e.

§ 178.3740 [Amended]

17. Amend § 178.3740 in paragraph (b) by removing the entries for “Butylbenzyl phthalate”, “Dihexyl phthalate”, and “Diphenyl phthalate”.

§ 178.3910 [Amended]

18. Amend § 178.3910 in paragraph (a)(2) by removing the entry for “Diethyl phthalate”.

Dated: May 11, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022-10531 Filed: 5/19/2022 8:45 am; Publication Date: 5/20/2022]