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Post-market Determinations that the Use of a Substance is not GRAS

Under the Federal Food, Drug, and Cosmetic (FD&C) Act, any substance used or intended for use in food must be authorized by FDA for use as a food additive unless the use of that substance is generally recognized as safe (GRAS) by qualified experts or meets a listed exception to the food additive definition in the Act (sections 201(s) and 409 of the FD&C Act; 21 U.S.C. 321(s) and 348). The use or intended use of a food additive that does not conform with an authorizing regulation (or effective food contact notification, if applicable) is an unapproved food additive and is deemed to be unsafe. Food that is or bears or contains a food additive that is unsafe is adulterated (section 402(a)(2)(C) of the FD&C Act; 21 U.S.C. 342(a)(2)(C)).

As part of its on-going compliance activities, FDA identifies foods that contain a substance for which there is no authorization as a food additive and then reviews the regulatory status of this substance. FDA scientists analyze whether there is a basis to conclude that the intended use of the substance is GRAS or meets a listed exception to the food additive definition. When FDA scientists determine that a substance is an unapproved food additive because it is not GRAS for its intended use (and does not meet a listed exception), they may document their findings in a memo.

These memos are available below, as well as links to FDA actions associated with these substances and other communications. These memos are specific to whether the use of a substance in food is an unapproved food additive. The use of such a substance may result in other violations of the FD&C Act. These other violations of the FD&C Act may be referenced in the links to activities related to that substance but are not addressed in these memos. This inventory is not a complete list of substances for which the intended use in food is not GRAS and may not include all actions the agency has taken with respect to unapproved food additives or a particular substance. This may not include memos related to ongoing investigations.

The inventory of these determinations provides the following information:

- Name of the substance
- Selection of known synonyms
- Chemical Abstracts Service (CAS) Registry Number®, if applicable

The substance name also serves as a hyperlink to the following additional information:

- Links to memos documenting FDA's determination that the use or intended use of the substance in food does not meet the statutory criteria for GRAS and is therefore an unapproved food additive
- Links to warning letters, enforcement actions, and other communications related to the substance

Search and display hints:

- Select the specific substance below to view additional details about any GRAS Notice.
- To sort by a specific field, click on the column header for that field.
- To browse the records, use the Show All, First/Previous/Next/Last, and Jump To options at the bottom of the data table.
- The search results will return hits of records containing words that include the search term. For example a search for the color **red** will return results that include terms such as **reduce**, **ingred**ient, and cultur**ed**. To limit results to only the searched term, place a space before and after the word in the basic search or in the advanced search "this exact phrase" field.

 [Download data](#)⁵ from this searchable database in Excel format. If you need help accessing information in different file formats, see [Instructions for Downloading Viewers and Players](#)⁶.

Basic Search	Advanced Search	Field Search
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Search:

Show Items Clear

Records Found: 15

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CAS Reg. No.*	Substance* (sorted A-Z)	Other names
63-05-8	4-androstenedione	<ul style="list-style-type: none"> ◆ androstenedione ◆ A4 ◆ androst-4-ene-3,17-dione
1420-49-1	Arimistane	<ul style="list-style-type: none"> ◆ androsta-3,5-diene-7,17-dione
—	Betel nut	<ul style="list-style-type: none"> ◆ areca nut ◆ Areca catechu seed
—	Caffeinated alcoholic beverages	
13956-29-1	Cannabidiol (CBD)	<ul style="list-style-type: none"> ◆ cannabidiol
5957-75-5	Delta-8-THC	<ul style="list-style-type: none"> ◆ delta-8-tetrahydrocannabinol
105-41-9	1,3-DMAA	<ul style="list-style-type: none"> ◆ 1,3-dimethylamylamine ◆ 1,3-dimethylpentylamine ◆ 2-amino-4-methylhexane ◆ 4-methyl-2-hexanamine ◆ 4-methyl-2-hexylamine ◆ dimethylamylamine ◆ DMAA ◆ Forthane ◆ Geranamine ◆ methylhexanamine ◆ methylhexanenamine ◆ 2-hexanamine, 4-methyl- ◆ pentylamine, 1,3-dimethyl-
2395737-08-1	<i>Ginkgo biloba</i>	<ul style="list-style-type: none"> ◆ Ginkgo ◆ maidenhair tree
—	Kava	<ul style="list-style-type: none"> ◆ Piper methysticum ◆ kava kava
73-31-4	Melatonin	<ul style="list-style-type: none"> ◆ melatonine ◆ N-acetyl-5-methoxytryptamine
—	Partially Hydrogenated Oils	<ul style="list-style-type: none"> ◆ PHOs
62936-56-5	Picamilon	<ul style="list-style-type: none"> ◆ picamilon sodium ◆ 4-nicotinamidobutanoic acid ◆ pikamilon ◆ nicotinoyl-GABA
—	Live microorganisms intended for use in food for pre-term infants	
—	Tara flour	<ul style="list-style-type: none"> ◆ <i>Caesalpinia spinosa</i> protein ◆ Ground tara germ ◆ <i>Tara spinosa</i> protein ◆ Tara protein
72797-41-2	Tianeptine	<ul style="list-style-type: none"> ◆ Tianaa ◆ Zaza ◆ Coaxil ◆ Stablon ◆ 7-[(3-Chloro-6,11-dihydro-6-methyl-5,5-dioxidodibenzo[c,f][1,2]thiazepin-11-yl)amino]heptanoic acid

Definitions

- **CAS Reg. No.:** Chemical Abstract Service (CAS) Registry Number® for the substance, if available.
- **Substance:** Name of the unsafe food additive.

Links on this page:

1. <http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain>
2. <http://www.addthis.com/bookmark.php>
3. <https://www.fda.gov/>

4. <https://www.fda.gov/food/food-ingredients-packaging/food-ingredient-and-packaging-inventories>
5. [cfc/XMLService.cfc?method=downloadxls&set=Postmarket](https://www.fda.gov/cfc/XMLService.cfc?method=downloadxls&set=Postmarket)
6. <http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/ViewingFiles/default.htm>

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