

GRAS Flavoring Substances 28

28. GRAS Flavoring Substances. This list of substances will appear in the 28th publication authored by the Expert Panel of the Flavor and Extract Manufacturers Association on recent progress in the consideration of flavoring ingredients “generally recognized as safe” (GRAS) under conditions of their intended use in food flavorings in accordance with the 1958 Food Additives Amendment to the Federal Food, Drug and Cosmetic Act. For more information on FEMA GRAS see “About the FEMA GRAS Program” on the FEMA website.

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DISCLAIMER: Interim GRAS 28 and the use categories, use levels and designated technical effect for FEMA GRAS flavor ingredients represent the conditions of intended use that serve as some of the bases for FEMA GRAS status. The use categories are limitations on GRAS status— if a use category is not listed then the substance is not GRAS for that use. Use levels are not limits but significant deviations from these conditions of intended use may result in a substance no longer qualifying as GRAS. The designated technical effect is an important component of the conditions of intended use – FEMA GRAS status provides regulatory authority to use the substance only for the designated technical effect. Some substances that are FEMA GRAS may have either a separate listing by FDA in the Code of Federal Regulations as an approved food additive or as a GRAS substance, and such listings may specify use consistent with good manufacturing practice or FDA-mandated use limitations. FEMA makes no warranty, express or implied, for the accuracy of this information. Information provided in this compilation should not be the only resource employed for any business purpose or for determining regulatory compliance such as whether specific flavor ingredients qualify as GRAS or are permitted for use in a specific jurisdiction. Users of this compilation and the information in it are solely responsible for compliance with all regulatory requirements in all jurisdictions, and agree that the use of this compilation is at the user’s sole risk and that FEMA shall have no liability to any person, corporation or other entity for any loss or damage arising out of the use of this compilation. The use categories and use levels contained herein are subject to change. It is the responsibility of the user to ensure the information is up to date.

STATEMENT REGARDING GENERALLY RECOGNIZED AS SAFE STATUS OF EUGENYL METHYL ETHER (METHYL EUGENOL)

The FEMA GRAS status of methyl eugenol (CAS NO. 93-15-2; FEMA No. 2475) under its conditions of intended use as a flavor ingredient, was reviewed by the FEMA Expert Panel. After reviewing the available information relevant to the FEMA GRAS status of methyl eugenol, including recent studies, the Expert Panel concluded that additional data are required to support the continuation of its GRAS status. Such data should clarify the relevance to humans of DNA adducts formed by methyl eugenol. Until such data are available for review by the Expert Panel, the flavor ingredient methyl eugenol has been removed from the FEMA GRAS list.

The Expert Panel also considered the FEMA GRAS status of herbs, spices, and essential oils that contain naturally-occurring methyl eugenol, including basil, pimento, allspice, etc. and their extractives. The Panel concluded that these flavorings continue to meet the criteria for FEMA GRAS under their conditions of intended use as flavorings.

Table 1. Primary names (in boldface) Synonyms (in lightface)

FEMA No.	Primary Names and Synonyms
4819	Erythritol (2 <i>R</i> ,3 <i>S</i>)- <i>rel</i> -1,2,3,4-Butanetetrol (2 <i>R</i> ,3 <i>S</i>)-Butane-1,2,3,4-tetrol meso-Erythritol Mesoerythritol
4820	Purified Damar Gum
4822	2,6-Dipropyl-5,6-dihydro-2<i>H</i>-thiopyran-3-carboxaldehyde
4824	2-(5-Isopropyl-2-methyl-tetrahydrothiophen-2-yl)-ethyl acetate Tetrahydro-2-methyl-5-(1-methylethyl)-2-thiopheneethanol acetate
4825	<i>E</i>-6-Nonenal <i>trans</i> -6-Nonenal
4829	2-Pyrrolidone
4832	2-(3-Benzoyloxypropyl)pyridine
4838	Valencene 80 Extract
4839	Mixture of 3- and 4-butyl-2-thiophenecarboxaldehyde
4867	(3<i>S</i>,5<i>R</i>,8<i>S</i>)-3,8-Dimethyl-5-prop-1-en-2-yl-3,4,5,6,7,8-hexahydro-2<i>H</i>-azulen-1-one
4868	4-(4-Methyl-3-penten-1-yl)-2(5<i>H</i>)-furanone
4869	4-(1-Menthoxy)-2-butanone
4878	<i>Cordyceps sinensis</i> fermentation product

Table 2. Average Usual Use Levels (ppm)/Average Maximum Use Levels (ppm) on which the FEMA Expert Panel based its judgments that the substances are generally recognized as safe (GRAS)

	Erythritol	2,6-Dipropyl-5,6-dihydro-2H-thiopyran-3-carboxaldehyde	2-(5-Isopropyl-2-methyl-tetrahydrothiophen-2-yl)-ethyl acetate	E-6-Nonenal	2-Pyrrolidone
Category/FEMA No.	4819	4822	4824	4825	4829
Baked Goods	0/0	0/0	0.3/1	0.001/0.01	5/20
Beverages, Non-Alcoholic	5000/12500	0.05/5	0.1/0.5	0.00001/0.0001	5/20
Beverages, Alcoholic	0/0	0.03/10	0.3/2	0.00001/0.0001	5/20
Breakfast Cereals	0/0	0/0	0.3/1	0.001/0.01	5/20
Cheeses	0/0	0/0	0/0	0.001/0.01	5/20
Chewing Gum	0/0	10/100	1/5	0.0001/0.001	50/200
Condiments and Relishes	0/0	0/0	0/0	0/0	5/20
Confections and Frostings	0/0	0.3/30	0.5/2	0.0001/0.001	10/40
Egg Products	0/0	0/0	0/0	0.0001/0.001	5/20
Fats and Oils	0/0	0/0	0.3/1	0.01/0.1	5/20
Fish Products	0/0	0/0	0/0	0.0001/0.001	5/20
Frozen Dairy	0/0	0.5/50	0.1/0.5	0.0001/0.001	5/20
Fruit Ices	5000/12500	0.05/5	0.1/0.5	0.0001/0.001	5/20
Gelatins and Puddings	0/0	0.2/10	0.1/0.5	0.0001/0.001	5/20
Granulated Sugar	0/0	0/0	0/0	0/0	40/160
Gravies	0/0	0/0	0/0	0.001/0.01	5/20
Hard Candy	0/0	0.5/50	0.5/2	0.001/0.01	10/40
Imitation Dairy	0/0	0.05/5	0/0	0.001/0.01	5/20
Instant Coffee and Tea	5000/12500	0.05/5	0.2/1	0.00001/0.0001	5/20
Jams and Jellies	0/0	0.5/20	0.3/1	0/0	10/40
Meat Products	0/0	0/0	0/0	0.0001/0.001	5/20
Milk Products	0/0	0.05/5	0.1/0.5	0.00001/0.0001	5/20
Nut Products	0/0	0/0	0/0	0.0001/0.001	5/20
Other Grains	0/0	0/0	0/0	0.0001/0.001	5/20
Poultry	0/0	0/0	0/0	0/0	5/20
Processed Fruits	5000/12500	0.05/5	0.1/0.5	0/0	5/20
Processed Vegetables	0/0	0/0	0/0	0/0	5/20
Reconstituted Vegetables	0/0	0/0	0/0	0/0	5/20
Seasonings and Flavors	0/0	0.5/20	0.1/0.5	0.1/1.0	5/20
Snack Foods	0/0	0/0	0.1/0.5	0.0001/0.001	5/20
Soft Candy	0/0	0.2/5	0.5/2	0.0001/0.001	10/40
Soups	0/0	0/0	0/0	0.0001/0.001	5/20
Sugar Substitutes	0/0	0/0	0/0	0/0	10/40
Sweet Sauces	0/0	0.2/10	0/0	0/0	5/20

Table 2. Average Usual Use Levels (ppm)/Average Maximum Use Levels (ppm) on which the FEMA Expert Panel based its judgments that the substances are generally recognized as safe (GRAS)

2-(3-Benzoyloxypropyl)pyridine	Valencene 80 extract	Mixture of 3- and 4-butyl-2-thiophenecarboxaldehyde	(3S,5R,8S)-3,8-Dimethyl-5-prop-1-en-2-yl-3,4,5,6,7,8-hexahydro-2H-azulen-1-one	4-(4-Methyl-3-penten-1-yl)-2(5H)-furanone	4-(1-Menthoxy)-2-butanone	<i>Cordyceps sinensis</i> fermentation product
4832	4838	4839	4867	4868	4869	4878
1/10	0.9/0.9	0/0	0.001/0.02	0.0001/0.001	0/0	30/50
0.1/1	0.6/0.6	0.2/5	0.0001/0.005	0.00001/0.0001	1/5	40/1000
0/0	0.9/0.9	0.5/10	0.0001/0.005	0.00001/0.0001	1/5	100/1000
0/0	0.9/0.9	0/0	0/0	0.0001/0.001	0/0	0/0
1/10	0/0	0/0	0/0	0.001/0.01	0/0	0/0
0/0	20/1000	1/20	0.001/0.02	0.0001/0.001	1/10	0/0
0/0	0/0	0/0	0/0	0/0	0/0	0/0
0/0	0.9/0.9	0.6/10	0.0003/0.005	0.0001/0.001	0/0	0/0
0.2/2	0/0	0/0	0.0003/0.005	0.0001/0.001	0/0	0/0
0/0	0/0	0.5/10	0.02/0.2	0.001/0.01	0/0	0/0
0.5/5	0/0	0/0	0.0003/0.005	0.0001/0.001	0/0	0/0
0.1/1	0.9/0.9	0.2/5	0.0002/0.003	0.0001/0.001	0/0	0/0
0/0	0/0	0.2/5	0.0002/0.003	0.00001/0.0001	0/0	0/0
0/0	0.9/0.9	0/0	0.0003/0.002	0.0001/0.001	0/0	0/0
0/0	0/0	0/0	0/0	0/0	0/0	0/0
1/10	0/0	0/0	0.001/0.01	0.001/0.01	1/5	0/0
0/0	0/0	0.6/10	0.001/0.01	0.0001/0.001	0/0	0/0
0.5/5	0/0	0/0	0.001/0.01	0.0001/0.001	0/0	0/0
0/0	0/0	0.3/5	0.0001/0.001	0.00001/0.0001	1/5	0/0
0/0	0/0	0.5/10	0/0	0/0	0/0	0/0
0.5/5	0/0	0/0	0/0	0.00001/0.0001	0/0	0/0
0.2/2	0.9/0.9	0/0	0.001/0.01	0.00001/0.0001	0/0	15/100
0.1/1	0/0	0/0	0.001/0.01	0.0001/0.001	0/0	0/0
0/0	0/0	0/0	0/0	0.0001/0.001	0/0	50/150
0/0	0/0	0/0	0/0	0/0	0/0	0/0
0/0	0/0	0.2/5	0/0	0.00001/0.0001	0/0	0/0
0.1/1	0/0	0/0	0/0	0/0	0/0	0/0
0.1/1	0/0	0/0	0/0	0/0	0/0	0/0
1/10	0/0	0.5/10	0.1/1	0.01/0.1	1000/5000	0/0
1/10	0/0	0/0	0.001/0.01	0.0001/0.001	0/0	0/0
0/0	0/0	0.6/10	0.001/0.01	0.0001/0.001	1/5	0/0
0.5/5	0/0	0/0	0.0001/0.002	0.0001/0.001	1/5	0/0
0/0	0/0	0/0	0/0	0/0	0/0	4/10
0/0	0/0	0/0	0.001/0.01	0/0	0/0	0/0

Table 3. Updated Average Usual Use Levels (ppm)/Average Maximum Use Levels (ppm) for flavoring substances previously recognized as FEMA GRAS. Superscript * represents a new use level.

	Thaumatococin	Neohesperidine dihydrochalcone	Thaumatococin B-Recombinant	N-(2-Methylcyclohexyl)-2,3,4,5,6-pentafluorobenzamide	Glucosyl steviol glycosides
Category/FEMA No.	3732	3811	3814	4678	4728
Baked Goods	7*/7*	5/7*	1/1	1*/5*	150*/500*
Beverages, Non-Alcoholic	7*/7*	5/15	5/7*	1/5	125/175*
Beverages, Alcoholic	7*/7*	5/15	5/7*	0/0	125/175*
Breakfast Cereals	7*/7*	8/20	1/2	0/0	200*/500*
Cheeses	7*/7*	3/4	7*/7*	0/0	100/133*
Chewing Gum	150*/150*	200/300	150/150*	10/20	500*/1500*
Condiments and Relishes	7*/7*	2/3	1/2	0/0	125/200*
Confections and Frostings	7*/7*	3/3	2/5	1/5	50/100
Egg Products	7/7*	2/3	2/5	0/0	0/0
Fats and Oils	7*/7*	4/4	0/0	0/0	125/189*
Fish Products	7*/7*	2/3	5/7*	0/0	0/0
Frozen Dairy	7/7*	2/8	1/2	1/5	125/133*
Fruit Ices	7/7*	2/3	2/5	1/5	125/133*
Gelatins and Puddings	7*/7*	3/8	1/2	1/5	125/133*
Granulated Sugar	0/0	0/0	0/0	0/0	0/0
Gravies	7*/7*	3/4	2/5	0/0	125/133*
Hard Candy	7*/7*	5/15	2/5	1/5	100/133*
Imitation Dairy	7*/7*	3/10	7*/7*	0/0	125/250*
Instant Coffee and Tea	7*/7*	3/6	2/5	1/5	125/175*
Jams and Jellies	7*/7*	2/3	2/5	1*/5*	125*/200*
Meat Products	7*/7*	2/3	2/2	0/0	0/0
Milk Products	7*/7*	3/10	3/6	1/5	133*/225*
Nut Products	7*/7*	3/4	5/7*	0/0	133*/175*
Other Grains	7*/7*	3/4	0/0	0/0	100/133*
Poultry	7*/7*	2/3	2/5	0/0	0/0
Processed Fruits	7*/7*	2/3	2/5	1/5	133*/200*
Processed Vegetables	7*/7*	2/3	2/5	0/0	100/133*
Reconstituted Vegetables	7*/7*	2/3	2/5	0/0	133*/133*
Seasonings and Flavors	7/7*	3/4	0.5/1	0/0	133*/175*
Snack Foods	7*/7*	3/3	1/2	0/0	133*/133*
Soft Candy	7*/7*	4/10	2/5	1/5	100/133*
Soups	7*/7*	5/7*	2/5	0/0	133*/133*
Sugar Substitutes	0/0	0*/0*	0*/0*	0/0	0*/0*
Sweet Sauces	7*/7*	2/3	2/5	1/5	133*/133*

Table 4. Identity for Natural Flavor Complexes as Evaluated by the FEMA Expert Panel

FEMA No.	FEMA Primary Name	The Identification value as reviewed by the FEMA Expert Panel
4728	Glucosyl steviol glycosides	Total steviol glycosides 80-90% inclusive of supraglucosylated steviol glycosides 75-80%; Rebaudioside A 1-6%; stevioside 2-4% and other individual steviol glycosides not further glucosylated each less than 3%. Maltodextrin 3-20%
4820	Purified Damar Gum	Oxygenated triterpenes and sesquiterpenes 34-39% typically measured as isomers of hydroxydammarone, dammerene diol, oleanonic aldehyde and urosonic aldehyde and acid and polycadenene 14-17%.
4878	<i>Cordyceps sinensis</i> fermentation product	Approximately 25% <i>alpha</i> -glucans; approximately 60-70% maltodextrin and its degradation products with no more than 1.5% protein.