

# GRAS Flavoring Substances 30

**30. GRAS Flavoring Substances.** This list of substances will appear in the 30<sup>th</sup> 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.

## **FEMA EXPERT PANEL**

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*The Expert Panel of the Flavor and Extract Manufacturers Association of the United States (FEMA) has evaluated substances for GRAS status under their conditions of intended use as flavoring substances since the early 1960s. The regulations of the U.S. Food and Drug Administration (FDA), and U.S. law, require that determinations that flavor substances and other food ingredients are “generally recognized as safe” (GRAS) be done in such a way that all information related to GRAS determinations is publicly available. The FEMA Expert Panel has met this requirement by publishing the identity of all flavoring substances determined to be GRAS by the Panel, and has submitted all information related to its GRAS reviews on these substances to the FDA for inclusion in the FDA databases. Information that was reviewed by the Expert Panel in the course of their evaluation of new flavoring substances is typically submitted to FDA within six months of the publication of their identity. The Expert Panel also publishes separate extensive reviews of scientific information on all FEMA GRAS flavoring substances in the peer-reviewed scientific literature in the form of reports on the safety of structurally-related groups of flavoring substances. These important actions assure that there is “general recognition” of the safety of these substances when used as flavors.*

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## FEMA GRAS Evaluation Update

The FEMA Expert Panel has considered the US Food and Drug Administration's [statement](#) regarding the regulation of dietary supplement and conventional food products containing cannabis and cannabis-derived compounds. While FDA notes that "Ingredients derived from cannabis that do not contain CBD or THC might be able to be used in foods and dietary supplements if all other FD&C requirements are met" the FEMA Expert Panel has concluded that it will not review cannabis derivatives for FEMA GRAS status under conditions of intended use as flavorings, including derivatives with only trace amounts of THC and CBD. The FEMA Expert Panel may review this policy in the event of new actions from the US FDA on regulatory considerations of cannabis-containing and cannabis-derived ingredients.

**Corrections and Errata to previous GRAS Publications**

**Use levels for FEMA 4601.** In GRAS 28 (Cohen et al., 2018), there was a clerical error, and the Anticipated Usual and Maximum Use Levels for FEMA 4601 in Baked Goods should read 20/30 ppm.

**Primary names of FEMA 2829 and 2830.** In GRAS 3 (Hall and Oser, 1965), the botanical name for FEMA 2829, Orris concrete liquid oil, and FEMA 2830, Orris root extract, was listed as *Iris Florentina* L. The botanicals *Iris pallida* and *Iris germanica* are also considered FEMA GRAS under the identities of FEMA 2829 and FEMA 2830.

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

FEMA No.	Primary Names and Synonyms
4943	<b>Decanedioic acid</b> 1,8-Octanedicarboxylic acid 1,10-Decanedioic acid Sebacic acid Decanedicarboxylic acid
4947	<b>Glucosylated stevia extract 40% with 14% Rebaudioside A</b>
4949	<b><i>Corynebacterium ammoniagenes</i> fermentation product</b> <i>C. ammoniagenes</i> dried fermentation broth
4957	<b>Rebaudioside M 85%</b> Rebaudioside X 85%
4958	<b>4-Formyl-2-methoxyphenyl 1-menthyl glutarate</b> 4-Formyl-2-methoxyphenyl-(1 <i>R</i> ,2 <i>S</i> ,5 <i>R</i> )-2-isopropyl-5-methylcyclohexyl pentanedioate Pentanedioic acid, 1-(4-formyl-2-methoxyphenyl) 5-[(1 <i>R</i> ,2 <i>S</i> ,5 <i>R</i> )-5-methyl-2-(1-methylethyl)cyclohexyl] ester
4959	<b>9-Dodecen-12-olide</b> Yuzu lactone Oxacyclotridec-10-en-2-one 1-Oxacyclotridec-10-en-2-one
4964	<b><i>Corynebacterium glutamicum</i> cell free fermentation product</b> <i>C. glutamicum</i> dried fermentation broth
4965	<b><i>N</i>-(1-((4-Amino-2,2-dioxido-1<i>H</i>-benzo[<i>c</i>][1,2,6]thiadiazin-5-yl)oxy)-2-methylpropan-2-yl)isonicotinamide</b>
4967	<b><i>delta</i>-Cadinene 93%</b>
4969	<b>Yerba mate extract (<i>Ilex paraguariensis</i> A. St.-Hil.)</b> Mate absolute <i>Ilex paraguariensis</i> A. St.-Hil. extract
4971	<b><i>beta</i>-Farnesene</b> 1,6,10-Dodecatriene, 7,11-dimethyl-3-methylene-, (6 <i>E</i> )- 1,6,10-Dodecatriene, 7,11-dimethyl-3-methylene-, ( <i>E</i> )- (6 <i>E</i> )-7,11-Dimethyl-3-methylene-1,6,10-dodecatriene ( <i>E</i> )-7,11-Dimethyl-3-methylene-1,6,10-dodecatriene ( <i>E</i> )- <i>beta</i> -Farnesene <i>trans</i> - <i>beta</i> -Farnesene
4972	<b>Diethyl mercaptosuccinate</b>
4973	<b>3-Mercapto-3-methyl-1-pentyl acetate</b>
4974	<b>Germacrene D ≥85%</b>
4977	<b>10-Hydroxy-4,8-dimethyldec-4-enal</b> 4-Decenal, 10-hydroxy-4,8-dimethyl-

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

	Decanedioic acid	Glucosylated stevia extract 40% with 14% Rebaudioside A	<i>Corynebacterium ammoniagenes</i> fermentation product	Rebaudioside M 85%	4-Formyl-2-methoxyphenyl l- menthyl glutarate	9-Dodecen-12-olide
Category/FEMA No.	4943	4947	4949	4957	4958	4959
Baked Goods	40/200	50/60	1000/7500	15/20	5/50	0.5/2
Beverages Type I, Non-Alcoholic	20/50	50/60		15/20		0.01/0.2
Beverages Type II, Alcoholic	15/30	50/60		15/20		0.01/0.2
Breakfast Cereals	50/100	50/60	1000/5000	15/20	1/10	0.3/1
Cheeses	40/100		2000/7500			0.1/0.5
Chewing Gum	100/300			15/20		1/4
Condiments and Relishes	30/100		3000/20000	15/20		0.3/1
Confections and Frostings	40/100	50/60		15/20	1/10	0.3/1
Egg Products	50/100		1000/10000			0.1/0.5
Fats and Oils	50/100	50/60				2/10
Fish Products	50/100		3000/10000			0.1/0.5
Frozen Dairy	40/100	50/60		15/20		0.1/0.5
Fruit Ices	30/60	50/60		15/20		0.1/0.5
Gelatins and Puddings	30/60	50/60		15/20		0.1/0.5
Granulated Sugar		50/60				
Gravies	40/100		3000/20000	15/20		0.2/2
Hard Candy	50/200	50/60		15/20		0.2/2
Imitation Dairy Products	40/100	50/60	2000/10000	15/20		0.5/3
Instant Coffee and Tea	30/100	50/60		15/20		0.1/0.5
Jams and Jellies	50/100	50/60		15/20		0.1/0.5
Meat Products	50/100		2000/15000			0.1/0.5
Milk Products	40/100	50/60		15/20		0.1/0.5
Nut Products	40/100	50/60	1000/10000	15/20		
Other Grains	50/200	50/60		15/20		
Poultry Products	50/100		2000/10000			0.1/0.5
Processed Fruits	50/100	50/60		15/20		0.1/0.5
Processed Vegetables	50/100			15/20		
Reconstituted Vegetable Protein	50/100			15/20		
Seasonings and Flavors	50/100	50/60	5000/50000	15/20		
Snack Foods	50/100	50/60	1000/10000	15/20		0.3/1
Soft Candy	50/200	50/60		15/20		0.3/2
Soups	50/300	50/60	3000/20000	15/20		0.05/0.5
Sugar Substitutes	30/60	50/60				
Sweet Sauces	40/100	50/60		15/20		0.1/1

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	<i>Corynebacterium glutamicum</i> cell free fermentation product	<i>N</i> -(1-((4-Amino-2,2-dioxido-1 <i>H</i> -benzo[c][1,2,6]thiadiazin-5-yl)oxy)-2-methylpropan-2-yl)isonicotinamide	<i>delta</i> -Cadinene 93%	Yerba mate extract ( <i>Ilex paraguariensis</i> A. St.-Hil.)	<i>beta</i> -Farnesene
Category/FEMA No.	4964	4965	4967	4969	4971
Baked Goods	1000/11000	10/22	0.9/0.9		10/50
Beverages Type I, Non-Alcoholic		15/22		400/1000	5/20
Beverages Type II, Alcoholic		10/22		400/1000	5/20
Breakfast Cereals	1000/11000	20/22			10/50
Cheeses	3000/11000				2/10
Chewing Gum		22/22			30/90
Condiments and Relishes	3000/18000	20/22	0.3/0.3	400/1000	5/15
Confections and Frostings		22/22		400/1000	20/60
Egg Products	1000/7000				
Fats and Oils					5/30
Fish Products	3000/9000				1/5
Frozen Dairy		15/22			5/40
Fruit Ices		15/22		400/1000	5/20
Gelatins and Puddings		15/22		400/1000	2/10
Granulated Sugar					
Gravies	3000/11000				5/20
Hard Candy		22/22	0.9/0.9	400/1000	10/50
Imitation Dairy Products	3000/11000	15/22			1/5
Instant Coffee and Tea		10/22		400/1000	5/20
Jams and Jellies		15/22		400/1000	2/10
Meat Products	3000/11000				1/5
Milk Products		15/22			10/30
Nut Products	1000/4000				5/20
Other Grains					10/50
Poultry Products	3500/7500				1/5
Processed Fruits				400/1000	5/30
Processed Vegetables				400/1000	5/10
Reconstituted Vegetable Protein					5/20
Seasonings and Flavors	20000/150000				10/50
Snack Foods	7500/20000				5/20
Soft Candy		20/22		400/1000	10/30
Soups	3500/18500			400/1000	5/20
Sugar Substitutes					1/10
Sweet Sauces		15/22		400/1000	2/10

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

	Diethyl mercaptosuccinate	3-Mercapto-3-methyl-1-pentyl acetate	Germacrene D ≥85%	10-Hydroxy-4,8-dimethyldec-4-enal
Category/FEMA No.	4972	4973	4974	4977
Baked Goods	1/10	0.001/0.05	0.5/0.5	
Beverages Type I, Non-Alcoholic	0.1/1	0.0001/0.002	0.2/0.2	0.5/5
Beverages Type II, Alcoholic	0.1/1	0.0001/0.002		0.5/5
Breakfast Cereals				
Cheeses		0.0005/0.005		
Chewing Gum	1/10	0.0005/0.01	3.4/4.8	2/20
Condiments and Relishes	1/10	0.0001/0.01		
Confections and Frostings	1/10	0.0005/0.005		2/20
Egg Products		0.0002/0.001		
Fats and Oils				
Fish Products				
Frozen Dairy	1/10	0.0002/0.003		
Fruit Ices	1/10	0.0002/0.003	0.3/0.3	0.5/5
Gelatins and Puddings	1/10	0.0002/0.003		
Granulated Sugar				
Gravies	0.1/1	0.0005/0.005		
Hard Candy	1/10	0.0005/0.01	0.5/0.5	1/10
Imitation Dairy Products				
Instant Coffee and Tea	1/10	0.0003/0.005		0.5/5
Jams and Jellies	1/10			1/10
Meat Products	1/10	0.001/0.01		
Milk Products		0.0001/0.001		
Nut Products	1/10			
Other Grains	0.1/1			
Poultry Products	0.1/1			
Processed Fruits	0.1/1			
Processed Vegetables	0.1/1			
Reconstituted Vegetable Protein				
Seasonings and Flavors	0.1/1	0.01/0.5		
Snack Foods		0.001/0.05		
Soft Candy	1/10	0.001/0.1		1/10
Soups	1/10	0.0003/0.003		
Sugar Substitutes				
Sweet Sauces		0.001/0.01		

**Table 3. Updated Average Usual Use Levels/Average Maximum Use Levels**

Average Usual Use Levels (ppm)/Average Maximum Use Levels (ppm) for flavoring substances previously recognized as FEMA GRAS

a represents a change from previous FEMA GRAS publications

c represents a correction and errata to previous GRAS publications

	Oak chips extract ( <i>Quercus alba</i> L.; <i>Quercus petraea</i> )	Rebaudioside A	<i>Cordyceps sinensis</i> fermentation product	Sodium gluconate
<b>GRAS Publication</b>	<b>3</b>	<b>28</b>	<b>28</b>	<b>29</b>
<b>Category/FEMA No.</b>	<b>2794</b>	<b>4601</b>	<b>4878</b>	<b>4934</b>
<b>Baked Goods</b>	72/90	20 <sup>c</sup> /30 <sup>c</sup>	30/50	5000 <sup>a</sup> /20000 <sup>a</sup>
<b>Beverages Type I, Non-Alcoholic</b>	550 <sup>a</sup> /1000 <sup>a</sup>	20/30	30 <sup>a</sup> /1000	1500/3500 <sup>a</sup>
<b>Beverages Type II, Alcoholic</b>	1000/1000	20/30	10 <sup>a</sup> /1000	1500/3500 <sup>a</sup>
<b>Breakfast Cereals</b>		20/30	10 <sup>a</sup> /100 <sup>a</sup>	2500/5000 <sup>a</sup>
<b>Cheeses</b>				5000 <sup>a</sup> /20000 <sup>a</sup>
<b>Chewing Gum</b>	115/200	200/200	20 <sup>a</sup> /100 <sup>a</sup>	10000 <sup>a</sup> /20000 <sup>a</sup>
<b>Condiments and Relishes</b>		20/30	1 <sup>a</sup> /30 <sup>a</sup>	2500 <sup>a</sup> /5000 <sup>a</sup>
<b>Confections and Frostings</b>		20/30	1 <sup>a</sup> /30 <sup>a</sup>	1500/2500
<b>Egg Products</b>			1 <sup>a</sup> /30 <sup>a</sup>	2500 <sup>a</sup> /5000 <sup>a</sup>
<b>Fats and Oils</b>				5000 <sup>a</sup> /10000 <sup>a</sup>
<b>Fish Products</b>			1 <sup>a</sup> /30 <sup>a</sup>	5000 <sup>a</sup> /20000 <sup>a</sup>
<b>Frozen Dairy</b>	52/200 <sup>a</sup>	20/30	10 <sup>a</sup> /100 <sup>a</sup>	1500/2500
<b>Fruit Ices</b>		20/30		1500/2500
<b>Gelatins and Puddings</b>	1 <sup>a</sup> /1 <sup>a</sup>	20/30		1500 <sup>a</sup> /2500 <sup>a</sup>
<b>Granulated Sugar</b>				
<b>Gravies</b>		20/30	10 <sup>a</sup> /100 <sup>a</sup>	2500/5000 <sup>a</sup>
<b>Hard Candy</b>	2.5/200 <sup>a</sup>	20/30	1 <sup>a</sup> /30 <sup>a</sup>	10000 <sup>a</sup> /20000 <sup>a</sup>
<b>Imitation Dairy Products</b>		20/30	10 <sup>a</sup> /150 <sup>a</sup>	5000 <sup>a</sup> /10000 <sup>a</sup>
<b>Instant Coffee and Tea</b>		20/30	10 <sup>a</sup> /150 <sup>a</sup>	1500/2500
<b>Jams and Jellies</b>		20/30	10 <sup>a</sup> /100 <sup>a</sup>	1000/2500
<b>Meat Products</b>		20/75	16 <sup>a</sup> /40 <sup>a</sup>	5000 <sup>a</sup> /20000 <sup>a</sup>
<b>Milk Products</b>		20/30	15/100	2500 <sup>a</sup> /5000 <sup>a</sup>
<b>Nut Products</b>			10 <sup>a</sup> /150 <sup>a</sup>	2500/5000 <sup>a</sup>
<b>Other Grains</b>			50/150	1500 <sup>a</sup> /5000 <sup>a</sup>
<b>Poultry Products</b>		20/75	10 <sup>a</sup> /150 <sup>a</sup>	5000 <sup>a</sup> /20000 <sup>a</sup>
<b>Processed Fruits</b>		20/30	20 <sup>a</sup> /50 <sup>a</sup>	1500/2500
<b>Processed Vegetables</b>		20/30	10 <sup>a</sup> /150 <sup>a</sup>	2500/5000 <sup>a</sup>
<b>Reconstituted Vegetable Protein</b>			10 <sup>a</sup> /150 <sup>a</sup>	5000 <sup>a</sup> /20000 <sup>a</sup>
<b>Seasonings and Flavors</b>		20/30	10 <sup>a</sup> /150 <sup>a</sup>	2500/20000 <sup>a</sup>
<b>Snack Foods</b>		20/30	10 <sup>a</sup> /150 <sup>a</sup>	2500/5000 <sup>a</sup>
<b>Soft Candy</b>	60/200 <sup>a</sup>	20/30	1 <sup>a</sup> /30 <sup>a</sup>	1500 <sup>a</sup> /2500 <sup>a</sup>
<b>Soups</b>		20/30	10 <sup>a</sup> /100 <sup>a</sup>	2500/5000 <sup>a</sup>
<b>Sugar Substitutes</b>			1 <sup>a</sup> /30 <sup>a</sup>	1500/3500 <sup>a</sup>
<b>Sweet Sauces</b>		20/30	1 <sup>a</sup> /30 <sup>a</sup>	1500/3500 <sup>a</sup>



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

<b>FEMA No.</b>	<b>FEMA Primary Name</b>	<b>The Identification Description as Reviewed by the FEMA Expert Panel</b>
<b>4947</b>	Glucosylated stevia extract 40% with 14% Rebaudioside A	35-45% Glucosylated steviol glycosides; 11-17% Rebaudioside A; 8-15% Stevioside; Less than 3% all other individual steviol glycosides not further glucosylated; Maltodextrin 23-45%
<b>4949</b>	<i>Corynebacterium ammoniagenes</i> fermentation product	20-25% Miscellaneous-nitrogen containing compounds; 2-5% Amino acids; 3-5% Minerals; <7% Carbohydrates typically monosaccharides; 50-55% Dextrins
<b>4957</b>	Rebaudioside M 85%	Rebaudioside M ≥85%; Rebaudioside D 3-12%; Total steviol glycosides no less than 95%.
<b>4964</b>	<i>Corynebacterium glutamicum</i> cell free fermentation product	No more than 30% glutamic acid; Up to 10% simple carbohydrates; Less than 5% sum of other individual amino acids; No more than 60% dextrins
<b>4967</b>	<i>delta</i> -Cadinene 93%	93-95% <i>delta</i> -Cadinene; approximately 3% other Aliphatic and aromatic hydrocarbons, with less than 3% <i>gamma</i> -cadinene
<b>4969</b>	Yerba mate extract ( <i>Ilex paraguariensis</i> A. St.-Hil.)	>95% DicaFFEoylquinic acids, chlorogenic acid and its related positional and stereo isomer as well as other related caffeic and quinic acid derivatives; <0.05% caffeine
<b>4974</b>	Germacrene D ≥85%	≥85% Germacrene D; <5% <i>trans</i> -Caryophyllene; <4% of Other aliphatic and aromatic hydrocarbons; <1% each of Aliphatic and aromatic tertiary alcohols and related esters, and epoxide derivatives