GRAS Flavoring Substances 30

30. GRAS Flavoring Substances. This list of substances will appear in the 30th 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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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.

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	**Decanedioic acid** 1,8-Octanedicarboxylic acid 1,10-Decanedioic acid Sebacic acid Decanedicarboxylic acid
4949	***Corynebacterium ammoniagenes* fermentation product** *C. ammoniagenes* dried fermentation broth
4957	**Rebaudioside M 85%** Rebaudioside X 85%
4958	**4-Formyl-2-methoxyphenyl *l*-menthyl glutarate** 4-Formyl-2-methoxyphenyl-(1*R*,2*S*,5*R*)-2-isopropyl-5-methylcyclohexyl pentanedioate Pentanedioic acid, 1-(4-formyl-2-methoxyphenyl) 5-[(1*R*,2*S*,5*R*)-5-methyl-2-(1-methylethyl)cyclohexyl] ester
4959	**9-Dodecen-12-olide** Yuzu lactone Oxacyclotridec-10-en-2-one 1-Oxacyclotridec-10-en-2-one
4964	***Corynebacterium glutamicum* cell free fermentation broth** *C. glutamicum* dried fermentation broth
4965	***N*-(1-((4-Amino-2,2-dioxido-1*H*-benzo[*c*][1,2,6]thiadiazin-5-yl)oxy)-2-methylpropan-2-yl)isonicotinamide**
4967	***delta*-Cadinene 93%**
4969	**Yerba mate extract (*Ilex paraguariensis* A. St.-Hil.)** Mate absolute *Ilex paraguariensis* A. St.-Hil. extract
4971	***beta*-Farnesene** 1,6,10-Dodecatriene, 7,11-dimethyl-3-methylene-, (6*E*)- 1,6,10-Dodecatriene, 7,11-dimethyl-3-methylene-, (*E*)- (6*E*)-7,11-Dimethyl-3-methylene-1,6,10-dodecatriene (*E*)-7,11-Dimethyl-3-methylene-1,6,10-dodecatriene (*E*)-*beta*-Farnesene *trans*-beta-Farnesene
4972	**Diethyl mercaptosuccinate**
4973	**3-Mercapto-3-methyl-1-pentyl acetate**
4974	**Germacrene D ≥85%**
4977	**10-Hydroxy-4,8-dimethyldec-4-enal** 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	*Corynebacterium ammoniagenes* fermentation product	Rebaudioside M 85%	4-Formyl-2-methoxyphenyl l-menthyl glutarate	9-Dodecen-12-olide	*Corynebacterium glutamicum* cell free fermentation product
Category/FEMA No.	**4943**	**4949**	**4957**	**4958**	**4959**	**4964**
Baked Goods	40/200	1000/7500	15/20	5/50	0.5/2	1000/11000
Beverages Type I, Non-Alcoholic	20/50		15/20		0.01/0.2	
Beverages Type II, Alcoholic	15/30		15/20		0.01/0.2	
Breakfast Cereals	50/100	1000/5000	15/20	1/10	0.3/1	1000/11000
Cheeses	40/100	2000/7500			0.1/0.5	3000/11000
Chewing Gum	100/300		15/20		1/4	
Condiments and Relishes	30/100	3000/20000	15/20		0.3/1	3000/18000
Confections and Frostings	40/100		15/20	1/10	0.3/1	
Egg Products	50/100	1000/10000			0.1/0.5	1000/7000
Fats and Oils	50/100				2/10	
Fish Products	50/100	3000/10000			0.1/0.5	3000/9000
Frozen Dairy	40/100		15/20		0.1/0.5	
Fruit Ices	30/60		15/20		0.1/0.5	
Gelatins and Puddings	30/60		15/20		0.1/0.5	
Granulated Sugar						
Gravies	40/100	3000/20000	15/20		0.2/2	3000/11000
Hard Candy	50/200		15/20		0.2/2	
Imitation Dairy Products	40/100	2000/10000	15/20		0.5/3	3000/11000
Instant Coffee and Tea	30/100		15/20		0.1/0.5	
Jams and Jellies	50/100		15/20		0.1/0.5	
Meat Products	50/100	2000/15000			0.1/0.5	3000/11000
Milk Products	40/100		15/20		0.1/0.5	
Nut Products	40/100	1000/10000	15/20			1000/4000
Other Grains	50/200		15/20			
Poultry Products	50/100	2000/10000			0.1/0.5	3500/7500
Processed Fruits	50/100		15/20		0.1/0.5	
Processed Vegetables	50/100		15/20			
Reconstituted Vegetable Protein	50/100		15/20			
Seasonings and Flavors	50/100	5000/50000	15/20			20000/150000
Snack Foods	50/100	1000/10000	15/20		0.3/1	7500/20000
Soft Candy	50/200		15/20		0.3/2	
Soups	50/300	3000/20000	15/20		0.05/0.5	3500/18500
Sugar Substitutes	30/60					
Sweet Sauces	40/100		15/20		0.1/1	

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)

	N-(1-((4-Amino-2,2-dioxido-1*H*-benzo[c][1,2,6]thiadiazin-5-yl)oxy)-2-methylpropan-2-yl)isonicotinamide	*delta*-Cadinene 93%	Yerba mate extract (*Ilex paraguariensis* A. St.-Hil.)	*beta*-Farnesene	Diethyl mercaptosuccinate
Category/FEMA No.	**4965**	**4967**	**4969**	**4971**	**4972**
Baked Goods	10/22	0.9/0.9		10/50	1/10
Beverages Type I, Non-Alcoholic	15/22		400/1000	5/20	0.1/1
Beverages Type II, Alcoholic	10/22		400/1000	5/20	0.1/1
Breakfast Cereals	20/22			10/50	
Cheeses				2/10	
Chewing Gum	22/22			30/90	1/10
Condiments and Relishes	20/22	0.3/0.3	400/1000	5/15	1/10
Confections and Frostings	22/22		400/1000	20/60	1/10
Egg Products					
Fats and Oils				5/30	
Fish Products				1/5	
Frozen Dairy	15/22			5/40	1/10
Fruit Ices	15/22		400/1000	5/20	1/10
Gelatins and Puddings	15/22		400/1000	2/10	1/10
Granulated Sugar					
Gravies				5/20	0.1/1
Hard Candy	22/22	0.9/0.9	400/1000	10/50	1/10
Imitation Dairy Products	15/22			1/5	
Instant Coffee and Tea	10/22		400/1000	5/20	1/10
Jams and Jellies	15/22		400/1000	2/10	1/10
Meat Products				1/5	1/10
Milk Products	15/22			10/30	
Nut Products				5/20	1/10
Other Grains				10/50	0.1/1
Poultry Products				1/5	0.1/1
Processed Fruits			400/1000	5/30	0.1/1
Processed Vegetables			400/1000	5/10	0.1/1
Reconstituted Vegetable Protein				5/20	
Seasonings and Flavors				10/50	0.1/1
Snack Foods				5/20	
Soft Candy	20/22		400/1000	10/30	1/10
Soups			400/1000	5/20	1/10
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)

	3-Mercapto-3-methyl-l-pentyl acetate	Germacrene D ≥85%	10-Hydroxy-4,8-dimethyldec-4-enal
Category/FEMA No.	**4973**	**4974**	**4977**
Baked Goods	0.001/0.05	0.5/0.5	
Beverages Type I, Non-Alcoholic	0.0001/0.002	0.2/0.2	0.5/5
Beverages Type II, Alcoholic	0.0001/0.002		0.5/5
Breakfast Cereals			
Cheeses	0.0005/0.005		
Chewing Gum	0.0005/0.01	3.4/4.8	2/20
Condiments and Relishes	0.0001/0.01		
Confections and Frostings	0.0005/0.005		2/20
Egg Products	0.0002/0.001		
Fats and Oils			
Fish Products			
Frozen Dairy	0.0002/0.003		
Fruit Ices	0.0002/0.003	0.3/0.3	0.5/5
Gelatins and Puddings	0.0002/0.003		
Granulated Sugar			
Gravies	0.0005/0.005		
Hard Candy	0.0005/0.01	0.5/0.5	1/10
Imitation Dairy Products			
Instant Coffee and Tea	0.0003/0.005		0.5/5
Jams and Jellies			1/10
Meat Products	0.001/0.01		
Milk Products	0.0001/0.001		
Nut Products			
Other Grains			
Poultry Products			
Processed Fruits			
Processed Vegetables			
Reconstituted Vegetable Protein			
Seasonings and Flavors	0.01/0.5		
Snack Foods	0.001/0.05		
Soft Candy	0.001/0.1		1/10
Soups	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 (*Quercus alba* L.; *Quercus petraea*)	Rebaudioside A	*Cordyceps sinensis* fermentation product	Sodium gluconate
GRAS Publication	**3**	**28**	**28**	**29**
Category/FEMA No.	**2794**	**4601**	**4878**	**4934**
Baked Goods	72/90	20[c]/30[c]	30/50	5000[a]/20000[a]
Beverages Type I, Non-Alcoholic	550[a]/1000[a]	20/30	30[a]/1000	1500/3500[a]
Beverages Type II, Alcoholic	1000/1000	20/30	10[a]/1000	1500/3500[a]
Breakfast Cereals		20/30	10[a]/100[a]	2500/5000[a]
Cheeses				5000[a]/20000[a]
Chewing Gum	115/200	200/200	20[a]/100[a]	10000[a]/20000[a]
Condiments and Relishes		20/30	1[a]/30[a]	2500[a]/5000[a]
Confections and Frostings		20/30	1[a]/30[a]	1500/2500
Egg Products			1[a]/30[a]	2500[a]/5000[a]
Fats and Oils				5000[a]/10000[a]
Fish Products			1[a]/30[a]	5000[a]/20000[a]
Frozen Dairy	52/200[a]	20/30	10[a]/100[a]	1500/2500
Fruit Ices		20/30		1500/2500
Gelatins and Puddings	1[a]/1[a]	20/30		1500[a]/2500[a]
Granulated Sugar				
Gravies		20/30	10[a]/100[a]	2500/5000[a]
Hard Candy	2.5/200[a]	20/30	1[a]/30[a]	10000[a]/20000[a]
Imitation Dairy Products		20/30	10[a]/150[a]	5000[a]/10000[a]
Instant Coffee and Tea		20/30	10[a]/150[a]	1500/2500
Jams and Jellies		20/30	10[a]/100[a]	1000/2500
Meat Products		20/75	16[a]/40[a]	5000[a]/20000[a]
Milk Products		20/30	15/100	2500[a]/5000[a]
Nut Products			10[a]/150[a]	2500/5000[a]
Other Grains			50/150	1500[a]/5000[a]
Poultry Products		20/75	10[a]/150[a]	5000[a]/20000[a]
Processed Fruits		20/30	20[a]/50[a]	1500/2500
Processed Vegetables		20/30	10[a]/150[a]	2500/5000[a]
Reconstituted Vegetable Protein			10[a]/150[a]	5000[a]/20000[a]
Seasonings and Flavors		20/30	10[a]/150[a]	2500/20000[a]
Snack Foods		20/30	10[a]/150[a]	2500/5000[a]
Soft Candy	60/200[a]	20/30	1[a]/30[a]	1500[a]/2500[a]
Soups		20/30	10[a]/100[a]	2500/5000[a]
Sugar Substitutes			1[a]/30[a]	1500/3500[a]
Sweet Sauces		20/30	1[a]/30[a]	1500/3500[a]

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

FEMA No.	FEMA Primary Name	The Identification Description as Reviewed by the FEMA Expert Panel
4949	*Corynebacterium ammoniagenes* fermentation product	20-25% Miscellaneous-nitrogen containing compounds; 2-5% Amino acids; 3-5% Minerals; <7% Carbohydrates typically monosaccharides; 50-55% Dextrins
4957	Rebaudioside M 85%	Rebaudioside M ≥85%; Rebaudioside D 3-12%; Total steviol glycosides no less than 95%.
4964	*Corynebacterium glutamicum* 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
4967	*delta*-Cadinene 93%	93-95% *delta*-Cadinene; approximately 3% other Aliphatic and aromatic hydrocarbons, with less than 3% *gamma*-cadinene
4969	Yerba mate extract (*Ilex paraguariensis* 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
4974	Germacrene D ≥85%	≥85% Germacrene D; <5% *trans*-Caryophyllene; <4% of Other aliphatic and aromatic hydrocarbons; <1% each of Aliphatic and aromatic tertiary alcohols and related esters, and epoxide derivatives