GRAS Flavoring Substances 32

32. GRAS Flavoring Substances. This list of substances will appear in the 32nd 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 submits all information related to the GRAS reviews on these substances to the FDA. The key findings related to the GRAS evaluations of these substances will be available in GRAS 32. The Expert Panel also publishes separate extensive reviews of scientific information on all FEMA GRAS flavoring substances in the peer-reviewed scientific literature 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.

Change in GRAS Status of Propyl Paraben (FEMA 2951) and 2-Phenylphenol (FEMA 3959)

The FEMA GRAS statuses of propyl paraben (FEMA No. 2951) and 2-phenylphenol (FEMA No. 3959) under their conditions of intended use as flavor ingredients were reviewed. There is little evidence that either propyl paraben or 2-phenylphenol are used for the technical effect of flavoring. Based on this lack of evidence, the Panel concluded that both should be removed from the FEMA GRAS list.

Corrections and Errata to previous GRAS Publications
Primary Name of FEMA 4878. The primary name of FEMA 4878, *Cordyceps sinensis fermentation product*, has been changed to mushroom mycelia fermentation product.

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

FEMA No.	Primary Names and Synonyms
5030	**4-(*l*-Menthoxy)-2-methyl-2-butanol**
5035	**Brazzein**
5038	**Hexahydro-6a,7-dimethyl-2,5-methano-2*H*-cyclopenta[b]furan**
5040	***Eucalyptus citriodora* oil**
5042	**Heat-treated Glucosylated Steviol Glycosides 35% with Steviol Glycosides 10%**
5044	**Sakura flower extract** *Prunus serrulata* flower extract *Cerasus serrulata* flower extract
5045	**Sakura flower distillate** *Prunus serrulata* flower distillate *Cerasus serrulata* flower distillate
5046	**Sakura leaf distillate** Oshima zakura cherry leaf distillate *Prunus speciosa* leaf distillate *Cerasus speciosa* leaf distillate
5047	**Sansho pepper extract** Japanese pepper extract Chopinamu extract *Fagara piperita* L. extract Sanshou pepper extract Sansyo pepper extract Kona-zanshō extract
5048	**Sansho pepper distillate** Japanese pepper distillate Chopinamu distillate *Fagara piperita* L. distillate Sanshou pepper distillate Sansyo pepper distillate Kona-zanshō distillate
5050	**1-(tert-Butyl)-*N*-(4-methoxyphenyl)cyclohexane-1-carboxamide**
5054	**Rosemary extract, rosmarinic acid 80%**
5060	**Rosemary extract, rosmarinic acid 15%**
5066	**4-(4-Methylpent-3-en-1-yl)thiophen-2(5*H*)-one**
5067	***alpha*-Bisabolene** (*E*)-*alpha*-bisabolene t*rans*-alpha-bisabolene 1-Methyl-4-[(2*E*)-6-methyl-2,5-heptadien-2-yl]cyclohexene 4-(1,5-Dimethyl-1,4-hexadienyl)-1-methyl cyclohexene 6-Methyl-2-(4-methylcyclohex-3-enyl)hept-2,5-diene Cyclohexene, 4-(1,5-dimethyl-1,4-hexadienyl)-1-methyl- Cyclohexene, 4-[(1*E*)-1,5-dimethyl-1,4-hexadien-1-yl]-1-methyl
5069	**Rebaudioside M 70%**
5073	***Corynebacterium glutamicum* fermentation product**

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)

	4-(*l*-Menthoxy)-2-methyl-2-butanol	Brazzein	Hexahydro-6a,7-dimethyl-2,5-methano-2*H*-cyclopenta[b]furan	*Eucalyptus citriodora* oil	Heat-treated glucosylated steviol glycosides 35% with steviol glycosides 10%	Sakura flower extract
Category/FEMA No.	**5030**	**5035**	**5038**	**5040**	**5042**	**5044**
Baked Goods		7/7	0.5/5		50/100	
Beverages Type I, Non-Alcoholic	1/5	7/7	0.1/1	280/280	50/100	
Beverages Type II, Alcoholic	1/5	7/7	0.1/1	315/315	50/100	1200/6000
Breakfast Cereals		7/7	0.1/1		50/100	
Cheeses			0.2/2		50/100	
Chewing Gum	1/10	30/30	5/50		50/100	
Condiments and Relishes		7/7	0.2/2		50/100	
Confections and Frostings		7/7	0.5/5		50/100	
Egg Products					50/100	
Fats and Oils			1/10		50/100	
Fish Products					50/100	
Frozen Dairy		7/7	0.1/1		50/100	
Fruit Ices		7/7	0.2/2		50/100	
Gelatins and Puddings		7/7	0.5/5		50/100	
Granulated Sugar			0.1/1			
Gravies	1/5		0.2/2		50/100	
Hard Candy		7/7	0.5/5		50/100	
Imitation Dairy Products		7/7			50/100	
Instant Coffee and Tea	1/5	7/7			50/100	
Jams and Jellies		7/7	0.2/2		50/100	
Meat Products					50/100	
Milk Products		7/7	0.1/1		50/100	
Nut Products		7/7	0.2/2		50/100	
Other Grains		7/7	0.1/1		50/100	
Poultry Products					50/100	
Processed Fruits		7/7	0.2/2		50/100	
Processed Vegetables			0.1/1		50/100	
Reconstituted Vegetable Protein			0.5/5		50/100	
Seasonings and Flavors		7/7	1/10		50/100	
Snack Foods		7/7	0.1/1		50/100	
Soft Candy	1/5	7/7	0.5/5		50/100	
Soups	1/5	7/7	0.1/1		50/100	
Sugar Substitutes						
Sweet Sauces		7/7	0.1/1		50/100	

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)

	Sakura flower distillate	Sakura leaf distillate	Sansho pepper extract	Sansho pepper distillate	1-(tert-Butyl)-*N*-(4-methoxyphenyl)cyclohexane-1-carboxamide	Rosemary extract, rosmarinic acid 80%
Category/FEMA No.	**5045**	**5046**	**5047**	**5048**	**5050**	**5054**
Baked Goods					0.05/20	80/200
Beverages Type I, Non-Alcoholic					0.15/10	55/150
Beverages Type II, Alcoholic	400/1000	0.3/3.2	80/400	120/620		55/150
Breakfast Cereals						50/100
Cheeses					0.1/15	80/150
Chewing Gum					0.05/500	200/500
Condiments and Relishes					0.05/40	100/200
Confections and Frostings						55/100
Egg Products					0.05/50	55/100
Fats and Oils						55/100
Fish Products					0.05/40	100/200
Frozen Dairy					0.05/20	25/125
Fruit Ices						50/100
Gelatins and Puddings						50/100
Granulated Sugar						
Gravies					0.05/50	80/200
Hard Candy						100/150
Imitation Dairy Products					0.125/15	55/100
Instant Coffee and Tea					0.05/20	55/100
Jams and Jellies						100/150
Meat Products					0.05/40	100/200
Milk Products					0.075/40	50/100
Nut Products						100/200
Other Grains						100/200
Poultry Products					0.05/40	100/200
Processed Fruits						55/100
Processed Vegetables						100/200
Reconstituted Vegetable Protein					0.05/100	100/250
Seasonings and Flavors					0.25/1000	500/1000
Snack Foods					0.25/1000	100/200
Soft Candy					0.05/20	80/150
Soups					0.15/15	60/200
Sugar Substitutes						
Sweet Sauces					0.05/20	

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)

	Rosemary extract, rosmarinic acid 15%	4-(4-Methylpent-3-en-1-yl)thiophen-2(5*H*)-one	*alpha*-Bisabolene	Rebaudioside M 70%	*Corynebacterium glutamicum* fermentation product
Category/FEMA No.	**5060**	**5066**	**5067**	**5069**	**5073**
Baked Goods	60/200	0.01/0.1	10/50		4400/4400
Beverages Type I, Non-Alcoholic	50/120	0.001/0.01	5/25	15/20	
Beverages Type II, Alcoholic	50/120	0.001/0.01	10/50	15/20	
Breakfast Cereals	50/80	0.01/0.1	5/25		4400/4400
Cheeses	60/100	0.1/1			4400/4400
Chewing Gum	200/400	0.1/1	10/50	15/20	
Condiments and Relishes	100/150				5000/5000
Confections and Frostings	50/100	0.01/0.1	10/50		
Egg Products	60/100	0.01/0.1			2800/2800
Fats and Oils	60/100	0.1/1	5/25		5000/5000
Fish Products	100/200				3600/3600
Frozen Dairy	20/80	0.01/0.1	7/35	15/20	
Fruit Ices	40/80	0.01/0.1	10/50	15/20	
Gelatins and Puddings	40/80	0.01/0.1	5/25		
Granulated Sugar					
Gravies	60/200	0.1/1			2500/2500
Hard Candy	60/150	0.01/0.1	10/50		
Imitation Dairy Products	40/100	0.01/0.1		15/20	4400/4400
Instant Coffee and Tea	40/100	0.001/0.01		15/20	
Jams and Jellies	40/100		5/25		
Meat Products	100/200	0.01/0.1			2700/2700
Milk Products	40/80	0.001/0.01		15/20	
Nut Products	60/120			15/20	1600/1600
Other Grains	80/200	0.01/0.1			
Poultry Products	80/200				2700/2700
Processed Fruits	40/100	0.01/0.1	7/35	15/20	
Processed Vegetables	60/200	0.01/0.1			
Reconstituted Vegetable Protein	80/250	0.01/0.1			
Seasonings and Flavors	500/1000	0.1/1		15/20	4000/4000
Snack Foods	100/250	0.01/0.1		15/20	4000/4000
Soft Candy	60/100	0.01/0.1	10/50		
Soups	60/150	0.01/0.1			2500/2500
Sugar Substitutes					
Sweet Sauces		0.01/0.1	5/25	15/20	

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

	Tartaric acid (D-, L-, DL-, Meso-)	L-Histidine	Yerba mate extract (*Ilex paraguariensis* A. St.-Hil.)	Mushroom mycelia fermentation product	3-(4-Hydroxy-phenyl)-1-(2,4,6-trihydroxy-phenyl)-propan-1-one	5,7-Dihydroxy-2-(3-hydroxy-4-methoxyphenyl)chroman-4-one
GRAS Publication	**29**	**30**	**30**	**30**	**30**	**26**
Category/FEMA No.	**3044**	**3694**	**4969**	**4878**	**4390**	**4313**
Baked Goods	0.9/1300	10/150	400[a]/1000[a]	30/50	50/150	
Beverages Type I, Non-Alcoholic	1/960	200/200	400/1000	30/1000	50/100	10/50
Beverages Type II, Alcoholic	5000/10000	100[a]/500[a]	400/1000	10/1000	15/50	10/100
Breakfast Cereals			400[a]/1000[a]	10/100	50/100	30/60
Cheeses			400/1000		10/50	20/150
Chewing Gum	500/5000			20/100		
Condiments and Relishes	2/10000	200[a]/1000[a]	400/1000	1/30	10/100	10/100
Confections and Frostings	200[a]/1000[a]	20/150	400/1000	1/150[a]	156[a]/312[a]	408[a]/816[a]
Egg Products				1/30		
Fats and Oils	200[a]/1000[a]	200[a]/1000[a]				
Fish Products			400[a]/1000[a]	1/30		
Frozen Dairy	2/570	60[a]/300[a]	400/1000	10/100	10/50	20/150
Fruit Ices	100[a]/500[a]	100[a]/500[a]	400/1000		20/50	20/100
Gelatins and Puddings	200[a]/1000[a]	200[a]/1000[a]	400/1000		10/100	10/100
Granulated Sugar					20/100	100/250
Gravies	200[a]/1000[a]	200[a]/1000[a]	400/1000	10/100	10/100	10/100
Hard Candy	10/5400		400/1000	1/150[a]	20/100	50/100
Imitation Dairy Products	60[a]/300[a]	60[a]/300[a]	400/1000	10/150	50/100	
Instant Coffee and Tea	100[a]/500[a]	100[a]/500[a]	400/1000	10/150	15/50	10/50
Jams and Jellies	200[a]/1000[a]	200[a]/1000[a]	400/1000	10/100	20/50	20/50
Meat Products	0.01/0.02	30/150	400[a]/1000[a]	16/40	50[a]/150[a]	
Milk Products	60[a]/300[a]	60[a]/300[a]	400/1000	15/100	10/50	20/150
Nut Products				10/150	20/50	20/50
Other Grains	0.2/0.2			50/150	50/100	30/60
Poultry Products			400[a]/1000[a]	10/150	50[a]/150[a]	
Processed Fruits	10/10		400/1000	20/50	20/50	20/50
Processed Vegetables			400/1000	10/150	20/50	20/50
Reconstituted Vegetable Protein			400/1000	10/150	50/150	20/50
Seasonings and Flavors			400[a]/1000[a]	10/1000[a]	10/100	10/100
Snack Foods			400[a]/1000[a]	10/150	50/100	60/120
Soft Candy	200[a]/1000[a]	200[a]/1000[a]	400/1000	1/150[a]	156[a]/312[a]	408[a]/816[a]
Soups	200[a]/1000[a]	200[a]/1000[a]	400/1000	10/100	10/100	10/100
Sugar Substitutes			400[a]/1000[a]	1/30	20/100	100/250
Sweet Sauces	60[a]/300[a]	60[a]/300[a]	400/1000	1/30	156[a]/312[a]	408[a]/816[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
5040	*Eucalyptus citriodora* oil	Prepared from the leaves and twigs of the *E. maculata citriodora* (syn. *Corymbia citriodora*) tree by steam distillation; 77-92% Unsaturated linear and branched-chain aliphatic, non-conjugated aldehydes, related primary alcohols, carboxylic acids and esters, including citronellal and citronellol; 2-11% Isopulegol; Up to 5% *p*-menthane-3,8-diol; Up to 3% eucalyptol
5042	Heat-treated glucosylated steviol glycosides 35% with steviol glycosides 10%	Prepared from enzymatically modified and heated steviol glycosides; >95% of identified constituents inclusive of: supraglucosylated steviol glycosides 30-40%, steviol glycosides not further glucosylated 8-13% with each individually less than 4%, dextrins 25-40%, monosaccharides 3-8%, disaccharides less than 1.5%, water not more than 6%, and other non-volatiles 5-10% including sugar alcohols, amino acids, proteins and lipids
5044	Sakura flower extract	Aqueous ethanol solution of approximately 0.06% Sakura flower extract derived from the water and ethanol extraction of the flowers of *Prunus serrulata* Lindl. of which the major marker constituents are saturated aliphatic, acyclic, linear primary alcohols, aldehydes, carboxylic acids and related esters, including ethyl acetate and acetic acid.
5045	Sakura flower distillate	Aqueous ethanol solution of approximately 0.02% Sakura flower distillate derived from the water and ethanol extraction of the flowers of *Prunus serrulata* Lindl. of which the major marker constituents are saturated aliphatic, acyclic, linear primary alcohols, aldehydes, carboxylic acids and related esters, including ethyl acetate, acetaldehyde, methanol and propanol; benzyl derivatives including benzaldehyde.
5046	Sakura leaf distillate	Aqueous ethanol solution of approximately 0.02% Sakura leaf distillate derived from the water and ethanol extraction of the leaves of *Prunus speciosa* (Koidz.) Nakai. of which the major marker constituents are saturated aliphatic, acyclic, linear primary alcohols, aldehydes, carboxylic acids and related esters, including ethyl acetate, acetaldehyde, methanol and propanol; benzyl derivatives; and aliphatic, alicyclic, alicyclic-fused and aromatic-fused ring lactones.
5047	Sansho pepper extract	Aqueous ethanol solution of approximately 0.02% Sansho pepper extract derived from the water and ethanol extraction of the dried berries of *Zanthoxylum piperitum* of which the major marker constituents are saturated aliphatic, acyclic, linear primary alcohols, aldehydes, carboxylic acids and related esters, including ethyl acetate; unsaturated linear and branched-chain aliphatic, nonconjugated aldehydes, related primary alcohols, carboxylic acids and esters; aliphatic, alicyclic, alicyclic-fused and aromatic-fused ring lactones; and phenol derivatives.

5048	Sansho pepper distillate	Aqueous ethanol solution of approximately 0.01% Sansho pepper distillate derived from the water and ethanol extraction of the dried berries of *Zanthoxylum piperitum* of which the major marker constituents are saturated aliphatic, acyclic, linear primary alcohols, aldehydes, carboxylic acids and related esters, including propanol and ethyl laurate; aliphatic linear and branched-chain *alpha*, *beta*-unsaturated aldehydes and related alcohols acids and esters, including geraniol; unsaturated linear and branched-chain aliphatic, nonconjugated aldehydes, related primary alcohols, carboxylic acids and esters, including lavandulyl acetate.
5054	Rosemary extract, rosmarinic acid 80%	Prepared from selective extraction of the aerial parts of rosemary (*Rosmarinus officinalis*); 83-96% Rosmarinic acid, up to 3% of other phenol derivatives and <0.5% of other volatile constituents.
5060	Rosemary extract, rosmarinic acid 15%	Prepared from selective extraction of the aerial parts of rosemary (*Rosmarinus officinalis*); 29-31% Carbohydrates, 15-16% rosmarinic acid, up to 25-31% of other phenol derivatives, <2% of other volatile constituents, 5-8% ash, 1-4% water, 1-2% protein, <2% fiber and <0.5% fat.
5069	Rebaudioside M 70%	76-77% Rebaudioside M, 16-18% Rebaudioside A, 7-8% Rebaudioside B.
5073	*Corynebacterium glutamicum* fermentation product	75-82% Protein, 9-15% carbohydrates, 3-5% ash, 3-5% water and <0.05% fat.