

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.

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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.

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

FEMA No.	Primary Names and Synonyms
5030	4-(1-Menthoxy)-2-methyl-2-butanol
5035	Brazzein
5038	Hexahydro-6a,7-dimethyl-2,5-methano-2H-cyclopenta[b]furan
5040	<i>Eucalyptus citriodora</i> oil
5042	Heat-treated glucosylated steviol glycosides 35% with steviol glycosides 10%
5044	Sakura flower extract <i>Prunus serrulata</i> flower extract <i>Cerasus serrulata</i> flower extract
5045	Sakura flower distillate <i>Prunus serrulata</i> flower distillate <i>Cerasus serrulata</i> flower distillate
5046	Sakura leaf distillate Oshima zakura cherry leaf distillate <i>Prunus speciosa</i> leaf distillate <i>Cerasus speciosa</i> leaf distillate
5047	Sansho pepper extract Japanese pepper extract Chopinamu extract <i>Fagara piperita</i> L. extract Sanshou pepper extract Sansyo pepper extract Kona-zanshō extract
5048	Sansho pepper distillate Japanese pepper distillate Chopinamu distillate <i>Fagara piperita</i> L. distillate Sanshou pepper distillate Sansyo pepper distillate Kona-zanshō distillate

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-(1-Menthoxy)-2-methyl-2-butanol	Brazzein	Hexahydro-6a,7-dimethyl-2,5-methano-2H-cyclopenta[b]furan	<i>Eucalyptus citriodora</i> 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
Category/FEMA No.	5045	5046	5047	5048
Baked Goods				
Beverages Type I, Non-Alcoholic				
Beverages Type II, Alcoholic	400/1000	0.3/3.2	80/400	120/620
Breakfast Cereals				
Cheeses				
Chewing Gum				
Condiments and Relishes				
Confections and Frostings				
Egg Products				
Fats and Oils				
Fish Products				
Frozen Dairy				
Fruit Ices				
Gelatins and Puddings				
Granulated Sugar				
Gravies				
Hard Candy				
Imitation Dairy Products				
Instant Coffee and Tea				
Jams and Jellies				
Meat Products				
Milk Products				
Nut Products				
Other Grains				
Poultry Products				
Processed Fruits				
Processed Vegetables				
Reconstituted Vegetable Protein				
Seasonings and Flavors				
Snack Foods				
Soft Candy				
Soups				
Sugar Substitutes				
Sweet Sauces				

Table 3. 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	<i>Eucalyptus citriodora</i> oil	Prepared from the leaves and twigs of the <i>E. maculata citriodora</i> (syn. <i>Corymbia citriodora</i>) 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% <i>p</i> -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%, dextrans 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 <i>Prunus serrulata</i> 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 <i>Prunus serrulata</i> 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 <i>Prunus speciosa</i> (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	Prepared by extraction of the dried berries of <i>Zanthoxylum piperitum</i> . On a concentrate basis excluding ethanol and water, FEMA 5047 is composed of 81-85% Saturated aliphatic, acyclic, linear primary alcohols, aldehydes, carboxylic acids and related esters, including ethyl acetate, ethyl laurate, propanol and methanol; and 13-17% Unsaturated linear and branched-chain aliphatic, non-conjugated esters, including geranyl formate and lavandulyl acetate.

5048	Sansho pepper distillate	Prepared by extraction of the dried berries of <i>Zanthoxylum piperitum</i> , followed by vacuum distillation. On a concentrate basis excluding ethanol and water, FEMA 5048 is composed of 53-57% Saturated aliphatic, acyclic, linear primary alcohols, aldehydes, carboxylic acids and related esters, including propanol, ethyl laurate and methanol; 31-35% Unsaturated linear and branched-chain aliphatic, non-conjugated aldehydes, related primary alcohols, carboxylic acids and esters, including geraniol, lavandulyl acetate and citronellal.
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