GRAS Flavoring Substances 31

31. GRAS Flavoring Substances. This list of substances will appear in the 31st 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 31. 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.

3-Acetyl-2,5-dimethylfuran DeGRAS

The FEMA GRAS status of 3-acetyl-2,5-dimethylfuran (FEMA 3391) under conditions of intended use as a flavor ingredient was reviewed. The Panel concluded that additional data are required. Such data would include comprehensive metabolism and toxicity data as well as in-depth evaluation of the mechanism of action for potential effects observed in toxicity and genotoxicity studies. Until such data are available for review, the flavor ingredient 3-acetyl-2,5-diemthylfuran has been removed from the FEMA GRAS list.

Corrections and Errata to previous GRAS Publications
Identity Description of FEMA 4845. In Supplementary Information 1 for GRAS 28, the identity description for FEMA 4845 erroneously omitted “inclusive of supraglucosylated steviol glycosides 50-70%”.

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

FEMA No.	Primary Names and Synonyms
4981	**8-Methyl-4-methylenenon-7-en-2-one**
4982	**4-(4-Methylpent-3-en-1-yl)-5,6-dihydro-2*H*-pyran-2-one**
4983	**4-Mercapto-1-octanol**
4984	**2,11-Tetradecadienal** 2,11-Tetradecadien-1-al
4985	**4,9-Dodecadienal** 4,9-Dodecadien-1-al
4986	**Hyaluronic acid, sodium salt** Polymeric structure of sodium salt of (2*S*,3*S*,4*R*,5*R*,6*R*)-3-[(2*S*,3*R*,5*S*,6*R*)-3-acetamido-5-hydroxy-6-(hydroxymethyl)oxan-2-yl]oxy-4,5,6-trihydroxyoxane-2-carboxylate Poly[(1→3)-2-acetamido-2-deoxy-β-d-glucose-(1→4)-β-d-glucopyranosyluronic acid] sodium salt Hyaluronan sodium Sodium hyaluronate
4991	***Persea americana* oil hydrolyzed fraction**
4992	**Rubusosides enriched Glucosylated Steviol Glycosides**
*5000	**Prepared Mixture of Chloride Salts of Potassium, Magnesium and Calcium**
5003	**2,6-Octadienal** 2,6-Octadien-1-al
5004	**2-Methyloctan-4-olide**
5005	**3-Hydroxyhexanoic acid**
5006	**3-Methyl-3-butene-1-thiol**
5010	**Thaumatin II** Thaumatin 2

* The molar composition of the chloride salts of potassium, magnesium and calcium in this mixture is 5:3:3. FEMA 5000 is considered GRAS as a liquid concentrate or a solid blend. The use levels for FEMA 5000 in Table 2 reflect the intended conditions of use for the liquid concentrate in finished food. The solid blend of FEMA 5000 is intended to be used at use levels consistent with providing the same final concentration of the constituent salts as would be provided from the liquid concentrate.

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)

	8-Methyl-4-methylenenon-7-en-2-one	4-(4-Methylpent-3-en-1-yl)-5,6-dihydro-2H-pyran-2-one	4-Mercapto-1-octanol	2,11-Tetradecadienal	4,9-Dodecadienal	Hyaluronic acid, sodium salt
Category/FEMA No.	**4981**	**4982**	**4983**	**4984**	**4985**	**4986**
Baked Goods	0.2/1	0.05/0.5		5/50	5/50	500/500
Beverages Type I, Non-Alcoholic	1/5	0.01/0.1	0.1/1	2/20	2/20	100/500
Beverages Type II, Alcoholic	5/25	0.05/0.5	0.1/1	2/20	2/20	150/500
Breakfast Cereals		0.05/0.5		5/50	5/50	200/500
Cheeses	0.1/0.5	0.01/0.1		1/10	1/10	
Chewing Gum	1/5	0.01/0.1	1/10	10/100	10/100	
Condiments and Relishes	0.5/2.5		1/10	2/20	2/20	
Confections and Frostings			1/10	2/20	2/20	
Egg Products		0.01/0.1		1/10	1/10	
Fats and Oils		0.01/0.1		5/50	5/50	200/500
Fish Products		0.01/0.1				
Frozen Dairy	0.1/0.5	0.01/0.1	1/10	2/20	2/20	200/500
Fruit Ices		0.01/0.1	1/10	2/20	2/20	
Gelatins and Puddings		0.01/0.1	1/10	2/20	2/20	
Granulated Sugar				5/50	5/50	
Gravies	0.1/1		0.1/1	2/20	2/20	
Hard Candy	0.5/2.5	0.01/0.1	1/10	5/50	5/50	
Imitation Dairy Products		0.01/0.1		2/20	2/20	200/500
Instant Coffee and Tea		0.05/0.5	1/10	5/50	5/50	100/500
Jams and Jellies		0.01/0.1	1/10	2/20	2/20	
Meat Products	0.1/0.5	0.01/0.1	1/10	1/10	1/10	200/500
Milk Products		0.05/0.5	1/10	2/20	2/20	200/500
Nut Products		0.01/0.1	1/10	2/20	2/20	
Other Grains		0.01/0.1	0.1/1	2/20	2/20	
Poultry Products			0.1/1			
Processed Fruits		0.01/0.1	0.1/1	1/10	1/10	
Processed Vegetables			0.1/1			
Reconstituted Vegetable Protein				2/20	2/20	
Seasonings and Flavors		0.5/5	0.1/1	10/100	10/100	200/500
Snack Foods		0.05/0.5	0.1/1	2/20	2/20	200/500
Soft Candy	0.5/2.5	0.01/0.1	1/10	2/20	2/20	
Soups		0.01/0.1	0.1/1	2/20	2/20	200/500
Sugar Substitutes		0.01/0.1		5/50	5/50	
Sweet Sauces		0.01/0.1		2/20	2/20	

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)

	Persea americana oil hydrolyzed fraction	Rubusosides enriched Glucosylated Steviol Glycosides	Prepared Mixture of Chloride Salts of Potassium, Magnesium and Calcium	2,6-Octadienal	2-Methyloctan-4-olide	3-Hydroxyhexanoic acid
Category/FEMA No.	**4991**	**4992**	***5000**	**5003**	**5004**	**5005**
Baked Goods	3/15	50/170		0.02/0.2		0.15/1
Beverages Type I, Non-Alcoholic		50/170	1424/1424	0.005/0.5	0.001/0.1	0.05/0.3
Beverages Type II, Alcoholic		50/170	1424/1424	0.005/0.5	0.001/0.1	0.05/0.3
Breakfast Cereals	3/15	50/170		0.02/0.2		0.15/1
Cheeses	3/15	50/170		0.05/0.5		0.05/0.5
Chewing Gum		50/170		0.05/0.5		0.15/1
Condiments and Relishes	5/15	50/170		0.05/0.5		0.1/0.5
Confections and Frostings		50/170		0.05/0.5		0.1/0.5
Egg Products		50/170		0.02/0.2		
Fats and Oils		50/170		0.1/1		0.05/0.3
Fish Products	3/15	50/170		0.1/1		
Frozen Dairy	3/15	50/170		0.05/0.5	0.001/0.1	0.05/0.3
Fruit Ices		50/170	1424/1424	0.05/0.5		0.05/0.3
Gelatins and Puddings		50/170		0.05/0.5		0.05/0.3
Granulated Sugar				0.1/1		
Gravies	3/15	50/170	1424/1424	0.1/1		0.15/1
Hard Candy		50/170		0.1/1		0.05/0.3
Imitation Dairy Products	3/15	50/170		0.05/0.5	0.001/0.1	0.05/0.3
Instant Coffee and Tea		50/170		0.05/0.5	0.001/0.1	0.05/0.3
Jams and Jellies		50/170	1424/1424	0.05/0.5		0.05/0.3
Meat Products	3/15	50/170		0.05/0.5		0.05/0.3
Milk Products	3/15	50/170		0.02/0.2	0.1/1	0.05/0.3
Nut Products	3/15	50/170		0.1/1	0.1/1	
Other Grains	3/15	50/170		0.1/1		
Poultry Products	3/15	50/170		0.5/5		0.05/0.3
Processed Fruits		50/170				0.05/0.3
Processed Vegetables	3/15	50/170		0.05/0.5		
Reconstituted Vegetable Protein	5/25	50/170		0.1/1		
Seasonings and Flavors	5/25	50/170		1/10	0.1/1	0.15/1
Snack Foods	3/15	50/170		0.1/1	0.1/1	0.1/0.5
Soft Candy		50/170		0.01/0.1		0.1/0.5
Soups	3/15	50/170		0.1/1	0.001/0.1	0.1/0.5
Sugar Substitutes			1424/1424	0.01/0.1		
Sweet Sauces		50/170	1424/1424	0.05/0.5		0.05/0.3

*Use levels for FEMA 5000 as a liquid concentrate in finished food

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-Methyl-3-butene-1-thiol	Thaumatin II
Category/FEMA No.	**5006**	**5010**
Baked Goods	0.1/1	7/7
Beverages Type I, Non-Alcoholic	0.01/0.1	7/7
Beverages Type II, Alcoholic	0.01/0.1	7/7
Breakfast Cereals	0.1/1	7/7
Cheeses	0.05/0.5	7/7
Chewing Gum		
Condiments and Relishes	0.1/1	7/7
Confections and Frostings	0.01/0.1	7/7
Egg Products		7/7
Fats and Oils		7/7
Fish Products		7/7
Frozen Dairy	0.01/0.1	7/7
Fruit Ices		7/7
Gelatins and Puddings	0.02/0.2	7/7
Granulated Sugar		
Gravies	0.1/1	7/7
Hard Candy	0.1/1	7/7
Imitation Dairy Products		7/7
Instant Coffee and Tea	0.1/1	7/7
Jams and Jellies	0.1/1	7/7
Meat Products	0.1/1	7/7
Milk Products	0.1/1	7/7
Nut Products	0.1/1	7/7
Other Grains	0.01/0.1	7/7
Poultry Products	0.1/1	7/7
Processed Fruits	0.01/0.1	7/7
Processed Vegetables		7/7
Reconstituted Vegetable Protein		7/7
Seasonings and Flavors	0.1/1	7/7
Snack Foods	0.1/1	7/7
Soft Candy	0.1/1	7/7
Soups	0.1/1	7/7
Sugar Substitutes		
Sweet Sauces		7/7

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

	Methylcyclopentenolone	4-Aminobutyric acid
GRAS Publication	**3**	**23**
Category/FEMA No.	**2700**	**4288**
Baked Goods	12/27	50/300
Beverages Type I, Non-Alcoholic	2/11	20/100
Beverages Type II, Alcoholic	0.9/9	30/200
Breakfast Cereals	40/100	30/100
Cheeses	2^a/15^a	10^a/100^a
Chewing Gum	690/3560	100/500
Condiments and Relishes		
Confections and Frostings		30/100
Egg Products		
Fats and Oils		30/100
Fish Products	2^a/15^a	10^a/100^a
Frozen Dairy	5/17	
Fruit Ices		20/100
Gelatins and Puddings	5/14	20/100
Granulated Sugar		
Gravies	4^a/30^a	
Hard Candy	17/18	40/300
Imitation Dairy Products	2^a/15^a	10^a/100^a
Instant Coffee and Tea		20/100
Jams and Jellies		
Meat Products	2/15^a	20/200
Milk Products	2^a/15^a	30/100
Nut Products		
Other Grains		
Poultry Products	2^a/15^a	10^a/100^a
Processed Fruits		
Processed Vegetables		
Reconstituted Vegetable Protein	2^a/15^a	10^a/100^a
Seasonings and Flavors	2^a/15^a	
Snack Foods	2^a/15^a	10/100
Soft Candy	9/26	20/200
Soups	2^a/15^a	30/200
Sugar Substitutes		
Sweet Sauces	10/30	

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
4991	*Persea americana* oil hydrolyzed fraction	Polyhydroxylated fatty alcohols (PFAs) typically measured as 60-80% avocadene and avocadyne; 10-30% Polyhydroxylated fatty alcohols - acetates (PFA acetates); 10-15% Citrates
4992	Rubusosides enriched Glucosylated Steviol Glycosides	Total steviol glycosides inclusive of glycosylated steviol glycosides 70-85%, glucosylated rubusosides 55-65%, rubusoside 9-13%, rebaudioside A <4%, stevioside <0.5%, not further glycosylated steviol glycosides individually <3%; Maltodextrin 10-20%.