

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

FEMA No.	Primary Names and Synonyms
4984	2,11-Tetradecadienal Tetradeca-2,11-dienal 2,11-Tetradecadien-1-al
4985	4,9-Dodecadienal Dodeca-4,9-dienal 4,9-Dodecadien-1-al
4986	Hyaluronic acid, sodium salt (2S,3S,4S,5R,6R)-6-[(2S,3R,5S,6R)-3-acetamido-2-[(2S,3S,4R,5R,6R)-6-[(2R,3R,5S,6R)-3-acetamido-2,5-dihydroxy-6-(hydroxymethyl)oxan-4-yl]oxy-2-carboxy-4,5-dihydroxyoxan-3-yl]oxy-5-hydroxy-6-(hydroxymethyl)oxan-4-yl]oxy-3,4,5-trihydroxyoxane-2-carboxylic acid Polymeric structure of sodium salt of (2S,3S,4R,5R,6R)-3-[(2S,3R,5S,6R)-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 Avocadene 30%
4992	Rubusosides enriched Glucosylated Steviol Glycosides

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)

	2,11-Tetradecadienal	4,9-Dodecadienal	Hyaluronic acid, sodium salt	<i>Persea americana</i> oil hydrolyzed fraction	Rubusosides enriched Glucosylated Steviol Glycosides
Category/FEMA No.	4984	4985	4986	4991	4992
Baked Goods	5/50	5/50	500/500	3/15	50/170
Beverages Type I, Non-Alcoholic	2/20	2/20	100/500		50/170
Beverages Type II, Alcoholic	2/20	2/20	150/500		50/170
Breakfast Cereals	5/50	5/50	200/500	3/15	50/170
Cheeses	1/10	1/10		3/15	50/170
Chewing Gum	10/100	10/100			50/170
Condiments and Relishes	2/20	2/20		5/15	50/170
Confections and Frostings	2/20	2/20			50/170
Egg Products	1/10	1/10			50/170
Fats and Oils	5/50	5/50	200/500		50/170
Fish Products				3/15	50/170
Frozen Dairy	2/20	2/20	200/500	3/15	50/170
Fruit Ices	2/20	2/20			50/170
Gelatins and Puddings	2/20	2/20			50/170
Granulated Sugar	5/50	5/50			
Gravies	2/20	2/20		3/15	50/170
Hard Candy	5/50	5/50			50/170
Imitation Dairy Products	2/20	2/20	200/500	3/15	50/170
Instant Coffee and Tea	5/50	5/50	100/500		50/170
Jams and Jellies	2/20	2/20			50/170
Meat Products	1/10	1/10	200/500	3/15	50/170
Milk Products	2/20	2/20	200/500	3/15	50/170
Nut Products	2/20	2/20		3/15	50/170
Other Grains	2/20	2/20		3/15	50/170
Poultry Products				3/15	50/170
Processed Fruits	1/10	1/10			50/170
Processed Vegetables				3/15	50/170
Reconstituted Vegetable Protein	2/20	2/20		5/25	50/170
Seasonings and Flavors	10/100	10/100	200/500	5/25	50/170
Snack Foods	2/20	2/20	200/500	3/15	50/170
Soft Candy	2/20	2/20			50/170
Soups	2/20	2/20	200/500	3/15	50/170
Sugar Substitutes	5/50	5/50			
Sweet Sauces	2/20	2/20			50/170

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
4991	<i>Persea americana</i> 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%, Rubusosides inclusive of Multiply-glucosylated rubusosides 55-78%, Rubusoside 9-13%, Rebaudioside A <4%, Stevioside <0.5%, Not further glycosylated steviol glycosides individually <3%; Maltodextrin 10-20%