

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.

FEMA EXPERT PANEL

Samuel M. Cohen, Ph.D., M.D., Chair of the FEMA Expert Panel, Professor, Dept. of Pathology and Microbiology, and Havlik-Wall Professor of Oncology, University of Nebraska Medical Center, Omaha, NE; Gerhard Eisenbrand, Ph.D. (Retired), Food Chemistry and Toxicology, University of Kaiserslautern, Kaiserslautern, Germany; Shoji Fukushima, M.D., Director, Japan Bioassay Research Center, Japan Industrial Safety and Health Association, Kanagawa, Japan; Nigel J. Gooderham, Ph.D., Professor of Molecular Toxicology and Senior College Consul, Dept. of Surgery and Cancer, Imperial College London, England; F. Peter Guengerich, Ph.D., Tadashi Inagami Professor of Biochemistry, Department of Biochemistry, Vanderbilt University School of Medicine, Nashville, TN; Stephen S. Hecht, Ph.D., Wallin Professor of Cancer Prevention, Masonic Cancer Center and Dept. of Laboratory Medicine and Pathology, University of Minnesota, Minneapolis, MN; Thomas J. Rosol, D.V.M., Ph.D., M.B.A., Ohio University, Athens, Ohio; and Ivonne M.C.M. Rietjens, Ph.D., Vice-Chair FEMA Expert Panel, Professor of Toxicology and Chair, Dept. of Toxicology, Wageningen.

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.

DISCLAIMER: The user of this list agrees that its use of this document and the information contained therein is at the user's sole risk and that FEMA shall have no liability to any person for any loss or damage arising out of the use of this document. This document and the information contained herein is subject to change. It is the responsibility of the user to ensure the information is up to date.

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-2H-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 (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	<i>Persea americana</i> oil hydrolyzed fraction
4992	Rubusosides enriched Glucosylated Steviol Glycosides
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

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)

	<i>Persea americana</i> oil hydrolyzed fraction	Rubosides enriched Glucosylated Steviol Glycosides	2,6-Octadienal	2-Methyloctan-4-olide	3-Hydroxyhexanoic acid	3-Methyl-3-butene-1-thiol
Category/FEMA No.	4991	4992	5003	5004	5005	5006
Baked Goods	3/15	50/170	0.02/0.2		0.15/1	0.1/1
Beverages Type I, Non-Alcoholic		50/170	0.005/0.5	0.001/0.1	0.05/0.3	0.01/0.1
Beverages Type II, Alcoholic		50/170	0.005/0.5	0.001/0.1	0.05/0.3	0.01/0.1
Breakfast Cereals	3/15	50/170	0.02/0.2		0.15/1	0.1/1
Cheeses	3/15	50/170	0.05/0.5		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	0.1/1
Confections and Frostings		50/170	0.05/0.5		0.1/0.5	0.01/0.1
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	0.01/0.1
Fruit Ices		50/170	0.05/0.5		0.05/0.3	
Gelatins and Puddings		50/170	0.05/0.5		0.05/0.3	0.02/0.2
Granulated Sugar			0.1/1			
Gravies	3/15	50/170	0.1/1		0.15/1	0.1/1
Hard Candy		50/170	0.1/1		0.05/0.3	0.1/1
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	0.1/1
Jams and Jellies		50/170	0.05/0.5		0.05/0.3	0.1/1
Meat Products	3/15	50/170	0.05/0.5		0.05/0.3	0.1/1
Milk Products	3/15	50/170	0.02/0.2	0.1/1	0.05/0.3	0.1/1
Nut Products	3/15	50/170	0.1/1	0.1/1		0.1/1
Other Grains	3/15	50/170	0.1/1			0.01/0.1
Poultry Products	3/15	50/170	0.5/5		0.05/0.3	0.1/1
Processed Fruits		50/170			0.05/0.3	0.01/0.1
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	0.1/1
Snack Foods	3/15	50/170	0.1/1	0.1/1	0.1/0.5	0.1/1
Soft Candy		50/170	0.01/0.1		0.1/0.5	0.1/1
Soups	3/15	50/170	0.1/1	0.001/0.1	0.1/0.5	0.1/1
Sugar Substitutes			0.01/0.1			
Sweet Sauces		50/170	0.05/0.5		0.05/0.3	

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%, glucosylated rubusosides 55-65%, rubusoside 9-13%, rebaudioside A <4%, stevioside <0.5%, not further glycosylated steviol glycosides individually <3%; Maltodextrin 10-20%.