GRAS Flavoring Substances 33

33. GRAS Flavoring Substances. This list of substances will appear in the 33rd 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

Ivonne M.C.M. Rietjens, Ph.D., Chair of the FEMA Expert Panel, Professor of Toxicology and Chair, Dept. of Toxicology, Wageningen; 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; 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; Samuel M. Cohen, Ph.D, M.D., Professor, Dept. of Pathology and Microbiology, and Havlik-Wall Professor of Oncology, University of Nebraska Medical Center, Omaha, NE; and Nigel J. Gooderham, Ph.D., Vice-Chair of the FEMA Expert Panel, Emeritus Professor of Molecular Toxicology in the Dept. of Metabolism, Digestion and Reproduction and Former Assistant Provost of Imperial College London.

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 33. 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.

The FEMA Expert Panel has well-defined and published procedures to protect against potential bias and conflicts of interest in its evaluations of substances whose uses may be determined to be "generally recognized as safe" (GRAS) for use as flavor ingredients (Marnett et al., 2013). The uses of the flavor ingredients in this report that were determined to be GRAS were evaluated by the Expert Panel in accordance with the Panel's bias and conflict of interest procedures. No conflicts or sources of potential bias were declared by any Panel members, or otherwise identified by the Expert Panel's Legal Advisor, in the course of the evaluations of the uses of the flavor ingredients described in this report.

Marnett L.J., Cohen S.M., Fukushima S., Gooderham N.J., Hecht S.S., Rietjens I.M.C.M., Smith R.L., Adams T.B., Hallagan J.B., Harman C., McGowan M.M. and Taylor S.V. GRAS flavoring substances 26. Food Technology. 67(8), 38. 2013.

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

FEMA No.	Primary Names and Synonyms
5088	***beta*-Sinensal fermentation product**
5089	**Fermented tomato powder**
5090	***Mortierella alpina* biomass**
5093	**Heat-treated glucosylated steviol glycosides 18% with steviol glycosides 6%**
5094	**Mixture of fatty acid ethyl esters**
5096	**2*S*-Hesperidin**
5099	**Polysorbate 65** Tween 65 Sorbimacrogol tristearate Sorbitan, trioctadecanoate, poly(oxy-1,2-ethanediyl) derivatives Sorbitan, tristearate, polyoxyethylene derivatives Polyoxyethylene sorbitan tristearate Polyoxyethylene 1,4-sorbitan-tristearate PEG-20 sorbitan tristearate
5100	***Stevia rebaudiana* extract, rebaudioside A 75%**
5102	**Glucosyl naringin**
5104	***Lemna gibba* extract** Gibbous duckweed extract Inflated duckweed extract

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)

	beta-Sinensal fermentation product	Fermented tomato powder	*Mortierella alpina* biomass	Heat-treated glucosylated steviol glycosides 18% with steviol glycosides 6%	Mixture of fatty acid ethyl esters	2*S*-Hesperidin
Category/FEMA No.	**5088**	**5089**	**5090**	**5093**	**5094**	**5096**
Baked Goods			3776/7080	50/150		
Beverages Type I, Non-Alcoholic	10/10	300/5000		50/150		100/300
Beverages Type II, Alcoholic				50/150		
Breakfast Cereals				50/150		
Cheeses		500/5000		50/150	5/30	
Chewing Gum				50/150		
Condiments and Relishes		500/5000		50/150	5/30	
Confections and Frostings				50/150		200/300
Egg Products		500/5000		50/150		
Fats and Oils		500/5000	3776/7080	50/150	7/35	
Fish Products		500/5000		50/150	5/30	
Frozen Dairy	10/10	500/5000		50/150		
Fruit Ices	10/10			50/150		
Gelatins and Puddings				50/150		
Granulated Sugar						
Gravies		500/5000	3776/7080	50/150	5/30	100/300
Hard Candy	10/10			50/150		
Imitation Dairy Products		500/5000		50/150		100/300
Instant Coffee and Tea				50/150		
Jams and Jellies		500/5000		50/150		
Meat Products	5/5	300/2500	3776/7080	50/150	2/10	100/300
Milk Products		400/3000		50/150		
Nut Products				50/150		
Other Grains				50/150		
Poultry Products		500/5000	3776/7080	50/150	2/10	100/300
Processed Fruits	5/5	300/2500		50/150		
Processed Vegetables	5/5	500/5000		50/150		100/300
Reconstituted Vegetable Protein		500/5000	3776/7080	50/150		100/300
Seasonings and Flavors	5/5	1000/5000		50/150	10/30	
Snack Foods		500/5000	3776/7080	50/150	5/30	200/300
Soft Candy				50/150		200/300
Soups	5/5	500/5000	3776/7080	50/150	5/30	100/300
Sugar Substitutes						
Sweet Sauces				50/150		

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)

	Polysorbate 65	*Stevia rebaudiana* extract, rebaudioside A 75%	Glucosyl naringin	*Lemna gibba* extract
Category/FEMA No.	**5099**	**5100**	**5102**	**5104**
Baked Goods		50/50	50/500	499/749
Beverages Type I, Non-Alcoholic	10/50	50/50	50/500	499/749
Beverages Type II, Alcoholic	10/50	50/50	50/500	999/1998
Breakfast Cereals			50/500	
Cheeses			50/500	499/749
Chewing Gum			50/500	
Condiments and Relishes			50/500	
Confections and Frostings			50/500	
Egg Products			50/500	250/499
Fats and Oils			50/500	
Fish Products			50/500	125/499
Frozen Dairy			50/500	499/749
Fruit Ices			50/500	
Gelatins and Puddings			50/500	
Granulated Sugar				
Gravies			50/500	
Hard Candy			50/500	
Imitation Dairy Products		50/50	50/500	499/749
Instant Coffee and Tea		50/50	50/500	60/80
Jams and Jellies			50/500	30/45
Meat Products			50/500	400/599
Milk Products		50/50	50/500	60/80
Nut Products			50/500	400/599
Other Grains			50/500	400/599
Poultry Products			50/500	649/849
Processed Fruits			50/500	25/75
Processed Vegetables			50/500	25/75
Reconstituted Vegetable Protein			50/500	499/499
Seasonings and Flavors			50/500	
Snack Foods			50/500	
Soft Candy			50/500	
Soups			50/500	400/749
Sugar Substitutes				1249/4994
Sweet Sauces			50/500	30/50

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
5088	*beta*-Sinensal fermentation product	50-63% *beta*-Farnesene; 20-25% *beta*-sinensal; 4-9% *beta*-sinensol; and 3-4% 2,6,10-trimethyldodeca-6,11-dienoic acid.
5089	Fermented tomato powder	69-78% Maltodextrin; 14-22% minerals, such as sodium and chloride; 2-3% D-maltose; 1-4% water; less than 1% dietary fiber; less than 0.5% lipids; less than 0.5% inactivated microbial cells (dried cell weight); and less than 1% volatile compounds including, phenethyl alcohol, amino acids and aliphatic primary alcohols, aldehydes, carboxylic acids, acetals and esters containing additional oxygenated functional groups.
5090	*Mortierella alpina* biomass	12-45% Protein; 17-40% fatty acids, of which >20% is arachidonic acid; 13-42% carbohydrates; <10% moisture; and <2% ash.
5093	Heat-treated glucosylated steviol glycosides 18% with steviol glycosides 6%	Produced from enzymatically modified and heated steviol glycosides; >95% of identified constituents inclusive of: supraglucosylated steviol glycosides 16-18%; steviol glycosides not further glucosylated 4-6% with each individually, less than 3%; dextrins 35-38%; monosaccharides 14-16%; water less than 4%; disaccharides 16-19%; and other non-volatiles 2-3% including sugar alcohols, amino acids, proteins, lipids and ash.
5094	Mixture of fatty acid ethyl esters	29-35% Ethyl palmitate; 12-13% ethyl myristate; 11-15% ethyl (*Z*)-hexadec-9-enoate; 7-15% ethyl oleate; 2-6% eicosapentaenoic acid ethyl ester; less than 5%, individually, of other identified C16-C22 ethyl esters; and 5-15% of other unidentified C14-C22 ethyl esters.
5099	Polysorbate 65	Produced from the polymerization of sorbitan stearate monomer, with an oxyethylene content (–C2H4O-) of not less than 46% and not more than 50%, equivalent to >95% (96-104%) polysorbate 65; ≤3%water; ≤0.25% sulfated ash; and ≤0.1 ppm residual ethylene oxide.

5100	*Stevia rebaudiana* extract, rebaudioside A 75%	Produced by aqueous/ethanol extraction of *Stevia rebaudiana* leaves; Total steviol glycosides no less than 95% inclusive of: rebaudioside A 73-77%; rebaudioside B 10-13%; rebaudioside D 7-9%; other steviol glycosides not further glucosylated present at <2% individually.
5102	Glucosyl naringin	Total naringenin glycosides ≥85%, inclusive of 57-75% monoglucosyl naringin (as 3”-monoglucosyl naringin) and 17-32% naringin.
5104	*Lemna gibba* extract	55-59% Water; 38-40% carbohydrates; 1-2% ash; <2% protein; <1% crude fiber; <1% fat; up to 10% phenol derivatives; <1% other volatile constituents