

GRAS Flavoring Substances 30

30. GRAS Flavoring Substances. This list of substances will appear in the 30th 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.

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

FEMA No.	Primary Names and Synonyms
4943	Decanedioic acid 1,8-Octanedicarboxylic acid 1,10-Decanedioic acid Sebacic acid Decanedicarboxylic acid
4949	<i>Corynebacterium ammoniagenes</i> fermentation product <i>C. ammoniagenes</i> dried fermentation broth
4957	Rebaudioside M 85% Rebaudioside X 85%
4964	<i>Corynebacterium glutamicum</i> cell free fermentation broth <i>C. glutamicum</i> dried fermentation broth
4965	<i>N</i>-(1-((4-Amino-2,2-dioxido-1<i>H</i>-benzo[<i>c</i>][1,2,6]thiadiazin-5-yl)oxy)-2-methylpropan-2-yl)isonicotinamide
4967	<i>delta</i>-Cadinene 93%
4969	Yerba mate extract (<i>Ilex paraguariensis</i> A. St.-Hil.) Mate absolute <i>Ilex paraguariensis</i> A. St.-Hil. extract
4971	<i>beta</i>-Farnesene 1,6,10-Dodecatriene, 7,11-dimethyl-3-methylene-, (6 <i>E</i>)- 1,6,10-Dodecatriene, 7,11-dimethyl-3-methylene-, (<i>E</i>)- (6 <i>E</i>)-7,11-Dimethyl-3-methylene-1,6,10-dodecatriene (<i>E</i>)-7,11-Dimethyl-3-methylene-1,6,10-dodecatriene (<i>E</i>)- <i>beta</i> -Farnesene <i>trans</i> - <i>beta</i> -Farnesene
4972	Diethyl mercaptosuccinate
4973	3-Mercapto-3-methyl-1-pentyl acetate
4974	Germacrene D ≥85%

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)

	Decanedioic acid	<i>Corynebacterium ammoniagenes</i> fermentation product	Rebaudioside M 85%	<i>Corynebacterium glutamicum</i> cell free fermentation product	<i>N</i> -(1-((4-Amino-2,2-dioxido-1 <i>H</i> -benzo[<i>c</i>]1,2,6]thiadiazin-5-yl)oxy)-2-methylpropan-2-yl)isonicotinamide
Category/FEMA No.	4943	4949	4957	4964	4965
Baked Goods	40/200	1000/7500	15/20	1000/11000	10/22
Beverages, Non-Alcoholic	20/50		15/20		15/22
Beverages, Alcoholic	15/30		15/20		10/22
Breakfast Cereals	50/100	1000/5000	15/20	1000/11000	20/22
Cheeses	40/100	2000/7500		3000/11000	
Chewing Gum	100/300		15/20		22/22
Condiments and Relishes	30/100	3000/20000	15/20	3000/18000	20/22
Confections and Frostings	40/100		15/20		22/22
Egg Products	50/100	1000/10000		1000/7000	
Fats and Oils	50/100				
Fish Products	50/100	3000/10000		3000/9000	
Frozen Dairy	40/100		15/20		15/22
Fruit Ices	30/60		15/20		15/22
Gelatins and Puddings	30/60		15/20		15/22
Granulated Sugar					
Gravies	40/100	3000/20000	15/20	3000/11000	
Hard Candy	50/200		15/20		22/22
Imitation Dairy	40/100	2000/10000	15/20	3000/11000	15/22
Instant Coffee and Tea	30/100		15/20		10/22
Jams and Jellies	50/100		15/20		15/22
Meat Products	50/100	2000/15000		3000/11000	
Milk Products	40/100		15/20		15/22
Nut Products	40/100	1000/10000	15/20	1000/4000	
Other Grains	50/200		15/20		
Poultry Products	50/100	2000/10000		3500/7500	
Processed Fruits	50/100		15/20		
Processed Vegetables	50/100		15/20		
Reconstituted Vegetable Protein	50/100		15/20		
Seasonings and Flavors	50/100	5000/50000	15/20	20000/150000	
Snack Foods	50/100	1000/10000	15/20	7500/20000	
Soft Candy	50/200		15/20		20/22
Soups	50/300	3000/20000	15/20	3500/18500	
Sugar Substitutes	30/60				
Sweet Sauces	40/100		15/20		15/22

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>delta</i> -Cadinene 93%	Yerba mate extract (<i>Ilex paraguariensis</i> A. St.-Hil.)	<i>beta</i> - Farnesene	Diethyl mercaptosuccinate	3-Mercapto-3-methyl-1-pentyl acetate	Germacrene D ≥85%
Category/FEMA No.	4967	4969	4971	4972	4973	4974
Baked Goods	0.9/0.9		10/50	1/10	0.001/0.05	0.5/0.5
Beverages, Non-Alcoholic		400/1000	5/20	0.1/1	0.0001/0.002	0.2/0.2
Beverages, Alcoholic		400/1000	5/20	0.1/1	0.0001/0.002	
Breakfast Cereals			10/50			
Cheeses			2/10		0.0005/0.005	
Chewing Gum			30/90	1/10	0.0005/0.01	3.4/4.8
Condiments and Relishes	0.3/0.3	400/1000	5/15	1/10	0.0001/0.01	
Confections and Frostings		400/1000	20/60	1/10	0.0005/0.005	
Egg Products					0.0002/0.001	
Fats and Oils			5/30			
Fish Products			1/5			
Frozen Dairy			5/40	1/10	0.0002/0.003	
Fruit Ices		400/1000	5/20	1/10	0.0002/0.003	0.3/0.3
Gelatins and Puddings		400/1000	2/10	1/10	0.0002/0.003	
Granulated Sugar						
Gravies			5/20	0.1/1	0.0005/0.005	
Hard Candy	0.9/0.9	400/1000	10/50	1/10	0.0005/0.01	0.5/0.5
Imitation Dairy			1/5			
Instant Coffee and Tea		400/1000	5/20	1/10	0.0003/0.005	
Jams and Jellies		400/1000	2/10	1/10		
Meat Products			1/5	1/10	0.001/0.01	
Milk Products			10/30		0.0001/0.001	
Nut Products			5/20	1/10		
Other Grains			10/50	0.1/1		
Poultry Products			1/5	0.1/1		
Processed Fruits		400/1000	5/30	0.1/1		
Processed Vegetables		400/1000	5/10	0.1/1		
Reconstituted Vegetable Protein			5/20			
Seasonings and Flavors			10/50	0.1/1	0.01/0.5	
Snack Foods			5/20		0.001/0.05	
Soft Candy		400/1000	10/30	1/10	0.001/0.1	
Soups		400/1000	5/20	1/10	0.0003/0.003	
Sugar Substitutes			1/10			
Sweet Sauces		400/1000	2/10		0.001/0.01	

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

	Oak chips extract (<i>Quercus alba</i> L.; <i>Quercus petraea</i>)	<i>Cordyceps sinensis</i> fermentation product
GRAS Publication	3	28
Category/FEMA No.	2794	4878
Baked Goods	72/90	30/50
Beverages, Non-Alcoholic	550 ^a /1000 ^a	30 ^a /1000
Beverages, Alcoholic	1000/1000	10 ^a /1000
Breakfast Cereals		10 ^a /100 ^a
Cheeses		
Chewing Gum	115/200	20 ^a /100 ^a
Condiments and Relishes		1 ^a /30 ^a
Confections and Frostings		1 ^a /30 ^a
Egg Products		1 ^a /30 ^a
Fats and Oils		
Fish Products		1 ^a /30 ^a
Frozen Dairy	52/200 ^a	10 ^a /100 ^a
Fruit Ices		
Gelatins and Puddings	1 ^a /1 ^a	
Granulated Sugar		
Gravies		10 ^a /100 ^a
Hard Candy	2.5/200 ^a	1 ^a /30 ^a
Imitation Dairy		10 ^a /150 ^a
Instant Coffee and Tea		10 ^a /150 ^a
Jams and Jellies		10 ^a /100 ^a
Meat Products		16 ^a /40 ^a
Milk Products		15/100
Nut Products		10 ^a /150 ^a
Other Grains		50/150
Poultry Products		10 ^a /150 ^a
Processed Fruits		20 ^a /50 ^a
Processed Vegetables		10 ^a /150 ^a
Reconstituted Vegetable Protein		10 ^a /150 ^a
Seasonings and Flavors		10 ^a /150 ^a
Snack Foods		10 ^a /150 ^a
Soft Candy	60/200 ^a	1 ^a /30 ^a
Soups		10 ^a /100 ^a
Sugar Substitutes		1 ^a /30 ^a
Sweet Sauces		1 ^a /30 ^a

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
4949	<i>Corynebacterium ammoniagenes</i> fermentation product	20-25% Miscellaneous-nitrogen containing compounds; 2-5% Amino acids; 3-5% Minerals; <7% Carbohydrates typically monosaccharides; 50-55% Dextrins
4957	Rebaudioside M 85%	Rebaudioside M ≥85%; Rebaudioside D 3-12%; Total steviol glycosides no less than 95%.
4964	<i>Corynebacterium glutamicum</i> cell free fermentation product	No more than 30% glutamic acid; Up to 10% simple carbohydrates; Less than 5% sum of other individual amino acids; No more than 60% dextrins
4967	<i>delta</i> -Cadinene 93%	93-95% <i>delta</i> -Cadinene; approximately 3% other Aliphatic and aromatic hydrocarbons, with less than 3% <i>gamma</i> -cadinene
4969	Yerba mate extract (<i>Ilex paraguariensis</i> A. St.-Hil.)	>95% Dicafeoylquinic acids, chlorogenic acid and its related positional and stereo isomer as well as other related caffeic and quinic acid derivatives; <0.05% caffeine
4974	Germacrene D ≥85%	≥85% Germacrene D; <5% <i>trans</i> -Caryophyllene; <4% of Other aliphatic and aromatic hydrocarbons; <1% each of Aliphatic and aromatic tertiary alcohols and related esters, and epoxide derivatives