

# GRAS Flavoring Substances 29

**29. GRAS Flavoring Substances.** This list of substances will appear in the 29<sup>th</sup> 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; 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
4880	<b>2-(4-Ethylphenoxy)-N-(1H-pyrazol-3-yl)-N-(thiophen-2-ylmethyl)acetamide</b> 2-(4-Ethylphenoxy)-N-(1H-pyrazol-5-yl)-N-(thiophen-2-ylmethyl)acetamide
4881	<b>N-(3-Hydroxy-4-methoxyphenyl)-2-isopropyl-5,5-dimethylcyclohexanecarboxamide</b>
4882	<b>N-(4-(Cyanomethyl)phenyl)-2-isopropyl-5,5-dimethylcyclohexanecarboxamide</b>
4884	<b>6-Methyl-5-hepten-2-ol</b> (+/-)-6-Methyl-5-hepten-2-ol Sulcatol (+/-)-Sulcatol 2-Methyl-2-hepten-6-ol 6-Hydroxy-2-methyl-2-heptene 6-Methylhept-5-en-2-ol
4890	<b>3-<i>p</i>-Menthen-7-al</b>
4891	<b>(E)-3-Methyl-4-dodecenoic acid</b>
4892	<b><i>cis</i>-2-Hexylcyclopropaneacetic acid</b>
4895	<b>Rebaudioside M</b>
4896	<b>N-(2-Hydroxy-2-phenylethyl)-2-isopropyl-5,5-dimethylcyclohexane-1-carboxamide</b>
4897	<b>Allulose</b> D-Psicose
4898	<b><i>trans</i>-5-Octenal</b>
4899	<b>N-(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)-2,6-dimethylisonicotinamide</b>
4903	<b>Ethyl 3-methyl-2-oxopentanoate</b>
4909	<b>Glucosylated steviol glycosides, 70-80%</b>
4914	<b><i>bis</i>-(3-Methyl-2-butenyl)disulfide</b> <i>bis</i> (3-methyl-2-buten-1-yl) disulfide
4915	<b>(5<i>Z</i>)-3,4-Dimethyl-5-propylidene-2(5<i>H</i>)-furanone</b>
4916	<b>2-Methyl-3-butene-2-thiol</b> $\alpha,\alpha$ -Dimethyl allyl mercaptan
4917	<b>(<i>Z</i>)-9-Dodecenoic acid</b> (9 <i>Z</i> )-9-Dodecenoic acid 9-Dodecenoic acid, ( <i>Z</i> )- <i>cis</i> -9-Dodecenoic acid Lauroleic acid
4920	<b>1-Ethyl-2-(1-pyrrolylmethyl)pyrrole</b>

**Table 2. Average Usual Use Levels (ppm)/Average Maximum Use Levels (ppm) on which the FEMA Expert Panel based its judgments that the substances are generally recognized as safe (GRAS)**

	2-(4-Ethylphenoxy)-N-(1H-pyrazol-3-yl)-N-(thiophen-2-ylmethyl)acetamide	N-(3-Hydroxy-4-methoxyphenyl)-2-isopropyl-5,5-dimethylcyclohexanecarboxamide	N-(4-(Cyanomethyl)phenyl)-2-isopropyl-5,5-dimethylcyclohexanecarboxamide	6-Methyl-5-hepten-2-ol	3- <i>p</i> -Menthen-7-ol
Category/FEMA No.	4880	4881	4882	4884	4890
Baked Goods	3/15	0/0	0/0	10/50	0.001/0.01
Beverages, Non-Alcoholic	1/3	0.1/10	0.1/10	5/25	0.0003/0.005
Beverages, Alcoholic	2/6	0.1/10	0.1/10	10/50	0.0003/0.005
Breakfast Cereals	3/15	0/0	0/0	5/25	0/0
Cheeses	0/0	0/0	0/0	7/35	0.001/0.01
Chewing Gum	75/150	1/100	1/100	0/0	0.001/0.01
Condiments and Relishes	3/15	0.1/10	0.1/10	5/25	0.01/0.1
Confections and Frostings	5/30	1/100	1/100	10/50	0.001/0.01
Egg Products	3/15	0/0	0/0	0/0	0/0
Fats and Oils	3/15	0.05/5	0.05/5	5/25	0.01/0.1
Fish Products	0/0	0/0	0/0	2/10	0/0
Frozen Dairy	1/3	0.1/10	0.1/10	0/0	0.001/0.01
Fruit Ices	1/3	0.1/10	0.1/10	10/50	0.0005/0.01
Gelatins and Puddings	1/3	0.05/5	0.05/5	0/0	0.0005/0.01
Granulated Sugar	0/0	0/0	0/0	0/0	0/0
Gravies	3/15	0.05/5	0.05/5	5/25	0/0
Hard Candy	5/15	0.1/10	0.1/10	0/0	0.001/0.01
Imitation Dairy	1/3	0.05/5	0.05/5	7/35	0/0
Instant Coffee and Tea	1/3	0.01/1	0.01/1	5/25	0/0
Jams and Jellies	1/3	0.1/10	0.1/10	20/100	0.0005/0.01
Meat Products	3/15	0/0	0/0	2/10	0.001/0.01
Milk Products	1/3	0.05/5	0.05/5	7/35	0/0
Nut Products	1/3	0/0	0/0	0/0	0/0
Other Grains	0/0	0/0	0/0	5/25	0/0
Poultry	3/15	0/0	0/0	2/10	0/0
Processed Fruits	1/3	0/0	0/0	7/35	0/0
Processed Vegetables	3/15	0/0	0/0	0/0	0/0
Reconstituted Vegetables	3/15	0/0	0/0	0/0	0/0
Seasonings and Flavors	3/15	3/900	3/900	5/25	0.05/0.3
Snack Foods	3/15	0.1/10	0.1/10	10/50	0.003/0.1
Soft Candy	5/15	0.1/10	0.1/10	0/0	0.001/0.01
Soups	3/15	0.1/10	0.1/10	5/25	0.0005/0.01
Sugar Substitutes	0/0	0.005/0.5	0.005/0.5	0/0	0/0
Sweet Sauces	5/15	0.5/50	0.5/50	5/25	0.001/0.01

**Table 2. Average Usual Use Levels (ppm)/Average Maximum Use Levels (ppm) on which the FEMA Expert Panel based its judgments that the substances are generally recognized as safe (GRAS)**

	(E)-3-Methyl-4-dodecenoic acid	cis-2-Hexylcyclopropaneacetic acid	Rebaudioside M	N-(2-Hydroxy-2-phenylethyl)-2-isopropyl-5,5-dimethylcyclohexane-1-carboxamide
Category/FEMA No.	4891	4892	4895	4896
Baked Goods	0.1/1	0.001/0.01	0/0	0/0
Beverages, Non-Alcoholic	0.001/0.1	0.0002/0.005	15/20	1/100
Beverages, Alcoholic	0.001/0.1	0.0002/0.005	0/0	1/100
Breakfast Cereals	0/0	0/0	0/0	0/0
Cheeses	0/0	0/0	0/0	0/0
Chewing Gum	0.001/0.1	0.001/0.01	0/0	10/1000
Condiments and Relishes	0/0	0.001/0.01	0/0	1/100
Confections and Frostings	0.001/0.3	0.0005/0.005	0/0	10/1000
Egg Products	0.001/0.3	0.0005/0.005	0/0	0/0
Fats and Oils	0.01/0.1	0.01/0.1	0/0	0.5/50
Fish Products	0.001/0.3	0.001/0.01	0/0	0/0
Frozen Dairy	0.001/0.2	0.001/0.01	15/20	1/100
Fruit Ices	0.001/0.2	0.0005/0.005	15/20	1/100
Gelatins and Puddings	0.01/0.1	0.0005/0.005	0/0	0.5/50
Granulated Sugar	0/0	0/0	0/0	0/0
Gravies	0.001/0.05	0/0	0/0	0.5/50
Hard Candy	0.001/0.3	0.001/0.01	0/0	1/100
Imitation Dairy	0.0001/0.05	0.001/0.01	15/20	0.5/50
Instant Coffee and Tea	0.0001/0.1	0.0002/0.005	15/20	0.1/10
Jams and Jellies	0/0	0.0005/0.005	0/0	1/100
Meat Products	0/0	0/0	0/0	0/0
Milk Products	0.001/0.05	0.001/0.01	15/20	0.5/50
Nut Products	0.001/0.05	0.001/0.01	0/0	0/0
Other Grains	0/0	0/0	0/0	0/0
Poultry	0/0	0/0	0/0	0/0
Processed Fruits	0/0	0/0	15/20	0/0
Processed Vegetables	0/0	0/0	0/0	0/0
Reconstituted Vegetables	0/0	0/0	0/0	0/0
Seasonings and Flavors	0.01/2	0.01/0.2	0/0	30/9000
Snack Foods	0.001/0.3	0.001/0.01	0/0	1/100
Soft Candy	0.001/0.3	0.001/0.01	0/0	1/100
Soups	0.0001/0.3	0.0002/0.005	0/0	1/100
Sugar Substitutes	0.001/0.05	0/0	0/0	0.05/5
Sweet Sauces	0/0	0.001/0.01	0/0	5/500

**Table 2. Average Usual Use Levels (ppm)/Average Maximum Use Levels (ppm) on which the FEMA Expert Panel based its judgments that the substances are generally recognized as safe (GRAS)**

	Allulose	<i>trans</i> -5-Octenal	<i>N</i> -(1-(4-amino-2,2-dioxido-1 <i>H</i> -benzo[ <i>c</i> ]1,2,6thiadiazin-5-yl)oxy)-2-methylpropan-2-yl)-2,6-dimethylisonicotinamide	Ethyl 3-methyl-2-oxopentanoate	Glucosylated steviol glycosides, 70-80%
Category/FEMA No.	4897	4898	4899	4903	4909
Baked Goods	0/0	5/50	0/0	10/100	0/0
Beverages, Non-Alcoholic	15000/20000	2.5/25	15/15	5/50	55/65
Beverages, Alcoholic	0/0	2.5/25	0/0	2.5/25	0/0
Breakfast Cereals	0/0	10/100	0/0	5/50	0/0
Cheeses	0/0	0/0	0/0	0/0	0/0
Chewing Gum	0/0	50/250	0/0	10/100	0/0
Condiments and Relishes	0/0	0/0	0/0	0/0	0/0
Confections and Frostings	0/0	5/50	0/0	5/50	0/0
Egg Products	0/0	0/0	0/0	0/0	0/0
Fats and Oils	0/0	3/30	0/0	5/50	0/0
Fish Products	0/0	3/30	0/0	0/0	0/0
Frozen Dairy	0/0	5/50	0/0	5/50	55/65
Fruit Ices	0/0	5/50	0/0	5/50	0/0
Gelatins and Puddings	0/0	10/100	0/0	5/50	0/0
Granulated Sugar	0/0	0/0	0/0	0/0	0/0
Gravies	0/0	0.5/5	0/0	0/0	0/0
Hard Candy	0/0	10/50	0/0	10/100	0/0
Imitation Dairy	0/0	3/30	6/15	2.5/25	55/65
Instant Coffee and Tea	0/0	5/50	6/15	5/50	55/65
Jams and Jellies	0/0	5/50	0/0	2.5/25	0/0
Meat Products	0/0	0/0	0/0	0/0	0/0
Milk Products	0/0	3/30	6/15	2.5/25	55/65
Nut Products	0/0	3/30	0/0	5/50	0/0
Other Grains	0/0	0/0	0/0	5/50	0/0
Poultry	0/0	0/0	0/0	0/0	0/0
Processed Fruits	0/0	0/0	0/0	0/0	0/0
Processed Vegetables	0/0	0/0	0/0	0/0	0/0
Reconstituted Vegetables	0/0	0/0	0/0	0/0	0/0
Seasonings and Flavors	0/0	0/0	0/0	10/100	0/0
Snack Foods	0/0	15/150	0/0	2.5/25	0/0
Soft Candy	0/0	10/100	0/0	5/50	0/0
Soups	0/0	0.5/5	0/0	2.5/25	0/0
Sugar Substitutes	0/0	0/0	0/0	0/0	0/0
Sweet Sauces	0/0	10/100	0/0	2.5/25	0/0

**Table 2. Average Usual Use Levels (ppm)/Average Maximum Use Levels (ppm) on which the FEMA Expert Panel based its judgments that the substances are generally recognized as safe (GRAS)**

	bis-(3-Methyl-2-butenyl)disulfide	(5Z)-3,4-Dimethyl-5-propylidene-2(5H)-furanone	2-Methyl-3-butene-2-thiol	(Z)-9-Dodecenoic acid	1-Ethyl-2-(1-pyrrolyl)methylpyrrole
Category/FEMA No.	4914	4915	4916	4917	4920
Baked Goods	0.1/1	0/0	0.001/0.05	1/10	0.00001/0.002
Beverages, Non-Alcoholic	0.005/0.05	0.01/0.1	0.0001/0.002	0.02/0.2	0.00001/0.002
Beverages, Alcoholic	0.005/0.05	0.01/0.1	0.0001/0.002	0.02/0.2	0.00001/0.002
Breakfast Cereals	0.1/1	0/0	0/0	0.05/5	0/0
Cheeses	0.1/1	0/0	0.0005/0.005	0.2/2	0/0
Chewing Gum	0.1/1	0/0	0.001/0.02	0.1/1	0/0
Condiments and Relishes	0.1/1	0.1/1	0.001/0.01	0.1/1	0.00001/0.002
Confections and Frostings	0.1/1	0/0	0.0005/0.005	0.1/1	0/0
Egg Products	0.1/1	0/0	0.0002/0.002	0.05/0.5	0/0
Fats and Oils	0.1/1	0/0	0/0	0.5/5	0.00001/0.002
Fish Products	0.1/1	0/0	0/0	0.05/0.5	0/0
Frozen Dairy	0.1/1	0/0	0.0002/0.003	0.05/0.5	0/0
Fruit Ices	0.1/1	0.001/0.01	0.0002/0.003	0.05/0.5	0/0
Gelatins and Puddings	0.1/1	0.001/0.01	0.0002/0.003	0.05/0.5	0/0
Granulated Sugar	0.1/1	0/0	0/0	0/0	0/0
Gravies	0.1/1	0/0	0.001/0.01	0.05/0.5	0/0
Hard Candy	0.1/1	0.1/5	0.001/0.01	0.05/0.5	0/0
Imitation Dairy	0.1/1	0/0	0/0	0.5/5	0/0
Instant Coffee and Tea	0.1/1	0.01/0.1	0.0003/0.005	0.02/0.2	0.00001/0.002
Jams and Jellies	0.1/1	0/0	0/0	0.05/0.5	0/0
Meat Products	0.1/1	0/0	0.001/0.01	0.05/0.5	0/0
Milk Products	0.1/1	0.01/0.1	0.0001/0.002	0.5/5	0/0
Nut Products	0.1/1	0/0	0/0	0.05/0.5	0.00001/0.002
Other Grains	0.1/1	0/0	0/0	0.05/0.5	0/0
Poultry	0.1/1	0/0	0/0	0.05/0.5	0/0
Processed Fruits	0.1/1	0/0	0/0	0/0	0/0
Processed Vegetables	0.1/1	0/0	0/0	0/0	0/0
Reconstituted Vegetables	0.1/1	0/0	0/0	0/0	0/0
Seasonings and Flavors	0.1/1	0.01/0.1	0.1/1	0.05/0.5	0/0
Snack Foods	0.1/1	0.01/0.1	0.005/0.1	0.05/0.5	0/0
Soft Candy	0.1/1	0/0	0.001/0.01	0.10/1	0/0
Soups	0.1/1	0/0	0.003/0.005	0.02/0.2	0.00001/0.002
Sugar Substitutes	0.1/1	0/0	0/0	0/0	0/0
Sweet Sauces	0.1/1	0.1/5	0.001/0.01	0.05/2	0/0

Table 3. Identity for Natural Flavor Complexes as Evaluated by the FEMA Expert Panel

FEMA No.	FEMA Primary Name	The Identification Value as Reviewed by the FEMA Expert Panel
4895	<b>Rebaudioside M</b>	Rebaudioside M $\geq$ 80%; Rebaudioside D 5-20%; Total steviol glycosides $\geq$ 95%.
4909	<b>Glucosylated steviol glycosides, 70-80%</b>	Supraglucosylated steviol glycosides 70-80%; Rebaudioside A 14-20%; Steviol glycosides not further glucosylated not to individually exceed 1% each; Maltodextrin 3-10%