

GRAS Flavoring Substances 29

29. GRAS Flavoring Substances. This list of substances will appear in the 29th 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
4880	2-(4-Ethylphenoxy)-<i>N</i>-(1<i>H</i>-pyrazol-3-yl)-<i>N</i>-(thiophen-2-ylmethyl)acetamide 2-(4-Ethylphenoxy)- <i>N</i> -(1 <i>H</i> -pyrazol-5-yl)- <i>N</i> -(thiophen-2-ylmethyl)acetamide
4881	<i>N</i>-(3-Hydroxy-4-methoxyphenyl)-2-isopropyl-5,5-dimethylcyclohexanecarboxamide
4882	<i>N</i>-(4-(Cyanomethyl)phenyl)-2-isopropyl-5,5-dimethylcyclohexanecarboxamide
4884	6-Methyl-5-hepten-2-ol (+/-)-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	3-<i>p</i>-Menthen-7-al
4891	(<i>E</i>)-3-Methyl-4-dodecenoic acid
4892	<i>cis</i>-2-Hexylcyclopropaneacetic acid
4896	<i>N</i>-(2-Hydroxy-2-phenylethyl)-2-isopropyl-5,5-dimethylcyclohexane-1-carboxamide
4898	<i>trans</i>-5-Octenal
4899	<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)-2,6-dimethylisonicotinamide
4903	Ethyl 3-methyl-2-oxopentanoate

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-(1 <i>H</i> -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-al
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	N-(2-Hydroxy-2-phenylethyl)-2-isopropyl-5,5-dimethylcyclohexane-1-carboxamide	trans-5-Octenal	N-(1-((4-amino-2,2-dioxido-1H-benzof[c][1,2,6]thiadiazin-5-yl)oxy)-2-methylpropan-2-yl)-2,6-dimethylisonicotinamide	Ethyl 3-methyl-2-oxopentanoate
4891	4892	4896	4898	4899	4903
0.1/1	0.001/0.01	0/0	5/50	0/0	10/100
0.001/0.1	0.0002/0.005	1/100	2.5/25	15/15	5/50
0.001/0.1	0.0002/0.005	1/100	2.5/25	0/0	2.5/25
0/0	0/0	0/0	10/100	0/0	5/50
0/0	0/0	0/0	0/0	0/0	0/0
0.001/0.1	0.001/0.01	10/1000	50/250	0/0	10/100
0/0	0.001/0.01	1/100	0/0	0/0	0/0
0.001/0.3	0.0005/0.005	10/1000	5/50	0/0	5/50
0.001/0.3	0.0005/0.005	0/0	0/0	0/0	0/0
0.01/0.1	0.01/0.1	0.5/50	3/30	0/0	5/50
0.001/0.3	0.001/0.01	0/0	3/30	0/0	0/0
0.001/0.2	0.001/0.01	1/100	5/50	0/0	5/50
0.001/0.2	0.0005/0.005	1/100	5/50	0/0	5/50
0.01/0.1	0.0005/0.005	0.5/50	10/100	0/0	5/50
0/0	0/0	0/0	0/0	0/0	0/0
0.001/0.05	0/0	0.5/50	0.5/5	0/0	0/0
0.001/0.3	0.001/0.01	1/100	10/50	0/0	10/100
0.0001/0.05	0.001/0.01	0.5/50	3/30	6/15	2.5/25
0.0001/0.1	0.0002/0.005	0.1/10	5/50	6/15	5/50
0/0	0.0005/0.005	1/100	5/50	0/0	2.5/25
0/0	0/0	0/0	0/0	0/0	0/0
0.001/0.05	0.001/0.01	0.5/50	3/30	6/15	2.5/25
0.001/0.05	0.001/0.01	0/0	3/30	0/0	5/50
0/0	0/0	0/0	0/0	0/0	5/50
0/0	0/0	0/0	0/0	0/0	0/0
0/0	0/0	0/0	0/0	0/0	0/0
0/0	0/0	0/0	0/0	0/0	0/0
0/0	0/0	0/0	0/0	0/0	0/0
0.01/2	0.01/0.2	30/9000	0/0	0/0	10/100
0.001/0.3	0.001/0.01	1/100	15/150	0/0	2.5/25
0.001/0.3	0.001/0.01	1/100	10/100	0/0	5/50
0.0001/0.3	0.0002/0.005	1/100	0.5/5	0/0	2.5/25
0.001/0.05	0/0	0.05/5	0/0	0/0	0/0
0/0	0.001/0.01	5/500	10/100	0/0	2.5/25