

# 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**

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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	<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>(<i>E</i>)-3-Methyl-4-dodecenoic acid</b>
4892	<b><i>cis</i>-2-Hexylcyclopropaneacetic acid</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>

**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-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	N-(2-Hydroxy-2-phenylethyl)-2-isopropyl-5,5-dimethylcyclohexane-1-carboxamide	Allulose
Category/FEMA No.	4891	4892	4896	4897
Baked Goods	0.1/1	0.001/0.01	0/0	0/0
Beverages, Non-Alcoholic	0.001/0.1	0.0002/0.005	1/100	15000/20000
Beverages, Alcoholic	0.001/0.1	0.0002/0.005	1/100	0/0
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	10/1000	0/0
Condiments and Relishes	0/0	0.001/0.01	1/100	0/0
Confections and Frostings	0.001/0.3	0.0005/0.005	10/1000	0/0
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	0.5/50	0/0
Fish Products	0.001/0.3	0.001/0.01	0/0	0/0
Frozen Dairy	0.001/0.2	0.001/0.01	1/100	0/0
Fruit Ices	0.001/0.2	0.0005/0.005	1/100	0/0
Gelatins and Puddings	0.01/0.1	0.0005/0.005	0.5/50	0/0
Granulated Sugar	0/0	0/0	0/0	0/0
Gravies	0.001/0.05	0/0	0.5/50	0/0
Hard Candy	0.001/0.3	0.001/0.01	1/100	0/0
Imitation Dairy	0.0001/0.05	0.001/0.01	0.5/50	0/0
Instant Coffee and Tea	0.0001/0.1	0.0002/0.005	0.1/10	0/0
Jams and Jellies	0/0	0.0005/0.005	1/100	0/0
Meat Products	0/0	0/0	0/0	0/0
Milk Products	0.001/0.05	0.001/0.01	0.5/50	0/0
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	0/0	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	30/9000	0/0
Snack Foods	0.001/0.3	0.001/0.01	1/100	0/0
Soft Candy	0.001/0.3	0.001/0.01	1/100	0/0
Soups	0.0001/0.3	0.0002/0.005	1/100	0/0
Sugar Substitutes	0.001/0.05	0/0	0.05/5	0/0
Sweet Sauces	0/0	0.001/0.01	5/500	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)**

	<i>trans</i> -5-Octenal	<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	Ethyl 3-methyl-2-oxopentanoate
Category/FEMA No.	4898	4899	4903
Baked Goods	5/50	0/0	10/100
Beverages, Non-Alcoholic	2.5/25	15/15	5/50
Beverages, Alcoholic	2.5/25	0/0	2.5/25
Breakfast Cereals	10/100	0/0	5/50
Cheeses	0/0	0/0	0/0
Chewing Gum	50/250	0/0	10/100
Condiments and Relishes	0/0	0/0	0/0
Confections and Frostings	5/50	0/0	5/50
Egg Products	0/0	0/0	0/0
Fats and Oils	3/30	0/0	5/50
Fish Products	3/30	0/0	0/0
Frozen Dairy	5/50	0/0	5/50
Fruit Ices	5/50	0/0	5/50
Gelatins and Puddings	10/100	0/0	5/50
Granulated Sugar	0/0	0/0	0/0
Gravies	0.5/5	0/0	0/0
Hard Candy	10/50	0/0	10/100
Imitation Dairy	3/30	6/15	2.5/25
Instant Coffee and Tea	5/50	6/15	5/50
Jams and Jellies	5/50	0/0	2.5/25
Meat Products	0/0	0/0	0/0
Milk Products	3/30	6/15	2.5/25
Nut Products	3/30	0/0	5/50
Other Grains	0/0	0/0	5/50
Poultry	0/0	0/0	0/0
Processed Fruits	0/0	0/0	0/0
Processed Vegetables	0/0	0/0	0/0
Reconstituted Vegetables	0/0	0/0	0/0
Seasonings and Flavors	0/0	0/0	10/100
Snack Foods	15/150	0/0	2.5/25
Soft Candy	10/100	0/0	5/50
Soups	0.5/5	0/0	2.5/25
Sugar Substitutes	0/0	0/0	0/0
Sweet Sauces	10/100	0/0	2.5/25