

Interim GRAS List

The Flavor and Extract Manufacturers Association (FEMA) is now offering GRAS applicants the option of publishing the identity of their new FEMA GRAS™ flavor ingredient on the FEMA website within 60 days of the Expert Panel's evaluation.

This list of substances will appear in the forthcoming publications 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.

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 is typically submitted to FDA within six months of the publication of the identity of newly GRASed substances. 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.

DISCLAIMER: The user of this list agrees that its use of this document and the information contained therein is at the user's sole risk and that FEMA shall have no liability to any person for any loss or damage arising out of the use of this document.

Interim GRAS List

Table 1. Primary Names & Synonyms

Primary Names (in all capital letters) & Synonyms (in lowercase)

FEMA No.	Substance Primary Name and Synonyms
4730	<i>O</i> -ETHYL <i>S</i> -1-METHOXYHEXAN-3-YL CARBONOTHIOATE Carbonothioic acid, <i>S</i> -[1-(2-Methoxyethyl)butyl] <i>O</i> -ethyl ester
4732	1,5-OCTADIEN-3-OL Octa-1,5-dien-3-ol
4735	(4 <i>Z</i> , 7 <i>Z</i>)-TRIDECA-4,7-DIENAL (<i>Z,Z</i>)-4,7-Tridecadienal <i>cis,cis</i> -4,7-Tridecadienal (4 <i>Z</i> ,7 <i>Z</i>)-Tridecadienal
4741	<i>N</i> 1-(2,3-DIMETHOXYBENZYL)- <i>N</i> 2-(2-(PYRIDIN-2-YL)ETHYL)OXALAMIDE Ethanediamide, <i>N</i> 1-[(2,3-dimethoxyphenyl)methyl]- <i>N</i> 2-[2-(2-pyridinyl)ethyl]-
4745	(±)-6-METHOXY-2,6-DIMETHYLHEPTANAL 6-Methoxy-2,6-dimethylheptanal
4751	(<i>R</i>)- <i>N</i> -(1-METHOXY-4-METHYLPENTAN-2-YL)-3,4-DIMETHYLBENZAMIDE Benzamide, <i>N</i> -[(1 <i>R</i>)-1-(methoxymethyl)-3-methylbutyl]-3,4-dimethyl-

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4753	1,3-PROPANEDIOL
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Table 2. Average Usual Use Levels/ Average Maximum Use Levels

Average usual use levels (ppm)/ average maximum use levels (ppm) for new FEMA GRAS flavoring substances on which the FEMA Panel based its judgements that the substances are generally recognized as safe (GRAS)

	O-ETHYL S-1-METHOXYHEXAN-3-YL CARBONOTHIOATE	1,5-OCTADIEN-3-OL	(4Z, 7Z)-TRIDECA-4,7-DIENAL	N1-(2,3-DIMETHOXYBENZYL)-N2-(2-(PYRIDIN-2-YL)ETHYL)OXALAMIDE	(±)-6-METHOXY-2,6-DIMETHYLHEPTANAL	(R)-N-(1-METHOXY-4-METHYLPENTAN-2-YL)-3,4-DIMETHYLBENZAMIDE	1,3-PROPANEDIOL
Categories	FEMA No. 4730	4732	4735	4741	4745	4751	4753
Baked goods				5/10	15/18	2/6	1300/1300
Beverages (non-alcoholic)	0.25/0.5	0.05/0.2			3/6		690/690
Beverages (alcoholic)							690/690
Breakfast cereal				25/50		2/6	
Cheese				5/15		2/6	
Chewing gum					200/200		1800/1800
Condiments/relishes				10/20		4/10	20/20
Confectionery frosting	0.4/0.8						
Egg products			0.001/0.05	5/10		2/6	
Fats/oils			0.001/0.05	10/20		2/8	
Fish products			0.001/0.05	5/15		4/10	
Frozen dairy	0.25/1				15/19		810/810
Fruit ices		0.1/1					810/810
Gelatins/ puddings					9/12	4/10	250/290
Granulated sugar							
Gravies			0.001/0.05	10/20		4/10	
Hard Candy	0.5/1				6/6		1300/1300
Imitation dairy							
Instant coffee/ tea	0.25/5	0.1/0.5					
Jams/jellies					5/5		
Meat products			0.001/0.05	5/15		4/10	
Milk products	0.4/0.8	0.1/1	0.001/0.05			2/6	
Nut products			0.001/0.05	5/10		2/6	
Other grains				5/10		2/6	
Poultry				5/15		2/6	
Processed fruits							300/300
Processed vegetables				5/15		2/6	
Reconstituted vegetables				5/10		2/6	
Seasonings/ flavors	2/25	0.01/0.1	0.001/0.05	25/50	5/5	4/10	
Snack foods		0.01/0.1	0.001/0.05	25/50		4/10	
Soft candy	0.5/1				6/6		1300/1300
Soups			0.001/0.05	10/20		4/8	20/20
Sugar substitutes							
Sweet sauces	0.25/0.5						7000/7000