

# 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 25<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.**

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 boldface) & Synonyms (in lightface)

FEMA No.	Substance Primary Name and Synonyms
4669	<p><b>4-Amino-5,6-dimethylthieno[2,3-<i>d</i>]pyrimidin-2(1<i>H</i>)-one</b>  <b>(also covers the salt form 4-Amino-5,6-dimethylthieno[2,3-<i>d</i>]pyrimidin-2(1<i>H</i>)-one hydrochloride)</b>                      Thieno[2,3-<i>d</i>]pyrimidin-2(1<i>H</i>)-one, 4-amino-5,6-dimethyl-                      Thieno[2,3-<i>d</i>]pyrimidin-2(1<i>H</i>)-one, 4-amino-5,6-dimethyl-, hydrochloride (1:1)                      4-Amino-5,6-dimethylthieno[2,3-<i>d</i>]pyrimidin-2(1<i>H</i>)-one                      4-Amino-5,6-dimethylthieno[2,3-<i>d</i>]pyrimidin-2(1<i>H</i>)-one hydrochloride</p>
4683	<p><b>2-Methyl-4,5-dihydrofuran-3-thiol</b>                      3-Furanthiol, 4,5-dihydro-2-methyl-                      4,5-Dihydro-2-methyl-3-mercaptofuran                      3-Mercapto-2-methyl-4,5-dihydrofuran</p>
4685	<p><b>(±)-6-Octyltetrahydro-2<i>H</i>-pyran-2-one</b>                      5-Tridecanolide                      6-Octyltetrahydro-2<i>H</i>-pyran-2-one                      Tetrahydro-6-octyl-2<i>H</i>-pyran-2-one  <i>delta</i>-Tridecalactone                      Tridecanoic acid, 5-hydroxy-, <i>delta</i>-lactone  <i>delta</i>-Octylvalerolactone                      Trideca-1,5-lactone</p>
4688	<p><b>1,1-Dipropoxyethane</b>                      Acetaldehyde dipropyl acetal                      1,1'-[Ethylidene<i>bis</i>(oxy)]<i>bis</i>[propane]                      Propane, 1,1'-[ethylidene<i>bis</i>(oxy)]<i>bis</i>-</p>
4691	<p><b>Yuzunone</b>                      6,8,10-Undecatrien-3-one, (8<i>E</i>)-                      (6<i>E</i>/<i>Z</i>, 8<i>E</i>)-Undeca-6,8,10-trien-3-one</p>
4697	<p><b>5-Methylfurfurylmercaptan</b>                      (5-Methylfurfuryl)mercaptan                      (5-methylfuran-2-yl)methanethiol                      2-Furanmethanethiol, 5-methyl-                      5-Methyl-2-furanmethanethiol</p>

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<b>4699</b>	<b>Ferrous lactate</b> Propanoic acid, 2-hydroxy-, Iron (2+) salt (2:1) L-2-Hydroxy-propanoic acid, Iron (2+) salt dihydrate Iron(II) (S)-2-hydroxy propanoate dihydrate Ferrous- <i>l</i> -lactate Lactic acid ferrous salt
<b>4701</b>	<b>3-[(4-Amino-2,2-dioxido-1H-2,1,3-benzothiadiazin-5-yl)oxy]-2,2-dimethyl-N-propylpropanamide</b> Propanamide, 3-[(4-amino-2,2-dioxido-1H-2,1,3-benzothiadiazin-5-yl)oxy]-2,2-dimethyl-N-propyl- 3-(1H-Benzo[c][1,2,6]thiadiazin-4-amine-2,2-dioxide)-5-yloxy-2,2-dimethyl-N-propylpropanamide 3-(4-Amino-1H-benzo[c][1,2,6]thiadiazin-5-yloxy)-2,2-dimethyl-N-propylpropanamide-2,2-dioxide



**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)

Processed vegetables								
Reconstituted vegetables								
Seasonings/ flavors	5/15	0.2/1					20/200	
Snack foods	5/15	3/10			0.006/ 0.12		20/200	
Soft candy	10/25				0.015/0. 2			15/75
Soups		0.3/2			0.003/0. 02		20/200	
Sugar substitutes	300/600							
Sweet sauces	10/25				0.03/0.1 2			10/22