11. GRAS Substances

BERNARD L. OSER and RICHARD A. FORD

□ THIS PAPER is the latest in a series reporting the results of deliberations of the independent panel of experts retained by the Flavor and Extract Manufacturers' Association (FEMA) for evaluation of GRAS (Generally Recognized as Safe) status of new flavoring substances. This panel consists of members chosen as described before (Hall and Oser, 1961) and is made up of experts who are qualified by training and years of experience in pharmacology and toxicology as well as in the safety evaluation of flavors. The criteria used by the Expert Panel in arriving at judgements of GRAS status have been discussed in a recent publication (Oser and Hall, 1977). The Panel currently consists of: Dr. Anthony M. Ambrose, Medical College of Virginia; Dr. John Doull, University of Kansas Medical Center; Dr. David W. Fassett; Dr. Howard C. Spencer; Prof. R. Tecwyn Williams, St. Mary's Hospital Medical School, University of London; and Dr. Lauren A. Woods, Virginia Commonwealth University. Dr. Doull only recently joined the Panel and was not a member during the discussion of the GRAS status of the substances listed herein.

SACCHARIN

The Expert Panel has not modified or retracted its GRAS determination of saccharin (Hall and Oser, 1965), despite the announced proposal of FDA to ban its use (FDA, 1977). It has taken cognizance of the three F_0/F_1 generation feeding studies, in particular that of the Canadian Health Protection Branch, which formed the basis for FDA's regulatory decision. It was noted that neither the WARF nor the FDA study were regarded as conclusive by the NAS/NRC Subcommittee on Non-Nutritive Sweeteners, (Safety of Saccharin and Sodium Saccharin in the Human Diet. Subcommittee on Non-Nutritive Sweeteners. Committee on Food Protection. Food and Nutrition Board. National Research Council/National Academy of Sciences, Washington, D.C. 1974) for several reasons, including uncertainty with respect to the suspected impurity, orthotoluene sulfonamide. Whereas the HPB study exonerated this impurity, the results of its single level (5%) test of saccharin were reported to have satisfied FDA of the carcinogenicity of this artifical sweetener.

The panel noted certain questionable aspects of

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these 2-generation studies, viz. a) the rationale for, and consequences of the use of the "maximum tolerated dose"; b) the excessive dietary dose levels (7.5% in the FDA study and 5% in the other two) at which malignant neoplasms were reported, as contrasted with human exposure levels; c) the significantly higher incidence of tumors in the second generation (\mathbf{F}_1) rats than in the parent generation; d) uncertainty (and appropriateness) concerning the dosages to which the F_1 rats were exposed in utero, during lactation, and during the post-weaning period of normally high food consumption relative to body weight; e) the higher incidence of tumors in male rats than in female rats; and f) the absence of control groups to clarify the effect of sodium intake of the high test groups compared to that of the animals receiving the unsupplemented basal diets.

Because of these questions concerning the Canadian study (stemming in part from the methodology employed), and viewed against the total present information on the tests and use of saccharin, the Expert Panel concludes that it should not change its present GRAS classification until research and review now planned permit further clarification.

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GRAS FLAVORING INGREDIENTS AND USAGE LEVELS

Flavor and Extract Manufacturer's Association average maximum levels (in ppm) on which the Expert Panel based its judgments that the substances are generally recognized as safe for their intended uses

Substance		Frozen Dairy	Meat Products	Soft Candy	Gelatins & Puddings	Soups	Snack Foods	Nonalcoholic Beverages	Alcoholic Beverages	Gravies	Other use Categories
Acetoin acetate											
see 3526											
3526 2-ACETOXY-3-BUTANONE	40.0	00.0									
Acetoxy-1-p-menthene	49.3	20.0	-	47.8	20.0	-	-	20.0	20.0	-	
see 3566											
B-Acetoxvoctene											
see 3582											
3527											
B-ACETYL-2,5-DIMETHYL-	2.0	0. 6	1.0	1.5	1.5	1.0	_	1.0	1.0		Milk
THIOPHENE											products-0.6
Acetyl ethyl carbinol see 3550					•						-
cetyl methyl carbinyl											
acetate see 3526											
-Acetylphenol											
see 3548											
myl ethyl carbinol											
see 3581											
myl ethyl carbinyl											
acetate see 3583											
so-Amyl acetoacetate											
see 3551											
myl vinyl carbinyl acetate see 3582											
.3-Benzenediol											
see 3589											
3528											
2-BUTANEDITHIOL **	0.2	-	0.2	-	-	0.2	0.2		-	0.2	Nut
											products-0.2
3529											
3-BUTANEDITHIOL"'	0.2	-	0.2	-	-	0.2	0.2	-	-	0.2	Nut products-0.2
Butanon-3-yl acetate see 3526 utyl ethyl carbinol see 3547 ampholenic aldehyde see 3592											,
arvomenthol											
see 3562											
elery ketone										•.	
see 3577											
3530											
-CRESOL	1.0	-	0.5	-	-	0.5	0.5	-	-	0.5	Nut products-0.5; Instant coffee & tea-0.5; Household seasonings & flavorings-0.5
3531 CYCLOHEXANECARBOXYLIC	2.0	1.0	-	_	1.0	-	_	1.0		_	Fruit ices-1.0
ACID ⁽⁶⁾	2.0	1.0	_	-	1.0	-	-	1.0	-		Confectionery & frost- ing-2.0; Chewing gum-1.5
3532											
-DECEN-2-ONE Dallyl di-, tri-, tetra-, and pentasulfides see 3533	19	5.8		7.8	4.8	-	-	4.3	4.0	_	
3533											_
DIALLYL POLYSULFIDES	1.0	-	1.0	-	-	-	0.1	-	-	0.1	Processed vegetables -1.0; House- hold season- ings & flavor- ings-1.0

"Total dithiol added to any food not to exceed 1.0 ppm.

^(e)Substance has not been covered in a Scientific Literature Review nor is it presently scheduled for future coverage. ^(e)To be used at not more than 10.0 ppm in the finished food. ^(d)To be used in accoa substitute only.

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Substance		Frozen Dairy	Meat Products	Soft Candy	Gelatins & Puddings	Soups	Snack Foods	Nonalcoholic Beverages	Alcoholic Beverages	Gravies	Other use Categories
3534 1,2-DI[(1'-ETHOXY)-ETHOXY] PROPANE	330	54.9	_	137			-	62.5	54.8		Milk products-54.9; Processed fruit-54.9; Fruit ices-54.9; Condiments & relishes-273; Confectionery & frosting- 137; Jams & jellies-273; Sweet sauce-273; Nut prod- ucts-62.5; Imitation dairy-54.9; Hard can- dy-137; Chewing gum-1546; Household seasonings & flavors-273
 3-Diethylacetonyl 3-methyl-3-furyl sulfide see 3570 cis-Dihydrocarvone see 3565 Dihydrocuminyl acetate see 3561 7-Dihydro-3,7-dimethyl- 1H-purine-2,6-dione see 3591 Dihydrojasmone see 3552 m-Dihydroxybenzene see 3589 Diisobutyl ketone see 3537 1,3-Diisopropylacetonyl 2-methyl-3-furyl sulfide see 3538 										•	
1,2-Dimercaptobutane see 3528 1,3-Dimercaptobutane see 3529 1,3-Dimercaptopropane see 3588 2,5-Dimethyl-3- acetylthiophene see 3527 3535						10					Condimonto &
2,3-DIMETHYLBENZOFURAN	2.0		1.0	-	-	1.0	-	-	-	-	Condiments & relishes-1.0; Household seasonings & flavorings-1.0
3536 DIMETHYL DISULFIDE	16.9	4.8	2.2	9.4	8.3	- •	-	4.8	2.0	-	Condiments & relishes-3.8; Sweet sauce0.007
3537 2,6- DIMETH YL-4-HEPTANONE 6,6- Dimethyl-3-hydroxy- 2-methylenebicyclo [3.1.1]heptane see 3587	5.0	2.0	-	5.0	1.1	-	_	0.8	1.1	-	
3538 2,6-DIMETHYL-3-[(2- METHYL-3-FURYL)THIO]- 4-HEPTANONE	1.0	-	1.0	-	-	1.0	1.0	-	-	1.0	Nut products—1.0

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^(c)To be used at not more than 10.0 ppm in the finished food. ^(d)To be used in cocoa substitute only.

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Substance		Frozen Dairy	Meat Products	Soft Candy	Gelatins & Puddings	Soups	Snack Foods	Nonalcoholic Beverages	Alcoholic Beverages	Gravies	Other use Categories
3539 3,7-DIMETHYL-1,3,6- OCTATRIENE 2,5-Dimethylphenol see 3595 3,4-Dimethylphenol see 3596	15.2	7.7	-	15.2	4.0	-	-	2.3	4.0	-	
see 3390 3540 2,6-DIMETHYLPYRIDINE	10.0	-	5.0	-	3.0	5.0	10.0	-	-	5.0	Confectionery & frost- ings-3.0; Nut products-5.0; Instant coffee & tea-0.15
3541 3,5-DIMETHYL-1,2,4-TRITHIOLANE	-	-	0.3	-	-	0.3	-	-	-	0.3	Milk products-0.3
3542 6,10-DIMETHYL-5,9- UNDECADIEN-2-ONE 3,7-Dimethylxanthine see 3591 1,3-Dipropylacetonyl 2-methyl-3-furyl sulfide see 3571	10.0	10.0	-	10.0	10.0	-	-	10.0	-	-	
3543 ETHYLENE BRASSYLATE Ethylene glycol brassylate cyclic diester see 3543	2.0	2.0	-	2.0	2.0	-	-	2.0	-	-	
3544 ETHYL CYCLOHEXANE- CARBOXYLATE ^(*)	0.01	0.01	-	-	0.01	-	-	0.01	-	-	Fruit ices-0.01; Confectionery & frost- ing-0.05
3545 ETHYL 3-HYDROXYHEXANOATE	5.0	1.0	-		1.0	-	_	1.0	1.0	_	Breakfast cer- eals-5.0; Oth- er grains-5.0; Milk products-1.0; Fruit ices-1.0; Confectionery & frostings- 1.0; Jams & jellies-1.0; Charies
3546 5-ETHYL-2-METHYLPRIDINE	1.5		1.0		_	0.5		_	_	0.5	Chewing gum—1.0 Breakfast cer-
Ethyl vinyl carbinol see 3584 2-Furfurylidenephenyl- acetaldehyde see 3586 Geranyl acetone see 3542	1.0		1.0			0.0				0.0	eals=1.0; Nut products=1.0; Instant coffee & tea=0.05
3547 3-HEPTANOL Hexahydrocarvacrol see 3562 2-Hexyl-2-cyclopenten-1- one and 2-hexylidene- cyclopentanone mixture see 3552	18.5	8.8	_	13.5	8.2	-	-	7.8	6.3	-	
3548 2-HYDROXYACETOPHENONE	0.2	_	0.1	-	_	0.1	0.2	_	_	0.1	Poultry-0.1; Condiments & relishes-0.1; Instant coffee & tea-0.1; Household seasoning & flavors-0.1

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^(*)To be used at not more than 10.0 ppm in the finished food.
⁽⁴⁾To be used in coccoa substitute only.

Substance		Frozen Dairy	Meat Products	Soft Candy	Gelatins & Puddings	Soups	Snack Foods	Nonalcoholic Beverages	Alcoholic Beverages	Gravies	Other use Categories
3549 6-HYDROX YDIH YDROTHEA- SPIRANE	-	0.2	_	0.2	0.2	-	_	0.05	-	-	
1-Hydroxy-2,5-dimethyl- benzene see 3595											
1-Hydroxy-3,4-dimethyl- benzene see 3596											
3550 3-HYDROXY-2-PENTANONE 5-Hydroxytetradecanoic acid lactone see 3590	10.0	. 10.0	-	10.0	10.0	-	-	10.0	. –	_	
6-Hydroxy-2,6,10,10- tetramethyl-1-oxaspiro- [4.5]decane see 3549 3-Hydroxytoluene											
see 3530 4-Hydroxy-2,6,6-trimethyl- bicyclo[3.1.1]hept-2-ene see 3594					1 - ^{1 - 1}					• :	
3551 ISOAMYL ACETOACETATE Isoamyl 3-oxobutanoate see 3551 3552	166	83.2	-	106	81.6	-	-	80.8	54.0	-	
JSSZ ISOJASMONE JS53	2.3	1.9	-	2.5	1.9	-	-	1.6	10.0	-	
ISOPHORONE	50.0	4.7	-	50.0	50.0	-	-	10.0	-	-	Condiments & relishes-1.0; Chewing gum-1.0; Household seasoning & flavors-1.0
 4-Isopropenyl-1-cyclohexene carbinyl acetate see 3561 4-Isopropenyl-1-cyclohexene- 1-carboxaldehyde see 3557 4-Isopropenyl-1-methyl- 1-cyclohexanol 											
see 3564 3-Isopropeny1-6- methylcyclohexanone see 3565 3-Isopropy1-6-methyl-										•.'	
cyclohexanol see 3562 4-Isopropyl-1-methyl-3- cyclohexen-1-01 see 3563											
3554 5-ISOPROPYL-2- METHYLPYRAZINE ^(*)	4.0	4.0	-	4.0	4.0	-	-	4.0	-	-	
3555 2-ISOPROPYL-4-METHYL- THIAZOLE	-	-	-	1.0	1.5	-	_	1.0	2.0	-	Confectionery & frosting- 2.0; Jams & jellies-2.0; Sweet sauce-1.5; Imitation dairy-2.0;
3556											Hard candy -2.0; Chewing gum-4.0; In- stant coffee & tea-2.0
ISOPROPYL MYRISTATE Isopropyl tetradecanoate see 3556 2,6-Lutidine see 3540	50.0	30.0	-	50.0	50.0	-	-	30.0	-	_	

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Substance		Frozen Dairy	Meat Products	Soft Candy	Gelatins & Puddings	Soups	Snack Foods	Nonalcoholic Beverages	Alcoholic Beverages	Gravies	Other use Categories
3557											
p-MENTHA-1,8-DIEN-7-AL 3558	4.5	6.3	20.0	9.7	4.5	-	-	4.0	6.0	-	
p-MENTHA-1,3-DIENE 3559	21.5	11.5	20.0	17.8	12.0	-	-	12.0	10.0	-	
<i>p</i> -MENTHA-1,4-DIENE	13.6	8.6	20.0	10.3	8.6	_	-	8.5	10.0	-	Hard can- dy–50.0; Chewing gum–25.0
3560 p-MENTHA-1,4(8)- DIEN-3-ONE	5.0	5.0	-	5.0	5.0	-	-	5.0	-		Bain-2010
3561 p-MENTHA-1,8-DIEN- 7-YL ACETATE	16.0	8.0	3.0	16.0	4.0	-	-	2.0	4.0		
3562 p-MENTHAN-2-OL	14.8	7.6	-	14.8	4.1	-	_	2.2	4.0	-	
3563 p-MENTH-3-EN-1-OL	30.0	10.0	-	25 .0	20.0	-	_	10.0	_	_	
3564 p-MENTH-8-EN-1-OL	47.5	20.0	10.0	37.5	20.0	-	_	14.6	10.0	_	
3565 p-MENTH-8-EN-2-ONE	15.7	7.3	-	14.0	4.7	_	_	2.7	4.0	-	
3566 1-p-MENTHEN-9-YL ACETATE	9.0	4.5	-	7.0	4.0	-	-	4.0	-	-	
3567 p-METHOXYCINNAMALDEHYDE 3-Methylbutyl 3-oxobutanoate	5.0	-	2.0	-	5.0	-	-	-	-	_	Milk products-2.0; Condiments & relishes-4.0; Confectionery & frosting- 5.0; Jams & jellies-5.0; Sweet sauce-4.0; Household seasoning & flavors-5.0
see 3551 3568 METHYL CYCLOHEXANE- CARBOXYLATE ^(h)	0.1	0.01	-	-	0.1	-	_	0.01	-	-	Fruit ices-0.01; Confectionery & frost- ing-0.05; Im- itation
Methyl disulfide see 3536 Methyldithio-1-propene see 3576 3569 2-METHYL-3,5 or 6-ETHOXY- PYRAZINE ^{(b) (b)} 2-Methyl-5-ethylpyridine see 3546 3-[(2-Methyl-3-furyl)thio]- 2,6-dimethyl-4-heptanone	_	0.5	-	_	3.0	_	_	0.5	-	-	dairy–0.01 Confectionery & frosting–2.0
see 3538 3570 3-[(2-METHYL-3-FURYL)- THIO]-4-HEPTANONE	1.0	-	1.0	-	-	1.0	1.0	-	-	1.0	Nut products-1.0
3571 4[(2-METHYL-3-FURYL)- THIO]-5-NONANONE 2572	1.0	-	1.0	-	-	1.0	1.0	-	-	1.0	Nut products-1.0
3572 5-METHYLHEXANOIC ACID [®]	10.0	-	-	-	-	3 .0	5.0	_	-	-	Imitation dairy–5.0
1-Methyl-3-hydroxybenzene see 3530 1-Methyl-4-isopropenylcyclo- hexan-1-ol see 3564											0.0

see 3564

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Substance		Frozen Dairy	Meat Products	Soft Candy	Gelatins & Puddings	Soups	Snack Foods	Nonalcoholic Beverages	Alcoholic Beverages	Gravies	Other use Categories
1-Methyl-4-isopropyl- 1,3-cyclohexadiene see 3558											
1-Methyl-4-isopropyl-1,4- cyclohexadiene see 3559											
1-Methyl-4-isopropyl-2- cyclohexanol see 3562											
1-Methyl-4-isopropyl-3- cyclohexen-1-ol see 3563											
see 3563 1-Methyl-4-isopropylidene- 1-cyclohexen-3-one see 3560 2-Methyl-5-isopropylpyrazine see 3554											
3573 METHYL 2-METHYL-3-FURYL DISULFIDE	0.5	-	0.5	-	-	0.5	0.5	-	-	0.5	Nut products-0.5
3574 4-METHYLNONANOIC ACID	10.0	-	5.0	-	-	2.5	10.0	-	-	2.5	Milk products–5.0; Imitation dairy–5.0
3575 4-METHYLOCTANOIC ACID ^(b)	-	3.0	0.15	-	0.15	0.15	3.0	-	-	0.15	Milk products-3.0; Cheese-3.0; Confectionery & frosting-0.5
3-Methylphenol see 3530 3576											
METHYL 1-PROPENYL DISULFIDE 3577	1.0	1.0	-	1.0	1.0	-	-	1.0	-	-	
3-METHYL-5-PROPYL-2- CYCLOHEXEN-1-ONE 3578	14.7	6.5	9.3	10.5	4.0	-	-	5.9	-	-	
2-METHYL-4-PROPYL-1,3- OXATHIANE	0.1	0.1	0.1	0.1	0.1	-	-	0.05	_	-	
3579 1,4-NONANEDIOL DIACETATE	9.0	7.0	-	7.0	7.0		-	7.0	-	-	
3580 cis-6-NONENAL	1.0	0.3	-	_	0.5	_	-	0.2	0.1	×	Breakfast cer- eals-0.1; Fruit ices-0.3; Con- diments & rel- ishes-0.1; Confectionery & frost- ing-1.5; Chewing gum-1.0
trans-β-Ocimene see 3539											
3581 3-OCTANOL	4.8	4.0	-	4.0	4.0	-	10.0	4.0	1.0	-	Chewing gum—11.2
3582 1-OCTEN-3-YL ACETATE 3583	4.8	4.0	12.0	4.0	4.0	-	10.0	4.0	-	-	
3-OCTYL ACETATE	4.4	4.0	2.6	4.0	4.0	-	10.0	4.0	-	-	Chewing gum—2.6
3584 1-PENTEN-3-OL Perillaldehyde see 3557 Perillyl acetate see 3561	8.8	4.3	-	5.0	4.3	-	-	3.5	2.0	-	
3585 L-PHENYLALANINE ⁽⁴⁾	110	60.0	10.0	268	60.0	-	-	-	-	-	Milk products-66.0; Condiments & relishes-10.0;

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"To be used in cocoa substitute only.

relishes-10.0; Confectionery & frosting-268; Sweet sauce-220

Substance		Frozen Dairy	Meat Products	Soft Candy	Gelatins & Puddings	Soups	Snack Foods	Nonalcoholic Beverages	Alcoholic Beverages	Gravies	Other use Categories
3586 2-PHENYL-3-(2-FURYL)- PROP-2-ENAL	2.0	1.0	-	-	2.0	_	-	1.0	-	-	Confectionery & frosting-2.0
3587 2(10)-PINEN-3-OL 2-Pinen-4-ol see 3594 Pinocarveol see 3587	1.0	1.0	-	1.0	1.0	-	-	1.0	-	-	Ū
Bee 3367 Piperitenone see 3560 3588 1,3-PROPANEDITHIOL(*) 1-Propenyl methyl disulfide	0.2	-	0.2	-	-	0.2	0.2	-	-	0.2	Nut products-0.2
see 3576 2-Propenyl polysulfides see 3533 3589											
RESORCINOL	15.0		5.0	-	-	5.0	10.0	-	-	5.0	Condiments & relishes-5.0; Household seasoning & flavors-10.0
Tirpilene see 3558 α·Terpinene see 3558 γ-Terpinene see 3559 1-Terpineol see 3563 β-Terpineol see 3564											
3590 A-TETRADECALACTONE	40.0	_	30.0	30.0	_	15.0	30.0	-	-	15.0	Fats & oils-30.0; Milk products-20.0; Cheese-30.0; Poultry-30.0; Confectionery & frost- ing-30.0; Im- itation dairy products-40.0;
									·	d.	Hard can- dy—15.0; Household seasoning & flavors—15.0
3591 THEOBROMINE ¹⁴⁷	1050	-	-	4020	795	_	_	-	-	-	Milk products-990; Confectionery & frost- ing-4020; Sweet sauces-3300
Tetradecanedioic acid cyclic ethylene glycol diester see 3543 3,5,5-Trimethyl-2-cyclo- hezen-1-one see 3553 3592											
2,2,3-TRIMETHYLCYCLOPENT- 3-EN-1-YLACETALDEHYDE	8.0	-	-	-	-	-	-	-	5.0	-	Condiments & relishes-5.0; Reconstituted vegetables-5.0

^(*)Total dithiol added to any food not to exceed 1.0 ppm.
^(b)Substance has not been covered in a Scientific Literature Review nor is it presently scheduled for future coverage.
^(c)To be used at not more than 10.0 ppm in the finished food.
^(d)To be used in cocoa substitute only.

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Substance		Frozen Dairy	Meat Products	Soft Candy	Gelatins & Puddings	Soups	Snack Foods	Nonalcoholic Beverages	Alcoholic Beverages	Gravies	Other use Categories
3593 1,2,3-TRIS [1-ETHOXY) ETHOXY]-PROPANE	308	51.3	_	128	255	-	_	58.3	51.1	-	Milk products-51.3; Processed fruit-51.3; Fruit ices-51.3; Confiectionery & frost- ing-128; Jams & jellies-255; Sweet sauce-255; Nut products-58.3; Imitation dai- ry products-51.3; Hard can- dy-128; Chewing gum-1442; Household seasoning & flavors-255
3594 VERBENOL	1.0	1.0	-	1.0	1.0	-	-	1.0	_		
3595 2,5-XYLENOL	4.0	-	2.0	-	-	2.0	-	-	-	2.0	Nut products—2.0; Instant coffee & tea—2.0; Household seasoning & flavors—2.0
3596 3,4-XYLENOL	4.0	-	2.0	-	_	2.0		_	-	2.0	Nut products—2.0; Instant coffee & tea—2.0; Household seasoning & flavors—2.0

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11. GRAS Substances . . .

^(a)Total dithiol added to any food not to exceed 1.0 ppm.
^(b)Substance has not been covered in a Scientific Literature Review nor is it presently scheduled for future coverage.
^(c)To be used at not more than 10.0 ppm in the finished food.
^(d)To be used in cocoa substitute only.