

***Acceptable Daily Intakes, other toxicological
information, and information on specifications***

1. Food additives and food ingredients

Substance	Specifi- cations ⁱ	Acceptable Daily Intake (ADI) and other toxicological recommendations
Antioxidant <i>tert</i> -Butylhydroquinone (TBHQ)	R	0-0.7 mg/kg bw
Emulsifiers Microcrystalline cellulose Sucrose esters of fatty acids and sucroglycerides	R R R	ADI "not specified" ⁱⁱⁱ } 0-30 mg/kg bw ⁱⁱⁱ
Enzyme preparations <i>alpha</i> -Acetolactate decarboxylase Maltogenic amylase	N,T N,T	Temporary ADI "not specified" ^{iv} Temporary ADI "not specified" ^d
Flavouring agent <i>trans</i> -Anethole	R	0-0.6 mg/kg bw ^v
Glazing agent Hydrogenated poly-1-decene	N	No ADI allocated ^{vi}
Sweetening agent Maltitol syrup	R	ADI "not specified" ^b
Miscellaneous substance Salatrim (short- and long-chain acid triacylglycerol molecules)	N	An adequate basis was not available for evaluating its safety and nutritional effects ^{vii}

2. Substances evaluated using the Procedure for the Safety Evaluation of Flavouring Agents

A. Flavouring agents evaluated toxicologically

No.	Flavouring agent	Specifications ^a	Conclusion based on current levels of intake
0021	Allyl 2-furoate	N,T	No safety concern
0079 0080 0081 0082 0083	Saturated aliphatic acyclic linear primary alcohols, aldehydes, and acids Formic acid Acetaldehyde Acetic acid Propyl alcohol Propionaldehyde	N,T N N N N	} No safety concern
0084 0085 0086 0087 0088	Propionic acid Butyl alcohol Butyraldehyde Butyric acid Amyl alcohol	N N N N N	} No safety concern
0089 0090 0091 0092 0093	Valeraldehyde Valeric acid Hexyl alcohol Hexanal Hexanoic acid	N N N N N	} No safety concern
0094 0095 0096 0097 0098	Heptyl alcohol Heptanal Heptanoic acid 1-Octanol Octanal	N N N N N	} No safety concern

No.	Flavouring agent	Specifications ^a	Conclusion based on current levels of intake
0099	Octanoic acid	N	} No safety concern
0100	Nonyl alcohol	N	
0101	Nonanal	N	
0102	Nonanoic acid	N	
0103	1-Decanol	N	
0104	Decanal	N	} No safety concern
0105	Decanoic acid	N	
0106	Undecyl alcohol	N	
0107	Undecanal	N	
0108	Undecanoic acid	N	
0109	Lauryl alcohol	N	} No safety concern
0110	Lauric aldehyde	N	
0111	Lauric acid	N	
0112	Myristaldehyde	N	
0113	Myristic acid	N	
0114	1-Hexadecanol	N	} No safety concern
0115	Palmitic acid	N	
0116	Stearic acid	N	
	Saturated aliphatic acyclic branched-chain primary alcohols, aldehydes, and acids A. Structural class I flavouring agents:		
0251	Isobutyl alcohol	NR	} No safety concern
0252	Isobutyraldehyde	NR	
0253	Isobutyric acid	NR	
0254	2-Methylbutyraldehyde	NR	
0255	2-Methylbutyric acid	NR	
0258	3-Methylbutyraldehyde	NR	} No safety concern
0259	Isovaleric acid	NR	
0260	2-Methylpentanal	NR	
0261	2-Methylvaleric acid	NR	
0262	3-Methylpentanoic acid	NR	

No.	Flavouring agent	Specifications ^a	Conclusion based on current levels of intake
0263	3-Methyl-1-pentanol	NR	} No safety concern
0264	4-Methylpentanoic acid	NR	
0265	2-Methylhexanoic acid	NR	
0266	5-Methylhexanoic acid	NR	
0268	3,5,5-Trimethyl-1-hexanol	NR	
0269	3,5,5-Trimethylhexanal	NR	} No safety concern
0270	2-Methyloctanal	NR	
0271	4-Methyloctanoic acid	NR	
0272	3,7-Dimethyl-1-octanol	NR	
0273	2,6-Dimethyloctanal	NR	
0274	4-Methylnonanoic acid	NR	} No safety concern
0275	2-Methylundecanal	NR	
0256	B. Structural class II flavouring agents:	NR	} No safety concern
0257	2-Ethylbutyraldehyde	NR	
0267	2-Ethylbutyric acid	NR	
	2-Ethyl-1-hexanol	NR	
0219	Aliphatic lactones A. Structural class I flavouring agents:		} No safety concern
	4-Hydroxybutyric acid lactone (γ -butyrolactone)	NR	
0220	γ -Valerolactone	NR	
0223	γ -Hexalactone	NR	
0224	δ -Hexalactone	NR	
0225	γ -Heptalactone	NR	
0226	γ -Octalactone	NR	} No safety concern
0228	δ -Octalactone	NR	
0229	γ -Nonalactone	NR	
0230	Hydroxynonanoic acid δ -lactone	NR	
0231	γ -Decalactone	NR	

No.	Flavouring agent	Specifications ^a	Conclusion based on current levels of intake
0232	δ-Decalactone	NR	} No safety concern
0241	_-Decalactone	NR	
0233	γ-Undecalactone	NR	
0234	5-Hydroxyundecanoic acid δ-lactone	NR	
0235	γ-Dodecalactone	NR	
	Aliphatic lactones (continued)		} No safety concern
0236	δ-Dodecalactone	NR	
0242	_Dodecalactone	NR	
0238	δ-Tetradecalactone	NR	
0239	_Pentadecalactone	NR	
0221	4-Hydroxy-3-pentenoic acid lactone	NR	
0247	5-Hydroxy-7-decenoic acid δ-lactone	NR	} No safety concern
0248	5-Hydroxy-8-undecenoic acid δ-lactone	NR	
0249	1,4-Dodec-6-enolactone	NR	
0240	_6-Hexadecenlactone	NR	
0227	4,4,-Dibutyl-γ-butyrolactone	NR	
0244	3-Heptyldihydro-5-methyl-2(3H)-furanone	NR	} No safety concern
-----	4-Hydroxy-3-methyloctanoic acid γ-lactone	NR	
0237	6-Hydroxy-3,7-dimethyloctanoic acid lactone	NR	
0250	γ-Methyldecalactone	NR	

No.	Flavouring agent	Specifications ^a	Conclusion based on current levels of intake
----- 0245 ----- ----- 0222 0243	B. Structural class III flavouring agents; 5-Hydroxy-2-decenoic acid δ -lactone 5-Hydroxy-2,4-decadienoic acid δ -lactone Mixture of 5-hydroxy-2-decenoic acid δ -lactone, 5-hydroxy-2-dodecenoic acid δ -lactone, and 5-hydroxy-2-tetradecenoic acid δ -lactone 5-Hydroxy-2-dodecenoic acid δ -lactone 5-Ethyl-3-hydroxy-4-methyl-2(5H)-furanone 4,5-Dimethyl-3-hydroxy-2,5-dihydrofuran-2-one	NR NR NR NR NR NR	} Not evaluated; evaluation deferred pending consideration of other α,β -unsaturated compounds.
0185 0186 0187 0188 0189	Esters of aliphatic acyclic primary alcohols with branched-chain aliphatic acyclic acids Methyl isobutyrate Ethyl isobutyrate Propyl isobutyrate Butyl isobutyrate Hexyl isobutyrate	N N N N N	} No safety concern
0190 0191 0192 0193 0194	Heptyl isobutyrate <i>trans</i> -3-Heptenyl 2-methylpropanoate Octyl isobutyrate Dodecyl isobutyrate Isobutyl isobutyrate	N N N N N	} No safety concern

No.	Flavouring agent	Specifications ^a	Conclusion based on current levels of intake
	Esters of aliphatic acyclic primary alcohols with branched-chain aliphatic acyclic acids (continued)		
0195	Methyl isovalerate	N	} No safety concern
0196	Ethyl isovalerate	R	
0197	Propyl isovalerate	N	
0198	Butyl isovalerate	N	
0199	Hexyl 3-methylbutanoate	N	
0200	Octyl isovalerate	N	} No safety concern
0201	Nonyl isovalerate	N	
0202	3-Hexenyl 3-methylbutanoate	N	
0203	2-Methylpropyl 3-methylbutyrate	N	
0204	2-Methylbutyl 3-methylbutanoate	N,T	
0205	Methyl 2-methylbutyrate	N	} No safety concern
0206	Ethyl 2-methylbutyrate	N	
0207	n-Butyl 2-methylbutyrate	N	
0208	Hexyl 2-methylbutanoate	N	
0209	Octyl 2-methylbutyrate	N	
0210	<i>iso</i> -Propyl 2-methylbutyrate	N,T	} No safety concern
0211	3-Hexenyl 2-methylbutanoate	N,T	
0212	2-Methylbutyl 2-methylbutyrate	N	
0213	Methyl 2-methylpentanoate	N,T	
0214	Ethyl 2-methylpentanoate	N,T	
0215	Ethyl 3-methylpentanoate	N,T	} No safety concern
0216	Methyl 4-methylvalerate	N	

No.	Flavouring agent	Specifications ^a	Conclusion based on current levels of intake
	Esters of aliphatic acyclic primary alcohols with aliphatic linear saturated carboxylic acids		
0117	Propyl formate	N	} No safety concern
0118	Butyl formate	N	
0119	<i>n</i> -Amyl formate	N	
0120	Hexyl formate	N	
0121	Heptyl formate	N,T	
0122	Octyl formate	N	} No safety concern
0123	<i>cis</i> -3-Hexenyl formate	N	
0124	Isobutyl formate	N	
0125	Methyl acetate	N	
0126	Propyl acetate	N	
0127	Butyl acetate	N	} No safety concern
0128	Hexyl acetate	N	
0129	Heptyl acetate	N	
0130	Octyl acetate	N	
0131	Nonyl acetate	N	
0132	Decyl acetate	N	} No safety concern
0133	Lauryl acetate	N	
0134	<i>cis</i> -3-Hexenyl acetate	N	
0135	<i>trans</i> -3-Heptenyl acetate	N	
0136	10-Undecenyl acetate	N	
0137	Isobutyl acetate	N	} No safety concern
0138	2-Methylbutyl acetate	N	
0140	2-Ethylbutyl acetate	N,T	
0141	Methyl propionate	N	
0142	Propyl propionate	N	

No.	Flavouring agent	Specifications ^a	Conclusion based on current levels of intake
0143	Butyl propionate	N	No safety concern
0144	Hexyl propionate	N	No safety concern
0145	Octyl propionate	N	No safety concern
0146	Decyl propionate	N	No safety concern
0147	<i>cis</i> -3 & <i>trans</i> -2-Hexenyl propionate	N	Postponed ^{viii}
0148	Isobutyl propionate	N	} No safety concern
0149	Methyl butyrate	N	
0150	Propyl butyrate	N	
0151	Butyl butyrate	N	
0152	<i>n</i> -Amyl butyrate	N	
0153	Hexyl butyrate	N	} No safety concern
0154	Heptyl butyrate	N,T	
0155	Octyl butyrate	N,T	
0156	Decyl butyrate	N,T	
0157	<i>cis</i> -3-Hexenyl butyrate	N	
0158	Isobutyl butyrate	N	} No safety concern
0159	Methyl valerate	N	
0160	Butyl valerate	N	
0161	Propyl hexanoate	N	
0162	Butyl hexanoate	N	
0163	<i>n</i> -Amyl hexanoate	N	} No safety concern
0164	Hexyl hexanoate	N	
0165	<i>cis</i> -3-Hexenyl hexanoate	N,T	
0166	Isobutyl hexanoate	N,T	
0167	Methyl heptanoate	N	
0168	Propyl heptanoate	N,T	} No safety concern
0169	Butyl heptanoate	N,T	
0170	<i>n</i> -Amyl heptanoate	N	
0171	Octyl heptanoate	N,T	
0172	Isobutyl heptanoate	N,T	

No.	Flavouring agent	Specifications ^a	Conclusion based on current levels of intake
0173	Methyl octanoate	N	} No safety concern
0174	<i>n</i> -Amyl octanoate	N	
0175	Hexyl octanoate	N	
0176	Heptyl octanoate	N,T	
0177	Octyl octanoate	N,T	
	Esters of aliphatic acyclic primary alcohols with aliphatic linear saturated carboxylic acids (continued)		
0178	Nonyl octanoate	N,T	} No safety concern
0179	Methyl nonanoate	N	
0180	Methyl laurate	N	
0181	Butyl laurate	N	
0182	Isoamyl laurate	N,T	
0183	Methyl myristate	N	} No safety concern
0184	Butyl stearate	N,T	
	Esters derived from branched-chain terpenoid alcohols and aliphatic acyclic carboxylic acids		
0053	Citronellyl formate	N	} No safety concern
0054	Geranyl formate	N	
0055	Neryl formate	N	
0056	Rhodinyll formate	N	
0057	Citronellyl acetate	N	
0058	Geranyl acetate	R	} No safety concern
0059	Neryl acetate	N	
0060	Rhodinyll acetate	N	
0061	Citronellyl propionate	N	
0062	Geranyl propionate	N	

No.	Flavouring agent	Specifications ^a	Conclusion based on current levels of intake
0063	Neryl propionate	N	} No safety concern
0064	Rhodinyll propionate	N,T	
0065	Citronellyl butyrate	N	
0066	Geranyl butyrate	N	
0067	Neryl butyrate	N	
0068	Rhodinyll butyrate	N	} No safety concern
0069	Citronellyl valerate	N,T	
0070	Geranyl hexanoate	N,T	
0071	Citronellyl isobutyrate	N	
0072	Geranyl isobutyrate	N,T	
0073	Neryl isobutyrate	N	} No safety concern
0074	Rhodinyll isobutyrate	N	
0075	Geranyl isovalerate	N,T	
0076	Neryl isovalerate	N	
0077	Rhodinyll isovalerate	N,T	
0078	3,7-Dimethyl-2,6-octadien-1-yl 2-ethylbutanoate	N,T	No safety concern

B. Flavouring agent considered for specifications only

Flavouring agent	Specifications ^a
Citric acid	R

3. Contaminants

Contaminant	Conclusions
Aflatoxins B, G, and M	See Annex 1

4. Food additives considered for specifications only

Food additive	Specifications ^a	Food additive	Specifications ^a
Agar	R	Isoamyl acetate (amyl acetate)	R
Alginic acid	R		
Aluminium powder	R	Microcrystalline wax	R
Ammonium alginate	R	Mixed carotenoids	R
Anoxomer	W	Modified starches	R
Calcium alginate	R	Petroleum jelly	R,T
Calcium propionate	R	Potassium alginate	R
Carbon dioxide	R	Potassium propionate	R
Carthamus red	R,T	Propionic acid	R,T
Carthamus yellow	R	Propylene glycol	R
Citric acid	R	Propylene glycol alginate	R
		Propylene glycol esters of fatty acids	R
Diacetyltartaric and fatty acid esters of glycerol (DATEM)	R	Sodium alginate	R
Enzyme-hydrolyzed carboxymethyl cellulose	N,T	Sodium propionate	R
Enzyme-treated starches	W	Sulfur dioxide	R
Ethyl hydroxyethyl cellulose	R	Talc	R

Food additive	Specifications ^a	Food additive	Specifications ^a
Gellan gum	R	Tartaric, acetic and fatty acid esters of glycerol, mixed	S,T
Gum arabic	R	Turmeric	W

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- i. N, new specifications prepared; O, no specifications prepared; R, existing specifications revised; S, specifications exist, revision not considered or not required; T, the existing, new or revised specifications are tentative and comments are invited; W, existing specifications withdrawn; NR, specifications not reviewed.
- ii. Applies to the product conforming to the revised specifications.
- iii. Group ADI for sucrose esters of fatty acids and sucroglycerides.
- iv. Temporary pending consideration of the “tentative” designation for the specifications. The “tentative” designation for Appendix B to the general specifications for enzyme preparations used in food processing will be reviewed in 1998.
- v. Temporary ADI extended to 1998 to review studies underway that were requested by earlier Committees.
- vi. Data were insufficient for establishing an ADI.
- vii. The Committee recommended that additional appropriately designed studies be performed to assess fully both the toxicological and nutritional consequences of ingestion of salatrim.
- viii. Postponed pending consideration of α,β -unsaturated carbonyl compounds. One of the predicted metabolites of *trans*-2-hexenyl propionate is *trans*-2-hexenol, which would be oxidized to the α,β -unsaturated substance, *trans*-2-hexenal.