



COMPENDIUM OF FOOD ADDITIVE SPECIFICATIONS

Joint FAO/WHO Expert Committee on Food Additives

**97th Meeting
Rome, 31 October – 9 November 2023**



**Food and Agriculture
Organization of the
United Nations**



**World Health
Organization**

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Introduction

This volume of FAO JECFA Monographs contains specifications prepared at the Ninety-seventh meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA), held in Rome, from 31 October to 9 November 2023. The specifications monographs are one of the outputs of JECFA's risk assessment of food additives, and should be read in conjunction with the safety evaluation, reference to which is made in the section at the head of each specifications monograph. Further information on the meeting discussions can be found in the summary report of the meeting (see Annex 1), and in the full report which will be published in the WHO Technical Report series. Toxicological monographs of the substances considered at the meeting will be published in the WHO Food Additive Series.

Specifications monographs prepared by JECFA up to the 65th meeting, other than specifications for flavouring agents, have been published in consolidated form in the Combined Compendium of Food Additive Specifications which is the first publication in the series FAO JECFA Monographs. This publication consists of four volumes, the first three of which contain the specifications monographs on the identity and purity of the food additives and the fourth volume contains the analytical methods, test procedures and laboratory solutions required and referenced in the specifications monographs. FAO maintains an online searchable database of all JECFA specifications monographs from the FAO JECFA Monographs, which is available at: <http://www.fao.org/food/food-safety-quality/scientific-advice/jecfa/jecfa-additives/en/>. The specifications for flavourings evaluated by JECFA, and previously published in FAO Food and Nutrition Paper 52 and subsequent Addenda, are included in a database for flavourings specifications. All specifications for flavourings that have been evaluated by JECFA since its 44th meeting, including the 79th meeting, are available in the online searchable database at the JECFA website at FAO: <http://www.fao.org/food/food-safety-quality/scientific-advice/jecfa/jecfa-flav/en/>. The databases have query pages and background information in Arabic, Chinese, English, French, and Spanish. Information about analytical methods referred to in the specifications is available in the Combined Compendium of Food Additive Specifications (Volume 4), which can be accessed from the query pages.

An account of the purpose and function of specifications of identity and purity, the role of JECFA specifications in the Codex system, the link between specifications and methods of analysis, and the format of specifications, are set out in the Introduction to the Combined Compendium, which is available in shortened format online on the query page, which could be consulted for further information on the role of specifications in the risk assessment of additives.

Chemical and Technical Assessments (CTAs) for some of the food additives have been prepared as background documentation for the meeting. These documents are available online at: <http://www.fao.org/food/food-safety-quality/scientific-advice/jecfa/technical-assessments/en/>.

Contact and Feedback

More information on the work of the Committee is available from the FAO homepage of JECFA at: <http://www.fao.org/food/food-safety-quality/scientific-advice/jecfa/en/>. Readers are invited to address comments and questions on this publication and other topics related to the work of JECFA to: jecfa@fao.org

Specifications for certain food additives

New and revised specifications

The Committee evaluated the safety of one food additive (R), and evaluated the safety of three groups of flavouring agents (N).

Titanium dioxide (INS 171) (R)

Aliphatic primary alcohols, aldehydes, carboxylic acids, acetals and esters containing additional oxygenated functional groups – Structural class I

Flavouring agent	No.	Specifications
(±)-6-Methoxy-2,6-dimethylheptanal	2308	N
Ethyl 5-formyloxydecanoate	2309	N
Mixture of ricinoleic acid, linoleic acid and oleic acid	2310	N
Ethyl 3-methyl-2-oxopentanoate	2311	N

Linear and branched-chain aliphatic, unsaturated and unconjugated alcohols, aldehydes, acids and related esters – Structural class I

Flavouring agent	No.	Specifications
(4Z,7Z)-Trideca-4,7-dienal	2286	N
cis-5-Dodecenyl acetate	2287	N
trans-5-Dodecenal	2288	N
cis-6-Dodecenal	2289	N
cis-9-Dodecenal	2290	N
(E)-3-Methyl-4-dodecenoic acid	2291	N
trans-5-Octenal	2292	N
trans-Tetradec-4-enal	2293	N
2,6-Dimethylheptenyl formate	2294	N
(Z)-9-Dodecenoic acid	2295	N
cis-Tridec-5-enal	2296	N
(Z)-8-Pentadecenal	2297	N

Saturated aliphatic acyclic linear primary alcohols, aldehydes and acids

Flavouring agent	No.	Specifications
Pentadecanoic acid	2300	N
Tridecanal	2301	N
Tridecanoic acid	2302	N
Acetaldehyde di-isobutyl acetal	2304	N
Acetaldehyde ethyl isobutyl acetal	2305	N

Titanium dioxide

Revised specifications prepared at the 97th JECFA (2023) and published in FAO JECFA Monographs 32 (2024), superseding specifications prepared at the 76th JECFA (2012) and published in FAO JECFA Monographs 13 (2012). The Committee reaffirmed the ADI “not specified” established at the 13th meeting (1969).

SYNONYMS

Titania; INS No. 171

DEFINITION

Titanium dioxide (TiO₂) is a white crystalline powder used as a colour in various food categories. Food-grade TiO₂ is produced from titanium-containing minerals by either the sulfate or chloride processes.

In the sulfate process, sulfuric acid is used to digest ilmenite (FeTiO₃) or ilmenite and titanium slag. Purification steps include removal of the iron sulfate and crystallization of the TiO₂ into either anatase or rutile forms based on the seed crystals used to induce it. The isolated TiO₂ is finally washed with water, calcined, and milled to a powder.

In the chloride process, titanium-containing mineral is reacted either with chlorine gas or concentrated hydrochloric acid to form titanium tetrachloride, which is purified and thermally oxidised or hydrolysed to give TiO₂. The compound crystallizes in the rutile form. It is then filtered, washed, and calcined.

The article of commerce is primarily produced via the sulfate process and is in the anatase crystal structure and in powder form. Its desired properties are attributed to particles (including aggregates and agglomerates) with size that ranges between 200 and 300 nm. The particle size distribution of food-grade TiO₂ is broad. Typical samples have been shown to contain particles that range approximately from 30 nm to 400 nm.

C.A.S. number 13463-67-7

Chemical formula TiO₂

Formula weight 79.87

Assay Not less than 99.0% on the dried basis

DESCRIPTION White to slightly coloured powder

FUNCTIONAL USES Colour

CHARACTERISTICS

IDENTIFICATION

Solubility (Vol. 4) Insoluble in water, hydrochloric acid, dilute sulfuric acid, and organic solvents. Dissolves slowly in hydrofluoric acid and hot concentrated sulfuric acid.

Colour reaction Add 5 ml sulfuric acid to 0.5 g of the sample, heat gently until fumes of sulfuric acid appear, then cool. Cautiously dilute to about 100 ml with water and filter. To 5 ml of this clear filtrate, add a few drops of hydrogen peroxide; an orange-red colour appears immediately.

PURITY

Loss on drying (Vol. 4) Not more than 0.5% (105 °C, 3 h)

Loss on ignition (Vol. 4) Not more than 1.0% (800 °C) on the dried basis

Acid-soluble substances Not more than 0.5%
Suspend 5.0 g of the sample in 100 ml 0.5 N hydrochloric acid and place on a steam bath for 30 min with occasional stirring. Filter through a suitable tared Gooch crucible fitted with a glass fibre filter paper. Wash with three 10-ml portions of 0.5 N hydrochloric acid, evaporate the combined filtrate and washings to dryness, and ignite at 450 °C ± 25 °C to constant weight. [Caution – Do not expose the crucible to sudden temperature changes.]

Water-soluble matter (Vol. 4) Not more than 0.5%
Proceed as directed under acid-soluble substances (above), using water in place of 0.5 N hydrochloric acid.

Impurities soluble in 0.5 N hydrochloric acid
Antimony: Not more than 2 mg/kg
Arsenic: Not more than 1 mg/kg
Cadmium: Not more than 0.5 mg/kg
Lead: Not more than 5 mg/kg
See description under TESTS

Mercury (Vol. 4) Not more than 1 mg/kg
Determine using AAS (Cold vapour generation technique). The selection of sample size and method of sample preparation may be based on principles of methods described in Volume 4 (under “General Methods, Metallic Impurities”).

TESTS

PURITY TESTS

Impurities soluble in 0.5 N hydrochloric acid

Antimony, arsenic, cadmium and lead (Vol.4)

Transfer 10.0 g of sample into a 250-ml beaker, add 50 ml of 0.5 N hydrochloric acid, cover with a watch glass, and heat to boiling on a hot plate. Boil gently for 15 min, pour the slurry into a 100- to 150-ml centrifuge bottle, and centrifuge for 10 to 15 min, or until undissolved material settles. Decant the supernatant through Whatman No. 4 filter paper, or equivalent, collecting the filtrate in a 100-ml volumetric flask and retaining as much as possible of the undissolved material in the centrifuge bottle. Add 10 ml of hot water to the original beaker, washing off the watch glass with the water, and pour the contents into the centrifuge bottle. Form a slurry, using a glass stirring rod, and centrifuge. Decant through the same filter paper and collect the washings in the volumetric flask containing the initial extract. Repeat the entire washing process two more times. Finally, wash the filter paper with 10 to 15 ml of hot water. Cool the contents of the flask to room temperature, dilute to volume with water, and mix.

Determine cadmium, and lead using an AA-Electrothermal atomization technique, antimony by ICP-AES technique and arsenic using atomic absorption hydride technique.

METHOD OF ASSAY

Weigh about 0.5 g of the sample to the nearest 0.1 mg, in a platinum or nickel crucible, add 5 g potassium hydroxide and 2 g boric acid, mix and melt completely using a torch burner and allow to stand at room temperature. Place the reaction product along with crucible into 150 ml hot deionized water in a 250-ml PTFE beaker and dissolve residue by agitation. Wash the crucible with hot deionized water and remove it. Add 50 ml hydrochloric acid and transfer the contents into a 250-ml polypropylene volumetric flask. Wash the beaker three times with hot deionized water, transfer the washings to the volumetric flask and make up to volume (Solution A). Prepare the test solution by 1000 times dilution of Solution A with 2% hydrochloric acid, taking care that dilution factor in each dilution step shall not be more than 20. Analyse titanium in the test solution by ICP-AES technique (Vol. 4). Set instrument parameters as specified by the instrument manufacturer. Use the analytical line for Ti (334.941 nm) and construct standard curve using Ti standard solutions: 0.5-1.5 µg/ml. Read the concentration in the sample solution (as µg/ml) and calculate the titanium dioxide content of the sample using the formula:

%TiO₂ (on the dried basis)

$$= \frac{1.668 \times C \times 250 \times 1000}{W \times 10^6}$$


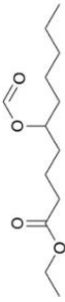
Where:

C is concentration of Ti in the test solution, µg/ml

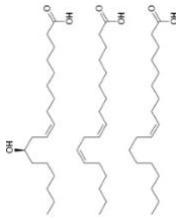
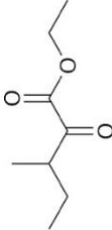
1.668 is a conversion factor from Ti to TiO₂

W is weight of sample on the dried basis, g



Aliphatic primary alcohols, aldehydes, carboxylic acids, acetals and esters containing additional oxygenated functional groups

JECFA No.	Name	FEMA	Chemical Formula	Solubility	ID test	R.I. (20°)	Other requirements
Status	Chemical Name	FLAVIS	M.W.	Solubility in ethanol	Assay min %	S.G. (25°)	
Session	Synonyms	COE	Physical form; Odour	B.P.°	Acid value		Information required
		CAS					
2308	(±)-6-Methoxy-2,6-dimethylheptanal	4745	C ₁₀ H ₂₀ O ₂	Insoluble in water	MS, HNMR, CNMR	1.430-1.436	
full	6-Methoxy-2,6-dimethylheptanal (+/-)-6-Methoxy-2,6-dimethylheptanal Methoxymelonal		172.26 Liquid; diffusive, fresh, watery fruity	Soluble 205 °C	>98%	0.889-0.896	
97		62439-41-2					
2309	Ethyl 5-formyloxydecanoate	4765	C ₁₃ H ₂₄ O ₄	Soluble in water	MS, HNMR, CNMR, IR	1.432-1.442	SC: 4% delta-decalactone (JECFA No. 232);
full	Ethyl 5-formyloxydecanoate Decanoic acid, 5-(formyloxy)-, ethyl ester		244.33 Colourless oil	Soluble 120 °C at 0.27 kPa	>91%	0.966-0.976	2% ethyl 5-acetoxydecanoate
97		1367348-37-5					


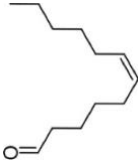
Aliphatic primary alcohols, aldehydes, carboxylic acids, acetals and esters containing additional oxygenated functional groups

JECFA No.	Name	FEMA	Chemical Formula	Solubility	ID test	R.I. (20°)	Other requirements
Status	Chemical Name	FLAVIS	M.W.	Solubility in ethanol	Assay min %	S.G. (25°)	
Session	Synonyms	COE	Physical form; Odour	B.P.°	Acid value		Information required
		CAS					
2310	Mixture of ricinoleic acid, linoleic acid, and oleic acid	4804	C ₁₈ H ₃₄ O ₃ C ₁₈ H ₃₂ O ₂ C ₁₈ H ₃₄ O ₂	Practically soluble in water	MS, HNMR, CNMR	1.472-1.479	Mixture consists of >80% ricinoleic acid, 7-8% linoleic acid (JECFA No. 332) and 5-6% oleic acid (JECFA No. 333). Optical rotation 6.67
full	Fatty acids of castor oil		298.46 280.45 282.46 Pale yellow oil; fatty, strong waxy, fatty mouthfeel, aldehydic, soapy and animalistic notes. oxidized, green aroma	Soluble	>92% (Sum of ricinoleic acid, linoleic acid (JECFA No. 332) and oleic acid (JECFA No. 333))	0.941-0.963	SC: 2-3% stearic acid (JECFA No. 116); 1-3% palmitic acid (JECFA No. 115)
97		61789-44-4					
2311	Ethyl 3-methyl-2-oxopentanoate	4903	C ₈ H ₁₄ O ₃	Soluble in water	MS, HNMR, CNMR	1.414-1.418	Optical rotation 1.66
full	Ethyl 3-methyl-2-oxopentanoate		158.20	Soluble	>95%	0.963-0.969	
	Ethyl 2-oxo-3-methylpentanoate Ethyl 2-oxo-3-methylvalerate		Pale yellow to yellow liquid	75-80 °C at 1.6kPa			
97		26516-27-8					


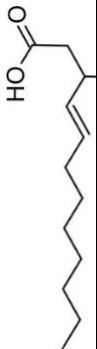
Linear and branched-chain aliphatic, unsaturated and unconjugated alcohols, aldehydes, acids and related esters

JECFA No.	Name	FEMA	Chemical Formula	Solubility	ID test	R.I. (20°)	Other requirements
Status	Chemical Name	FLAVIS	M.W.	Solubility in ethanol	Assay min %	S.G. (25°)	
Session	Synonyms	COE	Physical form; Odour	B.P.°	Acid value		Information required
		CAS					
2286	(4Z,7Z)-Trideca-4,7-dienal (4Z,7Z)-Trideca-4,7-dienal	4735	C ₁₃ H ₂₂ O	Slightly soluble	HNMR, CNMR	1.459-1.469	
full	(4Z,7Z)-Tridecadienal; cis, cis-4,7-Tridecadienal; (Z,Z)-4,7-Tridecadienal		194.31	Soluble	95%	0.847-0.867	
97		13552-95-9	Colourless oil	150 °C at 0.13 kPa			
2287	cis-5-Dodecenyl acetate [(Z)-Dodec-5-enyl] acetate	4841	C ₁₄ H ₂₆ O ₂	Slightly soluble	HNMR, CNMR	1.442-1.447	
full	5-Dodecen-1-ol, 1-acetate, (5Z)-		226.36 Colorless to pale yellow clear liquid; Fruity	Slightly soluble	95%	0.875-0.884	
97		16676-96-3					



Linear and branched-chain aliphatic, unsaturated and unconjugated alcohols, aldehydes, acids and related esters

JECFA No.	Name	FEMA	Chemical Formula	Solubility	ID test	R.I. (20°)	Other requirements
Status	Chemical Name	FLAVIS	M.W.	Solubility in ethanol	Assay min %	S.G. (25°)	
	Synonyms	COE	Physical form; Odour	B.P.°	Acid value		Information required
	Session	CAS					
2288	trans-5-Dodecenal	4885	C ₁₂ H ₂₂ O	Slightly soluble	HNMR, CNMR	1.443-1.449	
full	(E)-Dodec-5-enal		182.3	Slightly soluble	95%	0.837-0.845	
97	(5E)-Dodecenal		Colorless to pale yellow clear liquid; Waxy, dairy				
		68820-34-8					
2289	cis-6-Dodecenal	4886	C ₁₂ H ₂₂ O	Slightly soluble	HNMR, CNMR	1.436-1.456	
full	(Z)-Dodec-6-enal		182.3	Soluble	95%	0.825-0.865 at 20 °C	
97	(Z)-6-Dodecenal		Colorless to pale yellow clear liquid; Fruity, floral				
		126745-61-7					

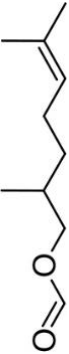
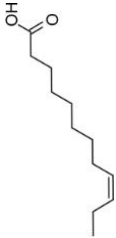
Linear and branched-chain aliphatic, unsaturated and unconjugated alcohols, aldehydes, acids and related esters

JECFA No.	Name	FEMA	Chemical Formula	Solubility	ID test	R.I. (20°)	Other requirements
Status	Chemical Name	FLAVIS	M.W.	Solubility in ethanol	Assay min %	S.G. (25°)	
	Synonyms	COE	Physical form; Odour	B.P.°	Acid value		Information required
	Session	CAS					
2290	cis-9-Dodecenal	4487	C ₁₂ H ₂₂ O	Insoluble	HNMR, CNMR	1.445-1.451	
full	(Z)-Dodec-9-enal		182.3	Soluble		0.842-0.850	
97	(9Z)-Dodecenal		Colorless to pale yellow clear liquid; Green, cooked, roasted		95%		
		56219-03-5					
2291	(E)-3-Methyl-4-dodecenoic acid	4891	C ₁₃ H ₂₄ O ₂	Practically insoluble	HNMR, CNMR, IR	1.446-1.456	
full	(E)-3-Methyldodec-4-enoic acid		212.33	Soluble	95%	0.891-0.901 at 20 °C	
97		2088117-65-9		Colorless oil; Fruity, spicy, herbal		120-150 °C at 100 Pa	

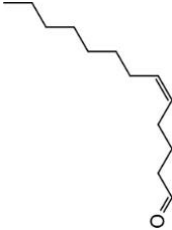
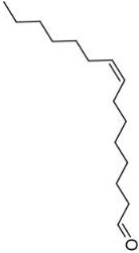
Linear and branched-chain aliphatic, unsaturated and unconjugated alcohols, aldehydes, acids and related esters

JECFA No.	Name	FEMA	Chemical Formula	Solubility	ID test	R.I. (20°)	Other requirements
Status	Chemical Name	FLAVIS	M.W.	Solubility in ethanol	Assay min %	S.G. (25°)	
	Synonyms	COE	Physical form; Odour	B.P.°	Acid value		Information required
	Session	CAS					
2292	trans-5-Octenal	4898	C ₈ H ₁₄ O	Insoluble	HNMR, CNMR, MS	1.420-1.460	
full	(E)-Oct-5-enal		126.2	Soluble	95%	0.830-0.870	
97	(5E)-5-Octenal; (E)-5-Octen-1-al		Colorless to pale yellow liquid; Fruity with spicy notes	182 °C			
		41547-29-9			5		
2293	trans-Tetradec-4-enal	4904	C ₁₄ H ₂₆ O	Insoluble	HNMR, CNMR	1.439-1.459	
full	(E)-Tetradec-4-enal		210.36	Soluble	95%	0.826-0.866	
97		115018-39-8	Colorless to pale brown liquid; Fatty, green, fruity				


Linear and branched-chain aliphatic, unsaturated and unconjugated alcohols, aldehydes, acids and related esters

JECFA No.	Name	FEMA	Chemical Formula	Solubility	ID test	R.I. (20°)	Other requirements
Status	Chemical Name	FLAVIS	M.W.	Solubility in ethanol	Assay min %	S.G. (25°)	
	Synonyms	COE	Physical form; Odour	B.P.°	Acid value		Information required
	Session	CAS					
2294	2,6-Dimethylheptenyl formate	4905	C ₁₀ H ₁₈ O ₂	Insoluble	HNMR, CNMR	1.432-1.452	
full	2,6-Dimethylhept-5-enyl formate		170.25	Soluble		0.879-0.919 at 20 °C	
97		2119671-25-7	Clear to yellow liquid; Fatty, green, floral		95%		
2295	(Z)-9-Dodecenoic acid	4917	C ₁₂ H ₂₂ O ₂	Practically insoluble	HNMR, CNMR, IR, MS	1.449-1.459	
full	(Z)-Dodec-9-enoic acid		198.3	Soluble	95%	0.904-0.914	
	(9Z)-9-Dodecenoic acid; 9-Dodecenoic acid, (Z)-; cis-9-Dodecenoic acid; Lauroleic acid		Colorless, slightly yellow oil; Seafood, meaty, fatty	130-135 °C at 100 Pa			
97		22032-47-9					



Linear and branched-chain aliphatic, unsaturated and unconjugated alcohols, aldehydes, acids and related esters

JECFA No.	Name	FEMA	Chemical Formula	Solubility	ID test	R.I. (20°)	Other requirements
Status	Chemical Name	FLAVIS	M.W.	Solubility in ethanol	Assay min %	S.G. (25°)	
Synonyms		COE	Physical form; Odour	B.P.°	Acid value		Information required
Session		CAS					
2296	cis-Tridec-5-enal	4918	C ₁₃ H ₂₄ O	Insoluble	HNMR, CNMR, MS	1.44-1.46	SC: >5% trans-tridec-5-enal
full	(Z)-tridec-5-enal		196.33	Soluble	90%	0.831-0.851 at 20 °C	
97		2112754-74-0; 68820-38-2	Colorless to pale brown liquid; Fishy, fatty	110 °C at 2 Torr			
2297	(Z)-8-Pentadecenal	4926	C ₁₅ H ₂₈ O	Practically insoluble	HNMR, CNMR, IR, MS	1.448-1.458	
full	(Z)-Pentadec-8-enal		224.38	Soluble	95%	0.840-0.850	
97		65398-36-9	Colorless, slightly yellow oil; Dairy, fruity	110-115 °C at 100 Pa			


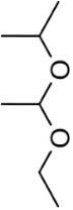
Linear and branched-chain aliphatic, unsaturated and unconjugated alcohols, aldehydes, acids and related esters

JECFA No.	Name	FEMA	Chemical Formula	Solubility	ID test	R.I. (20°)	Other requirements
Status	Chemical Name	FLAVIS	M.W.	Solubility in ethanol	Assay min %	S.G. (25°)	
	Synonyms	COE	Physical form; Odour	B.P.°	Acid value		Information required
	Session	CAS					
2298	4,7-Decadienal (mixture of isomers) (Safety evaluation not completed)	4927	C ₁₀ H ₁₆ O	Slightly soluble	HNMR, CNMR, IR, MS	1.456-1.465 at 25 °C	Safety evaluation not completed Mixture of isomers: 85-95% (4Z,7Z); 5-15% (4E,7Z); 0.5-1% (4Z,7E); 0.2-0.5% (4E,7E)
Tentative	4,7-decadienal		152.23	Soluble		0.865-0.872 at 20 °C	
					95%		
				42 °C at 1 Torr			
97		934534-30-2		Colorless oil; Dairy to fruity			

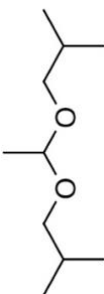
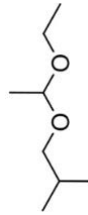
Saturated aliphatic acyclic linear primary alcohols, aldehydes and acids

JECFA No.	Name	FEMA	Chemical Formula	Solubility	ID test	R.I. (20°)	Other requirements
Status	Chemical Name	FLAVIS	M.W.	Solubility in ethanol	Assay min %	S.G. (25°)	
	Synonyms	COE	Physical form; Odour	B.P.°	Acid value		Information required
	Session	CAS					
2300	Pentadecanoic acid	4334	C ₁₅ H ₃₀ O ₂	Practically insoluble or insoluble	IR, MS		M.P. 51-54 °C
full	Pentadecanoic acid		242.4	Slightly soluble	98%		
	n-Pentadecanoic acid; n-Pentadecoic acid; Pentadecylic acid		Greasy aroma solid				
97		1002-84-2					
2301	Tridecanal	4335	C ₁₃ H ₂₆ O	Practically insoluble or insoluble	MS	1.435-1.440	
full	Tridecanal		198.35	Slightly soluble	95%	0.828-0.834	
	1-Tridecanal; Tridecyl aldehyde; Tridecanaldehyde; Tridecane aldehyde		Liquid; Sweet fatty aroma	132-136 °C			
97		10486-19-8					

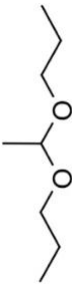
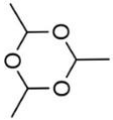
Saturated aliphatic acyclic linear primary alcohols, aldehydes and acids

JECFA No.	Name	FEMA	Chemical Formula	Solubility	ID test	R.I. (20°)	Other requirements
Status	Chemical Name	FLAVIS	M.W.	Solubility in ethanol	Assay min %	S.G. (25°)	
	Synonyms	COE	Physical form; Odour	B.P.°	Acid value		Information required
Session	CAS						
2302	Tridecanoic acid	4336	C ₁₃ H ₂₆ O ₂	Practically insoluble or insoluble	HNMR, CNMR, IR, MS		M.P. 41-42 °C
full	Tridecanoic acid		214.34	Slightly soluble	99%		
	n-Tridecanoic acid; n-Tridecoic acid; Tridecylic acid						
97		638-53-9					
2303	(+/-) Acetaldehyde ethyl isopropyl acetal (Safety evaluation not completed)	4432	C ₇ H ₁₆ O ₂	Slightly soluble	HNMR, CNMR, IR, MS	1.396	Safety evaluation not completed
tentative	2-(1-Ethoxyethoxy)propane		132.20	Soluble	90%	0.840	SC: 8% Acetaldehyde diethyl acetal (JECFA No. 941)
	1-Ethoxy-1-isopropoxyethane; 1-Ethoxy-1-(2-propoxy)ethane; Ethane, 1-Ethoxy-1-(2-methylpropoxy)		Liquid; Cooked, roasted fruit	126 °C			
97		25334-93-4					

Saturated aliphatic acyclic linear primary alcohols, aldehydes and acids

JECFA No.	Name	FEMA	Chemical Formula	Solubility	ID test	R.I. (20°)	Other requirements
Status	Chemical Name	FLAVIS	M.W.	Solubility in ethanol	Assay min %	S.G. (25°)	
Synonyms		COE	Physical form;	B.P.°	Acid value		Information required
Session		CAS					
2304	Acetaldehyde di-isobutylacetal	4527	C ₁₀ H ₂₂ O ₂	Insoluble	HNMR, CNMR, IR, MS	1.339-1.413	
full	2-Methyl-1-[1-(2-methylpropoxy)ethoxy]propane;		174.28	1 ml in 1 ml 95% EtOH	98%	0.817-0.840	
	1,1-Diisobutoxyethane ; Ethane, 1-ethoxy-1-(2-methylpropyloxy)Propane, 2-(1-ethoxyethoxy)-		Liquid; Fruity odour	171 °C			
97		5669-09-0			<2		
2305	Acetaldehyde ethyl isobutyl acetal	4528	C ₈ H ₁₈ O ₂	Slightly soluble	HNMR, CNMR, IR, MS	1.381-1.403	
full	1-(1-Ethoxyethoxy)-2-methylpropane		146.23	1 ml in 1 ml 95% EtOH	99%	0.818-0.840	
	1-Ethoxy-1-isobutoxyethane; 1-(1-Ethoxyethoxy)-2-methylpropane		Liquid; Fruity, winey odour	155 °C			
97		6986-51-2					

Saturated aliphatic acyclic linear primary alcohols, aldehydes and acids

JECFA No.	Name	FEMA	Chemical Formula	Solubility	ID test	R.I. (20°)	Other requirements
Status	Chemical Name	FLAVIS	M.W.	Solubility in ethanol	Assay min %	S.G. (25°)	
Session	Synonyms	COE	Physical form; Odour	B.P.°	Acid value		Information required
		CAS					
2306	1,1-Dipropoxyethane (Safety evaluation not completed)	4688	C ₈ H ₁₈ O ₂	Slightly soluble	IR, MS	1.380-1.420	Safety evaluation not completed
tentative	1-(1-Propoxyethoxy)propane		146.23	1 ml in 1 ml 95% EtOH	95%	0.780-0.900	
97	Acetaldehyde, dipropyl acetal 	105-82-8	Clear colourless liquid; Strong ethereal winey, fresh ethereal alcoholic, winey-fruity	147 °C			
2299	Paraldehyde (Safety evaluation not completed)	4010	C ₆ H ₁₂ O ₃	Slightly soluble	IR	1.402-1.408	Safety evaluation not completed
tentative	2,4,6-Trimethyl-1,3,5-trioxane Paracetaldehyde; Paral; Acetaldehyde, trimer; S-Trioxane; 2,4,6-Trimethyl-1,3,5-trioxane; 2,4,6-Trimethyl-1,3,5-trioxacyclohexane; Elaldehyde		132.16	125 °C	98%	0.991-0.997	
97		123-63-7	Clear, colourless to yellowish liquid; Fruity ethereal				

Annex 1: Summary and conclusions from JECFA97¹

JOINT FAO/WHO EXPERT COMMITTEE ON FOOD ADDITIVES

Ninety-seventh meeting (Safety evaluation of certain food additives)

31 October–9 November 2023

SUMMARY AND CONCLUSIONS

Issued on 24 November 2023

The Ninety-seventh meeting of the Joint FAO/WHO Executive Committee on Food Additives was held in Rome from 31 October to 9 November 2023. The purpose of the meeting was to evaluate the safety of certain food additives and flavourings. The present meeting was the Ninety-seventh in a series of similar meetings. The tasks before the Committee were to (a) further elaborate principles governing the evaluation of food additives; (b) undertake safety evaluations of certain food additives; (c) review and prepare specifications for certain food additives; and (d) establish specifications for certain flavouring agents.

Dr R. Cantrill served as Chairperson and Dr D. Bedford served as Vice-chairperson. Ms A. Vlachou and Mr K. Petersen served as joint secretaries.

The Committee evaluated the safety of one food additive, including revising its specifications, and evaluated the safety of three groups of flavouring agents.

The report of the meeting will be published in the WHO Technical Report Series (TRS 1051). The report will summarize the main conclusions of the Committee in terms of acceptable daily intakes (ADIs) and other toxicological, dietary exposure and safety recommendations. Information on deliberations and conclusions with regards to the specifications for the identity and purity of certain food additives examined by the Committee, and on specifications for the flavouring agents, will also be included.

The participants are listed in Annex 1. Future work and recommendations arising from the summary report of the Ninety-seventh JECFA meeting are summarized in Annex 2. Finally, Annex 3 includes requests for corrections that were reported to the JECFA Secretariat, evaluated by the Committee and found to be necessary (note that these corrections will only

¹ Please note that the annexes referred to in this document are to be found in the original summary of the 95th meeting and are not those in this volume of the FAO JECFA Monographs series.

be made in the electronic versions available in the online database).

Toxicological monographs summarizing the data that were considered by the Committee in establishing ADIs will be published in WHO Food Additives Series No. 88. New and revised specifications for the identity and purity of the compounds will be published in FAO JECFA Monographs No. 32.

More information on the work of JECFA is available at: <http://www.fao.org/food-safety/scientific-advice/jecfa/en/> and <https://www.who.int/foodsafety/en/>.

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Toxicological and dietary exposure information and conclusions

Food additive evaluated toxicologically and assessed for dietary exposure

Titanium dioxide (TiO₂)

The Committee evaluated TiO₂ (INS 171) at its Thirteenth meeting (1) and assigned an ADI “not specified”² based on an absence of significant absorption and a lack of toxicological effects in the available experimental animal and human studies at the time.

At the present meeting, the Committee considered additional toxicological studies relevant to the safety assessment of INS 171 that investigated the toxicokinetics, acute toxicity, short-term toxicity, long-term toxicity and carcinogenicity, genotoxicity, and reproductive and developmental toxicity, as well as special studies addressing the short-term initiation/promotion potential for colon cancer.

The Committee identified a number of TiO₂ test materials that were considered representative of INS 171. Further, the Committee recognized that a large number of toxicological studies have been conducted using test materials, including nanoparticles, having size distributions and physico-chemical properties not comparable to INS 171. These studies on non-representative materials were evaluated by the Committee, but it was concluded that they were not relevant to the safety assessment of INS 171.

INS 171 was poorly absorbed from the gastrointestinal tract of mice and rats. No adverse effects were observed in short-term studies in mice and rats receiving INS 171 in the diet, with NOAELs of 15 000 mg/kg bw per day and 5000 mg/kg bw per day in mice and rats, respectively, the highest doses tested. The Committee noted that the available data did not provide convincing evidence of genotoxicity for INS 171, but recognized the limitations in current methodologies with respect to the testing of poorly soluble particulate materials. Although there were uncertainties in the genotoxicity data, the Committee took into account the fact that INS 171 was not carcinogenic in adequately conducted 2-year studies in mice and rats at doses of up to 7500 mg/kg bw per day for mice and 2500 mg/kg bw per day for rats, the highest doses tested. There was no evidence of reproductive or developmental toxicity in studies in rats at INS 171 doses up to 1000 mg/kg bw per day, the highest doses tested.

² The Committee used the term “not limited”, a term that is no longer used by JECFA and that has the same meaning as ADI “not specified”.

Available studies in humans and postmortem analysis of tissues suggested that the oral bioavailability of TiO_2 in humans is very low. The Committee noted that there are currently no epidemiological studies that allow any conclusions to be drawn with respect to an association between dietary exposure to INS 171 and human health effects.

At the present meeting, the Committee evaluated estimates of dietary exposure to INS 171. Based on the estimates considered, the Committee selected a high P95 estimate of exposure to INS 171 of 10 mg/kg bw per day for the evaluation.

Considering the very low oral absorption of INS 171, and in the absence of any identifiable hazard associated with INS 171 in the diet, the Committee reaffirmed the ADI “not specified” established at the Thirteenth meeting.

A toxicological and dietary exposure monograph addendum was prepared.

The specifications monograph was revised. Specifications for the content of alumina and silica were removed, as TiO_2 coated with alumina or silica is not used as a food additive. The specification for the level of Pb soluble in 0.5 N HCl was reduced from 10 mg/kg to 5 mg/kg and the level of Cd soluble in 0.5 N HCl was reduced from 1 mg/kg to 0.5 mg/kg.

The chemical and technical assessment was revised.

Flavouring agents evaluated by the revised Procedure for the Safety Evaluation of Flavouring Agents

A. Aliphatic primary alcohols, aldehydes, carboxylic acids, acetals and esters containing additional oxygenated functional groups

The Committee decided not to review succinic acid (No. 2307) because it had previously been evaluated as a food additive at the Twenty-ninth meeting (2); at that meeting, the Committee concluded that succinic acid does not represent a hazard at the levels at which it is likely to be used as a food additive, due to its normal role in metabolism.

The Committee could not evaluate flavouring agents Nos 1973 and 1988. Only study summaries without the original full study reports had been submitted for evaluation for No. 1973, and no data were submitted for No. 1988.

Flavouring agent	No.	Specifications	Conclusion based on current estimated dietary exposure
Structural class I			
(±)-6-Methoxy-2,6-dimethylheptanal	2308	N	No safety concern
Ethyl 5-formyloxydecanoate	2309	N	No safety concern
Mixture of ricinoleic acid, linoleic acid and oleic acid	2310	N	No safety concern
Ethyl 3-methyl-2-oxopentanoate	2311	N	No safety concern

N: new specifications.

B. Linear and branched-chain aliphatic, unsaturated and unconjugated alcohols, aldehydes, acids and related esters

The studies of genotoxicity available for 4,7-decadienal (mixture of isomers) (No. 2298) indicated positive results in vitro, which did not allow the evaluation to be completed at this meeting. The Committee concluded that further investigation is required to demonstrate the absence of clastogenicity.

Flavouring agent	No.	Specifications	Conclusion based on current estimated dietary exposure
Structural class I			
(4Z,7Z)-Trideca-4,7-dienal	2286	N	No safety concern

<i>cis</i> -5-Dodecenyl acetate	2287	N	No safety concern
<i>trans</i> -5-Dodecenal	2288	N	No safety concern
<i>cis</i> -6-Dodecenal	2289	N	No safety concern
<i>cis</i> -9-Dodecenal	2290	N	No safety concern
(<i>E</i>)-3-Methyl-4-dodecenoic acid	2291	N	No safety concern
<i>trans</i> -5-Octenal	2292	N	No safety concern
<i>trans</i> -Tetradec-4-enal	2293	N	No safety concern
2,6-Dimethylheptenyl formate	2294	N	No safety concern
(<i>Z</i>)-9-Dodecenoic acid	2295	N	No safety concern
<i>cis</i> -Tridec-5-enal	2296	N	No safety concern
(<i>Z</i>)-8-Pentadecenal	2297	N	No safety concern

N: new specifications.

C. Saturated aliphatic acyclic linear primary alcohols, aldehydes and acids

Flavouring agents Nos 2299, 2303 and 2306 all exceeded their respective thresholds of toxicological concern. The structural analogue proposed to complete the evaluation of these three flavouring agents was acetaldehyde (No. 80) (3); however, the Committee considered that the use of acetaldehyde (No. 80) as a structural analogue in this safety assessment would require further evaluation. The Committee was therefore unable to complete the evaluation of Nos 2299, 2303 and 2306. The Committee also concluded that the use of acetaldehyde (No. 80) as a flavouring agent requires to be re-evaluated.

Flavouring agent	No.	Specifications	Conclusion based on current estimated dietary exposure
Structural class I			
Pentadecanoic acid	2300	N	No safety concern
Tridecanal	2301	N	No safety concern
Tridecanoic acid	2302	N	No safety concern
Acetaldehyde di-isobutyl acetal	2304	N	No safety concern
Acetaldehyde ethyl isobutyl acetal	2305	N	No safety concern

N: new specifications.

References

1. Specifications for the identity and purity of food additives and their toxicological evaluation: some food colours, emulsifiers, stabilizers, anticaking agents, and certain other substances: thirteenth report of the Joint FAO/WHO Expert Committee on Food Additives. Geneva: World Health Organization; 1970 (WHO Technical Report Series, No. 445, <https://iris.who.int/handle/10665/40773>, accessed 9 November 2023).
2. Evaluation of certain food additives and contaminants: twenty-ninth report of the Joint FAO/WHO Expert Committee on Food Additives. Geneva: World Health Organization; 1986 (WHO Technical Report Series, No. 733, <https://iris.who.int/handle/10665/37285>, accessed 15 November 2023).
3. Evaluation of certain food additives and contaminants: forty-ninth report of the Joint FAO/WHO Expert Committee on Food Additives. Geneva: World Health Organization; 1999 (WHO Technical Report Series, No. 884, <https://apps.who.int/iris/handle/10665/42142>, accessed 26 July 2023).

Annex 2. Recommendations and future work

The Committee asks the JECFA Secretariat to urge sponsors and Codex Members to ensure that all information is available for the evaluation of additional flavouring agents, including an updated literature search, a rationale for the choice of a comparator compound, and exposure data (both SPET and MSDI values) for all previously evaluated flavouring agents prior to requesting inclusion in the CCFA JECFA Priority List.

The Committee discussed the importance of receiving data in support of the establishment of specifications for flavouring agents. For future meetings, data should be provided by the sponsor in support of any parameter for which a numerical value is specified.

Specific recommendations for the three different groups of flavouring agents are provided below.

A. Aliphatic primary alcohols, aldehydes, carboxylic acids, acetals and esters containing additional oxygenated functional groups

The Committee requests that updated exposure data (including both MSDI and SPET values) be provided for the flavouring agents citronelloxyacetaldehyde (No. 592), 1,3-nonanediol acetate (No. 605), levulinic acid (No. 606), hydroxycitronellal diethyl acetal (No. 613), diethyl malonate (No. 614), diethyl tartrate (No. 622) and triethyl citrate (No. 629) within 2 years (i.e. by December 2025) so that a re-evaluation of these previously evaluated compounds can be completed.

B. Linear and branched-chain aliphatic, unsaturated and unconjugated alcohols, aldehydes, acids and related esters

The Committee requests that updated exposure data (including both MSDI and SPET values) be provided for the flavouring agents *cis*-3-hexen-1-ol (No. 315), 10-undecenal (No. 330), 10-undecenoic acid (No. 331), *cis*-3-hexenyl *cis*-3-hexenoate (No. 336), 5-hexenol (No. 1623) and methyl 10-undecenoate (No. 1639) within 2 years (i.e. by December 2025) so that a re-evaluation of these previously evaluated compounds can be completed.

C. Saturated aliphatic acyclic linear primary alcohols, aldehydes and acids

The Committee considered that the use of acetaldehyde (No. 80) as a structural analogue in the safety assessment of flavouring substances would require further evaluation. Furthermore, the Committee concluded that the use of acetaldehyde (No. 80) as a flavouring agent requires re-evaluation.

The Committee requests that updated exposure data (including both MSDI and SPET values) be provided for the flavouring agents acetaldehyde (No. 80), butyl alcohol (No. 85), butyraldehyde (No. 86), hexanoic acid (No. 93) and lauric aldehyde (No. 110) within 2 years (i.e. by December 2025) so that a re-evaluation of these previously evaluated compounds can be completed.

Annex 3. Corrigenda

The requests for corrections in the table below, reported to the JECFA Secretariat, were evaluated at the Ninety-seventh JECFA meeting and found to be necessary. Corrections will be made only in the online database for specifications.

Requests for corrections submitted to the JECFA Secretariat

Substance	Original text	Revised text	Additional information
Modified starches	Table on page 3 of specifications (1)	See revised table below	Revised table is in alignment with specifications
	Page 13 CAS numbers 601464-73-0 (Amylopectin, acetate)	CAS numbers 60164-73-0 (Amylopectin, acetate)	
	Page 22 Increase temperature to 250 °C at a rate of 14.5 °C/s. Hold at 250 °C for 1 min	Increase temperature to 250 °C at a rate of 14.5 °C/min, hold at 250 °C for 1 min	
	Page 22 Split/splitless injector settings Injector temperature: 250 °C Injection mode: splitless for 0.8 min	Split/splitless injector settings Injector temperature: 250 °C Injection mode: splitless for 0.8 min Recommended liner of at least: 870 µL	
Pullulan	Chemical formula: (C ₆ H ₁₀ O ₅) _x	Chemical formula: (C ₃₆ H ₆₀ O ₃₀) _n	
	Characteristics: Mono-, di- and oligosaccharides Not more than 10% (expressed as glucose)	Characteristics: Mono-, di- and oligosaccharides Not more than 10% (expressed as glucose), on the dried basis	
	Purity tests: Mono-, di- and oligosaccharides Procedure – Weigh accurately 0.8 g sample and dissolve in water to make 100 ml (stock solution).	Purity tests: Mono-, di- and oligosaccharides Procedure – Weigh accurately 0.8 g sample previously dried and dissolve in water to make 100 ml (stock solution).	
	Method of assay: P(%) = 100 – (L+C) where L is loss on drying; and C is taken from the calculation for mono-, di- and oligosaccharides.	Method of assay: P(%) = [100 – C] where C is taken from the calculation for mono-, di- and oligosaccharides.	
Spirulina extract (INS 134)	Method of assay: Calculate the allophycocyanin content (percent, w/w) as follows: TaPC = [(0.180 x A ₆₂₀) – (0.042 x A ₆₅₀) x V1 x 100] / W1	Method of assay: Calculate the allophycocyanin content (percent, w/w) as follows: TaPC = [(0.180 x A ₆₅₀) – (0.042 x A ₆₂₀) x V1 x 100] / W1	

Modified starches (1); revised table

Summary table							
GENERAL REQUIREMENTS							
IDENTIFICATION				PURITY			
Solubility	Microscopy	Iodine Stain	Copper Reduction	Loss on Drying	Lead	Microbiological Criteria	Sulfur dioxide
Insoluble in cold water, if not pre-gelatinised.	Granular structure typical of the starch source	Colour from dark blue to orange-red after addition of iodine TS	Red precipitate after addition of hot alkaline cupric tartrate to a test sample refluxed under acidic condition	Cereal starch ≤15.0%; Potato starch: ≤21.0%; Other starches: ≤18.0%	≤0.2mg/kg d.w. Pb (≤0.1 mg/kg) for starch sodium octenylsuccinate for infant formula	Aerobic Plate Count: ≤100,000 CFU/g; Yeasts and molds: ≤1,000 CFU/g; Total Coliforms: ≤100 CFU/g;	Modified cereal starches: ≤50 mg/kg d.w.; Other modified starches ≤10 mg/kg d.w.
SPECIFIC REQUIREMENTS							
Modified Starch	Annex	IDENTIFICATION		PURITY			
Dextrin roasted starch (INS 1400)	1	Dispersion test		No additional			
Acid treated starch (INS 1401)	1	Dispersion test		No additional			
Alkaline treated starch (INS 1402)	1	Dispersion test		No additional			
Bleached starch (INS 1403)	2	No additional		Carboxyl groups (≤0.1% d.w.); Residual oxidizing substances < 180 mg/kg calculated as H ₂ O ₂			
Oxidized starch (INS 1404)	5	Hypochlorite oxidized starch		Carboxyl groups (≤1.3% d.w.); Residual oxidizing substances < 180 mg/kg calculated as H ₂ O ₂			
Enzyme-treated starch (INS 1405)	1	Dispersion index (Information Required); Reducing sugars (Information Required) test		No additional			
Monostarch phosphate (INS 1410)	3	Phosphate groups		Phosphate (≤0.5% d.w. for potato or wheat starches; ≤0.4% d.w. for other starches)			
Distarch phosphate (INS 1412)	3	Crosslinking		Phosphate (≤0.5% d.w. for potato or wheat starches; ≤0.4% d.w. for other starches)			
Phosphated distarch phosphate (INS 1413)	3	Crosslinking		Phosphate (≤0.5% d.w. for potato or wheat starches; ≤0.4% d.w. for other starches)			
Acetylated distarch phosphate (INS 1414)	3, 4	Acetyl group; Ester group; Crosslinking		Phosphate (≤0.14% d.w. for potato or wheat starches; ≤0.04% d.w. for other starches) Acetyl groups (≤2.5% d.w.); Ester groups (≤0.5% d.w.)			
Starch acetate (INS 1420)	4	Acetyl group; Ester group		Acetyl groups (≤2.5% d.w.); Ester groups (≤0.5% d.w.)			
Acetylated distarch adipate (INS 1422)	4, 8	Acetyl group; Ester group; Crosslinking		Acetyl groups (≤2.5% d.w.); Vinyl acetate (≤0.1 mg/kg); Ester groups (≤0.5% d.w.) Adipate groups (≤0.135% d.w.); Residual free adipic acid (≤0.025% d.w.)			
Hydroxypropyl starch (INS 1440)	7	Hydroxypropyl ether groups		Hydroxypropyl groups (≤7.0% d.w.); Propylene chlorohydrins (≤1 mg/kg d.w.)			
Hydroxypropyl distarch phosphate (INS 1442)	3, 7	Hydroxypropyl ether groups; Crosslinking		Phosphate (≤0.14% d.w. for potato or wheat starches; ≤0.04% d.w. for other starches) Hydroxypropyl groups (≤7.0% d.w.); Propylene chlorohydrins (≤1 mg/kg d.w.)			
Starch sodium octenylsuccinate (INS 1450)	6	No additional		Octenylsuccinyl groups (≤3% d.w.); Residual free octenylsuccinic acid (≤0.3% d.w.);			
Acetylated oxidized starch (INS 1451)	4, 5	Acetyl group		Acetyl groups (≤2.5% d.w.); Vinyl acetate (≤0.1 mg/kg); Ester groups (≤0.5% d.w.) Carboxyl groups (≤1.3% d.w.); Residual oxidizing substances < 180 mg/kg calculated as H ₂ O ₂			

Reference

1. Online edition. Modified starches Monograph 27; 2021 (<https://www.fao.org/food/food-safety-quality/scientific-advice/jecfa/jecfa-additives/en/>, accessed 15 November 2023).

COMPENDIUM OF FOOD ADDITIVE SPECIFICATIONS

Joint FAO/WHO Expert Committee on Food Additives
97th Meeting, Rome, 31 October – 9 November 2023

This document contains food additive specification monographs, analytical methods, and other information prepared at the ninety-seventh meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA), which was held in Rome from 31 October to 9 November 2023. The specification monographs provide information on the identity and purity of food additives used directly in foods or in food production. The main three objectives of these specifications are to identify the food additive that has been subjected to testing for safety, to ensure that the additives are of the quality required for use in food or in processing and to reflect and encourage good manufacturing practice. This publication and other documents produced by JECFA contain information that is useful to all those who work with or are interested in food additives and their safe use in food.

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