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COMPENDIUM OF FOOD ADDITIVE SPECIFICATIONS

Joint FAO/WHO Expert Committee on Food Additives

73rd Meeting 2010

World Health Organization

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FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS
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Geneva, 8 – 17 June, 2010

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INTRODUCTION

This volume of FAO JECFA Monographs contains specifications of identity and purity prepared at the 73rd meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA), held in Geneva on 8 - 17 June 2010. 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 consist 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 on-line searchable database of all JECFA specifications monographs from the FAO JECFA Monographs, which is available at: http://www.fao.org/ag/agn/jecfa-additives/search.html . 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 (flavouring agent) specifications which has been updated and modernized. All specifications for flavourings that have been evaluated by JECFA since its 44th meeting, including the 73rd meeting, are available in the new format online searchable database at the JECFA website at FAO: http://www.fao.org/ag/agn/jecfa-flav/search.html. The databases have query pages and background information in English, French, Spanish, Arabic and Chinese. 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/ag/agn/agns/jecfa_archive_cta_en.asp .

Contact and Feedback

More information on the work of the Committee is available from the FAO homepage of JECFA at: http://www.fao.org/ag/agn/agns/jecfa_index_en.asp . Readers are invited to address comments and questions on this publication and other topics related to the work of JECFA to:

jecfa@fao.org

FAO TECHNICAL PAPERS

FAO JECFA MONOGRAPHS

1 Combined compendium of food additive specifications – JECFA specifications monographs from the 1st to the 65th meeting. (E)
Vol. 1 Food additives A – D
Vol. 2 Food additives E – O
Vol. 3 Food additives P – Z
Vol. 4 Analytical methods, test procedures and laboratory solutions

2 Residue evaluation of certain veterinary drugs - Joint FAO/WHO Expert Committee on Food Additives 66th meeting 2006 (E)

3 Compendium of food additive specifications - Joint FAO/WHO Expert Committee on Food Additives 67th meeting 2006 (E)

4 Compendium of food additive specifications - Joint FAO/WHO Expert Committee on Food Additives 68th meeting 2007 (E)

5 Compendium of food additive specifications - Joint FAO/WHO Expert Committee on Food Additives 69th meeting 2008 (E)

6 Residue evaluation of certain veterinary drugs - Joint FAO/WHO Expert Committee on Food Additives 70th meeting 2008 (E)

7 Compendium of food additive specifications - Joint FAO/WHO Expert Committee on Food Additives 71st meeting 2006 (E)

8 Safety evaluation of certain contaminants in food - Joint FAO/WHO Expert Committee on Food Additives 72nd meeting 2010 (E)
Joint FAO/WHO publication WHO Food Additives Series No. 63/ FAO JECFA Monographs 8, in preparation.

9 Residue evaluation of certain vweterinary drugs RESIDUE EVALUATION
Joint FAO/WHO Expert Committee on Food Additives Meeting 2010 – Evaluation of data on ractopamine residues in pig tissues (E)

Availability: 2010

Ar – Arabic
C – Chinese
E – English
F – French
P – Portuguese
S – Spanish

Multil – Multilingual
* Out of print
** In preparation

The FAO Technical Papers are available through the authorized FAO Sales Agents or directly from Sales and Marketing Group, FAO, Viale delle Terme di Caracalla, 00153 Rome, Italy.

TABLE OF CONTENTS

SPECIFICATIONS FOR CERTAIN FOOD ADDITIVES

New and revised specifications

New (N) or revised (R) specifications monographs were prepared for the following food additives and these are provided in this publication:

Activated carbon (R)
Cassia gum (R)
Indigotine (R)
Steviol glycosides (R)
Sucrose esters of fatty acids (R)
Sucrose monoesters of lauric, palmitic or stearic acid (N, T)
Titanium dioxide (R)

In the specifications monographs that have been assigned a tentative status (T), there is information on the outstanding information and a timeline by which this information should be submitted to the FAO JECFA Secretariat.

New and revised INS numbers assigned to food additives by the Codex Alimentarius Commission at its 33rd session in 2010, (ALINORM 10/33/12, Appendix IX) and a correction for the INS number for Stannous chloride to No. 512, have been introduced in the corresponding JECFA food additive specifications monographs in the on-line database, as appropriate, and these are not reproduced in this publication.

Minor editorial revisions and corrections to the limits and information relating to metals and arsenic as published in FAO JECFA Monographs 1 (2005, 2006), Combined Compendium of Food Additive Specifications, have been made to the following JECFA food additive specifications monographs in the on-line database and are not reproduced in this publication: Carotenes (Algae), Carotenes (Vegetable), Calcium silicate, Ferric ammonium citrate, Grape skin extract, Potassium carbonate, Trimagnesium phosphate and Trisodium phosphate. The corrected limits correspond to those agreed by the Committee and published in the reports of JECFA from the relevant meetings (57th, 59th and 63rd meetings of JECFA).

ACTIVATED CARBON

Prepared at the 73rd JECFA (2010) and published in FAO JECFA Monographs 10 (2010), superseding specifications prepared at the 37th JECFA (1990) and published in the Combined Compendium of Food Additive Specifications, FAO JECFA Monographs 1 (2005). No ADI was established at the 31st JECFA (1987).

SYNONYMS Activated charcoal, decolourizing carbon

DEFINITION A solid, porous, carbonaceous material prepared by carbonizing and activating organic substances. The raw materials, which include sawdust, peat, lignite, coal, cellulose residues, coconut shells, petroleum coke, etc., may be carbonized and activated at high temperature with or without the addition of inorganic salts in a stream of activating gases such as steam or carbon dioxide. Alternatively, carbonaceous matter may be treated with a chemical activating agent such as phosphoric acid or zinc chloride and the mixture carbonized at an elevated temperature, followed by removal of the chemical activating agent by water washing.

Chemical names: Carbon

C.A.S. number: 7440-44-0

Chemical formula: C

Formula weight: 12.01

DESCRIPTION Powder or granules, black, odourless

FUNCTIONAL USES Adsorbent, decolourizing agent

GENERAL SPECIFICATIONS Must conform to the latest edition of the JECFA General Specifications and Considerations for Enzyme Preparations Used in Food Processing.

CHARACTERISTICS

IDENTIFICATION

Solubility: Adsorbent, decolourizing agent

Adsorption: Place about 3 g of powdered sample in a glass-stoppered flask containing 10 ml of dilute hydrochloric acid (5%), boil for 30 s, and cool to room temperature. Add 100 ml of iodine TS, stopper, and shake vigorously for 30 sec. Filter through filter paper (Whatman No. 2 or equivalent), discarding the first portion of filtrate. Compare 50 ml of the filtrate with a reference solution prepared by diluting 10 ml of iodine to 50 ml with water, but not treated with carbon. The colour of the carbon treated iodine solution shall be lighter in colour than that of the reference solution, indicating the adsorptivity of the sample.

PURITY

Adsorption power	Not less than 90% and not more than 110% of the value stated on label. See description under TESTS
Loss on drying (Vol. 4)	Not more than 15% (120°, 4 h) (See Volume 4 under "GENERAL METHODS, Inorganic Components.")
Sulfide compounds	To 1.0 g of the sample in a conical flask add 5 ml of 1 N hydrochloric acid and 20 ml of water. Heat to boiling. The fumes released do not turn lead acetate paper brown. (Lead acetate paper is prepared by saturating filter paper with lead acetate TS and drying the paper at 100°).
Acid soluble substances	Not more than 3% To about 1 g of the sample, accurately weighed, add 25 ml of dilute nitric acid TS and boil for 5 min. Filter whilst hot through a sintered-glass filter (10) and wash with 10 ml of hot water. Evaporate the combined filtrate and washings to dryness on a water bath, add to the residue 1 ml of hydrochloric acid, evaporate to dryness again and dry the residue to constant weight at 103±2°.
Sulfated ash	Not more than 5% Heat a silica or platinum crucible to redness for 30 min, allow to cool in a desiccator and weigh. Accurately weigh about 1 g of sample in the crucible and add 2 ml of sulfuric acid TS. Heat at first on a water bath, then cautiously over a flame, then progressively to about 600°. Continue the incineration until all black particles have disappeared and allow the crucible to cool. Add a few drops of dilute sulfuric acid TS, heat and incinerate as before and allow to cool. Evaporate and incinerate carefully, allow to cool, weigh, and repeat the ignition for 15 min to constant weight.
Water extractable substances	Not more than 4% Transfer about 5 g of sample, accurately weighed, into a 250 ml flask provided with a reflux condenser and a Bunsen valve. Add 100 ml of water and several glass beads, and reflux for 1 h. Cool slightly, and filter through Whatman No 2 or equivalent filter paper, discarding the first 10 ml of filtrate. Cool the filtrate to room temperature, and pipet 25.0 ml into a tared dish. Evaporate the filtrate in the dish to incipient dryness on a hot plate never allowing the solution to boil. Dry for 1 h at 103±2° in a vacuum oven, cool and weigh. Calculate the percentage of water extractables in the filtrate, based on the sample weight and volume of sample taken for gravimetric measurement.
Alcohol soluble substances	Not more than 0.5% To 2.0 g of sample add 50 ml of ethanol (96 per cent) and boil under a reflux condenser for 10 min. Filter immediately, wash residue with 10 ml of warm ethanol and filter. Quantitatively transfer the combined filtrate into a tared beaker containing a few antibumping stones. Evaporate to dryness on a water bath and dry to a constant mass at 103±2°. The residue on evaporation weighs not more than 10 mg.
Alkali soluble coloured substances	To 0.25 g of sample add 10 ml of 2 N sodium hydroxide and boil for 1 min. Cool, filter and dilute the filtrate to 10 ml with water. Prepare a

reference solution by mixing 1.90 ml of solution A (1% hydrochloric acid) and 0.10 ml of a solution B (9.6 ml of ferric chloride TS + 0.2 ml of cobaltous chloride TS + 0.2 ml of cupric sulfate TS). The colour of sample solution shall not be more intense than that of the reference solution.

Cyanogen compounds

Mix 5 g of sample with 50 ml of water and 2 g of tartaric acid. Distil the mixture, collecting 25 ml of distillate below the surface of a mixture of 2 ml of sodium hydroxide TS and 10 ml of water contained in a small flask placed in an ice bath. Dilute the distillate to 50 ml with water, and mix. Add 12 drops of ferrous sulfate TS to 25 ml of the diluted distillate, heat almost to boiling, cool, and add 1 ml of hydrochloric acid. No blue colour is produced.

Higher aromatic hydrocarbons

Extract 5 g of the sample with about 45 ml of cyclohexane in a continuous extraction apparatus for 2 h. Collect the extract and dilute to 50 ml with cyclohexane. Examine under ultraviolet light at 365 nm. The colour or fluorescence of the solution is not more intense than that of a 83 ng/ml solution of quinine prepared in 0.01N sulfuric acid, examined under the same conditions.

Arsenic (Vol. 4)

Not more than 3 mg/kg
Accurately weigh about 4 g of the sample into a conical flask, add 80 ml of 2 N hydrochloric acid, extra pure, and boil gently under reflux for 1 h, filter and wash the filter with 2 N hydrochloric acid. Cool and quantitatively transfer the filtrate into 100 ml volumetric flask and make up to volume with the same acid. Determine arsenic using atomic absorption hydride generation technique.

Lead (Vol. 4)

Not more than 5 mg/kg
Determine using an AAS/ICP-AES technique appropriate to the specified level using the solution prepared under arsenic.

Zinc (Vol.4)

Not more than 25 mg/kg
Determine using an AAS/ICP-AES technique appropriate to the specified level using the solution prepared under arsenic.

TESTS

PURITY TESTS

Adsorption power

To about 0.3 g of dried sample, accurately weighed, in a 100 ml ground-glass-stoppered conical flask, add 25.0 ml of a freshly prepared solution of 0.5 g of phenazone in 50 ml of water. Shake thoroughly for 15 min. Filter and reject the first 5 ml of filtrate. Pipette 10.0 ml of the filtrate into a conical flask, add 1.0 g of potassium bromide and 20 ml of dilute hydrochloric acid TS. Using 0.1 ml of ethoxychrysoidine solution as indicator, titrate with 0.1 N potassium bromate until the colour changes from reddish-pink to yellowish-pink. Titrate slowly (1 drop every 15 sec) towards the end of the titration. Carry out a blank titration using 10.0 ml of the phenazone solution.

Calculate adsorption power from:

$$[235.3\ (a - b)]/[d \times m]$$

where

a is the volume (ml) of 0.1 N potassium bromate consumed by the blank;

b is the volume (ml) of 0.1 N potassium bromate consumed by the test solution;

m is the mass (g) of dried sample; and

d is the value stated on the label.

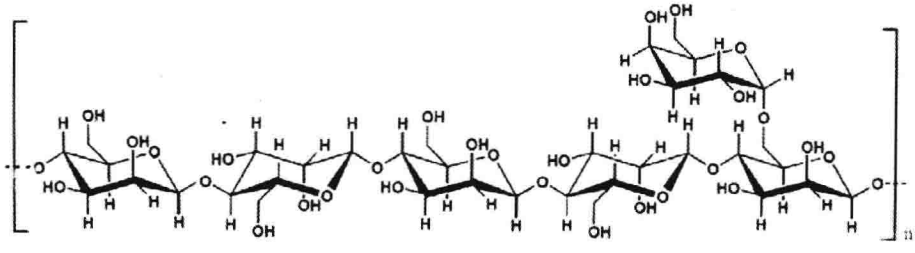
CASSIA GUM

Prepared at the 73rd JECFA (2010) and published in FAO JECFA Monographs 10 (2010), superseding tentative specifications prepared at the 71st JECFA (2009) and published in FAO JECFA Monographs 7 (2009). An ADI "not specified" was established at the 71st JECFA (2009).

SYNONYMS INS 427

DEFINITION Primarily the ground purified endosperm of the seeds of *Cassia tora* and *Cassia obtusifolia*, (Fam. *Leguminsae*) containing less than 0.05% of Cassia occidentalis. It consists mainly of high molecular weight (approximately 200,000-300,000) polysaccharides composed of galactomannans; the mannose: galactose ratio is about 5:1. The structural formula for cassia gum galactomannan is given below. The seeds are dehusked and degermed by thermal mechanical treatment followed by milling and screening of the endosperm. The ground endosperm is further purified by extraction with isopropanol.

Structural formula



Assay Not less than 75% of galactomannan

DESCRIPTION Pale yellow to off-white, odourless free-flowing powder

FUNCTIONAL USES Thickener, emulsifiier, foam stabilizer, moisture retention agent and texturizing agent.

CHARACTERISTICS

IDENTIFICATION

Solubility
Insoluble in ethanol
Disperses well in cold water forming colloidal solutions.

Gel formation with borate
Add sufficient amounts of sodium borate TS to an aqueous dispersion of the sample sufficient to raise the pH to above 9; a gel is formed.

Gel formation with xanthan gum
Passes test
See description under tests

Gum constituents (Vol. 4)
Proceed as directed under Gum Constituents Identification (Vol. 4) using 100 mg of sample instead of 200 mg and 1-10 µl of the hydrolysate instead of 1-5 µl. Use galactose and mannose as reference standards. These constituents should be present.

Viscosity	Less than 500 mPas (25°, 2h) (1% solution) See description under TESTS
pH (Vol. 4)	5.5-8.0 (1%)
PURITY	
Loss on drying (Vol. 4)	Not more than 12% (105° , 5 h)
Total ash (Vol. 4)	Not more than 1.2%
Acid-insoluble matter (Vol. 4)	Not more than 2.0%
Protein (Vol. 4)	Not more than 7.0% Proceed as directed under Nitrogen Determination (Kjeldahl Method; Vol. 4). The percent of nitrogen in the sample multiplied by 6.25 gives the percent of protein in the sample.
Crude fat	Not more than 1% See description under TESTS
Starch	To a 1 in 10 dispersion of the sample add a few drops of iodine TS; no blue colour is produced.
Anthraquinones	Not more than 0.5 mg/kg See description under TESTS
Residual solvents	Isopropanol: Not more than 1.0% See description under TESTS
Lead (Vol. 4)	Not more than 1 mg/kg Determine using an AAS/ICP-AES technique appropriate to the specified level. The selection of sample size and method of sample preparation may be based on the principles of the method described in Volume 4 (under "General Methods, Metallic Impurities").
Microbiological criteria (Vol. 4)	Total plate count: Not more than 5,000 cfu/g Yeast and mould: Not more than 100 cfu/g *E. coli*: Negative in 1 g *Salmonella*: Negative in 25 g

TESTS

IDENTIFICATION TESTS

Gel formation with xanthan gum	Weigh 1.5 g of the sample and 1.5 g of xanthan gum and blend them. Add this blend with (rapid stirring) into 300 ml water at 80° in a 400 ml beaker. Stir until the mixture is dissolved and continue stirring for an extra 30 min after dissolution (maintain the temperature above 60° during the stirring process). Discontinue stirring and allow the mixture to cool at room temperature for at least 2 h.

A firm, viscoelastic gel forms after the temperature drops below 40°, but no such gel forms in a 1% control solution of cassia gum or xanthan gum alone prepared in a similar manner.

Viscosity

Weigh 5 g of the sample in a plastic dish and 495 g of distilled water at 20° in a 1000 ml beaker. Add a magnetic bar and place the beaker on the agitation plate. Adjust the speed of agitation to 750 rpm. Introduce quickly the 5 g of sample in the water and cover the beaker with a watch glass. Keep the temperature at 90° for 15 min. Cool the solution at 25° (the cooling must be ±1.5°) in a water bath and measure the viscosity after 2 h at 25° using a RVT Brookfield Spindle 1, speed 20 rpm. Repeat the procedure with a sample of 5 g of carob (locust) bean gum.

(Note: The viscosity of the cassia gum (150 - 500 mPas) must be less than 50% that of carob bean gum (2000 - 3500 mPas))

PURITY TESTS

Crude fat

Apparatus

The apparatus consisting of a Butt-type extractor, as shown below, having a standard-taper 34/45 female joint at the upper end, to which is attached a Friedrichs- or Hopkins-type condenser, and a 24/40 male joint at the lower end, to which is attached a 125-ml Erlenmeyer flask.

Procedure

Transfer about 10 g of the sample, previously ground to 20-mesh or finer and accurately weighed, to a 15-cm filter paper, roll the paper tightly around the sample, and place it in a suitable extraction shell. Plug the top of the shell with cotton previously extracted with hexane, and place the shell in the extractor. Attach the extractor to a dry 125-ml Erlenmeyer flask containing about 50 ml of hexane and to a water-cooled condenser, apply heat to the flask to produce 150 to 200 drops of condensed solvent per min, and extract for 16 h. Disconnect the flask, and filter the extract to remove any insoluble residue. Rinse the flask and filter with a few ml of hexane, combine the washings and filtrate in a tared flask, and evaporate on a steam bath until no odor of solvent remains. Dry in a vacuum for 1 h at 100°, cool in a desiccator, and weigh.