NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

GB 1886.382-2025

Replacing GB 26405-2011

National food safety standard - Food additive - Lutein

食品安全国家标准 食品添加剂 叶黄素

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1 Scope and chemical identity

Clause 1 applies the standard to the food additive lutein made from the oleoresin of marigold, Tagetes erecta L., by saponification, refining and related processes.

Clause 2 gives the molecular formula as C40H56O2, refers to the structural formula, and gives the relative molecular mass as 568.85, computed from the 2022 international relative atomic masses.

3 Technical requirements

3.1 The sensory requirements of Table 1 are colour from orange yellow to orange red, a powder form, and the odour proper to the product with no off odour. They are judged by placing a suitable amount of the sample in a clean, dry white porcelain dish, observing the colour and the physical state in daylight and smelling the sample.

3.2 Table 2 fixes the physicochemical requirements together with the test method for each: total carotenoids at least 80.0 percent by mass and lutein at least 70.0 percent by mass, by A.3 and A.4 respectively; zeaxanthin at most 9.0 percent by mass, by A.4; loss on drying at most 1.0 percent by mass, by the reduced pressure drying method of GB 5009.3; ash at most 1.0 percent by mass, by GB 5009.4; n-hexane at most 50 mg/kg, by A.5; lead at most 3.0 mg/kg, by GB 5009.12 or GB 5009.75; and total arsenic, expressed as As, at most 3.0

mg/kg, by GB 5009.11 or GB 5009.76.

A note to Table 2 allows a commercial lutein product to be built on lutein complying with this standard, to which may be added the edible vegetable oil, dextrin, sugar, starch, starch sugar and other food raw materials the process calls for, together with antioxidants, emulsifiers, thickeners, stabilisers, anticaking agents, coating agents and other additives meeting the quality specifications for food additives. Such a product may be a powder, a granule, a suspension, a slurry or a paste, and its total carotenoid and lutein contents shall answer to what is claimed for it.

A Test methods (Annex A)

A.1 The reagents and water used are analytical grade reagents and grade one water as specified in GB/T 6682 wherever no other requirement is noted, and a solution whose solvent is not named is aqueous. During the determination the lutein samples and the related reference substances are stored strictly under the conditions marked on the label so that they do not degrade.

A.2 The identification tests are that the product is insoluble in water, slightly soluble in n-hexane and soluble in ethanol and in chloroform; that in the determination of total carotenoids the test solution shows its maximum absorbance near a wavelength of 446 nm; and that in the determination of lutein the retention time of lutein in the test solution matches the retention time of lutein in the standard solution.

A.3 For total carotenoids the reagents are n-hexane, acetone, toluene and absolute ethanol, and a mixed solvent of the four in the volume ratio 10 to 7 to 7 to 6; the apparatus is an analytical balance reading to 0.1 mg and an ultraviolet and visible spectrophotometer. Between 0.03 g and 0.05 g of sample, weighed to 0.0001 g, is dissolved in the mixed solvent and made up to 100 mL; 1 mL of that solution is transferred to a 100 mL flask and made up with absolute ethanol. The absorbance of the test solution is read in a 1 cm cell against absolute ethanol at the absorption maximum at 446 nm +/- 1 nm, the concentration being adjusted so that the absorbance falls between 0.3 and 0.7. The content follows Formula (A.1) from the measured absorbance, the mass of the sample in grams, the made-up volume in millilitres and the absorption coefficient 2550 of a 1 percent solution in absolute ethanol at 446 nm. The mean of parallel determinations is the result, two independent determinations under repeatability conditions differing by no more than 1.5 percent of their mean, and the result is given to one decimal place.

A.4 Lutein and zeaxanthin are determined by liquid chromatography with an ultraviolet detector at 446 nm, using chromatographic grade n-hexane and ethyl acetate and lutein and zeaxanthin reference substances of purity at least 80 percent or equivalent, stored as their labels require. The reference conditions are a silica column of 4.6 mm by 250 mm with a particle size of 3 μm or an equivalent column; a mobile phase of n-hexane and ethyl acetate in the volume ratio 70 to 30, mixed, filtered through a 0.45 μm membrane and

degassed by ultrasound; a column temperature of 30 °C; a flow rate of 1.5 mL/min; and an injection volume of 10 µL. For the standard solution 0.01 g of each reference substance, weighed to 0.0001 g, is dissolved in the mobile phase and made up to 50 mL, freshly prepared each time; for the test solution 0.02 g to 0.05 g of sample, weighed to 0.0001 g, is dissolved in the mobile phase and made up to 100 mL.

A.4.3 and A.4.5 The standard solution is measured first and the chromatogram recorded, the resolution between lutein and zeaxanthin, referred to the lutein peak, being at least 1.5; the reference chromatogram is Figure B.1. The test solution is then measured under the same conditions, the peaks being identified by the retention times of the reference substances and the chromatogram recorded, the sample chromatogram being shown as Figure B.2. The test is run twice and the mean percentages of the lutein and zeaxanthin peak areas in the total peak area are taken. The lutein content follows Formula (A.2) and the zeaxanthin content Formula (A.3), each as the product of the total carotenoid mass fraction found in A.3 and the corresponding mean area percentage. Two independent determinations under repeatability conditions shall differ by no more than 10 percent of their mean and the result is given to one decimal place.

A.5 n-Hexane is determined by headspace gas chromatography with a flame ionisation detector, using chromatographic grade n-hexane and N,N-dimethylformamide. The reference conditions are a capillary column of 0.53 mm internal diameter and 30 m length with a stationary phase of 6 percent cyanopropylphenyl and 94 percent dimethylsiloxane and a film thickness of 3.0 µm, or an equivalent column; nitrogen carrier gas at 3.0 mL/min; an inlet temperature of 220 °C; a detector temperature of 235 °C; an injection volume of one 1 mL sample loop; a split ratio of 3 to 1; and the three-stage temperature programme of Table A.1. The headspace conditions are an equilibration temperature of 80 °C, an equilibration time of 40.0 min, a loop temperature of 85 °C, a loop volume of 1 mL and a transfer line temperature of 100 °C. Table A.1 sets a heating rate in degrees Celsius per minute, a temperature in degrees Celsius and a hold time in minutes for each of three stages; in the extracted text the figures of that table run together and could not be assigned to their columns with certainty, so they are not reproduced here.

A.5.5 and A.5.6 For the reference solution 0.1 g of n-hexane, weighed to 0.1 mg, is placed in a 100 mL flask already holding 30 mL of dimethylformamide and made up to the mark with the same solvent; 0.2 mL of that solution is made up to 50 mL with dimethylformamide, giving a reference solution of 0.004 mg of n-hexane per millilitre. For the test solution 0.6 g of sample, weighed to 0.1 mg, is dissolved in 6.0 mL of dimethylformamide in a 20 mL headspace vial, which is then shaken and sealed. A 6.0 mL portion of the reference solution is placed in a 20 mL headspace vial and measured alongside the test solution, the reference chromatogram being Figure C.1. The residue follows Formula (A.4) from the peak areas of n-hexane in the reference and in the test solution, the mass concentration of the reference solution in milligrams per millilitre, the mass of the sample in milligrams, the made-up volume in millilitres and a conversion factor of ten to the sixth. Two independent

determinations under repeatability conditions shall differ by no more than 10 percent of their mean, the result is given to one decimal place, and the method has a detection limit of 2 mg/kg and a quantification limit of 10 mg/kg.