January 2025

BUREAU OF INDIAN STANDARDS

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भारतीय मानक मसौदा

डोडेसाइल गैलेट, खाद्य ग्रेड— विशिष्टि

(आइ एस 6794 का दूसरा पुनरीक्षण)

Draft Indian Standard

DODECYL GALLATE, FOOD GRADE — SPECIFICATION

(Second Revision of IS 6794)

ICS No. 67.220.20

Food Additives Sectional Committee, FAD 08 Last Date of Comments: 15 February 2025

FOREWORD

(Formal clauses would be added later)

Food additives are added to improve the appearance, flavour, texture or storage properties, etc of the processed foods. As certain impurities in these substances have been found to be harmful, it is necessary to have a strict quality control of these food additives. A series of standards have, therefore, been prepared to cover purity and identification of these substances. These standards would help in checking purity, which is required to be checked at the stage of manufacture, for it is extremely difficult to detect the impurity once these substances have been added to the processed foods. Besides, these standards are intended to guide the indigenous manufacturers in making their product conform to specifications that are accepted by scientists, health authorities and national/ international bodies.

Use of dodecyl gallate, food grade is permitted under the *Food Safety and Standards (Food Products Standards and Food Additives) Regulations*, 2011 as an anti-oxidant in edible oils and fats except *GHEE* and butter. Lauryl gallate is synonym of dodecyl gallate. Its chemical names are dodecyl gallate and n-dodecyl (or lauryl) ester of 3, 4,5- trihydroxybenzoic acid.

The empirical formula, structural formula and molecular mass of dodecyl gallate is as follows:

Empirical Formula	Structural Formula	Molecular Mass	
C ₁₉ H ₃₀ O ₅	HO O(CH ₂) ₁₁ CH ₃	338.45	

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This standard was first published in 1972. In the preparation of this standard, considerable assistance was derived from compendium of Food Additive Specifications, Volume 2, Joint FAO/WHO Expert Committee on Food Additives (JECFA), 1992 and this standard was harmonized with the standard of FAO/WHO.

It was first revised in 1997 to incorporate the requirement of solubility to keep it in line with Food Chemical Codex (FCC); to incorporate the limits for heavy metals, chlorinated organic compounds, free acid and absorption; and to provide for marking instructions for storage and expiry date.

In this revision, two amendments issued to the previous version of the standard has been incorporated and the following major changes have been made:

- a) The requirement for heavy metals has been removed as the limit of lead (contaminant in food colours) is already covered through the standard.
- b) The marking requirements have been updated.

For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test or analysis, shall be rounded off in accordance with IS 2: 2022. 'Rules for rounding off numerical values (second revision)' This number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

1 SCOPE

This standard prescribes the requirements and methods of sampling and test for dodecyl gallate, food grade.

2 REFERENCES

The following Indian Standards contain provisions which through reference in this text, constitute provision of this standard. At the time of publication, the editions indicated were valid. All standards are subject to revision and parties to agreements based on this standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below:

IS No.	Title
IS 1070 : 2023	Reagent grade water — Specification (fourth revision)
IS 1699 : 2024	Food colours - Methods of sampling and test (third revision)
IS 6798 : 1997	Octyl gallate, food grade — Specification (first revision)

3 DESCRIPTION

Dodecyl gallate is a creamy white waxy solid, which may have a slightly bitter taste. The material is insoluble in water, freely soluble in ethanol, ether and fat

NOTE – The solubility is intended only as information regarding approximate solubility and is not to be considered as a quality requirement and is of minor significance as a means of identification or determination of purity.

4 REQUIREMENTS

4.1 Identification Tests

- **4.1.1** Melting range shall be 95 °C to 98 °C after drying for 6 h at 90 °C.
- **4.1.2** Add 1 ml of ammonium hydroxide to 5 ml of one percent ethanolic solution of dodecyl gallate. A pink to red colour shall appear.
- **4.1.3** TLC Separation of Gallate Esters
- **4.1.3.1** Use a thin-layer plate prepared with silica gel G. Prepare a sample solution by dissolving 10 mg of sample in 10 ml ethanol. Prepare control solution A by dissolving 10 mg of dodecyl gallate in 10 ml ethanol, and control solution B by dissolving 10 mg of dodecyl gallate and 10 mg of octyl gallate in 10 ml ethanol.
- **4.1.3.2** Place 5 μ l of each solution on the plate. Develop the chromatogram to about 15 cm from the starting point using a developing solvent containing 20 volumes of glacial acetic acid, 40 volumes of petroleum ether and 40 volumes of toluene. Dry the plate in air. Spray the plate with an indicator solution, containing 20 percent (w/v) phosphomolybdic acid in ethanol until a yellow colouration persists.
- **4.1.3.3** Examine in daylight. After a few minutes there is a progressive change to blue colouration. After 5 to 10 min, expose the plate to ammonia vapours until the background is white.

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- **4.1.3.4** Examine in daylight. The principal spot of the sample solution corresponds with that for dodecyl gallate in the control solutions. Suitable resolution of dodecyl and octyl gallate spots is determined from control solution *B*.
- **4.2** The material shall also comply with the requirements given in Table 1.

Table 1 Requirements of Dodecyl Gallate, Food Grade (Clause 4.2)

Sl.	Characteristic	Requirements	Method of Test,
No.			Ref to
(1)	(2)	(3)	(4)
i)	Purity (as C ₁₉ H ₃₀ O ₅), percent by mass, <i>Min</i>	98.5	Annex A
ii)	Moisture, percent by mass, <i>Max</i>	0.5	IS 6798
iii)	Sulphated ash, percent by mass, <i>Max</i>	0.05	IS 6798
iv)	Chlorinated organic compounds (as Cl),	100	IS 6798
	mg/kg, Max		
v)	Free acid (as gallic acid), percent by mass,	0.5	IS 6798
	Max		
vi)	Specific absorption at 275 nm, <i>Min</i>	300	IS 6798
	Max	325	
vii)	Arsenic (as As), mg/kg, Max	3	IS 1699
viii)	Lead (as Pb), mg/kg, Max	2	IS 1699

5 PACKING

The material shall be securely packed in well-filled containers with minimum access to light and moisture. The containers shall be such as to preclude contamination of the contents with metals or other impurities.

6 STORAGE

The material shall be stored in a cool and dry place so as to avoid excessive exposure to heat.

7 MARKING

- **7.1** The containers shall be securely closed and shall bear legibly and indelibly the following information:
 - a) Name of the material including the words 'Food Grade';
 - b) Source of manufacture;
 - c) Net content when packed;
 - d) Batch or code number;
 - e) Date of manufacture; and
 - f) Expiry/ Best before date;
 - g) Any other requirements as specified under the *Legal Metrology* (*Packaged Commodities*) Rules, 2011 and Food Safety and Standards (*Labelling and Display*) Regulations, 2020.

7.2 BIS Certification Marking

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The product(s) conforming to the requirements of this standard may be certified as per the conformity assessment schemes under the provisions of the *Bureau of Indian Standards Act*, 2016 and the Rules and Regulations framed thereunder, and the products may be marked with the Standard Mark.

8 SAMPLING

Representative samples of the materials shall be drawn according to the method prescribed in IS 1699.

9 TESTS

Tests shall be carried out by the methods specified in co1 (4) of Table 1.

10 QUALITY OF REAGENTS

Unless specified otherwise, pure chemicals and distilled water (*see* IS 1070) shall be employed in tests.

NOTE – 'Pure chemicals' shall mean chemicals that do not contain impurities which affect the results of analysis.

ANNEX A

[*Table* 1, *Sl No.* (i)]

PURITY ANALYSIS OF DODECYL GALLATE

A-1 GENERAL

Two methods, namely, spectrophotometric and bismuth nitrate, have been specified. Either could be used depending upon the facilities available.

A-2 SPECTROSCOPIC METHOD

A-2.1 Procedure

Dry a suitable quantity of sample in an oven at 90 °C for 6 h, cool it in a desiccator. Prepare a solution of a dried sample in 80 percent ethanol containing 5 μ g/ml and determine the extinction at 218 nm and 276 nm.

$$1_{1\,cm}^{\%}$$
 (218 nm) 740-760, $1_{1\,cm}^{\%}$ (276 nm) 370

A-2.2 Calculation

Dodecyl gallate, percent by mass =
$$\frac{1_{1cm}^{\%} \ of \ sample}{1_{1cm}^{\%} \ of \ pure \ standard \ reference} \times 100$$

A-3 BISMUTH NITRATE PRECIPITATION

A-3.1 Reagents

A-3.1.1 *Acetone*

A-3.1.2 Bismuth Nitrate

Dissolve 5 g of bismuth nitrate in 25 ml of water and 25 ml of glacial acetic acid and dilute to 250 ml.

A-3.1.3 *Acetic Acid* – 0.1 N.

A-3.1.4 Nitric Acid – 0.05 N

A-3.2 Procedure

Dry a suitable quantity of sample in an oven at 90 °C for 6 h, cool it in a desiccator. Weigh 100 mg of dodecyl gallate into a 250 ml beaker, add 15 ml of acetone, 10 ml of water and bring to the boiling point. Add 10 ml of bismuth nitrate and bring again to the boiling point. Cool to room temperature. Filter through a tared sintered glass crucible. Wash twice with acetic acid and twice with water. Wash six times with nitric acid at 80 °C pressing the precipitate down well between each wash. Wash twice with water. Dry at 110 °C to constant mass.

A-3.3 Calculation

Dodecyl gallate, percent by mass =
$$\frac{Mass\ of\ precipiate \times 0.6017}{Mass\ of\ sample} \times 100$$