

1978 No. 105

**FOOD AND DRUGS**  
**COMPOSITION AND LABELLING**

**The Antioxidants in Food Regulations 1978**

<i>Made - - - -</i>	<i>24th January 1978</i>
<i>Laid before Parliament</i>	<i>7th February 1978</i>
<i>Coming into Operation</i>	<i>28th February 1978</i>

The Minister of Agriculture, Fisheries and Food and the Secretary of State for Social Services, acting jointly, in exercise of the powers conferred on them by sections 4, 7 and 123 of the Food and Drugs Act 1955(a) as amended by section 4(1) of, and paragraph 3(1) of Schedule 4 to, the European Communities Act 1972(b) and as read with the Secretary of State for Social Services Order 1968(c), and of all other powers enabling them in that behalf, hereby make the following regulations, after consultation with such organisations as appear to them to be representative of interests substantially affected by the regulations and after reference to the Food Hygiene Advisory Council under section 82 of the Food and Drugs Act 1955 (in so far as the regulations are made in exercise of the powers conferred by the said section 7):—

*Citation and commencement*

1. These regulations may be cited as the Antioxidants in Food Regulations 1978, and shall come into operation on 28th February 1978.

*Interpretation.*

2.—(1) In these regulations, unless the context otherwise requires—

“the Act” means the Food and Drugs Act 1955;

“anhydrous edible oils and fats” means oils and fats, intended for sale for human consumption, which have been derived from any animal, bird, fish or plant and from which all or almost all the water has been removed, and includes block suet and the fat content of shredded suet but does not include dairy products, essential oils or isolates from the concentrates of essential oils;

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(a) 1955 c. 16. 4 & 5 Eliz. 2

(b) 1972 c. 68.

(c) S.I. 1968/1699.

“antioxidant” means any substance which is capable of delaying, retarding or preventing the development in food of rancidity or other flavour deterioration due to oxidation but does not include—

- (a) any permitted artificial sweetener,
- (b) any permitted bleaching agent,
- (c) any permitted colouring matter,
- (d) any permitted emulsifier,
- (e) any permitted improving agent,
- (f) any permitted miscellaneous additive other than a permitted diluent combined with such an antioxidant,
- (g) any permitted preservative,
- (h) any permitted stabiliser,
- (j) any permitted solvent other than a permitted diluent combined with such an antioxidant,
- (k) esters of L-ascorbic acid with straight-chain C<sub>14</sub> and C<sub>18</sub> fatty acids used or for use to dilute or dissolve colouring matter in accordance with the Colouring Matter in Food Regulations 1973(a), as amended(b);

“appropriate designation” means, as respects any permitted antioxidant or permitted diluent, a name or description or a name and description sufficiently specific, in each case, to indicate to an intending purchaser the true nature of the permitted antioxidant or permitted diluent to which it is applied;

“block suet” means rendered beef suet free from fibrous tissue;

“butter fat” means the product obtained by removing all or almost all the water and milk solids other than fat from milk, cream or butter and includes anhydrous butter fat, butter oil, anhydrous butter oil and anhydrous milk fat;

“container” includes any form of packaging of food for sale as a single item, whether by way of wholly or partly enclosing the food or by way of attaching the food to some other article, and in particular includes a wrapper or confining band;

“dairy product” means any butter, butter fat, cream, dried cream, milk, condensed milk, evaporated milk, dried milk, cheese, dried cheese, dried whey or dried whey derivatives;

“diluent” means any substance used to dilute or dissolve antioxidant intended for use in food for human consumption;

“food” means food intended for sale for human consumption and includes drink, chewing gum and other products of a like nature and use, and articles and substances used as ingredients in the preparation of food or drink or of such products, but does not include—

- (a) water, live animals or birds,
- (b) fodder or feeding stuffs for animals, birds or fish, or
- (c) articles or substances used only as drugs;

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(a) S.I. 1973/1340.

(b) The relevant amending instruments are S.I. 1975/1488, 1976/2086.

“food and drugs authority” has the meaning assigned to it by section 198 of the Local Government Act 1972(a);

“human consumption” includes use in the preparation of food for human consumption;

“permitted antioxidant” means any antioxidant specified in Part I of Schedule 1 which satisfies the specific purity criteria relating to that antioxidant specified or referred to in Part II of that Schedule and, so far as is not otherwise provided by any such specific purity criteria, satisfies the general purity criteria specified in Part III of that Schedule, or any mixture of two or more such antioxidants and (except in the definition of appropriate designation in this regulation and Schedules 1 and 4) shall be construed as including any permitted diluent combined with such antioxidant or mixture of such antioxidants;

“permitted artificial sweetener” means any artificial sweetener in so far as its use is permitted by the Artificial Sweeteners in Food Regulations 1969(b);

“permitted bleaching agent” means any bleaching agent in so far as its use is permitted by the Bread and Flour Regulations 1963(c), as amended(d);

“permitted colouring matter” means any colouring matter in so far as its use is permitted by the Colouring Matter in Food Regulations 1973, as amended;

“permitted diluent” means any diluent described in Part I of Schedule 2 which satisfies the general purity criteria specified in Part II of that Schedule, or any of the permitted solvents ethyl alcohol (ethanol), propylene glycol and glycerol, or the permitted miscellaneous additive sorbitol and includes any combination of two or more such substances;

“permitted emulsifier” means any emulsifier in so far as its use is permitted by the Emulsifiers and Stabilisers in Food Regulations 1975(e), as amended(f);

“permitted improving agent” means any improving agent in so far as its use is permitted by the Bread and Flour Regulations 1963, as amended;

“permitted miscellaneous additive” means any acid, anti-caking agent, anti-foaming agent, base, buffer, firming agent, glazing agent, humectant, liquid frezant, packaging gas, propellant, release agent or sequestrant in so far as its use is, in each case, permitted by the Miscellaneous Additives in Food Regulations 1974(g), as amended(h);

“permitted preservative” means any preservative in so far as its use is permitted by the Preservatives in Food Regulations 1975(i), as amended(j);

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(a) 1972 c. 70.

(b) S.I. 1969/1817.

(c) S.I. 1963/1435.

(d) The relevant amending instrument is S.I. 1972/1391.

(e) S.I. 1975/1486.

(f) The relevant amending instrument is S.I. 1976/1886.

(g) S.I. 1974/1121.

(h) The relevant amending instrument is S.I. 1975/1485.

(i) S.I. 1975/1487.

(j) The relevant amending instruments are S.I. 1976/1887, 1977/645.

“permitted solvent” means any solvent in so far as its use is permitted by the Solvents in Food Regulations 1967(a), as amended(b);

“permitted stabiliser” means any stabiliser in so far as its use is permitted by the Emulsifiers and Stabilisers in Food Regulations 1975, as amended;

“sell” includes offer or expose for sale or have in possession for sale, and “sale” and “sold” shall be construed accordingly;

“shredded suet” means the product consisting of rendered beef suet, free from fibrous tissue, which has been shredded, flaked or otherwise comminuted, with or without farinaceous material;

“specified food” means any food of a description specified in column 1 of Part I, Part II, Part III or Part IV of Schedule 3:

AND other expressions have the same meaning as in the Act.

(2) The Interpretation Act 1889(c) shall apply to the interpretation of these regulations as it applies to the interpretation of an Act of Parliament, and as if these regulations and the regulations hereby revoked were Acts of Parliament.

(3) Unless a contrary intention is expressed, all proportions mentioned in these regulations are proportions calculated by weight of the product as sold.

(4) Any reference in these regulations to a label borne on a container shall be construed as including a reference to any legible marking on the container however effected.

(5) For the purposes of these regulations, the supply of food, otherwise than by sale, at, in or from any place where food is supplied in the course of a business shall be deemed to be a sale of that food.

(6) Any reference in these regulations to any other regulations shall be construed as a reference to such regulations as amended by any subsequent regulations.

(7) Any reference in these regulations to a numbered regulation or schedule shall be construed as a reference to the regulation or schedule bearing that number in these regulations.

### *Exemptions*

3. The provisions of these regulations shall not apply to food having any antioxidant in it or on it, to any antioxidant or to any diluent combined with any antioxidant or antioxidants which, in each case, is intended at the time of sale, consignment, delivery or importation, as the case may be, for exportation to any place outside the United Kingdom.

### *Sale, etc. of food containing antioxidants*

4.—(1) Save as hereinafter provided and subject to paragraph (2) of this regulation, no food sold, consigned or delivered, or imported into England

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(a) S.I. 1967/1582.

(b) S.I. 1967/1939.

(c) 1889 c. 63.

and Wales, shall have in it or on it any added antioxidant other than a permitted antioxidant:

Provided that apples and pears may have in them or on them diphenylamine in any proportion not exceeding 10 milligrammes per kilogramme, which is present solely by reason of the use of that substance as a scald inhibitor.

(2) Save as hereinafter provided, no food sold, consigned or delivered, or imported into England and Wales, shall have in it or on it any added permitted antioxidant specified in column 2 of Part I, Part II, Part III or Part IV of Schedule 3:

Provided that—

- (a) any specified food described in column 1 of any Part of Schedule 3 may have in it or on it permitted antioxidant of a description specified in relation thereto in column 2 of such Part and in the proportion so specified in column 3 thereof;
- (b) any food, other than a dairy product, containing as an ingredient any specified food described in column 1 of Part I of Schedule 3 may contain permitted antioxidant of a description specified in column 2 of that Part, in an amount not exceeding that appropriate to the quantity of that specified food in accordance with the descriptions and proportions specified in columns 2 and 3 respectively of that Part;
- (c) any food, other than a dairy product, containing milk fat by reason of the use as an ingredient in the preparation of that food of any dairy product, other than a dairy product described in column 1 of Part I of Schedule 3, may contain permitted antioxidant of a description specified in column 2 of Part I of Schedule 3, in an amount not exceeding that appropriate to the quantity of that milk fat in accordance with the descriptions and proportions specified in columns 2 and 3 respectively of Part I of Schedule 3;
- (d) any food containing as an ingredient any specified food described in column 1 of Part II or Part III of Schedule 3 may contain permitted antioxidant of a description specified in column 2 of such Part for that specified food, in an amount not exceeding that appropriate to the quantity of that specified food in accordance with the descriptions and proportions specified in columns 2 and 3 respectively of such Part.

(3) No person shall sell, consign or deliver, or import into England and Wales, any food which does not comply with this regulation.

*Sale, advertisement and labelling of antioxidants*

5.—(1) No person shall sell, consign or deliver, or import into England and Wales, or advertise for sale any antioxidant (including any antioxidant with which any other substance has been mixed) for use as an ingredient in the preparation of food unless such antioxidant is a permitted antioxidant.

(2) No person shall sell, consign or deliver any permitted antioxidant (including any permitted antioxidant with which any other substance has been mixed) for use as an ingredient in the preparation of food except in a container bearing a label in accordance with the requirements of Schedule 4.

*Food for babies and young children*

6.—(1) Subject to paragraph (2) of this regulation, no person shall—

- (a) give with any food sold by him any label, whether attached to or borne on the container or not, or display with any food offered or exposed by him for sale any ticket or notice, being a label, ticket or notice which bears any words, device or description calculated to indicate either directly or indirectly that the food is intended for babies or young children, or
- (b) publish, or be a party to the publication of, any advertisement for any food, being an advertisement which includes any words, device or description as aforesaid, or
- (c) use on, or in connection with, the sale of any food any such words, device or description as aforesaid,

if the food has in it or on it any butylated hydroxyanisole, butylated hydroxytoluene, propyl gallate, octyl gallate, dodecyl gallate or ethoxyquin.

(2) This regulation shall not apply to—

- (a) any specified food described in column 1 of item (b) of Part III of Schedule 3 which has in it or on it permitted antioxidant of a description specified in relation thereto in column 2 of that Part and in the proportion so specified in column 3 thereof;
- (b) any food which has in it or on it permitted antioxidant of the description specified in column 2 of item (b) of Part III of Schedule 3 introduced in the preparation of that food by the use of a specified food described in column 1 thereof if that permitted antioxidant is present in the food in no greater proportion in relation to the quantity of the specified food used than the proportion specified in column 3 of that item.

*Condemnation of food*

7. Where any food is certified by a public analyst as being food which it is an offence against regulation 4 to sell, consign or deliver, or import into England and Wales, that food may be treated for the purposes of section 9 of the Act (under which food may be seized and destroyed on the order of a justice of the peace) as being unfit for human consumption.

*Penalties and enforcement*

8.—(1) If any person contravenes or fails to comply with any of the foregoing provisions of these regulations he shall be guilty of an offence and shall be liable to a fine not exceeding one hundred pounds or to imprisonment for a term not exceeding three months, or to both, and, in the case of a continuing offence, to a further fine not exceeding five pounds for each day during which the offence continues after conviction.

(2) Every food and drugs authority shall enforce and execute such provisions in its area:

Provided that every port health authority shall enforce and execute in its district the provisions of regulations 4 and 5 in so far as they relate to importation.

(3) The requirements of section 109(3) of the Act (which requires notice to be given to the Minister of Agriculture, Fisheries and Food of intention to institute proceedings for an offence against any provisions of these regulations relating to the labelling, advertising or description of food) shall not apply as respects any proceedings instituted by a council for an offence against any such provisions of these regulations.

#### *Defences*

9.—(1) In any proceedings for an offence against these regulations in relation to the publication of an advertisement, it shall be a defence for the defendant to prove that, being a person whose business it is to publish or arrange for the publication of advertisements, he received the advertisement for publication in the ordinary course of business.

(2) In any proceedings against the manufacturer or importer of any anti-oxidant for use as an ingredient in the preparation of food, or of any food having added antioxidant in it or on it, for an offence against these regulations in relation to the publication of an advertisement, it shall rest on the defendant to prove that he did not publish, and was not a party to the publication of, the advertisement.

#### *Applications of various sections of the Act*

10.—(1) Sections 108(3) and (4) (which relate to prosecutions), 110(1), (2) and (3) (which relate to evidence of analysis), 112 (which relates to the power of a court to require analysis by the Government Chemist), 113 (which relates to a contravention due to some person other than the person charged), 115(2) (which relates to the conditions under which a warranty may be pleaded as a defence) and 116 (which relates to offences in relation to warranties and certificates of analysis) of the Act shall apply for the purposes of the regulations as if references therein to proceedings, or a prosecution, under or taken or brought under the Act included references to proceedings, or a prosecution as the case may be, taken or brought for an offence under these regulations and as if the reference in the said section 112 to subsection (4) of section 108 included a reference to that subsection as applied by these regulations.

(2) Paragraph (b) of the proviso to section 108(1) of the Act shall apply for the purpose of these regulations as if the reference therein to section 116 of the Act included a reference to that section as applied by these regulations.

#### *Revocation*

11. The Antioxidant in Food Regulations 1974(a), as amended by regulation 14 of the Emulsifiers and Stabilisers in Food Regulations 1975(b), are hereby revoked.

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(a) S.I. 1974/1120.

(b) S.I. 1975/1486.

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In Witness whereof the Official Seal of the Minister of Agriculture, Fisheries and Food is hereunto affixed on 21st January 1978.

(L.S.)

*John Silkin,*  
Minister of Agriculture,  
Fisheries and Food.

24th January 1978.

*David Ennals,*  
Secretary of State for  
Social Services.



Regulation 2(1)

## SCHEDULE 1

## PART I

## PERMITTED ANTIOXIDANTS

Column 1	Column 2
Name of Antioxidant	Serial Number
L-Ascorbic acid	E 300
Sodium L-ascorbate	E 301
Calcium L-ascorbate	E 302
6-O-Palmitoyl-L-ascorbic acid	E 304
Extracts of natural origin rich in tocopherols	E 306
Synthetic <i>alpha</i> -tocopherol	E 307
Synthetic <i>gamma</i> -tocopherol	E 308
Synthetic <i>delta</i> -tocopherol	E 309
Propyl gallate	—
Octyl gallate	E 311
Dodecyl gallate	E 312
Butylated hydroxyanisole (BHA)	E 320
Butylated hydroxytoluene (BHT)	E 321
Ethoxyquin	—

## PART II

## SPECIFIC PURITY CRITERIA FOR PERMITTED ANTIOXIDANTS

*E 300 L-Ascorbic acid*

Description ... ..	The product shall be (+)-L-ascorbic acid and shall be a white or slightly yellowish crystalline powder.
Content ... ..	Not less than 99 per centum of $C_6H_8O_6$ (after drying for 24 hours in a desiccator containing sulphuric acid or phosphorus pentoxide).

Melting range	...	...	...	189°C. to 193°C. with slight decomposition.
Specific rotation, $[\alpha]_{\text{D}}^{20^{\circ}\text{C.}}$	...	...	...	Not less than +22° and not more than +23° (using a 2 per centum weight/volume aqueous solution).
Volatile matter	...	...	...	Not more than 0.4 per centum (determined by drying for 24 hours in a desiccator containing sulphuric acid or phosphorus pentoxide).
Sulphated ash	...	...	...	Not more than 0.1 per centum (on a volatile matter-free basis).
pH (2 per centum weight/volume aqueous solution)	...	...	...	Not less than 2.4 and not more than 2.8.

*E 301 Sodium L-ascorbate*

Description	...	...	...	The product shall be a derivative of (+)-L-ascorbic acid and shall be a white or slightly yellowish crystalline powder.
Content	...	...	...	Not less than 99 per centum of $\text{C}_6\text{H}_7\text{O}_6\text{Na}$ (after drying for 24 hours in a desiccator containing sulphuric acid or phosphorus pentoxide).
Specific rotation, $[\alpha]_{\text{D}}^{20^{\circ}\text{C.}}$	...	...	...	Not less than +103° and not more than +106° (using a 5 per centum weight/volume aqueous solution).
Volatile matter	...	...	...	Not more than 0.3 per centum (determined by drying for 24 hours in a desiccator containing sulphuric acid or phosphorus pentoxide).
pH (10 per centum weight/volume aqueous solution)	...	...	...	Not less than 6.8 and not more than 8.0.

*E 302 Calcium L-ascorbate*

Description	...	...	...	The product shall be a derivative of (+)-L-ascorbic acid and shall be a white or very slightly greyish crystalline powder.
Content	...	...	...	Not less than 99 per centum of $(\text{C}_6\text{H}_7\text{O}_6)_2 \text{Ca} \cdot 2\text{H}_2\text{O}$ (after drying for 24 hours in a desiccator containing sulphuric acid or phosphorus pentoxide).
Specific rotation, $[\alpha]_{\text{D}}^{20^{\circ}\text{C.}}$	...	...	...	Not less than +95° and not more than +97° (using a 5 per centum weight/volume aqueous solution).

Volatile matter ... .. Not more than 0.3 per centum (determined by drying for 24 hours in a desiccator containing sulphuric acid or phosphorus pentoxide).

pH (10 per centum weight/volume aqueous solution) ... .. Not less than 6.0 and not more than 7.0.

*E 304 6-O-Palmitoyl-L-ascorbic acid*

Synonym ... .. Ascorbyl palmitate.

Description ... .. The product shall be the 6-O-palmitoyl derivative of (+)-L-ascorbic acid and shall be an impalpable white or yellowish-white powder or yellowish-white crystals.

Content ... .. Not less than 98 per centum of  $C_{22}H_{38}O_7$  (on a volatile matter-free basis).

Melting range ... .. 111°C. to 113°C. (oozes without melting distinctly).

Specific rotation,  $[\alpha]_D^{20^\circ C.}$  ... .. Not less than +21° and not more than +24° (using a 5 per centum weight/volume solution in methanol).

Volatile matter ... .. Not more than 1 per centum (determined by drying for 24 hours in a desiccator containing sulphuric acid or phosphorus pentoxide).

Sulphated ash ... .. Not more than 0.2 per centum (on a volatile matter-free basis).

*E 306 Extracts of natural origin rich in tocopherols*

Appearance ... .. Clear brownish-red to red viscous oil.

Content ... .. Not less than 34 per centum of total tocopherols.

Relative density,  $d_{4^\circ C.}^{20^\circ C.}$  ... .. Not less than 0.928 and not more than 0.951.

Free fatty acids ... .. Neutralisation of a 10 g. sample shall require not more than 10 ml. of 0.1N sodium hydroxide (or potassium hydroxide) solution using phenolphthalein as indicator.

*E 307 Synthetic alpha-tocopherol*

Description ... .. The product shall be synthetic DL-alpha-tocopherol and shall be a clear yellowish viscous oil which darkens on exposure to air or light.

Content	...	...	...	...	Not less than 96 per centum of $C_{29}H_{50}O_2$ .
Refractive index, $n_D^{20^\circ C}$	...	...	...	...	Not less than 1.503 and not more than 1.507.
Relative density, $d_{4^\circ C}^{20^\circ C}$	...	...	...	...	Not less than 0.947 and not more than 0.958.
Specific absorption, $E_{1\text{ cm.}}^{1\text{ per centum}}$					Not less than 72 and not more than 76 at the absorption maximum of 292 nm. Not less than 6 and not more than 8 at the absorption minimum of 255 nm. (determined in ethanol).
Sulphated ash	...	...	...	...	Not more than 0.1 per centum.

*E 308 Synthetic gamma-tocopherol*

Appearance	...	...	...	...	Clear slightly yellowish viscous oil which darkens on exposure to air or light.
Content	...	...	...	...	Not less than 97 per centum of $C_{28}H_{48}O_2$ .
Refractive index, $n_D^{20^\circ C}$	...	...	...	...	Not less than 1.503 and not more than 1.507.
Relative density, $d_{4^\circ C}^{20^\circ C}$	...	...	...	...	Not less than 0.948 and not more than 0.959.
Specific absorption, $E_{1\text{ cm.}}^{1\text{ per centum}}$					Not less than 91 and not more than 97 at the absorption maximum of 298 nm. Not less than 5 and not more than 8 at the absorption minimum of 256 nm. (determined in ethanol).
Sulphated ash	...	...	...	...	Not more than 0.1 per centum.

*E 309 Synthetic delta-tocopherol*

Appearance	...	...	...	...	Clear slightly yellowish or orange viscous oil which darkens on exposure to light or air.
Content	...	...	...	...	Not less than 97 per centum of $C_{27}H_{46}O_2$ .
Refractive index, $n_D^{20^\circ C}$	...	...	...	...	Not less than 1.500 and not more than 1.504.
Relative density, $d_{4^\circ C}^{20^\circ C}$	...	...	...	...	Not less than 0.952 and not more than 0.962.
Specific absorption, $E_{1\text{ cm.}}^{1\text{ per centum}}$					Not less than 89 and not more than 95 at the absorption maximum of 297 to 298 nm. Not less than 3 and not more than 6 at the absorption minimum of 257 nm. (determined in ethanol).

Sulphated ash ... .. Not more than 0·1 per centum.

*Propyl gallate*

Synonym ... .. Propyl 3, 4, 5-trihydroxybenzoate.

The criteria in the monograph for propyl gallate contained in the British Pharmacopoeia 1973 at page 399.

*E 311 Octyl gallate*

Synonym ... .. Octyl 3, 4, 5-trihydroxybenzoate.

Appearance ... .. White to very slightly yellowish crystalline powder.

Content ... .. Not less than 98·5 per centum of  $C_{15}H_{22}O_5$  (after drying at 60°C. for 4 hours).

Melting range ... .. 100·0°C. to 102·5°C. (after drying at 90°C. for 6 hours).

Specific absorption,  $E_{1\text{ cm.}}^{1\text{ per centum}}$  ... .. Not less than 375 and not more than 390 at 275 nm. (determined in ethanol).

Volatile matter ... .. Not more than 0·5 per centum (determined by drying at 60°C. for 4 hours).

Sulphated ash ... .. Not more than 0·05 per centum (on a volatile matter-free basis).

Free acids ... .. Not more than 0·5 per centum (expressed as gallic acid and on a volatile matter-free basis). (9·407 mg. of gallic acid corresponds to 1 ml. of 0·05N sodium hydroxide).

*E 312 Dodecyl gallate*

Synonym ... .. Dodecyl 3, 4, 5-trihydroxybenzoate.

Appearance ... .. White to cream crystalline powder.

Content ... .. Not less than 98·5 per centum of  $C_{19}H_{30}O_5$  (after drying at 60°C. for 4 hours).

Melting range ... .. 96°C. to 98°C. (after drying at 60°C. for 4 hours).

Specific absorption,  $E_{1\text{ cm.}}^{1\text{ per centum}}$  ... .. Not less than 300 and not more than 325 at 275 nm. (determined in ethanol).

Volatile matter ... .. Not more than 0·5 per centum (determined by drying at 60°C. for 4 hours).

Sulphated ash ... .. Not more than 0·05 per centum (on a volatile matter-free basis).

Free acids ... .. Not more than 0.5 per centum (expressed as gallic acid and on a volatile matter-free basis). (9.407 mg. of gallic acid corresponds to 1 ml. of 0.05N sodium hydroxide).

*E 320 Butylated hydroxyanisole (BHA)*

Description ... .. Powder or large crystals of waxy appearance, white to slightly yellowish with a slight aromatic odour.

Content ... .. Not less than 98.5 per centum of  $C_{11}H_{16}O_2$  and not less than 85 per centum of 3-*tert*-butyl-4-hydroxyanisole (2-*tert*-butyl-4-methoxyphenol).

Specific absorption,  $E_{1\text{ cm.}}^1$  per centum ... .. Not less than 191 and not more than 210 at 290 nm.  
Not less than 326 and not more than 345 at 228 nm. (determined in ethanol).

4-Hydroxyanisole content ... .. Not more than 0.5 per centum.

Sulphated ash ... .. Not more than 0.05 per centum.

*E 321 Butylated hydroxytoluene (BHT)*

Synonym ... .. 2, 6-di-*tert*-butyl-*p*-cresol.

Appearance ... .. Crystalline product or powdery white crystals.

Content ... .. Not less than 99 per centum of  $C_{15}H_{24}O$ .

Melting range ... .. 69°C. to 70°C.

Specific absorption,  $E_{1\text{ cm.}}^1$  per centum ... .. Not less than 81 and not more than 88 at 278 nm. (determined in ethanol).

Sulphated ash ... .. Not more than 0.005 per centum.

*Ethoxyquin*

Description ... .. Pale amber oil when freshly prepared. Tendency to polymerise on exposure to light and oxygen with darkening in colour.

Content ... .. Not less than 92 per centum of the monomer 1,2-dihydro-6-ethoxy-2,2,4-trimethylquinoline ( $C_{14}H_{19}NO$ ). The remainder shall consist of the dimer and higher polymers.

Boiling point ... .. 125°C. at 1 to 2 mm. of mercury.

Refractive index,  $n_D^{25^\circ C.}$  ... .. Not less than 1.569 and not more than 1.572.

**PART III****GENERAL PURITY CRITERIA FOR PERMITTED ANTIOXIDANTS**

No antioxidant shall contain more than—

- (a) 3 milligrammes per kilogramme of arsenic;
- (b) 10 milligrammes per kilogramme of lead;
- (c) 50 milligrammes per kilogramme of copper, or 25 milligrammes per kilogramme of zinc, or 50 milligrammes per kilogramme of any combination of copper and zinc.

**Regulation 2(1),**

**SCHEDULE 2****PART I****PERMITTED DILUENTS (SEE DEFINITION IN REGULATION 2(1))**

Drinking water, demineralised water, distilled water  
Edible oils and fats

**PART II****GENERAL PURITY CRITERIA FOR PERMITTED DILUENTS  
DESCRIBED IN PART I ABOVE**

No diluent shall contain more than—

- (a) 3 milligrammes per kilogramme of arsenic;
- (b) 10 milligrammes per kilogramme of lead;
- (c) 50 milligrammes per kilogramme of copper, or 25 milligrammes per kilogramme of zinc, or 50 milligrammes per kilogramme of any combination of copper and zinc.

## SCHEDULE 3

## Regulations 4 and 6

## ANTIOXIDANTS PERMITTED ONLY IN CERTAIN FOODS

## PART I

Column 1	Column 2	Column 3
Specified Food	Permitted Antioxidant	Milligrammes per kilogramme— not exceeding
Any of the following dairy products for use as ingredients in the preparation of food intended for sale for human consumption:—  butter, butter fat, dried cream, dried cheese, dried whey, dried whey derivatives	1. Propyl gallate or Octyl gallate or Dodecyl gallate or any mixture of two, or of all, of them  2. Butylated hydroxyanisole (BHA) or Butylated hydroxytoluene (BHT) or any mixture of BHA and BHT  3. Any mixture of one or more of the permitted antioxidants mentioned in item 1 of this column and either or both of the permitted antioxidants mentioned in item 2 of this column	100 (calculated on the milk fat content)  200 (calculated on the milk fat content)  300 (of which not more than 100 shall represent item 1 and not more than 200 shall represent item 2) (calculated on the milk fat content)

## PART II

Column 1	Column 2	Column 3
Specified Food	Permitted Antioxidant	Milligrammes per kilogramme— not exceeding
(a) Anhydrous edible oils and fats and vitamin oils and concentrates other than preparations of Vitamin A or Vitamin A esters containing more than 30,000 microgrammes retinol equivalents per gramme	1. Propyl gallate or Octyl gallate or Dodecyl gallate or any mixture of two, or of all, of them  2. Butylated hydroxyanisole (BHA) or Butylated hydroxytoluene (BHT) or any mixture of BHA and BHT  3. Any mixture of one or more of the permitted antioxidants mentioned in item 1 of this column and either or both of the permitted antioxidants mentioned in item 2 of this column	100  200  300 (of which not more than 100 shall represent item 1 and not more than 200 shall represent item 2)



Column 1	Column 2	Column 3
Specified Food	Permitted Antioxidant	Milligrammes per kilogramme— not exceeding
(b) Any permitted emulsifier or permitted stabiliser containing combined fatty acids whether or not those fatty acids have been polymerised	1. Propyl gallate or Octyl gallate or Dodecyl gallate or any mixture of two, or of all, of them	100
	2. Butylated hydroxyanisole (BHA) or Butylated hydroxytoluene (BHT) or any mixture of BHA and BHT	200
	3. Any mixture of one or more of the permitted antioxidants mentioned in item 1 of this column and either or both of the permitted antioxidants mentioned in item 2 of this column	300 (of which not more than 100 shall represent item 1 and not more than 200 shall represent item 2)
(c) Essential oils and isolates from the concentrates of essential oils	1. Propyl gallate or Octyl gallate or Dodecyl gallate or any mixture of two, or of all, of them	1,000
	2. Butylated hydroxyanisole (BHA) or Butylated hydroxytoluene (BHT) or any mixture of BHA and BHT	1,000
	3. Any mixture of one or more of the permitted antioxidants mentioned in item 1 of this column and either or both of the permitted antioxidants mentioned in item 2 of this column	1,000
(d) Potato powder, potato flakes and potato granules	Butylated hydroxyanisole (BHA) or Butylated hydroxytoluene (BHT) or any mixture of BHA and BHT	25
(e) Walnuts (shelled)	1. Butylated hydroxyanisole (BHA)	70
	2. Butylated hydroxytoluene (BHT)	70
	3. Any mixture of BHA and BHT	140 (of which not more than 70 shall represent item 1 and not more than 70 shall represent item 2)
(f) Apples and pears	Ethoxyquin	3

## PART III

Column 1	Column 2	Column 3
Specified Food	Permitted Antioxidant	Proportion—not exceeding
(a) Preparations of Vitamin A and Vitamin A esters containing more than 30,000 microgrammes retinol equivalents per gramme	Butylated hydroxyanisole (BHA) or Butylated hydroxytoluene (BHT) or any mixture of BHA and BHT	33.3 milligrammes per kilogramme of preparation for every 1,000 microgrammes retinol equivalents per gramme
(b) Preparations of Vitamin A and Vitamin A esters for use as ingredients in the preparation of food described directly or indirectly as intended for babies or young children	Butylated hydroxyanisole (BHA) or Butylated hydroxytoluene (BHT) or any mixture of BHA and BHT	0.35 milligrammes per kilogramme of preparation for every 1,000 microgrammes retinol equivalents per gramme

## PART IV

Column 1	Column 2	Column 3
Specified Food	Permitted Antioxidant	Milligrammes per kilogramme—not exceeding
(a) Chewing gum base	Butylated hydroxytoluene (BHT)	1,000
(b) Chewing gum manufactured from chewing gum base containing the permitted antioxidant Butylated hydroxytoluene	Butylated hydroxytoluene (BHT)	200

## Regulation 5(2)

## SCHEDULE 4

## LABELLING OF PERMITTED ANTIOXIDANTS AND PERMITTED DILUENTS

1.—(1) Every container to which regulation 5(2) applies shall bear a label on which is printed a true statement:—

- (a) in respect of each permitted antioxidant present, of the serial number, if any, as specified in relation thereto in column 2 of Part I of Schedule 1, and of the common or usual name or an appropriate designation of that permitted antioxidant;
- (b) where any other substance (whether or not a permitted diluent) is present, of the common or usual name or an appropriate designation of that substance; and
- (c) where two or more of the substances referred to in paragraph 1(1)(a) and (b) of this Schedule are present, of the proportion of each such substance present, save that the label shall only have printed on it a statement of the proportion of any substance present, other than a permitted antioxidant or a permitted diluent, if any regulations, other than these regulations or any amendment to these regulations, made under the Act contain a requirement to that effect.

(2) The said statement shall be headed or preceded by the words “for foodstuffs (restricted use)”.

2. Any statement required by the preceding paragraph—

- (a) shall be clear and legible;
- (b) shall be in a conspicuous position on the label which shall be marked on, or securely attached to, the container in such a manner that it will be readily discernible and easily read by an intending purchaser under normal conditions of purchase;
- (c) shall not be in any way hidden or obscured or reduced in conspicuousness by any other matter, whether pictorial or not, appearing on the label.

3. The figures and letters in every word in any statement to which the preceding paragraph applies—

- (a) shall be in characters of uniform colour and size (being not less than 1.5 millimetres in height for a label on a container of which the greatest dimension does not exceed 12 centimetres, and not less than 3 millimetres in height for a label on a container of which the greatest dimension exceeds 12 centimetres), but so that the initial letter of any word may be taller than any other letter in the word;
- (b) shall appear on a contrasting ground, so however that where there is no ground other than such as is provided by a transparent container and the contents of that container are visible behind the letters, those contents shall be taken to be the ground for the purposes of this paragraph;
- (c) shall be within a surrounding line and no other written or pictorial matter shall appear within that line.

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4. For the purposes of this Schedule—

- (a) The height of any lower case letter shall be taken to be the x height thereof, disregarding any ascender or descender thereof;
  - (b) any requirement that figures or letters shall be of uniform height, colour or size, shall be construed as being subject to the saving that any inconsiderable variation in height, colour or size, as the case may be, may be disregarded.
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EXPLANATORY NOTE

*(This Note is not part of the Regulations.)*

These Regulations, which apply to England and Wales only, come into operation on 28th February 1978. The Regulations re-enact with amendments the Antioxidant in Food Regulations 1974, as amended, which implemented Council Directive No. 70/357/EEC (OJ No. L157, 18.7.70, p. 31: OJ/SE 1970 (II) p. 429), on the approximation of the laws of the Member States concerning the antioxidants authorised for use in foodstuffs intended for human consumption, as amended by the Act annexed to the Treaty of Accession to the European Communities (Annex I: XI paragraph 3, Annex VII: IX paragraph 3 and Annex XI: X paragraph 5), and by Council Directive No. 74/412/EEC (OJ No. L221, 12.8.74, p. 18).

The principal changes are that the Regulations—

- (a) substitute a revised definition of “dairy product” (regulation 2(1));
- (b) extend the list of specified foods which may contain permitted antioxidants, within specified maximum levels of use (regulation 4 and Schedule 3);
- (c) permit the presence of diphenylamine on apples and pears, at levels not exceeding 10 mg. per kg., for the purpose of inhibiting scald (regulation 4(1));
- (d) permit the presence in food described as intended for babies or young children of BHA or BHT, or both, introduced in the preparation of that food by the use of Vitamin A preparations (regulation 6(2) and Schedule 3).

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