Butylated Hydroxyanisole

B

1 Nonproprietary Names

BP: Butylated Hydroxyanisole

PhEur: Butylhydroxyanisole

USP–NF: Butylated Hydroxyanisole

2 Synonyms

BHA; butylhydroxyanisolum; tert-butyl-4-methoxyphenol; 1,1-dimethylethyl-4-methoxyphenol; E320; *Nipanox BHA*; *Nipantiox 1-F*; *Tenox BHA*.

3 Chemical Name and CAS Registry Number

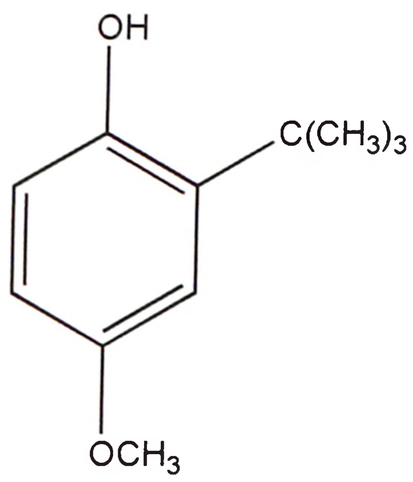
2-tert-Butyl-4-methoxyphenol [25013-16-5]

4 Empirical Formula and Molecular Weight

$C_{11}H_{16}O_2$ 180.25

The PhEur 9.2 describes butylated hydroxyanisole as 2-(1,1-dimethylethyl)-4-methoxyphenol containing not more than 10% of 3-(1,1-dimethylethyl)-4-methoxyphenol.

5 Structural Formula



6 Functional Category

Antioxidant; antimicrobial preservative.

7 Applications in Pharmaceutical Formulation or Technology

Butylated hydroxyanisole is an antioxidant (*see* Table I) with some antimicrobial properties.[1–5] It is used in a wide range of cosmetics, foods, and pharmaceuticals. When used in foods, it is used to delay or prevent oxidative rancidity of fats and oils and to prevent loss of activity of oil-soluble vitamins.

Table I: Antioxidant uses of butylated hydroxyanisole.

Antioxidant use	Concentration (%)
β-Carotene	0.01
Essential oils and flavoring agents	0.02–0.5
IM injections	0.03
IV injections	0.0002–0.0005
Oils and fats	0.02
Topical formulations	0.005–0.02
Vitamin A	10 mg per million units

Butylated hydroxyanisole is frequently used in combination with other antioxidants, particularly butylated hydroxytoluene and alkyl gallates, and with sequestrants or synergists such as citric acid.

FDA regulations direct that the total content of antioxidant in vegetable oils and direct food additives shall not exceed 0.02% w/w (200 ppm) of fat or oil content or essential (volatile) oil content of food.

USDA regulations require that the total content of antioxidant shall not exceed 0.01% w/w (100 ppm) of any one antioxidant or 0.02% w/w combined total of any antioxidant combination in animal fats.

Japanese regulations allow up to 1 g/kg in animal fats.

8 Description

Butylated hydroxyanisole occurs as a white or almost white crystalline powder or a yellowish-white waxy solid with a faint, characteristic aromatic odor.

9 Pharmacopeial Specifications

See Table II.

Table II: Pharmacopeial specifications for butylated hydroxyanisole.

Test	PhEur 9.2	USP 40–NF 35 S1
Identification	+	+
Characters	+	–
Appearance of solution	+	–
Residue on ignition	–	≤0.01%
Sulfated ash	≤0.1%	–
Related substances	+	–
Heavy metals	–	≤10 ppm
Assay	–	≥98.5%

10 Typical Properties

Antimicrobial activity Activity is similar to that of the *p*-hydroxybenzoate esters (parabens). The greatest activity is against molds and Gram-positive bacteria, with less activity against Gram-negative bacteria.

Boiling point 264°C at 745 mmHg

Density (true) 1.117 g/cm^3

Flash point 130°C

Melting point 47°C (for pure 2-*tert*-butyl-4-methoxyphenol); *see also* Section 18.

Solubility Practically insoluble in water; soluble in methanol; freely soluble in ≥50% aqueous ethanol, propylene glycol, chloroform, ether, hexane, cottonseed oil, peanut oil, soybean oil, glyceryl monooleate, and lard, and in solutions of alkali hydroxides.

Spectroscopy

IR spectrum *see* Figure 1.

NIR spectrum *see* Figure 2.

Raman spectrum *see* Figure 3.

Viscosity (kinematic) 3.3 mm^2/s (3.3 cSt) at 99°C.

11 Stability and Storage Conditions

Exposure to light causes discoloration and loss of activity. Butylated hydroxyanisole should be stored in a well-closed container, protected from light, in a cool, dry place.