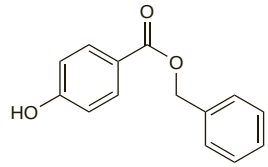
Benzyl Hydroxybenzoate

Benzyl Parahydroxybenzoate; Benzylparaben; Parahidroxibenzoato de bencilo. Benzyl 4-hydroxybenzoate.

$C_{14}H_{12}O_3$ = 228.2.

CAS — 94-18-8.



Pharmacopoeias. In *Br.* and *Int.*

BP 2008 (Benzyl Hydroxybenzoate). A white to creamy-white, odourless or almost odourless, crystalline powder. Practically insoluble in water; freely soluble in alcohol and in ether. It dissolves in solutions of alkali hydroxides. M.p. about 112°.

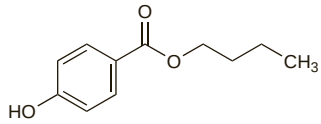
Incompatibility and stability. The incompatibilities and stability of hydroxybenzoates are described under Sodium Propyl Hydroxybenzoate, below.

Butyl Hydroxybenzoate

Butilo parahidroksibenzoatas; Butilparabeno; Butil-parahidroxibenzoát; Butyl Parahydroxybenzoate; Butyle, parahydroxybenzoate de; Butylis parahydroxybenzoas; Butylis Paraoxybenzoas; Butylparaben; Butylparabenum; Butylparahydroxibensoat; Butylu parahydroksybenzoesan; Butyyliparahydroksibentsoaatti. Butyl 4-hydroxybenzoate.

$C_{11}H_{14}O_3$ = 194.2.

CAS — 94-26-8.



Pharmacopoeias. In *Eur.* (see p.vii) and *Jpn.* Also in *USNF.*

Ph. Eur. 6.2 (Butyl Parahydroxybenzoate; Butyl Hydroxybenzoate BP 2008). Colourless crystals or a white or almost white crystalline powder. Very slightly soluble in water; freely soluble in alcohol and in methyl alcohol. M.p. 68° to 71°.

USNF 26 (Butylparaben). Small colourless crystals or a white powder. Very slightly soluble in water and in glycerol; freely soluble in alcohol, in acetone, in ether, and in propylene glycol. M.p. 68° to 71°.

Incompatibility and stability. The incompatibilities and stability of hydroxybenzoates are described under Sodium Propyl Hydroxybenzoate, below.

Ethyl Hydroxybenzoate

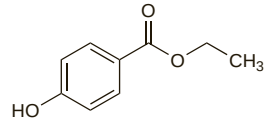
Aethylum Hydroxybenzoicum; E214; Ethyl Parahydroxybenzoate; Éthyle, parahydroxybenzoate d'; Ethylis parahydroxybenzoas; Ethylis Paraoxybenzoas; Ethylparaben; Ethylparabenum; Etilo parahidroksibenzoatas; Etilparabeno; Etil-parahidroxibenzoát; Etylparahydroxibensoat; Etylu parahydroksybenzoesan; Etyyliparahydroksibentsoaatti. Ethyl 4-hydroxybenzoate.

$C_9H_{10}O_3$ = 166.2.

CAS — 120-47-8.

ATC — D01AE10.

ATC Vet — QD01AE10.



Pharmacopoeias. In *Chin., Eur.* (see p.vii), *Int.*, and *Jpn.* Also in *USNF.*

Ph. Eur. 6.2 (Ethyl Parahydroxybenzoate; Ethyl Hydroxybenzoate BP 2008). Colourless crystals or a white or almost white crystalline powder. Very slightly soluble in water; freely soluble in alcohol and in methyl alcohol.

USNF 26 (Ethylparaben). Small colourless crystals or a white powder. Slightly soluble in water and in glycerol; freely soluble in alcohol, in acetone, in ether, and in propylene glycol.

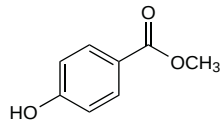
Incompatibility and stability. The incompatibilities and stability of hydroxybenzoates are described under Sodium Propyl Hydroxybenzoate, below.

Methyl Hydroxybenzoate

E218; Metagin; Methyl Parahydroxybenzoate; Méthyle, parahydroxybenzoate de; Methylis Oxybenzoas; Methylis parahydroxybenzoas; Methylis Paraoxibenzoas; Methylparaben *(USAN)*; Methylparabenum; Metilo parahidroksibenzoatas; Metilparabeno; Metil-parahidroxibenzoát; Metylparahydroxibensoat; Metylu parahydroksybenzoesan; Metyyliparahydroksibentsoaatti. Methyl 4-hydroxybenzoate.

$C_8H_8O_3$ = 152.1.

CAS — 99-76-3.



Pharmacopoeias. In *Eur.* (see p.vii), *Int.*, and *Jpn.* Also in *USNF.*

Ph. Eur. 6.2 (Methyl Parahydroxybenzoate; Methyl Hydroxybenzoate BP 2008). Colourless crystals or a white or almost white crystalline powder. Very slightly soluble in water; freely soluble in alcohol and in methyl alcohol. M.p. 125° to 128°.

USNF 26 (Methylparaben). Colourless crystals or a white crystalline powder. Soluble 1 in 400 of water, 1 in 50 of water at 80°, 1 in 3 of alcohol, and 1 in 10 of ether; freely soluble in methyl alcohol. M.p. 125° to 128°.

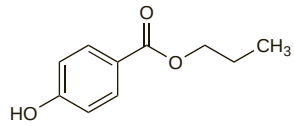
Incompatibility and stability. The incompatibilities and stability of hydroxybenzoates are described under Sodium Propyl Hydroxybenzoate, below.

Propyl Hydroxybenzoate

E216; Propagin; Propilo parahidroksibenzoatas; Propilparabeno; Propil-parahidroxibenzoát; Propyl Parahydroxybenzoate; Propyle, parahydroxybenzoate de; Propylis Oxybenzoas; Propylis parahydroxybenzoas; Propylis Paraoxibenzoas; Propylparaben *(USAN)*; Propylparabenum; Propylparahydroxibensoat; Propylu parahydrobenzoesan; Propylu parahydroksybenzoesan; Propyyliparahydroksibentsoaatti. Propyl 4-hydroxybenzoate.

$C_{10}H_{12}O_3$ = 180.2.

CAS — 94-13-3.



Pharmacopoeias. In *Eur.* (see p.vii), *Int.*, and *Jpn.* Also in *USNF.*

Ph. Eur. 6.2 (Propyl Parahydroxybenzoate; Propyl Hydroxybenzoate BP 2008). A white or almost white, crystalline powder. Very slightly soluble in water; freely soluble in alcohol and in methyl alcohol. M.p. 96° to 99°.

USNF 26 (Propylparaben). Small colourless crystals or a white powder. Soluble 1 in 2500 of water, 1 in 400 of boiling water, 1 in 1.5 of alcohol, and 1 in 3 of ether. M.p. 96° to 99°.

Incompatibility and stability. The incompatibilities and stability of hydroxybenzoates are described under Sodium Propyl Hydroxybenzoate, below.

Sodium Butyl Hydroxybenzoate

Butilparabeno sódico; Sodium Butyl Parahydroxybenzoate; Sodium Butylparaben.

$C_{11}H_{13}NaO_3$ = 216.2.

CAS — 36457-20-2.

Pharmacopoeias. In *Br.*

BP 2008 (Sodium Butyl Hydroxybenzoate). A white, odourless or almost odourless, hygroscopic powder. Freely soluble in water and in alcohol. A 0.1% solution in water has a pH of 9.5 to 10.5.

Incompatibility and stability. The incompatibilities and stability of hydroxybenzoates are described under Sodium Propyl Hydroxybenzoate, below.

Sodium Ethyl Hydroxybenzoate

E215; Ethyl parahydroxybenzoate sodium; Éthyle (parahydroxybenzoate d') sodique; Ethylis Parahydroxybenzoas Natricum; Ethylis parahydroxybenzoas natricus; Ethylparaben sodná sůl; Etilo parahidroksibenzoato natrio druska; Etilparabeno sódico; Etylparahydroxibensoatnatrium; Etyyliparahydroksibentsoaattinatrium.

$C_9H_9NaO_3$ = 188.2.

CAS — 35285-68-8.

Pharmacopoeias. In *Eur.* (see p.vii).

Ph. Eur. 6.2 (Ethyl Parahydroxybenzoate Sodium; Ethyl Hydroxybenzoate Sodium BP 2008). A white or almost white, hygroscopic, crystalline powder. Freely soluble in water; soluble in dehydrated alcohol; practically insoluble in dichloromethane. A 0.1% solution in water has a pH of 9.5 to 10.5. Store in airtight containers.

The BP 2008 gives Ethylparaben Sodium as an approved synonym.

Incompatibility and stability. The incompatibilities and stability of hydroxybenzoates are described under Sodium Propyl Hydroxybenzoate, below.

Sodium Methyl Hydroxybenzoate

E219; Méthyle (parahydroxybenzoate de) sodique; Methylis Parahydroxybenzoas Natricum; Methylis parahydroxybenzoas natricus; Methylparaben Sodium *(USAN)*; Methylparaben sodná sůl; Methylparabenum Natricum; Metilo parahidroksibenzoato natrio druska; Metilparabeno sódico; Metil-parahidroxibenzoátnátrium; Natriummetylparahydroxibensoat; Natriummetyylipara-hydroksibentsoaatti; Sodium Methyl Parahydroxybenzoate; Sodium Methylparaben; Soluble Methyl Hydroxybenzoate.

$C_8H_7NaO_3$ = 174.1.

CAS — 5026-62-0.

Pharmacopoeias. In *Eur.* (see p.vii). Also in *USNF.*

Ph. Eur. 6.2 (Sodium Methyl Parahydroxybenzoate; Sodium Methyl Hydroxybenzoate BP 2008). A white or almost white, crystalline powder. Freely soluble in water; sparingly soluble in alcohol; practically insoluble in dichloromethane. A 0.1% solution in water has a pH of 9.5 to 10.5.

USNF 26 (Methylparaben Sodium). A white, hygroscopic, powder. Freely soluble in water; sparingly soluble in alcohol; insoluble in fixed oils. A 0.1% solution in water has a pH of 9.5 to 10.5. Store in airtight containers.

Incompatibility and stability. The incompatibilities and stability of hydroxybenzoates are described under Sodium Propyl Hydroxybenzoate, below.

Sodium Propyl Hydroxybenzoate

E217; Natriumpropylparahydroxibensoat; Natriumpropyylipara-hydroksibentsoaatti; Propilo parahidroksibenzoato natrio druska; Propilparabeno sódico; Propil-parahidroxibenzoátnátrium; Propyle (parahydroxybenzoate de) sodique; Propylis Parahydroxybenzoas Natricum; Propylis parahydroxybenzoas natricus; Propylparaben Sodium *(USAN)*; Propylparaben sodná sůl; Propylparabenum Natricum; Sodium Propyl Parahydroxybenzoate; Sodium Propylparaben; Soluble Propyl Hydroxybenzoate.

$C_{10}H_{11}NaO_3$ = 202.2.

CAS — 35285-69-9.

Pharmacopoeias. In *Eur.* (see p.vii). Also in *USNF.*

Ph. Eur. 6.2 (Sodium Propyl Parahydroxybenzoate; Sodium Propyl Hydroxybenzoate BP 2008). A white or almost white, crystalline powder. Freely soluble in water; sparingly soluble in alcohol; practically insoluble in dichloromethane. A 0.1% solution in water has a pH of 9.5 to 10.5.

USNF 26 (Propylparaben Sodium). A white, hygroscopic, odourless powder. Freely soluble in water; sparingly soluble in alcohol; insoluble in fixed oils. A 0.1% solution in water has a pH of 9.5 to 10.5. Store in airtight containers.

Incompatibility and stability. The activity of hydroxybenzoates can be adversely affected by the presence of other excipients or active ingredients. There may be adsorption onto substances like magnesium trisilicate, aluminium magnesium silicate, talc, polysorbate 80,[1,2] carmellose sodium,[3] or plastics.[4] Nonionic surfactants can reduce hydroxybenzoate activity,[5] as may essential oils.[6] Other incompatibilities that have been reported include atropine,[7] iron,[4] sorbitol,[8] weak alkalis,[4] and strong acids.[4] Syrup preserved with hydroxybenzoates is incompatible with a range of compounds.[9,10] Methyl hydroxybenzoate 0.1% was reported[11] to be a poor preservative in insulin preparations, especially soluble insulin preparations. Increasing heat or pH can reduce stability and activity;[12] freeze-drying may also lead to a loss of activity.[13]

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8. Runesson B, Gustavii K. Stability of parabens in the presence of polyols. *Acta Pharm Suec* 1986; **23:** 151–62.
9. *PSGB Lab Report P/79/2* 1979.
10. *PSGB Lab Report P/80/1* 1980.