The BP 2008 directs that when Hydrogen Peroxide is prescribed or demanded, Hydrogen Peroxide Solution (6 per cent) shall be dispensed or supplied.

Hydrogen Peroxide Solution (30 per cent)

30 %-os hidrogén-peroxid-oldat; Hydrogen Peroxide Concentrate; Hydrogen Peroxide Solution (100-volume); Hydrogenii Peroxidum 30%; Hydrogenii Peroxidum 30 Per Centum; Peroxid vodíku 30%; Peróxido de hidrógeno, solución al 30%; Vandenilio peroksido 30% tirpalas; Väteperoxid 30%; Vetyperoksidi 30%; Wodoru nadtlenek 30%.

ATC — A01AB02; D08AX01; S02AA06.

ATC Vet — QA01AB02; QD08AX01; QS02AA06.

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

Chin. specifies 26 to 28%.

US and *Viet.* specify 29 to 32%.

Ph. Eur. 6.2 (Hydrogen Peroxide Solution (30 per cent)). A clear colourless liquid containing 29.0 to 31.0% w/w of H_2O_2 corresponding to about 110 times its volume of available oxygen. It decomposes in contact with oxidisable organic matter and with certain metals and if allowed to become alkali. It may contain a suitable stabilising agent. Solutions not containing a stabilising agent should be stored at a temperature below 15°. Protect from light.

The BP 2008 directs that when Hydrogen Peroxide is prescribed or demanded, Hydrogen Peroxide Solution (6 per cent) shall be dispensed or supplied.

USP 31 (Hydrogen Peroxide Concentrate). A clear, colourless liquid containing 29 to 32% w/w of H_2O_2. It may contain up to 0.05% of a suitable preservative or preservatives. It is acid to litmus. It slowly decomposes and is affected by light. Store in partially-filled containers having a small vent in the closure, at a temperature of 8° to 15°.

Adverse Effects and Precautions

Strong solutions of hydrogen peroxide produce irritating 'burns' on the skin and mucous membranes with a white eschar, but the pain disappears in about an hour. Continued use of hydrogen peroxide as a mouthwash may cause reversible hypertrophy of the papillae of the tongue.

It is dangerous to inject or instil hydrogen peroxide into closed body cavities from which the released oxygen has no free exit. Colonic lavage with solutions of hydrogen peroxide has been followed by gas embolism, rupture of the colon, proctitis, ulcerative colitis, and gangrene of the intestine.

Closed body cavities. Liberation of oxygen during the use of hydrogen peroxide in surgical procedures has resulted in oxygen embolism and local emphysema.[1-3] Gas embolism has also been reported after accidental ingestion of hydrogen peroxide solution.[4] Local damage to the colonic and rectal mucosa has followed the use of hydrogen peroxide 3% as an enema[5,6] and from residual hydrogen peroxide after disinfection of endoscopes.[7]

1. Sleigh JW, Linter SPK. Hazards of hydrogen peroxide. *BMJ* 1985; **291:** 1706.
2. Saïssy JM, *et al.* Risques de l'irrigation au peroxyde d'hydrogène en chirurgie de guerre. *Ann Fr Anesth Reanim* 1994; **13:** 749–53.
3. Konrad C, *et al.* Pulmonary embolism and hydrogen peroxide. *Can J Anaesth* 1997; **44:** 338–9.
4. Rackoff WR, Merton DF. Gas embolism after ingestion of hydrogen peroxide. *Pediatrics* 1990; **85:** 593–4.
5. Auroux J, *et al.* Rectocolite aiguë iatrogène après lavement à l'eau oxygénée. *Rev Geriatr* 1997; **22:** 21–4.
6. Gan SI, Price LM. Waiting-list induced proctitis: the hydrogen peroxide enema. *Can J Gastroenterol* 2003; **17:** 727–9.
7. Ryan CK, Potter GD. Disinfectant colitis: rinse as well as you wash. *J Clin Gastroenterol* 1995; **21:** 6–9.

Effects on the mouth. Use of hydrogen peroxide 3% as a mouthwash has been reported to cause mouth ulceration. A review[1] on the safety of hydrogen peroxide in dentistry concluded that low concentrations of hydrogen peroxide (1.5 to 3%) used long-term in mouthwashes and dentifrices, resulted in no adverse changes to the hard or soft tissues in the mouth. However, irritation may occur with low concentrations in patients with a thin or ulcerated oral mucosa. Short-term exposure to higher concentrations (30 to 35%), such as those used in teeth bleaching products and procedures, have resulted in mucosal erythema and sloughing, while long-term exposure may cause inflammation or hyperplasia.

1. Walsh LJ. Safety issues relating to the use of hydrogen peroxide in dentistry. *Aust Dent J* 2000; **45:** 257–69.

Intravascular administration. Intravenous injection of hydrogen peroxide solutions as unconventional therapy for AIDS or cancer has resulted in severe acute haemolysis.[1,2] Haemolysis and methaemoglobinaemia have been reported due to contamination of haemodialysis fluid with hydrogen peroxide.[3,4]

1. Jordan KS, *et al.* A 39-year-old man with acute hemolytic crisis secondary to intravenous injection of hydrogen peroxide. *J Emerg Nurs* 1991; **17:** 8–10.
2. Hirschtick RE, *et al.* Death from an unconventional therapy for AIDS. *Ann Intern Med* 1994; **120:** 694.
3. Gordon SM, *et al.* Hemolysis associated with hydrogen peroxide at a pediatric dialysis center. *Am J Nephrol* 1990; **10:** 123–7.
4. Davidovits M, *et al.* Methaemoglobinaemia and haemolysis associated with hydrogen peroxide in a paediatric haemodialysis centre: a warning note. *Nephrol Dial Transplant* 2003; **18:** 2354–8.

Poisoning. Ingestion of small quantities of hydrogen peroxide 3% generally results in only mild gastrointestinal effects. Ingestion of solutions of 10% or greater or large quantities of 3% solutions have been associated with severe morbidity and mortality. Irritation of the gastrointestinal tract with nausea, vomiting, foaming at the mouth, and haematemesis may occur. Blistering of the mucosa or oropharyngeal burns are common with solutions of 30% or greater. Large volumes of oxygen gas are produced in the stomach and this may result in painful gastric distension and belching. Apnoea, coma, convulsions, confusion, cyanosis, lethargy, stridor, and cardiorespiratory arrest have also been reported. Oxygen gas embolism is particularly dangerous. Immediate and permanent neurological damage has been reported after ingestion of hydrogen peroxide 35% and deaths have been reported in children and adults. Inhalation of high concentrations of hydrogen peroxide may cause irritation of the mucous membranes causing coughing and dyspnoea. Shock, convulsions, pulmonary oedema, and coma may follow. Exposure of the skin to concentrated solutions of hydrogen peroxide has resulted in blistering, erythema, focal epidermal necrosis, and purpura. Concentrations above 10% may result in ulceration or perforation of the cornea if they enter the eyes.[1]

1. Watt BE, *et al.* Hydrogen peroxide poisoning. *Toxicol Rev* 2004; **23:** 51–7.

Uses and Administration

Hydrogen peroxide is an oxidising agent used as an antiseptic, disinfectant, and deodorant. It has weak antibacterial activity and is also effective against viruses, including HIV. It also has a mild haemostatic action. It owes its antiseptic action to its ready release of oxygen when applied to tissues, but the effect lasts only as long as the oxygen is being released and is of short duration; in addition the antimicrobial effect of the liberated oxygen is reduced in the presence of organic matter. The mechanical effect of effervescence is probably more useful for wound cleansing (p.1624) than the antimicrobial action.

Hydrogen peroxide solutions are used to cleanse wounds and ulcers in concentrations of up to 6%; creams containing 1 or 1.5% stabilised hydrogen peroxide are also used. Although hydrogen peroxide alone is not considered effective on intact skin, it is used with other antiseptics for the disinfection of hands, skin, and mucous membranes. Injection into closed body cavities is dangerous (see above). Adhering and blood-soaked dressings may be released by the application of a solution of hydrogen peroxide.

A 1.5% solution of hydrogen peroxide has been used as a mouthwash in the treatment of acute stomatitis and as a deodorant gargle. A suitable solution can be prepared by diluting 15 mL of hydrogen peroxide 6% in half a tumblerful of warm water. An oral gel has also been used.

Hydrogen peroxide ear drops have been used for the removal of wax. Such ear drops were prepared by diluting a 6% solution of hydrogen peroxide with 3 parts of water preferably just before use.

Hydrogen peroxide 3% is used for disinfecting soft contact lenses.

Immersion for 30 minutes in hydrogen peroxide 6% has been suggested for disinfecting cleaned equipment.

For bleaching hair and delicate fabrics hydrogen peroxide 6% should be diluted with an equal volume of water.

Strong solutions (27 per cent and 30 per cent) of hydrogen peroxide are used for the preparation of weaker solutions and should not be applied to tissues undiluted.

Hydrogen peroxide and other peroxides have many industrial uses as bleaching and oxidising agents.

Disinfection. ***CONTACT LENSES.*** Hydrogen peroxide 3% is particularly useful for disinfecting soft contact lenses (p.1622) and lens storage cases since it is effective against *Acanthamoeba* spp. However, it is irritant to the cornea and requires inactivating with sodium pyruvate, catalase, or sodium thiosulfate, or with a platinum catalyst, before the lenses are used.

DIALYSIS EQUIPMENT. A disinfectant containing hydrogen peroxide and peracetic acid (*Renalin*) was not completely effective in killing *Mycobacterium chelonae* in high-flux dialysers. This possibly led to infection of 5 dialysis patients.[1] For a report of haemolysis and methaemoglobinaemia after inadvertent contamination of dialysis fluid with hydrogen peroxide, see Intravascular Administration under Adverse Effects and Precautions, above.

1. Lowry PW, *et al.* Mycobacterium chelonae infection among patients receiving high-flux dialysis in a hemodialysis clinic in California. *J Infect Dis* 1990; **161:** 85–90.

ENDOSCOPES. Peroxygen compounds have been suggested for disinfection of endoscopes as an alternative to glutaral (p.1623). In the USA, a product containing 7.5% hydrogen peroxide is available as a high level disinfectant for processing of reusable medical devices.[1] Products containing varying concentrations of hydrogen peroxide with peracetic acid have also been approved by the FDA.

Hydrogen peroxide damages external surfaces, particularly rubbers and plastics of the insertion tubes and can corrode aluminium, nickel-silver alloy, and chrome.[2,3] Other peroxygen-containing compounds have been assessed for disinfecting endoscopes, but they appear to be less active against enteroviruses[4] and mycobacteria.[5] The Working Party of the British Society of Gastroenterology does not recommend peroxygen disinfectants for gastrointestinal endoscopes.[3]

Residual hydrogen peroxide solution can cause mucosal damage (see Closed Body Cavities, under Adverse Effects, above) and endoscopes should be thoroughly rinsed before use.

1. FDA. FDA-cleared sterilants and high level disinfectants with general claims for processing reusable medical and dental devices (issued May 13, 2005). Available at: http://www.fda.gov/cdrh/ode/germlab.html (accessed 15/03/06)
2. Society of Gastroenterology Nurses and Associates, Inc. Guideline for the use of high-level disinfectants and sterilants for reprocessing of flexible gastrointestinal endoscopes. *Gastroenterol Nurs* 2000 **23:** 180–7. Also available at: http://www.sgna.org/Resources/guidelines/guideline6.cfm (accessed 08/03/06)
3. BSG Working Party. Cleaning and disinfection of equipment for gastrointestinal endoscopy: the report of a working party of the British Society of Gastroenterology Endoscopy Committee, 1997. Available at: http://www.bsg.org.uk/pdf_word_docs/glutaraldehyde.doc (accessed 15/03/06)
4. Tyler R, *et al.* Virucidal activity of disinfectants: studies with the poliovirus. *J Hosp Infect* 1990; **15:** 339–45.
5. Broadley SJ, *et al.* Antimycobacterial activity of 'Virkon'. *J Hosp Infect* 1993; **23:** 189–97.

Mouth ulceration and infection. The use of antiseptic mouthwashes may be helpful in the management of mouth ulcers (p.1700), although the use of high concentrations of hydrogen peroxide is not advisable (see Adverse Effects on the Mouth, above). Application of a 1.5% solution to individual ulcers with a topical corticosteroid may be useful. A randomised placebo-controlled study[1] to test the efficacy of a 1.5% hydrogen peroxide and 0.05% sodium fluoride-based mouthwash on gingivitis and tooth whitening, over a 6-month period found that it effectively whitened teeth and significantly reduced gingival redness. However, a review of the literature with practice guidelines pertaining to oral care of the critically ill[2] concluded that hydrogen peroxide could not be recommended as a mouthwash in this group, due to lack of evidence regarding its safety and efficacy in critically ill patients. A hydrogen peroxide denture cleaner was not effective in either preventing re-infection or in reducing mucosal inflammation in a study of 49 patients.[3] For oral candidal infections, specific antifungals are recommended (see p.518).

1. Hasturk H, *et al.* Efficacy of a fluoridated hydrogen peroxide-based mouthrinse for the treatment of gingivitis: a randomized clinical trial. *J Periodontol* 2004; **75:** 57–65.
2. O'Reilly M. Oral care of the critically ill: a review of the literature and guidelines for practice. *Aust Crit Care* 2003; **16:** 101–10.
3. Walker DM, *et al.* The treatment of denture-induced stomatitis: evaluation of two agents. *Br Dent J* 1981; **151:** 416–19.

Preparations

BP 2008: Hydrogen Peroxide Mouthwash;
USP 31: Hydrogen Peroxide Topical Solution.

Proprietary Preparations (details are given in Part 3)
Arg.: Aosept Plus; ***Austral.:*** Aosept; Focus Care One Step; Peroxyl; ***Belg.:*** Confosept Zuurstofwater; Crystacide†; ***Braz.:*** Aosept†; Oxysept; ***Canad.:*** Aosept; Orajel Periosceptic; ***Denm.:*** Brintoverilte; Microcid; ***Fr.:*** Dentex; Dosoxygenee; ***Ger.:*** Crystacide; ***Gr.:*** Peroxyl; ***Hong Kong:*** Crystacide†; ***Hung.:*** Microcid†; ***Irl.:*** Crystacide†; Hioxyl; ***Israel:*** Crystacide†; ***Ital.:*** Crystacide; Oragard; ***Neth.:*** Peroxyl; ***Norw.:*** Microcid; ***NZ:*** Aosept; Crystacide; Focus Care One Step†; ***Pol.:*** Peroxy-Dental; Peroxygel; ***Port.:*** Crystacide; ***Spain:*** Crystacide†; ***Swed.:*** Microcid; ***UK:*** Crystacide; Hioxyl†; Peroxyl; ***USA:*** Oxysept; Peroxyl.

Multi-ingredient: ***Arg.:*** One Step†; Oxysept Comfort; Plus & White†; ***Austral.:*** Omnicare I Step; Oxysept†; ***Austria:*** Kodan; Skinsept mucosa; ***Braz.:*** Malvatricin Branqueador; ***Canad.:*** UltraCare; ***Cz.:*** Skinsept mucosa†; ***Fr.:*** Anioxyde; Spitaderm†; ***Ger.:*** Peresal†; Skinsept F; Skinsept mucosa; ***Indon.:*** Spitaderm; ***Ital.:*** Eso 70; Esoform 7 mc; Esoform 70 mc; Peresal; Spitaderm; ***Neth.:*** Spitaderm; ***NZ:*** Omnicare I Step; ***Spain:*** Oximen; ***USA:*** Aosept; MiraSept; Soft Mate Consept; UltraCare.

Hydroxybenzoates

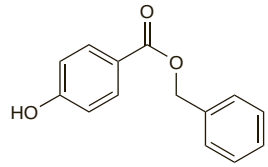
Parabenos; Parabens.

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°.

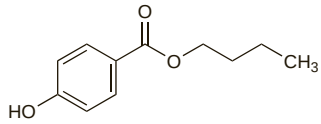
Incompatibility and stability. The incompatibilities and stability of hydroxybenzoates are described under Sodium Propyl Hydroxybenzoate, below.

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

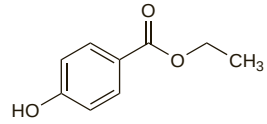
Aethylum Hydroxybenzoicum; E214; Ethyl Parahydroxybenzoate; Éthyle, parahydroxybenzoate d'; Ethylis parahydroxybenzoas; Ethylis Paraoxybenzoas; Ethylparaben; Ethylparabenum; Etilo parahidroksibenzoatas; Etilparabeno; Etil-parahidroxibenzoát; Etylparahydroxibensoat; Etylu parahydroksybenzoesan; Etyyliparahydroksibentsoaatti.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

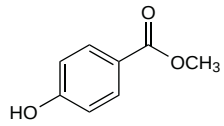
Incompatibility and stability. The incompatibilities and stability of hydroxybenzoates are described under Sodium Propyl Hydroxybenzoate, below.

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°.

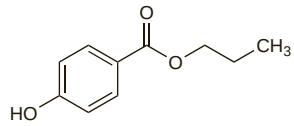
Incompatibility and stability. The incompatibilities and stability of hydroxybenzoates are described under Sodium Propyl Hydroxybenzoate, below.

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]

1. Yousef RT, *et al.* Effect of some pharmaceutical materials on the bactericidal activities of preservatives. *Can J Pharm Sci* 1973; **8:** 54–6.
2. Allwood MC. The adsorption of esters of p-hydroxybenzoic acid by magnesium trisilicate. *Int J Pharmaceutics* 1982; **11:** 101–7.
3. Fawcett JP, *et al.* Binding of parabens to sodium carboxymethylcellulose in oral liquid formulations. *Aust J Hosp Pharm* 1996; **26:** 552–4.
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