

**Extractable heavy metals (2.4.8).** Evaporate 50 ml of solution S3 to about 5 ml on a water-bath and dilute to 20 ml with *water R*. 12 ml of solution complies with limit test A for heavy metals (2.5 ppm). Prepare the standard using 2.5 ml of *lead standard solution (10 ppm Pb) R*.

**Sulphated ash (2.4.14).** Not more than 0.02 per cent, determined on 5.0 g.

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### 3.1.5. POLYETHYLENE WITH ADDITIVES FOR CONTAINERS FOR PARENTERAL PREPARATIONS AND FOR OPHTHALMIC PREPARATIONS

#### DEFINITION

Polyethylene with additives is obtained by the polymerisation of ethylene under pressure in the presence of a catalyst or by copolymerisation of ethylene with not more than 25 per cent of higher alkene homologues (C<sub>3</sub> to C<sub>10</sub>).

#### PRODUCTION

A certain number of additives are added to the polymer in order to optimise their chemical, physical and mechanical properties in order to adapt them for the intended use. All these additives are chosen from the appended list which specifies for each product the maximum allowable content. They may contain at most three antioxidants, one or several lubricants or antiblocking agents as well as titanium dioxide as an opacifying agent when the material must provide protection from light.

- butylhydroxytoluene (plastic additive 07) (not more than 0.125 per cent),
- pentaerythrityl tetrakis[3-(3,5-di-*tert*-butyl-4-hydroxyphenyl)propionate] (plastic additive 09) (not more than 0.3 per cent),
- 1,3,5-tris(3,5-di-*tert*-butyl-4-hydroxybenzyl)-s-triazine-2,4,6-(1*H*,3*H*,5*H*)-trione (plastic additive 13) (not more than 0.3 per cent),
- octadecyl 3-(3,5-di-*tert*-butyl-4-hydroxyphenyl)propionate, (plastic additive 11) (not more than 0.3 per cent),
- ethylene bis[3,3-bis[3-(1,1-dimethylethyl)-4-hydroxyphenyl]butanoate] (plastic additive 08) (not more than 0.3 per cent),
- dioctadecyl disulphide (plastic additive 15) (not more than 0.3 per cent),
- 4,4',4''-(2,4,6-trimethylbenzene-1,3,5-triyltris(methylene)tris[2,6-bis(1,1-dimethylethyl)phenol]) (plastic additive 10) (not more than 0.3 per cent),
- 2,2'-bis(octadecyloxy)-5,5'-spirobi[1,3,2-dioxaphosphinane] (plastic additive 14) (not more than 0.3 per cent),
- didodecyl 3,3'-thiodipropionate (plastic additive 16) (not more than 0.3 per cent),
- dioctadecyl 3,3'-thiodipropionate (plastic additive 17) (not more than 0.3 per cent),
- tris [2,4-bis(1,1-dimethylethyl)phenyl] phosphite (plastic additive 12) (not more than 0.3 per cent).

The total of antioxidant additives listed above does not exceed 0.3 per cent.

- hydrotalcite (not more than 0.5 per cent),
- alkanamides (not more than 0.5 per cent),
- alkenamides (not more than 0.5 per cent),

- sodium silico-aluminate (not more than 0.5 per cent),
- silica (not more than 0.5 per cent),
- sodium benzoate (not more than 0.5 per cent),
- fatty acid esters or salts (not more than 0.5 per cent),
- trisodium phosphate (not more than 0.5 per cent),
- liquid paraffin (not more than 0.5 per cent),
- zinc oxide (not more than 0.5 per cent),
- magnesium oxide (not more than 0.2 per cent),
- calcium stearate or zinc stearate or a mixture of both (not more than 0.5 per cent),
- titanium dioxide (not more than 4 per cent) only for materials for containers for ophthalmic use.

The supplier of the material must be able to demonstrate that the qualitative and quantitative composition of the type sample is satisfactory for each production batch.

#### CHARACTERS

Powder, beads, granules or, after transformation, translucent sheets of varying thicknesses or containers. It is practically insoluble in water, soluble in hot aromatic hydrocarbons, practically insoluble in ethanol, in hexane and in methanol. It softens at temperatures between 70 °C and 140 °C.

The relative density (2.2.5) of the material is 0.890 to 0.965.

#### IDENTIFICATION

*If necessary, cut the material to be examined into pieces of maximum dimension on a side of not greater than 1 cm.*

- A. To 0.25 g add 10 ml of *toluene R* and boil under a reflux condenser for about 15 min. Place a few drops of the solution on a sodium chloride disc and evaporate the solvent in an oven at 80 °C. Examine by infrared absorption spectrophotometry (2.2.24). The spectrum of the material to be examined shows maxima in particular at some of the following wave-numbers: 2920 cm<sup>-1</sup>, 2850 cm<sup>-1</sup>, 1465 cm<sup>-1</sup>, 1375 cm<sup>-1</sup>, 1170 cm<sup>-1</sup>, 730 cm<sup>-1</sup>, 720 cm<sup>-1</sup>; the spectrum obtained is identical to the spectrum obtained with the material selected for the type sample. If the material to be examined is in the form of sheets, the identification may be performed directly on a cut piece of suitable size.
- B. It complies with the supplementary tests corresponding to the additives present (see Tests).
- C. In a platinum crucible, mix about 20 mg with 1 g of *potassium hydrogen sulphate R* and heat until completely melted. Allow to cool and add 20 ml of *dilute sulphuric acid R*. Heat gently. Filter the resulting solution. To the filtrate add 1 ml of *phosphoric acid R* and 1 ml of *strong hydrogen peroxide solution R*. If the substance is opacified with titanium dioxide, an orange-yellow colour develops.

#### TESTS

*If necessary, cut the material to be examined into pieces of maximum dimension on a side of not greater than 1 cm.*

**Solution S1.** Place 25 g in a borosilicate-glass flask with a ground-glass neck. Add 500 ml of *water for injections R* and boil under a reflux condenser for 5 h. Allow to cool and decant. Reserve a portion of the solution for the test for appearance of solution and filter the rest through a sintered-glass filter (16). *Use within 4 h of preparation.*

**Solution S2.** Place 2.0 g in a conical borosilicate-glass flask with a ground-glass neck. Add 80 ml of *toluene R* and boil under a reflux condenser with constant stirring for 90 min. Allow to cool to 60 °C and add with continued stirring 120 ml of *methanol R*. Filter the solution through a sintered-glass filter (16). Rinse the flask and the filter with 25 ml of a

mixture of 40 ml of *toluene R* and 60 ml of *methanol R*, add the rinsings to the filtrate and dilute to 250.0 ml with the same mixture of solvents. Prepare a blank solution.

**Solution S3.** Place 100 g in a conical borosilicate-glass flask with a ground-glass neck. Add 250 ml of *0.1 M hydrochloric acid* and boil under a reflux condenser with constant stirring for 1 h. Allow to cool and decant the solution.

**Appearance of solution.** Solution S1 is clear (2.2.1) and colourless (2.2.2, *Method II*).

**Acidity or alkalinity.** To 100 ml of solution S1 add 0.15 ml of *BRP indicator solution R*. Not more than 1.5 ml of *0.01 M sodium hydroxide* is required to change the colour of the indicator to blue. To 100 ml of solution S1 add 0.2 ml of *methyl orange solution R*. Not more than 1.0 ml of *0.01 M hydrochloric acid* is required to reach the beginning of the colour change of the indicator from yellow to orange.

**Absorbance (2.2.25).** At wavelengths from 220 nm to 340 nm, the absorbance of solution S1 is not greater than 0.2.

**Reducing substances.** To 20 ml of solution S1 add 1 ml of *dilute sulphuric acid R* and 20 ml of *0.002 M potassium permanganate*. Boil under a reflux condenser for 3 min and cool immediately. Add 1 g of *potassium iodide R* and titrate immediately with *0.01 M sodium thiosulphate*, using 0.25 ml of *starch solution R* as indicator. Carry out a blank titration. The difference between the titration volumes is not more than 0.5 ml.

**Substances soluble in hexane.** Place 10 g in a 250 ml conical borosilicate-glass flask with a ground-glass neck. Add 100 ml of *hexane R* and boil under a reflux condenser for 4 h, stirring constantly. Cool in iced water and filter rapidly through a sintered-glass filter (16) maintaining the solution at 0 °C (the filtration time must be less than 5 min; if necessary the filtration may be accelerated by applying pressure to the solution). Evaporate 20 ml of the filtrate in a tared borosilicate-glass dish on a water-bath. Dry the residue in an oven at 100-105 °C for 1 h. The mass of the residue obtained must be within 10 per cent of the residue obtained with the type sample and does not exceed 5 per cent.

**Extractable aluminium.** Not more than 1 ppm of extractable Al, determined by atomic emission spectrometry in an argon plasma (2.2.22, *Method I*).

*Test solution.* Use solution S3.

*Reference solutions.* Prepare the reference solutions using *aluminium standard solution (200 ppm Al) R*, diluted with *0.1 M hydrochloric acid*.

Carry out the determination using the emission of aluminium at 396.15 nm, the spectral background being taken as 396.25 nm.

Verify the absence of aluminium in the hydrochloric acid used.

**Extractable chromium.** Not more than 0.05 ppm of extractable Cr, determined by atomic emission spectrometry in an argon plasma (2.2.22, *Method I*).

*Test solution.* Use solution S3.

*Reference solutions.* Prepare the reference solutions using *chromium standard solution (100 ppm Cr) R*, diluted with a mixture of 2 volumes of *hydrochloric acid R* and 8 volumes of *water R*.

Carry out the determination using the emission of chromium at 205.55 nm, the spectral background being taken as 205.50 nm.

Verify the absence of chromium in the hydrochloric acid used.

**Extractable titanium.** Not more than 1 ppm of extractable Ti, determined by atomic emission spectrometry in an argon plasma (2.2.22, *Method I*).

*Test solution.* Use solution S3.

*Reference solutions.* Prepare the reference solutions using *titanium standard solution (100 ppm Ti) R*, diluted with *0.1 M hydrochloric acid*.

Carry out the determination using the emission of titanium at 336.12 nm, the spectral background being taken as 336.16 nm.

Verify the absence of titanium in the hydrochloric acid used.

**Extractable vanadium.** Not more than 0.1 ppm of extractable V, determined by atomic emission spectrometry in an argon plasma (2.2.22, *Method I*).

*Test solution.* Use solution S3.

*Reference solutions.* Prepare the reference solutions using *vanadium standard solution (1 g/l V) R*, diluting with a mixture of 2 volumes of *hydrochloric acid R* and 8 volumes of *water R*.

Carry out the determination using the emission of vanadium at 292.40 nm, the spectral background being taken as 292.35 nm.

Verify the absence of vanadium in the hydrochloric acid used.

**Extractable zinc.** Not more than 1 ppm of extractable Zn, determined by atomic absorption spectrometry (2.2.23, *Method I*).

*Test solution.* Use solution S3.

*Reference solutions.* Prepare the reference solutions using *zinc standard solution (10 ppm Zn) R*, diluted with *0.1 M hydrochloric acid*.

Measure the absorbance at 213.9 nm using a zinc hollow-cathode lamp as a source of radiation and an air-acetylene flame.

**Extractable zirconium.** Not more than 0.1 ppm of extractable Zr, determined by atomic emission spectrometry in an argon plasma (2.2.22, *Method I*).

*Test solution.* Use solution S3.

*Reference solutions.* Prepare the reference solutions using *zirconium standard solution (1 g/l Zr) R*, diluted with a mixture of 2 volumes of *hydrochloric acid R* and 8 volumes of *water R*.

Carry out the determination using the emission of zirconium at 343.82 nm, the spectral background being taken as 343.92 nm.

Verify the absence of zirconium in the hydrochloric acid used.

**Extractable heavy metals (2.4.8).** Evaporate 50 ml of solution S3 to about 5 ml on a water-bath and dilute to 20.0 ml with *water R*. 12 ml of solution complies with limit test A for heavy metals (2.5 ppm). Prepare the standard using 2.5 ml of *lead standard solution (10 ppm Pb) R*.

**Sulphated ash (2.4.14).** Not more than 1.0 per cent, determined on 5.0 g. This limit does not apply to material opacified with titanium dioxide.

#### SUPPLEMENTARY TESTS

*These tests are to be carried out, in whole or in part, only if required by the stated composition of the material.*

**Phenolic antioxidants.** Examine by liquid chromatography (2.2.29).

The chromatographic procedure may be carried out using:  
– a stainless steel column 0.25 m long and 4.6 mm in internal diameter packed with *octadecylsilyl silica gel for chromatography R* (5 µm),

- as mobile phase one of the 3 following mixtures:  
Mobile phase 1 at a flow rate of 2 ml/min: 30 volumes of *water R*, 70 volumes of *acetonitrile R*,  
Mobile phase 2 at a flow rate of 1.5 ml/min: 10 volumes of *water R*, 30 volumes of *tetrahydrofuran R*, 60 volumes of *acetonitrile R*,  
Mobile phase 3 at a flow rate of 1.5 ml/min: 5 volumes of *water R*, 45 volumes of *2-propanol R*, 50 volumes of *methanol R*,

– as detector a spectrophotometer set at 280 nm.

The chromatographic system must ensure the following:

- a resolution of not less than 8.0 between the peaks corresponding respectively to plastic additive 07 and plastic additive 08, with mobile phase 1,
- a resolution of not less than 2.0 between the peaks corresponding respectively to plastic additive 09 and plastic additive 10, with mobile phase 2,
- a resolution of not less than 2.0 between the peaks corresponding respectively to plastic additive 11 and plastic additive 12, with mobile phase 3.

**Test solution S21.** Evaporate 50 ml of solution S2 to dryness in vacuo at 45 °C. Dissolve the residue with 5.0 ml of a mixture of equal volumes of *acetonitrile R* and *tetrahydrofuran R*. Prepare a blank solution from the blank solution corresponding to solution S2.

**Test solution S22.** Evaporate 50 ml of solution S2 to dryness in vacuo at 45 °C. Dissolve the residue with 5.0 ml of *methylene chloride R*. Prepare a blank solution from the blank solution corresponding to solution S2.

*Of the following reference solutions, only prepare those that are necessary for the analysis of the phenolic antioxidants stated in the composition of the substance to be examined.*

**Reference solution (a).** Dissolve 25.0 mg of *butylhydroxytoluene CRS* (plastic additive 07) and 60.0 mg of *plastic additive 08 CRS* in 10.0 ml of a mixture of equal volumes of *acetonitrile R* and *tetrahydrofuran R*. Dilute 2.0 ml of the solution to 50.0 ml with a mixture of equal volumes of *acetonitrile R* and *tetrahydrofuran R*.

**Reference solution (b).** Dissolve 60.0 mg of *plastic additive 09 CRS* and 60.0 mg of *plastic additive 10 CRS* in 10.0 ml of a mixture of equal volumes of *acetonitrile R* and *tetrahydrofuran R*. Dilute 2.0 ml of the solution to 50.0 ml with a mixture of equal volumes of *acetonitrile R* and *tetrahydrofuran R*.

**Reference solution (c).** Dissolve 60.0 mg of *plastic additive 11 CRS* and 60.0 mg of *plastic additive 12 CRS* in 10.0 ml of *methylene chloride R*. Dilute 2.0 ml of the solution to 50.0 ml with *methylene chloride R*.

**Reference solution (d).** Dissolve 25.0 mg of *butylhydroxytoluene CRS* (plastic additive 07) in 10.0 ml of a mixture of equal volumes of *acetonitrile R* and *tetrahydrofuran R*. Dilute 2.0 ml of the solution to 50.0 ml with a mixture of equal volumes of *acetonitrile R* and *tetrahydrofuran R*.

**Reference solution (e).** Dissolve 60.0 mg of *plastic additive 08 CRS* in 10.0 ml of a mixture of equal volumes of *acetonitrile R* and *tetrahydrofuran R*. Dilute 2.0 ml of the solution to 50.0 ml with a mixture of equal volumes of *acetonitrile R* and *tetrahydrofuran R*.

**Reference solution (f).** Dissolve 60.0 mg of *plastic additive 13 CRS* in 10.0 ml of a mixture of equal volumes of *acetonitrile R* and *tetrahydrofuran R*. Dilute 2.0 ml of the solution to 50.0 ml with a mixture of equal volumes of *acetonitrile R* and *tetrahydrofuran R*.

**Reference solution (g).** Dissolve 60.0 mg of *plastic additive 09 CRS* in 10.0 ml of a mixture of equal volumes of *acetonitrile R* and *tetrahydrofuran R*. Dilute 2.0 ml of the solution to 50.0 ml with a mixture of equal volumes of *acetonitrile R* and *tetrahydrofuran R*.

**Reference solution (h).** Dissolve 60.0 mg of *plastic additive 10 CRS* in 10.0 ml of a mixture of equal volumes of *acetonitrile R* and *tetrahydrofuran R*. Dilute 2.0 ml of the solution to 50.0 ml with a mixture of equal volumes of *acetonitrile R* and *tetrahydrofuran R*.

**Reference solution (i).** Dissolve 60.0 mg of *plastic additive 11 CRS* in 10.0 ml of *methylene chloride R*. Dilute 2.0 ml of the solution to 50.0 ml with *methylene chloride R*.

**Reference solution (j).** Dissolve 60.0 mg of *plastic additive 12 CRS* in 10.0 ml of *methylene chloride R*. Dilute 2.0 ml of the solution to 50.0 ml with *methylene chloride R*.

If the substance to be examined contains plastic additive 07 and/or plastic additive 08, use mobile phase 1 and inject 20 µl of test solution S21, 20 µl of the corresponding blank solution, 20 µl of reference solution (a), and either 20 µl of reference solution (d) or (e), or 20 µl of reference solutions (d) and (e).

If the substance to be examined contains one or more of the following antioxidants:

- plastic additive 09,
- plastic additive 10,
- plastic additive 11,
- plastic additive 12,
- plastic additive 13,

use mobile phase 2 and inject 20 µl of test solution S21, 20 µl of the corresponding blank solution, 20 µl of reference solution (b) and 20 µl of the reference solutions of the antioxidants on the list above that are stated in the composition.

If the substance to be examined contains plastic additive 11 and/or plastic additive 12, use mobile phase 3 and inject 20 µl of test solution S22, 20 µl of the corresponding blank solution, 20 µl of reference solution (c), and either 20 µl of reference solution (i) or (j), or 20 µl of reference solutions (i) and (j).

In all cases record the chromatograms for 30 min; the chromatograms corresponding to test solutions S21 and S22 only show peaks due to antioxidants stated in the composition and minor peaks that also appear in the chromatograms corresponding to the blank solutions. The areas of the peaks of test solutions S21 and S22 are less than the areas of the corresponding peaks in the chromatograms obtained with reference solutions (d) to (j).

**Non-phenolic antioxidants.** Examine by thin-layer chromatography (2.2.27), using a *TLC silica gel GF<sub>254</sub> plate R*.

**Test solution S23.** Evaporate 100 ml of solution S2 to dryness in vacuo at 45 °C. Dissolve the residue in 2 ml of *acidified methylene chloride R*.

**Reference solution (k).** Dissolve 60 mg of *plastic additive 14 CRS* in *methylene chloride R* and dilute to 10 ml with the same solvent. Dilute 2 ml of the solution to 10 ml with *acidified methylene chloride R*.

**Reference solution (l).** Dissolve 60 mg of *plastic additive 15 CRS* in *methylene chloride R* and dilute to 10 ml with the same solvent. Dilute 2 ml of the solution to 10 ml with *acidified methylene chloride R*.

**Reference solution (m).** Dissolve 60 mg of *plastic additive 16 CRS* in *methylene chloride R* and dilute to 10 ml with the same solvent. Dilute 2 ml of the solution to 10 ml with *acidified methylene chloride R*.

**Reference solution (n).** Dissolve 60 mg of *plastic additive 17 CRS* in *methylene chloride R* and dilute to 10 ml with the same solvent. Dilute 2 ml of the solution to 10 ml with *acidified methylene chloride R*.

**Reference solution (o).** Dissolve 60 mg of *plastic additive 16 CRS* and 60 mg of *plastic additive 17 CRS* in *methylene chloride R* and dilute to 10 ml with the same solvent. Dilute 2 ml of the solution to 10 ml with *acidified methylene chloride R*.

Apply separately to the plate 20 µl of test solution S23, 20 µl of reference solution (o) and 20 µl of the reference solutions corresponding to all the phenolic and non-phenolic antioxidants mentioned in the type composition of the material to be examined.

Develop over a path of 18 cm using *hexane R*. Allow the plate to dry. Develop a second time over a path of 17 cm using *methylene chloride R*. Allow the plate to dry and examine in ultraviolet light at 254 nm. Spray with *alcoholic iodine solution R* and examine in ultraviolet light at 254 nm after 10-15 min. Any spots in the chromatogram obtained with test solution S23 are not more intense than the spots in the same locations in the chromatograms obtained with the reference solutions. The test is not valid unless the chromatogram obtained with reference solution (o) shows two clearly separated spots.

**Amides and stearates.** Examine by thin-layer chromatography (2.2.27), using 2 plates of the *TLC silica gel GF<sub>254</sub> plates R* type.

**Test solution.** Use test solution S23 described in the test for non-phenolic antioxidants.

**Reference solution (p).** Dissolve 20 mg of *stearic acid CRS* (plastic additive 19) in *methylene chloride R* and dilute to 10 ml with the same solvent.

**Reference solution (q).** Dissolve 40 mg of *plastic additive 20 CRS* in *methylene chloride R* and dilute to 20 ml with the same solvent.

**Reference solution (r).** Dissolve 40 mg of *plastic additive 21 CRS* in *methylene chloride R* and dilute to 20 ml with the same solvent.

Apply to each of the 2 plates 10 µl of test solution S23. Apply 10 µl of reference solution (p) to the first and 10 µl of reference solutions (q) and (r) to the second. Develop the first plate over a path of 10 cm using a mixture of 25 volumes of *ethanol R* and 75 volumes of *trimethylpentane R*. Allow the plate to dry in air. Spray with a 2 g/l solution of *dichlorophenolindophenol sodium salt R* in *ethanol R* and heat in an oven at 120 °C for a few minutes to intensify the spots. Any spot corresponding to plastic additive 19 in the chromatogram obtained with test solution S23 is identical in position ( $R_f$  about 0.5) but not more intense than the spot in the same location in the chromatogram obtained with reference solution (p).

Develop the second plate over a path of 13 cm using *hexane R*. Allow the plate to dry in air. Develop a second time over a path of 10 cm using a mixture of 5 volumes of *methanol R* and 95 volumes of *methylene chloride R*. Allow the plate to dry. Spray with a 40 g/l solution of *phosphomolybdic acid R* in *ethanol R*. Heat in an oven at 120 °C until spots appear. Any spots corresponding to plastic additive 20 or plastic additive 21 in the chromatogram obtained with test solution S23 are identical in position

( $R_f$  about 0.2) but not more intense than the corresponding spots in the chromatograms obtained with reference solutions (q) and (r).

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### 3.1.6. POLYPROPYLENE FOR CONTAINERS AND CLOSURES FOR PARENTERAL PREPARATIONS AND OPHTHALMIC PREPARATIONS

#### DEFINITION

Polypropylene consists of the homopolymer of propylene or of a copolymer of propylene with not more than 25 per cent of ethylene or of a mixture (alloy) of polypropylene with not more than 25 per cent of polyethylene. It may contain additives.

#### PRODUCTION

A certain number of additives are added to the polymer in order to optimise their chemical, physical and mechanical properties in order to adapt them for the intended use. All these additives are chosen from the appended list which specifies for each product the maximum allowable content.

They may contain at most three antioxidants, one or several lubricants or antiblocking agents as well as titanium dioxide as opacifying agent when the material must provide protection from light.

- butylhydroxytoluene (plastic additive 07) (not more than 0.125 per cent),
- pentaerythrityl tetrakis[3-(3,5-di-*tert*-butyl-4-hydroxyphenyl)propionate] (plastic additive 09) (not more than 0.3 per cent),
- 1,3,5-tris(3,5-di-*tert*-butyl-4-hydroxybenzyl)-*s*-triazine-2,4,6-(1*H*,3*H*,5*H*)-trione (plastic additive 13) (not more than 0.3 per cent),
- octadecyl 3-(3,5-di-*tert*-butyl-4-hydroxyphenyl)propionate, (plastic additive 11) (not more than 0.3 per cent),
- ethylene bis[3,3-bis[3-(1,1-dimethylethyl)-4-hydroxyphenyl]butanoate] (plastic additive 08) (not more than 0.3 per cent),
- dioctadecyl disulphide (plastic additive 15) (not more than 0.3 per cent),
- 2,2',2'',6,6',6''-hexa-*tert*-butyl-4,4',4''-[(2,4,6-trimethyl-1,3,5-benzenetriyl)trismethylene]triphenol (plastic additive 10) (not more than 0.3 per cent),
- 2,2'-bis(octadecyloxy)-5,5'-spirobi[1,3,2-dioxaphosphinane] (plastic additive 14) (not more than 0.3 per cent),
- didodecyl 3,3'-thiodipropionate (plastic additive 16) (not more than 0.3 per cent),
- dioctadecyl 3,3'-thiodipropionate (plastic additive 17) (not more than 0.3 per cent),
- tris(2,4-di-*tert*-butylphenyl) phosphite (plastic additive 12) (not more than 0.3 per cent),

The total of antioxidant additives listed above does not exceed 0.3 per cent.

- hydrotalcite (not more than 0.5 per cent),
- alkanamides (not more than 0.5 per cent),
- alkenamides (not more than 0.5 per cent),
- sodium silico-aluminate (not more than 0.5 per cent),
- silica (not more than 0.5 per cent),
- sodium benzoate (not more than 0.5 per cent),
- fatty acid esters or salts (not more than 0.5 per cent),