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 1 h 30 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) (*2.1.2*). 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 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*): maximum 0.2, determined between wavelengths of 220 nm and 340 nm on solution S1.

Reducing substances. To 20 mL of solution S1 add 1 mL of *dilute sulfuric 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 thiosulfate*, 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) (*2.1.2*) 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 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 is within 10 per cent of the residue obtained with the type sample and does not exceed 5 per cent.

Additives. Thin-layer chromatography (*2.2.27*).

Test solution. Evaporate 50 mL of solution S2 to dryness *in vacuo* at 45 °C. Dissolve the evaporation residue with 5 mL of *methylene chloride R*. Prepare a blank solution from the blank solution corresponding to solution S2.

Reference solution. Dissolve 20 mg of *plastic additive 15 CRS* and 20 mg of *plastic additive 08 CRS* in *methylene chloride R* and dilute to 10 mL with the same solvent.

Plate: *TLC silica gel G plate R*.

Mobile phase A: *hexane R*.

Mobile phase B: *methanol R, methylene chloride R* (5:95 *V/V*).

Application: 10 μL.

Development A: over a path of 13 cm using mobile phase A.

Drying A: in air.

Development B: over a path of 10 cm using mobile phase B.

Drying B: in air.

Detection: spray with a 40 g/L solution of *phosphomolybdic acid R* in *ethanol (96 per cent) R* and heat at 120 °C until the spots appear in the chromatogram obtained with the reference solution.

System suitability: reference solution:

- the chromatogram shows 2 separated spots.

Limit: no spot appears in the chromatogram obtained with the test solution, except for a spot which may be at the solvent front from the first development and which corresponds to oligomers. Disregard any spots corresponding to those obtained in the chromatogram with the blank solution.

Extractable heavy metals (*2.4.8*): maximum 2.5 ppm.

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 test A. Prepare the reference solution using 2.5 mL of *lead standard solution (10 ppm Pb) R*.

Sulfated ash (*2.4.14*): maximum 0.02 per cent, determined on 5.0 g.

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corrected 7.0

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_3 to C_{10}).

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 3 antioxidants, 1 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): maximum 0.125 per cent;
- pentaerythrityl tetrakis[3-(3,5-di-*tert*-butyl-4-hydroxyphenyl)propionate] (plastic additive 09): maximum 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): maximum 0.3 per cent;
- octadecyl 3-(3,5-di-*tert*-butyl-4-hydroxyphenyl)propionate, (plastic additive 11): maximum 0.3 per cent;
- ethylene bis[3,3-bis[3-(1,1-dimethylethyl)-4-hydroxyphenyl]butanoate] (plastic additive 08): maximum 0.3 per cent;
- dioctadecyl disulfide (plastic additive 15): maximum 0.3 per cent;
- 4,4′,4″-(2,4,6-trimethylbenzene-1,3,5-triyltrismethylene)tris[2,6-bis(1,1-dimethylethyl)phenol] (plastic additive 10): maximum 0.3 per cent;
- 2,2′-bis(octadecyloxy)-5,5′-spirobi[1,3,2-dioxaphosphinane] (plastic additive 14): maximum 0.3 per cent;
- didodecyl 3,3′-thiodipropionate (plastic additive 16): maximum 0.3 per cent;
- dioctadecyl 3,3′-thiodipropionate (plastic additive 17): maximum 0.3 per cent;
- tris [2,4-bis(1,1-dimethylethyl)phenyl] phosphite (plastic additive 12): maximum 0.3 per cent.

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

- hydrotalcite: maximum 0.5 per cent;
- alkanamides: maximum 0.5 per cent;
- alkenamides: maximum 0.5 per cent;

- sodium silico-aluminate: maximum 0.5 per cent;
- silica: maximum 0.5 per cent;
- sodium benzoate: maximum 0.5 per cent;
- fatty acid esters or salts: maximum 0.5 per cent;
- trisodium phosphate: maximum 0.5 per cent;
- liquid paraffin: maximum 0.5 per cent;
- zinc oxide: maximum 0.5 per cent;
- magnesium oxide: maximum 0.2 per cent;
- calcium stearate or zinc stearate or a mixture of both: maximum 0.5 per cent;
- titanium dioxide only for materials for containers for ophthalmic use: maximum 4 per cent.

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

Appearance: powder, beads, granules or, after transformation, translucent sheets of varying thicknesses or containers.

Solubility: practically insoluble in water, soluble in hot aromatic hydrocarbons, practically insoluble in anhydrous ethanol, in hexane and in methanol.

It softens at temperatures between 70 °C and 140 °C.

Relative density: 0.890 to 0.965.

IDENTIFICATION

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

A. Infrared absorption spectrophotometry (*2.2.24*).

Preparation: 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.

Absorption maxima: at 2920 cm^{-1}, 2850 cm^{-1}, 1465 cm^{-1}, 1375 cm^{-1}, 1170 cm^{-1}, 730 cm^{-1} and 720 cm^{-1}.

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 sulfate R* and heat until completely melted. Allow to cool and add 20 mL of *dilute sulfuric 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 samples of 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) (*2.1.2*). *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) (*2.1.2*). 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*): maximum 0.2, determined between wavelengths of 220 nm and 340 nm on solution S1.

Reducing substances. To 20 mL of solution S1 add 1 mL of *dilute sulfuric 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 thiosulfate*, 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) (*2.1.2*) 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: maximum 1 ppm.

Atomic emission spectrometry (*2.2.57*).

Test solution. Use solution S3.

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

Wavelength: use 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: maximum 0.05 ppm.

Atomic emission spectrometry (*2.2.57*).

Test solution. Use solution S3.

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

Wavelength: use 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: maximum 1 ppm.

Atomic emission spectrometry (*2.2.57*).

Test solution. Use solution S3.

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

Wavelength: use 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: maximum 0.1 ppm.

Atomic emission spectrometry (*2.2.57*).

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.*

Wavelength: use 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: maximum 1 ppm.

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,* diluting with *0.1 M hydrochloric acid.*

Source: zinc hollow-cathode lamp.

Wavelength: 213.9 nm.

Atomisation device: air-acetylene flame.

Extractable zirconium: maximum 0.1 ppm.

Atomic emission spectrometry (*2.2.57*).

Test solution. Use solution S3.

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

Wavelength: use 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*): maximum 2.5 ppm.

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 the solution complies with test A. Prepare the reference solution using 2.5 mL of *lead standard solution (10 ppm Pb) R.*

Sulfated ash (*2.4.14*): maximum 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. Liquid chromatography (*2.2.29*).

Solvent mixture: *acetonitrile R, tetrahydrofuran R* (50:50 *V/V*).

Test solution S21. Evaporate 50 mL of solution S2 to dryness *in vacuo* at 45 °C. Dissolve the residue with 5.0 mL of the solvent mixture. 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 the solvent mixture. Dilute 2.0 mL of this solution to 50.0 mL with the solvent mixture.

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 the solvent mixture. Dilute 2.0 mL of this solution to 50.0 mL with the solvent mixture.

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 this 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 the solvent mixture. Dilute 2.0 mL of this solution to 50.0 mL with the solvent mixture.

Reference solution (e). Dissolve 60.0 mg of *plastic additive 08 CRS* in 10.0 mL of the solvent mixture. Dilute 2.0 mL of this solution to 50.0 mL with the solvent mixture.

Reference solution (f). Dissolve 60.0 mg of *plastic additive 13 CRS* in 10.0 mL of the solvent mixture. Dilute 2.0 mL of this solution to 50.0 mL with the solvent mixture.

Reference solution (g). Dissolve 60.0 mg of *plastic additive 09 CRS* in 10.0 mL of the solvent mixture. Dilute 2.0 mL of this solution to 50.0 mL with the solvent mixture.

Reference solution (h). Dissolve 60.0 mg of *plastic additive 10 CRS* in 10.0 mL of the solvent mixture. Dilute 2.0 mL of this solution to 50.0 mL with the solvent mixture.

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 this 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 this solution to 50.0 mL with *methylene chloride R.*

A. If the substance to be examined contains plastic additive 07 and/or plastic additive 08, proceed as follows.

Column:

- *size*: l = 0.25 m, Ø = 4.6 mm;
- *stationary phase*: *octadecylsilyl silica gel for chromatography R* (5 µm).

Mobile phase: *water R, acetonitrile R* (30:70 *V/V*).

Flow rate: 2 mL/min.

Detection: spectrophotometer at 280 nm.

Injection: 20 µL of test solution S21, of the corresponding blank solution, of reference solution (a), and either reference solution (d) or (e), or reference solutions (d) and (e).

Run time: 30 min.

System suitability:

- *resolution*: minimum 8.0 between the peaks due to plastic additive 07 and plastic additive 08 in the chromatogram obtained with reference solution (a);
- the chromatogram corresponding to test solution S21 only show peaks due to antioxidants stated in the composition and minor peaks that also appear in the chromatogram corresponding to the blank solution.

Limit: the areas of the peaks of test solution S21 are less than the areas of the corresponding peaks in the chromatograms obtained with reference solutions (d) and/or (e).

B. 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;

proceed as described above with the following modifications.

Mobile phase: *water R, tetrahydrofuran R, acetonitrile R* (10:30:60 *V/V/V*).

Flow rate: 1.5 mL/min.

Injection: 20 µL of test solution S21, of the corresponding blank solution, of reference solution (b) and reference solutions of the antioxidants on the list above that are stated in the composition.

System suitability:

- *resolution*: minimum 2.0 between the peaks due to plastic additive 09 and plastic additive 10 in the chromatogram obtained with reference solution (b);
- the chromatogram corresponding to test solution S21 only show peaks due to antioxidants stated in the composition and minor peaks that also appear in the chromatogram corresponding to the blank solution.

Limit: the areas of the peaks of test solution S21 are less than the areas of the corresponding peaks in the chromatograms obtained with reference solutions of the antioxidants on the list above that are stated in the composition.

C. If the substance to be examined contains plastic additive 11 and/or plastic additive 12, carry out the test as described for plastic additive 07 and/or plastic additive 08 with the following modifications.

Mobile phase: *water R, 2-propanol R, methanol R* (5:45:50 *V/V/V*).

Flow rate: 1.5 mL/min.

Injection: 20 μL of test solution S22, of the corresponding blank solution, of reference solution (c), and either of reference solution (i) or (j), or reference solutions (i) and (j).

System suitability:

- *resolution*: minimum 2.0 between the peaks due to plastic additive 11 and plastic additive 12 in the chromatogram obtained with reference solution (c);
- the chromatogram corresponding to test solution S22 only show peaks due to antioxidants stated in the composition and minor peaks that also appear in the chromatogram corresponding to the blank solution.

Limit: the areas of the peaks of test solution S22 are less than the areas of the corresponding peaks in the chromatograms obtained with reference solutions (i) and/or (j).

Non-phenolic antioxidants. Thin-layer chromatography (*2.2.27*).

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 this 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 this 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 this 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 this 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 this solution to 10 mL with *acidified methylene chloride R.*

Plate: *TLC silica gel* GF_{254} *plate R.*

Mobile phase A: *hexane R.*

Mobile phase B: *methylene chloride R.*

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

Development A: over a path of 18 cm with mobile phase A.

Drying A: in air.

Development B: over a path of 17 cm with mobile phase B.

Drying B: in air.

Detection: 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.

System suitability: reference solution (o):

- the chromatogram shows 2 clearly separated spots.

Limits: 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.

Amides and stearates. Thin-layer chromatography (*2.2.27*).

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.

Plates: *TLC silica gel* GF_{254} *plates R* (2 plates).

A. *Mobile phase*: *anhydrous ethanol R, trimethylpentane R* (25:75 *V/V*).

Application: 10 μL of test solution S23 and reference solution (p).

Development: over a path of 10 cm.

Drying: in air.

Detection: spray with a 2 g/L solution of *dichlorophenolindophenol sodium salt R* in *anhydrous ethanol R* and heat in an oven at 120 °C for a few minutes to intensify the spots.

Limit: 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).

B. *Mobile phase A*: *hexane R.*

Mobile phase B: *methanol R, methylene chloride R* (5:95 *V/V*).

Application: 10 μL of test solution S23 and reference solutions (q) and (r).

Development A: over a path of 13 cm with mobile phase A.

Drying A: in air.

Development B: over a path of 10 cm with mobile phase B.

Drying B: in air.

Detection: spray with a 40 g/L solution of *phosphomolybdic acid R* in *anhydrous ethanol R* and heat in an oven at 120 °C until spots appear.

Limit: any spots corresponding to plastic additive 20 or plastic additive 21 in the chromatogram obtained with the 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).