Composition of fatty acids (2.24.22, Method C). The fatty-acid fraction of the substance has the following composition:
- palmitic acid: not more than 12.0 per cent,
- stearic acid: not more than 6.0 per cent,
- oleic acid: not less than 60.0 per cent,
- linoleic acid: not more than 35.0 per cent,
- linolenic acid: not more than 2.0 per cent,
- arachidic acid: not more than 2.0 per cent,
- eicosenoic acid
- the name and concentration of any added antioxidant.

Water (2.5.12). Not more than 1.0 per cent, determined on 1.00 g by the semi-micro determination of water. Use as the solvent a mixture of equal volumes of anhydrous methanol R and methylene chloride R.

Total ash (2.4.16). Not more than 0.1 per cent, determined on 1.00 g.

ASSAY
Determine the free glycerol content and the mono-, di- and triacylglycerol contents by size-exclusion chromatography (2.2.30).

Test solution. Into a 15 ml flask, weigh about 0.2 g (m), to the nearest 0.1 mg. Add 5 ml of tetrahydrofuran R and shake to dissolve. Reweigh the flask and calculate the total mass of solvent and substance (M).

Reference solutions. Into four 15 ml flasks, respectively weigh, to the nearest 0.1 mg, about 2.5 mg, 5 mg, 10 mg and 20 mg of glycerol R. Add 5 ml of tetrahydrofuran R and shake until well mixed. Weigh the flasks again and calculate the concentration of glycerol in milligrams per gram for each reference solution.

The chromatographic procedure may be carried out using:
- a gel-permeation column 0.6 m long and 7 mm in internal diameter packed with styrene-divinylbenzene copolymer R (particle diameter 5 µm and porosity 10 nm),
- as mobile phase at a flow rate of 1 ml/min tetrahydrofuran R,
- a differential refractive index detector.

Inject 40 µl of each solution. When the chromatograms are recorded in the prescribed conditions, the retention times relative to glycerol are about 0.85 for the monoacylglycerols, about 0.79 for the diacylglycerols and about 0.76 for the triacylglycerols. From the calibration curve obtained with the reference solutions determine the concentration (C) in milligrams per gram of glycerol in the test solution.

Calculate the percentage content of free glycerol in the substance to be examined using the following expression:
\[
\frac{C \times M}{m \times 10}
\]
Calculate the percentage content of mono-, di- and triacylglycerols in the substance to be examined by the normalisation procedure.

STORAGE
Store in an airtight container, protected from light.

LABELLING
The label states:
- the nominal content of monoacylglycerol,
Composition of fatty acids (2.4.22, Method C). The fatty acid fraction of the substance to be examined has the following composition:

<table>
<thead>
<tr>
<th>Fatty acid used for production by esterification</th>
<th>Composition of fatty acids</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glycerol monostearate 40-55 type I</td>
<td>Stearic acid: 40.0 per cent to 60.0 per cent</td>
</tr>
<tr>
<td></td>
<td>Sum of the contents of palmitic and stearic acids: not less than 90.0 per cent</td>
</tr>
<tr>
<td>Glycerol monostearate 40-55 type II</td>
<td>Stearic acid: 60.0 per cent to 80.0 per cent</td>
</tr>
<tr>
<td></td>
<td>Sum of palmitic and stearic acids: not less than 90.0 per cent</td>
</tr>
<tr>
<td>Glycerol monostearate 40-55 type III</td>
<td>Stearic acid: 90.0 per cent to 99.0 per cent</td>
</tr>
<tr>
<td></td>
<td>Sum of the contents of palmitic and stearic acids: not less than 96.0 per cent</td>
</tr>
</tbody>
</table>

Nickel (2.4.27). Not more than 1 ppm of Ni.
Water (2.5.12). Not more than 1.0 per cent, determined on 1.00 g by the semi-micro determination of water. Use pyridine R as the solvent and heat gently.
Total ash (2.4.16). Not more than 0.1 per cent, determined on 1.00 g.

ASSAY
Determine the free glycerol content and the mono-, di- and triacylglycerol contents by size-exclusion chromatography (2.2.30).

Test solution. Into a 15 ml flask, weigh about 0.2 g (m), to the nearest 0.1 mg. Add 5 ml of tetrahydrofuran R and shake to dissolve. Reweigh the flask and calculate the total mass of solvent and substance (M).

Reference solutions. Into four 15 ml flasks, respectively weigh, to the nearest 0.1 mg, about 2.5 mg, 5 mg, 10 mg and 20 mg of glycerol R. Add 5 ml of tetrahydrofuran R and shake until well mixed. Weigh the flasks again and calculate the concentration of glycerol in milligrams per gram for each reference solution.

The chromatographic procedure may be carried out using:
- a gel-permeation column 0.6 m long and 7 mm in internal diameter packed with styrene-divinylbenzene copolymer R (particle diameter 5 µm and porosity 10 nm),
- as mobile phase at a flow rate of 1 ml/min tetrahydrofuran R,
- a differential refractive index detector.

Inject 40 µl of each solution. When the chromatograms are recorded in the prescribed conditions, the retention times relative to glycerol are about 0.86 for the monoacylglycerols, about 0.81 for the diacylglycerols and about 0.77 for the triacylglycerols. From the calibration curve obtained with the reference solutions determine the concentration (C) in milligrams per gram of glycerol in the test solution.

Calculate the percentage content of free glycerol in the substance to be examined using the following expression:

\[ C \times \frac{M}{m} \times 10 \]

Calculate the percentage content of mono-, di- and triacylglycerols in the substance to be examined by the normalisation procedure.

LABELLING
The label states the type of glycerol monostearate 40-55.

C$_3$H$_5$N$_3$O$_9$  
$M$, 227.1

DEFINITION
Ethanolic solution of glycerol trinitrate.

Content: 1 per cent m/m to 10 per cent m/m of propane-1,2,3-triyl trinitrate and 96.5 per cent to 102.5 per cent of the declared content of glycerol trinitrate stated on the label.

CHARACTERS
Appearance: clear, colourless or slightly yellow solution.
Solubility: miscible with acetone and with ethanol.
Solubility of pure glycerol trinitrate: practically insoluble in water, freely soluble in ethanol, miscible with acetone.

IDENTIFICATION
First identification: A, C.
Second identification: B, C.

Upon diluting glycerol trinitrate solution, care must be taken to always use anhydrous ethanol, otherwise droplets of pure glycerol trinitrate may precipitate from the solution.

After examination, the residues and the solutions obtained in both the identification and the test sections must be heated on a water-bath for 5 min with dilute sodium hydroxide solution R.

A. Infrared absorption spectrophotometry (2.2.24).
Preparation: place 50 µl of a solution diluted, if necessary, with ethanol R, to contain 10 g/1 of glycerol trinitrate, on a disc of potassium bromide R and evaporate the solvent in vacuo.

B. Thin-layer chromatography (2.2.27).
Test solution. Dilute a quantity of the substance to be examined corresponding to 50 mg of glycerol trinitrate to 100 ml with acetone R.
Reference solution. Dilute 0.05 ml of glycerol trinitrate solution CRS to 1 ml with acetone R.
Plate: TLC silica gel G plate R.
Application: 5 µl.
Development: over 2/3 of the plate.
Drying: in air.
Detection: spray with freshly prepared potassium iodide and starch solution R. Expose the plate to ultraviolet light at 254 nm for 15 min. Examine in daylight.
Results: the principal spot in the chromatogram obtained with the test solution is similar in position, colour and size to the principal spot in the chromatogram obtained with the reference solution.

C. It complies with the limits of the assay.