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Hydrogenated Polydecene

$C_{30 \le n \le 70}H_{2n+2}$
1-Decene, homopolymer, hydrogenated
CAS RN®: 68037-01-4.

DEFINITION

Hydrogenated Polydecene is a mixture of saturated, synthetic hydrocarbons in the range $C_{30}H_{62}$ through $C_{70}H_{142}$ made from direct oligomerization of 1-decene (C_{10} alpha olefin). The oligomer mixture may be distilled to fractions of a suitable calculated viscosity and hydrogenated to reach saturation, or it may be hydrogenated to reach saturation and then distilled to the desired viscosity. The requirements for specific gravity, viscosity, and content of decene oligomer differ for the various types of Hydrogenated Polydecene, as set forth in the two tables below. Hydrogenated Polydecene may contain a suitable stabilizer.

Specific Gravity and Viscosity

Type	Specific Gravity	Kinematic Viscosity Range, Centistokes (mm^2/s)
I	0.814-0.819	16.0-20.0
II	0.823-0.827	28.0-34.0
III	0.828-0.832	40.0-52.0

Content of Decene Oligomers

Type	$C_{30}H_{62}$	$C_{40}H_{82}$	$C_{50}H_{102}$	$C_{60}H_{122}$	$C_{70}H_{142}$
I	70-93	5-25	0-5	0-1	0-1
II	13-40	35-70	9-25	0-7	0-2
III	3-15	25-55	25-40	13-28	0-10

IDENTIFICATION

- **A.** The chromatogram of the *Sample solution* from the test for *Content of Decene Oligomer* exhibits major peaks for trimers, tetramers, pentamers, hexamers, and possibly heptamers. The decene oligomer content is within the range given in the table *Content of Decene Oligomers* in the *Definition* for the labeled type of Hydrogenated Polydecene.

ASSAY

- **Content of Decene Oligomer**

  System suitability solution: 10 mg/mL of hexadecane, 10 mg/mL of squalane, and 1 mg/mL of tetradecane in pentane

  Sample solution: Dissolve 0.1 mL of Hydrogenated Polydecene in 10 mL of pentane.

  Chromatographic system

(See Chromatography ⟨621⟩, System Suitability.)

Mode: GC

Detector: Flame ionization

Column: 0.52-mm × 16-m fused-silica capillary; coated with 0.1-mm stationary phase G2

Carrier gas: Helium

Flow rate: 10 mL/min

Injection volume: 2 µL

Temperatures

Injection port: 310°

Detector: 320°

Column: See *Table 1*.

Table 1

Initial Temperature (°)	Ramp (°/min)	Final Temperature (°)	Hold Time at Final Temperature (min)
35	5	50	—
50	12	170	—
170	10	310	18

System suitability

Sample: *System suitability solution*

[Note—The retention time for squalane is about 18 min; the relative retention times for tetradecane, hexadecane, and squalane are about 0.5, 0.6, and 1.0, respectively.]

Suitability requirements

Resolution: NLT 2.0 between tetradecane and hexadecane

Relative standard deviation: NMT 2.0% for each peak

Analysis

Sample: *Sample solution*

Record the chromatogram, and measure the areas for the major peaks.

[Note—The tetramer oligomer has a retention time of about 23 min. The trimer, pentamer, hexamer, and heptamer oligomers, if present, have relative retention times of about 0.8, 1.1, 1.3, and 1.4, respectively, relative to the tetramer.]

Calculate the percentage of each oligomer present:

$$\text{Result} = (r_U/r_T) \times 100$$

r_U = response of each oligomer

r_T = sum of the responses of all the peaks, excluding the solvent peak

Acceptance criteria: The decene oligomer content is within the limits specified in the table *Content of Decene Oligomers* in the *Definition*.

IMPURITIES

- **Limit of Nickel**

Nickel stock solution: Immediately before use, dilute an appropriate quantity of organometallic standard[1] with kerosene to prepare a solution containing the equivalent of 1.0 µg/mL of nickel.

Standard solutions: Transfer 0.5, 1.0, 2.0, and 4.0 mL of *Nickel stock solution*, respectively, to four identical 10-mL volumetric flasks, dilute the contents of each flask with kerosene to volume, and mix. These *Standard solutions* contain, respectively, 0.05, 0.1, 0.2, and 0.40 µg/mL of nickel. [Note—The calibration range, especially the upper limit, can be adjusted for certain instruments, provided that instrument validation and calibration linearity are achieved.]

Sample solution: 0.3 g/mL of Hydrogenated Polydecene in kerosene. [Note—If necessary, dilute with an appropriate quantity of kerosene to obtain a reading within the calibrated absorbance range.]

Instrumental conditions

(See *Atomic Absorption Spectroscopy ⟨852⟩*.)

Mode: Graphite furnace atomic absorption spectrophotometer equipped with a deuterium background corrector and a pyrolytically coated tube with platform

Analytical wavelength: 232.0 nm (nickel emission line)

Injection volume: 20 µL

Lamp: Nickel hollow-cathode

Blank: Kerosene

Temperature: See *Table 2*.

[NOTE—The temperature program may be modified to obtain optimum furnace temperatures.]

Table 2

Step	Temperature (°)	Hold Time (s)
Drying	80	1
Drying	120	10
Drying	300	20
Ashing	600	20
Ashing	1000	20
Atomization	2500	3
Cleaning	2600	5

Analysis

Samples: *Standard solutions* and *Sample solution*

Place the *Standard solutions* and the *Sample solution* in an oven, setting the temperature at about 60° during the period of determination, and shake these solutions vigorously before analysis. Use micropipettor and pipettor tips to make all injections. [NOTE—Positive displacement pipets can be used when viscosity may become a problem.]

Pretreat the pipettor tip by pipetting and then discarding 20 µL of heptane. The tip must be pretreated before each injection. [NOTE—The film of heptane remaining on the wall of the tip facilitates a reproducible transfer of the oil sample.]

Separately inject the *Standard solutions* and the *Sample solution* into a graphite furnace, and concomitantly determine the integrated absorbances of the *Standard solutions* and the *Sample solution*.

Plot the integrated absorbances of the *Standard solutions* versus concentration, in µg/mL, of nickel, and draw the straight line best fitting the four plotted points. From the graph so obtained, determine the concentration of nickel, *C*, in µg/mL, in the *Sample solution*.

Calculate the content of nickel in the Hydrogenated Polydecene taken:

$$\text{Result} = C/C_U$$

C = concentration of nickel obtained from the graph (µg/mL)

C_U = concentration of nickel in the *Sample solution* (g/mL)

Acceptance criteria: NMT 1 µg/g

- **LIMIT OF SHORT-CHAIN HYDROCARBONS**

System suitability solution, Sample solution, Chromatographic system, System suitability, and **Analysis:** Proceed as directed in the test for *Content of Decene Oligomer*.

Calculate the percentage of each of the short-chain hydrocarbons present:

$$\text{Result} = (r_U/r_T) \times 100$$

r_U = peak response of any peak eluting before the trimer but different from the solvent peak

r_T = sum of the responses of all the peaks in the chromatogram, excluding the solvent peak

Acceptance criteria: NMT 2.5% of total short-chain hydrocarbons is found.

SPECIFIC TESTS

- **Specific Gravity ⟨841⟩**

Analysis: Determine at 20°.

Acceptance criteria: Meets the requirements of the specific gravity range specified in the table *Specific Gravity and Viscosity* in the *Definition* for the labeled type

- **Viscosity—Capillary Methods ⟨911⟩**

Analysis: Determine using a capillary viscometer, in a liquid bath maintained at 40.0 ± 0.1°.

Acceptance criteria: Meets the requirements of the viscosity range specified in the table *Specific Gravity and Viscosity* in the *Definition* for the labeled type.

- **Readily Carbonizable Substances Test ⟨271⟩**

Standard solution: 3 mL of ferric chloride CS, 1.5 mL of cobaltous chloride CS, and 0.5 mL of cupric sulfate CS in a glass-stoppered test tube previously treated to remove organic matter (see *Cleaning Glass Apparatus* ⟨1051⟩).

Sample: 5 mL

Analysis: Transfer the *Sample* to a glass-stoppered test tube previously treated to remove organic matter (see *Cleaning Glass Apparatus* ⟨1051⟩), add 5 mL of sulfuric acid, and heat in a boiling water bath for 30 s. Quickly remove the test tube, and, while holding the stopper in place, shake three times in a vertically reciprocating cycle with an amplitude of about 13 cm. Repeat this procedure every 30 s for 10 min. Do not keep the test tube out of the water bath any longer than 3 s for each shaking cycle. Remove the test tube from the water bath, and let it cool for about 20 min to room temperature.

Acceptance criteria: The oil phase of the *Sample* may turn hazy but remains colorless; the interface between the two layers is free from solids; and the acid layer does not become darker than the standard color produced by the *Standard solution*, the *Standard solution* being overlaid with 5 mL of Hydrogenated Polydecene.

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in tight containers. No storage requirements are specified.
- **Labeling:** Label it to indicate, as part of the official title, the Hydrogenated Polydecene type (Type I, Type II, or Type III), and label it to indicate the name and concentration of any added stabilizer.

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[1] Suitable organometallic standards are available from, e.g., Continental Oil Co., Ponca City, OK (Conostan, 100 ppm), or Merck, D-6100 Darmstadt, Germany (metal in standard oil, 1000 ppm).

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
HYDROGENATED POLYDECENE	Documentary Standards Support	CE2020 Complex Excipients
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	CE2020 Complex Excipients

Chromatographic Database Information: Chromatographic Database

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