



**International
Standard**

ISO 5076

**Traditional Chinese medicine —
Angelica dahurica root**

**First edition
2024-05**

STANDARDSISO.COM : Click to view the full PDF of ISO 5076:2024

STANDARDSISO.COM : Click to view the full PDF of ISO 5076:2024



COPYRIGHT PROTECTED DOCUMENT

© ISO 2024

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

Contents

Page

Foreword	iv
Introduction	v
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Descriptions	1
5 Quality and safety requirements and recommendations	2
5.1 General characteristics	2
5.2 Morphological features	2
5.3 Thin-layer chromatogram (TLC) identification	3
5.4 Moisture	3
5.5 Total ash	3
5.6 Acid-insoluble ash	3
5.7 Dilute ethanol-soluble extractives	3
5.8 Heavy metals	3
5.9 Pesticide residues	3
5.10 Marker compound	3
6 Sampling	3
7 Test methods	3
7.1 Macroscopic identification	3
7.2 Thin-layer chromatogram (TLC) identification	4
7.3 Determination of moisture content	4
7.4 Determination of total ash content	4
7.5 Determination of acid-insoluble ash content	4
7.6 Determination of dilute ethanol-soluble extractives content	4
7.7 Determination of heavy metal contents	4
7.8 Determination of pesticide residues contents	4
7.9 Determination of marker compound	4
8 Test report	4
9 Packaging, storage and transportation	4
10 Marking and labelling	5
Annex A (informative) Thin-layer chromatogram (TLC) identification	6
Annex B (informative) Determination of marker compound	8
Annex C (informative) Reference information of national and regional requirements	10
Bibliography	12

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO document should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

ISO draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). ISO takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, ISO had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at www.iso.org/patents. ISO shall not be held responsible for identifying any or all such patent rights.

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 249, *Traditional Chinese medicine*.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

Angelica dahurica root (also known as *Angelicae dahuricae* Radix or "baizhi") is one of the commonly used herbal medicines in traditional Chinese medicine (TCM). For instance, of 1607 formulae in the Pharmacopoeia of the People's Republic of China (2020 edition),^[1] 131 (8,2 %) contain the *Angelica dahurica* root.

Angelica dahurica root was firstly recorded in "Shen Nong Ben Cao Jing"^[2] (神农本草经), and has been used in TCM for a very long time to treat headache, supraorbital neuralgia, stuffy nose, nasosinusitis and toothache. Modern pharmacological studies demonstrate that *Angelica dahurica* root possesses anti-inflammatory, antioxidant, antibacterial, and anticancer properties. The main chemical constituents of *Angelica dahurica* root are coumarins and volatile oils. The coumarins contained in *Angelica dahurica* root, such as imperatorin and isoimperatorin, have been demonstrated to have anticancer, antiviral, antidepressive, antiallergic, anti-lipogenic, antioxidant, vasodilation and radical-scavenging effects.

In the global trade of *Angelica dahurica* root, mainland China is a main exporter. According to China customs data from 2015 to 2019, the average annual export volume of *Angelica dahurica* root was 2 557 tons, worth 11 891 630 US\$. The main destination countries and regions included Japan, the Republic of Korea, Hong Kong, Taiwan, Vietnam, Malaysia, Thailand, New Zealand, the United States and Germany.

Angelica dahurica root has been recorded in the Pharmacopoeia of the People's Republic of China,^[1] the European Pharmacopoeia,^[3] the Japanese Pharmacopoeia^[4] and the Korean Pharmacopoeia^[5]; and the requirements of each pharmacopoeia are different. Currently, there's no globally unified standard for *Angelica dahurica* root; and regulators in many countries and regions have different levels of regulation. Therefore, the establishment of an International Standard is necessary to guarantee the quality, safety and consistency of the valuable herbal medicine.

As national implementation can differ, national standards bodies are invited to modify the values given in [5.5](#) and [5.7](#) in their national standards. Example of national values are given in [Annex C](#).

[STANDARDSISO.COM](https://standardsiso.com) : Click to view the full PDF of ISO 5076:2024

Traditional Chinese medicine — *Angelica dahurica* root

1 Scope

This document specifies the quality and safety requirements of *Angelica dahurica* root [the dried root of *Angelica dahurica* (Fish.ex Hoffm.) Benth. et Hook. f. ex Franch. et Sav.].

This document applies to *Angelica dahurica* root that is sold and used as natural medicine in international trade, including Chinese materia medica (whole medicinal materials) and decoction pieces derived from the plant.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 18664, *Traditional Chinese Medicine — Determination of heavy metals in herbal medicines used in Traditional Chinese Medicine*

ISO 21371, *Traditional Chinese medicine — Labelling requirements of products intended for oral or topical use*

ISO 22217, *Traditional Chinese medicine — Storage requirements for raw materials and decoction pieces*

ISO 22258, *Traditional Chinese medicine — Determination of pesticide residues in natural products by gas chromatography*

ISO 23723, *Traditional Chinese medicine — General requirements for herbal raw material and materia medica*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <https://www.electropedia.org/>

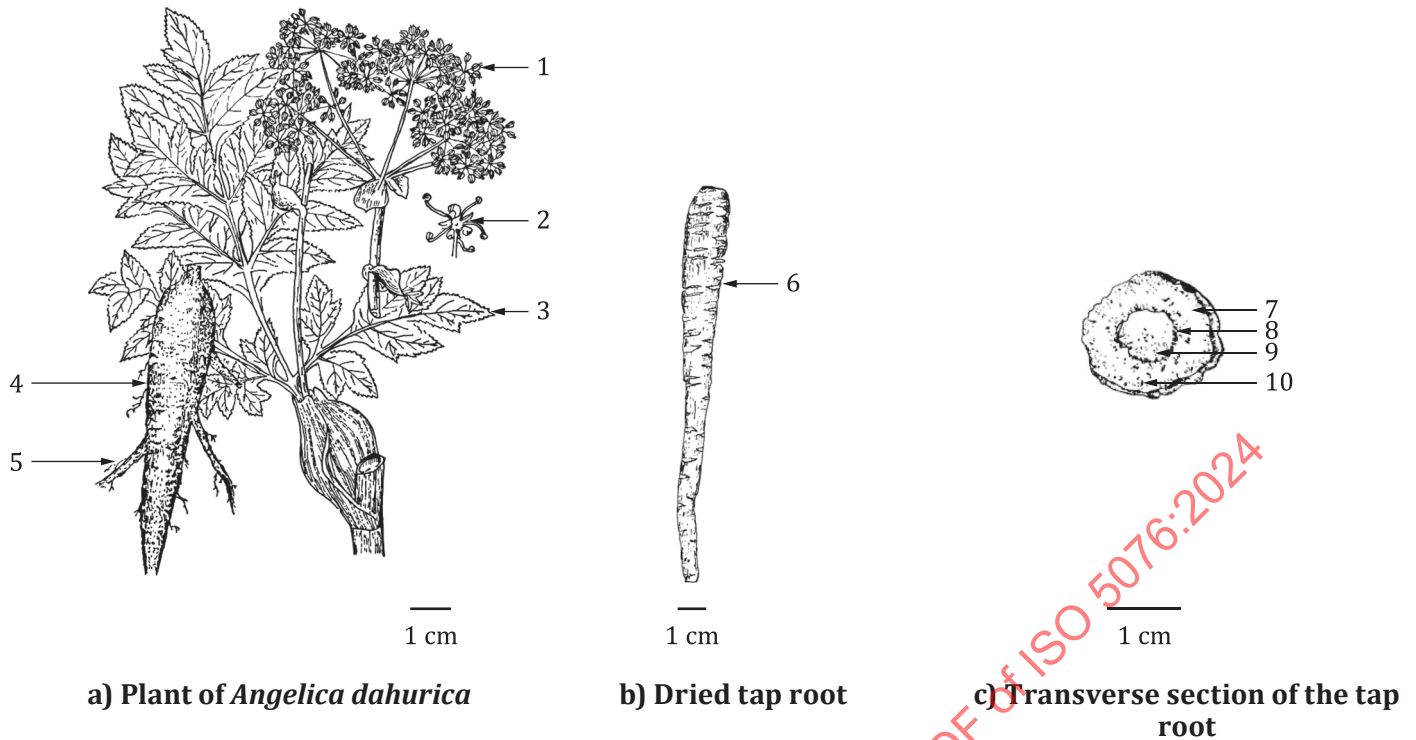
3.1

***Angelica dahurica* root**

dried root of *Angelica dahurica* (Fish.ex Hoffm.) Benth. et Hook. f. ex Franch. et Sav.

4 Descriptions

Angelica dahurica root is collected in summer or autumn with rootlets removed and dried in the sun or with other appropriate methods (see [Figure 1](#)).

**Key**

- 1 fruit
- 2 flower
- 3 leaf
- 4 tap root
- 5 secondary root
- 6 lenticel-like transverse protuberance
- 7 cortex
- 8 cambium
- 9 xylem
- 10 oil dot

Figure 1 — Structure of *Angelica dahurica***5 Quality and safety requirements and recommendations****5.1 General characteristics**

The following requirements shall be met before sampling.

- a) *Angelica dahurica* root shall be clean and free from rootlets and foreign matter.
- b) The presence of living insects, mouldy root and external contaminants which are visible to the naked eye shall not be permitted.

5.2 Morphological features

- a) The roots are long and conical.
- b) The roots are 10 cm to 25 cm long, with diameters of 1,5 cm to 2,5 cm.

- c) The outer surface is greyish-brown or yellowish-brown, the root stock obtusely quadrangular or subrounded, with longitudinal wrinkles, rootlet scars and lenticel-like transverse protuberances.
- d) The texture is compact.
- e) The fracture is starchy, white or grey-white. The cambium occurs as a brown ring; and many brown oil dots are visible in the cortex.
- f) The odour is aromatic.
- g) The taste is pungent and slightly bitter.

5.3 Thin-layer chromatogram (TLC) identification

The thin-layer chromatogram (TLC) of *Angelica dahurica* root should present the spots with the same colour and position corresponding to those of the reference solutions.

5.4 Moisture

The content of moisture as a mass fraction should be determined.

5.5 Total ash

The content of total ash as a mass fraction should not be more than 7,0 %.

5.6 Acid-insoluble ash

The acid-insoluble ash content as a mass fraction should be determined.

5.7 Dilute ethanol-soluble extractives

When it is measured, the content of dilute ethanol (50 %)-soluble extract as a mass fraction should not be less than 15,0 %.

5.8 Heavy metals

The contents of heavy metals, such as arsenic, mercury, lead and cadmium, shall be determined.

5.9 Pesticide residues

The contents of pesticide residues should be determined.

5.10 Marker compound

The content of marker compound such as imperatorin ($C_{16}H_{14}O_4$) should be determined.

6 Sampling

Sampling of *Angelica dahurica* root shall be carried out in accordance with the method specified in ISO 23723.

7 Test methods

7.1 Macroscopic identification

Samples are examined by the naked eye, tasted and smelled.

7.2 Thin-layer chromatogram (TLC) identification

See [Annex A](#) for additional information on thin-layer chromatogram (TLC) identification.

7.3 Determination of moisture content

The test method specified in ISO 23723 shall apply.

7.4 Determination of total ash content

The test method specified in ISO 23723 shall apply.

7.5 Determination of acid-insoluble ash content

The test method specified in ISO 23723 shall apply.

7.6 Determination of dilute ethanol-soluble extractives content

The test method specified in ISO 23723 shall apply.

7.7 Determination of heavy metal contents

The test method specified in ISO 18664 shall apply.

7.8 Determination of pesticide residues contents

The test method specified in ISO 22258 shall apply.

7.9 Determination of marker compound

See [Annex B](#) for additional information on determination of marker compound.

8 Test report

For each test method, the test report shall specify the following:

- a) all information necessary for the complete identification of the sample;
- b) the sampling method used;
- c) the test method used, with reference to this document;
- d) the test result(s) obtained;
- e) all operating details not specified in this international standard, or regarded as optional, together with details of any incidents which can have influenced the test result(s);
- f) any unusual features (anomalies) observed during the test;
- g) the date of the test.

9 Packaging, storage and transportation

The packaging and transportation shall not transmit any odour or flavour to the product and shall not contain substances which can damage the product or constitute a health risk. The packaging shall be strong enough to withstand normal handling and transportation.

The storage conditions specified in ISO 22217 shall apply.

The products shall be protected from light, moisture, pollution and entry of foreign substances during long distance delivery. Carriers should be well ventilated to stay dry and moisture-proof.

10 Marking and labelling

The following items shall be marked or labelled on the packages in accordance with the method specified in ISO 21371:

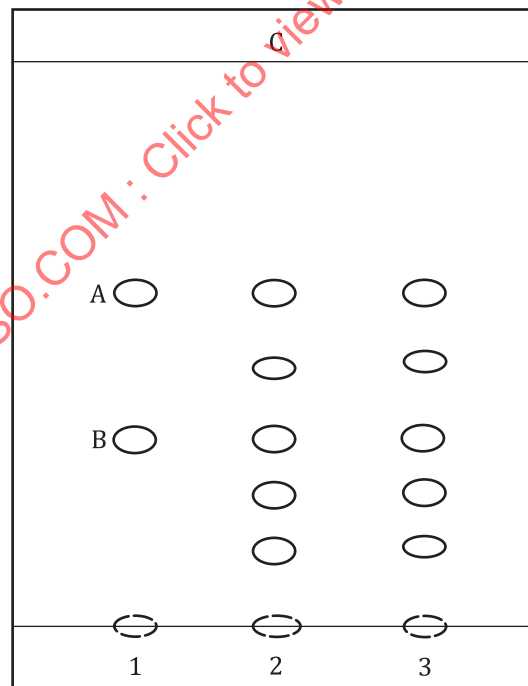
- a) all quality features indicated in [Clause 5](#), determined in accordance with methods specified in [Clause 7](#);
- b) gross mass and net mass of the package;
- c) country of origin and province or state of the products;
- d) date of production and expiry date of the products;
- e) storage and transportation method.

STANDARDSISO.COM : Click to view the full PDF of ISO 5076:2024

Annex A (informative)

Thin-layer chromatogram (TLC) identification

- Weigh 0,5 g of the powdered *Angelica dahurica* root being examined (through 50 mesh sieve), add 10 ml of ether, soak for 1 h and shake frequently, filter. Evaporate the filtrate to dryness and dissolve the residue in 1 ml of ethyl acetate as the test solution.
- Weigh 0,5 g of the powdered reference drug of *Angelica dahurica* root, add 10 ml of ether, soak for 1 h and shake frequently, filter. Evaporate the filtrate to dryness and dissolve the residue in 1 ml of ethyl acetate as the herbal reference solution.
- Dissolve imperatorin chemical reference substance (CRS) and isoimperatorin CRS in ethyl acetate to produce a mixture containing 1 mg of each per ml as the CRS reference solution.
- Carry out the method for thin layer chromatography, using silica gel G as the coating substance and a mixture of petroleum ether (30 °C to 60 °C) and ether (3:2) as the mobile phase. Apply separately 4 µl of the test solution, the herbal reference solution and the CRS reference solution to the silica gel G thin layer plate. Develop the plate at room temperature in a developing cylinder.
- After developing and removal of the plate, dry the plate in air, examine the plate under ultraviolet light at 365 nm. The fluorescent spots in the chromatogram obtained with the test solution correspond in position and colour to the spots in the chromatogram obtained with the reference solutions. Typical TLC chromatograms are shown in [Figure A.1](#).



Key

- A isoimperatorin
B imperatorin
C top of the plate

- 1 reference solution of imperatorin CRS and isoimperatorin CRS
- 2 test solution of *Angelica dahurica* root
- 3 herbal reference solution of *Angelica dahurica* root

Figure A.1 — Schematic diagram of typical TLC chromatograms of *Angelica dahurica* root

STANDARDSISO.COM : Click to view the full PDF of ISO 5076:2024

Annex B (informative)

Determination of marker compound

B.1 Preparation of test solution

Weigh 0,4 g of the powdered *Angelica dahurica* root sample (through 50 mesh sieve) to a 50 ml volumetric flask, add 45 ml of methanol, ultrasonicate (power, 300 W, frequency, 50 kHz) for 1 h, cool, dilute with methanol to volume, mix well, filter and use the successive filtrate as the test solution.

B.2 Preparation of reference solution

Weigh a quantity of imperatorin CRS in [Table B.1](#), dissolve in methanol to produce a solution containing 10 µg of imperatorin CRS per millilitre as the reference solution.

Table B.1 — Structural information of imperatorin

Name	Molecular formula	CAS Registry Number	Molecular mass
imperatorin	C ₁₆ H ₁₄ O ₄	482-44-0	270,28

B.3 Chromatographic conditions

- Stationary phase: octadecylsilane bonded silica gel
- Column size: 4,6 µm, 5 mm × 250 mm
- Mobile phase: a mixture of methanol and water (65:35, volume fraction)
- Flow rate: 1,0 ml/min
- Injection volume: 20 µl
- Temperature of column oven: 30 °C
- Detector: a spectrophotometer set at 300 nm

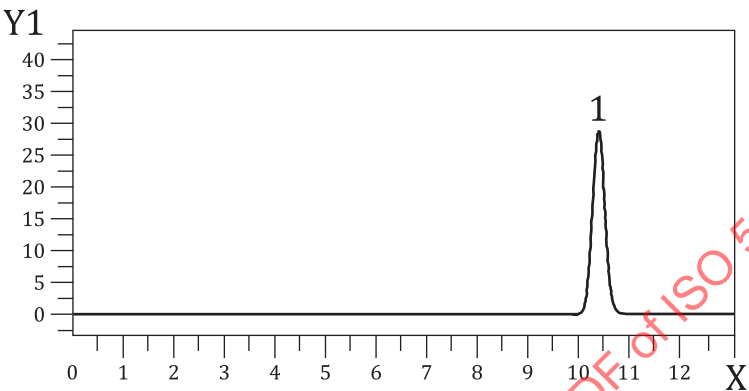
B.4 Determination

Inject 20 µl of the reference solution and the test solution into the column respectively and calculate the content of imperatorin in mass fraction with reference to the dried drug. Validate the methodology for accuracy, precision, and repeatability if necessary. A typical HPLC-UV chromatogram of *Angelica dahurica* root is shown in [Figure B.1](#).

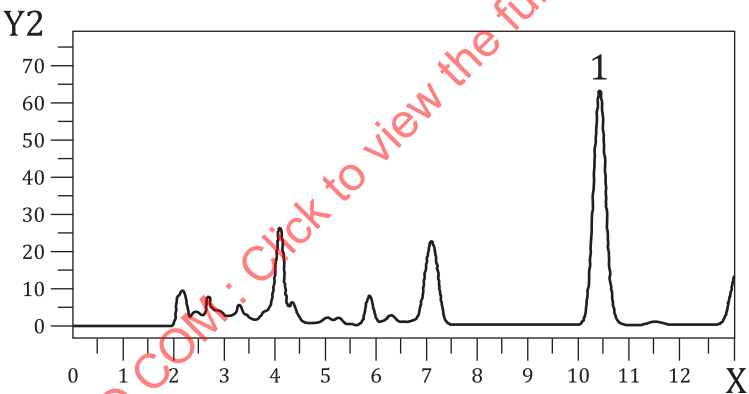
$$M_m = \frac{C_m \times 10^{-3} \times 100}{m \times (1 - W_M)} \times 100 \% \quad (B.1)$$

where

- M_m is the mass fraction of imperatorin (%);
- C_m is the average content of imperatorin of the sample (mg/ml);
- m is the mass of *Angelica dahurica* root taken to prepare the test solution (g);
- W_M is the moisture content of the sample (%).



a) HPLC-UV chromatogram of imperatorin reference solution



b) HPLC-UV chromatogram of *Angelica dahurica* root test solution

- Key**
- X min
 - Y1, Y2 mAU
 - 1 imperatorin

Figure B.1 — Typical HPLC-UV chromatogram of *Angelica dahurica* root

Annex C

(informative)

Reference information of national and regional requirements

Different countries and regions give their own quality requirement items on *Angelica dahurica* root as shown in [Table C.1](#).

Table C.1 — National and regional quality requirement items of *Angelica dahurica* root

Items		Chinese Pharmacopoeia (Ch. P) 2020 edition ^[1]	European Pharmacopoeia (EP) 10.0 edition ^[3]	Japanese Pharmacopoeia (JP) 18 th edition ^[4]	Korean Pharmacopoeia (KP) 12 th edition ^[5]
Plant origin		<i>Angelica dahurica</i> (Fish. ex Hoffm.) Benth. et Hook.f. ex Franch. et Sav.	<i>Angelica dahurica</i> (Fish. ex Hoffm.) Benth. et Hook.f. ex Franch. et Sav.	<i>Angelica dahurica</i> (Fish. ex Hoffm.) Benth. et Hook.f. ex Franch. et Sav.	<i>Angelica dahurica</i> Benth. et Hooker f.
		<i>Angelica dahurica</i> (Fish. ex Hoffm.) Benth. et Hook.f. var. <i>formosana</i> (Boiss.) Shan et Yuan			<i>Angelica dahurica</i> Benth. et Hooker f. var. <i>formosana</i> Shan et Yuan
Identification		TLC	TLC	Fluorometry	TLC
Moisture		≤ 14,0 %	≤ 12,0 %	—	—
Total ash		≤ 6,0 %	≤ 6,0 %	≤ 7,0 %	≤ 7,0 %
Acid-insoluble ash		—	≤ 1,5 %	≤ 2,0 %	≤ 2,0 %
Dilute ethanol (50 %)-soluble extractives		≥ 15,0 %	—	≥ 25,0 %	≥ 25,0 %
Heavy metals	Lead	≤ 5,0 mg/kg	≤ 5,0 ppm	a	≤ 5,0 ppm
	Cadmium	≤ 1,0 mg/kg	≤ 1,0 ppm		≤ 0,3 ppm
	Mercury	≤ 0,2 mg/kg	≤ 0,1 ppm		≤ 0,2 ppm
	Arsenic	≤ 2,0 mg/kg	—	≤ 5,0 ppm	≤ 3,0 ppm
Pesticide residuals	Total DDT	33 kinds of pesticides shall not be detected	69 kinds of pesticide residues shall meet the limits	—	≤ 0,1 ppm
	Endrin				≤ 0,01 ppm
	Total BHC				≤ 0,2 ppm
	Aldrin				≤ 0,01 ppm
	Dieldrin				≤ 0,01 ppm
Sulfur dioxide		—	—	—	≤ 30 ppm

Key

— not required

ppm parts per million

DDT dichlorodiphenyltrichloroethane

BHC benzene hexachloride

^a The heavy metals are the metallic inclusions that are darkened with sodium sulfide test solution in acidic solution, as their quantity is expressed in terms of the quantity of lead (Pb), not more than 10 ppm.