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Rubber and plastics gloves for food services — Limits for extractable substances

Gants en caoutchouc et en plastique pour les services alimentaires — Limites pour les substances extractibles

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Foreword

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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 documents 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).

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For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 45, *Rubber and rubber products*, Subcommittee SC 4, *Products (other than hoses)*.

Rubber and plastics gloves for food services — Limits for extractable substances

WARNING — Persons using this International Standard should be familiar with normal laboratory practice. This International Standard does not purport to address all of the safety problems, if any, associated with its use. It is the responsibility of the user to establish appropriate safety and health practices and to ensure compliance with any national regulatory conditions.

1 Scope

This International Standard specifies limits for extractable chemical substances for single-use gloves made from natural rubber, synthetic rubber, or plastic materials that are intended for use in food preparation, food handling, and related application in food service industry.

This International Standard does not cover the specification for extractable biological substances and physical requirements of the gloves. It is not applicable to gloves used under extreme conditions such as those having pH less than 4,5 and/or temperature above 40 °C. This International Standard does not cover gloves being exposed to fat and oil foods.

NOTE The physical requirements specified for gloves could be found in related International Standards, for example, ISO 11193-1 and ISO 11193-2.

This International Standard does not cover safe and proper application of the gloves with subsequent handling, packaging, and storage procedures.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

EN 14372:2004, *Child use and care articles – Cutlery and feeding utensils – Safety requirements and tests*

3 Types

Gloves are classified into the following types:

a) type 1: natural rubber latex;

b) type 2: synthetic latex;

c) type 3: polyvinyl chloride (PVC);

d) type 4: polyethylene (PE);

e) type 5: polypropylene (PP).

NOTE Gloves made from blend polymer are not covered in this International Standard.

4 Requirements

4.1 Allowable limits of extractable substances from the gloves

The allowable extractable substances for all types of glove shall not exceed the limits presented in Table 1.

Determination of the extractable substances shall be carried out according to the test methods given in Table 1.

Table 1 — Maximum limits for allowable extractable substances from food-contact gloves

Parameters	Maximum limit	Test methods
Heavy metals, µg/ml	See Table 2	Annex A
Potassium permanganate consumption, µg/ml	≤10	Annex B
Evaporation residue, µg/ml		
Distilled water	≤100	Annex C
10 % ethanol	≤100	

4.2 Heavy metals

The heavy metals shall not exceed the limits given in Table 2 when tested in accordance with Annex A.

Table 2 — Limits of heavy metals

Element	Maximum limit µg/ml
Arsenic, As	0,05
Cadmium, Cd	0,05
Chromium, Cr	0,5
Lead, Pb	0,5
Zinc, Zn	15,0

4.3 Phthalate content

The total content of phthalate for Type 3 glove shall not exceed 0,1 % (m/m). The determination of phthalate content shall be carried out as described in Annex D, or in 6.3.2 of EN 14372.

5 Sample preparation

5.1 Determination of heavy metals

Cut one piece of 5 cm × 5 cm test sample to provide a surface area of 50 cm^2 taken from the palm or the back of a glove.

The extraction is done by immersing the test piece in a container of 100 ml of the recommended extraction medium. Use water bath to control the temperature, according to the condition given in Table 3.

After extraction, remove the test piece from the container and keep the solution for the determination of heavy metals.

Table 3 — Conditions for sample preparation

Parameters	Extraction medium	Conditions
Heavy metals	4 % acetic acid	(40 ± 1) °C for (10 ± 1) min
Potassium permanganate consumption	Distilled water	(40 ± 1) °C for (10 ± 1) min
Evaporation residue	Distilled water 10 % ethanol	(40 ± 1) °C for (10 ± 1) min

5.2 Determination of potassium permanganate consumption and the evaporation residue

Cut two pieces of 5 cm × 5 cm from the palm or the back of gloves to provide a total surface area of 100 cm^2. Wash the test samples with distilled water to remove any lubricant or powder used to prevent the gloves from sticking together.

The extraction is done by immersing the test pieces in a container of 200 ml of the recommended extraction medium. Use water bath to control the temperature, according to the condition given in Table 3.

After extraction, remove the test pieces from the container and keep the solution for the determination of potassium permanganate consumption and the evaporation residue.

5.3 Determination of the phthalate content

The extraction procedure is as described in Annex D, or in EN 14372.

6 Provision for use

6.1 The manufacturer shall provide information on the provision of the gloves for application in wet or dry conditions.

6.2 The glove should remain intact after exposure to wet surfaces throughout the food preparation or handling processes as recommended by the manufacturer.

6.3 The glove shall be used only once.

7 Labelling and marking

7.1 The language used for labelling and marking shall be as agreed upon between the interested parties.

7.2 Information provided shall be at the box or packaging container.

7.3 Appropriate labelling for food service gloves shall include instructions for use that identify materials or conditions with which contact should be avoided.

7.4 Gloves made of natural rubber latex shall be provided with the following label: “Natural rubber latex, which may cause an allergic reaction has been used in the manufacturing of this product”, or words to that effect.

Annex A
(normative)

Determination of heavy metals

A.1 Principle

This test procedure describes the method for the determination of an individual heavy metal element extracted from gloves using inductively coupled plasma optical emission spectroscopy (ICP-OES). The basis of the method is the measurement of emission of light by an optical spectroscopic technique. The sample solutions are nebulized and the aerosol that is produced is transported to the plasma torch where the excitation occurs. Characteristic emission spectra are produced by radio frequency inductively coupled plasma (ICP). The spectra are dispersed by a grating spectrometer and the intensities of the lines are monitored by a detector. The signals from the detector(s) are processed and controlled by a computer system. A suitable background correction technique is used to compensate for variable background contributions to the determination of trace elements.

A.2 Apparatus

Use usual laboratory apparatus and, in particular, the following.

A.2.1 ICP-OES, equipment consisting of sample holder, plasma torch, spray chamber, nebulizer, optical unit, detector, system control, and data output device.

NOTE Detailed operating instructions is not provided due to the differences between various makers and models.

A.2.2 Analytical balance, capable of measuring accurately up to 0,0001 g.

A.2.3 Containers, for storage of standard solution and calibrant.

NOTE All containers shall be cleaned with 10 % (v/v) nitric acid before use.

A.2.4 Glassware, all glassware shall be soaked with 10 % (v/v) nitric acid at least 24 h before use.

A.2.4.1 Glass beakers, of suitable capacity.

A.2.4.2 Volumetric flasks, of suitable size.

A.2.4.3 Erlenmeyer flask.

A.2.4.4 Pipette.

A.2.4.5 Funnel.

A.2.5 Micropipettes.

A.3 Reagents

A.3.1 Argon gas, gas with purity of over 99,99 % (v/v).

A.3.2 Nitrogen gas, gas with purity of over 99,99 % (v/v).

A.3.3 Nitric acid, $\rho(HNO_3)$ = 1,4 g/ml [w(HNO_3) = 650 g/kg].

A.3.4 Deionised water.

A.3.5 Nitric acid solution 5 % (v/v), prepare by adding 50 ml of nitric acid (**A.3.3**) to deionised water (**A.3.4**) and bring the volume to 1 000 ml of volumetric flask (**A.2.4.2**).

A.3.6 Standard stock solutions, 100 mg/l of arsenic (As), cadmium (Cd), chromium (Cr), lead (Pb), and zinc (Zn).

NOTE Standard stock solutions of other concentrations can be used. The standard stock solutions can be purchased or prepared from high purity grade chemicals or metals. Traceable standard solutions might be preferred.

A.4 Standard solutions

The following standard solutions for the five elements, i.e. arsenic (As), cadmium (Cd), chromium (Cr), lead (Pb), and zinc (Zn) shall be prepared.

A.4.1 Standard solution of 100 µg/l

Pipette 50 µl of standard stock solution of the element standard (A.3.6) in a 50 ml volumetric flask. Add 5 % nitric acid solution (A.3.5) to bring the total volume of 50 ml.

A.4.2 Standard solution of 500 µg/l

Pipette 250 µl of standard stock solution of the element standard (A.3.6) in a 50 ml volumetric flask. Add 5 % nitric acid solution (A.3.5) to bring the total volume of 50 ml.

A.4.3 Standard solution of 1 000 µg/l

Pipette 500 µl of standard stock solution of the element standard (A.3.6) in a 50 ml volumetric flask. Add 5 % nitric acid solution (A.3.5) to bring the total volume of 50 ml.

A.5 Laboratory reagent blank

The procedure is identical to that of sample solution preparation and is carried out concurrently but without the sample.

A.6 Determination

A.6.1 General

A.6.1.1 Set up the instrument with proper operating parameters established from the manufacturer’s instruction manual. Allow the instrument to achieve thermal stability before beginning. Instructions provided by the manufacturer should be followed.

A.6.1.2 Initiate the appropriate operating configuration of the computer.

A.6.1.3 Profile and calibrate the instrument according to the manufacturer's recommended procedures using the standard solutions (A.4).

A.6.1.4 Begin the sample run by flushing the system with the reagent blank (A.5) between each sample.

A.6.2 Recommended wavelengths and important spectral interferences

Table A.1 lists the recommended wavelengths and the important spectral interferences.

Table A.1 — Recommended wavelengths and the important spectral interferences

Element	Wavelength nm	Interfering elements
As	188,979	Al, Cr, Fe, Ti
	193,696	Al, Co, Fe, W, V
	197,197	Al, Co, Fe, Pb, Ti
Cd	214,441	As, Cr, Fe, Sc, Sb
	226,502	As, Co, Fe, Ni
	228,802	As, Co, Sc
Cr	205,559	Be, Fe, Mo, Ni, Ti
	267,719	Mn, P, V
	283,563	Fe, Mo, V, W
	284,324	Fe
Pb	220,353	Al, Co, Fe, Ti
	283,305	Cr, Fe
Zn	202,548	Cr, Cu, Co, Ni
	206,200	Cr
	213,857	Cu, Fe, Ni

NOTE 1 The choice of wavelengths for a specific instrument should be carried out with respect to the manufacturer's recommendation.

NOTE 2 Wavelengths in this table are taken from ISO 11885:2007.

A.6.3 Limit of detection

A.6.3.1 The limit of detection, expressed as the concentration or the quantity, is derived from the smallest measure that can be detected with reasonable certainty for a given analytical procedure (IUPAC).

NOTE IUPAC - International Union of Pure and Applied Chemistry.

A.6.3.2 The limit of detection (LOD) shall be calculated using Formula (A.1):

$$\mathrm{LOD} = 3 \times sd \quad \text{(A.1)}$$

where *sd* is the standard deviation of the outlier-free results of at least three measurements of a reagent blank solution (A.5).

A.6.3.3 Actual working detection limits are dependent on the type of instrumentation, detection device and sample introduction system used, and on the sample matrix. Therefore, these concentrations can vary between different instruments.

A.7 Expression of results

State as many significant figures as acceptable, but not more than three significant figures, according to the precision of the measuring values.

EXAMPLE 1 Lead (Pb) 0,042 µg/ml.

EXAMPLE 2 Zinc (Zn) 3,9 µg/ml.

Annex B
(normative)

Determination of potassium permanganate consumption

B.1 Principle

Determination of the amount of a material that is oxidized by potassium permanganate after the glove sample is extracted in water.

B.2 Apparatus

Use typical laboratory apparatus and, in particular, the following.

B.2.1 Erlenmeyer flask, of 100 ml capacity.

B.2.2 Balance, accurate up to 0,000 1 g.

B.3 Reagents

Use only reagents of recognized analytical grade, except for reference materials and distilled water.

B.3.1 Potassium permanganate standard solution ($KMnO_4$), 0,002 M.

B.3.2 Sulphuric acid (H_2SO_4), containing 1:2 of H_2SO_4:H_2O.

B.3.3 Sodium oxalate standard solution ($Na_2C_2O_4$), 0,005 M.

B.3.4 Distilled water.

B.4 Standard solutions

B.4.1 Potassium permanganate standard solution (0,002 M)

Dissolve approximately 0,33 g of potassium permanganate in water to bring the total volume to 1 000 ml. Store in a light-blocking stoppered bottle. When needed, use 0,005 M sodium oxalate solution to standardize.

B.4.2 Sodium oxalate standard solution (0,005 M)

Dissolve 0,670 0 g of anhydrous sodium oxalate in water to bring the total volume to 1 000 ml. Store in a light-blocking stoppered bottle. Use within a month of preparation.

B.5 Determination

Add 100 ml of water, 5 ml of sulphuric acid, 5 ml of potassium permanganate into an Erlenmeyer flask. Boil for 5 min, then discard the solution and wash the flask with water.

Add 100 ml of sample solution, 5 ml of sulphuric acid, and 10 ml of potassium permanganate. Boil for 5 min. For a blank solution, use 100 ml of distilled water instead of the sample solution.

Immediately after boiling, remove the flask from the hot plate and add 10 ml of sodium oxalate to decolourise the solution. Titrate the solution with 0,002 M potassium permanganate until a slight red colour remains in the solution without fading away.

B.6 Expression of result

The potassium permanganate consumption is determined using Formula (B.1):

$$\text{Potassium permanganate consumed } (\mu\text{g/ml}) = \frac{(a-b)\times 0{,}316\times f\times 1\,000}{100} \qquad \text{(B.1)}$$

where

a is the amount of 0,002 M potassium permanganate used for the sample solution test, expressed in millilitres;

b is the amount of 0,002 M potassium permanganate used for the blank test, expressed in millilitres;

f is the factor for 0,002 M potassium permanganate.

Annex C
(normative)

Determination of evaporated residue

C.1 Principle

Determination of the amount of substances transported from the sample into an extraction solution.

C.2 Apparatus

Use typical laboratory apparatus and, in particular, the following.

C.2.1 Erlenmeyer flasks, of 100 ml, 250 ml, and 500 ml capacity.

C.2.2 Evaporating dish.

C.2.3 Water bath.

C.2.4 Desiccators.

C.2.5 Balance, accurate up to 0,000 1 g.

C.3 Reagents

C.3.1 Ethanol (C_2H_6O), 10 %.

C.3.2 Distilled water.

C.4 Determination

Place an empty evaporating dish in a normal oven for 1 h at 105 °C, let it cool in a desiccator and weigh. Place 100 ml of a sample solution in the evaporation dish and heat on a water bath until the solution evaporates to dryness.

After drying, place the evaporating dish in the oven for further 2 h at 105 °C, let it cool in a desiccator and re-weigh.

For a blank solution, place 100 ml of the same the extraction medium in an evaporation dish and conduct the test using the same procedure.

C.5 Expression of result

The evaporation residue is determined using Formula (C.1):

$$\text{Evaporation residue } (\mu\text{g/ml}) = \frac{(a-b)\times 1\,000}{v} \tag{C.1}$$

where

a is the amount of residue obtained from the sample solution, expressed in milligrams;

b is the amount of residue obtained from the blank solution, expressed in milligrams;

v is the volume of the sample solution used, expressed in millilitres.

Annex D
(normative)

Determination of phthalate content

D.1 Principle

To extract, identify and quantify monomeric phthalates (with wider application to other types of plasticisers) contained in PVC samples. The extraction method uses Soxhlet extraction apparatus with diethyl ether. The total diethyl ether extractable plasticiser content is calculated by mass with gas chromatography-mass spectroscopy (GC-MS) detection to identify and quantify individual phthalates.

D.2 Apparatus

Use typical laboratory apparatus and, in particular, the following.

D.2.1 Balance, accurate up to 0,000 1 g.

D.2.2 Oven.

D.2.3 Soxhlet extractor with siphon cup.

D.24 Soxhlet thimble.

D.2.5 Condenser.

D.2.6 Steam bath.

D.2.7 Desiccator.

D.2.8 Flat bottom flask, of 150 ml capacity.

D.2.9 Volumetric flask, of 200 ml capacity.

D.2.10 Gas chromatography-mass spectrometer.

D.3 Reagents

Use reagents of analytical grade.

D.3.1 Diethyl ether.

D.3.2 *n*-hexane.

D.3.3 Di-isononyl phthalate (DINP), CAS No. 28553-12-0.

D.3.4 Di-(2-ethylhexyl) phthalate (DEHP), CAS No. 117-81-7.

D.3.5 Di-*n*-octyl phthalate (DNOP), CAS No. 117-84-0.

D.3.6 Di-iso-decyl phthalate (DIDP), CAS No. 26761-40-0.

D.3.7 Butyl benzyl phthalate (BBP), CAS No. 85-68-7.

D.3.8 Di-butyl phthalate (DBP), CAS No. 84-74-2.

D.4 Standard solutions

Prepare a series of individual stock standard solutions of the individual phthalate esters in *n*-hexane as shown in Table D.1.

Table D.1 — Stock solutions

Phthalate ester	DIDP	DINP	DBP	BBP	DNOP	DEHP
Concentration, µg/ml	5 000	5 000	200	200	200	200

Where appropriate from the stock standard solutions, prepare two sets of five phthalate esters GC-MS calibration solutions in *n*-hexane to the maximum linear concentration shown in Table D.2 (Calibration Set 1), and Table D.3 (Calibration Set 2).

Table D.2 — Calibration Set 1

Phthalate ester	DINP	DBP	BBP	DEHP
Concentration, µg/ml	5 000	20	20	20

Table D.3 — Calibration Set 2

Phthalate ester	DIDP	DNOP
Concentration, µg/ml	5 000	20

D.5 Determination

D.5.1 Sampling, extraction, and gravimetric analysis for phthalate plasticisers

D.5.1.1 Place the sample in a pre-weighed 150 ml flat bottom flask and heat in an oven at (105 ± 5) °C for (30 ± 5) min. Allow to cool in a desiccator.

D.5.1.2 Weigh the flask and sample. Use a scalpel or other appropriate cutting utensil to cut a representative portion from the sample into small pieces, $\Phi < 5$ mm.

D.5.1.3 Weigh accurately (2 ± 0,2) g of the pieces into a Soxhlet thimble and add cotton wool to the top of the thimble.

D.5.1.4 Add approximately (50 ± 10) ml of diethyl ether into the flask. Reflux gently for 6 h ± 30 min. Allow sufficient time for the diethyl ether to cool.

D.5.1.5 Evaporate the diethyl ether completely by mean of steam bath.

D.5.1.6 Place the flask in an oven at (105 ± 5) °C for (30 ± 5) min. Allow to cool in a desiccator and weigh.

D.5.1.7 Repeat the drying and cooling cycles until the difference between two consecutive weighings are not more than 0,0005 g. A blank solution shall be run consecutively.

D.5.2 Preparation of sample extract solution for gas chromatography-mass spectrometry (GC-MS)

D.5.2.1 To the weighed extract (D.5.1), add (50 ± 2) ml of *n*-hexane.

D.5.2.2 Place a stopper to the flask and swirl to completely dissolve the extract.

D.5.2.3 Decant the solution into a 200 ml volumetric flask, repeatedly rinsing the flask with *n*-hexane.

D.5.2.4 Add *n*-hexane to the volumetric flask to bring the total volume to 200 ml.

D.5.2.5 Prepare (if necessary) further diluted solutions using n-hexane such that the final concentration in solution is within the linear calibration concentration for phthalate present.

D.5.2.6 Transfer a portion of the *n*-hexane solution into a capped vial for GC-MS analysis.

D.5.2.7 The samples can be analysed for phthalate plasticisers by conditioning the GC-MS as follows.

For gas chromatograph (GC) Model 5890[1] with a Hewlett Packard 5971A[2] Mass Selective Device (MSD) with scan range 50 atomic mass unit to 500 atomic mass unit, and column 30 m, 0,25 mm I.D. and 0,15 µm film thickness, 50 % dimethyl to 50 % diphenyl-polysiloxane, e.g. DB-17HT.

Carrier gas:	Helium
Flow rate:	0,8 ml/min
Injector temperature:	290 °C
Injection volume:	2 µl
Injection type:	Splitless
Detector:	MSD
Transfer line temperature:	280 °C
MSD mode:	Electron impact
Temperature programme:	40 °C for 4 min.
	From 40 °C to 300 °C at 10 °C/min.
	Isothermal 4,00 min.
	Total run time is 34 min.

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[1] This information is given for the convenience of users of this International Standard and does not constitute an endorsement by ISO of the product named. Equivalent products can be used if they can be shown to lead to the same results.

[2] This information is given for the convenience of users of this International Standard and does not constitute an endorsement by ISO of the product named. Equivalent products can be used if they can be shown to lead to the same results.

Because of the differences between various makers and models of satisfactory instruments, the instructions provided by the manufacturer of the particular instrument can be used.

D.6 Expression of results

D.6.1 Compare the obtained GC-MS spectra to known spectra of phthalate ester standards to allow qualitative identification of phthalate ester plasticisers or any other compounds.

D.6.2 Plot a calibration graph of the response against the known standard concentrations.

D.6.3 From the calibration graph determine the response of phthalate ester found in the blank and sample. Interpolate the concentration of phthalate ester in µg/ml correcting for any dilutions as follows.

a) Gravimetric analysis:

$$\% \text{ extract (m/m)} = \frac{w_E}{w_S} \times 100 \qquad \text{(D.1)}$$

where

w_E is the weight of the extract, expressed in grams;

w_S is the weight of the sample, expressed in grams.

b) GC-MS analysis:

$$\% \text{ extract (m/m)} = \frac{E_S}{w_S} \times \frac{200 \text{ ml}}{10\,000} \times d_f \qquad \text{(D.2)}$$

where

E_S is the extract of the solution, expressed in micrograms per millilitres;

w_S is the weight of the sample, expressed in grams;

d_f is the dilution factor.