BS ISO 14285:2014

BSI Standards Publication

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

bsi.

...making excellence a habit.™

Document Sharing Hub

Full document details: BS ISO 14285:2014

National foreword

This British Standard is the UK implementation of ISO 14285:2014.

The UK participation in its preparation was entrusted to Technical Committee CH/205/3, Medical gloves.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

© The British Standards Institution 2014. Published by BSI Standards Limited 2014

ISBN 978 0 580 69660 2

ICS 67.250; 83.140.99

Compliance with a British Standard cannot confer immunity from legal obligations.

This British Standard was published under the authority of the Standards Policy and Strategy Committee on 28 February 2014.

Amendments issued since publication

Date	Text affected

Documents
Document Sharing Hub

Full document details: BS ISO 14285:2014

INTERNATIONAL STANDARD

ISO 14285

First edition
2014-02-15

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

Reference number
ISO 14285:2014(E)

Documents
Document Sharing Hub

© ISO 2014

Full document details: BS ISO 14285:2014

COPYRIGHT PROTECTED DOCUMENT

© ISO 2014

All rights reserved. Unless otherwise specified, 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
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

Published in Switzerland

© ISO 2014 – All rights reserved

Documents
Document Sharing Hub

Full document details: BS ISO 14285:2014

Contents

Page

Foreword ..... **iv**

1 Scope **1**

2 Normative references **1**

3 Types **1**

4 Requirements **2**
4.1 Allowable limits of extractable substances from the gloves 2
4.2 Heavy metals 2
4.3 Phthalate content 2

5 Sample preparation **2**
5.1 Determination of heavy metals 2
5.2 Determination of potassium permanganate consumption and the evaporation residue 3
5.3 Determination of the phthalate content 3

6 Provision for use **3**

7 Labelling and marking **3**

Annex A (normative) **Determination of heavy metals** **4**

Annex B (normative) **Determination of potassium permanganate consumption** **8**

Annex C (normative) **Determination of evaporated residue** **10**

Annex D (normative) **Determination of phthalate content** **12**

Annex E (informative) **Precision** **16**

Bibliography **18**

© ISO 2014 – All rights reserved

Documents
Document Sharing Hub
Full document details: BS ISO 14285:2014

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 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).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

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

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)*.

© ISO 2014 – All rights reserved
Documents
Document Sharing Hub
Full document details: BS ISO 14285:2014

INTERNATIONAL STANDARD ISO 14285:2014(E)

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.

© ISO 2014 – All rights reserved

Documents
Document Sharing Hub
Full document details: BS ISO 14285:2014

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		Annex C
Distilled water	≤100	
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.

© ISO 2014 – All rights reserved
Documents
Document Sharing Hub
Full document details: BS ISO 14285:2014

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.

© ISO 2014 – All rights reserved

Documents
Document Sharing Hub
Full document details: BS ISO 14285:2014