INTERNATIONAL STANDARD

ISO 8670-3

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Ostomy collection bags —

Part 3: Determination of odour transmission of colostomy and ileostomy bags

Poches de recueil pour stomie —

Partie 3: Détermination de la fuite d'odeur des poches de recueil pour colostomie et iléostomie

Reference number
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Foreword

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International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 3.

Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this part of ISO 8670 may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

International Standard ISO 8670-3 was prepared by Technical Committee ISO/TC 173, *Technical systems and aids for disabled or handicapped persons*, Subcommittee SC 3, *Aids for ostomy and incontinence*.

ISO 8670 consists of the following parts, under the general title *Ostomy collection bags*:

— *Part 1: Vocabulary*

— *Part 2: Requirements and test methods*

— *Part 3: Determination of odour transmission of colostomy and ileostomy bags*

Introduction

This test is designed to determine the odour transmission of one-piece and multiple-piece ostomy bag systems. Good odour barrier properties are very important for ostomy bags. Detection of oxygen transmission is usually used to assess the efficacy of barrier materials against odour transmission, but this measurement is not always helpful in choosing suitable materials for ostomy bags because odour barrier properties are not always related to oxygen transmission. The organoleptic test described has been found to distinguish between systems which are considered to be odour-proof and those which are not. By enclosing the bag in a glass jar, any significant transmission of odour through the film will build up into a strong odour. In this method, as in practice, any faint odours will dissipate and be unnoticeable.

Ostomy collection bags —

Part 3:
Determination of odour transmission of colostomy and ileostomy bags

1 Scope

This part of ISO 8670 specifies a test method for the determination of odour transmission of colostomy and ileostomy bags. This method covers one-piece and multiple-piece systems having both closed-, and open-ended bags.

2 Terms and definitions

For the purposes of this part of ISO 8670, the following terms and definitions apply.

2.1
ostomy bag
flexible container for collecting body effluent from a stoma

[ISO 8670-1:1988, 2.1]

2.2
closed-ended bag
flexible container, without an opening for drainage, for collecting body effluent from a stoma

NOTE Adapted from ISO 8670-1:1988, 2.3.

2.3
open-ended bag
flexible container, with an opening for drainage, for collecting body effluent from a stoma

NOTE Adapted from ISO 8670-1:1988, 2.4.

2.4
one-piece ostomy system
effluent collection system in which all the component parts are removed from the body when the bag is changed

[ISO 8670-1:1988, 2.8]

2.5
multiple-piece flange system
effluent collection system in which a component is positioned around the stoma; this component allows an effluent collection bag to be attached or removed, while itself remaining in position

NOTE This definition also includes two-piece ostomy system [ISO 8670-1:1988, 2.9] and multiple-piece flange system [ISO 8670-2:1996, 2.4].

2.6
stoma
abnormal opening established on the body surface

[ISO 8670-2:1996, 2.10]

3 Principle

Odoriferous material (fresh onion) is sealed inside an ostomy bag. The ostomy bag is placed in a sealed jar and the jar sniffed after four hours to detect whether a strong onion odour is transmitted through the bag.

4 Reagents

4.1 **Fresh onion** (*Allium cepa*).

4.2 **Distilled** or **deionized water**.

5 Apparatus

5.1 **Glass jar**, of capacity 2,0 l ± 1,0 l with a top opening of 100 mm ± 50 mm diameter, capable of being sealed by means of a glass or metal lid.

5.2 **Glass beakers**, of a suitable size to fit inside the glass jar.

5.3 **Water bath** or **oven**, capable of being controlled at 34 °C ± 1 °C.

5.4 **Stopwatch**, or other similar timing device.

5.5 Stainless steel **chopping knife** or **mechanical chopping device**.

NOTE A blender (mixer) is suitable for the purpose of this test.

5.6 **Balance**, or similar weighing device with an accuracy of at least ± 0,1 g.

5.7 **Equipment**, for making welded joints in plastic materials.

5.8 Metal, plastic or glass **plate** for closing the stoma opening of the bag. The plate shall be at least as big as the adhesive plate of the bag and it shall be impermeable to onion odour.

5.9 **Sealing film**, taken from another bag of the type being tested.

5.10 **Double-sided tape**.

6 Detection of odour

Three persons with normal sense of smell shall be chosen as sniffers to judge the presence of odour at the end of the test.

7 Procedure

7.1 If a filter is present, seal the filter from either the outside or the inside as appropriate by means of sealing bag film taken from another bag of the type being tested to which double-sided tape has been applied. The sealing film shall be stuck so that there is at least 10 mm width of seal around the filter.

7.2 When testing open-ended bags, the opening of the bag shall be sealed by welding.

7.3 When testing multiple-piece products, assemble the bag to the flange.

7.4 Chop the onions using the knife or the mechanical chopping device so that the pieces are less than 5 mm in size. Place 20 g ± 2 g in the bag through the bag opening, ensuring that none of the onion comes into contact with the outer surface of the bag or with the flange.

NOTE One way of avoiding contamination is to weigh the onion on a square of bag film, which is then folded over to make a parcel of the onion. The parcel is then inserted into the bag through the bag opening and the onion is released into the bag. The piece of used film is left in the bag during the test.

Cut onions shall be wrapped in aluminium foil and stored at room temperature no longer than 1 h before the test.

7.5 Seal the bag opening by means of a metal, plastic or glass plate, ensuring that there are no creases which could create leaks.

7.6 Add 50 ml ± 10 ml of water to the bottom of the jar and place the upturned beaker on the bottom of the jar to form a platform. Place the bag on top of the beaker in such a way that it is not in contact with the water. Seal the jar and place it in the water bath or oven at a temperature of 34 °C ± 1 °C. Start the stopwatch.

NOTE The purpose of the water is to create humidity in the jar similar to that found underneath clothing. The odour transmission properties of some materials are affected by humidity and temperature.

7.7 After 10 min open the jar and sniff for any onion odour. If odour is present, and suspected to be due to a false positive result, then repeat the test.

NOTE The purpose of the 10 min check is to overcome problems caused by contamination on the outside of the bag. It may well be that the breakthrough time is below 10 min and that is the reason for doing the 10 min check once only.

7.8 After a minimum of 4 h and a maximum of 4,5 h determine whether a strong odour of onion is detectable by the procedure given in 7.9.

7.9 Remove the closure from the jar and allow one sniffer to sniff the atmosphere inside the jar. Close the jar after a maximum time of 5 s. After a minimum of 1 min, remove the closure from the jar and allow the next sniffer to sample the atmosphere inside the jar. Repeat the procedure until each of the three sniffers has sampled the atmosphere inside the jar once.

Odour emanating from bag films and adhesives shall be ignored and only the odour due to onion shall be recorded.

NOTE The length of time for which the jar is opened is kept to a minimum to prevent the smell of onion decreasing.

It is recommended that a negative control is run using a bag with no onion, as bag films and adhesives may have odours of their own.

7.10 Record the result of the sniffing as either "strong odour" or "no odour". If the three sniffers are not in full agreement, a majority opinion shall be used.

"A majority opinion" means that if two out of three sniffers find a strong odour, the result is reported as "strong odour". If only one sniffer finds a strong odour, the result is reported as "no odour".

To determine what constitutes a "strong odour" it is recommended that a bag made from low-density polyethylene (LDPE) is used as a positive control.

7.11 Wash the jar thoroughly and change the water before the next test.

8 Test report

The test report shall include the following information:

a) reference to this part of ISO 8670;

b) the date of testing;

c) the identity of the bag;

d) whether a strong odour of onion was detectable in the jar at the end of the test period or whether there was no odour;

e) any deviation from the test procedure.

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