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Water-absorbent polyacrylate in urine absorbing products — Requirements

Polyacrylate hydrophile dans les produits pour absorption d'urine — Exigences

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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).

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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 173, *Assistive products*, Subcommittee SC 3, *Aids for ostomy and incontinence*.

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

This document is based on JIS S0251, developed by JHPIA (Japan Hygiene Products Industry Association) and JASPIA (Japan Superabsorbent Polymers Industry Association). It refers to methods that have been in use for several years to characterize the safety and performance of water-absorbent polyacrylate in urine absorbing products.

Product type names of absorbent incontinence products for urine and/or faeces are found in ISO 22748.

Water-absorbent polyacrylate in urine absorbing products — Requirements

1 Scope

This document specifies requirements for water-absorbent crosslinked polyacrylate in urine absorbing products.

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 17190-1, *Urine-absorbing aids for incontinence — Polyacrylate superabsorbent powders — Part 1: Test method for determination of pH*

ISO 17190-2, *Urine-absorbing aids for incontinence — Polyacrylate superabsorbent powders — Part 2: Test method for determination of the amount of residual acrylate monomers*

ISO 17190-3, *Urine-absorbing aids for incontinence — Polyacrylate superabsorbent powders — Part 3: Test method for determination of the particle size distribution by sieve fractionation*

ISO 17190-4, *Urine-absorbing aids for incontinence — Polyacrylate superabsorbent powders — Part 4: Test method for estimation of the moisture content as weight loss upon heating*

ISO 17190-6, *Urine-absorbing aids for incontinence — Polyacrylate superabsorbent powders — Part 6: Test method for determination of the fluid retention capacity in saline solution by gravimetric measurement following centrifugation*

ISO 17190-9, *Urine-absorbing aids for incontinence — Polyacrylate superabsorbent powders — Part 9: Test method for gravimetric determination of flow rate and bulk density*

The Japanese Pharmacopoeia 1.07 Heavy Metals Limit Test, Method 2

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
water-absorbent polyacrylate
powdered or fibrous resin comprising of polyacrylate that can absorb and retain water and/or aqueous solutions 10 times to 1 000 times its own weight

3.2
heavy metal
metallic inclusions that is darkened with sodium sulphide test solution in acidic solution

Note 1 to entry: The quantity of heavy metals is expressed in terms of the quantity of lead (Pb).

4 Requirements

4.1 Pass criteria

The pass criteria for a range of test methods for water-absorbent polyacrylate used in urine absorbing products shall be in accordance with Table 1.

Table 1 — Pass criteria

Property	Unit	Requirement	Test method
Absorbing capacity	g/g	≧10,0	ISO 17190-6
Residual monomer	mg/kg	≦1 000	ISO 17190-2
pH		4,5 to 8,0	ISO 17190-1
Moisture content	%	≦20,0	ISO 17190-4
Particle size distribution	%	≦1,0 % particles greater than 850 µm ≦1,0 % particles smaller than 45 µm	ISO 17190-3
Bulk density	g/ml	0,30 to 1,00	ISO 17190-9
Quantity of heavy metals	mg/kg	≦20	The Japanese Pharmacopoeia 1.07 Heavy Metals Limit Test, Method 2
NOTE There are alternative ways of determining a quantity of heavy metals. An overview is found in ISO/TR 17276.			

4.2 Constituent

Acrylamide shall not be used or added in manufacturing of water-absorbent polyacrylate.

5 Product storage

The product shall be packed in a closed bag and stored indoors and out of direct sunlight.

6 Information provided by the supplier

Information provided for the identification of water-absorbent polyacrylate for urine absorbent products should include at least the following:

a) product name;

b) confirmation that the product conforms with this document, i.e. ISO 24669;

c) manufacturer name and/or abbreviation;

d) information that can uniquely identify the product batch.

This information should be included in any paperwork relating to the product batch, including product labels, packaging, certificates of analysis, and product invoices.