

Contact lenses —

Part 2: Method of classifying contact lens materials

BSI Standards Publication

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Committees responsible for this British Standard

The preparation of this British Standard was entrusted by the Health Care Standards Policy Committee (HCC/-) to Technical Committee HCC/78, upon which the following bodies were represented:

- Association for Consumer Research (ACRE)
- Association of British Dispensing Opticians
- Association of Contact Lens Manufacturers
- British College of Optometrists
- British Contact Lens Association
- British Medical Association
- British Spectacle Frame Makers' Association
- British Universities Committee of Contact Lens Educators
- College of Ophthalmologists
- Consumer Policy Committee of BSI
- Department of Health
- Department of Trade and Industry (National Physical Laboratory)
- Federation of Manufacturing Opticians
- Federation of Ophthalmic and Dispensing Opticians
- Flat Glass Manufacturers' Association
- Optic (UK)

This British Standard, having been prepared under the direction of the Health care Standards Policy Committee, was published under the authority of the Standards Board and comes into effect on 31 January 1992

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The following BSI references relate to the work on this standard:
Committee reference HCC/78
Draft for comment 90/57493 DC

ISBN 0 580 20213 5

Amendments issued since publication

Amd. No.	Date	Comments

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Foreword

This Part of BS 7208 has been prepared under the direction of the Health Care Standards Policy Committee.

The need for having a standardized method of classifying the materials from which contact lenses are made has been apparent for many years. For example, the requirements of some regulatory bodies are such that a positive identity of the chemical constituents of biomedical devices has to be demonstrated. Also, the lens fitter wishes to be certain that the received product is that specified and, moreover, the manufacturer often needs to have more than one source of the raw materials and be sure that any source meets a common specification.

Polymers are more difficult to identify than other chemical compounds that have unique formulae and can be identified accordingly. A close examination of the different contact lens materials currently available (as far as manufacturer's confidentiality would allow) disclosed that there are only relatively few components in the different polymers. Therefore this standard was drafted to enable the classification of these materials into groups containing common monomer units. Furthermore this standard describes a procedure for labelling the material with certain physical properties which are known to have a very significant effect upon the physiology of an eye when wearing a contact lens and which, therefore, are of prime interest to the prescriber of a contact lens.

This Part of BS 7208 is based on a classification system that has been used with only minor amendments by the contact lens industry since 1986.

The methods for determining the physical properties referred to in this standard are presently being prepared by the International Organization for Standardization (ISO) and will be published in due course. Although it is expected that novel contact lens materials may be developed having improved surface properties and physical strength, the underlying polymeric composition is likely to remain very similar to the materials currently available. In the event that future compositions having significant physiological or clinical importance emerge, amendments to this standard will be issued.

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Summary of pages

This document comprises a front cover, an inside front cover, pages i and ii, pages 1 to 8, an inside back cover and a back cover.

This standard has been updated (see copyright date) and may have had amendments incorporated. This will be indicated in the amendment table on the inside front cover.

1 Scope

This Part of BS 7208 describes a method of classifying the materials used in the manufacture of contact lenses. It permits the identification, in simplified form, of the major chemical components of the material. For soft lens materials, the identification gives an indication whether the material is ionic and therefore liable to be influenced by pH changes in the environment of the lens. In addition, the identification of soft lens material allows either the water content or the oxygen permeability to be shown (so as to enable the correct mode of use to be ascertained); for rigid lens material, only the oxygen permeability is shown.

NOTE The titles of the publications referred to in this standard are listed on the inside back cover.

2 Definitions

For the purposes of this Part of BS 7208, the definitions given in BS 3521-3 apply.

3 Principle

A contact lens material is identified by a generic name indicating the general physical form (soft or rigid) of the material, and by an alphanumeric code indicating its major chemical components. The identification is completed by a number which is either in parentheses, i.e. (), to indicate its water content (for hydrophilic lens materials) or in square brackets, i.e. [], to indicate its oxygen permeability (for all contact lens materials except focon 1). Examples of the system are given in 6.2.

4 Soft lens materials

4.1 Generic name

"Filcon" is used as the generic name to identify soft (flexible) lens materials.

4.2 Chemical composition

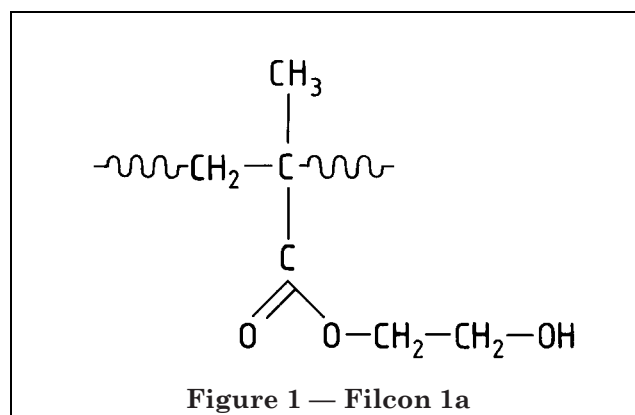
4.2.1 General

The major chemical components in each material are classified by use of one of the alphanumeric codes given in 4.2.2 to 4.2.10.

NOTE Polymer formulations may require small amounts of initiators, catalysts, cross-linking agents, fillers and wetting agents and some of these may remain in the final material. For clarity and simplicity, these additives, together with hydrating media, are ignored.

4.2.2 Filcon 1a

Filcon 1a materials are essentially poly(2-hydroxyethyl methacrylate), containing not more than 0.2 % (*m/m*) of any ionizable monomer, e.g. methacrylic acid. (See Figure 1.)



4.2.3 Filcon 1b

Filcon 1b materials are as described in 4.2.2, but they contain more than 0.2 % (*m/m*) of any ionizable monomer.

4.2.4 Filcon 2a

Filcon 2a materials are either of the following:

- a) copolymers of 2-hydroxyethyl methacrylate (see Figure 1) and other hydroxyalkyl methacrylates [see Figure 2(a)] and/or alkyl methacrylates [see Figure 2(b)];
- b) homopolymers and copolymers of hydroxyalkyl methacrylates (other than 2-hydroxyethyl methacrylate) and/or any dihydroxyalkyl methacrylate [see Figure 2(c)], and/or alkyl methacrylates.

They contain not more than 0.2 % (*m/m*) of any ionizable monomer. (See Figure 2.)

4.2.5 Filcon 2b

Filcon 2b materials are as described in 4.2.4, but they contain more than 0.2 % (*m/m*) of any ionizable monomer.

4.2.6 Filcon 3a

Filcon 3a materials are copolymers of hydroxyalkyl methacrylate [see Figure 3(a)] with an *N*-vinyl lactam [see Figure 3(b)] and/or an alkylacrylamide [see Figure 3(c)] but containing not more than 0.2 % (*m/m*) of any ionizable monomer.