
**Ophthalmic optics — Spectacle frames —
Method for the simulation of wear and
detection of nickel release from coated
metal and combination spectacle frames**

*Optique ophtalmique — Montures de lunettes — Méthode de simulation
de l'usure et de détection de la libération du nickel de montures de
lunettes en métal revêtu et combinées*

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Case postale 56 • CH-1211 Geneva 20
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Fax + 41 22 749 09 47
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Foreword

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ISO/TS 24348 was prepared by Technical Committee ISO/TC 172, *Optics and optical instruments*, Subcommittee SC 7, *Ophthalmic optics and instruments*.

Introduction

Adverse skin reaction to nickel has been known for many decades. Nickel is now the most frequent cause of contact allergy, and a significant proportion of the female population is allergic to nickel. Skin absorption of nickel ions, which are released from some nickel-containing materials in direct and prolonged contact with the skin, causes sensitization. Further exposure to soluble nickel salts results in allergic contact dermatitis. It is known that sensitization to nickel requires higher exposure levels than does the elicitation in already sensitized individuals. Amongst individuals there is a large variation in the degree of sensitivity to nickel.

This widespread health problem has forced the introduction of a number of measures designed to reduce its prevalence. They include this Technical Specification which provides two procedures for testing those parts of metal and combination spectacle frames that come into direct and prolonged contact with the skin.

The first part specifies a method for accelerated wear to simulate two years use of coated metal and combination spectacle frames. The coatings may include rolled gold, electro- and other plating methods, varnish and other organic treatments. The second part attempts to provide an *in-vitro* chemical test that correlates as far as possible with the variable human biological reactions that occur when metallic articles containing nickel are in direct and prolonged contact with the skin. This part provides a measure of the amount of nickel release from a spectacle frame when immersed for one week in artificial sweat.

Clinical patch-testing of a small selection of nickel-containing alloys and coatings on nickel-sensitized persons indicates that high and low results achieved with the present analytical method correspond closely with patch-test reactivity. Moreover, a nickel release rate threshold of $0,5 \mu\text{g}/\text{cm}^2/\text{week}$ has been set in European Parliament and Council Directive 94/27/EC (O.J. No. L188 of 1994-07-22). In order to ensure that articles yielding values near this figure are not unnecessarily excluded from European trade as a result of the difficulties inherent in the test method, particularly when applied to intricately-shaped articles, the measured release figures are multiplied by a factor of 0,1. Materials recognized as causing sensitization to nickel would not become acceptable by use of this adjustment. Application of this Technical Specification is confidently expected to significantly reduce the development of allergic contact dermatitis due to nickel.

NOTE Experience of its use and further epidemiological and clinical research may justify changes to test procedure and/or interpretation of the test result.

Ophthalmic optics — Spectacle frames — Method for the simulation of wear and detection of nickel release from coated metal and combination spectacle frames

1 Scope

This Technical Specification specifies methods for simulating two years' use and for testing for the release of nickel from those parts of metal and combination spectacle frames intended to come into direct and prolonged contact with the skin, in order to determine whether such parts release nickel at a rate greater than $0,5 \mu\text{g}/\text{cm}^2/\text{week}$.

This Technical Specification aims to control those frames that, if produced with materials and/or surface treatments containing nickel, can be worn by nickel-sensitized persons.

2 Normative references

The following referenced documents are indispensable for the application 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 12870:—¹⁾, *Ophthalmic optics — Spectacle frames — Requirements and test methods*

3 Requirement

Those parts of metal and combination spectacle frames that come into direct and prolonged contact with the skin of the wearer shall have a nickel release of less than $0,5 \mu\text{g}/\text{cm}^2/\text{week}$ when tested in accordance with this Technical Specification.

Frames having a non-nickel coating shall be subject to the wear pre-treatment described in Clause 4, which simulates two years' typical wear.

Frames that are made of homogeneous alloy or pure metal and are uncoated go direct to the nickel release test procedure described in Clauses 5 to 8.

Parts to be tested shall include:

- the rear surface of rims;
- nasal-bearing surfaces, including metal nose pads;
- sides, excluding the joints and the zone immediately around the joints, and parts intended to be protected by plastics endcovers (tips).

1) To be published. (Revision of ISO 12870:1997)

4 Method for the abrasion of metal spectacle frames before the determination of nickel release

4.1 Materials

4.1.1 Abrasive paste

Inorganic abrasive paste produced for dry tumbling barrels.

The abrasive paste shall be made of the following components:

- a) pumice (Al and Si oxides) powder, where the abrasive particles have dimensions of $200 \mu\text{m} \pm 15 \mu\text{m}$;
- b) mixture of emulsifying agents, mineral oils and water, having the following physical properties:
 - softening point: $30 \text{ }^\circ\text{C}$ to $35 \text{ }^\circ\text{C}$
 - flash point: $> 250 \text{ }^\circ\text{C}$
 - pH: 6 to 7

The ratio of a) to b) shall be 4:1.

NOTE Information on sourcing a suitable paste is available from the ISO Central Secretariat.

4.1.2 Wood granules

This material shall be made of the following components.

Outer shells of coconuts, walnuts, peanuts, almond, mixed in a ratio 1:1:1:1 by weight, ground and sieved to give a mixture of particles having dimensions between 0,8 mm and 1,3 mm.

Equilibrium moisture at a temperature of $30 \text{ }^\circ\text{C}$ and a relative humidity of 75 % shall be 14 %.

Before use, the required amount of granulate shall be conditioned in standard laboratory conditions for at least 24 h.

NOTE Information on sourcing suitable granules is available from the ISO Central Secretariat.

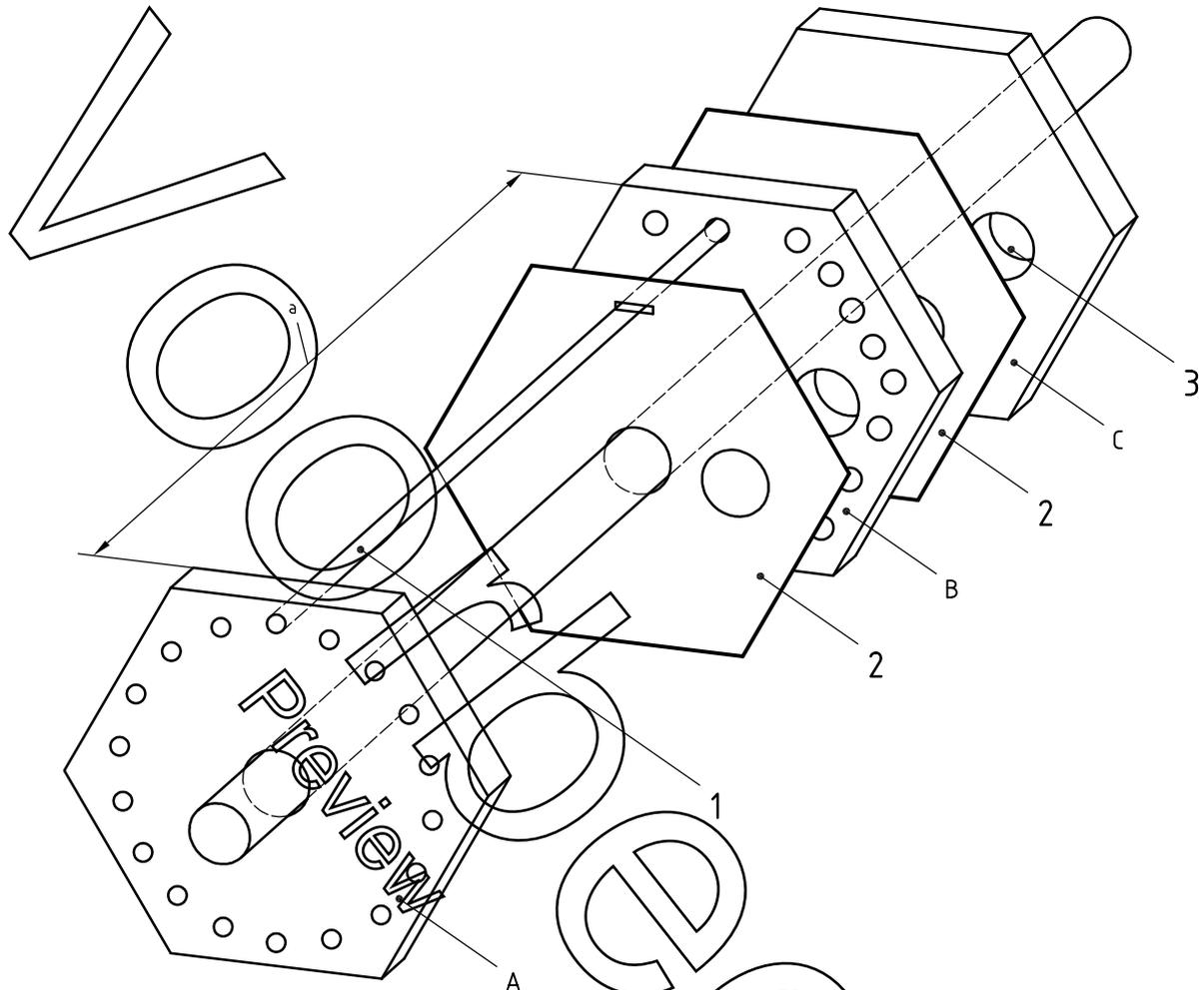
4.1.3 Tumbling barrel

The tumbling barrel and retaining assembly shall be in accordance with the following description.

Barrel of hexagonal cross-section designed to rotate around its axis of symmetry, which is orientated horizontally. The spectacle fronts or sides are mounted in a retaining assembly that slides into the barrel.

For use with spectacle sides, the assembly consists of a threaded rod which carries three metal hexagonal plates (see Figures 1 and 2). The end plate (A) is drilled part way through with holes of nominal diameter 1,5 mm or, as appropriate, to take the ends of the tips of the sides. The next plate (B) is perforated with holes of nominal diameter 5,0 mm or, as appropriate, to take the joint ends of the sides, together with an aperture of 40 mm nominal diameter to act as a filling hole for the abrasive mixture. The final plate (C) is undrilled apart from the filling hole. Threaded nuts either side of the last two plates secure them at the required distance from plate A, while silicone rubber sheets hold the sides firmly to prevent them from rotating in the assembly. The volume between the first and second plates is approximately $5 \text{ l} \pm 0,5 \text{ l}$.

There are two proposed assemblies for retaining spectacle fronts. In the first, short pieces of side are attached to the front half joints in the usual manner, and these pieces of side are inserted in a similar assembly. In the second, the central threaded rod carries two six-sided "spiders" carrying six radiating threaded rods (see Figure 3). The fronts are attached to these rods by means of holes in the test lenses, and are held at the appropriate distance of 80 mm from the axis of the barrel by nuts.



Key

- 1 sample side
- 2 silicone sheet
- 3 filling hole
- a Adjust as required.

Figure 1 — Exploded schematic illustration of the assembly for holding sides, which inserts into the tumbling barrel

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