

# Are we dispensing with safety?

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## Safety spectacles or spectacle safety?

- Whose safety - patients or us?
  - Medical Devices Directive 93/42/EC
  - Finnish law and regulatory authorities?
    - MHRA in UK
  - European & ISO standards

- EN 12472, 1997: Method for the simulation and corrosion for the detection of nickel release from coated items
- EN 1811, 1999: Reference test method for release of nickel from products intended to come into direct and prolonged contact with the skin.
- ISO 12870, 2004: Ophthalmic Optics.  
Spectacle frames. General requirements and test methods

# The only named material is nickel

- Present on surface of 5-10% of NEW frames?
- Almost 100% of used frames with nickel in them

ISO 12870, 2009

“4.2.1 General physiological compatibility: The manufacturer of spectacle frames shall exclude from contact with the skin, any materials that, amongst a significant proportion of users, during wear are known to cause irritation, allergic or toxic reaction to skin in a normal state of health.

NOTE Rare or idiosyncratic reaction to any material may occur and may indicate the need for the individual to avoid particular types of material. Adverse skin reaction may be due to other causes, e.g. excessive contact pressure.”

Testing: "5.1 General: The minimum level of conformity testing requires that two test specimens of each spectacle frame model shall be selected by an established random sampling technique.



These specimens shall be identified as test sample 1 and test sample 2, and shall be conditioned as described in Clause 6 before testing as described in Clauses 7 and 8."

" 5.3 Change in spectacle frame model:

If a range of spectacle frame models is made from the same material(s) and with the same manufacturing procedures including surface treatments, it is acceptable to perform test sequences 3 (subclause 8.3), 7 (subclause 8.6) and, if required, 8 (subclause 8.7) and/or 9 (subclause 8.8) on only one of the spectacle frame models."



Why don't we know (1990s)?

"Unfortunately I cannot offer you any information on the composition of the gold plate etc. as it's against company policy." ...



Why don't we know (2012)?

"We'll send you some data sheets"

- Never arrived or contained no useful information

"I'll e-mail back"

- Still waiting after repeat enquiries

## Incidence of spectacle frame allergy/ toxicity?

- No collated data available
- Very low figures from UK NHS dermatology departments
- Never been collated (1%? as presenting symptom)
- Considered a significant problem.
- Most don't get to dermatology depts.

Does Finland have an adverse reaction

reporting scheme for opticians?

- UK does, but never used for spec. frames

- What' s likely to be there?
- No real data available
- Reviews:
  - Smith & Calnan (1966)
  - Walsh & Wilkinson (2006)
- Nickel - clearly number 1 in allergy incidence in UK
  - Up to 13% of some general populations

## 2nd place?

- Only guessing at this
- Cobalt?
  - Common allergen, but how common in frames?
  - Complicated by cross-reactions with nickel
- Palladium
  - Common allergen, any more common in frames?
  - Complicated by cross-reactions with nickel

Names get less memorable, but still looking for second place

- Colophony?
  - Soap & cosmetics
  - Rosin
    - Violinists etc.
  - Not common in spectacle polish used in Europe
  - Where are frames made?
- Bisphenol-A?
  - Monomer in epoxy resins
  - Could explain problems with nickel free frames?
  - More likely to be nickel plating?

“The violin player  
wanted fifty quid”

- Para-phenylenediamine diamine?
  - Dye raw material and breakdown product
  - Many dyes now banned from leather and clothing
    - But not spectacle frames
  - Anaphylaxis?

Other relatively common problem materials?

Surprise entry?

- Gold
  - Relatively common allergen in the elderly
  - Because of gold injections for arthritis
    - Sodium aurothiomalate

Copper

- Not such a common allergen but  
very common in frames

What else?

Metals?

- Common alloys:

- Often no information available...
- Material generic name often hidden by fancy frame company name.

- Unlikely to have been developed

specifically for spectacle use

- Whatever salesman says!



b-titanium, Titan Next Generation	Ti, V, Al
"Cobalt alloy"	Co, Ni, Cr, Mo
Copper-beryllium bronze	Cu, Be
FX9	Cu Mn Sn Al
Genium	Fe, Cr, Mn, C, Si
Monel	Ni, Cu, Fe, Mn, C, Si
Nibrodal	Cu, Ni, Sn
Nichrome	Ni, Cr
Nickel silver	Cu, Ni, Zn, Mn, Fe
NiTiNOL (Flexon, Euroflex)	Ti, Ni or Ni, Ti
Stainless steel	Fe, Cr, Ni (?)
Super Invar	Fe, Ni, Co
Ticral	Ti, Cu, Cr

- Metallic platings?
  - Alloys?
    - “Gold” is
    - But are others?
  - What may be in a “base metal” alloy?
- Solders

“Of the metallic substances listed (our) frames contain only one - palladium”



### Gold finish

Gold 24cts 1.5□
Gold 24cts 2.5□
Gold 22cts 3□
Basic material

### Platinum finish

Platine 0.2□
Palladium 2□
Gold 24cts 1.5□
Gold 22cts 2.5□
Palladium 2□
Basic material

## Use of metals in spectacle frames

material	colour	density g.cm-3	role	safe
Aluminium Al		2.7	base metal, pure & alloy	yes
Antimony Sb		6.7	Solders?	no

<p>Beryllium Be</p>		<p>1.8</p>	<p>base metal, pure &amp; alloy</p>	<p>maybe/ no</p>
<p>Carbon (graphite) C</p>		<p>1.7-2.3</p>	<p>fibres (in composites), base metal alloys.</p>	<p>yes</p>
<p>Chromium Cr</p>		<p>7.2</p>	<p>plating, base metal alloy</p>	<p>maybe/ no</p>
<p>Cobalt Co</p>		<p>8.9</p>	<p>base metal, pure &amp; alloy</p>	<p>no</p>

<p>Copper Cu</p>		<p>9</p>	<p>base metal alloy, interplating</p>	<p>maybe</p>
<p>Gold Au</p>		<p>19.3</p>	<p>plating, interplating</p>	<p>maybe</p>
<p>Iridium Ir</p>		<p>22.7</p>	<p>plating</p>	<p>maybe</p>
<p>Iron Fe</p>		<p>7.9</p>	<p>base metal alloy</p>	<p>yes/ maybe</p>

Lead Pb		11.3	solder?	maybe
Magnesium Mg		1.7	base metal alloy	yes
Manganese Mn		7.44	base metal alloy	maybe
Molybden- -um Mo		10.2	base metal alloy	maybe

<p>Nickel Ni</p>		<p>8.9</p>	<p>base metal, pure &amp; alloy, inter plating, plating (pure &amp; alloy)</p>	<p>no</p>
<p>Niobium Ni</p>		<p>8.6</p>	<p>plating, interplating</p>	<p>maybe</p>
<p>Palladium Pd</p>		<p>12</p>	<p>plating, interplating</p>	<p>no</p>
<p>Platinum Pt</p>		<p>21.5</p>	<p>plating</p>	<p>maybe</p>



Rhodium  
Rh



12.4

plating

maybe

Ruthenium  
Ru



12.3

plating

maybe

Silicon  
Si



2.3

base metal alloy

yes

Silver  
Ag



10.5

base metal, pure & alloy,  
inter-plating

maybe

<p>Tin Sn</p>		<p>*4</p>	<p>Solder, base metal alloy</p>	<p>maybe</p>
<p>Titanium Ti</p>		<p>4.5</p>	<p>base metal, pure &amp; alloy</p>	<p>yes</p>
<p>Vanadium V</p>		<p>6.1</p>	<p>base metal alloy</p>	<p>probably</p>
<p>Zinc Zn</p>		<p>7.1</p>	<p>Solder, base metal alloy, rarely plating alloy</p>	<p>yes</p>

Zirconium  
Zr



6.5

Plating

maybe

If a polished metal is any colour other than silvery

- Even the slightest yellow tinge

It must contain:



Caesium



Copper



Gold

Which plastics might be there

- Mostly safe IF fully polymerised
- AND in pure form
- Never going to be either

Cellulose plastics – best known?

- Acetate
- Propionate
- Butyrate
- Co-polymers & mixtures

## Acrylics

- Perspex (UK)
- PMMA/ poly-methylmethacrylate
- Lucite (US)
- Lacquers

## Epoxies

- Optyl
- Lacquers

## Polyamides & mixtures

- Nylon
- SPX
- Grilamid
- Acelon
- Trogamid

## Polycarbonate

- Used to be just safety/ sports/ sun specs
- Started appearing in fashion specs couple of years ago?

## Polyurethane

- Lacquers

## Rubbers

- Silicone
- F-PVC
- “ Natural”

## Acrylonitrile butadiene styrene

- ABS
- Only sunspecs?



## Composites:

- Carbon fibre
- Kevlar
- Glass-fibre
  
- Many mostly "nylon"
- Often mostly an un-named plastic

## Additives:

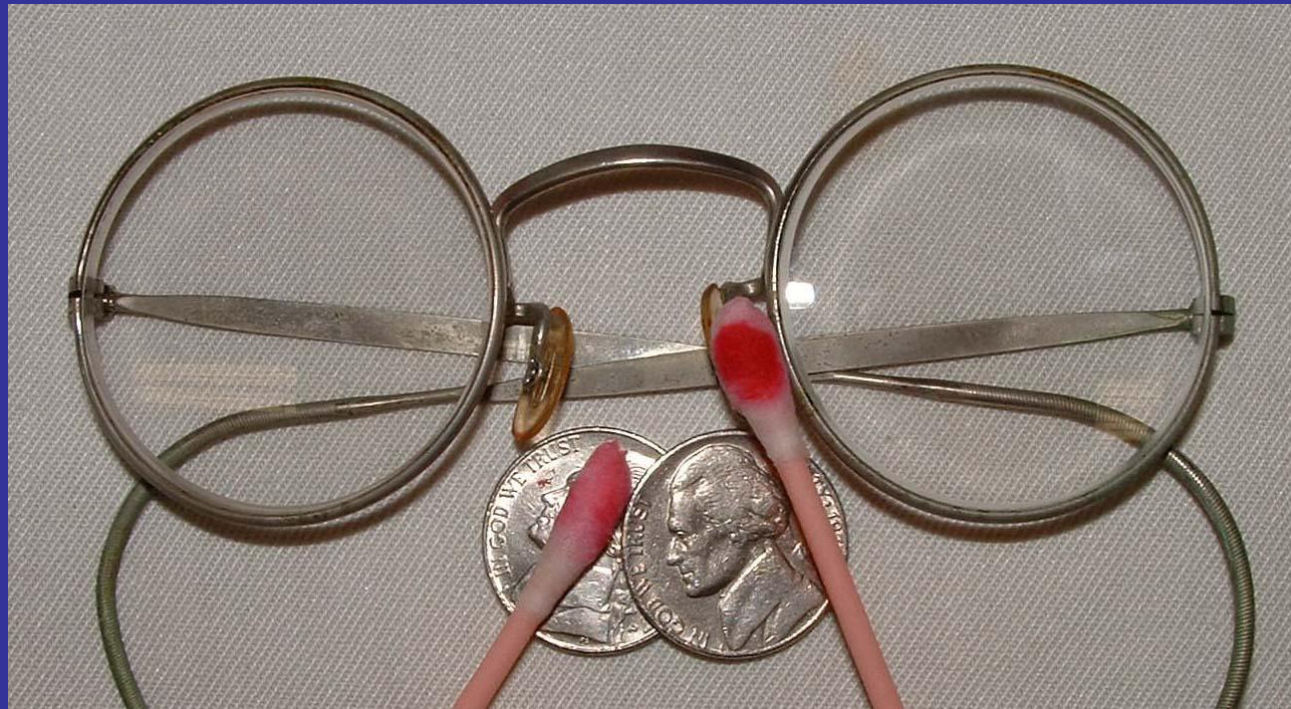
- Dyes & pigments
  - Many para-phenyleneamine diamine based?
  - Almost all dyes & pigments are anthraquinone, perinone or azo
- Plasticisers
  - Include organo-phosphates
    - Tricresylphosphate
    - Tri-phenylphosphates
    - Phthalates (diethylphthalate & dimethylphthalate)
  - UV inhibitors: resorcinol, resorcinol monobenzoate, phenyl salicilate

## Additives:

- UV inhibitors
- Resorcinol
- Resorcinol monobenzoate
- Phenyl salicylate

## DMG (dimethylglyoxime) test

- Saturated solution DMG in ethanol
- 18% (approx?) ammonia solution
- Cotton bud
  - 1 drop ammonia solution
  - 1 drop DMG
- Rub frame
- Goes bright pink if nickel present



ISO 12870, 2009

“4.2.1 General physiological compatibility: ..... Adverse skin reaction may be due to other causes, e.g. excessive contact pressure.’

- Frames weighing up to 25g should have a minimum nose-pad contact area of 200 mm<sup>2</sup>
- Those weighing over 25g should have a minimum contact area of 250 mm<sup>2</sup>.
- These recommendations are being almost universally ignored for frames with separate pads on arms.

(2010)

Spectacles aren't (UK) ready meals

Could they get us as much free PR?