SUNGLASS and Rx STANDARDS - UV Protection

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There are standards in a number of countries for sunglasses, an ISO standard for Rx sunglasses, and a new ISO International Sunglass standard which will be published soon. These standards cover requirements and test methods for limiting UV transmittance.

What is driving the standardisation of UV limits?

Eye care professionals, consumers and patients are becoming more and more aware of the risks to the health of their skin and eyes caused by the harmful effects of UV rays in sunlight.

For skin protection the use of protective clothing and sunscreen is improving dramatically with increasing education and awareness of the risk of serious sun damage.

But for protecting the eyes, the wearing of hats gives only partial protection, especially from UV radiation (UVR) reflected from the ground.

So sunglasses are the only effective way to significantly reduce eye exposure to safe levels along with achieving reduced glare levels.

The demonstrated risk and public awareness associated with UVR exposure is the main driver for standards to be created which can be trusted to be used for regulating the manufacture and use of sunglasses.

The risks to the eye from UVR exposure

The large number of studies about the harmful effects to the eye of UVR exposure have created widespread acceptance that there are strong links between levels of eye exposure to UVR and the incidence and severity of a number of conditions including cataract, pterygium, snow blindness, macular degenerations, eyelid cancers and accelerated orbit skin aging.

And there are some unexpected risks. While the damage to the skin is greatest when the sun is highest in the sky, the eyes are deep set in the orbit, and partially protected when the sun is high in the sky. For most seasons, maximum solar UV exposure occurs between 8:00 and 10:00 am, and
And the exposure levels are not the same everywhere. People living in equitable climates, in latitudes closer to the equator, especially in the Southern Hemisphere, and in places with high number of sunny days per year receive up to 15% more exposure to UVR than the average.

The experts contributing to formulation of the eye protection standards interpret these risks, the science, and use data from recognised authoritative sources to formulate UV limits.

It is important that standards hold wide margins of safety to deliver the confidence in the sunglasses to protect well in all circumstances and location of wear.

**Consumer awareness and expectations**

In a recent consumer survey of purchasing behaviour across all major markets, the following result was obtained.

These sunglasses:

![Fig. 1: For Eyeglass wearers who wear plano sunglasses (measure of importance to consumers when purchasing sunglasses, scale 1-10)](image)

This indicates that UVR protection is very important for consumers.

Standards provide a reference for regulation against which the performance of products can be determined. The standards set a benchmark for performance based on the best scientific information available.

Good standards are an agent to prevent the sale and use of sunglass products which perform badly or give poor protection.

Confidence created by the active use of standards generates increased sales of sunglasses. Sales volumes are underpinned by standards which guarantee good performance.

In parallel with the increased awareness for plano sunglass consumers, we also see an increase in the use of prescription tinted lenses or Rx sunglasses. The eye care professionals and their patients are becoming more aware of the protective benefits from providing a second pair of Rx sunglasses for times when exposure to the sun may be higher than usual.

**The standards for sunglasses**

**PLANO POWER**

**AUSTRALIA: AS/NZS1067:2003 (with amendments) [2]**

Australia published the first general purpose sunglass standard in 1971 which is the only sunglass standard enacted in law. (Australian Federal Government Trade Practices Act).

Compliance is assessed and enforced by the ACCC (Australian Competition and Consumer Commission). It is therefore mandatory.
Australia has a combination of a geographic location much of which is close to the equator, with a high number of sunny days/year, and is influenced by the fact the earth is always nearer to the sun in the Australian summer than during the Northern Hemisphere summer. In addition, the air is cleaner in the Southern Hemisphere than in the North, so more UVR reaches the earth’s surface. In addition, the lifestyle is very much outdoors-oriented in Australia. The combination of these effects means that Australians receive approximately 15% more solar UVR than those living in equivalent locations in the Northern Hemisphere.

It explains why Australia’s standards have a very strong focus on protecting its citizens by maintaining tough UV protection requirements for sunglasses, and enforcing that by law.

Australia maintains 400 nm as its defined upper limit of the range considered to be UV, while the other sunglass standards use 380 nm. Regulation in the Australian sunglass industry imposes large fines, and non-compliant sunglasses banned from sale – sometimes involving big brand names.

**USA: ANSI Z80.3:2010 Non-prescription sunglasses and fashion eyewear** [1]

This standard was created and is regularly updated by an ANSI accredited committee of experts, and the Sunglass Association of America is the chair for the committee.

The standard is not mandatory, but relies on voluntary manufacturer regulation. However, nonprescription sunglasses are classified and regulated by FDA as Class I devices in accordance with Title 21 of the Code of Federal Regulations (CFR). Sunglasses that are imported into the US must comply with country of origin marking requirements in the United States Tariff Act. Manufacturers and initial importers/distributors must register their establishments with the FDA annually and foreign manufacturers must also designate a U.S. Agent.

Nonprescription sunglasses are generally marketed as “Over The Counter” medical devices and are subject to general labeling and OTC labeling requirements outlined in Title 21 CFR Part 801 - Labeling.

There are 4 classifications in Z80.3-2010 used to define the UV transmittance and traffic signal recognition requirements.

Sunglasses which comply with the traffic signal recognition requirements are categorised as cosmetic (luminous transmittance $Tv>40\%$), or General Purpose ($Tv$ from 8 to 40%). If sunglasses in these two categories don’t meet the traffic signal recognition requirements, they must be labeled “not intended for driving”.

**EUROPEAN UNION: EN1836:2005 + A12007 Sunglasses and fashion spectacles** [3]

Sunglasses cannot be sold in Europe without the CE mark. The CE mark is a claim of compliance with the PPE EU Directive 89/686/EEC. The normal way to comply with the Directive is to comply with the EN1836:2005 standard.

Compliance is by self-declaration and there is little evidence of surveillance of compliance.

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EN1836 has 4 transmittance or tint categories requiring different UV transmittance limits.

The standard has means to verify claims about UV transmittance (and absorption) for Solar UV, UV-A, UV-B and for blue light.

While a study in UNSW Australia found that 17% of CE marked sunglasses did not comply with the EN1836 standard, only a small 1.8% failed for the UV requirements.

This is a vast improvement on past surveys, and indicates the sunglass manufacturers have responded well to the demand for good UV protection.

China (PRC) GB xxxx-1-20xx Eye and face protection - Sunglasses and related eyeware -Part 1 Sunglasses for general use [4]

This is a newly developed draft standard awaiting approval before publishing.

It supersedes an Industry Sunglass Standard and is based on EN1836. It has been adapted to be close to ISO12312.1, but notably with tougher UV requirements.

ISO 12312.1 Eye and face protection - Sunglasses and related eyewear [5]

ISO TC94/SC6/WG3 has almost completed its work to create an International Standard for Sunglasses (and related Test Methods standard). (See part "ISO Sunglasses standard 12312.1").

**UV requirements in the major standards**

The following is an informative Annex in the ISO12312.1 Sunglass standard.

“The eyes have a natural aversion response to bright light that limits outdoor filter exposure when one is not wearing sunglasses. This aversion response that provokes squinting limits filter exposure greatly, but sunglasses without side shields may permit peripheral exposure of biological significance due to the Coroneo effect: The analytic characterization of ultraviolet skylight, as adapted for calculating corneal irradiance show that the largest influence on filter exposure in temperate regions is the seasonal variation of solar irradiance as adjusted by ground reflectance and the time from solar noon. Diffuse sky radiation decreases with increasing altitude, and corneal irradiation varies significantly with lid opening and ground cover. The adopted transmittance limits are based on calculations of the biologically weighted exposure doses. The ultraviolet transmittance limits for sunglasses will keep these doses below a recognized safe limit even for exceptional daily exposure except over snow. Further margins of safety to account for tropical conditions or walking over snowfields in late spring have been incorporated. This has been done by adding additional safety factors to those implicit in the exceptional exposure experiences at mid-latitudes over normal terrain. The specification of spectral (instead of average or weighted) transmittance limits provides a further very large increase in the margin of safety.”

There are some differences in the way the UV requirements are defined in the various sunglass standards. Some specify spectral transmittance limits for specified wavelength bands, while others set integrated transmittance limits.
But in practice, studies show that the number of sunglasses passing one standard and failing another is exceedingly small. UV protection is almost guaranteed with modern sunglass lens materials.

**Comparison of the major sunglass standards for UV requirements**

**The categories**

Generally sunglasses and Rx sunglasses are categorised according to the luminous transmittance.

- **Category 0** is where $0\leq T_v \leq 80\%$
- **Category 2** is $43\% < T_v \leq 80\%$
- **Category 3** is $18\% < T_v \leq 43\%$
- **Category 4** is $3\% < T_v \leq 18\%$

*Tab. 1: UV-B Protection Requirements*

*Tab. 2: UV-A Protection Requirements*

**Claims for UV transmittance or absorption**

All sunglass standards have the means to verify claims for a specific % transmittance or absorption.

For example, the ISO standard has “In the case where it is claimed that a filter has x % UV absorption, the solar UV transmittance of the filter TSUV shall not exceed (100.5 - x) %.”

So for a sunglass claimed to absorb 99% UV, the solar UV transmittance shall not exceed 1.5%.

**Prescription Sunglasses**

ISO 8980.3:2003 [7] Transmittance for finished uncut spectacle lenses is the international reference for prescription tinted lenses and Rx sunglasses. It was formulated and maintained by ISOTC172/SC7/WG3.

The UV requirements are not as tough as for plano sunglasses. UVB – for category 0, TSUVB shall be $\leq T_v$, for categories 1 to 3, TSUVB $\leq 0.125 T_v$, and category 4 TSUVB $\leq 1\%$ absolute.

UVA – For categories 0 to 2, TSUVA shall be $\leq T_v$, and for categories 3 and 4, TSUVA $\leq 0.5 T_v$.

For photochromic lenses the UV requirements must be met both in the dark and light states.

There is a constant challenge for the committees in ISOTC94/SC6 eye protection and ISOTC172/SC7/WG3 spectacle lenses to ensure that the requirements in the sunglass standards are not in conflict with those in the prescription transmittance standard.

**How is UV performance measured?**

There are some differences between the standards but the most up-to-date methodology is in the latest draft of ISO12311 Test methods for sunglasses [6].
Measurement is permitted with spectrophotometric equipment capable of measuring spectral transmittance with specified uncertainties. Measurements are made normal to the surface of the lens.

The spectral values are measured at no more than 5nm intervals and the solar UV values calculated by integrating over the specified range of wavelengths taking into account the spectral distribution of sunlight and the spectral sensitivity of the eye. Data is provided in the standard to calculate:

- Luminous transmittance TV
- Solar UV transmittance TSUV
- Solar UV-A transmittance TSUVA
- Solar UV-B transmittance TSUVB

**How do the standards define UV?**

Since spectacle lens and sunglass standards define 380 nm as the upper limit of the UV range, there is opportunity for manufacturers to make claims like “UV400” – or similar for another wavelength.

Because it wasn’t possible in the ISO forums to agree a definition for UV400, it was decided to write a Technical Report called “Short Wavelength Visible” This is intended to explain and educate those who are interested in the effects on the eye in this interface range and how lenses attenuate these effects.

The Technical Report is currently in formulation with contributions from experts around the world.

**A challenge for manufacturers**

Increased public awareness of UV and the harmful effects has driven manufacturers to eliminate more and more UVR, to create sharper cutoff lenses, and to cut more and more of the blue light region.

The consequence of removing blue light is a possible yellowing of clear lenses and failure to comply with the coloration limits for traffic signal recognition.

The challenge is to create superior products recognising these limitations.

**ISO Sunglasses standard 12312.1 [5]**

Since 2004, ISO committee TC94/SC6/WG3 has been developing the sunglass standard ISO12312.1 and its supporting test methods standard ISO12311. These standards are intended to be published simultaneously.

The UVR values in EN1836 were used as a starting point for 12312.1. The spectral values were replaced by integrated values, which are tougher, and the UVA requirements have been tightened also.

The ISO standards for sunglasses are close to completion and are expected to be published during 2012.

When the ISO standards are published, EN1836 will be withdrawn and the ISO standard will become the reference for claiming conformity to the EU Directive, allowing CE marking and sale in Europe.
Trends for the future

The most significant event in the near future will be the publishing and adoption of the ISO sunglass standards.

Countries will need to decide about adoption of these new standards to replace their national standards – where they exist.

If there is a wide acceptance of the ISO standard that will benefit those engaging in cross-border trade in sunglasses since only one international standard will need to be respected.

Further in the future it is expected that UV protection requirements will become tougher. We can also expect labelling requirements to increase which will better inform consumers at point of sale about the protective level of products.

References

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Footnote page:

1. The standard has not been published in China so it doesn't have a number or year of publication

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