

Approved: Aug 19, 2020

Title:

**Protocol Number:** 

NONPRESCRIPTION SUNGLASSES & FASHION GLASSES (INCLUDING BLUE LIGHT BLOCKING GLASSES) KOHL'S – 911-0

Test Property	Test Method	Samples	Test Principle / Requirements	Rating (Section or exec. Summary which failed items can be referenced)
LABELING				
General Labeling Provisions	FDA 21 CFR 801.1 - 801.15	All Samples	<ul> <li>Name and place of business of manufacturer, packer or distributor</li> <li>Intended uses (labeled or advertised)</li> <li>No misleading statements</li> <li>Adequate directions for use</li> <li>Prominence of required label statements</li> </ul>	
Labeling Requirement For Over-the-Counter Sunglasses	FDA 21 CFR 801.60 - 801.62	All Samples	<ul> <li>Principal display panel</li> <li>Statement of identity</li> <li>Declaration of net quantity</li> <li>Use of impact resistant lenses In sunglasses</li> </ul>	
Country Of Origin Marking	19 CFR 134/ ANSI Z80.3 Section 6	All Samples	<ul> <li>Shall indicate country of origin legibly and permanently and in a conspicuous place.</li> <li>Must be in a close proximity and in comparable size to the name of country or locality other than the country of origin appears on the marking</li> <li>Must be visible at point of purchase</li> </ul>	
#Verify Label Claims	Visual Check	All Samples	The labeling must comply and valid with all claims.	
Adult Tracking Label: **If space limitations exist, contact Kohl's Quality Assurance & Product Integrity teams to discuss minimum required information mr.qa.pi@kohls.com	Kohl's Requirement	All	Can be included on packaging when necessary: Kohl's Assigned Factory Number Manufacture Date (Month/Year) UPC #	

PHYSICAL CHARACTERISTICS					
Frame Size Measurement	Standard Measure	3 samples	As approved/ product specification/ as claimed/ as measured (+5% / -0%)		



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Kohl's Workmanship	Visual Check	All	All components shall be provided as	
Review	/ Actual Use	Samples	claimed and shall not be deformed or	
			fractured.	
			All hardware shall be provided	
			All welds shall be smoothly finished and	
			free from pits and splatter	
			All components shall not contain any	
			burrs or sharp edges (Test by touch or	
			sight)	
			Product shall not contain any loose	
			components or unsecured fastening	
			where rigidity is required	
Frame Finish	ANSI Z80.3	All	The surface finish of metal and plastic frames	
	Section 4.4	Samples	shall be free of significant imperfections or	
			roughness. All hardware or other components	
			shall be free of burrs or hazardous projections. Excessive polishing compounds or other	
			processing residue shall not be present. The	
			surface finish of plastic frames shall be free of	
			significant imperfections or roughness. All	
			hardware or other metal components shall be	
			free of burrs, and all exposed metal parts shall	
			be corrosion resistant as defined in 4.5.	
Frame Corrosion	ANSI Z80.3	1	Corrosion resistance of metal parts shall be	
	Section 4.5	Samples	sufficient to pass the test method described in	
			5.4. Frames with movable hinges shall move as	
			designed after being subjected to test	
-			conditions.	
Frame deformation and	ANSI Z80.3	1	When tested in accordance with the procedure	
retention of lenses	Section 4.7	Samples	described in ISO 12311 Section 9.6, the frame	
			fitted with lenses shall not: 1) fracture or crack at any point;	
			<ul><li>2) be permanently deformed from its original</li></ul>	
			configuration by more than 2% of the	
			distance, between the boxed centers of	
			the sunglass frame; that is, the residual	
			deformation x shall not exceed 0.02c; and	
			3) neither lens shall be displaced from the	
			frame	
Cosmetic Quality Of The	ANSI Z80.3	All	Within an area of 30 mm diameter around the	
Lens	Section 4.8	Samples	reference point, and except in a marginal area 5	
			mm wide, lenses shall be reasonably free of	
			pits, scratches, grayness, water marks,	
			bubbles, striae, local aberrations, and	
			inclusions, so as not to impair or prevent the	
			use of the lenses for their intended purpose as	
		1	determined by product experience and actual	

In addition to this protocol, any product designed for, intended for or appealing to children, requires additional testing per Kohl's Protocol 8601. KOHL'S, AGENT'S & VENDORS USE ONLY Page 2 of 8



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*Impact Resistance Of The Lens	FDA 21 CFR 801.410 / ANSI Z80.3 Section 4.2	Refer to Annex A	Under 21 CFR 801.410(c)(3), it is required to test a statistically significant sample of over-the-counter glass lenses from each production batch. And FDA accepts the Acceptable Quality Level (AQL) of 6.5, General Inspection Level II. (See Annex A) A lens will be considered as not complying with the requirements when it has fractured as one of the followings: (i) It cracks through its entire thickness, including a laminar layer; (ii) It cracks across a complete diameter into two or more separate pieces, or (iii) Any lens material visible to the naked eyes becomes detached from the ocular surface; (iv) The test ball passes through the lens. In lieu of testing, Certification Statement (See Annex B) dated within one year can be submitted for review. Note: Supplier shall maintain the records of testing for a period of three (3) years from the date of shipment, and copies will be forwarded to FDA upon request.



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LENS PERFORMANCE				
Optical Quality of Lense Refractive Properties	ANSI Z80.3 Section 4.9	2 Samples	Refractive power: $0 \pm 0.13 \text{ D}$ Astigmatic power:Within an individual lens:shall not exceed 0.13 D.Prismatic power(ISO 12311, section 8.2)Between lens: shall not exceed 0.50 $\Delta$ horizontally and 0.25 $\Delta$ vertically.	
Luminous Transmittance	ANSI Z80.3 Section 4.10.1	2 Samples	The luminous transmittance of a lens shall comply with the appropriate intended primary function requirements of Table 4.	
Color Limit	ANSI Z80.3 Section 4.10.2.1	2 Samples	The x and y chromaticity coordinates of traffic signals and average daylight (D65), as viewed through the lens, shall not fall outside prescribed regions on the CIE (1931) standard chromaticity diagram in accordance with the appropriate intended primary function requirements of Table 4.	
Transmittance Properties Related To Traffic Signal Recognition	ANSI Z80.3 Section 4.10.2.2	2 Samples	<ul> <li>Luminous transmittance: ≥ 8%</li> <li>Transmittance of the traffic signal through the lens shall be Red signal ≥ 8% Yellow signal ≥ 6% Green signal ≥ 6%</li> </ul>	
Spectral transmittance	ANSI Z80.3 Section 4.10.2.3	2 Samples	The spectral transmittance, $\tau(\lambda)$ , of a tinted lens shall be not less than 0.2 $\tau v$ between 475 and 650 nm.	
Ultraviolet Mean Transmittance	ANSI Z80.3 Section 4.10.3	2 Samples	The UV mean transmittance of a lens shall comply with the appropriate intended primary function requirements of Table 4.	
*Polarizing Lens	ANSI Z80.3 Section 4.11.1 & 4.13	2 Samples	Type I : luminous transmittance ratio>20 Type II: luminous transmittance ratio>8 Axis of polarization: shall not deviate from the vertical by more than ±3.	

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Gradient tint lens	ANSI Z80.3 Section 4.11.3	2 Samples	Horizontal relative difference in luminous transmittance: shall not exceed 35% Within the 10-mm radius about the reference point: the minimum luminous transmittance at any point on the lens shall be 3%.		
Uniform tint lens	ANSI Z80.3 Section 4.11.4	2 Samples	<ul> <li>The relative difference in luminous transmittance of a</li> <li>1) general purpose uniform tint lens: shall not exceed 10%</li> <li>2) special-purpose very dark lens: shall not exceed 20%</li> </ul>		
Tint imbalance between lenses	ANSI Z80.3 Section 4.12	2 Samples	The relative difference shall not exceed 15%.		
Resistance to Radiation	ANSI Z80.3 Section 4.14	2 Samples	<ul> <li>The relative change in the luminous transmittance shall not exceed:</li> <li>1) 5% for Cosmetic lens category;</li> <li>2) 8% for General Purpose category; or</li> <li>3) 10% for Special Purpose category.</li> </ul>		

Remark: Vendor must specify the primary function and intended use of the sunglasses on the test request form



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Normal Use/Functionality	Actual Use	1 Sample	Shall withstand 500 cycles of normal use. No	
	riotadi 000	r campio	structural failure. No loose parts. Temple	
			arms, hinges and nose pads must be	
			functional as intended after testing.	
Impact Resistance	ASTM F963	1 Samples	Shall be functional after 4 drops from 3 feet	
		i Campico	height.	
Effects Of Extreme	Kohl's TM 30	1 Sample	24 Hours @ 0° F (-18°C) and 24 Hours @	
Temperature			180° F (82°C). No fractured, crazed or	
(Environmental)			delaminated lens. No frame damage or flaws.	
,			Any marking on the frame should remain	
			permanent and legible.	
Boiling Water Test	Visual Check	1 Sample	Tinted lens is boiled in water for a period of	
(Applicable to Tinted Lens)			10 minutes. No fractured, crazed or	
			delaminated lens.	
Boiling Salt Water and	ASTM D3359	1 Sample	Coated lens is boiled in 1% saline water	
Cross-Cut Adhesion Test	(Mod.) Visual		for a period of 10 minutes. No fractured,	
(Applicable to Coated Lens)	Check		crazed or delaminated lens.	
			<ul> <li>1" long X-cut is made in the coating at</li> </ul>	
			the clean and dried center position. Any	
			peeling or removal of coating along the	
			incisions or at their intersection by the	
			tape should be not more than 1/16".	
Flammability	ANSI Z80.3	1 Sample	Flammability testing shall be performed in	
	Section 4.3		accordance with the procedures specified in	
			5.3.	
			Compliance with flammability requirements	
			shall be determined by the manufacturer for	
			each type of material when first used, or when	
			change is made in any coatings used on the	
			material. This applies to plastic frames, plastic	
	1		lenses, or the assembled product.	

ANALYTICAL				
*Toxicology (Plastic Components)	FDA 21 CFR 170-189	1 Sample	MSDS document review <u>or must</u> comply with applicable requirements of FDA.	
*Lead In Scrapable Surface Coating	CPSC-CH- E1003-09	1 Sample	≤90 ppm (0.0090% by weight). (CPSA – 16 CFR 1303)	
*Nickel Spot Test – Metal Frame (Qualitative) <b>– If</b> Claimed	PD CR 12471	1 Sample	Negative test result (Applicable to direct & prolong skin contact metallic components only)	
*Lead in Accessible Plastic Component	EPA SW 846 Method # 3050B/3051A /3052 (Mod.)	1 Sample	Lead ≤ 200ppm (0.02% by weight)	

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Protocol Number: KOHL'S – 911-0					
* CA Prop 65	Refer to Protocol 1300	All Samples	All samples shall be reviewed against the require Proposition 65 to determine if additional testing required.		
Polycarbonate eyewear products (prescription glasses and sunglasses, over-the counter (OTC) reading glasses, non- prescription sunglasses, and safety glasses)	Acetonitrile extraction & LC/MS/MS	1 Sample	Bisphenol A (BPA): PC Temple ≤ 25 μg/g PC Nose pad ≤ 68 μg/g PC Frame ≤ 120 μg/g PC Lens ≤ 302 μg/g SUD 2020-04-17 by OEHHA	If pass below BPA requirements, Prop 65 warning is not needed. If fail requirements need to	
BPA in sunglasses Accessible coating and plastic only		1 samples	Client requirement Product shall carry an appropriate warning label WARNING: This product can expose you to chemicals including Bisphenol A, which is known to the State of California to cause birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov	discuss with Kohl's Pl to use Prop 65 Warning	



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### PRICING AND ADDITIONAL NOTE:

\*Please refer to Kohl's preferred third party labs for individual pricing and samples.

# Annex A: Impact Resistance Test (21 CFR 801.410)

Lot or Batch Size (Pairs of sunglasses)	Test sample size (Pairs of sunglasses) required	
2 - 8	2	
9 - 15	3	
16 - 25	5	
26 - 50	8	
51 - 90	13	
91 - 150	20	
151 - 280	32	
281 - 500	50	
501 - 1200	80	
1201 - 3200	125	
3201 - 10000	200	

### Test sample size for Pairs of Sunglasses (L.H.S. Lens & R.H.S. Lens)

# Annex B

Certification Statement of Impact Resistance

"\_\_\_\_\_" (Name of manufacturer or seller) hereby guarantees that the articles listed herein are impact-resistant within the meaning of 21 CFR 801.410 and have been tested pursuant to that section. Impact-resistant lenses are not unbreakable or shatterproof. Records of testing will be maintained for a period of three (3) years from the date of shipment, and copies will be forwarded to FDA upon request.

(Signature and street address of manufacturer or seller)



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Protocol Version	Description of Change	Revised by / Date	Approved by / Date
1208 – 0	Initial Release	Simon Leung Oct 24, 2008	Ro Jain Oct. 31, 2008
911-A	Changed protocol number from 1208-0 to 911-A, price adjustment, changed test method for scrapable surface from ASTM to CPSC, added 3052 to test method for lead and cadmium in plastic components and lead in plated or unplated metal frames	Elizabeth Armstrong April 1, 2010	Ro Jain April 1, 2010
911-B	Added phthalates testing. Lowered lead in scrapable surface coating from 600 to 90ppm	Elizabeth Armstrong September 15, 2011	Ro Jain September 15, 2011
911-C	Added composite testing requirements for phthalates testing changed nickel spot test to "if claimed". Removed lead in accessible substrate testing for children only	Elizabeth Armstrong February 1, 2012	Ro Jain February 1, 2012
911-D	Separate the test line of Prop 65 to supplementary protocol	John Wong Mar 07, 2013	Ro Jain April 15, 2013
911-E	Removed Cadmium in Accessible Plastic Component	Birkoff Chen Jan 30, 2014	Jeetendra Shelatkar Jan 30, 2014
911-F	Rephrased the wording of test items in Pricing structure to match with protocol content Price Adjustment on Lead content	Birkoff Chen Jul 30, 2014	Jeetendra Shelatkar Aug 4, 2014
911-G	Renamed in-house methods	Birkoff Chen Sep. 4, 2014	Teana Robinette Oct 27, 2014
911-H	Add BPA Warning Label Req	Elizabeth Armstrong April 6, 2016	Jeetendra Shelatkar April 6, 2016
911-I	Update Refractive Property Requirements	Teana Robinette Aug 24, 2016	Teana Robinette Aug 24, 2016
911-J	Updated/ Added test line of ANSI Z80.3-2015	John Wong Mar 27, 2017	Teana Robinette Mar 29, 2017
911-K	Updated Prop 65 Warning – New Verbiage	Teana Robinette June 27, 2018	Teana Robinette June 27, 2018
911-L	Added In lieu of testing, we also accept certification statement dated within one year for impact testing to avoid having to send numerous samples for testing Added claim verification, updated luminous transmittance, updated ultraviolet mean transmittance	Elizabeth Armstrong June 11, 2019	Elizabeth Armstrong June 11, 2019
911-M	Expand the scope to fashion glasses (including blue light blocking glasses)	Elizabeth Armstrong June 21, 2019	Elizabeth Armstrong June 21, 2019

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9 <mark>11-N</mark>	Added adult tracking label requirements		Elizabeth Armstrong June 15, 2020
911-O	Added BPA testing requirements	Armstrong	Elizabeth Armstrong Aug 19, 2020