

Presented by



# Fashion Masks

US Market Regulatory Requirements and  
Industry Practice

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# Agenda

- Classifications of Face Masks
- FDA and CDC Actions on Face Masks
- Regulatory Requirements and Industry Best Practices
  - Chemical Requirements
    - Adult
    - Children's
  - Labeling
  - Physical
  - Sizing ,Odor and Workmanship
  - Color Fastness
- Duke University Study – Droplet Transmission of Common Material Types
- Resources
- Questions



# Face Masks

Classifications

# Face Masks – Classifications

- Non-medical face masks
  - Construction masks / costume masks / sports masks
  - Not considered medical devices and not regulated by FDA



# Face Masks – Classifications

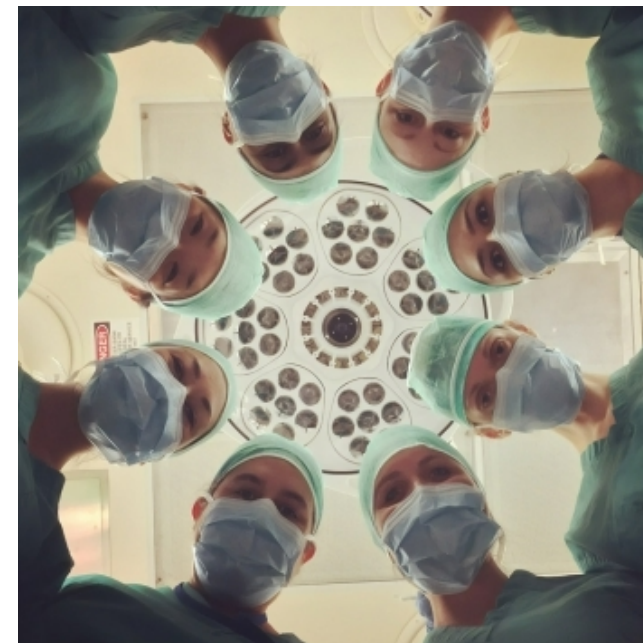
- General medical face masks (non-surgical)
  - Class I medical device
  - 510(K) premarket notification exempt
  - Not suitable for surgical settings
  - No special performance requirements
  - For source control only
  - Reporting requirements
    - FDA has temporarily suspended some reporting requirements, but adverse reporting is still required
  - Quality systems and product identification requirements
    - Note: FDA has temporarily suspended these





# Face Masks – Classifications

- Surgical face masks
  - Class II medical device
  - 510(K) premarket notification required
  - Intended for surgery
  - Significant additional performance requirements
  - Reporting requirements
    - Note: FDA has temporarily suspended some reporting requirements, but adverse reporting is still required
  - Quality systems and product identification requirements
    - Note: FDA has temporarily suspended these







# Face Masks

FDA and CDC Actions

# FDA and CDC Actions – CDC Guidance

- Center for Disease Control (CDC) guidance
  - Cloth face coverings are a critical tool in the fight against COVID-19
  - Recommends wearing masks in public and around people not living in your household
  - Masks should NOT be worn by:
    - Children under age 2
    - Anyone who has trouble breathing, is unconscious, incapacitated, or otherwise unable to remove the mask without assistance
  - **Masks or cloth masks with exhalation valve or vent NOT recommended for source control (e.g. construction mask with dust filter)**

# FDA and CDC Actions – FDA EUA

- FDA emergency use authorization (EUA)
  - Authorizes use of face masks, including cloth face masks, as source control
  - For use by the general public and health care providers (HCPs)
  - NOT intended as personal protective equipment (PPE)
  - Must meet these requirements
    - Report adverse events (FDA has a reporting website)
    - Cannot label in any of the following ways
      - In any way that misrepresent the product's intended use, which is source control, such as antimicrobial, antiviral, infection prevention, infection reduction
      - As a respiratory protective device / use for particle filtration
      - **For use in high risk aerosol generating procedures**
      - **With Any claim that it is intended for use as a surgical mask or to provide liquid barrier protection**

# FDA and CDC Actions – FDA EUA

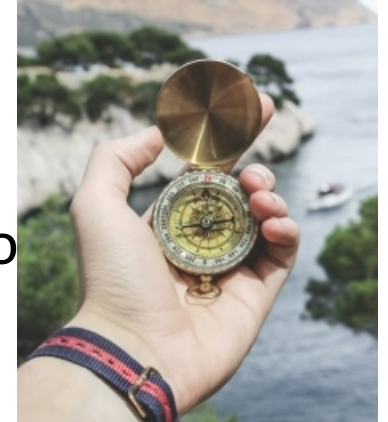
- FDA emergency use authorization (EUA)
  - Must meet these requirements (continued)
    - Labeling that must be present
      - Describing the product as a face mask
      - Listing of body contacting materials (which does not include any drugs or biologics)
      - **recommending against use in a clinical setting where the infection risk level through inhalation exposure is high**
      - Instructions for cleaning (if applicable)

# FDA and CDC Actions – FDA EUA

- FDA Emergency Use Authorization (EUA)
  - Required Statements on all promotional descriptive and printed matter:
    - The product has not been FDA cleared or approved
    - The product has been authorized by FDA under an EUA for use as source control by the general public as well as by HCP in healthcare settings as to help prevent the spread of infection or illness during the COVID-19 pandemic.
    - This product is authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of medical devices, including alternative products used as medical devices, during the COVID-19 outbreak, under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1) unless the authorization is terminated or revoked sooner.

# FDA and CDC Actions – FDA Enforcement Guidance

- FDA enforcement guidance
  - Face masks intended for a medical purpose that are NOT intended to provide liquid barrier protection
    - Temporarily exempt from registration, some reporting requirements, and unique identification requirements - **(also covered in EUA)**
    - Labeling that accurately describes the product as a face mask (as opposed to a surgical mask or FFR) and includes a list of the body contacting materials (which does not include any drugs or biologics) - **(also covered in EUA)**
    - **Labeling that makes recommendations that would reduce sufficiently the risk of use - (next slide has recommended labels for addressing this)**
    - The product is not intended for any use that would create an undue risk in light of the public health emergency for example the labeling does not include uses for antimicrobial or antiviral protection or related uses or uses for infection prevention or reduction or related uses and does not include particulate filtration claims - **(also covered in EUA)**



# FDA and CDC Actions – FDA Enforcement Guidance

- FDA Enforcement guidance
  - Face masks intended for a medical purpose that are NOT intended to provide liquid barrier protection
    - Recommended labeling:
      - **Not recommended for use in any surgical setting or where significant exposure to liquid, bodily or other hazardous fluids, may be expected**
      - **Not recommended for use in a clinical setting where the infection risk level through inhalation exposure is high**
      - **Not recommended of use in the presence of a high intensity heat source or flammable gas**





# Face Masks

Regulatory Requirements and Industry Best Practices:  
Adult Chemical requirements

# Face Masks – Adult Chemical requirements: California Proposition

## 65

- Background
  - Approved by direct ballot in 1986
  - Calls for the creation of a list of chemicals that carcinogenic and / or reproductive toxicants (currently 800+ chemicals listed)
  - Products must be labeled to warn the public against exposure
- Enforcement
  - Allows for private enforcement
  - Enforcers only have to prove a Proposition 65 chemical is present
  - Hundreds of settlements reached every year with millions of dollars being paid by companies.



# Face Masks – Adult Chemical requirements: California Proposition

## 65

- Approaches for addressing Proposition 65
  - Actual compliance (not common)
  - Follow finalized settlements that targeted the specific product (standard industry approach)
    - No finalized settlements involving fashion face masks exist
  - Follow finalized settlements for other masks / apparel items
    - 90 ppm total lead in surface coatings
    - 300 ppm total lead in substrates
      - **Textiles typically wouldn't be tested due to low risk**
    - 1000 ppm DEHP, BBP, DBP, DINP, DIDP each
      - **Textiles typically wouldn't be tested due to low risk**



# Face Masks – Adult Chemical Requirements: Flame Retardants

- PentaBDE / OctaBDE / DecaBDE
  - Requirement - 1000 ppm each
  - Uses - mainly in foam and materials covering foam, and plastic of electronics
    - **Textiles that haven't been treated with a flame retardant typically would not be tested due to their low risk**
- Approaches – Testing of high risk materials only and / or vendor declaration that no flame retardants have been added to materials



# Face Masks – Adult Chemical Requirements: Toxics in Packaging

- Toxics in packaging
  - Requirement – The sum of total lead, cadmium, mercury, and hexavalent chromium  $\leq 100$  ppm
    - Only applies to packaging materials – polybags, hang tags, stickers, etc.
  - Uses – Typically present as contaminants
  - Approaches - Testing and / or vendor declaration that packaging meets toxics in packaging requirements



# Face Masks – Adult Chemical Requirements: Industry Best Practices

- Non-regulatory (voluntary)
  - Formaldehyde – 75 ppm
    - Used in fabrics as anti wrinkle treatment
    - Can cause skin irritation and fishy odor
    - Testing conducted on fabrics with prolonged skin contact
  - Nickel Release -  $0.5 \mu\text{g} / \text{cm}^2 / \text{week}$ 
    - Used in metal alloys
    - Can cause skin irritation
    - Testing conducted on metals with prolong skin contact
  - pH – 6-8
    - High or low pH can cause skin irritation
    - Testing conducted on fabrics with prolonged skin contact



# Face Masks

Regulatory Requirements and Industry Best Practices:  
Children's Chemical requirements



# Face Masks – Children’s Chemical requirements: Lead and Cadmium

- Total Lead (CPSIA)
  - 90 ppm total lead in surface coatings (16 CFR 1303)
  - 100 ppm total lead in substrates (CPSIA)
    - **Textiles typically wouldn’t be tested due to low risk**
- Total Cadmium (Washington State)
  - 40 ppm total cadmium in surface coatings and substrates
    - **Textiles typically wouldn’t be tested due to low risk**
- Phthalates (Washington State)
  - 1000 ppm DEHP, DBP, BBP, DINP, DIDP, DnOP
    - **Textiles typically wouldn’t be tested due to low risk**
- Flame retardants (Washington State)
  - 1000 ppm TBBPA, HBCD
    - **Textiles that haven’t been treated with a flame retardant typically would not be tested due to their low risk**



# Face Masks – Children’s Chemical Requirements: County Laws in New York State

- New York State
  - Only Suffolk, Albany and Westchester counties
- Products Scope
  - All children’s products
- Limit
  - Antimony (60 ppm), Arsenic (25 ppm), Cadmium (75 ppm), lead (90 ppm surface coating / 100 ppm substrate), mercury (60 ppm)
    - Similar to ASTM-F963 requirements for toys

# Face Masks – Children’s Chemical Requirements: State Reporting Requirements

- States with reporting requirements – WA, VT, ME, OR, NY
  - NY State recently enacted a reporting law but no reporting is currently required at this time.
- Products Scope
  - All children’s products
- Chemicals
  - WA (85), ME (14), VT(86), OR (68)



# Face Masks – Children's Chemical Requirements: Industry Best Practices

- Non-regulatory (voluntary)
  - Formaldehyde – 75 ppm or 16 ppm (under 3)
    - Use in fabrics as anti wrinkle treatment
    - Can cause skin irritation and fishy odor
    - Testing conducted on fabrics with prolonged skin contact
  - Nickel Release - 0.5  $\mu\text{g}$  /  $\text{cm}^2$  / week
    - Used in metal alloys
    - Can cause skin irritation
    - Testing conducted on metals with prolong skin contact
  - pH – 6-8
    - High or low pH can cause skin irritation
    - Testing conducted on fabrics with prolonged skin contact



# Face Masks

Regulatory Requirements and Industry Best Practices:  
Labeling

# Face Masks – Regulatory Requirements and Industry Best Practices: Labeling

Labeling Element	Requirement	Regulation or Test Method
Textile Fiber Identification	Regulatory	Federal and Various State Requirements
Care Instructions	Regulatory	Federal and Various State Requirements
Tracking Labels for children's product	Regulatory	Federal - CPSIA Section 103
Country of Origin	Regulatory	Federal and Various State Requirements
Sizing instruction	Best Practice	N / A
Intended use of products	Best Practice	N / A
Directions for use of products	Best Practice	N / A



# Face Masks

Regulatory Requirements and Industry Best Practices:  
Physical



# Face Masks – Regulatory Requirements and Industry Best Practices: Physical

Test Description	Requirement	Test Method	Test Limits
Flammability of Wearing Apparel	Regulatory	16 CFR 1610 / ASTM D1230	Class 1: Plain surface -Average burn time > 3.5 sec , Raised surface- Average burn time > 7.0 s OR Average burn time is 0-7 s with no base burns.
Fiber content (if applicable)	Regulatory	AATCC 20/20A	"Multiple Fibers: +/- 3% maximum Single Fiber: No tolerance"
Breathing Resistance	Best Practice	ASTMD 737	"Using a standard 125Pa pressure drop. Use the standard 38.3 cm2 test area should exhibit a minimum of a minimum of 37.5 ft3/min/ft2"
Breaking strength	Best Practice	ASTMD5034	Attachments should withstand a minimum of 10 lbf (44.5 N)
Stretch and Recover for Elastic Straps	Best Practice	ASTMD 4964	"Should exhibit a 90% recovery after 60 seconds. Maximum Load determined by elastic width. Width ≥ 1": 10 lbf (44.5 N) 1" > width > ½": 5 lbf (22.3 N) ≤ ½" width: 2 lbf (8.93 N)"
Dimensional Stability (Reusable Masks only)	Best Practice	AATCC 135/150	Max +/- 5%, Satisfactory appearance after washing
Attachment Strength strap	Best Practice	ASTMD 5034 modified	Minimum 10 lbs.



# Face Masks

Regulatory Requirements and Industry Best Practices:  
Sizing, Odor and Workmanship

# Face Masks – Regulatory Requirements and Industry Best Practices: Sizing, Odor and Workmanship

Test Description	Requirement	Test Method	Test Limits
Odor	Best Practice	In-House	No Odor
Mask Dimensions	Best Practice	In-House	comply with Claim
Fit	Best Practice	In-House	Fit and handling perfect
Size	Best Practice	In-House	comply with Claim
Workmanship	Best Practice	In-House	No defects



# Face Masks

Regulatory Requirements and Industry Best Practices:  
Colorfastness

# Face Masks – Regulatory Requirements and Industry Best Practices: Colorfastness

Test Description	Requirement	Test Method	Test Limits
CF to Crocking	Best Practice	AATCC 8/116	Dry: Grade 4 minimum Wet: Grade 3 minimum
CF to Perspiration	Best Practice	AATCC 17	Grade: 4-5
CF to Water	Best Practice	AATCC 107	Grade: 4
CF to Saliva(Children's Product)	Best Practice	DIN 53160-1	Grade: 4-5
Dimensional Stability	Best Practice	AATCC 135/150	Max+/- 5%
Appearance after Laundering	Best Practice	AATCC 135/150	Satisfactory appearance after washing



# Duke University Study

Droplet Transmission of Common Material Types

# Duke University Study - Droplet Transmission of Common Material Types

- Duke University Study – Measured droplet transmission of 14 masks and ranked them from best to worst





# Duke University Study - Droplet Transmission of Common Material Types

- Duke University study – Measured droplet transmission of 14 masks and ranked them from best to worst

Rank	Description	Rank	Description
1	Medical N95 mask	8	Hand-sewn cotton
2	Surgical mask	9	'MAXIMA AT' mask
3	Polypropylene and cotton	10	Single-layer cotton
4	Polypropylene apron mask	11	Pleated two-layer cotton
5	Cotton mask with ties	12	Knitted
6	Two-layer cotton with ties	13	Bandanna
7	Valved N95	14	Neck gaiter

Best

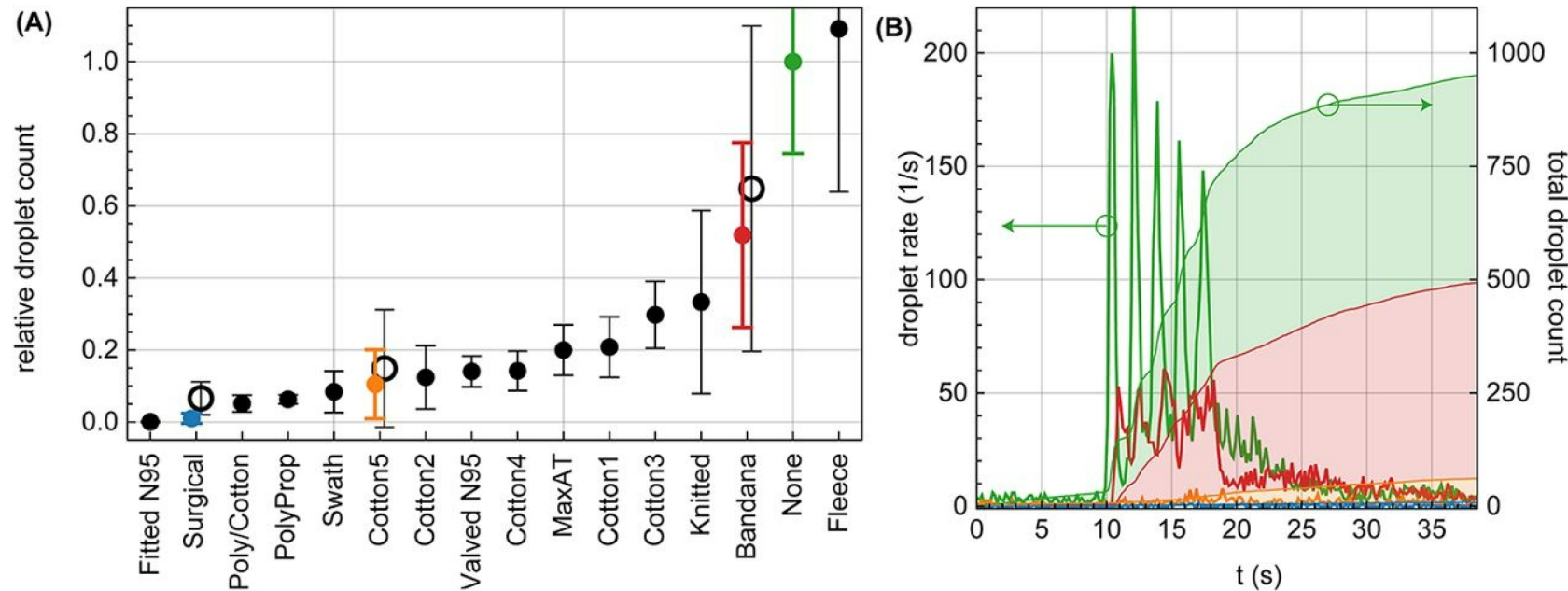


Worst



# Duke University Study - Droplet Transmission of Common Material Types

- Duke University Study – Graph of results



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Thank You!

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# Resources

- **CDC Guidance for Face Masks:**
  - <https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/about-face-coverings.html>
- **FDA Guidance and EUAs for Face masks:**
  - <https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/face-masks-and-surgical-masks-covid-19-manufacturing-purchasing-importing-and-donating-masks-during>
- **FDA Medical Device Reporting:**
  - <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>
- **PPAI:**
  - [www.ppai.org](http://www.ppai.org)
- **PPAI Product Responsibility:**
  - <http://www.ppai.org/inside-ppai/corporate-responsibility/product-responsibility/>
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