

Product Safety Basics

Anne Stone, CAE PPAI Director of Advocacy and Member Engagement

But first a disclaimer...

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Emerging Challenges

- Increasingly end buyers and government agencies are demanding more from our industry
 - Social
 - Environmental
 - Product responsibility



Product Responsibility Is Everyone's Job

- Distributors must protect their customer's brand as if it were their own and do their own due diligence
- Suppliers must ensure compliance with all regulations and oversee all factories
- Everyone is responsible for providing safe products that will not cause harm to the end user
 - Education and awareness are critical

US Regulatory Agencies









Consumer Product Safety Improvement Act of 2008 (CPSIA)

- Applies to all consumer products regulated by CPSC
- Focus on children's products
- Defines a child as 12 years of age and younger
- Applies to:
 - Children's products
 - Childcare articles
 - Children's toys



CPSIA requirements for Children's Products

- Third party testing mandatory:
 - Lead in substrate
 - Lead in paint and surface coatings
 - Some phthalates
- Children's Product Certificate mandatory
- Tracking labels mandatory
- Makes previously voluntary standards mandatory



Lead in substrate

Substrate is the material of which something is made, and to which surface coating (i.e. paint) may be applied

100 ppm lead as of August 14, 2011



Lead Paint Rule

Decorated or scrapable surface coatings

- 16 CFR 1303 in effect since 1978 at 600 ppm
- As of August 14, 2009, sets limit at 90 ppm



Phthalates

- Applies only to children's toys and child care products
- Eight phthalates are restricted to a limit of 0.1%
 - DEHP, DBP, BBP, DINP, DIBP, DPENP, DHEXP, DCHP
- Applies to accessible materials only (before and after use and abuse testing)
- Material exemptions apply

Mandatory Toy Safety Standard

- ASTM F963 has long been a voluntary standard
- Adopted by CPSC as mandatory CPSC safety standard
- Includes additional requirements for toys

Children's Product Certificate (CPC)

- Importer or Domestic manufacturer is responsible for testing and certification
- All testing must be reflected in Children's Product Certificate (CPC) - or General Conformity Certificate (GCC) for general use items
- Must be produced and made available for every youth order
- Sample certificates on the CPSC website

Children's Product Certificate (CPC)

Sample Children's Product Certificate (CPC) Format From CPSC

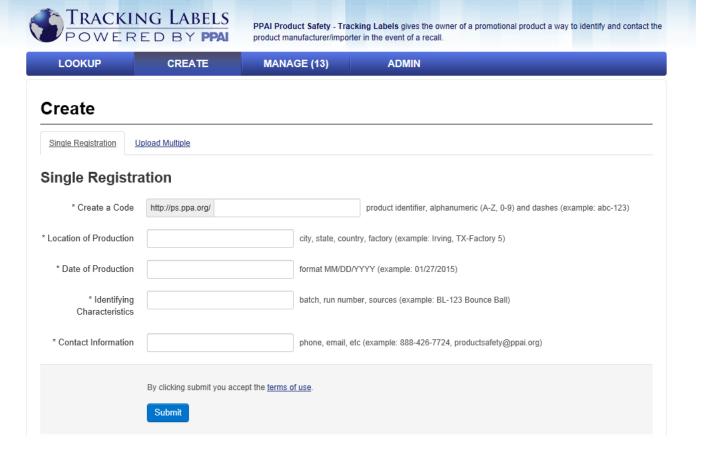
This is the information required by the CPSC. There is no standard format for providing this information.

CHILDREN'S PRODUCT CERTIFICATE

- 1. Identification of the product covered by this certificate
- 2. Citation to each CPSC product safety regulation to which this product is being certified
- 3. Identification of the U.S. importer or domestic manufacturer certifying compliance of the product
- Contact information for the individual maintaining records of test results
- 5. Date and place where this product was manufactured
- 3. Date and place where this product was tested for compliance with the regulation cited above
- 7. Identification of any third-party laboratory on whose testing the certificate depends

- Required for all children's products manufactured after August 14, 2009
- Enhance recall effectiveness
- Required information:
 - Manufacturer name
 - Month & year of manufacture
 - City & state of manufacture
 - Batch or internal order number (P.O. number)
 - Contact information (phone / email)

- Must be permanent
 - Hangtags and adhesive labels <u>not</u> acceptable
- Supplier should include tracking label information
- Depending on changes made to the supplier's product, distributor may need to include additional tracking label markings



 Example using the PPAI tracking label system: ps.ppa.org/SAMPLE003
 Promotional Products Association International



PPAI Product Safety - Tracking Labels gives the owner of a promotional product a way to identify and contact the product manufacturer/importer in the event of a recall.

Product Tracking Label Information

Promotional Products Association International (UPIC: PPAI)
Dallas

09/15/2009, Order123456



Question...

 How do you determine if something is a children's product?

Factors to Consider

- Size and Shape
- Materials Used
- Number of Parts
- Motor Skills Required
- Classic Product
- Colors
- Cause & Effect
- Sensory Elements
- Level of Realism/Detail
- Licensing/Theme





Top Product Categories

- Apparel
- Toys
- Drinkware
- Electronics
- Health and Beauty Products
- Writing Instruments
- Luggage and Bags

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Consider...

For children's apparel:

- Size
- Imprint
- Children's Product Certificate (CPC)
- Secondary tracking labels
- Drawstrings

Size...







For the garment...

- Flammability of Wearing Apparel, 16 CFR 1610
- Fiber Identification Act
- Care Labeling Act
- Country of Origin
- RN number







Imprint...

Ask yourself – are you now the manufacturer?
 Are you making a material change to the product?

Imprint...

- CPSIA, Section 101 Lead Paint Rule
 - Applicable if the ink can be scraped off the garment
 - 90ppm limit
 - TESTING REQUIRED

What about bling?

- Any hard attachments?
 - Both lead limits apply to the decoration
 - Use and abuse testing for attachments is recommended (small parts, sharp points, sharp edges)
- Ask yourself are you now the manufacturer?
 Are you making a material change to the product?

Not just lead, phthalates too But not for everything...for apparel, think apparel intended for ages three and under, sleepwear, baby blankets, sleep mats, bibs and more





Specific examples

 Likely to be found in decoration or attachments such as Velcro, vinyl, zippers, buttons, clasps, and rhinestones.





What can you do?

- No need to change how you handle adult garment decorations
- Work with a screen printer who has tested all inks for children's garments
- Rely on ink suppliers' tests and component testing rule to create the secondary CPC
- Perform third-party tests on finished product to support the secondary CPC
- Make sure a secondary tracking label is affixed to the product
- Look for PPAI best practices

Secondary tracking label

- When a distributor sources from an apparel distributor, contracts with a third-party decorator to apply ink or thread to a garment, and sells the product, the garment has been altered and requires <u>a second tracking label</u> for the same purpose as the first...
 - A secondary tracking label is still required for embroidered items even though most embroidery threads are exempt from testing.

Secondary tracking label

- Required information:
 - Distributor's (Decorator's) name
 - Month & year decoration was applied
 - City & state where decoration was applied
 - Decorator's batch or internal order number
 - Distributor's contact information

Secondary tracking label best practices

- Label location:
 - Bottom hemline
 - Inside back neck
 - Sewn in as a label behind the original care/tracking label



Secondary tracking label best practices

- Permanent tracking labels
 - Mandatory for all children's products
 - Can be incorporated into the decoration if done at different time or by a different vendor







to your product. The CPSC is available to help steer you in the right direction.

Become a Member

Tracking Labels

Learn More

Tracking labels are required for all children's products manufactured one year after enactment of the CPSIA (August 14, 2009) regardless of whether they are domestic or imported products. Below are links to helpful tracking label information.

REGISTRATION

Register Single Tracking Label

The PPAI Tracking Label System complies with CPSIA requirements and is designed to enable the ultimate recipient of a product to identify and contact the manufacturer or importer of a product in the event of a recall.

Register Multiple Tracking Labels (batch upload)

The PPAI Tracking Label System allows you to key in one-off's, import batches with Excel or, if you have IT resources available, develop automated processes to push data into the database using XML web services.

FAQs

CPSC Tracking Label FAQs

Find answers to your tracking label questions on this comprehensive webpage.

Drawstrings

- Short answer...no drawstrings in children's upper outerwear
- Hood, neck and waist drawstrings on children's upper outerwear presents a substantial strangulation hazard (sizes 2T to 12 or equivalent)

Primary Reasons For Apparel Recalls

- Managed by the CPSC
 - Failure to meet federal flammability standards for children's sleepwear
 - Strangulation in case of drawstring around neck or waist area
 - Choking hazards
 - Lack of conformity with CPSIA

Top Product Categories

- Apparel
- Toys
- Drinkware
- Electronics
- Health and Beauty Products
- Writing Instruments
- Luggage and Bags

Children's products

 Primary consideration for all children's products and toys is the Consumer Product Safety Improvement Act (CPSIA)



Primary Reasons For Toy Recalls

- Managed by the CPSC
 - Lack of conformity with CPSIA
 - Excessive lead or phthalates
 - Choking
 - Laceration
 - Strangulation
 - Burn
 - Intestinal obstructions

Top Product Categories

- Apparel
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Drinkware

- Unlike many consumer products, most of the items in the drinkware category do not fall under the CPSIA, unless primarily intended for children 12 years of age or younger
- Most of the items in the houseware and drinkware category are covered not by the CPSC but rather by the FDA, the Food and Drug Administration.
- In addition, there are FDA Guidelines for items such as ceramic drinking vessels and other ceramic items in contact with food.

Food Contact Substance

A food-contact substance is defined as "any substance intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use is not intended to have a technical effect in such food."

Primary Reasons For Drinkware Recalls

- Managed by the CPSC
 - Fire and burns
 - Lacerations
 - Lead
 - Choking

Generally Recognized as Safe (GRAS)

 Designation that a chemical or substance added to food is considered safe by experts, and so is exempted from the usual Federal Food, Drug, and Cosmetic Act (FFDCA) food additive tolerance requirements

• Example: Stainless Steel

Beyond FDA... CA Prop 65

- Ceramicware that is externally decorated
- Aluminum cookware
- Beverage containers with colored artwork, made of glass, plastic, ceramic, resin, vacuum metalizing, dolomite, and/or metal
- Brass handled cookware
- Food use items such as glasses, pilsners, mugs, carafes, tumblers, bottles, condiment dispensers, bowls, cups, saucers, plates, trays, pitchers, punch bowls, serving utensils and serving platters
- Water bottles and soft beverage containers made of PVC

Consider Quality and Performance Concerns

- Labeled claims
- Leakage (burn hazard)
- Breakage
- Drinking spout detachment
- Handle temperature
- Handle strength
- Lid fit
- Microwave compatibility
- Dishwasher compatibility
- Heat retention
- Stain resistance
- Thermal shock
- Cycle testing

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Lithium battery issues

- Ingestion incidents are life-threatening
- Packaging requires special precautions
- Overheating and fire dangers lead to scores of recalls
- Fire risks lead to regulations for air transport
- Defects in manufacturing reveal QA challenge
- Replacement is not always foolproof
- End-of-life disposal creates safety and handling challenges

Why is it dangerous?

- Over voltage
- Over current
- Over temperature
- Internal forces
- External forces









Promo Products and Recommended Testing/ Certification

Type of Promotional Product	Type of Test Work or	Deliverable
	Certification Services	
Portable Battery Power (aka Power Bank / USB Battery Back-Up Charger)	UL 2054 test report only (may include UL/CSA 60950-1 requirements) UL 2054 certification for USA market	Not a certified product. Test report stored with battery mfr. and/or supplier. UL in a Circle Certification Mark (USA only)
	UL 2054+UL/CSA 60950-1 certification for USA/CAN market	UL in a Circle Certification Mark (USA/CAN)
	IEC 62133 CB for international market	CB Certificate (can be also test report only)
Wall Plug-In Charger and/or Adapter	UL 1310 certification for USA market	UL in a Circle Certification Mark (USA only)
	UL 1310+CAN/CSA-C22.2 No. 223 certification for USA/CAN market	UL in a Circle Certification Mark (USA/CAN)
Bluetooth Audio/Video Device	UL 60065 test report only	Not a certified product. Test report stored with mfr. and/or supplier.
	UL 60065 certification for USA market	UL in a Circle Certification Mark (USA only)
	UL 60065 + CAN/CSA-C22.2 No. 60065 certification for USA/CAN market	UL in a Circle Certification Mark (USA/CAN)
	IEC 60065 CB for international market	CB Certificate
	Bluetooth Frequency Testing – FCC Part 15.247 (USA)	Test Report
	Bluetooth Frequency Testing - EN300-328 (Europe)	Test Report
	Bluetooth Frequency Testing - Other Bluetooth Standards	Test Report
Portable Vehicle Battery Adapter	UL 2089 test report only	Not a certified product. Test report stored with mfr. and/or supplier.
	UL 2089 for USA/CAN market	UL in a Circle Certification Mark (USA only)
	UL 2089 + CSA-C22.2 No. 107.2 certification for USA/CAN market	UL in a Circle Certification Mark (USA/CAN)
Laser Pointers	IEC 60825-1 test report only	Not a certified product. Test report stored with mfr. and/or supplier.
	IEC 60825-1 certification for USA market (includes UL Follow-Up Services program)	UL in a Circle Certification Mark (USA/CAN)
	IEC 60825-1 CB for international market	CB Certificate

Primary Reasons For Electronic Recalls

- Managed by the CPSC
 - Fires or burns
 - Shock

Top Product Categories

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Labeling for promotional products

- Cosmetics
- Over-the-Counter (OTC) Drugs
- Consistency in Principle Display Panel (PDP) Requirements
 - » Statement of Identity
 - » Weight

Is it a drug or a cosmetic?

- Drug is defined as a "product intended to treat or prevent disease, or affect the structure or function of the body."
- Examples:
 - Sunscreen
 - Dandruff Shampoo
 - Acne treatment
 - Antiperspirants
 - Anything that makes a claim to treat or prevent

Cosmetics

- Cosmetics are defined as "articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body...for cleansing beautifying, promoting attractiveness, or altering the appearance."
- Doesn't claim to treat or prevent anything.
- Examples:
 - Moisturizers
 - Perfumes
 - Lipstick
 - Fingernail polish
 - Cleansing shampoos
 - Hair colors

How do I tell the difference?

- Drugs make claims. Cosmetics do not.
 » Balm is a claim. Moisturizer is not.
- It is possible to be both a drug and a cosmetic.
- Proper labeling is imperative for FDA compliance.



Cosmetic label sample



OTC drug label sample

Sunscreen Labeling According to 2011 Final Rule

If used as directed with other sun protection measures, this product reduces the risk of skin cancer and early skin aging, as well as helps prevent sunburn.

Only products labeled with both "Broad Spectrum" AND SPF15 or higher have been shown to provide all these benefits.





Drug Facts Active Ingredients Purpose Avobenzone 3% Homosalate 10% Sunscreen Octyl methoxycinnamate 7.5% Uses helps prevent sunburn If used as directed with other sun protection measures (see decreases the risk of skin cancer and early skin aging caused by the sun Warnings For external use only Do not use on damaged or broken skin When using this product keep out of eyes. Rinse with water to remove. Stop use and ask a doctor if rash occurs Keep out of reach of children, If product is swallowed, get medical help or contact a Poison Control Center right away. apply liberally 15 minutes before sun exposure reapply: · after 40 minutes of swimming or sweating · immediately after towel drying at least every 2 hours Sun Protection Measures. Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a broad spectrum SPF of 15 or higher and other sun protection measures including: limit time in the sun, especially from 10 a.m. - 2 p.m. · wear long-sleeve shirts, pants, hats, and sunglasses children under 6 months: Ask a doctor Inactive ingredients aloe extract, barium sulfate, benzyl alcohol, carbomer, dimethicone, disodium EDTA, Jojoba oil, methylparaben, octadecene/MA. copolymer, polyglyceryl-3 distearate, phenethyl alcohol, propylparaben, sorbitan isostearate, sorbitol, stearic acid, tocopherol (vitamin E). triethanolamine, water Other information protect this product from excessive heat and direct sun.

Questions or comments?

Call toll free 1-800-XXX-XXXX



Remember...

• Regardless of the size of the container, it must be labeled properly. If you have a lip moisturizer, in a lip balm tube, making an SPF claim-it must be labeled as an OTC. So, you must put all the information on the sunscreen bottle on the label of that lip balm tube.

Primary Reasons For Recalls

- Managed by the CPSC and FDA
 - Lack of conformity with the Poison Prevention Packaging Act

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Writing instruments

 In most cases, pens are considered general use...even if sold in school stores, back to school bins and include a school logo or mascot.



Pens can become children's products if...

- They have play value
- Licensing or theme has diminishing appeal to adults (mortification rule)





Due care still required...

- LHAMA, ASTM D4236
- CPSC Guidance for extractable lead
 - Art materials (crayons, colored per citations)

etc.)

- Lacey Act
 - Wood pencils









APPROVED

December 12, 1998 recall Voluntary recall due to imprinted message.



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Luggage and bags

- There are no Federal regulatory requirements regarding luggage or bags unless the item is intended to hold food, in which case, applicable FDA requirements would apply.
- If the item is a children's product it would require CPSIA lead compliance and possibly other children's product safety requirements.
- For adult bags, there are no Federal requirements.

Luggage and bags

- Consider state regulations
- Reusable or disposable?

970+ Letters of Advice (LOA) for violation of a mandatory standard within 12 month period

- 304 tracking label violation
- 180 third party certificate violation
- 251 lead in children's products/lead in paint
- 60 sleepwear labeling or flammability failure
- 56 art materials labeling
- 17 exceeds phthalate ban limit (stop sale)
- 14 misbranded toys, small parts, balloons
- 13 bicycle helmets
- 12 small parts violations
- 8 ASTM toy standard violation
- 4 durable nursery product
- 1 art materials labeling

Product Responsibility Resources PPAI: www.ppai.org

PPAI Corporate Responsibility:

http://www.ppai.org/corporate-responsibility/

QIMA: QIMA.com

Questions? AnneS@ppai.org 972-258-3041