



## Priority Chemical Reporting Regulation – Chapter 882/883 Reporting Guidance

As set forth in the web links available on this website, the Maine Legislature has conferred upon the Maine Department of Environmental Protection (the “Department”) the regulatory authority to collect information on the use of priority chemicals in product categories defined by rule. The purpose of this guidance is to clarify questions that may arise during the submission of information using the Department’s reporting form.

Reports due to the Department before October 3, 2011, are detailed in the Department’s rule *Designation of Bisphenol A as a Priority Chemical and Regulation of Bisphenol A in Children’s Products*, 06-096 CMR 882 and *Designation of the Chemical Class Nonylphenol and Nonylphenol Ethoxylates as a Priority Chemical* 06-096 CMR 883, as well as *P.L. 2011, Chapter 319* (formerly L.D. 1129, 125th Maine Legislature, First Regular Session).

The Department’s Safer Chemicals web page, with links to in-depth background information and references, such as those mentioned above can be found at:

<http://www.maine.gov/dep/oc/safechem/>

Where consistent with Maine law and rule, much of the language and examples used in this document are based on a recently released rule (WAC 173-334) and associated reporting guidance from the Washington State Children’s Safe Product Act program. The intent is to make state programs as consistent as practicable, to aid reporting, and to allow states to share information where feasible. The Department would like to thank Washington State’s Department of Ecology for their assistance and continued collaboration.

**Please Note: The Department recognizes that future rule making may modify reporting requirements and would, therefore, amend this guidance as required. To meet the intent of recently enacted legislation, the Basis Statements for rules currently published are considered to be superseded by *P.L. 2011, Chapter 319* (formerly L.D. 1129).**



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Each reporting form posted by the Department begins with general contact information. Please list the Manufacturer's registered name and address. The contact name and address should be the program manager the Department would contact with questions of clarification. Forms are designed for a one-to-many relationship, the one manufacturer listed will provide information on many product categories reported. Please note, if you are an industry group representing multiple manufacturers a separate report must be completed for each manufacturer; for ease of use the copy/paste function is available for repeating information.

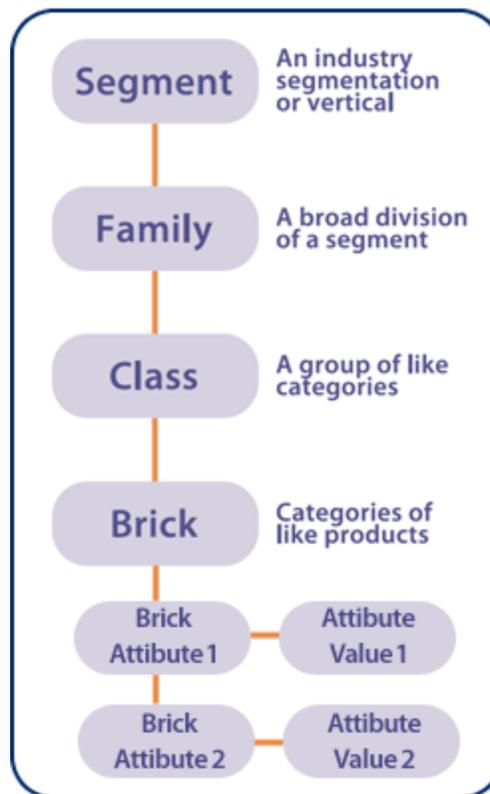
For guidance purposes this document is divided into sections for use as a reference:

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## Section 1 – Explanation of GPC categories

In order to facilitate reporting, Product Categories are identified using the “Brick” level of the GS1 Global Product Classification (GPC) system as an existing product categorization system used by industries worldwide. This system identifies the products that serve a common purpose, are of similar form and material, and share the same set of category attributes. The following explanation is from the GS1 website:



To ensure products are classified correctly and uniformly, the Global Data Synchronization Network (GDSN) uses the GS1 Global Product Classification (GPC), a system that gives buyers and sellers everywhere in the world a common language for grouping products in the same way.

This improves the Global Data Synchronization Network's data accuracy and integrity, speeds up the supply chain's ability to react to consumer needs, and contributes to breaking down language barriers. It also facilitates the reporting process across product silos.



The foundation of GPC is called a “Brick;” GPC bricks define categories of similar products. Using the GPC brick as part of GDSN ensures the correct recognition of the product category across the extended supply chain, from seller to buyer. Bricks can be further characterized by Brick Attributes, however, the Department reporting form requires the Brick level only.

*The web browser for products and their respective categories can be found at:*

<http://www.gs1.org/1/productssolutions/gdsn/gpc/browser/>

*The GPC schemas can also be downloaded in Excel and XML format:*

<http://www.gs1.org/gsm/kc/gpc> .

## **Section 2 – Reporting Threshold Guidance**

Maine *P.L. 2011, Chapter 319*, establishes a reporting threshold as follows:

- A. For a chemical of high concern or priority chemical that is an intentionally-added chemical in a component of a children’s product, the practical quantification limit;
- B. For a chemical of high concern or priority chemical that is a contaminant present in a component of a children’s product, a concentration of 100 parts per million.

“Intentionally added” is defined as a chemical that is added during the manufacture of a product or product component to provide a specific characteristic, appearance or quality, or to perform a specific function.

“Practical quantification limit” (PQL) means the lowest concentration of a chemical that can be reliably measured within specified limits of precision, accuracy, representativeness, completeness and comparability during routine laboratory operating conditions.

“Contaminant” means trace amounts of chemicals that are incidental to manufacturing. They serve no intended function in the product component. Contaminants can include, but are not limited to, unintended by-products of chemical reactions during the manufacture of a product component, trace impurities in feed-stock, incompletely reacted chemical mixtures, and degradation products. *(This definition is expected to be reviewed during upcoming rule making and, as written, mirrors Washington State Rule (WAC 173-334-040).)*



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This section of guidance intends to offer clarification about the information the Department will look for in the event that we must evaluate the sufficiency of manufacturer efforts to minimize the presence of contaminants in their products.

The party responsible for reporting data has one of two options for contaminants:

- 1) Report to the Department if the chemical is measured above 100 ppm, or
- 2) Rely on the quality of their manufacturing control program to eliminate the need to report the concentration of contaminants.

If the Department determines that a chemical present in a product category was not reported, the reporting party will be contacted. If the manufacturer has relied on the use of an effective manufacturing program – in place **at the time of manufacturing** – the manufacturer will need to demonstrate the sufficiency of such a program to the Department.

A manufacturer of children's products is responsible for knowing the amount of priority chemical in its finished products sent to market. To control the amount of any contaminants present in its final children's product, the manufacturer may choose to establish and conduct a manufacturing control program. At a minimum, a reasonable manufacturing control program includes those methods and procedures required to comply with federal regulations for children's products and may include recognized industry best manufacturing practices, e.g., compliance with: relevant International Standards Organization (ISO) requirements, American Society for Testing and Materials (ASTM) standards, or other widely established certification or standards programs.

Actions demonstrating diligence **may** include, but are not limited to:

- Use and enforcement of contract specifications.
- Procedures to ensure the quality/purity of feedstock (whether raw or recycled).
- Use and enforcement of contract specifications for manufacturing process parameters (e.g., drying and curing times when relevant to the presence of high priority chemicals in the finished children's product components).
- Periodic testing for the presence and amount of priority chemicals.
- Auditing of contractor or supplier manufacturing processes.
- Use of a chemical educational outreach program for members of supply chain.
- Other practices reasonably designed to ensure the manufacturer's knowledge of the presence, use, and amount of priority chemicals in its children's product components.



The Department's compliance assurance efforts will include an investigation prior to any formal enforcement actions. As part of any investigation the Department will make a good faith effort to provide notice to the responsible party and an opportunity to respond to any Department concerns. It is during this response period that the responsible party can present their justification for relying on their manufacturing control program.

While the Department cannot provide the specifics of a "one size fits all" manufacturing control and due diligence program, any person wishing to demonstrate compliance with this provision must establish both the presence and implementation of the appropriate actions listed above when evaluating submitted information.

If a manufacturer does not have confidence in its ability to demonstrate an appropriate manufacturing control and due diligence program, it is expected that they will report all priority chemicals that are present as contaminants above a concentration 100ppm.

The Department anticipates that there will be situations where the same chemical in the same product category or component could be considered a contaminant in one situation and intentionally added in another. Below are examples to illustrate this point.

**Example 1:** A manufacturer makes a variety of infant pajamas. Some are designed to be wrinkle free and others that are not. Where Chemical Z is added to help the shirt remain wrinkle-free, the Department would consider Chemical Z to be intentionally-added and the manufacturer would have to report the amount, irrespective of the concentration. For infant pajamas where Chemical Z is not added intentionally and does not perform a specific function, but there is some present in the final product, the manufacturer has one of two options:

- 1) Report the presence of Chemical Z if its concentration is above 100 ppm;
- 2) Rely on the ability to demonstrate to the Department that a manufacturing control and due diligence program was in place that minimized the presence of Chemical Z.



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**Example 2:** If Metal Y is used to provide malleability in a metal used to make a child's bracelet, the concentration of Metal Y added must be reported at any concentration above the practical quantification limit (the lowest concentration that can be reliably measured) but if Metal Y is present in the jewelry due to small amounts inadvertently being transferred from the mold to the jewelry, it would be considered a contaminant. The manufacturer has one of two options:

- 1) Report the presence of Metal Y if its concentration is above 100 ppm;
- 2) Rely on their ability to demonstrate to the Department that a manufacturing control and due diligence program was in place that minimized the presence of Metal Y.

**Example 3:** A manufacturer is making a material to be molded into a plastic toy. Chemical A is combined with Chemical B to make Plastic Material C that has essential properties needed to produce the plastic toy. Some trace amounts of Chemicals A and B remain in Plastic Material C, neither chemical serves a function in the final product. Chemicals A and B would be considered contaminants. The manufacturer has one of two options:

- 1) Report the presence of Chemicals A and B if the concentration of either chemical is above 100 ppm;
- 2) Rely on their ability to demonstrate to the Department that a manufacturing control and due diligence program was in place that minimized the presence of Chemicals A and B.



### Section 3 – Product Data

#### GS1 Segments Subject to Reporting

The Maine reporting form GPC categories appear in the following format:

GPC Segment	GPC Family	GPC Class	GPC Brick Category	GPC Code
Toys/Games	Toys/Games	Musical Toys	[Redacted]	
			Musical Toys (Non Powered)	
			Musical Toys (Powered)	
			Musical Toys Other	

The Department has provided drop-down options that mirror the choices established by the GPC system for the relevant segments. Each row in the Excel spreadsheet must begin with a GPC Segment choice as a required field before the GPC Family may be chosen (the first choice effects the second and this pattern cascades through to the GPC code, which will automatically populate based on prior selections).

Reporting categories are limited to the following segments in the GPC system based on the priority chemical identified:

#### Reporting Submission Required for Infant Formula and Baby Food (CMR 882(4)(A))

##### GPC Segments

- Food/Beverage
- Kitchen Merchandise

“Infant formula” means a liquid that purports to be or is represented for special dietary use solely as a food for infants by reason of its simulation of human milk or its suitability as a complete or partial substitute for human milk.

“Baby food” means a prepared solid food consisting of a soft paste or an easily chewed food that is intended for consumption by children two years of age or younger and is commercially available.



**Reporting Submission Required for Toys, Childcare Articles and Tableware (CMR 882(4)(B))**

GPC Segments

- Arts/Crafts/Needlework
- Baby Care
- Beauty/Personal Care/Hygiene
- Camping
- Cleaning Hygiene Products
- Clothing
- Footwear
- Household/Office Furniture/Furnishings
- Kitchen Merchandise
- Personal Accessories
- Stationery/Office Machinery/Occasion Supplies
- Toys/Games

“Toy” means a consumer product designed or intended by the manufacturer for a child 12 years of age or younger for use by the child when the child plays. “Toy” does not include helmets, masks, goggles or other personal protective equipment designed to protect the wearer’s body from injury during sports and recreation activities.

“Child care article” means a consumer product designed or intended by the manufacturer to facilitate sleep or the feeding of children age 3 and younger, or to help such children with sucking or teething.

“Tableware” means reusable or disposable dishes, utensils and other articles used in setting a table and/or serving a meal. “Tableware” includes but is not limited to: plates, bowls, cups/glasses, spoons, knives and forks.



**Reporting Submission Required for Nonylphenol and Nonylphenol Ethoxylates (CMR 883(4))**

GPC Segments

- Baby Care
- Beauty/Personal Care/Hygiene
- Building Products
- Camping
- Cleaning Hygiene Products
- Clothing
- Footwear
- Household/Office Furniture/Furnishings
- Kitchen Merchandise
- Lubricants
- Personal Accessories
- Plumbing/HVAC
- Stationery/Office Machinery/Occasion Supplies
- Storage/Haulage Containers
- Toys/Games

“Household and commercial cleaning products” means soaps, detergents and other chemically formulated consumer products designed for fabric care, dish and other ware washing and/or surface cleaning in residential, institutional or commercial establishments.

“Home maintenance products” means products used for the repair or maintenance of the inside or outside of a home, including, but not limited to, adhesives, caulking, grouts, fillers, sealants, paints and other surface finishes.

“Cosmetics and personal care products” means articles intended to be rubbed, poured, sprinkled, or sprayed on, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and articles intended for use as a component of any such articles.

**Product Brand Name**

If available, please provide the brand name for the product categories reported.

Product Brand Name



**BPA Amount in Product Unit**

Analysis of the measurable amounts of priority chemicals found in reportable product categories is reported in parts per million (ppm) (please note in the additional information column if you must report this amount in an alternative format). BPA amount in product unit refers to the highest concentration of a priority chemical in a component across the entire product category.

Offered in ranges, this column is a drop down choice.

BPA Amount in Product Unit
>=100 ppm (0.01%) and <500 ppm (0.05%)
>=PQL and <100 ppm (0.01%)
>=100 ppm (0.01%) and <500 ppm (0.05%)
>=500 ppm (0.05%) and <1,000 ppm (0.10%)
>=1,000 ppm (0.10%) and <5,000 ppm (0.5%)
>=5,000 ppm (0.5%) and <10,000 ppm (1.0%)
>=10,000 ppm (1.0%)

**BPA Function**

BPA Function	Number of Units Sold
Binding Agent	
Catalyst	
Coloration/Pigment/Dye	
Component of plastic resin	
Conductive material (Electronics)	
Contaminant	
Dispersant	
Emulsifier	

A drop down list of the most commonly reported functions of reportable priority chemicals is provided; please choose the function that most closely represents the manufacturer’s use. (This drop-down list includes “Contaminant”.)

**Number of Units**

Number of Units Sold
50,000-100,000
50,000-100,000
100,000-150,000
150,000-200,000
200,000-250,000
250,000-300,000
300,000-350,000
350,000-400,000
400,000-450,000

**Units Sold Where**

Sold	Units Sold Where
	Nationally
	Nationally
	Within Maine

Please report the number of units sold annually using the most recent sales data available. While the number of Units Sold is a numeric range, the adjacent column asks for further detail, a National figure or the number of units sold in the State of Maine, making this distinction will allow a clearer representation of potential population exposure.



## Section 4 – Component Data

Component Exposure/Accessibility
Exposed
Accessible
Exposed & Accessible

### **Component Exposure/Accessibility**

Component refers to a uniquely identifiable material or coating that is intended to be included as a part of a finished product. It is presumed that reporting components of a product category will result in a one-to-many relationship within the form (one product category may have more than one component), in addition to the possibility of two different variations of the same component.

**Example:** A manufacturer makes a pair of children’s pants with a plastic button and a metal zipper.

The product contains three components: textile, plastic (button), and metal (zipper). The component reported within this product category will likely be the plastic button.

Component Exposure/Accessibility will equal “Exposed & Accessible” as the plastic button in this example is exposed and is accessible.

**Example** (multiple components reported for one category): A manufacturer makes an action figure that has red plastic arms and blue plastic legs, each with intentionally-added BPA.

This product contains two reportable components, red and blue plastic. The two different colors of plastic are uniquely identifiable and reasonable to separate and report as two components.



### **Formulated Products with Reportable Components**

Formulated products, such as personal care products, will most often be classified as containing a single component (homogeneous mixtures). However, it is possible that a formulated product might contain more than one component.

**Example:** A manufacturer makes hair gel that contains glitter.

**The product contains two components:** a homogenous mixture (the gel) and the glitter (plastic).

The plastic glitter containing a priority chemical is the reportable component.

The Department expects reports will detail the highest concentration of each priority chemical for each product component in a product category; the manufacturer must also report the highest amount of priority chemical in the product unit across the entire product category (as detailed in the Product Data section of our reporting form).

Component Size
Mouthable (<5cm in at least one dimension)
Not Mouthable (>5cm in all dimensions)

### **Component Size**

CMR 882(4)(A)(3) details the importance of size by specifying, *“A toy can be placed in a child’s mouth if any part of the toy can actually be brought to the mouth and kept in the mouth by a child so that it can be sucked and chewed. If a toy or part of a toy in one dimension is smaller than 5 centimeters, it can be placed in the mouth.”*

**Example:** The blue plastic legs and red plastic arms of an action figure are the components reported; component size is 10 centimeters long by 4 centimeters wide.

Size will be reported as “Mouthable < 5cm in at least one dimension”. Drop-down choices in this column are greater than 5 centimeters in all dimensions or less than 5 centimeters in at least one dimension based on the data required by rule. An alternate measurement may be typed into this cell (please note an error message will appear but is inconsequential to the form; choose “Yes” to continue through the error message without concern for the data entered).



### **Inaccessible Components**

Manufacturers are not required to report on the presence of a priority chemical if during “reasonable and foreseeable use and abuse” of the product a child’s skin or mouth would not come into direct contact with the component.

**Example:** A manufacturer makes a stuffed animal. The stuffed animal has a fur and textile covering, black plastic eyes, red plastic lips, foam stuffing, a metal music box in the middle that contains a priority chemical.

In this case, the fur covering, the textile covering, the black plastic and red plastic would all be considered **separate components** of the unit and reportable; the metal music box in the middle is considered inaccessible and therefore does not require reporting. If, however, during reasonable and foreseeable use and abuse, the child would come into direct contact with the metal of the music box, the metal is considered a reportable component.

While the number of potential combinations and scenarios for all children’s products covered by Maine’s *Toxic Chemicals in Children’s Products* program cannot be covered in their entirety in this document, the above should provide an indication of how the Department interprets the general reporting concepts in rule.



**BPA Measured in Component**

BPA Measured in Component	
>=PQL and <100 ppm (0.01%)	▼
>=PQL and <100 ppm (0.01%)	
>=100 ppm (0.01%) and <500 ppm (0.05%)	
>=500 ppm (0.05%) and <1,000 ppm (0.10%)	
>=1,000 ppm (0.10%) and <5,000 ppm (0.5%)	
>=5,000 ppm (0.5%) and <10,000 ppm (1.0%)	
>=10,000 ppm (1.0%)	

The Department expects reports will detail the highest concentration of each priority chemical for each product component in a category; the manufacturer must also report the highest amount of priority chemical in the product unit (as a whole) across the entire product category (as detailed in the Product Data Section).

**Additional Info**

Additional Information

Other information the manufacturer deems relevant to the reporting of the priority chemical.

This may include an alternatives assessment already performed by the manufacturer of the availability, cost, feasibility and/or performance of a safer alternative chemical to replace the reported priority chemical. Additional information may be specified in the column with a brief description and added as a supplemental document if necessary.