



Connectivity & Products

## Juvenile Products: Chemical Requirements for the EU and North American Markets


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### Presenter


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With a background in chemistry, Hing has 15+ years experience in consumer product safety and quality, particularly restricted substances and chemicals in the Hardlines industry.

He joined the Global Hardlines team in 2013 and manages the technical aspects, ranging from regulatory and standard developments to chemical projects.

He is also a member of SGS's committee on chemicals in toy safety and food contact materials and articles.



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### Agenda

- European Union
  - General Product Safety Directive (GPSD)
    - Harmonized Standards for Presumption of Conformity
  - Other Applicable Legislation:
    - REACH, POP Recast and Food Contact
- North America
  - Canada Consumer Product Safety Act (CCPSA)
  - US Federal, US State/Local Laws (Prop 65, Reporting Rules for Children's Products, BPA, Flame Retardants)
  - Composite Wood Products
- Q&A

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## Juvenile Products: Chemical Requirements for the EU




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### General Product Safety Directive (GPSD, Directive 2001/95/EC)

- To ensure a high level of product safety throughout the EU for consumer products that are not covered by specific sector legislation (e.g. cribs and cradles)
- Product is considered safe if it meets all statutory safety requirements under European or national law
- Several EU standards for juvenile products are cited in the Official Journal of the EU (OJEU) for presumption of conformity with the GPSD
  - If there are no regulations or EU standards cited in the OJEU, a product's compliance is determined according to other documents such as European standards, national or international standards, Commission recommendations, or codes of practice




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### Implementing Decisions (EU) 2020/1808 & (EU) 2019/1698

Representative Juvenile Product Standards		
No	Standard	Title
11	EN 1130-1:1996	Cribs and cradles for domestic use – Safety requirements*
13	EN 1273:2005	Baby walker frames – Safety requirements and test methods*
16	EN 1930:2011	Safety barriers – Safety requirements and test methods*
31	EN 12221-1:2008+A1:2013	Changing units for domestic use – Part 1: Safety requirements*
39	EN 13209-1:2004	Baby carriers – Safety requirements and test methods – Part 1: Framed back carrier*
40	EN 13209-2:2015	Baby carriers – Safety requirements and test methods – Part 2: Soft carrier*
46	EN 14344:2004	Child seats for cycles – Safety requirements and test methods*
52a	EN 16890:2017	Mattresses for cots and cribs – Safety requirements and test methods*
52b	EN 17022:2018	Bathing aids – Safety requirements and test methods*
52c	EN 17072:2018	Bath tubs, stands and non-standalone bathing aids – Safety requirements and test methods*

\*Latest EN 71-3 for soluble elements  
\*EN 71-3:2013+A1:2016 for soluble elements



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### REACH Annex XVII (1/2)

Representative Restricted Substances/Scope under Annex XVII of REACH

Entry No	Substance	Scope	Requirement
20	Organotin Compounds (as tin)	Articles	≤ 0.1% (tri-substituted such as TBT and TPT)
		Articles and mixtures	≤ 0.1% dibutyltin (DBT)
		Certain articles e.g. childcare articles	≤ 0.1% dioctyltin (DOT)
23	Cadmium	Certain synthetic polymers (plastics) Paint on painted articles	≤ 100 mg/kg ≤ 1,000 mg/kg
43	Azo dyes	Textiles and leather which may come into direct and prolonged contact with the skin	≤ 30 mg/kg each listed aromatic amine
47	Chromium (VI)	Leather articles coming into contact with the skin	≤ 3 mg/kg
50	8 Polycyclic aromatic hydrocarbons (PAHs)	Toys and childcare articles (rubber or plastic components in direct and prolonged or short-term repetitive contact with the human skin or oral cavity, under normal or reasonably conditions of use)	≤ 0.5 mg/kg each PAH

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### REACH Annex XVII (2/2)


Representative Restricted Substances/Scope under Annex XVII of REACH

Entry No.	Substance	Scope	Requirement
51	Phthalates (BBP, DBP, DEHP and DIBP)	- Plasticized materials in toys and childcare articles as well as other articles	< 0.1% (individually and in combination)
52	Phthalates (DIDP, DINP and DNOP)	Plasticized materials in toys and childcare articles which can be placed in the mouth	≤ 0.1% (sum)
68	C <sub>2</sub> -C <sub>14</sub> PFCAs and their salts	- Substances on their own	- Prohibited
		- As a constituent of another substance	- < 25 ppb (sum of C <sub>2</sub> -C <sub>14</sub> PFCAs and their salts)
72	33 CMR category 1A or 1B substances	- C <sub>2</sub> -C <sub>14</sub> PFOA-related substances and their salts	- < 260 ppb (sum of C <sub>2</sub> -C <sub>14</sub> PFOA-related substances) (effective 25 February 2023)
		- Footwear, clothing or related accessories	Limit is substance dependent (Appendix 12)
72	33 CMR category 1A or 1B substances	- Textiles other than clothing which, under normal or reasonably foreseeable use, come into contact with the human skin to an extent similar to clothing, e.g. blankets, cushion covers, sleeping bags, towels and upholstery (fabric chair covering)	Limit is substance dependent (Appendix 12)

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### REACH – Candidate List SVHCs in Articles

Substance Category	Obligation	Effective Date
Substances in articles (include packaging articles)	<b>Article 33 of REACH 'Communication in the Supply Chain'</b> If requested by consumers (the general public), suppliers of an article* containing > 0.1% of an SVHC are obliged to provide sufficient information to allow the safe use of the article within 45 days. The minimum information is the name of SVHC	Date of inclusion
	<b>Article 7(2) of REACH 'Notification'</b> Suppliers of an article* containing an SVHC are obliged to notify the European Chemicals Agency (ECHA) if both of these conditions are met: - SVHC is more than 0.1%, and - Total quantity of SVHC in (all) articles is more than 1 tonne per year	Within 6 months of inclusion

\*Article means an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition. The threshold limit of 0.1% for an SVHC in an article applies to the article as produced

Note – suppliers of an article containing more than 0.1% of a Candidate List SVHC are also obliged to report to the SCIP database (Waste Framework Directive, WFD)

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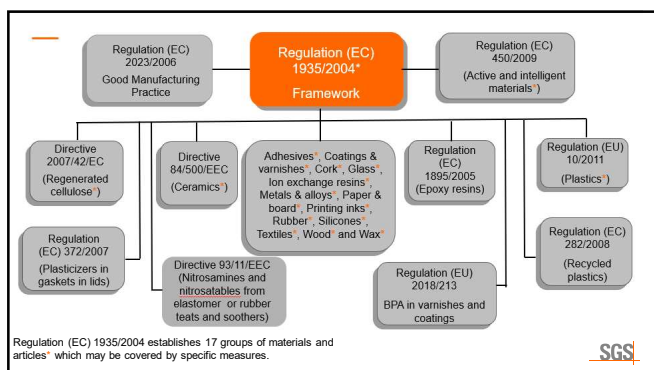
### Persistent Organic Pollutants (POPs)



- Stockholm Convention
  - Global treaty to protect human health and the environment from POPs
  - POPs are chemicals that can become widely distributed geographically and remain in the environment for long periods
- Regulation (EU) 2019/1021 (POP Recast)
  - Prohibits more than 25 POP chemicals but some are allowed to be used under strict conditions, for example:
    - < 0.15% short chain chlorinated paraffins (SCCPs) in articles
    - < 0.025 mg/kg PFOA and its salts and ≤ 1 mg/kg PFOA-related substances
    - ≤ 5 mg/kg pentachlorophenol (PCP) in mixtures and articles

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### Juvenile Products: Chemical Requirements for North America



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### Canada Consumer Product Safety Act (CCPSA, 1/2)

Item	Citation	Requirement
1	Consumer Products Containing Lead Regulations (CPCLR, SOR 2018/83) <b>Scope includes, for example:</b> - Products brought into contact with mouth during normal use - Childcare articles intended to facilitate the relaxation, sleep, hygiene, carrying or transportation of a child under 4 years of age	≤ 90 mg/kg lead content otherwise ≤ 90 mg/kg migratable lead using EN 71-3 or other alternative method with Good Laboratory Practice (GLP)
2	Infant Feeding Bottle Nipples Regulations (SOR/2016-180)	≤ 10 µg/kg n-nitrosamines
3	Pacifier Regulations (SOR 2016/184)	≤ 10 µg/kg n-nitrosamines
4	Phthalates Regulations (SOR 2010-298)	≤ 0.1% each of DEHP, DBP and BBP (vinyl materials in toys and childcare articles)  ≤ 0.1% each of DIDP, DINP and DNOP (vinyl materials in toys and childcare articles that can, in a reasonably foreseeable manner, be placed in the mouth of a child under 4)

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### Canada Consumer Product Safety Act (CCPSA, 2/2)

Item	Citation	Requirement
5	Surface Coating Materials Regulations (SOR/2016-193) <b>Scope includes, for example:</b> - Surface coatings on children's products  Surface coating materials under: - Carriages and Strollers Regulation (SOR/2016-167) - Cribs, Cradles and Bassinets Regulations (SOR/2016-152) - Expansion Gates and Expandable Enclosures Regulations (SOR/2016-179) - Playpens Regulations (SOR/2018-186)	≤ 90 ppm mg/kg lead content  ≤ 90 ppm mg/kg lead content ≤ 0.1% for migration of antimony, arsenic, cadmium, selenium or barium Prohibits mercury
6	Products made in whole or in part of textile fibers, intended for use as wearing apparel (Schedule 2, item 10)	Prohibits tris (2,3 dibromopropyl) phosphate (TDBPP)
7	PU foam-containing products for children under 3 (Schedule 2, item 16; SOR/2014-79)	Prohibits tris (2-chloroethyl) phosphate (TCEP)

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### CPSIA of 2008

Consumer Product Safety Improvement Act (CPSIA) of 2008		
Substance	Scope*	Requirement
Lead content	- Paint/similar coating materials - Paint on children's products - Paint on furniture - Substrates in children's products*	≤ 90 ppm  ≤ 100 ppm <sup>2</sup>

\*Accessible materials  
<sup>2</sup>Certain materials are exempt, for example:  
 - 16 CFR 1500.91 Determinations regarding lead content for certain materials or products under Section 101 of the CPSIA  
 - 16 CFR 1500.88 Exemptions from lead limits under section 101 of the CPSIA for certain electronic devices

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### Comparison of Phthalates – US, Canada and EU

Item	Phthalate	Scope	US Federal 16 CFR 1107	Canada SOR 2016-188	EU REACH XVII Entries 51 & 52
			Requirement	Scope	Requirement
1	BBP	Accessible	≤ 0.1%	Vinyl materials in toys and childcare articles	≤ 0.1%
2	DBP	plasticized materials in toys and childcare articles	≤ 0.1%	---	Plasticized materials* in toys, childcare articles and other articles
3	DEHP	---	≤ 0.1%	---	---
4	DIBP	---	≤ 0.1%	---	---
5	DPENP	---	≤ 0.1%	---	---
6	DHEXP (DnHP)	---	≤ 0.1%	---	---
7	DCHP	---	≤ 0.1%	---	---
8	DINP	---	≤ 0.1%	Vinyl materials in toys and childcare articles	≤ 0.1%
9	DNOP	---	---	that can, in a reasonably foreseeable manner, be placed in the mouth of a child under 4	≤ 0.1%
10	DIDP	---	---	---	≤ 0.1% (sum)

\*Certain derogations apply, e.g. food contact materials and articles in Regulations (EC) 1935/2004 and (EU) 10/2011 are exempt (BBP, DBP, DEHP and DIBP)


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### California Proposition 65 (Prop 65)

- Background**
  - Enacted in November 1986 as 'The safe Drinking Water and Toxic Enforcement Act of 1986'
  - To protect California citizens and the state's drinking water sources from chemicals that cause cancer, birth defects and/or reproductive harm
- Prop 65 list contains approx. 900 chemicals e.g.**
  - Heavy metals – e.g. lead and cadmium
  - Bisphenol A (BPA), chromium (VI), formaldehyde, flame retardants (e.g. TCEP, TDBPP and TDCPP)
  - Phthalates (BBP, DBP, DEHP, DIDP, DINP and DnHP)
  - PFOA, PFOS, styrene, solvents, pharmaceuticals, etc.

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### Prop 65

- Scope and requirements**
  - Businesses (e.g. manufacturers, distributors and retailers) are obliged to comply with two main provisions:
    - Prohibited from knowingly discharging a listed chemical into sources of drinking water – becomes effective 20 months after chemical has been listed
    - Required to provide a **clear and reasonable warning** before exposing anyone to a listed chemical – becomes effective 12 months after a chemical has been listed
      - Consumer products may use a standard warning or short-form warning

Businesses with less than 10 employees are exempt!

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### Selected Prop 65 Settlements

Item	Scope	Reformulation/Warning
1	Children's products	≤ 0.1% DEHP
2	PU foam, cushioning or padding used as a filling material in juvenile products such as pads for children and infants to lie on, mattress toppers and mats, strollers, children's car seats, infant walkers, bouncers, highchairs, nap/rest mats and positioning pillows	TDCPP, TCEP and TDBPP prohibited
3	Soft baby potty seats	≤ 1000 ppm each of DEHP and other phthalates on the Prop 65 list otherwise warning
4	PVC packaging	≤ 0.1% each of DEHP, DBP, BBP, DnHP, DIDP and DINP

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### California – PFAS in Juvenile Products

California AB 652 (2021-22 Regular Session)  
Product Safety: Juvenile Products: Chemicals: Perfluoroalkyl and Polyfluoroalkyl Substances

Substance	Scope	Requirement	Effective Date
Perfluoroalkyl and polyfluoroalkyl substances (PFAS)	Juvenile products for children under 12 <sup>1</sup>	Prohibited if either intentionally added that has a functional or technical effect, or ≥ 100 ppm (as total fluorine)	July 1, 2023

<sup>1</sup>Derogations, including:

- Second-hand juvenile products
- Internal components of juvenile products that would not come into direct contact with a child's skin or mouth during reasonably foreseeable use and abuse of the product
- Children's electronic products, including, but not limited to, personal computers, audio and video equipment, wireless phones and handheld devices incorporating a video screen or any associated peripherals
- Medical devices and adult mattress

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### Illinois Public Act 097-0612 Lead Poisoning Prevention Act (LPPA)

Substance	Scope	Requirement
Lead content	Children's products: - Childcare articles to facilitate sleep, relaxation, or feeding of children or to help with sucking or teething (children = children under the age of 6) - Toys containing paint for children under 12 - Children's jewelry for children under 12	Warning <sup>1</sup> required if lead is more than 40 ppm but less than federal standards

<sup>1</sup>Warning to contain at least the following:  
WARNING: CONTAINS LEAD. MAY BE HARMFUL IF EATEN OR CHEWED. COMPLIES WITH FEDERAL STANDARDS

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### States with Reporting Rules – Children's Products

	Oregon	Vermont	Washington
Citation	ORS 431A.250 'Toxic-Free Kids Act'	18 VSA Chapter 38A § 1772 'Chemicals of high concern to children'	RCW Chapter 70.240 'Children's Safe Products Act'
Scope	Children's products	Children's products	Children's products
Reporting criteria	All materials	Accessible	Accessible
Chemicals to be reported	High priority chemicals of concern for children's health (HPCCCHs) <sup>1</sup>	Chemicals of high concern to children (CHCCs)	Chemicals of high concern to children (CHCCs)
Reporting criteria	HPCCCH is: - ≥ PQL if intentionally added - ≥ 100 ppm if a contaminant	CHCC is: - > PQL if intentionally added - ≥ 100 ppm if a contaminant	CHCC is: - > PQL if intentionally added - > 100 ppm if a contaminant
No. of entries /chemicals	68	86 (formaldehyde includes formaldehyde donors)	85
Next reporting deadline	January 1, 2022 (biennially)	January 31, 2022 then annually	January 31, 2022 (annually)

<sup>1</sup>HPCCCHs to be phased-out by third biennial notice (January 1, 2022) if chemicals present in a children's product that is mouthable, a cosmetic or is intended for children under 3  
<sup>2</sup>PQL = Practical Quantification Limit

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### Maine – Toxic Chemicals in Children's Products

- Toxic Chemicals in Children's Products
  - 3 tiers of chemicals:
    - Chemicals of concern (CoCs)
    - Chemicals of high concern (CHCs)
    - Priority chemicals (PCs) – resulting in regulatory action
  - Children's products:
    - A consumer product intended for children under 12 years of age AND
    - Any consumer product containing a chemical of high concern (CHC) that when used or disposed of will likely result in a child under 12 years of age or a fetus being exposed to that chemical

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### Maine – Reporting PCs in Children's Products (1/2)

Rule Chapter	Priority Chemical (PC)	Scope of children's products for disclosure to the Department of Environmental Protection (DEP) if PC is intentionally added and exceeds the practical quantification limit (PQL)
882	Bisphenol A (BPA)	- Infant formula and baby food sold in plastic containers, jars or cans - Toys, childcare articles and tableware
883	Nonylphenol/Nonylphenol ethoxylates (NPs/NPEOs)	- Household and commercial cleaning products - Cosmetics and personal care products - Home maintenance products intended for use by consumers
884	Cadmium	- Childcare articles, clothing, cosmetics, craft supplies
885	Formaldehyde	- Footwear, games, jewelry and embellishments
886	Mercury	- Occasion supplies
887	Arsenic	- Personal accessories, personal care products - Safety seats, school supplies and toys
888	4 Phthalates – BBP, DBP, DEHP and DEP	- Building and home maintenance products - Clothing and footwear, cosmetics and personal products, craft supplies - Household and commercial cleaning products - Household furniture and furnishings - Personal accessories and jewelry

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### Maine – Reporting PCs in Children’s Products (2/2)

Rule Chapter	Priority Chemical (PC)	Scope of children’s products for disclosure to the Department of Environmental Protection (DEP) if PC is intentionally added and exceeds the practical quantification limit (PQL)
889	Decabromodiphenyl ether (Deca-BDE) Hexabromocyclododecane (HBCD/HBCCD)	<ul style="list-style-type: none"> <li>- Childcare articles</li> <li>- Children’s clothing, footwear, sleepwear and toys</li> <li>- Electronic devices</li> <li>- Household furniture and furnishings</li> <li>- Mattresses and mattress pads</li> </ul>
890	Perfluorooctane sulfonic (PFOS) and its salts - PFOS - Potassium perfluorooctane sulfonate - Lithium perfluorooctane sulfonate - Ammonium perfluorooctane sulfonate - Diethanolammonium perfluorooctane sulfonate	<ul style="list-style-type: none"> <li>- Childcare articles</li> <li>- Clothing, footwear, sleepwear</li> <li>- Cookware, tableware, reusable food and beverage containers*</li> <li>- Cosmetics and personal care products</li> <li>- Craft supplies, electronic devices</li> <li>- Household furniture and furnishings</li> <li>- Toys</li> </ul> <p>*Containers with a lid, cover, cap or nipple, such as baby bottles, spill-proof cups, sports bottles and thermoses, as well as disposable and reusable dishes such as plates, bowls, cups/glasses and cutlery. Receptacles containing food or beverage at the time of sale are exempt.</p>

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### BPA Prohibition/Restriction in Food Contact Containers for Young Children

Item	Jurisdiction	Item	Jurisdiction	Item	Jurisdiction
1	Federal <sup>1</sup>	7	Maine	13	New York State <sup>2</sup>
2	California <sup>2</sup>	8	Maryland	14	Vermont
3	Chicago	9	Massachusetts	15	Washington DC
4	Connecticut	10	Minnesota	16	Washington DC
5	Delaware	11	Multnomah County (Oregon)	17	Wisconsin
6	Illinois	12	Nevada		

<sup>1</sup>Prohibits polycarbonate (PC) resins in infant feeding bottles and spill-proof cups  
<sup>2</sup>≤ 0.1 ppb BPA  
<sup>3</sup>Scope includes pacifiers

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### General Overview of Flame Retardants

Item	Jurisdiction <sup>1</sup>	Item	Jurisdiction <sup>1</sup>	Item <sup>1</sup>	Jurisdiction
1	Alaska – Anchorage	8	Massachusetts	15	Oregon
2	California	9	Michigan	16	Rhode Island
3	California – San Francisco	10	New Hampshire	17	Vermont
4	Hawaii	11	Nevada	18	Washington
5	Illinois	12	Minnesota	19	Washington DC
6	Maine	13	New Hampshire		
7	Maryland	14	New York State		

<sup>1</sup>Scope of products, flame retardants and requirements is specific to each jurisdiction

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### Composite Wood Products

- US Federal
  - Toxic Substances Control Act Title VI (TSCA Title VI) 'Formaldehyde Standards for Composite Wood Products Act'
- US California
  - Airborne Toxic Control Measure (ATCM) to Reduce Formaldehyde Emissions from Composite Wood Products
- Canada
  - Formaldehyde Emissions from Composite Wood Products Regulations (SOR/2021-148)

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### How can SGS help?



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### SGS Services

- EU
  - REACH (SVHCs and restricted substances), Food Contact, POP Recast Regulation and European Standards (EN)
- North America
  - Formaldehyde Emissions from Composite Wood
- US
  - CPSIA, Food Contact (FDA), State/Local Laws e.g. Prop 65, BPA, flame retardants, Reporting Rules for Children’s Products
- Canada
  - Canada Consumer Product Safety Act (CCPSA)

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