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As the pilot phase of the Children’s Safe Products Act concludes, you requested participant comments. Johnson & Johnson Consumer and Personal Products Worldwide appreciated the opportunity to participate. The partnership and the collaboration in discussing the proposals appeared to weigh the interests of all parties, while furthering the main aim of ensuring safe products for children. We thank you for the opportunity. Our comments follow.

Our comments focus primarily on our analysis of the list of chemicals proposed by Washington State that could possibly require reporting.

In Table 1, the following ingredients are not used by the Cosmetics Industry and therefore, do not have a credible potential for exposure to children through these kinds of products, which is one of the requirements for a chemical to remain on the list. We recommend that the ingredients listed in Table 1 be dropped from reporting requirements for cosmetic products.

Table 1.
Ingredients NOT Found in the FDA Voluntary Cosmetics Registration Program (VCRP)

CAS No.	Ingredient (INCI name if different)	Restriction (Source)
75-15-0	Carbon Disulfide	Not used
79-34-5	1,1,2,2-Tetrachloroethane	Not used
79-94-7	Tetrabromobisphenol A	Not used
80-05-7	Bisphenol A (4,4'-Isopropylidenediphenol)	Not used
87-68-3	Hexachlorobutadiene	Not used
95-53-4	2-aminotoluene	Not used
95-80-7	2,4-diaminotoluene	Not used
99-96-7	p-hydroxybenzoic acid (2-Hydroxybenzoic Acid)	Not used
100-41-4	Ethylbenzene	Not used
104-40-5	4-nonylphenol; 4-np	Not used
106-47-8	p-chloroaniline	Not used
107-13-1	Acrylonitrile	Not used
109-86-4	2-methoxyethanol (Methoxyethanol)	Not used
110-80-5	ethylene glycol monoethyl ether (Ethoxyethanol)	CIR unsafe; not used

May 25, 2010

115-96-8	tris(2-chloroethyl) phosphate	Not used
118-74-1	hexachlorobenzene	Not used
127-18-4	perchloroethylene	Not used
140-66-9	4-tert-octylphenol; 1,1,3,3-tetramethyl-4-butylphenol	Not used
149-57-5	2-ethylhexanoic acid	Prohibited (EU Annex II)
842-07-9	CI solvent yellow 14	Prohibited (EU Annex II)
1163-19-5	2,2',3,3',4,4',5,5',6,6'-decabromodiphenyl ether; BDE-209	Not used – flame retardant
1763-23-1	Perfluorooctanyl Sulphonic Acid and its salts; PFOS	Not used
1806-26-4	Phenol, 4-octyl	Not used
7439-98-7	Molybdenum & Molybdenum compounds	Not used
7440-41	Beryllium & Beryllium compounds	Prohibited (EU Annex II)

In Table 2, the ingredients listed provide important benefits – either preservation in the case of the parabens or sunscreen protection for the latter. Numerous public authoritative reviews of their safety exist looking at the weight of evidence in making a determination. References and sources can be found at www.CosmeticsInfo.org.

The few parabens used in cosmetic products are effective preservatives, and all authoritative bodies and government agencies around the world continue to find them safe as used. These parabens have been used for decades as preservatives in the food, drug and personal care industries and are even found in nature.

The US FDA regulates octinoxate, and they have found it to be safe and effective as a sunscreen active ingredient.

Finally, these ingredients are part of the ingredient list on the product label and therefore, reporting their use to Washington State is redundant. Furthermore, the FDA has this information as part of the Voluntary Cosmetics Reporting Program, and summaries of the use of these materials can be obtained from the US FDA. The materials listed in Table 2 should be removed from the list requiring reporting.

Table 2.
Ingredients That are Listed on the Product Label

CAS No.	Ingredient (INCI name if different)	Restriction (Source)
94-13-3	Propylparaben	0.4% (acid) for 1 ester 0.8% (acid) for mixture of esters
94-26-8	Butylparaben	0.4% (acid) for 1 ester 0.8% (acid) for mixture of

		esters
99-76-3	Methylparaben	0.4% (acid) for 1 ester 0.8% (acid) for mixture of esters
120-47-8	Ethylparaben	0.4% (acid) for 1 ester 0.8% (acid) for mixture of esters
5466-77-3	2-Ethyl-hexyl-4 methoxycinnamate (Ethylhexyl Methoxycinnamate OTC Octinoxate) ²	OTC drug active approved by US FDA

With the exception of diethyl phthalate, the materials listed in Table 3 are traces and not intentionally added. It is possible that they could be detected at very low levels in a variety of products. While it may be possible to minimize their presence; complete elimination is not feasible. When a source is listed parenthetically, this indicates that the trace level is found acceptable up to the restriction level. When USP is the source, the trace level is found acceptable up to the threshold listed in orally ingested pharmaceutical products. Otherwise, a *de minimus* level of 100 ppm has been proposed, which is consistent with proposed regulations in elsewhere in the United States.

Diethyl phthalate is used as a solvent in some fragrances and has been found safe in numerous authoritative reviews. Based on these scientific reviews, there is no country in the world that prohibits the use of diethyl phthalate.

We propose that any material that is in a product exceeding the thresholds listed below be included in the reporting requirements.

Table 3.
Trace / Incidental Ingredients with Suggested de Minimus Level

CAS No.	Ingredient (INCI name if different)	Restriction (Source)
84-66-2	Diethyl Phthalate ¹	<100 ppm (inferred from SCCP)
50-00-0	Formaldehyde	<500 ppm (EU warning requirement) Permitted up to 0.2% (EU Annex VI). All finished products containing formaldehyde or substances in ANNEX VI which release formaldehyde must be labeled with the warning "contains formaldehyde" where the concentration of formaldehyde in the finished product exceeds 0.05%. Quaternium-15 max use limit 0.2% DMDM Hydantoin max use limit 0.6%

78-93-3	Methyl ethyl ketone (MEK)	<5000 ppm (USP)
107-21-1	Ethylene Glycol (Glycol)	<620 ppm (USP)
108-88-3	Toluene	<890 ppm (US)
108-95-2	Phenol	<100 ppm
872-50-4	N-Methylpyrrolidone (Methyl Pyrrolidone)	<530 ppm (USP)
7439-97-6	Mercury & Mercury compounds including Methyl Mercury (22967-92-6) (Thimerosal)	Ingredient prohibited (EU Annex II) Total heavy metals as unavoidable traces <20 ppm (German MOH)
7440-36-0	Antimony & Antimony compounds (Antimony Potassium Tartrate)	Ingredient prohibited (EU Annex II) Total heavy metals as unavoidable trace <20 ppm (German MOH)
7440-48-4	Cobalt & Cobalt compounds (Cobalt Aluminum Oxide)	Ingredient prohibited (EU Annex II) Total heavy metal as unavoidable trace <20 ppm (German MOH)

Finally, we are interested in the proposal to modify the reporting schedule so that a safer alternatives assessment could be conducted. We would voluntarily conduct alternative assessments for the materials listed in Table 4 with mutually agreed upon time period to replace these materials or set a *de minimus* threshold.

Table 4.
Materials Subject to Alternatives Assessment

131-55-5	Benzophenone-2	Safe up to 6% (CIR)
556-67-2	Octamethylcyclotetrasiloxane (Cyclotetrasiloxane)	Safe at levels >50% (CIR)
25013-16-5	Butylated Hydroxyanisole (BHA)	2000 ppm (CIR)

Thank you for the opportunity to participate. If you would like any additional information, please contact me at 908-874-1625 or by e-mail at kwille1@its.jnj.com

Sincerely,

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May 25, 2010