

Williams, John (ECY)

From: Frances Wu [wuf@personalcarecouncil.org]
Sent: Tuesday, April 20, 2010 8:35 AM
To: Williams, John (ECY)
Cc: Linda Loretz
Subject: CSPA Pilot
Attachments: CSPA CHCC list cmt 042010.PDF

John:

Attached below is the Personal Care Product Council's informal feedback during this pilot on the CHCC list developed by WA DOE. We have divided the DOE list into the following:

1. **INGREDIENTS TO REMOVE FROM LIST:** DEP, four parabens, OTC drug active ingredient. An explanation/rationale for removal of these ingredients is attached.
2. **TRACES/INCIDENTALS:** This list sets forth the name of the trace/incidental and the restriction/limit only.
3. **INTENTIONALLY ADDED:** Our industry has long abided by the "incidental ingredient" definition of FDA (21 CFR 701.3) for ingredients that need not be listed on the product label because they are present in such small/insignificant amounts. Intentionally added ingredients exclude any that are "incidental ingredients, as defined by FDA.
4. **NOT FOUND IN VCRP/NOT USED LIST:** These ingredients are not used in our products.
5. **FORMALDEHYDE:** Formaldehyde is listed separately, as it does not fall into any of the other categories (see note of explanation at the top of this list).

This feedback only addresses the chemical list. We would also like to comment on the draft pilot regulation that DOE has published. Given schedule conflicts and our upcoming legal conference, would it be possible for us to submit comments on the pilot regulation in early May?

Best regards,
Frances

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INGREDIENTS TO REMOVE FROM LIST

CAS No.	Ingredient (INCI name if different)	Restriction (Source)	Function
84-66-2	Diethyl Phthalate ¹	None known	Solvent Remove from list, authoritative bodies find it safe as used
94-13-3	Propylparaben	0.4% (acid) for 1 ester 0.8% (acid) for mixture of esters	Preservative Remove from list, authoritative bodies find it safe as used
94-26-8	Butylparaben	0.4% (acid) for 1 ester 0.8% (acid) for mixture of esters	Preservative Remove from list, authoritative bodies find it safe as used
99-76-3	Methylparaben	0.4% (acid) for 1 ester 0.8% (acid) for mixture of esters	Preservative Remove from list, authoritative bodies find it safe as used
120-47-8	Ethylparaben	0.4% (acid) for 1 ester 0.8% (acid) for mixture of esters	Preservative Remove from list, authoritative bodies find it safe as used
5466-77-3	2-Ethyl-hexyl-4-methoxycinnamate (Ethylhexyl Methoxycinnamate OTC Octinoxate) ₂	OTC drug active approved by US FDA	Sunscreen active – Regulated by FDA; remove from list

ENDOCRINE DISRUPTION (ED) ENDPOINT

There is a strong point of view from many scientists that ED is a mode of action, not a toxicological endpoint. The potential to interact with the endocrine system does not necessarily constitute a risk and does not necessarily translate to an adverse physiological effect. The EU Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE) states that: "It is important to realize that endocrine disruption is not a toxicological endpoint *per se* as is cancer or allergy, but that it is a descriptor for a functional change that may lead to adverse health effects. Rather, endocrine disruption should be seen in the context of well-established endpoints, primarily reproductive toxicity and impaired development." (EU CSTEE, Opinion on BKH Consulting Engineers Report

http://ec.europa.eu/health/ph_risk/committees/sct/docshhtml/sct_out73_en.print.htm)

Washington's Chemicals of High Concern for Children list already captures reproductive/developmental endpoints. The category of endocrine disrupting chemicals should be removed.

The Endocrine Disrupter priority list that resulted from studies commissioned by the European Commission, DG Environment does not represent scientific consensus. As stated in the preface of the most recent report (May 2007), the priority list of substances was established "for further evaluation of their role in endocrine disruption". The report also states "(T)he compilation of the priority list was based on a screening of available literature and should therefore be regarded as a starting point for further in-depth evaluation of the substances placed on the priority list...The evaluations....are NOT considered comprehensive risk assessments." Further, the "choice of categories was made solely by the consultant, and apart from the clear evaluation criteria for the categories given above, it may thus be regarded as subjective."

Considerations related to specific chemicals are below.

METHYLPARABEN, ETHYLPARABEN, PROPYLPARABEN, BUTYLPARABEN

Four parabens – methyl, ethyl, propyl, and butyl – are included on the CHCC list of 66. Parabens function as preservatives and are highly effective in preventing the growth of microorganisms such as bacteria and fungi and are used to greatly extend product shelf life. These ingredients have been used for decades in the food, drug and cosmetic industries. They are effective at low use levels, possess a broad spectrum of antimicrobial activity, are relatively non-irritating, non-sensitizing, and of low toxicity, are stable over a wide pH range, and are sufficiently water soluble to be effective in the aqueous phase of formulations. These characteristics make them especially versatile and valuable as preservatives.

The EU Endocrine Disruption list is cited as the reason for their listing on the CHCC list; the parabens do not meet any of the other toxicity criteria. As stated above, the use of the EU Endocrine Disruption list, and the endocrine disruption endpoint in general, do not provide scientific justification for listing. Therefore, we request that the parabens be removed from the CHCC list.

Other reviews of the endocrine disrupting activity of the parabens have been conducted, and while estrogenic activity has been reported in some studies at high concentrations, the activity is weak. The issue of estrogenic activity is addressed in a 2003 report from the Norwegian Institute of Public Health, which concluded that "(d)ifferent parabens have varying estrogenic potential in cell cultures and animal studies, but their potency is 1000 to 1,000,000 times lower

than the potency of 17 β -estradiol or testosterone.” A 2005 opinion of the Scientific Committee on Cosmetic Products (SCCP) in the European Union similarly concluded that in *in vitro* studies, the estrogenic potency of the parabens “remains at all times 1000 to 1,000,000 times below the potency of 17 β -estradiol”, and that values from *in vivo* assays again “remained several magnitudes of order below the potency of 17 β -estradiol.” The Cosmetic Ingredient Review (CIR) reviewed the parabens and considered the issues of endocrine disruption and reproductive toxicity, and concluded that these ingredients were “safe as used” (International Journal of Toxicology, 27(Suppl. 4): 1–82, 2008).

DIETHYL PHTHALATE

Like the parabens, diethyl phthalate is on the CHCC list on the basis of its presence on the EU endocrine disruption list. As stated above, the use of the EU Endocrine Disruption list, and the endocrine disruption endpoint in general, do not provide scientific justification for listing. Therefore, we request that diethyl phthalate be removed from the CHCC list.

In reviewing the European Endocrine Disruptors website, diethyl phthalate appears in both the 2000 European Commission report “Towards the establishment of a priority list of substances for further evaluation of their role in endocrine disruption” and the 2002 report “Study on Gathering Information on 435 Substances with insufficient data”. While DEP appears in Category 1 in the latter document, it was categorized as “Category 3: No evident scientific basis” in the former report for both Wildlife Data and Human Health Data (Annex 13, “List of 146 substances with endocrine disruption classifications prepared in the Expert meeting”). The disparate conclusions help illustrate the lack of consensus on the identification of diethyl phthalate as an endocrine disrupter.

Diethyl phthalate has been extensively tested for reproductive and developmental effects, and the results indicate that DEP is not a developmental or reproductive toxicant. Effects seen in the study cited in the European Endocrine Disruption reports were at dosing levels well above the high-dose limits described in current regulatory protocols for reproduction studies (>1%). Levels at which there are no adverse effects have been identified, supporting the safety of this ingredient.

Diethyl phthalate is also noted in the Phase 2 score sheet as having reproductive effects at a TDLo of less than 50 mg/kg, a finding that is to be explored further in Phase 3 of the Children’s Safe Product Act. We were unable to identify the study in the RTECS database and request clarification so that we can respond to the finding. Importantly, the RTECS database references a significant number of reproductive studies in which the TDLo values were extremely high. Thus, a weight of the evidence evaluation would conclude that reproductive effects from DEP do not occur at low or moderate exposure levels.

Diethyl phthalate has been evaluated for its use in cosmetics by both the Cosmetic Ingredient Review in the U.S. and by the Scientific Committee on Consumer Products in Europe, both with favorable outcomes.

2-ETHYL-HEXYL-4-METHOXYCINNAMATE (ETHYLHEXYL METHOXYCINNAMATE OTC OCTINOXATE)

2-Ethyl-hexyl-4-methoxycinnamate is also on the CHCC list. This ingredient is approved by the U.S. Food and Drug Administration as an over-the-counter sunscreen drug active ingredient, and therefore provides important public health benefits.

The basis for listing 2-ethyl-hexyl-4-methoxycinnamate is also its presence on the EU endocrine disruption list. None of the other toxicity criteria for listing are met. Once again, we do not believe this list, or the endocrine disruption endpoint in general, provide scientific justification for listing.

Further, the mammalian study (rat uterotrophic assay) cited in the EU Endocrine Disruption report was reviewed by the Scientific Committee on Cosmetics and Non-Food Products (SCCNFP) in Europe and was found to have "a number of important technical and scientific shortcomings" (http://ec.europa.eu/health/ph_risk/committees/sccp/docshtml/sccp_out145_en.htm). The conclusion of the SCCNFP opinion was that "(B)ased on the actual scientific knowledge, the SCCNFP is of the opinion that the organic UV-filters used in cosmetic sunscreen products, allowed in the EU market today, have no estrogenic effects that could potentially affect human health."

We request that 2-Ethyl-hexyl-4-methoxycinnamate be removed from the CHCC list.

TRACE/INCIDENTAL INGREDIENTS

CAS No.	Ingredient (INCI name if different)	Restriction (Source)
60-29-7	Diethyl Ether (Ethyl Ether)	<5000 ppm (USP)
71-36-3	n-Butanol (n-Butyl Alcohol)	<5000 ppm (USP)
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
131-11-3	Dimethyl Phthalate	<100 ppm does not indicate a risk to the health of the consumer (SCCP)
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)
2-53-3	Aniline	Proposition 65 (100µg/day) / <0.2% in colors
62-75-9	N-nitrosodimethylamine	Proposition 65 (8µg/day)
71-43-2	benzene	Proposition 65 (6.4µg/day oral, 13µg/day inhalation) <2 ppm (USP)

TRACE/INCIDENTAL INGREDIENTS

75-01-4	vinyl chloride	Proposition 65 (3µg/day)
75-07-0	Acetaldehyde (Acetaldehyde)	Proposition 65 (90µg/day inhalation)
75-09-2	methylene chloride	Proposition 65, FDA prohibits ingredient use
84-75-3	di-n-hexyl phthalate	Not used
86-30-6	N-nitrosodiphenylamine	Proposition 65 (30µg/day) FDA prohibits ingredient use
100-42-5	styrene	Not used
119-93-7	3,3'dimethylbenzidine and dyes metabolized to 3,3-dimethylbenzidine	Traces < 5 ppm (EU Annex IV)
123-91-1	1,4-dioxane	Prohibited as an ingredient (FDA, EU, WW); Proposition 65 safe harbor established
140-67-0	Estragole	Proposition 65 – natural sources permitted

INTENTIONALLY ADDED

<u>CAS No.</u>	<u>Ingredient (INCI name if different)</u>	<u>Restriction (Source)</u>	<u>Typical Concentration in Finished Products</u>	<u>Function / Comment</u>
57-55-6	Propylene Glycol	<50% (CIR)	<50% Level in baby products typically much lower than 50%	Skin conditioning agent
131-55-5	Benzophenone-2	Safe up to 6% (CIR)	Not used in baby products	Photostabilizer
556-67-2	Octamethylcyclotetrasiloxane (Cyclotetrasiloxane)	Safe at levels >50% (CIR)	Minimal use, possible trace at <1% in other siloxanes	Emollient, solvent
25013-16-5	Butylated hydroxyanisole (BHA)	Proposition 65 (4000µg/day)	Use must be well under risk level	Antioxidant

Note: Intentionally added ingredients would exclude any that fall within FDA's definition of "incidental ingredient." See 21 C.F.R. § 701.3(l) at http://edocket.access.gpo.gov/cfr_2009/apr/qtr/pdf/21cfr701.3.pdf.

NOT USED

<u>CAS No.</u>	<u>Ingredient (INCI name if different)</u>	<u>Restriction (Source)</u>
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
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	c.i. 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	phenoI, 4-octyl	Not used
4376-20-9	mono-2-ethyl hexylphthalate; mehph	Not used
7439-98-7	molybdenum & molybdenum compounds	Not used
7440-41	beryllium & beryllium compounds	Prohibited (EU Annex II)
85-449	Phthalic anhydride	Not used

Formaldehyde is listed separately here because it is neither an intentionally added ingredient, nor a trace/incidental (as defined in 21 CFR 701.3(I)). Rather, it arises as a reaction of in situ chemistry when certain ingredients are present.

<u>CAS No.</u>	<u>Ingredient (INCI name if different)</u>	<u>Restriction (Source)</u>	<u>Typical Concentration in Finished Products</u>	<u>Function</u>
50-00-0	Formaldehyde	<p>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%.</p> <p>Quaternium-15 max use limit 0.2%</p> <p>DMDM Hydantoin max use limit 0.6%</p>	<p>Free formaldehyde in products with formaldehyde releaser < 1ppm</p> <p>Formaldehyde not typically used to preserve baby products. May be introduced through raw materials.</p> <p>Concentration of formaldehyde from all sources easily under 500 ppm.</p>	Preservative