

RATIONALE FOR DEVELOPING SAFER PERSONAL CARE PRODUCTS

. Chemicals that mimic or antagonize naturally-occurring estrogens or androgens *in vitro* or *in vivo* are said to have estrogenic (EA) or anti-estrogenic (AEA) activity [EA**] or androgenic (AnA) or anti-androgenic (AAnA) activity [AnA**]. **EA**/AnA**-free means free of detectable EA** and AnA**** (as measured by six MCF-7, BG1Luc and MDA-Kb2 *in vitro* assays)

Personal care products (PCPs) are non-prescription products applied to the body (e.g., hair colorants, shampoos, soaps, deodorants, suntan lotions, lipsticks, makeups, nail polishes, etc.). Daily, the average American uses 10 such products, totaling 126 ingredients, most usually **not** listed on the label.

- About 3-10,000 chemicals are suspected to have EA**and/or AnA** .
- Chemicals with EA**and/or AnA** reportedly have adverse health effects, sometimes at low (10^{-7} M - 10^{-13} M) concentrations in fetal, infant and juvenile mammals (including humans).
- CertiChem (CCi) has recently developed six robotized, sensitive, reliable and accurate *in vitro* assays to detect EA** (MCF-7, BG1Luc) or AnA** (MDA-Kb2) in single chemicals, PCPs, plastics, and other consumer products.
 - In part in collaboration with the National Toxicology Program (NTP), CCi has shown that PCPs and/or some of their ingredients used by pregnant mothers infants and juveniles (especially African-Americans) often contain chemicals that have detectable EA**/AnA** , sometimes after UV stresses.
 - Epidemiological studies suggest that PCPs might have adverse health effects.
 - Other studies have shown that **PCPs may also contain metallic, formaldehyde-releasing, allergenic, or skin-irritating substances (MFASS substances)** that are absorbed via the skin or ingested and that potentially have adverse health effects.
 - Although many academic scientists, NIH/NIEHS/NICHD/EPA and NGOs acknowledge that widespread EA**/AnA** exposure is a cause for concern, especially for the fetus, infants and juveniles, the FDA has published cautionary concerns for only one such substance (BPA). PCPs on the US and international markets are not yet required to specify levels of EA** or AnA** or be free of known MFASS.
 - No commercial entity is currently offering PCP formulations with no detectable EA**/AnA** according to sensitive and accurate *in vitro* or *in vivo* assays, especially for pregnant mothers, infants, and children.
 - CCi is using a battery of six sensitive and accurate *in vitro* assays to show that it is feasible to detect EA**/AnA** in PCP ingredients and to use EA**/AnA** free ingredients to develop PCP formulations in collaboration with \$x Naturals that are MFASS-free and EA**/AnA**-free.

Safer PCPs have well-established market appeal with many firms or NGOs advertising avoidance of one or two chemicals having adverse EA** and/or AnA** effects, e.g., chemicals such as BHT, BHA, BPA, BPS, parabens, or phthalates. No company or NGO known to CCi advertises or recommends PCPs that are EA**/AnA**-free, i.e, do not release chemicals having EA**/AnA**. CertiChem believes that developing drop-in EA**/AnA**-free ingredients and producing EA**/AnA**-free products with innovative PCPs companies like 4X Naturals enables rapid development of safer PCPs with a waiting market channel.