



DUKE UNIVERSITY SCHOOL OF MEDICINE

**Department of Community & Family Medicine
Division of Occupational & Environmental Medicine
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February 26, 2018**

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Ross Vocke
US Greentech
3607 Church St.
Cincinnati, Ohio 45244

Dear Mr. Vocke:

I have completed a toxicologist's risk assessment (TRA) on your product ENVIROFILL. This assessment includes the following.

I have completed the evaluation for labeling as required by the Federal Hazardous Substances Act and in conformance with the American Society for Testing and Materials Practice D4236, Labeling of Art Materials for Chronic Health Hazards. This practice has been adopted into law as part of the Federal Hazardous Substances Act administered by the Consumer Product Safety Commission (CPSC) as the Labeling of Hazardous Art Materials Act (LHAMA). The toxicological procedures we use have been reviewed by the California Department of Health Services (CDHS) and the Health Science Directorate of CPSC. CDHS has found that the exposure presumptions we use are conservative.

In assessing whether or not a product is potentially hazardous, we look at the toxicity of the various ingredients, projecting the results to the product as a whole. If interactive effects are expected, these are taken into account.

For liquids, we presume that a 10 kg child will ingest or come into skin contact with 5 gm/kg of the material acutely (or the product size, if less) or 1 gm/day chronically for life. For solids, we presume that exposure will be to 1 gm/kg acutely (or the product size if less) and 0.1 gm/day chronically for life. For markers we assume that 2 cm of line can get into the eye and that 25 cm of line will be absorbed each day. We assume that 100% of any vapor or aerosol is absorbed. We use the following safety factors or limits in determining whether or not a product would require acute or chronic health hazard labeling:

<u>Effect</u>	<u>Safety Factor</u>
Acute effects (from inhalation, skin or gastrointestinal absorption):	10-100x
Eye irritation (Draize or equivalent)	less than mild
Skin irritation (Draize)	mild
Chronic health effects	100-1000x

For reproductive toxicants, we defer to California's Office of Environmental Health Hazard Assessment (OEHHA) published maximum allowable daily levels under Proposition 65 or, if they are not available, use an uncertainty factor of 1000 on the no effect level. For potential carcinogenic contaminants we defer to OEHHA's no significant risk levels under Proposition 65. When these have not been developed, we use a quantitative risk assessment approach using 10^{-6} risk at the 95% upper bound of a multistage model as being acceptable.

We do require bioavailability testing of consumer products or ingredients of concern for potential toxins. Synthetic intestinal or gastric juice is used for amines and metals and aerodynamic diameter measurement is used for dusty materials. If no bioavailability test method has been developed, quantitative testing is used (such as for PCBs and hexachlorobenzene).

Any talc in this product(s) has been analyzed for asbestos by TEM/X-ray diffraction and no detectable asbestos was found.

I have completed this type of toxicological evaluation of your product(s).

- I have found no toxic component or contaminant level or effect of the products themselves that would require acute or chronic hazard labeling to conform with ASTM D4236, the Labeling for Hazardous Art Materials Act, LHAMA regulations (16 CFR 1500.14(B)(8), or the Federal Hazardous Substances Act.
- Your product(s) is classified as NOT being toxic, corrosive, a skin or eye irritant, a strong sensitizer or combustible/flammable as defined in 16 CFR 1500.3(b)(5), and 1500.3(b)(7) – (10) of the Federal Hazardous Substances Act regulations.
- Your product(s) does not require labeling under California's Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65).
- We evaluate for the presence of VOCs and reactive VOCs in compliance with regulations of the California (CARB), NH, PA, EPA and 40 CFR Part 59.
- Your products do not contain hazardous substances when evaluated under ASTM F963.8.2 of the Standard Consumer Safety Specification for Toy Safety.

My evaluation is in accord with the 1984 CPSC Policy Statement on Animal Testing. I am a board certified toxicologist as defined by 16 CFR 14(B)(8).

I hope this information is useful to you.

Sincerely,

Consulting Toxicologist
thomas.brock@duke.edu

The following list of brands/colors is covered by this certification:

ENVIROFILL

Colors:

ENVIROFILL GREEN

ENVIROFILL BLACK

ENVIROFILL TAN