PETRA
PET Resin Association

June 25, 2014

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Via email: cynthia.oshita@oehha.ca.gov

Subject: NOIL - Ethylene Glycol
Prop 65 labeling of ethylene glycol as a reproductive toxicant,

1) **The PET Resin Association (PETRA), the industry association representing North American producers of polyethylene terephthalate (PET) resin supports the data analysis submitted by the American Chemistry Council, which demonstrates that ethylene glycol should not be classified as a reproductive toxicant under the California Prop 65 program.**
2) **Even if OEHHA does not accept this data analysis, and classifies ethylene glycol as a reproductive toxicant, PETRA is submitting data demonstrating that PET-based food and beverage packaging, including plastic water bottles, contain ethylene glycol below the No Observed Effect Level that would be set based on the reproductive data cited by OEHHA and thus PET-based food and beverage packaging should be exempt from labeling for ethylene glycol under Prop 65**

Dear Ms. Oshita:

The PET Resin Association (PETRA) is the industry association representing North American producers of polyethylene terephthate (PET) resin.[1] PET resin has US FDA approval for use in food contact articles under 21 C.F.R § 177.1630. PET resin is widely used in food and beverage packaging, including plastic water bottles, where globally it is used for more than 80% of packaged water. The purpose of this letter is to provide comments regarding the proposed classification of ethylene glycol as a reproductive toxicant under California Prop 65.

1) **PETRA fully supports the data analysis submitted by the Ethylene Glycols Panel of the American Chemistry Council, which demonstrates that ethylene glycol should not be classified as a reproductive toxicant under the California Prop 65 program.**

2) **Even if OEHHA does not accept this data analysis, and classifies ethylene glycol as a reproductive toxicant, PETRA is submitting data in this correspondence demonstrating that PET-based food and beverage packaging, including plastic water bottles, contain ethylene glycol below the No Observed Effect Level (NOEL) that would be set based on the reproductive data cited by OEHHA, and thus PET-based food and beverage packaging should be exempt from labeling for ethylene glycol under Prop 65.**

[1] For more information about PETRA, please see: http://petresin.org/about_petra.asp.

Article 8 (No Observed Effect Levels) of Title 27 of the California Code of Regulations of July 2012, outlines procedures for determining the NOEL for reproductive toxicants under the Prop 65 program. This section indicates that the NOEL should be based on the lowest NOAEL/LOAEL from the reproductive endpoint. As indicated in the information provided by OEHHA, the lowest endpoint for developmental toxicity was at a dose of ≥500 mg/kg bw/d, indicating that the dose of 500 mg/kg bw/d is a LOAEL. Dividing by 10 to derive a NOAEL gives a value of 50 mg/kg bw/d and dividing by a safety factor of 1000 gives the NOEL of 0.05 mg/kg bw/d. **For a 70 kg adult, the NOEL is 0.05 x 70 = 3.5 mg/d.**

Should OEHHA not find the scientific data provided by the Ethylene Glycols Panel to be persuasive, then products to which exposure to ethylene glycol is less than the NOEL should be excluded from the Prop 65 labeling requirement. As we will demonstrate below, PET is such a product.

The basic building blocks of PET are ethylene glycol and terephthalic acid, which are combined to form PET resin, which is then shaped into final products. PET products contains low (part per million) residual levels of ethylene glycol. For instance, the study by Kim et al.[2] found 14.4 ppm ethylene glycol in PET commercial amber bottles while the study by Kashock and Breder[3] found 5 ppm in PET bottles.

Testing to measure migration of ethylene glycol from PET products has demonstrated that migration levels are even lower than residual levels:

1) In a new study[4] (enclosed with this letter), migration of ethylene glycol from 1/2-liter PET bottles into water was measured. The results showed that after four weeks at 40 C the bottle contents were 57 parts per billion (ppb) ethylene glycol. After four weeks at room temperature, bottle contents were 23 ppb ethylene glycol.
2) Kashtook and Breder[2] reported ethylene glycol migration of 0.1 ppm from 32 oz PET bottles filled with 3% acetic acid (food simulant) and stored for six months at 32 C.
3) Morelli-Cardoso et al.[5] conducted a series of specific migration studies on PET bottles using food simulants (distilled water, 3% acetic acid and 5% aqueous ethanol) stored 10 days at 40 C. The levels of ethylene glycol migrating were below the method detection limits, 2.2 ppm for acetic acid, lower for the other food simulants.
4) Farhoodi et al.[6] measured the migration of ethylene glycol into the food simulate 3% acetic acid and stored for 4 months at 4, 25 and 45 C. Note that the authors considers these to represent "worst case" storage conditions. The maximum level of ethylene glycol detected was 2 ppm at 25 C after four months and 3 ppm after four months at 45 C.

Taking the worst case migration data (3 ppm after 4 months at 45 C in 3% acetic acid), it is a straightforward calculation to demonstrate that worst case ethylene glycol exposure from PET is lower than the NOEL.

The standard exposure assessment assumption is that adult daily consumption of food is 1 kg/d. Assuming (worst case) that this is all packaged in PET gives: 1 kg/d x 3 ppm = 0.003 mg/d ethylene glycol

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[2] Kim, H., Gilbert., S.G., Johnson, J.B., Determination of potential migrants from commercial amber polyethylene terephthalate bottle wall, Pharm. Res. 7(2): 176-9 (1990).
[3] Kashtock, M., Breder, C.V., Migration of ethylene glycol from polyethylene terephthalate bottles into 3% acetic acid, J. Assoc. Off. Anal. Chem. 63(2):168-72 (1980).
[4] Smith, B.L., Ethylene glycol (EG) migration from half-liter PET bottles, Analytical report from Indorama Ventures to Auriga Polymers Inc., Spartanburg, SC, June 19, 2014.
[5] Morelli-Cardoso, M.H.W., Tabak, D., Cardoso, J.N.Pereira, A.S., Application of capillary gas chromatography to the determination of ethylene glycol migration from PET bottle in Brazil, J High Resol. Chromatogr. 20:183-5 (1997).
[6] Farhoodi, M., Emam-Djomeh, Z., Ehsani, M.R. Oromiehie, A., Migration of model contaminants (ethylene glycol, DEHA and DEHP) from PET bottles into Iranian yogurt drink, e-Polymers 2008, no 037, p. 418-26, http://www.degruyter.com/view/j/epoly.2008.8.issue-1/issue-files/epoly.2008.8.issue-1.xml, ISSN 1618-7229, 7 March 2008.

The standard exposure assessment assumption is that adult daily consumption of water/beverages is 2 liters. Again assuming this is all packaged in PET gives: 2 liters/d x 3 ppm = 0.006 mg/d ethylene glycol

Total daily ethylene glycol from food and water/beverages = 0.009 mg/d ethylene glycol. This value is based on experimental data conducted under worst case migration conditions. Actual exposure to ethylene glycol is likely to be much lower than the worst case prediction.

Based on this data, should ethylene glycol be classified as a reproductive toxicant - a regulatory action we feel is not supported by the available scientific data as present by ACC - the data provided in this communication document that PET products should be excluded from labeling under Prop 65.

Sincerely,

Ralph Vasami
Executive Director