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CLIENT ALERT

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Updates on California's Proposition 65 for 2020

New year, same notices! Prop. 65 filings have not slowed down, and predictably, the same chemicals are being targeted by noticing parties.

In my survey of notices filed between December 15, 2019 and the present date, there are over 100 notices that fall into nine general categories, and which cover a wide range of common consumer products as set forth below. As usual, phthalates (DEHP) and (DINP) are the biggest targets, as they have been for many years. It appears the plaintiff's bar and noticing parties are also tracking FDA trends and piggy-backing on regulatory action taken by the FDA. This is especially true with respect to ranitidine (a popular heartburn medicine) containing the alleged cancer causing chemical N-Nitrosodimethylamine ("NDMA"). Beginning late last year through the present date, many companies have issued voluntary recalls of ranitidine after the FDA issued a statement alerting patients and health care professionals that NDMA samples were found in ranitidine. Office of Environmental Health Hazard Assessment ("OEHHA"), which implements Prop. 65, has also taken action on cannabis, which the FDA has identified as potentially causing male reproductive harm.

Summary of Recent Notices of Violation

1. **Acrylamide (5 notices)**: ice cream cones, frozen waffles, burgers, fried chicken and fried fish;
2. **Arsenic (4 notices)**: dried shrimp and seaweed;
3. **BPA (2 notices)**: iphone case and sunglasses;
4. **Cadmium and cadmium compounds (7 notices)**: seaweed, anchovies, dietary supplements;
5. **Di(2-ethylhexyl) phthalate (48 notices)**: tote, home case, comforter, jump ropes, bicycle grips, armbands, bat quiver, purses, ratchet tie downs, vinyl clutches;
6. **Diisononyl phthalate (DINP) (14 notices)**: purse, school bags with plastic components, polymer cosmetic bag, fanny pack with plastic components, outdoor patio cord, oxygen bag, cooler;
7. **Lead (9 notices)**: ceramic mugs and dishes, glassware, dried seaweed, wallet, canned squid;
8. **Lead and lead compounds (6 notices)**: torch, embroidery hoop, ground spices, dietary supplements;
9. **N-Nitrosodimethylamine (2 notices)**: Over the counter ranitidine (heartburn) drugs.

Other Regulatory News from OEHHA

1. On December 31, 2019 the Office of Administrative Law approved amendments to Article 6, Section 25600.2, subsections (b), (c), (f) and (i) that are intended to provide more guidance to businesses in the chain of commerce on how to satisfy their warning responsibilities in light of ever-expanding marketplaces. It is OEHHA's position that the overall structure of Prop. 65 minimizes the burden on retail sellers, and the intent with these amendments is to continue with this spirit and approach. The amendments will become effective on **April 1, 2020**.

   This action was taken because in some situations, the original manufacturer, distributor, importer or others in the chain of commerce did not know who would be ultimately selling to a consumer. The amendment allows a business in the chain of commerce to give the notice and warning materials directly to the designated agent for the business to which it is transferring or selling the product in order to discharge their duty to warn under the Act. What is key here is that the responsibility can only be shifted to an entity that is subject to Prop. 65. In the alternative, it may provide the warnings on the product or product label to satisfy the Act. If there is no authorized agent, the notice can be served on the legal agent. This notice must be renewed annually while the product is sold in California by the retailer.

   In both situations, the business providing the notice and warning materials must obtain verification of receipt electronically or in hard copy. If you cannot obtain confirmation from the downstream entity, you should opt for on product labeling. Further, if you do not have a designated agent with the California Secretary of State, you should designate one who can understand, handle and distribute these warnings as appropriate.

   The amendments also modified the definition of "actual knowledge" to mean when the retail seller receives information from any reliable source that allows it to identify the specific product/products that cause the consumer product exposure. The key is that this knowledge must be received by the authorized agent or a person whose knowledge can be imputed to the retail seller. If the retailer has such knowledge and does not provide a warning, it has knowingly and intentionally caused an unwarned exposure.

   While it may seem more practical to simply use on product labels, the law does not require this, as warnings may be provided through various means. You should consider these risks and benefits when determining your company's labeling strategy and where you fall in the chain of commerce.

2. OEHHA has jumped into a matter of public interest. On January 3, 2020, OEHHA added cannabis (marijuana) smoke and Δ^9-tetrahydrocannabinol (Δ^9-THC) to the list of chemicals known to the state to cause reproductive toxicity (developmental endpoint). This decision follows multiple public meetings with input from the Developmental and Reproductive Toxicant Identification Committee

(DARTIC). Prior to this, cannabis (marijuana) smoke and Δ^9-tetrahydrocannabinol (Δ^9-THC) were listed as cancer-causing only. While OEHHA operates separately from the FDA, they both take an interest in matters involving consumer products including food and dietary supplements. In late 2019, the FDA published information on its website identifying male reproductive toxicity as a potentially unknowable "side effect" of cannabis. The FDA states that its goal is to warn the public about the many side effects and unknowable consequences of products containing cannabis or cannabis derived compounds, including CBD. The FDA will seek to enforce unsubstantiated drug claims related to CBD since the only FDA approved pharmaceutical containing CBD is Epidiolex. This drug treats a rare, severe form of epilepsy. We can expect to see an influx of notices related to these chemicals and more FDA enforcement action this year.

3. OEHHA received a request for a Safe Use Determination (SUD) for styrene in Fiber Care Baths, Inc. bathware products. A SUD is a written statement issued by OEHHA which interprets and applies Prop. 65 to a specific set of facts in response to a request by a business or trade group. The SUD was ultimately granted, despite the fact that there was no hearing requested and no public comments were received. The SUD covered styrene *exposures to occupants* of homes and other buildings with Fiber Care Baths, Inc. bathware products installed*, when the bathware products have been* manufactured by the specified standardized process utilizing 1st and 2nd laminations systems. This is a promising development for other industries seeking a SUD as these are relatively rare to obtain.

I look forward to hearing from you this year and will keep you updated on developments related to Prop. 65!

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