



Chemistry Council Asks Supreme Court To Overrule Appellate Court Ruling Upholding DINP Listing

PROPOSITION 65, APPELLATE CASES, LITIGATION, CHEMICALS OF INTEREST, OEHHA, US EPA, CIC

By ROGER PEARSON, September 13, 2020

The American Chemistry Council (ACC) is asking the California Supreme Court to reverse a lower court decision upholding the listing of diisononyl phthalate (DINP) as a Proposition 65 carcinogen. The ACC acted shortly after the Third District Court of Appeals upheld the 2013 listing of the widely used plasticizer.

DINP is used to soften vinyl for use in flooring, wire insulation, gloves, garden hoses, artificial leather and roofing materials. The state's experts for identifying chemicals as Proposition 65 carcinogens, the Carcinogen Identification Committee (CIC), identified DINP as a possible carcinogen for listing in 2009. The staff of the Office of Environmental Health Hazard Assessment (OEHHA) prepared Hazard Identification Documentation (HID) summarizing those animal and human (epidemiological) studies that had been done on the results of exposure to the substance. The HID found that there was no relevant epidemiological data. However, the HID identified 12 relevant animal studies that showed three cancers seen at statistically significant levels: liver tumors, mononuclear cell leukemia, and kidney tumors. The HID noted that the mechanisms by which DINP induces tumors are unknown. However, the document noted several studies identified possible mechanisms of action.

When the HID was released for public comment it received complaints from the ACC and other industry groups who pointed out that all public health agencies that had studied DINP had determined that it was non-carcinogenic to humans. That included U.S. EPA and public health agencies from the European Union and Australia. ACC noted that these agencies had generally found that none of the mechanisms of action causing the cancers in animals were operable to cause the cancer in humans.

The HID and all of the public comments were released to the members of the CIC a little over two weeks prior to the Committee's December 5 meeting. At that meeting 6 of the seven members present voted to recommend listing DINP as a carcinogen with one abstention. Following the CIC recommendation OEHHA placed DINP on its list of carcinogens "known to the state" under Proposition 65 on December 20, 2013 [see **CIC Lists One Phthalate But Declines to List a Second**¹⁾, February 18, 2015].

The ACC filed a lawsuit challenging the DINP listing. The trial court dismissed the suit concluding that the ACC had failed to show that the listing violated any state law [see **Judge's Tentative Ruling Upholds Listing of DINP**²⁾, February 18, 2015]. The ACC then filed this appeal with the Third District.

The Third District Decision

The Third District issued its initial ruling, in **ACC v. OEHHA**³⁾, on June 10, 2020. The Court directed that the ruling should not be published meaning that it would not serve as precedent for any future action. After OEHHA argued that the ruling should be published, the Court agreed and ordered publication on July 8, 2020.

This appeal and the ACC's subsequent Supreme Court petition center on interpretation of **Guidance Criteria**⁴⁾ that the CIC uses to make its listing decisions. In particular the case centers on Criteria 1D, which states that the CIC will "normally identify a chemical for listing" if "the weight of evidence clearly shows that [the] chemical causes invasive cancer in humans or that it causes invasive cancer in animals (unless the mechanism of action has been shown not to be relevant to humans.)"

At the December 5 meeting the Committee first heard the OEHHA staff present its summary of the HID. It then heard a presentation from ACC and its scientists outlining their contention that none of the mechanisms of action suggested for the animal cancers were applicable to humans.

The Committee then discussed the evidence presented by both the staff and the ACC contingent with several of the Committee members acknowledging the strength of the animal carcinogenicity evidence, but expressing their concern over the lack of evidence showing a link with humans. Immediately prior to the vote on whether to recommend the listing of DINP the Committee Chairman Dr. Mack noted that due to the lack of epidemiological evidence they were limited to discussing the animal evidence.

Attorney Stanley Landfair, who represented an ACC member, then acknowledged that "everyone concedes" that the animal data does show different cancers in different animals. He then noted that the "question before the Committee is whether those data are relevant to humans." Chairman Mack then interjected noting that he drafted Criteria 1D and that the intent of that particular section was to apply to the situation where there was relevant animals data showing carcinogenicity but there was some contrary epidemiological data. In this case, noted Mack, there is no epidemiological data thus the Committee should base its vote solely on the animal data.

The Committee then voted to list DINP.

In its opinion the Third District acknowledges Dr. Mack's possible misleading instructions. However, it notes that the Committee is instructed to follow the Criteria and in the absence of evidence to the contrary it must be presumed it did so, despite Mack's misleading statements.

The Court then considered ACC's argument that it should overturn the listing based on the failure of the HID to adequately discuss the problems with the lack of data on the mechanism of action. The Court rejected this argument pointing out that the Committee members were provided copies of the ACC presentations prior to the meeting and that it assumes that the members read and considered this evidence.

Finally, ACC argues that failure to reverse the listing carries severe consequences in that it may cause manufacturers to replace the chemical with less safe replacements and would lead to an increase in unnecessary Prop. 65 warnings thereby diluting the effectiveness of the law. The Court rejects this argument noting that ACC fails to address the propriety of the decision itself. The Court also notes that the listing does not automatically require a Prop. 65 warning. A manufacturer still has the option to demonstrate that the particular dose of DINP in its product is below the level that will have no significant risk.

Decision to Publish Ruling

As noted above the Third District initially decided not to publish its ruling. However, the California Attorney General's office, on behalf of OEHHA, argued that the opinion was worth publishing as being the first appellate decision to address the state's "qualified experts" mechanism for listing a chemical under Prop. 65. The AG also noted the significance of the language in the opinion noting that the guidance criteria are not intended to be binding regulations nor are they to be "slavishly followed" by the CIC itself.

Finally, the AG argued that the decision is important "because it succinctly draws the distinction between objections to a listing decision which are governed by the applicable rules and legal standards, and objections to the alleged consequences of a listing decision."

On July 8 the Court reversed itself and agreed to publish the decision "for good cause."

ACC Asks the Supreme Court to Intervene

On **August 17 ACC filed a Petition⁵⁾** with the California Supreme Court asking it to review and reverse the Third District decision. Very few such petitions are granted each year by the high court. In order to induce the Court to consider and reverse this one ACC makes the following arguments:

- In upholding OEHHA's decision to list DINP the Court of Appeal has set a dangerous precedent that gives the CIC unfettered discretion to change the **Guidance Criteria⁶⁾** at will to reach a desired result. As support for this argument ACC points to the A.G.'s publication request approvingly citing the Third District's statement that the **Guidance Criteria⁶⁾** do not have to be "slavishly followed."
- The Court of Appeal erred in approving the listing even though studies have shown that all possible mechanisms of action do not apply to humans.
- The case presents an issue of "extreme importance" because a listing under Proposition 65 has wide-ranging and serious consequences.

Resources for this article

1. CIC Lists One Phthalate But Declines to List a Second

<https://prop65clearinghouse.com/articles/2661>

2. Judge's Tentative Ruling Upholds Listing of DINP

<https://prop65clearinghouse.com/articles/2851>

3. ACC v. OEHHA

<https://prop65clearinghouse.com/documents/64391>

4. Guidance Criteria

<https://prop65clearinghouse.com/documents/64392>

5. August 17 ACC filed a Petition

<https://www.americanchemistry.com/Media/PressReleasesTranscripts/ACC-news-releases/ACC-Petitions-California->

