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Via E-mail: P65Public.comments@oebha.ca.gov

Michelle Robinson
Office of Environmental Health Hazard Assessment
P.O. Box 4010, MS-12B
Sacramento, CA 95814

Re: Big Lots Petition to delist Diaminotoluene (Mixed) and Hazard Identification
Comments on 2, 5 Diaminotoluene

Dear Chairman Mack and CIC Members:

Big Lots Stores, Inc. ("Big Lots")¹ appreciates the opportunity to provide comments to the Carcinogen Identification Committee ("CIC") in support of Big Lots Petition to Reconsider the Listing of *Diaminotoluene (Mixed)* as a Carcinogen ("Petition"). These comments have been prepared in association with Chris MacKay, Ph.D., Amec Foster Wheeler.² In interest of justice, sound science, and regulatory integrity, Big Lots requests that the CIC take the following actions: 1) remove the current iteration of "diaminotoluene (mixed)" from the Proposition 65 list; 2) if diaminotoluene (mixed) or *any* individual isomer or compound is listed, *clearly define what it is* and *include a CAS number*; and 3) do not list 2, 5 diaminotoluene, as there is no evidence that it is a carcinogen.

I. Big Lots Filed the Petition "In the Public Interest"

Executive Summary of the Petition.

Big Lots submitted the Petition on October 21, 2014 providing four independent bases on which OEHHHA could suspend the diaminotoluene (mixed) listing. All of the bases are based on the facts that the 1990 listing of diaminotoluene (mixed) was deeply flawed; did not comply with OEHHHA's listing procedures; did not provide the public with sufficient information to determine what "diaminotoluene (mixed)" is or what chemicals or mixture of chemicals it might include.

¹ Big Lots is a retailer that operates stores in California, and filed the Petition in the public interest pursuant to Title 27 Code of Regulations § 25306(j).

² Dr. MacKay reviewed the technical documents that formed the bases for the listing as received from OEHHHA pursuant to a public record act request, and provided technical analysis in support of this Petition. He has also reviewed the OEHHHA staff reports, materials in the public record, and the studies referenced therein. The Comments of Dr. Chris MacKay, dated October 23, 2015, are attached hereto as Exhibit A and incorporated as if fully set forth herein.

Diaminotoluene (mixed) was listed pursuant to the so-called administrative body listing mechanism of the Safe Drinking Water and Toxic Enforcement Act of 1986 (“Proposition 65”). According to the Notice of Intent to List Chemicals dated November 1, 1989, Diaminotoluene (Mixed) was “formally identified” as a carcinogen by the Environmental Protection Agency (“EPA”) in External Review Draft: Methodology for Evaluating Potential Carcinogenicity to Support Reportable Quantity Adjustments Pursuant to CERCLA Section 102, 1986, Office of Health and Environmental Assessment, OHEA-C-073 (“*EPA Document*”).

The Petition³ set forth four principal grounds, each of which is sufficient to delist:

1. EPA has not “formally identified” diaminotoluene (mixed) as causing cancer within the meaning of Cal. Code Regs. tit. 27 § 25306 (b), (d), (e) and (h). (See Petition II.A)
2. The *EPA Document* does not meet the standard of scientific rigor and critical analysis necessary to support a finding that diaminotoluene (mixed) is a carcinogen. (See Petition II & III)
3. *Diaminotoluene (mixed)* is vague and ambiguous on its face, in that the qualifier “mixed” is not a proper chemistry term, and also the listing failed to include CAS number 00095807 which EPA used to specify the chemical in the *EPA Document*. (See Petition II.B)
4. The administrative listing of diaminotoluene (mixed) based on the *EPA Document* violates the Due Process Clause of the Federal Constitution. (among other things because the 1989 notice of intent to list was based on an *EPA Draft Document*, not the final document.) (See Petition III)

Big Lots' Petition requests that OEHHA take all appropriate and reasonable steps to prevent further harm to the public interest as a consequence of the improper and ambiguous listing of *Diaminotoluene (Mixed)*.

What Happened in Real Life – An Example of the Harm Caused by the Flawed Listing.

There has been a great deal of Proposition 65 litigation over hair dye spawned from the 1990 diaminotoluene (mixed) listing. As the PCPC comments make clear, for the past 40 years no diaminotoluene isomers, except 2,5, diaminotoluene, have been used in these products – but the flawed and unclear 1990 diaminotoluene (mixed) listing has been used by private enforcers as “cover” to sue the industry. Big Lots' story is illustrative of the real life problems and confusion this listing has caused.

Review of the public records of Proposition 65 notices of intent to sue maintained by the Office of the Attorney General indicates that since 2007, thirty (30) notices against about 60 businesses have been issued based on alleged exposure to diaminotoluene (Mixed) by private plaintiff Consumer Advocacy Group (“CAG”). On January 1, 2014, CAG issued a notice of intent to sue to Big Lots concerning Revia, a hair care product, manufactured by Verona Laboratories, CAG allegedly purchased at a Big Lots store in

³ Big Lots understands that OEHHA has provided the CIC with the Petition, and that it is part of the record on which CIC will make its determination. As such, Big Lots requests that the Petition be incorporated as if fully set forth herein. Accordingly, we refer to sections in the Petition, and only summarize those arguments here.

California. Big Lots does not manufacture, import or distribute the Revia product – Big Lots simply sold it at retail.

During the 60-day notice period, Big Lots sought indemnity from the product manufacturer, Verona Laboratories, which is located in the European Union. Verona Laboratories declined to assist Big Lots, stating that diaminotoluene (mixed) is not in their product, and that Revia complies fully with EU and US law.

Big Lots hired a toxicologist to determine what the chemical in the notice, “diaminotoluene (mixed),” was and whether it was in the Revia product. Preliminary review of the record suggested that the EPA documents that formed the bases for the listing assigned diaminotoluene (mixed) a CAS number 00095807. This CAS number was also associated with 2,4 diaminotoluene, thus, Big Lots’ toxicologist concluded that diaminotoluene (mixed) was a mixture of isomers that contained 2,4 diaminotoluene. As a next step, Big Lots tested the Revia product for 2,4 diaminotoluene, and ***obtained an analysis that shows that 2,4 diaminotoluene was not detected!***

Big Lots advised CAG and the Office of the Attorney General that the product did not contain 2,4 diaminotoluene, and provided a declaration of Dr. Chris MacKay and a copy of the certified test report attesting that since 2,4 diaminotoluene was not detected it followed that diaminotoluene (mixed) was not present as well. Not only did CAG refuse to drop their claim, but they refused to exchange their test showing diaminotoluene (mixed) was present, and ***CAG also continued to hide the ball by refusing to specify or explain their contention as to what diaminotoluene (mixed) is.*** To this day, they have not stated what chemical(s) they contend are included in the 1989 diaminotoluene (mixed) listing.

On August 5, 2014, CAG filed suit against Big Lots in Los Angeles Co. Superior Court, BC 553792, alleging an exposure from “*Diaminotoluene.*” Big Lots demurred, on the ground that “diaminotoluene” is not on the Proposition 65 list, although 2,4 diaminotoluene and diaminotoluene (mixed) are listed. CAG opposed the demurrer in part on the ground that “a little discovery” would clear up the specific chemical at issue in the case. The court overruled the demurrer. Big Lots filed an answer. Notably, CAG failed to serve Verona Laboratories – probably because service must be done through the Hague Convention, so Big Lots the retailer is the sole defendant. A trial date was set, but has been vacated and the action stayed⁴ pending the resolution of Big Lot's Petition.

Based on the complaint and discovery, CAG interprets the “diaminotoluene (mixed) listing broadly to mean any of a host of chemical molecules that are distinctly different, but may be considered a “diaminotoluene” on the ground that they contain “diamine” and “toluene” as constituents. Although they have still not

⁴ OEHHA's consideration of Big Lot's Petition and its referral to the CIC, provided the legal bases for the court to grant a stay of the action under the Primary Jurisdiction Doctrine. The California Supreme Court firmly established the Primary Jurisdiction Doctrine in *Farmers Ins. Exchange v. Superior Court* (1992) 2 Cal.4th 377. The Supreme Court found the Primary Jurisdiction Doctrine “applies where a claim is originally cognizable in the courts, and ***comes into play whenever enforcement of the claim requires the resolution of issues which, under a regulatory scheme, have been placed within the special competence of an administrative body; in such a case the judicial process is suspended pending referral of such issues to the administrative body for its views.***”

disclosed what variant of “diaminotoluene” CAG contends is in the Revia product, we now assume that CAG contends that 2, 5 diaminotoluene sulfate is subsumed into the 1989 diaminotoluene (mixed) listing.

II. The 1990 Diaminotoluene (mixed) Listing Was Flawed and Should Be Withdrawn

As a matter of law, if the listing process is flawed, the listing is void *ab initio*. Since many of the errors can be found by a simple review of the listing file and the notice, OEHHA could, and in our view should, have set aside the 1990 diaminotoluene (mixed) listing immediately, and still referred the matter to CIC to determine if a "new" listing of diaminotoluene (mixed) is merited.

The fact that OEHHA referred the question to the CIC on the scientific issues, without addressing the procedural improprieties and lack of clarity in the 1990 listing, makes it imperative that CIC look closely at the 1990 listing and make findings concerning its validity – both from the perspective of whether OEHHA followed the correct process for an administrative body listing and whether the listing of diaminotoluene (mixed) was clear and valid as a matter of science.

As a practical matter, and to avoid further legal proceedings, it is imperative that CIC and OEHHA acknowledge the errors that were made over twenty-five years ago; and delist the 1990 diaminotoluene (mixed). If there is evidence to list diaminotoluene (mixed) under either CAS 00095807 or 25376-45-8, then the new diaminotoluene (mixed) listing should include the CAS numbers, or make clear the chemical range and boundaries of the listing.

III. 2,5 Diaminotoluene Is Not a Carcinogen and Should Not Be Listed

As explained in the attached Comments of Dr. Chris MacKay, dated October 23, 2015, and separately filed Hazard Identification Materials on Diaminotoluenes Comments by the Personal Care Products Council, there is scientifically valid evidence on which to base a listing of 2,5 diaminotoluene. International and federal regulatory agencies unanimously hold that 2.5 diaminotoluene is not a carcinogen. It should not be listed under Proposition 65.

IV. Should CIC Decide to List Diaminotoluene (mixed) or Any Isomer or Mixture, That New Listing Should Be Clear and Include a CAS Number

Other than asking that the 1990 diaminotoluene (mixed) listing be formally rescinded and 2,5 diaminotoluene not be listed, Big Lots does not take any position on the new listing of any of diaminotoluene isomers before the CIC. However, Big Lots urges CIC to heed the words attributed to Winston Churchill⁵: "Those who fail to learn from history are doomed to repeat it." Much confusion, consternation, and needless litigation can be avoided if listings are made clear and specific as possible. Wherever feasible listings should include a CAS number.

⁵ George Santayana was the source of the thought (in *The Life of Reason*, 1905).

V. Conclusion

For the above reasons, Big Lots respectfully requests that the CIC find that the 1990 listing of diaminotoluene (mixed) was flawed, and withdraw the old listing. If CIC decides to list diaminotoluene (mixed), or any isomer or mixture, based on the current proceeding, make sure the chemical or mixture of chemicals that are being listed are clear and include the CAS number. Finally, CIC should not list 2,5 diaminotoluene as there is no scientifically valid study or other bases to do so.

Very truly yours,



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CRB/wp