PETITION OF

BIG LOTS STORES, INC.

TO

RECONSIDER THE PROPOSITION 65 LISTING OF

Diaminotoluene (Mixed)

AS A CARCINOGEN PURSUANT TO

PROPOSITION 65’S AUTHORITATIVE BODY MECHANISM

Carol René Brophy

Sedgwick, LLP
333 Bush St.
San Francisco, California 94104
(415) 267-3466

October 21, 2014
PETITION OF BIG LOTS STORES, INC. TO RECONSIDER THE PROPOSITION 65 LISTING OF DIAMINOTOLUENE (MIXED) AS A CARCINOGEN

Big Lots Stores, Inc. ("Big Lots")\(^1\) by and through their counsel Sedgwick, L.L.P., hereby submits this Petition to Reconsider the Listing of Diaminotoluene (Mixed) as a Carcinogen ("Petition") to the Office of Environmental Health Hazard Assessment ("OEHHA") pursuant to Title 27 Code of Regulations § 25306(j). In 1990, OEHHA listed Diaminotoluene (Mixed) pursuant to the so-called administrative body listing mechanism of the Safe Drinking Water and Toxic Enforcement Act of 1986 ("Proposition 65"). The listing was based on the premise that the U.S. Environmental Protection Agency ("EPA"), an authoritative body for Proposition 65 purposes, had "formally identified" Diaminotoluene (Mixed) as a carcinogen. According to the Notice of Intent to List Chemicals dated November 1, 1989, Diaminotoluene (Mixed) was formally identified as a carcinogen in EPA, 1986, External Review Draft: Methodology for Evaluating Potential Carcinogenicity to Support Reportable Quantity Adjustments Pursuant to CERCLA Section 102, Office of Health and Environmental Assessment, OHEA-C-073 ("EPA Document").

I. INTRODUCTION AND SUMMARY

Big Lots petitions OEHHA to reconsider the Proposition 65 listing of Diaminotoluene (Mixed) as a carcinogen for the following reasons:

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).

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. (Cal. Code Regs. tit. 27 § 25306 (b), (d) and (e))

3. Diaminotoluene (Mixed) is vague and ambiguous on its face, in that the qualifier "Mixed" is not proper chemistry term, and also the listing failed to include CAS number 00095807 that EPA used to specify the chemical in the EPA Document.


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\(^1\) Big Lots is a retailer that operates stores in California, and files this Petition in the public interest. In addition to Big Lot's staff and legal counsel, Dr. Chris MacKay, Ph.D., Senior Toxicologist, AMEC, reviewed the technical documents that formed the bases for the listing as received from OEHHA pursuant to a public record act request, and provided technical analysis in support of this Petition. The Declaration of Dr. Chris MacKay is attached hereto as Exhibit A and incorporated as if fully set forth herein.
For each of these reasons, Big Lots petitions OEHHA to reconsider and remove Diaminotoluene (Mixed) from the Proposition 65 list as a carcinogen, or take appropriate steps to clarify the listing, at minimum to include the CAS number assigned to Diaminotoluene (Mixed) in the EPA Document.

II. THE EPA DOCUMENT DOES NOT MEET THE STATUTORY AND REGULATORY CRITERIA FOR LISTING VIA THE AUTHORITATIVE BODY MECHANISM

For purposes of listing chemicals as carcinogens under its authoritative body mechanism, Proposition 65 provides:

A chemical is known to the state to cause cancer... if a body considered to be authoritative, by [the state’s experts] has formally identified it as causing cancer...

Cal. Health & Safety Code § 25249.8(b). Under the statute and its implementing regulations, there are three prerequisites for an administrative listing: 1) the State’s experts must designate the body as authoritative for the purpose; and 2) the designated body must “formally identify” the chemical 3) as “causing cancer.” In the case of Diaminotoluene (Mixed), the EPA Document fails to meet the second and third prerequisites, and thus, cannot serve as the basis to support the listing of Diaminotoluene (Mixed) as a Proposition 65 carcinogen.

A. EPA Has Not “Formally Identified” Diaminotoluene (Mixed) as Causing Cancer Within the Meaning of Proposition 65

To avoid listings based upon incomplete consideration, the Carcinogen Identification Committee (“CIC”) has adopted certain minimum indicia of finality and consensus that must be present in the authoritative body’s finding for a chemical to be “formally identified” as causing cancer. These indicia have been codified in Proposition 65’s implementing regulations.

A chemical is considered to be “formally identified” by an authoritative body when OEHHA determines that:

1. The chemical has been included on a list of chemicals causing cancer or reproductive toxicity issued by an authoritative body; or is the subject of a report, which is published by the authoritative body and which concludes that the chemical causes cancer or reproductive toxicity; or has otherwise been identified


3 The regulations that applied at the time of the Diaminotoluene (Mixed) listing were Cal. Code Regs. tit. 22, § 12306 (1989). The current authoritative body standards are found at Cal. Code Regs. tit. 27, § 25306.
as causing cancer or reproductive toxicity by the authoritative
body that indicates that such identification is a final action.

Cal. Code Regs. tit. 22, § 12306(d) (1999) (emphases added). In addition, the regulations specify
that the list or report must have been subject to public review and comment prior to its issuance;
issued by the Chief Administrative Officer of the administrative body; adopted as a final rule; or
set forth in a document used by the authoritative body for regulatory purposes. These
requirements also apply under the current regulations.

The EPA Document does not meet the minimum standards required to allow OEHHA to
use it as the basis for an administrative listing. First, the cover page and even the title indicates
that the document is a DRAFT. Second, the EPA Document cover page contains a disclaimer,
which expressly cautions that the contents have not been adopted or even released to the public.

DRAFT: DO NOT QUOTE OR CITE

This document is a preliminary draft. It has not been formally
released by the U.S. Environmental Protection Agency and should
not at this stage be construed to represent Agency policy. It is being
circulated for comments on its technical merit and policy
implications.

Third, even if there was a decision by EPA to adopt the conclusions in the document, the
decision was not made at a public meeting nor were the findings issued pursuant to notice and
comment. Fourth, the EPA Document was never published in the Federal Register. Thus, the
EPA Document does not meet the requirement that the public must have the opportunity for
comment before the agency adopted it. Fifth, the EPA Document was not signed by the Chief
Administrative Officer of EPA.

Sixth, the EPA Document is not an examination of the carcinogenic properties of any chemical or
group of chemicals: it is a guidance document – or methodology – EPA is proposing to use for
assessing carcinogenicity of chemicals pursuant to CERCLA section 102. It was not intended to
designate chemicals as carcinogenic, nor does it purport to do so. Diaminotoluene (Mixed) is not
found in the body or the report. The only place that Diaminotoluene (Mixed) appears is in the
Appendix as item 77 on the list of 191. This Appendix appears to identify chemicals that may be
assessed if the methodology is adopted, or Appendix could reference chemicals that were used as
exemplars to test and develop the methodology. There is nothing in the EPA Document - even
the final version – that suggests that by adopting the methodology, EPA was also issuing a final
determination that the chemicals in the Appendix were carcinogens.

Finally, Appendix identifies Diaminotoluene (Mixed) as a “medium” hazard classification. It is
unclear how the “medium” classification may equate to a determination that Diaminotoluene
(Mixed) causes cancer within the meaning of Proposition 65.

Because the EPA document does not meet the criteria necessary to “formally identify” Diaminotoluene (Mixed) as a carcinogen, such listing would constitute an abuse of OEHHA discretion and be subject to judicial challenge.

B. The Diaminotoluene (Mixed) Listing Is Vague and Ambiguous, and Does Not Conform to the Chemical Named in the EPA DOCUMENT that Formed the Basis for Listing.

On its face, the chemical listing for Diaminotoluene (Mixed) is vague and ambiguous. In chemical nomenclature diaminotoluene is an imprecise term that could, for instance, mean any one of ten different and unique congener substances with the same molecular formula and contain two amine moieties on a toluene structural base. The qualifier “Mixed” is not proper chemistry term. Thus, the regulated community cannot discern the specific chemical identify that OEHHA intended to list.

Another practical problem is that there is nothing in the Proposition 65 listing that defines what the composition of the mixture could be. For instance, it could be more than one or more congeners of diaminotoluene. Alternately, it could refer to a specific congener of diaminotoluene (e.g. 2,4-diaminotoluene), but refer to a mixture of 2,4-diaminotoluene salts (chlorides, sulfates, phosphates, carbonates, etc) since all diaminotoluene congeners are weak bases. It is impossible to tell since the Proposition 65 listing does not include a CAS number.

EPA included CAS numbers in the EPA Document.. CAS numbers are assigned to uniquely describe single chemical compounds or common mixtures with chemical, commercial, or regulatory importance. Review of the EPA Document Appendix, shows the number 77 entry for diaminotoluene (mixed) identifies the substance specifically by CAS number 00095807. This number identifies the free base of the 2,4-diaminotoluene congener. To be consistent with the EPA Document, Proposition 65 listing should have included the CAS number 00095807. It is likely that the most correct definition of diaminotoluene (Mixed) is a formulation of mixed salts of 2,4-diaminotoluene. At the very least, the mixture must contain 2,4-diaminotoluene as component of CAS number 00095807 that EPA used to specify the chemical in the EPA Document.

III. THE DIAMINOTOLUENE (MIXED) LISTING BASED ON THE EPA DOCUMENT “FINDING” VIOLATES THE DUE PROCESS CLAUSE OF THE FEDERAL CONSTITUTION

It is well established that any designation of a chemical as a carcinogen or reproductive toxin by the federal government is an agency action that triggers constitutional due process protections of the Fifth and Fourteenth Amendments to the Constitution of the United States. Dow Chemical, USA v. Consumer Product Safety Commission, 459 F. Supp. 378 (W.D. La, 1978). In ruling that administrative listing of a chemical posed a violation to the public’s right to due process, the Court in that case recognized that a hazard determination may result not only in regulatory burdens, but also in significant economic injury. Id. at 393. Further, the designation must be made pursuant to the federal Administrative Procedures Act, which incorporates notice and comment requirements. Id. at 390-391 (solicitation of comments is the basis of informal
rule-making.

As indicated above, the EPA Document was not final agency action, and also did not “formally identify” Diaminotoluene (Mixed) as a carcinogen. Also, the EPA Document alleged determination of carcinogenicity was not made pursuant to the federal Administrative Procedures Act. Given these origins, the use of the EPA Document (including any “findings” contained in it) for a regulatory purpose would violate the Due Process Clauses of the Fifth and Fourteenth Amendments to the Constitution, and any such regulations would be void ab initio.

Although Proposition 65 contains a provision which provides that the listing of chemicals is exempted from the California Administrative Procedures Act that would otherwise apply when a state agency engages in rulemaking, this exemption from state administrative process requirements cannot and does not supercede the public’s right to procedural due process guaranteed by both the United States Constitution and the State Constitution. Simply, Due Process requires that the public have notice and the right to comment at the time the government finds that a health hazard is posed by a chemical. Dow Chemical, supra at 392.

Where, as here, the underlying document or finding was not adopted in a manner that satisfied due process, such document or finding is not suitable as the basis for an authoritative body listing. If OEHHA were to list Diaminotoluene (Mixed) as a carcinogen on the basis of the EPA Document, Big Lots and the general public would be denied their constitutional right to due process, because at no time have they or any other member of the public been provided an opportunity to comment to the governmental agency making the determination.

Moreover, EPA itself does not consider the EPA Document to be a formal and final agency finding regarding the carcinogenicity of the chemicals. Under these circumstances, OEHHA’s use of the EPA Document as the basis for a Proposition 65 listing was arbitrary and irrational as well as a violation of due process, because such use is beyond the intent of the adopting agency. Clearly, OEHHA cannot use any agency decision or document that is not considered an official determination by the agency that adopted it, as the basis of an authoritative body listing under Proposition 65.

IV. CONCLUSION

For the reasons stated above, OEHHA should reconsider the Diaminotoluene (Mixed) as a carcinogen pursuant to an authoritative body listing. If you have any questions or require further information, please contact us.

Carol René Brophy
Counsel for Big Lots Stores, Inc.

DECLARATION OF DR. CHRIS MACKAY

1, Chris Mackay, do hereby declare that:

1. I am giving this declaration as an expert in the fields of toxicology, human health risk and exposure assessment, as well as the application of these disciplines to California’s Safe Drinking Water and Toxic Enforcement Act of 1986 ("Proposition 65") and its implementing regulations. The basis for my expertise is as follows:

2. I am a Senior Associate Toxicologist with AMEC Environment and Infrastructure, an environmental sciences consulting firm. I have held my current position since 2005. Prior to that, I was a Managing Scientist at Exponent for 10 years. I earned my Honors Baccalaureate in Toxicology and Masters in Environmental Biology from the University of Guelph. I earned my doctoral degree in Pharmacology and Toxicology from the University of California, Davis in 1996.

3. I have over 20 years of experience in evaluating the potential health impacts of chemical substances. This experience has been gained in scientific research as well as providing technical assistance in complying with environmental and workplace regulations that are intended to protect the health of workers, consumers and members of the general public.

4. I am familiar with California’s Safe Drinking Water and Toxic Enforcement Act of 1986 ("Proposition 65"). I have detailed knowledge of Proposition 65’s regulations (27 C.C.R. §§ 25001, et seq.) and of the implementing agency’s Statement of Reasons. I have an extensive working knowledge of Proposition 65-required methods for determining exposures to listed chemicals.

5. I have conducted hundreds of health risk assessments to support Proposition 65 compliance efforts, including those in response to lawsuits alleging violations of the requirement to warn of an exposure to listed chemicals in consumer products. I have assessed Proposition 65 warning obligations from exposure to numerous consumer products, including products containing lead.

6. Based on my personal and professional experience, the above stated activities, and review of the 60-Day notice of intent to sue issued to Big Lots Stores, Inc. ("Big Lots") by
Consumer Advocacy Group ("CAG") on or about January 17, 2014, concerning Proposition 65 exposures to diaminotoluene (mixed). I have also reviewed the complaint filed by CAG against Big Lots and other defendants in Los Angeles Superior Court on August 5, 2014 alleging a Proposition 65 exposure from certain hair care products concerning "diaminotoluene." I have acquired personal knowledge of the matters discussed herein, and can and will competently testify thereto.

7. I have reviewed the Proposition 65 list of chemicals; the Notice of Intent to List dated November 1, 1989 (Exhibit A); the technical documents that formed the bases for California to include diaminotoluene (mixed) on the Proposition 65 list;¹ and other materials I received from the Office of Environmental Health Hazard Assessment pursuant to a California Public Records Act Request. The EPA document used as the technical basis of the listing is not an examination of the carcinogenic properties of any chemical or group of chemicals, but rather a guidance on the general approach proposed by EPA for examining chemicals for carcinogenetic properties. A series of chemicals with EPA classifications were provided as an appendix to this document (Exhibit B). Number 77 on the list of 191 chemicals is diaminotoluene (mixed); a CAS number 00095807 is included for specificity.² This is the only mention of the chemical in the entire report.

8. The Proposition 65 Notice of Intent to List diaminotoluene (mixed) was issued pursuant to the authoritative body mechanism cited an EPA determination as the bases for the listing. The EPA determination used, Methodology for evaluating potential carcinogenicity in support of reportable quantity adjustments pursuant to CERCLA section 102, is an external review draft and clearly stated on the report title page (Exhibit C):

DRAFT: DO NOT QUOTE OR CITE

This means that EPA had disavowed the technical merit of the document in the form used by California as the authoritative body finding to add diaminotoluene (mixed) on the


² Notably, the Chemical Abstract Service has assigned CAS 00095807 to 2.4 diaminotoluene free base.
Proposition 65 list. Since EPA does not recognize the document as a competent technical
analysis, it appears that California should not have used this document as an EPA determination
for purposes of authoritative body listing of diaminotoluene (mixed). A copy of the title page of
the technical document cited as the basis for the Proposition 65 listing of diaminotoluene
(mixed) is provided as Exhibit 3.

9. The Proposition 65 listing of diaminotoluene (mixed) is unclear and confusing.
In chemical nomenclature diaminotoluene is an imprecise term that could, for instance, mean
any one of ten different and unique congener substances with the same molecular formula and
contain two amine moieties on a toluene structural base. The qualifier "(mixed)" is not a term
of chemistry. If it is to be taken at its classical definition, we assume that it referrers to an
identifiable entity composed on more than one constituent. The problem is that there is nothing
in the State's Proposition 65 listing that defines what the composition of this mixture could be.
For instance, it could be more than one congeners of diaminotoluene. Alternately, it could refer
to a specific congener of diaminotoluene (e.g. 2,4-diaminotoluene), but refer to a mixture of
2,4-diaminotoluene salts (chlorides, sulfates, phosphates, carbonates, etc) since all
diaminotoluene congeners are weak bases. It is impossible to tell since the Proposition 65
listing does not include a CAS number.

10. CAS numbers are assigned to uniquely describe single chemical compounds or
common mixtures with chemical, commercial, or regulatory importance. Review of the EPA
document that forms the bases of the Proposition 65 listing shows the number 77 entry for
diaminotoluene (mixed) identifies the material specifically as CAS number 00095807
(Exhibit 2). This number identifies specifically the free base of the 2,4-diaminotoluene
congener. Consequently, to be consistent with the EPA document, it is my opinion that the
most correct definition of diaminotoluene (mixed) is a formulation of mixed salts of
2,4-diaminotoluene. At the very least, the mixture must contain in part a component of

3 This also begs the question whether a "Methodology Report" is a sufficient bases to
constitute a authoritative body determination for Proposition 65 listing purposes

DECLARATION OF CHRIS MACKAY IN SUPPORT OF BIG LOTS STORES, INC
2,4-diaminotoluene. Otherwise the mixture has no relation to the chemical identified by EPA as 0009587; 2,4-diaminotoluene.

11. On or about August 15, 2014, I was engaged by Carol Brophy, Sedgwick, LLP, and counsel for Big Lots to assist her in evaluating the scientific merit of putative plaintiff CAG’s claims concerning exposures to diaminotoluene in Revia hair care products. In this capacity, I arranged for an independent third party laboratory, Exova Laboratories in Santa Fe Springs, California, to perform analytical tests for 2,4diaminotoluene as it is the only identifiable chemical entity that is a congener of diamine toluene AND is listed by EPA and Proposition 65 as a known suspected human carcinogen.

12. The samples were prepared in a manner consistent with EPA Method 3542. The content of the extract was determined by GC-MS in a manner consistent with EPA 8270. Both the extraction and analytical methods applied in this investigation meet the standard for compliance testing under California Code of Regulations Title 27§25900. No 2,4-diaminotoluene was detected in either replication. Results are attached as Exhibit D.

13. California Code of Regulations Title 27, section 25900 provides that no exposure or discharge occurs if “all the reported results show that the chemical in question was not detected”. There are several caveats associated with this determination including that the method of detection and analysis is properly applied (i.e., the method is an approved method, used by authoritative bodies) and the method of detection and analysis evaluates the appropriate media. From a technical perspective, I believe that the analyses performed fulfill all of these requirements.

14. Therefore, based on the lack of detectable 2,4-diaminotoluene available in the Revia Hair Dye, it is my opinion that the potential exposure from 2,4-diaminotoluene and also diaminotoluene (mixed) is zero within the meaning of Code of Regulations Title 27, section 25900. As there was no potential for exposure, there is no necessity for a Proposition 65 warning as related to the presence of 2,4 diaminotoluene or diaminotoluene (mixed).

15. I reserve the right to modify my opinions as new information is discovered or brought to my attention.
I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct and that this declaration was executed on this 21st day of October 2013, at Irvine, Orange County, California.

[Signature]

Dr. CHRIS MACKAY
Declarant
NOTICE OF INTENT TO LIST CHEMICALS

November 1, 1989

Under the Safe Drinking Water and Toxic Enforcement Act of 1986 [Health and Safety Code Section 25249.8(b)], one of the ways a chemical is known to the State to cause cancer or reproductive toxicity is if a body considered to be authoritative by the Scientific Advisory Panel has formally identified it as causing cancer or reproductive toxicity. The Health and Welfare Agency has adopted a regulation to guide this part of the implementation of the Act (Title 22, California Code of Regulations, Section 12306).

The Panel has identified the U.S. Environmental Protection Agency (EPA), the International Agency for Research on Cancer (IARC), and the National Toxicology Program (NTP) as authoritative bodies.

Pursuant to Section 12306, the Agency intends to designate the following chemicals for listing as known to the State to cause cancer. Anyone objecting to the addition of a chemical to the list of chemicals known to the State to cause cancer on the basis that there is no substantial evidence that the criteria identified in 22 CCR Section 12306(d) have been satisfied should provide comments, along with supporting documentation, to the Health and Welfare Agency no later than December 1, 1989. Comments should be directed to:

Dr. Steven A. Book  
California Health and Welfare Agency  
1600 Ninth Street, Room 460  
Sacramento, CA 95814

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<th>Reference</th>
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Captan 6
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p-Chloro-o-toluidine 7,8
Chrysene 7
Daminozide 6
Diaminotoluene (mixed) 7
1,4-Dichloro-2-butene 5
1,1-Dichloroethane 5
1,2-Dichloropropane 4,9
Dicofol 6
7,12-Dimethylbenz(a)anthracene 7
Ethyl-4,4'-dichlorobenzilate 7
Furazolidone 5
Furium 5
Furmecyclox 1
Glu-P-1 (2-Amino-6-methyldipyrido[1,2-a:3',2'-d]imidazole) 8
Glu-P-2 (2-Aminodipyrido[1,2-a:3',2'-d]indole) 8
Griseofulvin 8
Mancozeb 6
Maneb 6
Me-A-alpha-C (2-Amino-3-methyl-9H-pyrido[2,3-b]indole) 8
Medroxyprogesterone acetate 8
3-Methylcholanthrene 7
N-Methyl-N-nitrosoureathane 8
Metiram 6
Nitrofurazone 5
Pentachlorophenol 10,11
Phenobarbital 8
Potassium bromate 8
1,2-Propyleneimine 7
Sodium o-phenylphenate 8
p,a,a,a-Tetrachlorotoluene 5
p-Toluidine 7
Zineb 6

References


APPENDIX

HAZARD RANKING OF POTENTIAL CARCINOGENS
EXHIBIT C
Research and Development

METHODOLOGY FOR EVALUATING POTENTIAL CARCINOGENICITY IN SUPPORT OF REPORTABLE QUANTITY ADJUSTMENTS PURSUANT TO CERCLA SECTION 102

Prepared for
OFFICE OF EMERGENCY AND REMEDIAL RESPONSE

Prepared by
Carcinogen Assessment Group
Office of Health and Environmental Assessment
Washington DC 20460

DRAFT: DO NOT QUOTE OR CITE
This document is a preliminary draft. It has not been formally released by the U.S. Environmental Protection Agency and should not at this stage be construed to represent Agency policy. It is being circulated for comments on its technical merit and policy implications.
2,4-Diaminotoluene by GC-MS
Gas Chromatography-Mass Spectrometry

Sample preparation: Each sample was accurately weighed (~1 g) and extracted in methylene chloride (5 mL). An aliquot of each extract was spiked with internal standards and analyzed by GC-MS.

**GC-MS Conditions**

- **Column:** 30 m x 0.32 mm RxI-5Sil MS, 1 µm Film
- **Column Temp:** 80°C (hold 1 min) to 320°C at 15°C/min (hold 3 min)
- **Injector Temp:** 320°C
- **Mass Range:** 35-475 amu; 3.3 scans/sec

**Parts per million (ppm)**

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**Date Analyzed:** 09-09-14

**Quality Control Summary**

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**QC Guidelines**

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**CHAIN-OF-CUSTODY RECORD**

**PROJECT NAME:** Big Lots - Revia Hair Dye  
**PROJECT NUMBER:** BLR-8-15-14-1

**RESULTS TO:**  
Chris Mackay

**TURNOVER TIME:** 10-day

**SAMPLE SHIPMENT METHOD:** FedEx

**ANALYSES**

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**RELIQUIDATION:**  
- 06-18-14  
- 06-18-14-2

**RECEIVED BY:**  
Chris Mackay

**SAMPLING COMMENTS:**  
*2,4-Diamino-toluene*