

November 30, 2018

TSCA Confidential Business Information Center (7407M)
EPA East - Room 6428, Attn: Section 8(e)
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue N.W.
Washington, DC 20460-0001

**CONTAINS NO TSCA
CONFIDENTIAL
BUSINESS
INFORMATION**

Re: TSCA Section 8(e) Submission N-(1,3-Dimethylbutyl)-N'-phenyl-p-phenylenediamine (6PPD; CAS 793-24-8)

Dear Sir or Madam,

The following information is being submitted by Eastman Chemical Company pursuant to the Environmental Protection Agency's current interpretation and guidance regarding Section 8(e) of the Toxic Substances Control Act (TSCA). This submission is also made in the name of LANXESS Corporation and Sennics Inc.

Eastman has obtained **unaudited preliminary data** on an ongoing OECD 443 Extended 1-Generation Reproductive Study for 6PPD. Data from an earlier range-finding study for this current extended 1-generation study resulted in a TSCA 8(e) submission (8EHQ-18-21258) based on findings of dystocia and subsequent euthanasia for humane reasons. The current study generally shows the same findings, and a second 8(e) notice is being submitted due to the use of lower dose levels in the full study. In this study, four (4) groups of at least twenty-five (25) Sprague-Dawley rats per group and thirty (30) in the high dose group, were treated with 6PPD in corn oil via oral gavage at concentrations of 0, 7, 20 or 60 mg/kg/day. A number of dams died or were euthanized in extremis in late gestation/parturition, along with findings of total litter losses, as reported by the laboratory in the following table:

Preliminary Study Findings			
Group	Dose	Finding	Number of animals
1	0 mg/kg/day (control)	Total litter loss*	3
2	7 mg/kg/day	No findings	0
3	20 mg/kg/day	Found dead in late gestation	2
		Total litter loss*	1
4	60 mg/kg/day	Adverse clinical signs and dystocia	5
		Total litter loss*	4
* Total litter loss is generally not considered to be test article related without additional data. As this is preliminary data obtained immediately after perturbation, any potential supplemental information is not currently available.			

This testing is being conducted in compliance with an order issued under the European Union's Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals ("REACH") to the European affiliates of Eastman, LANXESS Corporation and Sennics Inc., co-registrants of the substance.

Eastman has not determined whether these results, in fact, represent a substantial risk of injury to health or the environment under TSCA. The submission of this information is intended to discharge any TSCA Section S(e) responsibilities that might exist for these findings. If you have any questions or require further information, please contact Dr. Steven Green at (423) 229-2466.

Sincerely yours,

John L. Hott, Ph.D.
 Director
 Global Product Stewardship and Regulatory Affairs
 Eastman Chemical Company
 Kingsport, TN 37660-5075



United States Environmental Protection Agency
Washington, DC 20460

Section 8(e) Notice

This is an original submission:



This is an amendment:



CERTIFICATION

I hereby certify to the best of my knowledge and belief that all information entered on this form is complete and accurate. I further certify that, pursuant to 15 U.S.C. § 2613(c), for all claims for protection for any confidential information made with this submission, all information submitted to substantiate such claims is true and correct, and that it is true and correct that the person submitting the claim has:

- (i) taken reasonable measures to protect the confidentiality of the information;
- (ii) determined that the information is not required to be disclosed or otherwise made available to the public under any other Federal law;
- (iii) a reasonable basis to conclude that disclosure of the information is likely to cause substantial harm to the competitive position of the person; and
- (iv) a reasonable basis to believe that the information is not readily discoverable through reverse engineering.

Any knowing and willful misrepresentation is subject to criminal penalty pursuant to 18 U.S.C. § 1001.

Signature:

ES/steven green

Official Title:

Associate Toxicologist

Contact Person:

steven green

Email Address:

sgreen@eastman.com

Date Signed:

11/30/2018

PART 1

Contact Information

Submission Information

Case Number:

Submission Alias:

Fri Nov 30 13:34:52 EST 2018

Date Submitted:

11/30/2018

Submitter Information

CBI:

Yes: ☐ No: ☒

Company Name:

Eastman Chemical Company

Address:

200 S. Wilcox Drive

	Contact Person: steven green	Kingsport, TN, 37662			
	Phone Number: 4232292466	Email Address: sgreen@eastman.com			
Technical Contact	CBI: Yes: <input type="checkbox"/> No: <input checked="" type="checkbox"/>				
	Company Name: Eastman Chemical Company	Address: 200 S. Wilcox Drive Kingsport, TN, 37662 United States			
	Contact Person: Dr steven green				
	Phone Number: 4232292466	Email Address: sgreen@eastman.com			
PART 2	Chemical Reports				
Chemical Identification	Chemical Report Folder Alias:				
	Chemical Identifying #: CASRN: 793-24-8	CBI: Yes: <input type="checkbox"/> No: <input checked="" type="checkbox"/>			
	Chemical Name: 1,4-Benzenediamine, N1-(1,3-dimethylbutyl)-N4-phenyl-				
Attached Document(s)	Report Study Title: Extended 1-generation study of 6-PPD in Rats				
	Original Document: Eastman 6PPD submission final Nov 30 2018.pdf	Submission Type: Initial Submission			
	Effects: Health Effects	Endpoints: Toxicity to Reproduction			

Paperwork Reduction Act

The information collection requirements contained in the information collection request (ICR) have been submitted for OMB approval under 15 U.S.C. 2607(e). The ICR prepared by EPA, identified under EPA ICR No. 0794.13 and OMB control number 2070-0046, is available in the docket for the ICR. ICR No. 0794.13 addresses the incremental changes to the currently approved ICR documents that cover the existing reporting and record keeping programs that are approved under OMB control number 2070-0046. An agency may not conduct or sponsor, and a person is not required to, respond to a collection of information unless it displays a currently valid OMB control number.

Authority

The Government Paperwork Elimination Act (GPEA) (44 U.S.C. 3504) provides that, when practicable, Federal organizations use electronic forms, electronic filings, and electronic signatures to conduct official business with the public. EPA's Cross-Media Electronic Reporting Regulation (CROMERR) (40 CFR part 3) (Ref. 2), provides that any requirement in title 40 of the CFR to submit a report directly to EPA can be satisfied with an electronic submission that meets certain conditions once the Agency published a document in the **Federal Register** announcing that EPA is prepared to receive certain documents in electronic form. For more information about CROMERR, go to <http://www.epa.gov/cromerr/>.