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Via CDX
TSCA Confidential Business Information Center (7407M)
WJC East - Room 6428 Attn: Section 8(e)
U.S. Environmental Protection Agency
1201 Constitution Avenue, NW
Washington, DC 20004-3302

Subject: Notice in Accordance with TSCA Section 8(e): **Results of a Range Finding Study for 90-day inhalation study, 5-day exposure, rats, with recovery period, with CASRN 177997-13-6.**

Dear Section 8(e) Coordinator:

BASF Corporation is submitting results of a Range finding study for 90-day inhalation study with Aluminum cobalt lithium nickel oxide, CASRN 177997-13-6, conducted by BASF SE, Ludwigshafen, Germany. A short-term inhalation lung toxicity study in male Wistar rats, dust exposure with bronchoalveolar lavage, 3 weeks recovery period. The substance is used as cathode material in batteries.

The inhalation exposure and examination of local and systemic toxicity was carried out in accordance with the requirements of the international guideline:

- OECD Guidelines for Testing of Chemicals, Guideline 412

Groups of male Wistar rats were exposed nose-only to the liquid aerosol of the test item for 6 hours per day on 5 consecutive days. The target concentrations were 0.2, 0.5, 2 and 10 mg/m³. A concurrent control group is exposed to clean air. Daily clinical observations, body weights were recorded. Additional assessments including clinical chemistry, hematology, bronchoalveolar lavage, and histopathology of the respiratory tract were carried out at the termination of the study.

The following is a summary of the most relevant results:

10 mg/m³

- Accelerated respiratory rate on study days 4 and 5
- Reduced body weight gain during exposure period
- Increased hemoglobin and hematocrit values in blood
- Increased absolute and relative neutrophil and relative monocyte counts in blood
- Decreased relative monocyte counts in blood
- Increased total cell and absolute and relative neutrophil, monocyte and eosinophil counts in BAL
- Increased absolute lymphocyte and epithelial cell counts in BAL
- Decreased relative macrophage counts in BAL
- Increased total protein levels, lactate dehydrogenase (LDH), alkaline phosphatase (ALP), β-N-Acetyl glucosaminidase (NAG), and γ-Glutamyl transferase (GGT) activities in BAL

Lungs:

- Statistically significant increase of the mean absolute (229%) and relative (239%) weight
- Inflammation, mixed-cellular: in all animals (slight to severe), alveolar, peribronchial, peribronchiolar, and perivascular (polymorphonuclear granulocytes, lymphocytes, and macrophages)

- Hypertrophy / hyperplasia, epithelial in all animals (slight to moderate), in bronchi and bronchioles (including terminal bronchioles)
- Hyperplasia, type-II pneumocytes in all animals (slight to severe; with atypia in one out of 5 animals)
- Edema, alveolar in 2 out of 5 animals (minimal to moderate)

Trachea:
- Hypertrophy / hyperplasia, epithelial in 4 out of 5 animals (minimal to slight)

2 mg/m³
- Increased total cell and absolute and relative neutrophil counts in BAL
- Decreased relative macrophage counts in BAL
- Increased total protein levels, lactate dehydrogenase (LDH), β-N-Acetyl glucosaminidase (NAG), and γ-Glutamyl transferase (GGT) activities in BAL

Lungs:
- Inflammation, mixed-cellular: in 3 out of 5 animals (minimal), alveolar, peribronchial, peribronchiolar, and perivascular (polymorphonuclear granulocytes, lymphocytes, and macrophages)
- Hypertrophy / hyperplasia, epithelial in 2 out of 5 animals (minimal), in bronchi and bronchioles (including terminal bronchioles)

0.5 mg/m³ and 0.2 mg/m³
No treatment-related, adverse effects.

Test group 14 (10 mg/m³ – recovery)
- Accelerated respiration from study day 4 to day 12
- Reduced body weight gain during exposure period
- Increased total cell and absolute and relative neutrophil, lymphocyte and monocyte counts in BAL
- Increased absolute, but decreased relative macrophage counts in BAL
- Increased total protein levels, lactate dehydrogenase (LDH), alkaline phosphatase (ALP), β-N-Acetyl glucosaminidase (NAG), and γ-Glutamyl transferase (GGT) activities in BAL

Lungs:
- Statistically significant increase of the mean absolute (147%) and relative (147%) weight
- Inflammation, mixed-cellular: in 3 out of 5 animals (minimal to slight), alveolar, peribronchial, peribronchiolar, and perivascular (polymorphonuclear granulocytes, lymphocytes, and macrophages)
- Histiocytosis, alveolar in all animals (slight to moderate), accompanied by cell debris (damaged histiocytes)

BASF Corporation understands that reporting of the results from this study under TSCA 8(e) is in accordance with EPA's policy.

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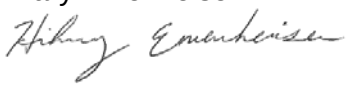
Please direct all correspondence regarding this submission to the technical contact below. If you have any questions, please call (248) 304-5219.

Sincerely,

Technical Contact: Hilary Emenheiser



BASF Corporation, Product Regulations Specialist
Product Regulatory Center of Expertise – North America
24700 W. Eleven Mile Rd., Southfield, MI 48033

Ref. 2415

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:	Official Title:
ES/Hilary Emenheiser	Product Regulatory Specialist
Contact Person: Hilary Emenheiser	Email Address: hilary.newman@partners.basf.com
Date Signed: 04/10/2018	

PART 1	**Contact Information**	
Submission Information	Case Number:	Date Submitted: 04/10/2018
	Submission Alias: Tue Apr 10 12:46:08 EDT 2018	
Submitter Information	CBI: Yes: ☐ No: ☑	
	Company Name: BASF CORPORATION	Address: 26701 TELEGRAPH ROAD

	Contact Person: Hilary Emenheiser	SOUTHFIELD, MI, 48034
	Phone Number: 2483045219	Email Address: hilary.newman@partners.basf.com
Technical Contact	CBI: Yes: ☐ No: ☑	
	Company Name: BASF CORPORATION	Address: 26701 TELEGRAPH ROAD SOUTHFIELD, MI, 48034 United States
	Contact Person: Mrs Hilary Emenheiser	
	Phone Number: 2483045219	Email Address: hilary.newman@partners.basf.com
PART 2	**Chemical Reports**	
Chemical Identification	Chemical Report Folder Alias:	
	Chemical Identifying #: CASRN: 177997-13-6	CBI: Yes: ☐ No: ☑
	Chemical Name: Aluminum cobalt lithium nickel oxide	
Attached Document(s)	Report Study Title: Results of a Range Finding Study for 90-day inhalation study, 5-day exposure, rats, with recovery period, with CASRN 177997-13-6.	
	Submission Type:	
	Summary Original Document: 2415 EPA CDX Letter for TSCA 8(e) Submission.pdf	
	Effects:	Endpoints:

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/.