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8EHQ-1010-18129A

Via Federal Express

United States Environmental Protection Agency - East
Attn: TSCA Section 8(e)
Room 6428
1201 Constitution Avenue, NW
Washington, DC 20004



DCN:8811000013

Subject: Notice in Accordance with Section 8(e): Results of a Repeated Dose 28-Day Oral Toxicity Study with Bis(1,2,2,6,6,-pentamethyl-4piperidyl)sebacate (CAS No. 41556-26-7) and methyl1,2,2,6,6,-pentamethyl-4-piperidyl sebacate (CAS No. 82919-37-7)

Dear Sir/Madam:

BASF Corporation is submitting results of a Repeated Dose 28-day Oral Toxicity Study with a recovery period of 2 weeks in Wistar rats [CrI:WI(HAN)] with Bis(1,2,2,6,6,-pentamethyl-4piperidyl)sebacate (CAS No. 41556-26-7) and methyl1,2,2,6,6,-pentamethyl-4-piperidyl sebacate (CAS No. 82919-37-7), conducted by BASF SE, Ludwigshafen, Germany. The substance is a light stabilizer.

The objective of the study was to determine the toxicological profile of the test item including the target organs and the "no observed adverse effect level" (NOAEL) after 28-day oral administration in the rat. Additional animals of the high-dose and control groups were maintained for two weeks without treatment in order to demonstrate reversibility of the possible effects.

- OECD Guidelines for Testing of Chemicals; Method No. 407: Repeated Dose 28-day Oral Toxicity Study in Rodents; adopted 03 Oct 2008
- Commission Regulation (EC) No 440/2008 of 30 May 2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), Part B: Methods for the determination of toxicity and other health effects: B.7. Repeated Dose (28 Days) Toxicity (Oral); Official Journal of the European Union, No. L 142

The substance was administered daily by gavage to male and female Wistar rats at dose levels of 0 (corn oil served as vehicle), 100, 300 and 750 (males)/1000 (females) mg/kg body weight/day over a period of 28 days. The test groups consisted of each 5 animals per sex which were sacrificed after four weeks of treatment. The control and high-dose groups enclosed another 5 rats per sex which were maintained for 14 days without dosing prior to sacrifice after the 4-week treatment period.

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The animals were examined for signs of toxicity and mortality at least once a day. Clinical parameters, functional observational battery (FOB), motor activity, clinical pathology as well as post mortem examinations including histopathology were performed according to guideline.

The following is a summary of the most relevant results:

Adverse findings were confined to the high-dose group, only. The predominant effect was detected during the FOB examination on days 23/24 of treatment and affected the pupillary reflex. No adaptation of the pupil to light was noted in 7 female animals and retarded adaptation of the pupil to light in 1 male and 3 female animals. In addition, slight closure of eyelid(s) were observed in 4 males and 7 females at the same investigation timepoint. This effect was not observed when examined during the recovery period. Furthermore, the standard pathology investigations did not elucidate any adverse findings.

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

If you have any questions, please call Janet Cerra at (973) 245-6693.

Sincerely,

Janet Cerra

Janet Cerra
Product Regulatory Center of Expertise
North America

/jc

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From: Origin ID: LKKA (973) 245-6693
Janet Cerra
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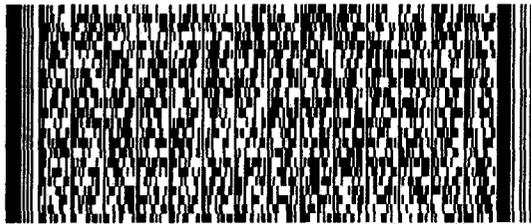


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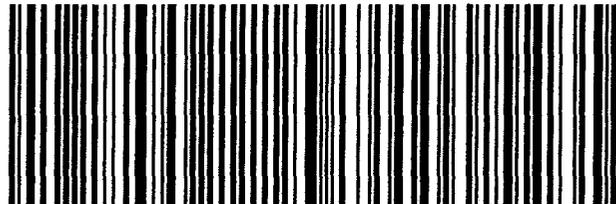


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