Joint Exhibit 8

EPA OALJ Docket No. FIFRA-HQ-2022-0002

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

Office of Chemical Safety & Pollution Prevention

MEMORANDUM

Date: April 16, 2015

SUBJECT: **DCPA:** HED Review of the Revised Comparative Thyroid Toxicity Study Protocol.

PC Code: 078701
Decision No.: NA
Petition No.: NA
Risk Assessment Type: NA
TXR No.: 0054026
MRID No.: NA

DP Barcode: D424915
Registration No.: GDCI-078701-1140
Regulatory Action:
Case No.: NA
CAS No.: 1861-32-1
40 CFR: 180.185

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THRU: Michael Metzger, Branch Chief
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TO: Marquea King, Ph.D., Chemical Review Manager
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I. CONCLUSIONS: The comparative thyroid toxicity study protocols submitted *via* email on April 1, 2015 are adequate.

II. ACTION REQUESTED: Please review the revised protocols for the comparative thyroid toxicity test for DCPA.

III. BACKGROUND: The thyroid assay protocols submitted originally were found to be inadequate (D413170, dated 11/19/2013), and the registrant submitted an additional revised comparative thyroid protocol (HLS Study # BDG0203, dated November 26, 2014). A conference

call was held between the registrant and EPA toxicologist (Elizabeth Mendez, Elissa Reaves, Marquea, Linda Taylor) on March 19, 2015 to discuss these revised protocols. The following summarizes points discussed.

- No acute treatment (single exposure study) is needed
- Repeat dosing range is adequate
- Include positive control (PTU)
- ADME/time course inclusion – provide discussion for 2 hours vs. 24 hours
- Standard curves for thyroid hormone measures need to be submitted with final study
- Integrate gestational protocol with post-natal for one study (all 4 protocols should be in 1)

IV. RESULTS/DISCUSSION: The registrant subsequently re-submitted a revised comparative thyroid toxicity study protocols (HLS Study # HLS1095; HLS Study BDG0204; HLS Study BDG0202) *via* email on April 1, 2015, which incorporate the recommended modifications and adequately address the concerns and issues discussed. The registrant will be performing a positive control study (PTU) first, in order to gain expertise in blood sampling from young animals. The Phase I range-finding study will be used to optimize doses and sampling times, and determine whether direct dosing of pups will be necessary. They revised their methods of kill and anaesthesia, as per discussion/concerns raised in the 3/19/15 meeting. Additionally, they intend to provide the results of the PTU and range-finding studies prior to performing the definitive studies.

V. CONCLUSION: The April 1, 2015 thyroid protocols are adequate.