



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

OPP OFFICIAL RECORD  
HEALTH EFFECTS DIVISION  
SCIENTIFIC DATA REVIEWS  
EPA SERIES 361

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

August 16, 1993

**Naptalam** Reregistration. Uniroyal's 3/12/92, 3/19/92 & 4/13/93 responses [62-1, 62-3, 171-4(a & e), & LV/MU waiver request data] to Agency 12/28/92 & 3/12/93 Letters and CBRSS 7733 & 8322. MRIDs 422501-00 & -01. CBRs 12159. Barcode D192766. Rereg case 0183.

from: K. Dockter, Chemist *KD*  
Special Review Section I  
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to: L. Propst / S. Cerrelli, PM Team 73  
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Uniroyal Chemical Company, Inc. has submitted.

1. Descriptions of the methods used to determine the active ingredient and impurities, including validation data as an Appendix in a study dated 03/19/92 for their technical [40% naptalam; sodium 2-[(1-naphthalenylamino)carbonyl benzoate]
2. A request dated 4/13/93 for low volume/minor use waivers.

The Branch is instructed to review this material together with a BEAD memo dated 5/24/93, which recommends for the waiver, and:

1. Indicate overall status of product and residue chemistry requirements.
2. Indicate if the proposed approach for fulfilling the cucumber metabolism requirement is acceptable.
3. Determine adequacy of MRID 42250101.



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4. Indicate whether low-volume minor use status effects CBRS data requirements: 171-4a, 61-3, 62-1, 62-2, and 171-4e.

### Conclusions

1. Low volume minor use status does not effect GLNs 61-3, 62-1, 62-2, and 171-4(a & e).

2a. The acceptability of the proposed cucumber metabolism approach cannot be determined prior to receipt and evaluation of the promised detailed study protocol.

2b. Multiple radiolabeling is still required because the naptalam parent compound is a complex molecule containing multiple ring structures separated by a reactive, labile functional group.

3. MRID 42250101 is not adequate. The analytical method description and validation data for the a.i. and two impurities are adequate. However, the analytical method descriptions and validation data provided for seven other impurities are insufficient and do not fully support the previously reviewed preliminary analysis of technical naptalam sodium. See the Confidential Appendix for specific deficiencies.

### Recommendations

We recommend that the registrant be informed of the above conclusions.

### **Detailed Considerations**

#### 62-1. Preliminary analysis

The current data [MRID 422501-01] are a resubmission of the data provided in MRID 421941-03. These data were judged inadequate because the method descriptions and validation data were not provided at that time. The current study dated 03/19/92 contains in an Appendix the information which supports this topic. It is discussed below under GLN 62-3.

#### 62-3. Enforcement analytical method

An HPLC method, Uniroyal Chemical AC 1080B was submitted for the determination of the active ingredient and two of the impurities. This method is discussed in the Confidential Appendix.

The analytical method submitted for determination of naptalam sodium and two impurities satisfies the requirements of 40 CFR §158.180 [Guideline Reference No. 62-3] regarding enforcement analytical methods. The methods submitted for the determination

of seven other impurities of the TGAI in the 40% product do not fully satisfy the requirements of 40 CFR §158.180 [Guideline Reference No. 62-3] regarding enforcement analytical methods because: 1] method sensitivities were insufficient, 2] one method description was vague and sans validation data, and 3] methods were not submitted for all impurities of toxicological significance. Additional data are required. See the Confidential Appendix for specific deficiencies concerning methods for impurities.

Confidential Appendix (2 pages)

cc [w/ Confidential Appendix]: KDockter, SF, <sup>REG. SLD.</sup> ~~List 2~~ File \*  
cc [w/o Confidential Appendix]: circ, RF  
RD/I RBPerferti 8/13/93; EZager 8/16/93  
H7509C:CBRS:CM#2:RM804B:3057886:396C.P:KD/kd:8/16/93

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Pages   4   through   5   are not included in this copy.

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The material not included contains the following type of information:

  X   Identity of product inert ingredients.

     Identity of product impurities.

  X   Description of the product manufacturing process.

     Description of quality control procedures.

     Identity of the source of product ingredients.

     Sales or other commercial/financial information.

     A draft product label.

     The product confidential statement of formula.

     Information about a pending registration action.

     FIFRA registration data.

     The document is a duplicate of page(s) \_\_\_\_\_.

     The document is not responsive to the request.

     Internal deliberative information.

     Attorney-Client work product.

     Claimed Confidential by submitter upon submission to the Agency.

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

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R115924

**Chemical:** Benzoic acid, 2-((1-naphthalenylamino)carbonyl)-

**PC Code:**  
030702

**HED File Code:** 11100 Other Chemistry Documents

**Memo Date:** 8/16/1993

**File ID:** DPD192766

**Accession #:** 412-06-0011

**HED Records Reference Center**  
9/14/2007