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

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HEALTH EFFECTS DIVISION  
SCIENTIFIC DATA REVIEWS  
EPA SERIES 361

AUG 4 1994

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Naptalam. Storage Stability in/on Cucumber and  
Cantaloupe. Case No. 0183. Chemical I.D. No. 030703.  
MRID No. 42866901. CBRS No. 12345. DPBarcode D194016.

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Attached are reviews of storage stability data in or on cucumbers and cantaloupe submitted in support of reregistration of naptalam. These data were reviewed by Dynamac Corporation under supervision of CBRS and have been revised to reflect Branch policies.

The data submitted are adequate and show that residues of naptalam are stable in cantaloupe and cucumber for up to 6 months and one year, respectively. Since the nature of the residue in plants is not adequately understood, if the requested data on plant metabolism indicate the presence of additional metabolites of concern, then data depicting the stability of those residues during storage will be required.

If additional input is needed, please advise.

cc: Reviewer(F. Fort), Reg. Std. File, RF, SF, Circ., Dynamac  
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Final Report

**NAPTALAM**  
**Shaughnessy No. 030703;**  
**Case No. 0138**  
**(CBRS No. 12345; DP Barcode**  
**D194016)**

**TASK 4**  
**Registrant's Response to Residue**  
**Chemistry Data Requirements**

January 12, 1994

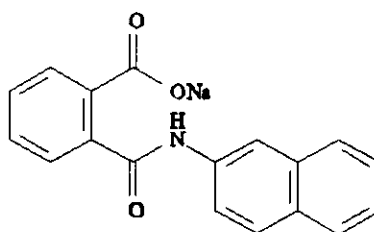
**Contract No. 68-D2-0053**

**Submitted to:**  
U.S. Environmental Protection Agency  
Arlington, VA 22202

**Submitted by:**  
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## NAPTALAM



Shaughnessy No. 030703; Case 0183

(CBRS No. 12345; DP Barcode D194016)

### Task 4

## REGISTRANT'S RESPONSE TO RESIDUE CHEMISTRY DATA REQUIREMENTS

### BACKGROUND

The Naptalam Reregistration Standard Update Addendum No. 1, dated 4/12/91, concluded that the previously submitted storage stability study (1990; MRID 41664002), which depicts the frozen storage stability of residues of naptalam in/on cucumbers and cantaloupe, was unacceptable to satisfy reregistration requirements for storage stability [Guideline 171-4 (e)] for the following reasons: (i) details regarding the test compounds used for fortification (purity, concentration) were not supplied; (ii) specific details of storage conditions (containers, temperatures, lighting, humidity) were not indicated; and (iii) no data were supplied for peanuts and soybeans.

In response to the above deficiencies, Uniroyal Chemical Company has submitted supplemental data (1993; MRID 42866901) to upgrade the cantaloupe and cucumber storage stability study. CBRS is aware that the registrant does not intend to support naptalam uses on peanuts and soybeans (letter dated 2/26/93 from L. Rossi of SRRD to J. Ball of Uniroyal). The supplemental data are evaluated in this document for upgrading the previously submitted storage stability data. The Conclusions and Recommendations stated in this document pertain only to the storage stability of naptalam residues in/on cantaloupe and cucumbers. Other data requirements stated in the Naptalam Reregistration Standard Update are not addressed herein.

The qualitative nature of the residue in plants is not adequately understood; additional data are

needed to upgrade a metabolism study on cucumbers. The requirements for peanut and soybean metabolism studies are no longer in effect since the registrant has deleted peanut and soybean uses from its naptalam end-use product labels.

Tolerances for residues of naptalam in/on plant commodities are currently expressed in terms of *N*-1-naphthyl phthamic acid from application of its sodium salt [40 CFR §180.297]. Adequate methodology is available for enforcement of tolerances. The Pesticide Analytical Manual (PAM), Vol. II lists two colorimetric methods, Methods A and B, as available for the enforcement of tolerances for determination of residues of naptalam in/on plant commodities. As there are no Codex MRLs for residues of naptalam, there are no questions with respect to Codex/U.S. tolerance compatibility.

### CONCLUSIONS AND RECOMMENDATIONS

1. The registrant has adequately addressed the cantaloupe and cucumber storage stability data deficiencies. The following information relating to good laboratory practices during the conduct of the study was provided: (i) the test compound used for fortification (purity and concentration) of the cantaloupe and cucumber storage stability samples; and (ii) the storage conditions (containers, temperature, lighting, and humidity) used in the study.
2. Residues of naptalam are relatively stable in fortified samples of cantaloupe stored frozen for up to 6 months; a significant decline in stability (38-69% of initial fortifications) occurs after ~ 8 months in storage. The magnitude of the residue studies in cantaloupe and watermelon are now validated by acceptable storage stability data. Field samples of cantaloupe and watermelon were stored frozen for 4-11 months. The majority of samples were analyzed within 6 months. Furthermore, most samples (including those analyzed within 6 months) bore nondetectable residues (0.05 ppm).
3. Residues of naptalam are relatively stable in fortified samples of cucumbers stored frozen for up to one year. The magnitude of the residue studies in cucumbers are now validated by acceptable storage stability data.
4. The registrant does not intend to support naptalam uses on peanuts and soybeans; therefore, storage stability data are no longer needed for these commodities.
5. The nature of the residue in plants is not adequately understood. If the requested data on plant metabolism indicate the presence of additional metabolites of concern, then data depicting the stability of those residues during storage will be required.

## DETAILED CONSIDERATIONS

### Storage Stability

The Naptalam Reregistration Standard Update Addendum No. 1, dated 4/12/91, concluded that the submitted storage stability data (1990; MRID 41664002) for naptalam in/on cucumbers and cantaloupe were not adequate for the following reasons: (1) details regarding the test compound used for fortification (purity, concentration) were not supplied; (2) specific details of storage conditions (containers, temperatures, lighting, humidity) were not indicated; and (iii) no data were supplied for soybeans and peanuts.

In response, Uniroyal Chemical Company (1993; 42866901) has submitted supplemental data addressing these deficiencies. The registrant's response to each deficiency and the CBRS conclusions are presented below.

Registrant's Response to Deficiency No. 1: The naptalam test substances used in the storage stability study had purities of 89.4-95.2%. These test substances were analytical standards used for fortification, analytical method evaluation, and instrument calibration during the period from 1976 to 1986, when Uniroyal was conducting residue studies with naptalam. Although no information is available indicating the precise test substance used in the fortification of the cantaloupe and cucumber storage stability studies, the test substance identity has been determined from a comparison of the dates of sub-sampling of the test substances with the dates of sample processing from the submitted raw data sheets for the storage stability studies.

We conclude that Deficiency No. 1 is resolved. The identity of the test compound used for fortification (purity, concentration) has been adequately addressed.

Registrant's Response to Deficiency No. 2: The registrant provided specific details of storage conditions (containers, temperature, lighting, and humidity) used in the storage stability study. Treated samples of cantaloupe, cucumbers, and watermelon were stored frozen at -17 to -12°C in plastic bags or plastic-lined cloth bags sealed in cardboard boxes.

We conclude that Deficiency No. 2 is resolved.

Registrant's Response to Deficiency No. 3: The registrant does not intend to support naptalam uses on peanuts and soybeans; therefore storage stability data are no longer needed for these commodities.

We conclude that Deficiency No. 3 is resolved.

In summary, the registrant has adequately addressed the cantaloupe and cucumber storage stability data deficiencies.

Residues of naptalam are relatively stable in fortified samples of cantaloupe stored frozen for

up to 6 months; a significant decline in stability (38-69% of initial fortifications) occurs after ~ 8 months in storage. The magnitude of the residue studies in cantaloupe and watermelon are now validated by acceptable storage stability data. Field samples of cantaloupe and watermelon were stored frozen for 4-11 months. The majority of samples were analyzed within 6 months. Furthermore, most samples (including those analyzed within 6 months) bore non-detectable residues (0.05 ppm).

Residues of naptalam are relatively stable in fortified samples of cucumbers stored frozen for up to one year. The magnitude of the residue studies in cucumbers are now validated by acceptable storage stability data.

#### AGENCY MEMORANDA CITED IN THIS DOCUMENT

CBRS Nos.: 7333 and 7743

Subject: Addendum #1 to the Naptalam Residue Chemistry Reregistration Standard and Product and Residue Chemistry Reviews of Additional Responses (MRID #'s 416664001, 00153372, 41664002, 00157184, and 41790500. Barcodes: D158499 and D162082).

From: E. Zager

To: L. Rossi and R. Engler

Date: 4/17/91

MRID(s): 41664001, 00153372, 41664002, 00157184, and 41790500.

#### MASTER RECORD IDENTIFICATION NUMBERS

The citation for the MRID document used in this review is presented below.

42866901 Smudin, D.J. (1993) Storage Stability of Naptalam in Curcubits. Uniroyal Response to EPA Comments on Study MRID No. 41664002. Unpublished study submitted by Uniroyal Chemical Company, Bethany, CT. 83 p.



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**9/14/2007**