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

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OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Response to Data Gaps in the Product Chemistry Chapter of the Benomyl Registration Standard

FROM: Gobind P. Makhijani, Chemist RB Perfetti for
Residue Chemistry Branch
Hazard Evaluation Division (TS-769C)

TO: Henry Jacoby
Product Manager, Team #21
Fungicide-Herbicide Branch
Registration Division (TS-767C)

and

Amy Rispin, Chief
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Hazard Evaluation Division (TS-769C)

THRU: Charles L. Trichilo, Chief
Residue Chemistry Branch
Hazard Evaluation Division (TS-769C)

In response to the Agency's 3(c)(2)(B) letter of May 14, 1985, E. I. du Pont de Nemours and Company, Wilmington, Delaware has submitted additional product chemistry data for technical benomyl (EPA Accession No. 259470, September 4, 1985).

61-2 - Description of Beginning Materials and Manufacturing Process (61-2)

The manufacturing process for benomyl is discussed in Confidential Appendix A of this report. Names and addresses of the suppliers of certain beginning materials were not submitted. This is required and therefore this data gap still exists.

61-3 - Discussion of Formation of Impurities

The registrant has submitted a comprehensive discussion (Exihibit 5) on:

a. Impurities that are actually found in the technical material,

b. A discussion of the impurities that could theoretically be formed but which are not found in the final product.

In addition to the above submission, the registrant has provided (under Exhibit 9), a discussion entitled "Nitrosamine levels in MBC/Benomyl Samples," dated May 2, 1985. All the samples were found to be free of nitrosamines at the 0.1 ppm level.

No other information is required on this topic.

Analysis and Certification of Product Ingredients

62-1 - Preliminary Analysis

The registrant has provided preliminary analysis of 6 batches of technical grade benomyl, 1984 Belle Plant Production, along with the methods of analysis (see discussion under 62-3).

The results of the preliminary analysis of these six batches are discussed in Confidential Appendix B.

The data submitted by the registrant meets our requirements and no further information is required for this topic.

62-2 - Certification of Ingredient Limits

The registrant has submitted a statement of composition giving the lower and the typical average (and not the upper) limit for active ingredients, along with the upper limit for the impurities in

technical benomyl. This does not qualify as a certification of limits statement.

This is a data gap.

62-3 - Analytical Methods to Verify Certified Limits

The registrant has submitted methods for the determination of active ingredients and impurities. These procedures are discussed in Confidential Appendix C, attached to this report. The methods appear to be satisfactory.

No further information is required from the registrant for this topic.

63-2 to 13 - Physical and Chemical Characteristics

The physical and chemical characteristics of benomyl have been updated by the registrant and are as follows:

63-2 Color: Tan

63-3 Physical State: Solid

63-4 Odor: Negligible

63-5 Melting Point: Decomposes without melting

63-7 Bulk Density: 28 lbs/cu ft

63-8 Solubility (g/100 g solvent at 25 °C)

Solvent	Solubility
Chloroform	9.4
Dimethylformamid	5.3
Acetone	1.8
Xylene	1.0
Ethanol	0.4
Heptane	0.04
Water	approx. 2ppm

63-9 Vapor Pressure: Negligible

63-10 Dissociation Constant: N/A

63-11 Octanol/Water Partition Coefficient: 23

63-12 pH: N/A

63-13 Stability: Stable under normal, dry storage conditions. Decomposes in the presence of moisture.

The vapor pressure should be given as other than negligible, if it is less than 1×10^{-7} mm Hg it should be given as that. Also, the pH of a water solution of benomyl is needed. These are data gaps.

Revised Tables A and B are attached to this report.

Attachment I: Tables A and B (2 pages)
copies to: Benomyl Registration Standard, S.F., Reviewer, PMSD/ISB, Jacoby, PM#21, R.F., Circu
Attachment II: Confidential Appendices A, B, and C (6 pages)
copies to: Benomyl Registration Standard, Reviewer, PMSD/ISB, S.F., Toxicology (M. Copley), Jacoby, PM#21,

cc: Benomyl Registration Standard, R.F., Reviewer, PMSD/ISB, S.F., Circu, Jacoby PM#21, Toxicology (M. Copley)
RDI:R.B.Perfetti: 11/04/85:RDSCHMITT:11/14/85.
TS-769:RCB:Reviewer:G.P.Makhijani:557-7484:RM:800:CM#2
KENDRICK CONTRACT TYPING

Table A. Generic Data Requirements for Technical Benomyl

Guideline Citation and Name of Test		Test Substance	Guideline Status	Are Additional Data Required? [yes]	[no]	Reference Citation
Product Identity and Composition:						
61-1	Identity of Ingredients	TGAI	R		x	See Product Chemistry Chapter
61-2	Materials and Process	TGAI	R	x		
61-3	Formation of Impurities	TGAI	R		x	EPA Accession No. 259470
Analysis and Certification of Product Ingredients:						
62-1	Preliminary Analysis	TGAI	R		x	EPA Accession No. 259470
62-2	Certification of Ingredient Limits	TGAI	R	x		
					x[a]	EPA Accession No. 259470
62-3	Analytical Methods to Verify Certified Limits	TGAI	R			
Physical and Chemical Characteristics:						
63-2	Color	TGAI	R		x	See Product Chemistry Chapter
63-3	Physical State	TGAI	R		x	See Product Chemistry Chapter
63-4	Odor	TGAI	R		x	See Product Chemistry Chapter
63-5	Melting Point	TGAI	R		x	See Product Chemistry Chapter
63-6	Boiling Point	TGAI	N/A			
63-7	Bulk Density	TGAI	R		x	EPA Accession No. 259470
63-8	Solubility	TGAI	R		x	
63-9	Vapor Pressure	TGAI	R	x		
63-10	Dissociation Constant	TGAI	R		x	EPA Accession No. 259470
63-11	Octanol/Water Partition Coefficient	TGAI	R		x	EPA Accession No. 259470
63-12	pH	TGAI	R	x		
63-13	Stability	TGAA	R		x	EPA Accession No. 259470
64-1	Submittal of Samples	TGAI or PAI	R		x	

TGAI = Technical grade active ingredient; PAI = Purified active ingredient; R = Required; NA = Not Applicable.

[a] Information as to what detector was utilized in the gas chromatographic procedure for determination of 1,3-dibutylurea in technical benomyl is required.

Table B. Product Specific Data Requirements for Manufacturing-Use Products Containing Benomyl[a]

Guideline Citation and Name of Test		Test Substance	Guideline Status	Are Additional Data Required? [yes]	[no]	Reference Citation
Product Identity and Composition:						
61-1	Product Identity and Disclosure of Ingredients	MP	R		x	See Product Chemistry Chapter
61-2	Description of Beginning Materials and Manufacturing Process	MP	R	x		
61-3	Discussion of Formation of Impurities	MP	R		x	EPA Accession No. 259470
Analysis and Certification of Product Ingredients:						
62-1	Preliminary Analysis of Product Samples	MP	R		x	EPA Accession No. 259470
62-2	Certification of Ingredient Limits	MP	R	x		
62-3	Analytical Methods to Verify Certified Limits	MP	R		x[b]	EPA Accession No. 259470
63-12	pH	MP	R	x		
Other Requirements						
64-1	Submittal of Samples	MP	R		x	

MP = Manufacturing-use product; R = Required; NA = Not applicable.

[a] The technical also serves as a Manufacturing-Use Product.
[b] Information as to what detector was utilized [redacted] in technical benomyl is required.

QUALITY CONTROL INFORMATION IS NOT INCLUDED

6 689

BENOMYL SCIENCE REVIEWS

Pages 7 through 12 are not included. The pages contain manufacturing processes and quality control procedures.