US ERA ARCHIVE DOCUMENT



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

MEMORANDUM

SUBJECT:

Meniquat Chloride. List B. Case No. 2375, Chemical No. 109101. Product

Glowell!

and Residue Chemistry Chapters for the Reregistration Eligibility Decision

Document (RED). CBRS No.16830. DP Barcode D222340.

FROM:

Chemistry Pilot Review Team JA Jost

Chemistry Branch II: Reregistration Support

Health Effects Division (7509C)

THRU:

Edward Zager, Branch Chief

Chemistry Branch II: Reregistration Support

Health Effects Division (7509C)

TO:

Mary Clock/Paula Deschamp

Risk Characterization and Analysis Branch

Health Effects Division (7509C)

Attached are the Product and Residue Chemistry Chapters for the Mepiquat Chloride RED. This information was compiled by Dynamac Corporation under supervision of CBRS, HED. These chapters have undergone secondary review in CBRS and have been revised to reflect Branch policies.

All product chemistry data (received by CBRS through 8/9/95) submitted in support of the reregistration of mepiquat chloride have been evaluated and have been found to be satisfactory. CBRS has no objections to the reregistration of mepiquat chloride with respect to product chemistry.

All residue chemistry data (received by CBRS through 5/1/96) submissions in support of the reregistration of mepiquat chloride have been reviewed. Field residue data must be submitted for cotton gin byproducts and a tolerance must be proposed for this commodity when adequate field residue data have been submitted. Additionally, tolerance revisions have been required. Tolerances for residues of mepiquat in/on cotton forage, cottonseed meal, eggs, milk, poultry fat, meat and meat byproducts, grape pomace, raisin, and raisin waste'

must be revoked. CBRS believes the existing data constitutes a substantially complete database sufficient to assess dietary exposure and has no objections to the reregistration of mepiquat chloirde with respect to residue chemistry.

cc: Reviewer(F. Fort), Reg. Std. File, RF, SF, Circ. RDI:Pilot Team:5/2/96:RPerfetti:5/6/96:EZager:5/6/96 7509C:CBRS:CM#2:Rm804S:305-7478:FAFort/FF:5/2/96 Disk8:mepiquat.red

MEPIQUAT CHLORIDE Shaughnessy No. 109101; Case 2375

Reregistration Eligibility Decision Product Chemistry Considerations

December 7, 1995

Contract No. 68-D4-0010

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

Submitted by:
Dynamac Corporation
The Dynamac Building
2275 Research Boulevard
Rockville, MD 20850-3268

MEPIQUAT CHLORIDE

REREGISTRATION ELIGIBILITY DECISION:

PRODUCT CHEMISTRY CONSIDERATIONS

Shaughnessy No. 109101; Case No. 2375

DESCRIPTION OF CHEMICAL

Mepiquat chloride [N,N-dimethylpiperidinium chloride] is a plant growth regulator registered for use on cotton.

Empirical Formula: C₇H₁₆ClN

Molecular Weight: 149.66

CAS Registry No.: 24307-26-4

Shaughnessy No.: 109101

IDENTIFICATION OF ACTIVE INGREDIENT

Mepiquat chloride is an off-white powdery solid with a melting point of $\sim 220\text{-}300$ C. Mepiquat chloride is soluble in water at > 50 g/100 mL. Mepiquat chloride is soluble in ethanol, moderately soluble in acetone and chloroform, and only sparingly soluble in benzene, cyclohexane, ethyl acetate, and ether.

MANUFACTURING-USE PRODUCTS

A search of the Reference Files System (REFS) conducted 10/18/95 identified a single mepiquat chloride manufacturing-use product (MP) registered to Micro-Flo Company under Shaughnessy No. 109101; the 99% formulation intermediate (FI; EPA Reg. No. 51036-187). We note that although REFs identifies the Micro-Flo 99% product as an FI, data addressed in an Registration Division (RD) memorandum (6/9/92) indicate that this product is correctly identified as a technical product. BASF Corporation has submitted data concerning its mepiquat chloride TGAI, which is used in the manufacture of end-use products by an integrated system. In addition, an Agency memorandum (CBRS No. 11966, D191871)

indicates that BASF initiated registration of a 58% FI (MC[©]-6; no File Symbol No.) in 1992. Because mepiquat chloride is a List B chemical, only the BASF TGAI and Micro-Flo 99% T are subject to a reregistration eligibility decision.

REGULATORY BACKGROUND

The Mepiquat Chloride Phase IV Review dated 1/15/91 by S. Funk, determined that BASF data submissions for GLNs 63-8 and 63-9 met the acceptance criteria for Phase V review; BASF committed to provide new studies for the remaining data requirements. The Micro-Flo 99% T was registered after the Phase IV Review was issued, and data were reviewed by the Registration Division (RD). In 1993 Micro-Flo submitted a request for "Me-Too" registration of the 99% T in conjunction with the BASF TGAI; however, the Agency was unable to recommend for "Me-Too" registration because the database for the BASF TGAI was incomplete (CBRS Nos. 11121 and 11137; D186268 and D186278).

The current status of the product chemistry data requirements for the BASF meniquat chloride TGAI and the Micro-Flo 99% T is presented in the attached data summary tables. Refer to these tables for a listing of the outstanding product chemistry data requirements.

CONCLUSIONS

Data requirements for the Micro-Flo 99% T and BASF TGAI are satisfied. CBRS has no objections to the reregistration of mepiquat chloride with respect to product chemistry data requirements.

AGENCY MEMORANDA CITED IN THIS DOCUMENT

CBRS No(s).:

None (RD Memorandum)

Subject:

Product Chemistry Review of Mepiquat Chloride 99% (EPA ID#

51036-RIT)

From:

A. Smith

To:

C. Lewis

Dated:

6/9/92

MRID(s):

42231901-42231904

CBRS No(s).:

8335

DP Barcode(s):

D166841

Subject:

Reregistration of Mepiquat Chloride. BASF Product Chemistry.

Considerations.

From:

K. Dockter

To:

R. Whiters

Dated:

8/6/92

MRID(s):

41889001-41889004 and 41910101

CBTS No(s).:

11121 and 11137

DP Barcode(s):

D186268 and D186278

Subject:

Mepiquat Chloride. Comments on "Me-Too" Registration of 99% A.I.

Manufacturing and End-Use Products.

From:

J. Stokes

To:

C. Giles-Parker/J. Stone

Dated:

6/4/93

MRID(s):

None

CBRS No(s).:

11966

DP Barcode(s):

D191871

Subject:

Mepiquat Chloride Reregistration. BASF's 3/5/93 Response [61-1, 62-

1, 62-2, & 63s data for 96% T & 58% MP] to Agency 11/12/92

Letter, & to Our 8/6/92 Review; CBRS 8335.

From:

K. Dockter

To:

R. Whiters

Dated:

7/27/93

MRID(s):

42690701 and 42690702

CBRS No(s).:

12131

DP Barcode(s):

D192713

Subject:

Mepiquat Chloride Reregistration. BASF's 8/25/90 Responses [Series

63 data] to CBRS 11966.

From:

K. Dockter

To:

R. Whiters

Dated:

8/11/93

MRID(s):

41626701 and 41626702

CBRS No(s).:

14099

DP Barcode(s):

D205898

Subject:

BASF 4/26/94 Response [61-1, Series 62 data, & a CSF for the 58%

MP] to an Agency 2/28/94 Letter, & to a K. Dockter 7/27/93 Review.

From

K. Dockter

To:

R. Whiters

Dated:

8/9/95

MRID(s):

43209701

PRODUCT CHEMISTRY CITATIONS

Bibliographic citations include only MRIDs containing data which fulfill data requirements.

References:

41626701 Panek, E. (1990) Determination of the Color, Physical State, Odor, Melting Point, Bulk Density, and PH of Mepiquat Chloride TGAI: Lab Project Number: F9018. Unpublished study prepared by BASF Corp. 11 p.

41626702 Fersch, J. (1990) Stability of Mepiquat Chloride When Exposed to Heat, Sunlight and Some Metals and Metal Ions: Lab Project Number: F9010. Unpublished study prepared by BASF Corp. 22 p.

41889001 Panek, E. (1991) Mepiquat Chloride: Product Identity and Composition: Lab Project Number: 91/5077. Unpublished study prepared by BASF. 87 p.

41889002 Panek, E. (1991) Mepiquat Chloride: 5-Batch Analysis and Method Validations: Lab Project Number: 91/5075. Unpublished study prepared by BASP. 87 p.

41889003 Panek, E. (1991) Mepiquat Chloride: Certification of Limits: Lab Project Number: 91/5076. Unpublished study prepared by BASF. 11 p.

41889004 Woodson, E. (1991) Determination of the Solubility of Mepiquat Chloride in Selected Solvents: Lab Project Number: 91/5085. Unpublished study prepared by EPL Bio-Analytical Services, Inc. 41 p.

41910101 Schweitzer, M. (1991) Determination of the n-Octanol/Water Partition Coefficient of Mepiquat Chloride: Lab Project Number: 91/5084. Unpublished study prepared by Battelle. 40 p.

42231901 Lovell, J. (1992) Product Identity and Composition, Description of Manufacturing Process and Discussion of the Formation of Impurities in the Production of Mepiquat Chloride 99%: Lab Project Number: AI-92-01. Unpublished study prepared by Micro Flo Co. 41 p.

42231902 Lovell, J. (1992) Summary of Preliminary Analysis of Product Samples, Certification of Ingredients Limits, Analytical Methods, and Physical and Chemical Properties of Mepiquat Chloride 99%: Lab Project Number: AI-92-04. Unpublished study prepared by Micro Flo Co. 9 p.

42231903 Clark, A.; Tippin, S. (1991) Preliminary Analysis of Product Samples: Analysis of Mepiquat Chloride: Lab Project Number: 9941-02. Unpublished study prepared by Midwest Research Institute. 51 p.

42231904 Clark, A.; Tippin, S. (1992) Physical and Chemical Characteristics Testing for Mepiquat Chloride: Lab Project Number: 9941-02. Unpublished study prepared by MidWest Research Institute. 47 p.

42690701 Panek, E. (1992) Mepiquat Chloride: Certification of Limits: Lab Project Number: FR9250: 92/5208: D12: FR9250.RPT. Unpublished study prepared by BASF. 7 p.

42690702 Pawliczek, ?. (1987) Mepiquat Chloride Water Solubility: Method and Raw Data for MRID 41491001: Lab Project Number: 93/5020. Unpublished study prepared by BASF AG. 22 p.

Case No. 2375

Chemical No. 109101

Case Name: Mepiquat chloride Registrant: BASF Corporation

Product(s): TGAI

PRODUCT CHEMISTRY DATA SUMMARY

Guideline Number	Requirement	Are Data Requirements Fulfilled?	MRID Number ^b
61-1	Product Identity and Disclosure of Ingredients	Y	41889001
61/2	Starting Materials and Manufacturing Process		41889001
61-3	Discussion of Formation of Impurities	Y	41889001
62-1	Preliminary Analysis		
62-2	Certification of Ingredient Limits	Y	41889003 , <u>42690701</u>
62-3	Analytical Methods to Verify the Certified Limits		41889002
63-2	Color	Y	41626701
63-3	Physical State		41626701
63-4	Odor	Y	41626701
63-5	Melting Point		41626701
63-6	Boiling Point	N/A°	A tomorrow or an array of the second
63-7	Density, Bulk Density or Specific Gravity		41626701
63-8	Solubility	Y	4188900442690702
63-9	Vapor Pressure		41626701
63-10	Dissociation Constant	' N/A -	
63-11	Octanol/Water Partition Coefficient		41910101
63-12	pH	Y	41626701
63-13	Stability		41626702

^a Y = Yes; N = No; N/A = Not Applicable.

^b Bolded citations were reviewed under CBRS No. 8335, D166841, 8/6/92, K. Dockter; underlined citations were reviewed under CBRS No. 11966, D191871, 7/27/93, K. Dockter; italicized citations were reviewed under CBRS No. 14099, D205898, 8/9/95, K. Dockter; and all other citations were reviewed under CBRS No. 12131, D192713, 8/11/93, K. Dockter.

[°] Data are not required because the TGAI is a solid at room temperature.

d Data are not required because the TGAI is a salt and will dissociate immediately in water.

Case No. 2375

Chemical No. 109101

Case Name: Mepiquat chloride Registrant: Micro-Flo Company

Product(s): 99% T (EPA Reg. No. 51036-187)

PRODUCT CHEMISTRY DATA SUMMARY

Guideline	Are Data Requirements				
Number	Requirement	Fulfilled?	MRID Number ^b		
61-1	Product Identity and Disclosure of Ingredients	Y	42231901		
61-2	Starting Materials and Manufacturing Process		42231901		
61-3	Discussion of Formation of Impurities	Y	42231901		
62-1	Preliminary Analysis		42231902, 42231903		
62-2	Certification of Ingredient Limits	Y	42231902		
62-3	Analytical Methods to Verify the Certified Limits	ar was in X ower 1969	42231902		
63-2	Color		42231902, 42231904		
63-3	Physical State		42231902, 42231904		
63-4	Odor	Y	42231902, 42231904		
63-5	Melling Point	o journat y projekty.	42231902, 42231904		
63-6	Boiling Point	N/A °	* * * * * * * * * * * * * * * * * * * *		
63-7	Density, Bulk Density or Specific Gravity		42231902, 42231904		
63-8	Solubility	Y	42231902, 42231904		
63-9	Vapor Pressure	ing the later was a second of the later	42231902 42231904		
63-10	Dissociation Constant	N/A	Markaman in in in and and		
63-14			42231902, 42231904		
63-12	pH	Y	42231902, 42231904		
63-13	Stability		42231902, 42231904		

^a Y = Yes; N = No; N/A = Not Applicable.

^b All citations were reviewed by the Registration Division (6/9/92, A. Smith).

^c Data are not required because the TGAI is a solid at room temperature.

^d Data are not required because the TGAI is a salt and will dissociate immediately in water.

MEPIQUAT CHLORIDE Shaughnessy No. 109101; Case 2375

Reregistration Eligibility Decision Residue Chemistry Considerations

December 7, 1995

Contract No. 68-D4-0010

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

Submitted by:
Dynamac Corporation
The Dynamac Building
2275 Research Boulevard
Rockville, MD 20850-3268

MEPIQUAT CHLORIDE

REREGISTRATION ELIGIBILITY DECISION

RESIDUE CHEMISTRY CONSIDERATIONS

Shaughnessy No. 109101; Case 2375

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MEPIQUAT CHLORIDE

REREGISTRATION ELIGIBILITY DECISION

RESIDUE CHEMISTRY CONSIDERATIONS

Shaughnessy No. 109101; Case 2375

INTRODUCTION

Mepiquat chloride [N,N-dimethylpiperidinium chloride] is a List B chemical registered solely for use on cotton as a plant growth regulator. As a plant regulator, mepiquat chloride modifies the growth of cotton plants in several ways but the overall objective of its use is to shorten the production season in order to reduce any risks associated with yield and quality loss due to delayed and prolonged harvest. Mepiquat chloride is sold in the United States by its basic producer, BASF Corporation, under the trade name Pix®. The products registered for use on cotton include soluble concentrate/liquid (SC/L) and dry flowable (DF) formulations. These formulations may be applied foliarly to cotton plants using ground or aerial equipment.

REGULATORY BACKGROUND

The Chemistry Branch completed the Mepiquat Chloride Phase 4 Review on 1/15/91. Data-Call-In (DCI) Notices were issued on 4/5/91 and 1/10/94 requiring the registrant(s) to submit several residue chemistry studies for mepiquat chloride in order to fulfill reregistration requirements. The basic producer has submitted all of the DCI-requested data and these data have undergone Phase 5 Review by the Branch.

The Agency has recently updated Table II of the Pesticide Assessment Guidelines (Subdivision O, Residue Chemistry, issued 9/95). Additional mepiquat chloride residue data are now required for cotton gin byproducts as a result of changes in Table II; this data requirement has been incorporated into this document. This new data requirement will be imposed at the issuance of the Mepiquat Chloride RED but should not impinge on the reregistration eligibility decisions for mepiquat chloride. The appropriate tolerance level for cotton gin byproducts and the need for any revisions to dietary exposure/risk assessments will be determined upon receipt of the required residue chemistry data.

Tolerances are currently established [40 CFR §180.384, 40 CFR §185.2275 (a), (b), and (c), and 40 CFR §186.2275 (a) and (b)] and expressed in terms of residue of mepiquat chloride per se. Tolerances have been established for cotton forage (3.0 ppm), cottonseed (2.0 ppm), eggs and milk (each at 0.05 ppm), and for the fat, meat, and meat byproducts of cattle, goats, hogs, horses, poultry, and sheep (each at 0.1 ppm). A food additive tolerance has been established for raisins (6.0 ppm). Feed additive tolerances have been established for cottonseed meal (3.0 ppm), wet and dry grape pomace (3.0 ppm), and raisin waste (26.0

ppm). Adequate methods are available for the enforcement of established tolerances, as currently defined.

The information contained in this document outlines the Residue Chemistry Science Assessments with respect to the reregistration of mepiquat chloride. A tabular summary of the residue chemistry science assessments for reregistration of mepiquat chloride is presented in Table A. The conclusions listed in Table A regarding the reregistration eligibility of mepiquat chloride food/feed uses are based on the use patterns registered by the basic producer, BASF Corporation. When end-use product DCIs are developed (e.g., at issuance of the RED), RD should require that all end-use product labels (e.g., MAI labels, SLNs, and products subject to the generic data exemption) be amended such that they are consistent with the basic producer labels.

SUMMARY OF SCIENCE FINDINGS

GLN 171-3: Directions for Use

A REFs search conducted 10/18/95 identified three mepiquat chloride end-use products (EPs) registered to the basic producer, BASF Corporation. In addition, five mepiquat chloride EPs are registered to Gowan Company, Gowan Pacific Group, L.C, and Micro-Flo Company. These EPs are listed below.

Mepiquat Chloride end-use products (EPs) with food/feed uses.

Registrant EPA Reg. No.	Acceptance Date	Formulation	Product Name
BASF Corporation			1
7969-52	2/28/94	0.35 lb/gal SC/L	Pix® Plant Regulator
7969-97	2/24/94	2.01 lb/gal SC/L	Pix Concentrate Plant Regulator
7969-107	6/21/94	35% DF	Pix® DF Plant Regulator
Gowan Company	.•	,	
10163-186	6/93	SC/L	Gowan Mepiquat Chloride 4.2 Liquid
Gowan Pacific Group, L.C.			•
66996-1	12/93	FIC	Gowan Pacific Mepiquat Chloride
Micro-Flo Company	•		
51036-188	10/93	EC	Mepiquat Chloride, 4.2% Liquid
51036-189	10/93	SC/L	Mepiquat Chloride Liquid Concentrate
51036-191	7/94	WP	Micro Flo Cotton Growth Regulator

Use patterns registered to BASF Corporation: BASF Corporation's 0.35 and 2.01 lb/gal SC/L (EPA Reg. Nos. 7969-52 and 7969-97, respectively) and 35% DF (EPA Reg. No. 7969-107) formulations are registered for multiple foliar spray applications to cotton plants. The

parameters of registered use patterns relevant for residue chemistry assessments are described below.

The maximum single application rate is 0.044 lb ai/A/application. Up to four low-rate applications, with 7- to 14-day retreatment intervals, may be made provided the maximum seasonal rate of 0.066 lb ai/A is not exceeded. Application(s) may be made using ground or aerial equipment in a minimum of 2 gal of water per acre (GPA) except when application is made in CA. In CA, the minimum spray volume for ground and aerial equipment is 5 GPA. Ultra low volume (ULV) aerial applications, using oil as diluent (minimum spray volume of 2 pints oil/A), are permitted for the SC/L formulations in AL, AR, FL, GA, LA, MO, MS, NC, OK, SC, TN, and TX. The established restricted entry interval is 12 hours. The established pregrazing/feeding and preharvest interval is 30 days. A grazing/feeding restriction is in effect following ULV aerial applications in oil and for the DF formulation. No plantback intervals have been established for rotational crops.

The Chemistry Branch has evaluated the available study pertaining to magnitude of the residue in cottonseed in conjunction with the maximum registered use patterns described above. Adequate field trial data are available to support the presently registered maximum use patterns. Adequate field trial data are also available to support the registrant's proposal to increase the maximum seasonal rate from 0.066 lb ai/A (1x) to 0.088 lb ai/A (1.3x) or 0.132 lb ai/A (2x). Except for the need to establish a plantback interval, the reregistration requirements for this guideline topic (GLN 171-3) are fulfilled. Based on an acceptable confined rotational crop study, the registrant must amend all of its mepiquat chloride end-use products to establish a plantback interval of 2.5 months.

GLN 171-4 (a): Plant Metabolism

The reregistration requirements for plant metabolism are fulfilled. An acceptable study, depicting the qualitative nature of the residue in cotton plants, has been submitted and evaluated. Based on this study, the Branch has determined that the residue of concern in/on plant commodities is mepiquat chloride *per se*. The current tolerance expression for plant commodities is appropriate.

GLN 171-4 (b): Animal Metabolism

The reregistration requirements for animal metabolism are fulfilled. Acceptable studies, depicting the qualitative nature of the residue in ruminant and poultry, have been submitted and evaluated. The residue of concern in animal commodities is mepiquat chloride per se. The current tolerance expression for animal commodities is appropriate.

GLN 171-4 (c) and (d): Residue Analytical Methods - Plants and Animals

The reregistration requirements for residue analytical methods are fulfilled. Acceptable methods are available for enforcement and data collection purposes for both plant and animal commodities.

Enforcement methods: The Pesticide Analytical Manual (PAM Volume II) lists Method I as available for the determination of residues of mepiquat chloride per se in/on plant and animal commodities, This GLC method, with nitrogen detection, has undergone successful Agency method tryout using plant (cottonseed, cotton forage, and cottonseed processed fractions) and animal (milk, eggs, and meat of chicken and beef) matrices. The stated limit of quantitation is 0.1 ppm for cotton and 0.05 ppm for animal products.

Multiresidue methods: The FDA PESTDATA database dated 1/94 (PAM Volume I, Appendix I) does not have an entry for mepiquat chloride. The existing FDA multiresidue methods are not likely to recover mepiquat chloride residues because of its ionic nature.

GLN 171-4 (e): Storage Stability

The reregistration requirements for storage stability data are adequately fulfilled. Adequate information is available concerning the maximum storage intervals as well as the conditions of plant and processed commodities used in support of tolerance establishment or in support of data requested for reregistration. Acceptable storage stability studies have been submitted for cotton and its processed commodities. These studies have demonstrated that residues of mepiquat chloride *per se* are stable under frozen storage conditions at least 25 months in/on cottonseed and for at least 28.5 months in cottonseed hulls, meal, crude oil, refined oil, and soapstock.

The available plant and animal metabolism studies are validated by adequate storage stability data. In conjunction with the ruminant metabolism study, it was demonstrated that residues of mepiquat chloride *per se* are stable under frozen storage conditions for at least 45 months in milk and liver. An additional study depicting the freezer storage stability of residues of mepiquat chloride *per se* found residues to be stable for at least 26 months in ruminant and poultry tissue and eggs.

GLN 171-4 (k): Magnitude of the Residue in Plants

The reregistration requirements for magnitude of the residue in/on cottonseed are fulfilled. Adequate cottonseed field trial data, reflecting use of the registered SC/L and DF formulations at the presently registered maximum use patterns, have been submitted. Adequate field trial data ere also available to support the registrant's proposal to increase the maximum seasonal rate on cotton plants from 0.066 lb ai/A to 0.132 lb ai/A. The Branch previously concluded that the established tolerance of 2 ppm for cottonseed is sufficient to cover additional residues

of mepiquat chloride per se that may result from an increase in the maximum seasonal rate to 0.132 lb ai/A.

According to Table II of the Pesticide Assessment Guidelines (Subdivision O, Residue Chemistry, issued 9/95), cotton forage is no longer considered a significant livestock feed item and has been deleted from the table. Therefore, the previously requested data for cotton forage are no longer required and the established tolerance for this item should be revoked. Table II now recognizes cotton gin byproducts as a raw agricultural commodity of cotton. Therefore, field residue data must be submitted for cotton gin byproducts and a tolerance must be proposed for this commodity when adequate field residue data have been submitted. Data are required on residues of mepiquat chloride in/on cotton gin byproducts harvested at normal maturity from plants treated at the maximum seasonal application rate. Cotton must be harvested by commercial equipment (stripper and mechanical picker) to provide an adequate representation of plant residue for the ginning process. A minimum of three field trials for each type of harvesting (stripper and mechanical picker) are required, for a total of six field trials (See Follow-up Guidance for the Number and Location of Domestic Crop Field Trials, EPA 738-K-94-001).

GLN 171-4 (I): Magnitude of the Residue in Processed Food/Feed

The reregistration requirements for magnitude of the residue in processed cottonseed commodities are fulfilled. An acceptable cottonseed processing study has been submitted. Any residue that may result in cottonseed meal as a result of processing will be covered by the RAC tolerance. Therefore, the established feed additive tolerance of 3.0 ppm for cottonseed meal should be revoked.

The temporary food and feed additive tolerances for grape processed commodities, originally established in accordance with an approved experimental use program, expired on 6/30/91. Since there are presently no registered uses of mepiquat chloride on grapes, these expired food and feed additive tolerances should be revoked.

GLN 171-4 (j): Magnitude of the Residue in Meat, Milk, Poultry, and Eggs

The reregistration requirements for magnitude of the residue in livestock are fulfilled. There are no registered direct animal treatments for mepiquat chloride on cattle, goats, hogs, horses, sheep or poultry. The residue of concern in animals is mepiquat per se, and acceptable animal feeding studies depicting mepiquat chloride have been submitted and evaluated.

The cattle feeding study indicated that the established tolerances of 0.1 ppm for mepiquat residues in fat, meat, and meat byproducts of cattle, goats, hogs, horses, and sheep are

adequate. With regard to milk, a 40 CFR 180.6(a)(3) [Category 3] situation exists. The milk tolerance should be revoked since data indicated that no residues are likely in this commodity.

The poultry feeding study indicated that no residues were found in poultry tissue samples at any dosage. A 40 CFR 180.6(a)(3) [Category 3] situation exists with respect to poultry and eggs. Poultry and egg tolerances established at 0.1 ppm for poultry fat, meat, and meat by-products and at 0.05 ppm for eggs should be revoked since data indicate that no residues are likely in these commodities.

GLN 171-4 (f, g, and h): Nature and Magnitude of the Residue in Potable Water, Fish and Irrigated Crops

Mepiquat chloride is presently not registered for direct use on potable water and aquatic food and feed crops; therefore, no residue chemistry data are required under these guideline topics.

GLN 171-4 (i): Magnitude of the Residue in Food-Handling Establishments

Mepiquat chloride is presently not registered for use in food-handling establishments; therefore, no residue chemistry data are required under this guideline topic.

GLNs 165-1 and 165-2: Confined/Field Rotational Crops

The reregistration requirements for confined and field rotational crop studies are fulfilled. An acceptable confined rotational crop study (GLN 165-1) has been submitted and evaluated. The Chemistry Branch has determined that tolerances on rotational crops are not needed and field rotational studies (GLN 165-2) are not required. Based on the total radioactive residues from the earliest crop interval, the registrant must establish a plantback interval of 2.5 months on all product labels. If the registrant wishes to establish a less-restrictive plantback interval, an additional confined rotational crop study reflecting a rotation interval of 30 days will be required.

Table A. Residue Chemistry Science Assessments for Reregistration of Mepiquat Chloride.

GLN: Data Requirements	Current Tolerances, ppm [40 CFR]	Must Additional Data Be Submitted?	References 1
171-3: Directions for Use	N/A = Not Applicable	. Yes ²	Mepiquat chloride EPs registered to BASF Corp. (EPA Reg. Nos. 7969-52, 7969-97, and 7969-107)
171-4 (a): Plant Metabolism	N/A	No	42330804 ³ , 43024701 ⁴
171-4 (b): Animal Metabolism	N/A	No	41585201, 41585202, 41585203, 41585204, 41585205, 41585206,
		•	42394301 ⁵ , 42394302 ⁵ , 42394303 ⁵ , 43290401 ⁶ , 43290402 ⁶ , 43290403 ⁶ ,
		٠	43290404 ⁶ , 43290405 ⁶ , 43440301 ⁶
171-4 (c/d): Residue Analytical Methods	}		
- Plant commodities	N/A	` No	92091023 ⁷ , 42426801 ⁸ , 42734601 ⁹ , 42734602 ⁹
- Animal commodities	N/A	No .	92091023 ⁷ , 42394303 ⁵ , 42394304 ⁵ , 42546201 ¹⁰ 42546202 ¹⁰
171-4 (e): Storage Stability	N/A	No	92091025 11, 42734601 9 42734602 9, 42892201 12, 43379501 13, 43738603
171-4 (k): Magnitude of the Residue in	Plants		
- Cottonseed and gin byproducts	3.0 (cotton forage); 2.0 (cottonseed) [§180.384]	Yes 15	92091024 ¹⁶ , 92091032 ¹⁷ 42426802 ⁸ , 42554111 ¹⁸ , 42734601 ⁹ , 42734602
171-4 (l): Magnitude of the Residues in	Processed Food/Feed		
- Cottonseed processed commodities	3.0 (cottonseed meal) [§186.2275]		92091024 ¹⁶ , 92091032 ¹ 42426803 ⁸

Table A (continued).

GLN: Data Requirements	Current Tolerances, ppm [40 CFR]	Must Additional Data Be Submitted?	References ¹
- Grape processed commodities	6.0 (raisins) [§185.2275] 3.0 (grapé pomace, wet and dry); 26.0 (raisin waste) [§186.2275]	No ²¹	
171-4 (j): Magnitude of the Residue in	Meat, Milk, Poultry, an	d Eggs	
- Milk and the Fat, Meat, and Meat Byproducts of Cattle, Goats, Hogs,	0.05 (milk); 0.1 (fat, meat, meat	No	43738601 14
Horses, and Sheep	byproducts) [§180,384]	* * * * * * * * * * * * * * * * * * *	
- Eggs and the Fat, Meat, and Meat Byproducts of Poultry	0.05 (eggs); 0.1 (fat, meat, meat byproducts) [§180.384]	No	43738602 14
171-4 (f): Nature and Magnitude of the Residue in Potable Water	N/A·	N/A	
171-4 (g): Nature and Magnitude of the Residue in Fish	N/A	N/A	·
171-4 (h): Nature and Magnitude of the Residue in Irrigated Crops	N/A	N/A	
171-4 (i): Magnitude of the Residue in Food-Handling Establishments	N/A	N/A	
165-1: Rotational Crops (Confined)		No	42733601 22,2
165-2: Rotational Crops (Field)	en v	No	

^{1.} Bolded references were evaluated in the Mepiquat Chloride Phase IV Review by S. Funk dated 1/15/91; all other references were reviewed as noted.

^{2.} The registrant(s) must amend all of its mepiquat chloride end-use products to establish a plantback interval of 2.5 months.

Table A (continued).

- 3. CBRS No. 10229, DP Barcode 180700, 3/5/93, R. Perfetti.
- 4. CBRS No. 13220, DP Barcode D199513, 6/28/95, F. Fort.
- CBRS Nos. 10685 and 11386, DP Barcodes D183217 and D188232, 9/30/93, S. Funk.
- CBRS Nos. 13220, 14230, 14703, and 14891, DP Barcodes D199513, D206656, D209020, and D210500, 6/28/95, F. Fort.
- MRIDs 92091022 and 92091023 are a summary and reformat, respectively, of MRID 00135138 and related MRIDs 00140864 and 40308313.
- 8. CBTS Nos. 10671, 10689, 10690, DP Barcodes D183140, D183187, and D183197, 10/12/93, J. Stokes.
- 9. CBRS No. 12046, DP Barcode D192305, 1/27/94, S. Knizner.
- 10. CBRS No. 11202, DP Barcode D186624, 8/16/93, S. Knizner.
- MRID 92091025 is a reformat of MRID 00135138 and related MRID 00140864; MRID 92091031 is a summary of 00135137.
- 12. CBRS No. 12702, DP Barcode D195902, 2/18/94, S. Knizner.
- 13. CBRS No. 14703, DP Barcode D209020, 6/28/95, F. Fort.
- 14. CBRS No. 16080, DP Barcode D218492, 1/25/96, F. Fort.
- 15. The reregistration requirements for magnitude of the residue in/on cottonseed are fulfilled. Cotton forage is no longer considered a significant livestock feed item and has been deleted from the livestock feeds table (Table II of Subdivision O's PAG, issued 9/95). Therefore, the previously requested data for cotton forage are no longer required and the established tolerance for this item should be revoked. However, the Agency currently recognizes cotton gin byproducts (commonly called gin trash which include the plant residues from ginning cotton consisting of burrs, leaves, stems, lint, immature seeds, and sand and/or dirt) as a RAC. Data are required on residues of mepiquat chloride in/on cotton gin byproducts harvested at normal maturity from plants treated at the maximum seasonal application rate. Cotton must be harvested by commercial equipment (stripper and mechanical picker) to provide an adequate representation of plant residue for the ginning process. A minimum of three field trials for each type of harvesting (stripper and mechanical picker) are required, for a total of six field trials. An appropriate tolerance for this RAC should be proposed once acceptable data have been submitted and evaluated.
- 16. MRID 92091024 is a reformat of MRID 00135137 and related MRIDs 00140864 and 00147113; MRID 92091026 is a summary of MRID 00135137 and related MRIDs 00135138, 00140864 and 00147113.
- 17. MRIDs 92091031 and 92091032 are a summary and reformat, respectively, of MRID 00135137.
- 18. CBTS No. 13002, DP Barcode D197745, 5/25/94, J. Stokes.

Table A (continued).

- 19. Based on the re-evaluation of an existing cottonseed processing study, a Section 409 tolerance or a Section 701 MRL is not needed for cottonseed meal. Therefore, the established feed additive tolerance of 3.0 ppm for cottonseed meal should be revoked.
- 20. CBRS No.17180, DP Barcode D225850, 5/7/96.
- 21. The temporary food and feed additive tolerances for grape processed commodities, originally established in support of an experimental use program, expired on 6/30/91. Since there are presently no registered uses of mepiquat chloride on grapes, these expired food and feed additive tolerances should be revoked.
- 22. CBRS No. 12307, DP Barcode D193581, 1/27/94, S. Knizner.

TOLERANCE REASSESSMENT SUMMARY

The tolerances listed in 40 CFR §180.384, 40 CFR §185.2275 (a), (b), and (c), and 40 CFR §186.2275(a) and (b) are expressed in terms of mepiquat chloride [N,N-dimethylpiperidinium].

Tolerances Listed Under 40 CFR §180.384:

Sufficient data are available to ascertain the adequacy of the established tolerance for cottonseed. Cotton forage is no longer considered a significant livestock feed item and has been deleted from Table II of the Pesticide Assessment Guidelines (Subdivision O, Residue Chemistry, issued 9/95). Therefore, the established tolerance for cotton forage should be revoked.

The data indicate that tolerances for ruminant tissue are sufficient. The established tolerances of 0.1 ppm for mepiquat residues in fat, meat, and meat byproducts of cattle, goats, hogs, horses, and sheep are adequate. With regard to milk, poultry and egg commodities, a 40 CFR 180.6(a)(3) [Category 3] situation exists. Milk, poultry and egg tolerances should be revoked since data indicate that no residues are likely in these commodities.

Tolerance That Needs To Be Proposed Under 40 CFR §180.384:

Table II (issued 9/95) now recognizes cotton gin byproducts as a raw agricultural commodity of cotton. Therefore, field residue data must be submitted for cotton gin byproducts and a tolerance must be proposed for this commodity when adequate field residue data have been submitted and evaluated.

Tolerance Listed Under 40 CFR §185,2275 (a), (b), and (c):

The temporary food additive tolerance for raisin at 6 ppm, originally established in accordance with an approved experimental use program, expired on 6/30/91. Since there are presently no registered uses of mepiquat chloride on grapes, this expired food additive tolerance should be revoked.

Tolerances Listed Under 40 CFR §186.2275 (a):

A Section 409 tolerance or a Section 701 MRL is not needed for cottonseed meal. Any residue that may result in cottonseed meal as a result of processing will be covered by the reassessed RAC tolerance. Therefore, the established feed additive tolerance of 3.0 ppm for cottonseed meal should be revoked.

Tolerances Listed Under 40 CFR §186,2275 (b):

The temporary feed additive tolerances for grape pomace (wet and dry) at 3.0 ppm and raisin waste at 26.0 ppm, originally established in accordance with an approved experimental use program, expired on 6/30/91. Since there are presently no registered uses of mepiquat chloride on grapes, these expired feed additive tolerances should be revoked.

A summary of mepiquat chloride tolerance reassessments is presented in Table B.

Table B. Tolerance Reassessment Summary for Mepiquat Chloride.

	Current Tolerance	Tolerance	Comment/	
Commodity	(ppm)	Reassessment (ppm)	[Correct Commodity Definition]	
t .		•		
····	Toleran	ces Listed Under 40 CF		
Cotton forage	3	Revoke	Not considered a significant livestock feed item (Table II, 9/95).	
Cottonseed	2	2	[Cotton, undelinted seed]	
Eggs	0,05	Revoke	40 CFR 180.6(a)(3) [Category 3] situation	
Cattle, fat	0.1	0.1		
Cattle, mbyp	0.1	0.1		
Cattle, meat	0.1	0.1		
Goats, fat	0.1	0.1		
Goats, mbyp	0.1	0.1		
Goats, meat	0.1	0.1		
Hogs, fat	0.1	0.1		
Hogs, mbyp	0.1	0.1		
Hogs, meat	0.1	. 0.1	•	
Horses, fat	0.1	0.1		
Horses, mbyp	0.1	0.1		
Horses, meat	0.1	0,1		
Milk	0.05	Revoke	40 CFR 180.6(a)(3) [Category 3] situation	
Poultry, fat	0.1	Revoke	40 CFR 180.6(a)(3) [Category 3] situation	
Poultry, mbyp	0.1	Revoke	40 CFR 180.6(a)(3) [Category 3] situation	
Poultry, meat	0.1	Revoke ,	40 CFR 180.6(a)(3) [Category 3] situation	
Sheep, fat	0.1	0.1		
Sheep, mbyp	0.1	0.1		
Sheep, meat	. 0.1	0.1		
	Tolerance That N	leeds To Be Proposed U	Inder 40 CFR §180.384	
Cotton gin byproducts	N/A¹	TBD²	A tolerance must be proposed for this commodity when adequate field residue data have been submitted and evaluated.	
•	Toleran	ce Listed Under 40 CF	R §185.2275:	
Raisins .	6.0	Revoke	No registered uses on grapes.	
	3	ı		
	Toleranc	e Listed Under 40 CFR		
Cottonseed meal	3.0	Revoke	Any residue that may result in cottonseed meal as a result of processing will be covered by the reassessed RAC tolerance.	
	Tolerance	s Listed Under 40 CFR	l 8186.2275(b):	
Grape pomace (wet and dry)	3.0	Revoke	No registered uses on grapes.	

Table B (continued).

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/ [Correct Commodity Definition]
Raisin waste	26.0	Revoke	No registered uses on grapes; no longer considered a significant livestock feed item (Table II, September, 1995).

CODEX HARMONIZATION

No maximum residue limits (MRLs) for mepiquat chloride have been established by Codex for any agricultural commodity. Therefore, no compatibility questions exist with respect to U.S. tolerances.

N/A = not applicable
TBD = to be determined.

AGENCY MEMORANDA RELEVANT TO THIS DOCUMENT

CBRS No.:

10229

DP Barcode:

D180700

Subject:

Response to the Mepiquat Chloride Phase IV Review: Cotton Metabolism.

From:

R. Perfetti

To:

R. Whiters and E. Saito

Dated:

3/5/93

MRID(s):

423308804

CBRS No.:

11202

DP Barcode:

D186624

Subject:

Meniquat Chloride. Guideline 171-4(d) Analytical Method for Milk.

Reregistration Case No. 2375. Chemical No. 109101.

From:

S. Knizner

To:

R. Whiters

Dated:

8/16/93

MRID(s):

42546201 and 42546202

CBRS Nos.:

10685 and 11386

DP Barcodes:

D183217 and D188232

Subject:

Reregistration of Mepiquat Chloride (List B, Case 2375, Chemical 109101).

BASF Corporation Nature of the Residue in Ruminants and Poultry

Submissions.

From:

S. Funk

To:

K. Davis/R. Whiters

Dated:

9/30/93

MRID(s):

42394301-42394304 and 41585201-41585204.

CBTS Nos.:

10671, 10689, and 10690

DP Barcodes:

D183140, D183187, and D183197

Subject:

Mepiquat Chloride on Cotton. Proposed Increases in the Maximum Seasonal

Rate.

From:

J. Stokes

To:

C. Giles-Parker/D. Wilson and R. Whiters

Dated:

10/12/93

MRID(s):

42426801-42426803.

CBTS Nos.:

12880 and 12904

DP Barcodes:

D197207 and D197191

Subject:

Mepiquat Chloride on Cotton. FAP#4H5684. Amendments dated November

17 and 19, 1993.

From:

J. Stokes

To:

C. Giles-Parker/D. Wilson and R. Whiters

Dated:

1/10/94

MRID(s):

None.

CBRS No.:

12307

DP Barcode:

D193581

Subject:

Mepiquat Chloride. Confined Rotational Crop Study. Reregistration Case

No. 2375. Chemical No. 109101.

From:

S. Knizner

To:

R. Whiters

Dated:

1/27/94

MRID(s):

42733601.

CBRS No.:

12046

DP Barcode:

D192305

Subject:

Mepiquat Chloride. Magnitude of the Residue in Cottonseed and Cottonseed

Processed Commodities. Reregistration Case No. 2375. Chemical No.

109101.

From:

S. Knizner

To:

R. Whiters

Dated:

1/27/94

MRID(s):

42734601 and 42734602.

CBRS No.:

12702

DP Barcode:

D195902

Subject:

Mepiquat Chloride. Interim Storage Stability Study for Cottonseed Processed

Commodities. Reregistration Case No. 2375. Chemical No. 007969.

From:

S. Knizner

To:

R. Whiters

Dated:

2/18/94

MRID(s):

42892201

CBTS No.:

13002

DP Barcode:

D197745

Subject:

ID# 007969-RNT. Mepiquat Chloride. New Product (PIX® DF, EPA Reg.

No. 7969-RNT) for Use on Cotton, Additional Field Residue Data.

From:

J. Stokes

To:

C. Giles-Parker/D. Wilson

Dated:

5/25/94

MRID(s):

42554111

CBRS Nos.:

13220, 14230, 14703, and 14891

DP Barcodes:

D199513, D206656, D209020, D210500

Subject:

Mepiquat Chloride. List B Case No. 2375. Chemical I.D. No. 109101.

Registrant's Response to Data Requirements.

From:

F. Fort

To:

R. Whiters/K. Davis

Dated:

6/28/95

MRID(s):

43290401-43290404, 43379501, 43024701, and 43440301

CBRS No.:

16080

DP Barcode:

D218492

Subject:

Magnitude of the Residue in Milk, Meat, Poultry and Eggs.

From:

F. Fort

To:

P. Dobak/K. Depukat

Dated:

1/25/96

MRID(s):

43738602 and 43738603

MASTER RECORD IDENTIFICATION NUMBERS

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