DATE OUT: SEP 26 1995

DP BARCODE: D219079 **SUBMISSION:** S493480 **REG/FILE SYMBOL No.:** 1812-GAG
CHEMICAL NAME: 080808 2-Chloro-4,6-bis(isopropylamino-s-triazine
COMMON NAME: Propazine **CAS Registry No.:** 139-40-2

REGISTRATION DIVISION/REGISTRATION SUPPORT BRANCH/PRODUCT CHEMISTRY REVIEW SECTION TRANSMITTAL/PRODUCT CHEMISTRY REVIEW OF A REGISTRATION ACTION FOR A TECHNICAL GRADE ACTIVE INGREDIENT, ACTION CODE 115 NEW CHEMICAL/NON-FOOD/FEED USES

DATA SUBMITTER: 001812 Griffin Corporation **RECEIVED DATE:** 08/29/95
MRID #: 435101-03 to 435101-09 & 435129-01
RD PM#/NAME: 25 Robert Taylor **Phone #:** 305-6800
RD CRM NAME: Terri Stowe **Phone #:** 305-6117

CONCLUSIONS:

1. The registrant will need to submit product chemistry data requirements of GRNs 63-4 & 63-13 pertaining to product's odor and stability.

2. The registrant will need to submit samples of propazine technical to EPA's Analytical Chemistry Laboratory in Beltsville, Maryland for validation along with a copy of the procedure as outlined in MRID #435101-05. A sample of propazine technical must also be submitted to the Pesticide and Industrial Chemical Repository, Research Triangle Park, North Carolina. (addresses below):

   U. S. EPA/OPPTS
   Analytical Chemistry Laboratory
   BARC East - Buidling 306, ERm. 113
   Beltsville, MD 20705

   U. S. EPA Research Center
   Pesticide and Industrial Chemical Repository
   Research Triangle Park, NC 27711

3. Adequate analytical methods were submitted for the analysis of the active ingredient, propazine, per se, and impurities. The method for the TGAI is to be found in MRID #435101-05, entitled: "Griffin Analytical Method TM-1103: Propazine In Technical Product by Megabore GLC, Data Requirements of Guidelines 62-3". The method was authored by Carol A Dowler of Griffin Corporation, dated 12/2/94, 23 pages.

4. With the exception of the data gaps cited in Conclusion 1 above, the remaining product chemistry data included with this submission is adequate.

5. The submitted label for technical Propazine, Reg. No. 1812-GAG, EPA received 8/29/95 is acceptable.

6. The submitted CSF for technical Propazine, Reg. No. 1812-GAG, EPA received 8/29/95, dated 12/2/94 is acceptable.

7. We defer to TOX/HED as to their concern with propazine impurities at their indicated upper limits as shown in product's CSF, Reg. No. 1812-GAG, dated 12/2/94.

RECOMMENDATIONS

After resolving Conclusion 1, 2 & 7 above, we can recommend for registration of technical Propazine Technical, Reg. No. 1812-GAG.

NOTES TO CRM: (1) A Status Report of Product Chemistry Data Requirements is Included on Page 3; (2) Information presented on pages 8 to 13 is confidential.

Sami Malak — 09/26/95
Reviewer: Sami Malak, Ph.D., Chemist — **Date**

Harold E. Podall — 09/26/95
Section Head: Harold Podall, Ph.D., Chemist — **Date**

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STATUS REPORT OF PRODUCT CHEMISTRY DATA REQUIREMENTS FOR REREGISTRATION OF A TECHNICAL GRADE ACTIVE INGREDIENT

REVIEWER: Sami Malak **DATE REVIEW WAS COMPLETED:** 09/26/95

GRN #	TITLES	Ac	NA	UP	Dg	MRID No.
Series 61-Product Identity and Composition (40CFR§158.155, 160, 162, 165 & 167)						
61-1	Product Identity & Disclosure of Ingredients	X				435129-01
61-2	Description of Starting Materials & Manufacturing Process	X				435129-01
61-3	Discussion of Formation of Impurities	X				435129-01
Series 62-Analysis and Certification of Product Ingredients (40CFR§158.170, 175 & 180)						
62-1	Preliminary Analysis of Product Samples	X				435101-04
62-2	Certification of Ingredient Limits	X				435101-04
62-3	Analytical Methods to Verify Certified Limits	X				435101-05 to 435101-09
Series 63-Physical and Chemical Characteristics (40CFR§158.190)						
63-2	Color	X				434101-03
63-3	Physical State	X				435101-03
63-4	Odor				X	
63-5	Melting Point	X				435101-03
63-6	Boiling Point		X			
63-7	Density, Bulk Density, or Specific Gravity	X				435101-03
63-8	Solubility	X				435101-03
63-9	Vapor Pressure	X				435101-03
63-10	Dissociation Constant	X				435101-03
63-11	Octanol/Water Partition Coefficient	X				435101-03
63-12	pH	X				435101-03
63-13	Stability				X	
64-1	Submittal of Samples				X	

EXPLANATIONS::

AC = Acceptable.
NA = Not Applicable/Waiver Acceptable.
Up = Needs upgrading.
Dg = Data Gap.
GLR# = Guideline Reference Number.

DP BARCODE: D219079 **SUBMISSION:** S493480 **REG/FILE SYMBOL No.:** 1812-GAG
CHEMICAL NAME: 080808 2-Chloro-4,6-bis(isopropylamino-s-triazine
COMMON NAME: Propazine **CAS Registry No.:** 139-40-2

Detailed Considerations

PRODUCT CHEMISTRY DATA REVIEW

1. Statements of data confidentiality were included with this submission claiming confidentiality of some of the data requirements on the basis of its falling within the scope of FIFRA§10(d)(1)(A), (B), or (C). Review of CBI information is to be found in Confidential Appendix A.

2. GLP statements were included with this submission to the effect that the submitted studies were conducted in full compliance with GLP requirements of 40CFR§160.

Series 61 Product Identity and Composition

MRID #435129-01 The submitted study entitled "Technical Propazine, Product Chemistry Data requirements of Series 61", was authored by Patrick McCain of Ciba-Geigy, dated 12/12/94, 168 pages.

61-1 Product Identity & Disclosure of Ingredients

Chemical Name: 080808 2-Chloro-4,6-bis(isopropylamino-s-triazine.

Common Name: Propazine

Chemical Class: Triazine

EPA Reg. No.: 1812-GAG

CAS Registry No.: 139-40-2

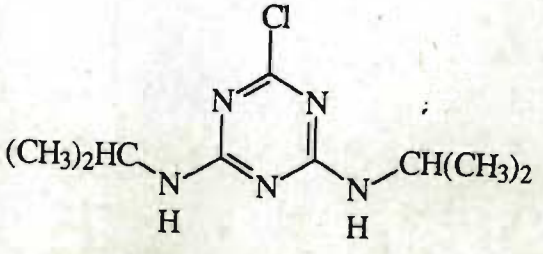
Type: Herbicide

Uses:For the manufacturing of products to control greenhouse weeds.

Empirical Formula: $C_9H_{16}N_5Cl$

Molecular Weight: 229.7

Structural Formula:



Nominal Concentration.... 98.0%
Upper Limit..... 100.0%
Lower Limit..... 95.1%

61-2 Description of Starting Materials and Manufacturing Process
See Confidential Appendix A.

61-3 Discussion of Formation of Impurities
See Confidential Appendix A.

Series 62 Analysis and Certification of Product Ingredients

62-1 Preliminary Analysis of Product Samples
See Confidential Appendix A.

62-2 Certification of Ingredient Limits
See Confidential Appendix A.

62-3 Analytical Methods to Verify Certified Limits

Method for the Active Ingredient:

MRID #435101-05 The submitted study entitled "Griffin Analytical Method TM-1103: Propazine In Technical Product by Megabore GLC, Data requirements of Guidelines 62-3", was authored by Carol A Dowler of Griffin Corporation, dated 12/2/94, 23 pages.

The method was designed to determine propazine, per se, in technical propazine or products containing the active ingredient.

In this method, propazine is extracted from the technical product using acetone, with dipropyl phthalate serving an internal standard for chromatographic analysis. Propazine is separated from the solvent, internal standard and the inert ingredients by gas-liquid chromatography and detected by flame ionization detector. Ana analytical standard, SAN 0177, propazine, 98.2% pure was used as a reference standard.

Method accuracy (deviation of the observed from the expected) was tested and the percent relative difference was near zero indicating that the method is accurate over a series of sample injections. Similarly, method precision was tested using triplicate sample preparation of propazine, as well as replicate injections (10 times) of one sample. The percent relative standard deviation was calculated at 0.14% for the triplicate sample preparation and 0.05% for the replicate injections, indicating consistent results over a series of sample preparation and sample injections, respectively.

No validation data was included since because of the high purity of technical propazine. No chromatographic interferences were observed. Method precision was reported at <1%, making it suitable for enforcement.

Sample calculations and sample chromtograms were included in this submission.

NOTE: Review of additional analytical methods is to be found in Confidential Appendix A because they are recommended for the analyses of confidential ingredients.

Series 63 Physical and Chemical Characteristics

MRID #435101-03 The submitted study entitled "Technical Propazine, Product Chemistry Data requirements of Guidelines 63-1 through 63-21", was authored by Carol A Dowler of Griffin Corporation, dated 12/2/94, 12 pages.

63-2	Color:	White.
63-3	Physical State:	Powdery solid.
63-4	Odor:	Data Gap.
63-5	Melting Point:	217.7°C.
63-6	Boiling point:	N/A
63-7	Density, Bulk Density, Specific Gravity:	0.46 gm/ml
63-8	Solubility at 25°C:	Water..... 3.8 ppm Acetone..... 14,252 ppm 1-Octanol..... 4,696 ppm
63-9	Vapor Pressure:	2.98 X 10^{-5}torr at 45°C
63-10	Dissociation Constant:	N/A. Practically water insoluble.
63-11	Octanol/Water Partition Coefficient:	P = 1234.7 Log P = 3.08
63-12	pH:	5.66

63-13	Stability:	Data Gap.
63-14	Oxidizing of Reducing Action:	Product is stable to the action of hexane, water, monoammonium phosphate and zinc metal, and neutral potassium permanganate solution.
63-15	Flammability	N/A. Technical propazine is not a combustible liquid.
63-16	Explodability	N/A. Technical propazine contains no explosive ingredients.
63-17	Storage Stability	Data Gap.
63-18	Viscosity	N/A. Product is solid.
63-19	Miscibility	N/A. The product does not involve the use of hydrocarbon solvents.
63-20	Corrosion Characteristics	Non corrosive to its commercial packaging.
63-21	Dielectric Breakdown Voltage:	N/A. Product is not recommended for use around electrical equipment.

Attachment: Confidential Appendix A (pages 8 to 134).

cc: Sami Malak and Central File (Reg. No. 1812-GAG).
7505W:RD:RSB:PCRS:S.Malak:CS-1:Rm650:s.m.:09/26/95:308-8392:<1812-GAG>

Page _____ is not included in this copy.

Pages __8__ through __13__ are not included in this copy.

The material not included contains the following type of information:

_____ Identity of product inert ingredients.

__X__ Identity of product impurities.

__X__ Description of the product manufacturing process.

__X___ 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 privilege.

_____ 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.