

DATE: 09/FEB/1999

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A. E. Munnis
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SUBJECT: PRODUCT CHEMISTRY REVIEW OF MP [] TGAI [X]
DP BARCODE No.: D252069 REG./File Symbol No.: 11603-EO
PRODUCT NAME: Galigan(Oxyfluorfen) Technical
COMPANY: AGAN MFG., Ltd.

FROM: Shyam B. Mathur, Chemist
Product Chemistry Team
Technical Review Branch/RD (7505C)

*S. B. Mathur
02-9-99*

TO: Joanne Miller, PM 23
Herbicide Branch/RD(7505C)

INTRODUCTION

The registrant has submitted the product chemistry data to support the registration of the Oxyfluorfen technical and is seeking a cite-all "me-too" registration. The application petitions the Agency's approval for the technical product manufactured by AGAN in Israel; in the USA the technical is produced by Rohm & Haas Co. and Dow AgroSciences LLC. The AGAN Chemical is seeking US registration for exactly the same corps, rates and timings as currently approved by the Agency. According to the registrant, the Agency's approval will not increase incremental risk.

SUMMARY OF FINDINGS

1. The subject product contains Oxyfluorfen as the active ingredient with product label claim of 97.4%.
2. The basic formulation CSF(dated 12-04-98) is filled out correctly and completely in compliance with PR Notice 91-2 and agree with the label claim nominal concentration.
3. The data submitted corresponding to guideline reference 830.1550 (Product identity & composition), 830.1620(Production process), and 830.1670(Discussion on the formation of impurities) satisfy the data requirements of 40CFR§158.155, 158.162, & 158.167 respectively.
[MRID No. 447202-01]
4. The data submitted corresponding to guideline reference 830.1700 (Preliminary analysis), 830.1750(certified limits), & 830.1800 (Enforcement of analytical method) satisfy the data requirements of 40CFR§158.170, 158.175, & 158.180 respectively.
[MRID No. 447120-01 & 447120-02]
5. The data submitted corresponding to guideline reference 830.Sub Group B-Physical-chemical properties satisfy the data requirements of 40CFR§158.190.

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CONCLUSION:

The product chemistry data submitted on the Galigan technical was reviewed by the TRB and concluded that:

1. The basic formulation CSF(dated 12-04-98) is filled out correctly and completely in compliance with PR Notice 91-2 and agree with the label claim nominal concentration and is acceptable.
2. The data submitted corresponding to guideline reference 830.1550 (Product identity & composition), 830.1620 (Production process), and 830.1670 (Discussion on the formation of impurities) satisfy the data requirements of 40CFR§158.155, 158.162, & 158.167 respectively and are acceptable.
3. The data submitted corresponding to guideline reference 830.1700 (Preliminary analysis), 830.1750 (certified limits), & 830.1800 (Enforcement of analytical method) satisfy the data requirements of 40CFR§158.170, 158.175, & 158.180 respectively and are acceptable.
4. The data submitted corresponding to guideline reference 830.Sub Group B-Physical-chemical properties satisfy the data requirements of 40CFR§158.190 and are acceptable.

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The registrant provided the following Physical-Chemical properties Group B of the Test Guidelines(830 Series):

Guideline Number & Name	Results	MRID Number												
830.6302. Color	Yellow	447120-03												
830.6303. Physical State	Solid Powder	" "												
830.6304. Odor	Mild halide	" "												
830.7200. M.P.	86.5°C	" "												
830.7300. Density	1.050 ± 0.01 at 25°C	" "												
830.7000. pH	6.03 at 25°C	" "												
830.6314. Oxi/Red	None	" "												
830.6320. Corrosion characteristics	None	" "												
830.7950. Vapor Pressure	<table border="1"> <thead> <tr> <th>Temperature</th> <th>VP(pa)</th> <th>VP(Torr)</th> </tr> </thead> <tbody> <tr> <td>30°C</td> <td>3.7 x 10⁻⁵</td> <td>2.8 x 10⁻⁷</td> </tr> <tr> <td>45°C</td> <td>1.8 x 10⁻⁴</td> <td>1.3 x 10⁻⁶</td> </tr> <tr> <td>59°C</td> <td>2.6 x 10⁻³</td> <td>1.9 x 10⁻⁵</td> </tr> </tbody> </table>	Temperature	VP(pa)	VP(Torr)	30°C	3.7 x 10 ⁻⁵	2.8 x 10 ⁻⁷	45°C	1.8 x 10 ⁻⁴	1.3 x 10 ⁻⁶	59°C	2.6 x 10 ⁻³	1.9 x 10 ⁻⁵	447120-06
Temperature	VP(pa)	VP(Torr)												
30°C	3.7 x 10 ⁻⁵	2.8 x 10 ⁻⁷												
45°C	1.8 x 10 ⁻⁴	1.3 x 10 ⁻⁶												
59°C	2.6 x 10 ⁻³	1.9 x 10 ⁻⁵												
830.7550. Log K _{ow}	4.7 (Shake Flask Method)	447120-07												
830.6313. Stability	<table border="1"> <thead> <tr> <th>Conditions</th> <th>Results</th> </tr> </thead> <tbody> <tr> <td>Elevated temp (50-51°C) 14 days</td> <td>Stable</td> </tr> <tr> <td>Room temp (15-21°C) 28 days</td> <td>Stable</td> </tr> <tr> <td>Artificial sunlight 24 hours</td> <td>Stable</td> </tr> <tr> <td>Metal carbon</td> <td>Stable</td> </tr> </tbody> </table>	Conditions	Results	Elevated temp (50-51°C) 14 days	Stable	Room temp (15-21°C) 28 days	Stable	Artificial sunlight 24 hours	Stable	Metal carbon	Stable	447120-08		
Conditions	Results													
Elevated temp (50-51°C) 14 days	Stable													
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The registrant provided the following Physical-Chemical properties Group B of the Test Guidelines(830 Series) Contd.:

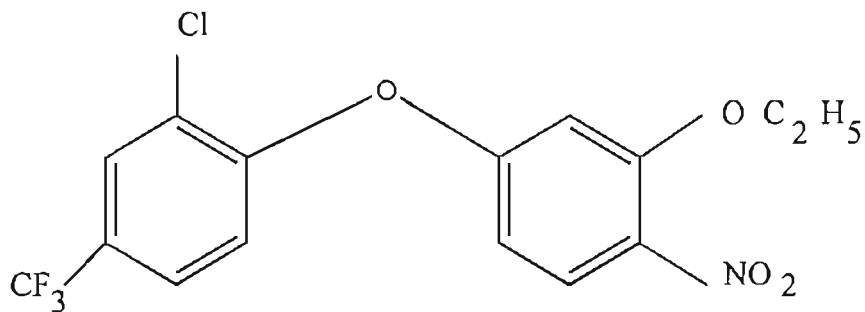
830.7840. Solubility	<u>Solvent</u>	<u>G/ml at 25°C</u>	447120-04
	Water	4.20 x 10 ⁻⁶	447120-05
	acetone	39.80	
	Dichloromethane	40.90	
	Ethylacetate	39.60	
	Hexane	0.615	
	Methanol	3.53	
	Toluene	39.70	

Guideline Number & Name	Results	MRID Number
830.6317. Storage stability	<p>the test substance was found to be stable at 50°C for 28 days.</p> <p>The one year storage stability study of the test substance in the commercial packaging & in an environmental chamber (25°C) did not show any sign of degradation and corrosion. No change in physical appearance was seen. The two year study is in progress & the results will be reported on completion of the study.</p>	4457120-09

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830.1550. Product identity and composition:
(MRID No. 447202-01)

Product name: Oxyfluorfen technical
Chemical name: 2-chloro-1-(3-ethoxy-4-nitrophenoxy)-4-tri
Fluoromethylbenzene [CAS]
2-chloro- α,α,α -trifluoro-p-tolyl-3-ethoxy-
4-nitrophenyl ether [IUPAC]
Trade name: Galigan
CAS No.: 42874-03-3
Molecular formula: $C_{15}H_{11}ClF_3NO_4$
Mol. Weight: 361.7
Structural formula:



[OXYFLUORFEN]

Manufacturing process information may be entitled to confidential treatment

CONFIDENTIAL APPENDIX

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The registrant has provided the following Confidential Statement of formula (dated December 4, 1998) for the technical product:

Ingredient	EPA Reg. No.	Component		certified limits % by weight	
		a. Amount	b. % by wt.	UCL	LCL
Oxyfluorfen (AI)		974.0	97.40	99.50	97.00
Total			100%		

830.1620. Description of the Production Process:
(MRID No. 447202-01)

The technical oxyfluorfen was produced in batch process involving following [REDACTED]:

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830.1670. Discussion on the formation of impurities:
(MRID No. 447202-01)

The registrant provided the following information on this topic:



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830.1700. Preliminary analysis: (MRID No. 447120-02)

Five lots of oxyfluorfen technical were analyzed for oxyfluorfen and other organic components present at $\geq 0.1\%$ by gas chromatograph equipped with FID. Oxyfluorfen content was determined by GC using tetraphenylethylene as an internal standard; other organic components were determined by using external standards. The identity of the components was verified by mass spectrometry. KCl content was determined by potentiometric titrations. The moisture content was determined by Karl Fischer method.

The GC system consisted of the following equipment:

GC- HP Model 5890 Series II equipped with FID detector.

Autosampler- HP7673

Spectra Physics SP4270 integrator

Column-DB-5MS 30M 0.25mm ID, film thickness 0.25m(J & W Scientific)

Injector temperature- 200°C

Detector temperature- 280°C

Oven temperature- 50°C to 260°C [5 min, 8°C/min, 20 min final time)

Carrier gas- He. 2.5 ml/min

Injection volume- 1µl

Split ratio- 1/60

The results are provided in the following table:

Oxyfluorfen technical components	Average results % (w/w)

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Determination of purity of the active ingredient in Galigan technical and Galigan Pure active ingredient: (MRID No. 447120-01)

The samples were analyzed using HPLC with photodiode array detection (HPLC-DAD), a reference of standard oxyfluorfen was used to calibrate the instrumental response for this method. The purity was calculated from the observed oxyfluorfen peak area in the test material samples compared to the observed oxyfluorfen peak area in the reference material samples. The precision of the analytical method was evaluated based on the RSD of the replicate results along with linearity and reproductivity of calibration standards analyzed with Galigan test samples. Mass spectra were obtained for the active ingredient in galigan and the reference material.

Instrumentation:

HPLC with photodiode array detection (HPLC-DAD) system consisting of:

Injector:	HP Model M-1100
Pump:	HP Model M-11
Degasser:	HP Model M-100
ChemStation:	HP ChemStation version A.04.01 system controller & HP 1040A diode array with Pascal HPLC ChemStation data system.
Column:	Inertsil ODS2, 250 mm x 4.6 mm(id)
Mobile Phase:	80:20:0.1/acetonitrile:water:H ₃ PO ₃
Wavelength:	Channels: 273 nm, 254 nm, 230 nm

A HP 5890 GC was for separation and screening of test and reference solutions. The analyses were performed using the following instrumental conditions:

Column:	Rtx, 30m x 0.25 mm(id) x 25µm coating
Carrier gas:	He 12 lbs/sq inch(psi)
Inj. Volume:	1 ml, splitless
Inj. Temp.:	250°C
Column gradient:	140°C to 260°C (3 min, 5 or 10°C/min)
Detection:	Mass spectrometry

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Mass Spectrometry: Electron ionization mass spectrometry was conducted using HP5970 mass spectrometer equipped with column interface. The analyses were performed using the following instrumental conditions:

Interface:	Direct
Transferline Temp.:	280°C
Acquisition mode:	70 eV electron impact (EI)
Scan mode:	50 through 370 amu

Flame ionization Detection: the analyses were done using the following instrumental conditions:

carrier gas:	He 1 ml/min
Make-up gas:	He 29 ml/min
Hydrogen:	30 ml/min
Air:	300 ml/min

Results:

The purities of Galigan technical and Galigan PAI were measured to be 96.4% and 97.4% respectively using the HPLC with diode array detection.