

7-2-96

DATE OUT: _____

SUBJECT: PRODUCT CHEMISTRY REVIEW OF MP [] EP [X]
DP BARCODE No.: D223751 REG./File Symbol No.: 279-GRTL
PRODUCT NAME: Authority BL Co-Mix Formulation

DATE: July 2, 1996

TO: Joanne Miller, PM 23
Fungicide-Herbicide Branch
Registration Division(7505C)

FROM: Shyam B. Mathur, Ph.D., Chemist
Product Chemistry Review Section
Registration Support Branch/RD (7505W)

THRU: Harold Podall, Ph.D., Section Head
Product Chemistry Review Section
Registration Support Branch/RD(7505W)

S. B. Mathur
7-2-96

H. P.
7/2/96

SUMMARY OF FINDINGS

1. This product can not be registered until the Agency approves the registration of the source product 279-GRUI.
2. The basic formulation CSF(dated 01-19-96) 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 61-1, 61-2, and 61-3 satisfy the data requirements of 40CFR§158.155, 158.165 and 158.167 respectively.
4. The data submitted corresponding to Guideline reference 62-2, and 62-3 satisfy the data requirements of 40CFR§158.175 and 158.180 respectively.
5. The data submitted corresponding to Guideline reference 63-3, 7, 12, 14-17, 20, & 21 satisfy the data requirements of 40CFR §158.190.
6. It is recommended that registrant generate data for one year storage stability and corrosion characteristics studies and submit the results to the Agency for evaluation.
7. The information provided on the product label concur with that on the CSF and is acceptable.

Note to PM: The registrant has determined during explodability studies that the product should not be exposed to temperatures exceeding 291°F(144°C).

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1. Reviewer: S.B.Mathur 2. Company: FMC Corporation
3. Type of Submission: Registration ☒ Reregistration ☐
 New ☒ Resubmission ☐ Amendment ☐ "ME-TOO" ☐
 Alternate Formulation ☐ Experimental Use Permit ☐
 Other (Specify) _____
4. If "Me-TOO" Registration, this product is ☐ is not ☐
 similar or substantially similar to EPA's Reg. No.: _____

If not, comment in Confidential Appendix A on the differences between the registered and the new source where significant.

CONFIDENTIAL STATEMENT OF FORMULA

5. Type of formulation and the sources of active ingredients:
- Non-integrated formulation system.....☒
 - Are all technical grade active ingredients used registered?
 - yes ☐ • no ☒ If no, specify 279-GRUI is under process of registration with Agency
 - Integrated formulation system.....☐
6. Clearance of intentionally added ingredients in the formulation for the intended use (indicate in the Confidential Appendix those that are not cleared; the PC Codes should be provided by the chemist on the CSF for those that are cleared):
- 6(a) Formulation intended for food use under 40CFR§180.1001:
- yes ☒ • no ☐ • Some are cleared, others are not ☐
 - Cleared under list: • c ☐ • d ☐ • e ☐
 - Are there any limitations for use as an inert under 40CFR§180.1001?
 - yes ☐ • no ☐ If yes, specify _____
- 6(b) Formulation intended for non-food use:
- yes ☐ • no ☒ • Some are cleared, others are not ☐
- 6(c) Clearance by the FDA of certain formulations under 21CFR§170 to 199. Examples: (a) indirect food additives, such as food contact surface sanitizers; adhesives, coatings, paper and paperboard products that may contact food in packaging or holding; and (b) substances generally recognized as safe (GRAS).
- yes ☐ • no ☐ • Some are cleared, others are not ☐
 - If yes, the entire formulation is cleared under 21CFR§_____.

7. The density, pH, and flammability values given on the CSF are identical with those of GRN 63-7, 63-12, and 63-15, respectively:
 • yes [X] • no []
8. The nominal concentrations (NC) of the active ingredients and the upper and lower certified limits (UCL & LCL) are as follows:

Active ingredient(s)		% by weight		
		NC	UCL	LCL
Authority 75 DF (Sulfentrazone)	279-GRUI	62.5 (46.87)	48.2	45.4
Sencor75 DF (Metribuzin)		37.50 (28.12)	28.9	27.20
Or Lexone 75DF				

9. The calculated NCs, based on the pure active ingredients (PAI), are identical to those on the label:
 • yes [X] • no []
10. The certified limits are within the standard limits as per 40CFR§158.175 or are adequately explained if different:
 • yes [X] • no []

PRODUCT LABEL

11. The chemical names of the active ingredients on the label are identical to those on the CSF:
 • yes [X] • no []
12. The appropriate physical and chemical hazards statement regarding flammability or explosive characteristics of the product are given on the label:
 • yes [X] • no [] • not applicable []
13. The storage and disposal instructions for the pesticide and container are in compliance with PR Notice 84-1 for household use products or PR Notice 83-3 for all other uses:
 • yes [X] • no []

PRODUCT CHEMISTRY DATA (SERIES 61, 62, 63)

<u>14. Chemical IDs/Manufacture/ Analytical Information</u>	<u>Data Required Fulfilled</u>	<u>MRID No.</u>
61-1 Chemical Identity(CSF)	Y	01-19-96
61-2 Start.Mat.& Manu.Process	Y	439267-01
61-3 Discussion of Impurities	Y	439267-01
62-1 Preliminary Analysis	NA	
62-2 Certified Limits(CSF)	Y	439267-01
62-3 Enforcement Analytical Method	Y	439267-01

<u>15. Physical/Chemical</u>	<u>Pro per tie s</u>	<u>Data Required Fulfille d</u>	<u>Value or Qualitat. Descrip.</u>	<u>MRID No.</u>
63-3 Physical State		Y	Dry granules	439267-01
63-7 Density/Bulk Density		Y	37.21 lbs /cu.ft	" "
63-12 pH of Product		Y	6.81-6.99	" "
63-14 Oxid/Red Action		Y	None	" "
63-15a Flamma.-Flsh.Pt.		NA		
63-15b Flame Extension		NA		
63-16 Explodability		Y	Note 1	" "
63-17 Storage Stability		Y	Note 2	-01,-02 & -03
63-18 Viscosity		NA		
63-19 Miscibility		NA		
63-20 Corrosion Charac.		Y	Note 3	" "
63-21 Dielec.Bkd.Vltg.		NA		

Explanations: Y = The Requirements Were Fulfilled; N = The Requirements Were Not Fulfilled; NA = Not Applicable; G = Data Gap; U = Requires Upgrading; I = Incomplete or In Progress; W = Waived.

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Note 1. 63-16. Explodability: Sulfentrazone 75DF ground powder is classified as flammable. The minimum ignition temperature has been tested as 400-420°C. The thermal instability, as tested by bulk powder test is 214°C(417.2°F). Therefore, the maximum exposure temperature recommended is 144°C(291.2°F).

Note 2. 63-17. Storage stability:
(MRID No. 439267-02)

30 day stability of Sulfentrazone/Metribuzin Blend:

The GC analysis method(Test Method APG No. 333) was used for the analysis of sulfentrazone 75DF formulation in combination with metribuzin 75DF formulation. The procedure uses internal standard (IS; dodecanophenone) calibration techniques and peak area measurements for quantitative determinations.

Instrument & its Parameters:

GC: HP5890A with FID
Column: J&W Scientific DB-1 Megabore, 30 m length,
0.525 mm id, film thickness 1 µm
Oven Temp.: 200°C(hold 4 min) to 250°C(20°C/min; 3.5 min.)
Inj. Port Temp.: 240°C
Det. Temp.: 300°C
Carrier gas: 18 ml/min

Results: The blend was shown to be stable for at least one month stored at room temperature. The test material is considered to be stable if the test analysis indicate 10% or less degradation of the substance under study.

Storage stability for two weeks at 54°C and 3 months at 50°C of Authority 75DF/Sencor 75DF Dry blend(1:0.60 ratio):
(MRID No. 439267-03)

The Test Method APG No. 333(GC) was used for this analysis which has been described earlier.

Results: Authority 75DF/Sencor DF75 was shown to be stable for at least two weeks when stored at 54°C and stable for at least 3 months when stored at 50°C.

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Note 3. 63-20. Corrosion Characteristics:

The registrant reported that the examination of the containers in which this end-use product has been stored for three months at elevated temperatures (50°C or 122°F) indicates the product is compatible with high density polyethylene (HDPE). The studies also indicate that the product is stable for one month at elevated temperatures (50°C or 122°F) when stored in paper bags.

Information on Active ingredients:

1. AUTHORITY 75 DF

Chemical Name: N-[2,4-dichloro-5-[4-(difluoromethyl)-4,5-dihydro-3-methyl-5-oxo-1H-1,2,4-triazol-1-yl]phenyl]methanesulfonamide

CAS Number: 122836-35-5

Common Name: (ISO) sulfentrazone

Trade Name: Authority •

EPA Shaughnessy code: Not yet assigned

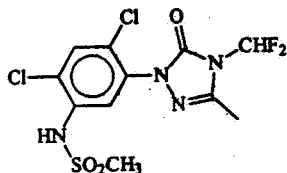
Company Code Numbers: FMC 97285, F6285

Chemical Family: Aryl Triazolinones

Molecular Formula: $C_{11}H_{10}Cl_2F_2N_4O_3S$

Molecular Weight: 387.2

Structural Formula:



Sulfentrazone (active ingredient)

2. SENCOR 75 DF

Chemical Name: 4-Amino-6-(1,1-dimethylethyl)-3-(methylthio)-1,2,4-triazin-5-(4H)-one (CAS)

CAS Number: 21087-64-9

Common Name: Metribuzin

Trade Name: Sencor •

EPA Shaughnessy Code: not yet assigned

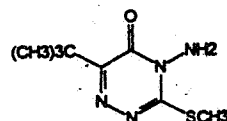
Company Code Numbers: Not available

Chemical Family: Triazinone

Molecular Formula: $C_8H_{11}N_4OS$

Molecular Weight: 356.43

Structural Formula:



Metribuzin (active ingredient)