

DATE OUT: 03/NOV/2005

SUBJECT: FEE: PRODUCT CHEMISTRY REVIEW OF MP [] EP [X]
DP BARCODE No.: 322804 **File Symbol No.:** 62719-519
PRODUCT NAME: Milestone
COMPANY: Dow Agrosiences, LLC
FOOD USE [X] INTEGRATED FORMULATION []
PCC: 005209 **Decision No.** 361584

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INTRODUCTION:

The registrant has submitted the results of an 8 week and 12 month storage stability and corrosion characteristics studies, MRID No. 466613-02, for the subject product, Milestone. The subject product contains Triisopropanolamine salt of aminopyralid (40.6%) as the active Ingredient (AI). The Technical Review Branch (TRB) has been asked to review for acceptability the submitted data for the subject product.

SUMMARY OF FINDINGS

1. The currently accepted basic CSF (dated 26/AUG/2005) has a nominal concentration of 40.6% of the AI, Triisopropanolamine salt of aminopyralid, which concurs with the label claim nominal concentration of 40.6%.
2. Two studies were submitted for reference guidelines 830.6317 (storage stability) and 830.6320 (corrosion characteristics) of the AI, Triisopropanolamine salt of aminopyralid, in the subject product. In the first study, the test samples were evaluated over the course of 8 weeks while being stored at 40 °C. In the second submitted study, the test samples were evaluated for 24 months at temperatures classified as room (ambient). The time points for evaluation were 0, 3, 6, 9, and 12 months. Two commercial containers were used in the storage stability studies; 1) high density polyethylene (HDPE) blow molded pint size blue pigmented bottles and 2) polyethylene (PET) amber pigmented pint sized bottles. [MRID No. 466613-02]
3. The chemical stability of the AI was determined by the percent of the active ingredient measured in the test samples over the course of the studies. The Triisopropanolamine salt of aminopyralid analysis was determined using high performance liquid chromatography (HPLC) with UV detection (270 nm). [MRID No. 466613-02]
4. The registrant performed a physical evaluation of the test product and packaging, including weight, clumping, paneling, ballooning and phase separation at each time point, to determine the corrosion characteristics (830.6320) due to long term storage of the end-use product, Milestone. The storage containers and test substances were recorded as showing no signs of change during the studies, and only slight weight variation was observed.
5. The analytical results of the samples under study indicated that the % AI falls within the certified limits of the end-use product, as per the basic CSF (dated 26/AUG/2005), with only minor changes (< 1%).
6. The data submitted corresponding to the reference guideline 830.6317 (storage stability) and 830.6320 (corrosion characteristics) are adequate and therefore satisfy the data requirements of 40§CFR158.190. [MRID No. 466613-02]

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7. The studies submitted in MRID No. 466613-02 were completed in accordance with good laboratory practice (GLP). This satisfies the requirements of 40§CFR160.

CONCLUSIONS:

TRB has reviewed the product chemistry data submitted for the end-use product, Milestone and has concluded that:

1. The product chemistry data submitted corresponding to 830 Series Subgroup B, 830.6317 (storage stability) and 830.6320 (corrosion characteristics) are acceptable.

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830.1800 (Enforcement Analytical Method): [MRID No. 466613-02]

Reagents:

Phosphoric acid 85%, reagent grade

Water, HPLC grade

Acetonitrile, HPLC grade

Eluent 55/45 v/v acetonitrile/water adjusted to pH 2.5 with phosphoric acid

Water, analytical grade

Standard solutions at pH 4.00, pH 7.00, and pH 10.00

Standard water "C" prepared according to the CIPAC MT 18 method

Diethyl phthalate, analytical grade internal standard

Equipment and Operating Conditions:

HPLC: Hewlett Packard Model 1100 equipped with UV/Vis detector, isocratic pump, auto sampler and HP Chemstation

HPLC Column: Zorbax SB Phenyl; 5 μ m, 250 X 4.6 mm

Thermostatic oven: ISCO FTD 100, ChemService code No. 130

Thermostat: ISCO Nte200, maintained, controlled at 40 \pm 2°C, ChemService code No. 188.

Analytical balance: Mettler AG204, ChemService code No. 102

Technical balance: Mettler B3002 Delta range, ChemService code No. 53

pH meter: Equipped with glass electrode (Mettler MP125) ChemService code No. 179

Usual laboratory glassware

UV Detector: 270 nm

Column Temperature: room temperature

Total run time: 10 minutes

Eluent Flow rate: 1.5 ml / min

Volume of injection: 10 μ l

Retention Times:

Test Sample: 2.3 min

Diethyl phthalate: 7.1 min

830.6317 (Storage Stability)

Storage Container: HDPE and PET containers [MRID No. 466613-02]

The %AI is measured as the acid equivalent of the Triisopropanolamine salt of aminopyralid.

8 week study at 40°C:

Test	GF-871 at time 0 (% AI, aminopyralid)	HDPE after 8 weeks	PET after 8 weeks
% AI (as acid equivalent)	21.8% w/w 247 g/L	21.8 % w/w 248 g/L	21.6% w/w 246 g/L
Appearance	Red-brown liquid Odorless	Unchanged	Unchanged
Relative density at 20 °C	1.1370 g / ml	1.1374 g / ml	1.1395 g / ml
pH value (1% aqueous dilution)	6.69	6.68	6.70
Dilutions Stability	Homogeneous after 18 h at 20°C	Unchanged	Unchanged
Corrosion characteristics		Compatible	Compatible
Weight variation (%)		-0.04 %	-0.67 %

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12 month study results at ambient temperatures:

Test	HDPE 3 months (% AI, aminopyralid)	PET 3months % AI	HDPE 6 months %AI	PET 6 months %AI
% AI (as acid equivalent)	21.7 % w/w 247 g / L	21.8 % w/w 248 g / L	21.6 % w/w 246 g / L	21.5 % w/w 245 g / L
Appearance	Red-brown liquid, Odorless	Unchanged	Red-brown liquid, Odorless	Unchanged
Relative density at 20 °C	1.1372 g / ml	1.1365 g / ml	1.1377 g / ml	1.1372 g / ml
pH value (1% aqueous dilution)	6.66	6.68	6.67	6.67
Dilutions Stability	Unchanged	Unchanged	Unchanged	Unchanged
Corrosion characteristics	Compatible	Compatible	Compatible	Compatible
Weight variation (%)	<0.01%	-0.22%	-0.02%	-0.29%

Test	HDPE 9 months (% AI, aminopyralid)	PET 9months % AI	HDPE 12 months %AI	PET 12 months %AI
% AI (as acid equivalent)	21.3 % w/w 242 g / L	21.3 % w/w 243 g / L	21.3 % w/w 242 g / L	21.5 % w/w 245 g / L
Appearance	Red-brown liquid, Odorless	Unchanged	Red-brown liquid, Odorless	Unchanged
Relative density at 20 °C	1.1382 g / ml	1.1388 g / ml	1.1385 g / ml	1.1388 g / ml
pH value (1% aqueous dilution)	6.51	6.47	6.67	6.68
Dilutions Stability	Unchanged	Unchanged	Unchanged	Unchanged
Corrosion characteristics	Compatible	Compatible	Compatible	Compatible
Weight variation (%)	<0.02%	-0.38%	-0.01%	-0.50%

830.6320 (Corrosion Characteristics) [MRID No. 466613-02]

No corrosive effects from the product have been observed in the packaging tested and no changes in physical properties of the test substance.