

DATE OUT: 11/JUL/2006

SUBJECT: **PRODUCT CHEMISTRY REVIEW OF MP [X] EP [ ]**  
DP BARCODE No.: 329396 File Symbol No.: 70552-1  
PRODUCT NAME: Paraquat Technical Concentrate  
COMPANY: Sinon Corp  
FOOD USE [X] INTEGRATED FORMULATION [ ]  
PCC: 061601 Decision No. 367652

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**INTRODUCTION:**

The registrant has submitted the results of a one year storage stability and corrosion characteristics study [MRID No. 468305-01] for the subject product containing paraquat dichloride (46.2%) as the active ingredient. TRB has been asked to evaluate the product chemistry data submitted for the manufacturing-use product.

**SUMMARY OF FINDINGS**

1. The manufacturing-use product contains paraquat dichloride as the active ingredient (AI) with a product label claim of 46.2%.
2. The storage stability and corrosive characteristics of the active ingredient, paraquat dichloride, were evaluated for one year under ambient temperatures and warehouse conditions. The storage containers used in this study were high density polyethylene (HDPE), 250 ml bottles.
3. The time points used in the study were 0, 3, 6, 9, and 12 months. The active ingredient, paraquat dichloride, was determined by HPLC / UV (254 nm). (Details of the method follow.)
4. The corrosion characteristics of the test substance and storage containers were visually examined at each time point for physical changes such as discoloration, perforation, leaking, rusting or changes in appearance. The registrant recorded no changes or corrosion of the containers storing the test substance during the one year study.
5. The registrant has reported that the % AI recovered from the sample product during the one year study shows no significant changes. The % AI in each of the test substances (at each time point) fell within the Agency standards for upper and lower certified limits as per 40§CFR158.175(b)(2).
6. The data submitted corresponding to the guideline reference 830.6317 (storage and stability) and 830.6320 (corrosion characteristics) satisfy the data requirements of 40§CFR158.190. [MRID No. 468305-01]
7. All of the studies submitted [MRID No. 468305-01] have been 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 proposed end-use product and has concluded that:

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

**Storage Stability (830.6317) of Paraquat Technical Concentrate:**

Time Interval (months)	Average (% AI, w/w)	Storage Container
0	46.33 %	The package shows no perforations, leaks, darkening, or rust and weight have no change
3	46.28 %	The package shows no perforations, leaks, darkening, or rust and weight have no change
6	46.23 %	The package shows no perforations, leaks, darkening, or rust and weight have no change
9	46.24 %	The package shows no perforations, leaks, darkening, or rust and weight have no change
12	46.16 %	The package shows no perforations, leaks, darkening, or rust and weight have no change

Method of % AI evaluation: Method Number 036B

**Reagents:**

Analytical standard of Paraquat dichloride  
1-Heptane sulphonic acid sodium salt, HPLC grade  
Phosphoric acid, GR grade  
Diethylamine, EP grade  
D.I. Water obtained with a Millipore Milli-Q system.

**Apparatus:**

HPLC: Agilent 1100 series LC with a DAD and autosample injector, or equivalent  
Data System: Agilent LC ChemStation, or equivalent  
Column: Zorbax Eclipse XDB-C8, 4.6 X 155 mm, 5 $\mu$ m

**Chromatographic Conditions:**

Column: Zorbax Eclipse XDB-C8, 4.6 X 155 mm, 5 $\mu$ m  
Mobile Phase: 10:90 Water:1-Heptane sulphonic acid sodium salt  
Column Temperature: 30°C  
Flow Rate: 1.0 ml / min  
Detector (UV): 254 nm  
Injection volume: 5  $\mu$ l

**Retention times:**

Paraquat dichloride: ~6.0 min

**Corrosion Characteristics Study (830.6320):**

No physical changes in the appearance of the commercial storage containers or test substance were observed at any of the time points through out the study.