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United States Environmental Protection Agency
Washington, DC 20460

ORIGINAL

Document Description	Date
Focus Notes P01-0783	9/4/01

[redacted]

EPA Form 7740-9 (rev. 10/92) Previous edition is obsolete

[redacted] **Final** **FOCUS REPORT**
New Chemicals Program

PART I: BACKGROUND

Written By: LMB

FOCUS DATE: 8/20/01 **FOCUS CHAIR:** A. Binder

COMPANY: Solutia, Inc

CASE NUMBER(S): P01-0783 **through** **and**

PART II: SAT RESULTS

HEALTH: 2 **ECOTOX:** 2 **OCCUPATIONAL EXPOSURE:** 2* **CONSUMER EXPOSURE:** **ENVIRONMENTAL RELEASES:**

ADDITIONAL SAT INFORMATION:

PART III: OTHER FACTORS

a. **PRODUCTION VOLUME:** [redacted] kg/yr

b. **PROD VOL OTHER:** ***Binding Option Not Marked***

c. **USE:** Scale inhibition, downhole use in oil fields, oil production

d. **REGULATORY HISTORY:** NRC

e. **TEST DATA:**

f. **IMPORTED** ☑ **MANUFACTURED** ☐ **BOTH** ☐

g. **MSDS:** ☑

h. **CATEGORY:** **CATEGORY 2:**

PART IV: SUMMARY OF SAT ASSESSMENT

[redacted]

CASE NUMBER: P01-0783

FATE: Solid
S (25°C) = 1000 g/L(E); H < 1.00E-8(E)
BP (C) > 400(E); VP @ 25C (mm) < 1.0E-6(E)
POTW removal (%) = 0; Analog data: OECD 306(Biodeg in seawater): 0%/28d; other tests gave little removal over 28d.
Time for complete ultimate aerobic biodeg = mo
PBT Potential: P2B1T1
Sorption to soils/sediments = moderate

HEALTH: Absorption is nil through the skin based on physical/chemical properties and good through the lungs and GI tract based on analogs. The PMN material is a chelator although it is already partially chelated [redacted]. Because of potential chelating activity, there is concern for neurotoxicity thorough effects on neuromembranes, effects on blood coagulation, and developmental toxicity (see [redacted] and submitted analog studies). There is concern for oncogenicity (bone cancer) by analogy to [redacted].

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SUBMITTED DATA for free acid or sodium salt:
negative in Salmonella
negative for gene mutations in CHO cells
mouse lymphoma - in vitro study was positive with activation
mouse lymphoma in vitro - negative with and without activation

negative for chromosomal aberration in rat bone marrow cells
range-finding developmental toxicity study in rats - no effects noted at doses up to 2 g/kg
developmental toxicity study in rats (0.5, 1, 2 g/kg) - lower maternal weight gain at 2 g/kg, vertebral anomalies at 1 and 2 g/kg
1-generation reproduction study in rats (300, 1000, 3000 ppm) - reduced number of live pups, increase in dead pups at 3000 ppm; reduced pup weight at 1000 and 3000 ppm; reduced pregnancy rate at 3000 ppm
acute dermal and oral studies
skin and eye irritation studies

On page 21 of the submission, it was noted that there is a carcinogenicity and chronic study for the neutralized acid with a maximum dose of 100 mg/kg with no effects on mineralization of bone, chondral ossification and bone formation/resorption and no changes in neoplastic findings. However this analogy study did not appear to be included in the submission.

ECOTOX: Predicted (P) and measured (M) toxicity values in mg/L (ppm) are:
fish 96-h LC50 > 100.0 P
daphnid 48-h LC50 > 100.0 P
green algal 96-h EC50 = 20.0 P
fish Chronic Value (ChV) > 10.0 P
daphnid ChV > 10.0 P
algal ChV = 2.0 P
based on SAR-nearest analogue method for chelators; SAR chemical class = a[redacted]- chelator;[redacted] hardness <180.0 mg/L as $CaCO_3$, 100% active ingredients, mean measured concentrations, and TOC <2.0 mg/L;
moderate concern for algae only;
assessment factor = 10.0
concern concentration (CC) = 0.050

PART V: SUMMARY OF EXPOSURE/RELEASE

Proc1:
[redacted]

Fate:
[redacted]

Proc2:
1[redacted]

Use:
[redacted]

[redacted]

Fate:
[redacted]

PART VI: FOCUS DECISION AND RATIONALE

DISPOSITION: Category-5(e) Order

RATIONALE: P01-0783 was regulated with a category 5(e) for exposure-based eco and human health and risk-based eco. The PMN substance met CEB exposure-based review criteria for drinking water dose [redacted] The PMN substance met EAB exposure-based review for drinking water dose [redacted]. Concerns for human health and the environment were moderate due to inhalation exposure, and releases to water, respectively. The Agency requires base set with static conditions, nominal concentrations for eco, and a repeated dose study for health or a chronic study on the Free acid (to be determined). Risk-based eco concerns are based on surface water concentrations exceeding the COC [redacted] d/yr.

PART VII: CCD DISPOSITION / DD

CCD: