Focus Report

New Chemicals Program

PMN Number: **P-09-0398**

Focus Date:	06/21/2009 11:00:00 PM	Report Status:	Completed
Consolidated Set:			
Focus Chair:	Rose Allison	Contractor:	Christina Stanley

I. Notice Information

Submitter: [redacted] CAS Number: [redacted]

Chemical Name: [redacted]

Use: Anti-scaling agent for water treatment ([redacted]); co-builder (cation sequestrant) for detergents ([redacted]); viscosity modifier for drilling muds ([redacted]); dispersant in water-based coatings ([redacted]). [redacted]

Other Uses: [redacted]

PV-Max: [redacted]

Manufacture: X Import: X

II. SAT Results

(1) **Health Rating:** 1-2 **Eco Rating:** 2 **Comments:** ;

Occupational: 2-3D **Non-Occupational:** **Environmental:** 3

(1) **PBT:** 3 1 1 **Comments:**

III. OTHER FACTORS

Categories:

Health Chemical Category: Ecotox Category: polyanionic polymers

Related Cases/Regulatory History:

Health related Cases: [redacted]

Ecotox Related Cases: [redacted]

Regulatory History:

CRSS P2Rec: NX-Non Exposure-Based 5(e); P2Rec-P2 Recognition

MSDS/Label Information:

MSDS: Yes Label: No

General Equipment: compatible chemical-resistant gloves, chemical safety glasses

Respirator: wear respirators and components tested and approved under appropriate government standards such as NIOSH or CEN; where risk assessment shows air-purifying respirators are appropriate use a dust mask type N95 or type P1 respirator

Health Effects: may cause skin or eye irritation, may be irritating to mucous membranes and upper respiratory tract; may be harmful by inhalation, ingestion, or skin absorption

TLV/PEL (PMN or raw material): - none established

Exposure Based Information:

Exposure Based Review:	N	Exposure Based Review (Health):	N
Exposure Based Review (Eco):	Y	Exposure Based (Occupational):	No
Exposure Based Review (Non Occupatuional):		Exposure Based (Environmental):	

IV. Summary of SAT Assessment

Fate:

Fate Summary:

P-09-0398
FATE: [redacted]
Solid
S > 800 g/L at 25℃ (M)
VP < 1.0E-6 torr at 25 EC (E)
BP > 400 EC (E)
H < 1.00E-8 (E)
POTW removal (%) = 0
Time for complete ultimate aerobic biodeg > mo
Sorption to soils/sediments = low - moderate
PBT Potential: P3B1
*CEB FATE: Migration to ground water = moderate

Health:

Health Summary: Absorption is nil all routes (pchem). Uncertain concern for irritation to eyes, mucous membranes and lung based on the pH of the material (5.3 - 5.4).

Ecotox:

Ecotox Values:

Fish 96-h LC50:	>100(P)
Daphnid 48-h LC50:	>100(P)
Green algal 96-h EC50:	5.3(P)
Fish Chronic Value:	>10(P)
Daphnid ChV:	>10(P)
Algal ChV:	3.4(P)

Ecotox values comments: Predictions are based on SARs for polyanionic polymers; SAR chemical class = polymer - anionic - chelator; [redacted]; effective concentrations based on 100% active ingredients and nominal concentrations; hardness <180.0 mg/L as CaCO3; and TOC <2.0 mg/L;

Ecotox Factors:

Assessment Factor:	10
Concern Concentration:	340

V. Summary of Exposures/Releases

Engineering Summary: P-09-0398

Exposures/Releases	**Release**	**Release**	**Release**
Scenario	[redacted]	[redacted]	[redacted]
Sites	[redacted]	[redacted]	[redacted]
Media	[redacted]	[redacted]	[redacted]
Descriptor A	Typical	Conservative	Typical
Quantity A (kg/site/day)	[redacted]	[redacted]	[redacted]
Frequency A (day/year)	[redacted]	[redacted]	[redacted]
Descriptor B	Worst Case		Worst Case
Quantity B (kg/site/day)	[redacted]		[redacted]
Frequency B (day/year)	[redacted]		[redacted]
From	[redacted]	[redacted]	[redacted]
Workers			
Exposure Type			

Engineering Summary: Exposures/Releases	**Release**	**Release**	**Release**
Scenario	[redacted]	[redacted]	[redacted]
Sites	[redacted]	[redacted]	[redacted]
Media	[redacted]	[redacted]	[redacted]
Descriptor A	High End	Conservative	Typical
Quantity A (kg/site/day)	[redacted]	[redacted]	[redacted]
Frequency A (day/year)	[redacted]	[redacted]	[redacted]
Descriptor B			Worst Case
Quantity B (kg/site/day)			[redacted]
Frequency B (day/year)			[redacted]
From	[redacted]	[redacted]	[redacted]
Workers			
Exposure Type			

V. Summary of Exposures/Releases

Engineering Summary: P-09-0398

Exposures/Releases	**Release**	**Release**	**Release**
Scenario	[redacted]	[redacted]	[redacted]
Sites	[redacted]	[redacted]	[redacted]
Media	[redacted]	[redacted]	[redacted]
Descriptor A	Typical	High End	Conservative
Quantity A (kg/site/day)	[redacted]	[redacted]	[redacted]
Frequency A (day/year)	[redacted]	[redacted]	[redacted]
Descriptor B	Worst Case		
Quantity B (kg/site/day)	[redacted]		
Frequency B (day/year)	[redacted]		
From	[redacted]	[redacted]	[redacted]
Workers			
Exposure Type			

Engineering Summary: Exposures/Releases	**Release**	**Release**	**Release**
Scenario	[redacted]	[redacted]	[redacted]
Sites	[redacted]	[redacted]	[redacted]
Media	[redacted]	[redacted]	[redacted]
Descriptor A	Typical	Typical	High End
Quantity A (kg/site/day)	[redacted]	[redacted]	[redacted]
Frequency A (day/year)	[redacted]	[redacted]	[redacted]
Descriptor B	Worst Case	Worst Case	
Quantity B (kg/site/day)	[redacted]	[redacted]	
Frequency B (day/year)	[redacted]	[redacted]	
From	[redacted]	[redacted]	[redacted]
Workers			
Exposure Type			

V. Summary of Exposures/Releases

Engineering Summary: P-09-0398

Exposures/Releases	Release	Release	Release
Scenario	[redacted]	[redacted]	[redacted]
Sites	[redacted]	[redacted]	[redacted]
Media	[redacted]	[redacted]	[redacted]
Descriptor A	Output 2	Typical	High End
Quantity A (kg/site/day)	[redacted]	[redacted]	[redacted]
Frequency A (day/year)	[redacted]	[redacted]	[redacted]
Descriptor B		Worst Case	
Quantity B (kg/site/day)		[redacted]	
Frequency B (day/year)		[redacted]	
From	[redacted]	[redacted]	[redacted]
Workers			
Exposure Type			

Engineering Summary: Exposures/Releases	Release	Release	Release
Scenario	[redacted]	[redacted]	[redacted]
Sites	[redacted]	[redacted]	[redacted]
Media	[redacted]	[redacted]	[redacted]
Descriptor A	Conservative	Low End of Range	Output 2
Quantity A (kg/site/day)	[redacted]	[redacted]	[redacted]
Frequency A (day/year)	[redacted]	[redacted]	[redacted]
Descriptor B		High End of Range	
Quantity B (kg/site/day)		[redacted]	
Frequency B (day/year)		[redacted]	
From	[redacted]	[redacted]	[redacted]
Workers			
Exposure Type			

V. Summary of Exposures/Releases

Engineering Summary: P-09-0398

Exposures/Releases	**Release**	**Release**	**Release**
Scenario	[redacted]	[redacted]	[redacted]
Sites	[redacted]	[redacted]	[redacted]
Media	[redacted]	[redacted]	[redacted]
Descriptor A	Typical	Typical	High End
Quantity A (kg/site/day)	[redacted]	[redacted]	[redacted]
Frequency A (day/year)	[redacted]	[redacted]	[redacted]
Descriptor B	Worst Case	Worst Case	
Quantity B (kg/site/day)	[redacted]	[redacted]	
Frequency B (day/year)	[redacted]	[redacted]	
From	[redacted]	[redacted]	[redacted]
Workers			
Exposure Type			

Engineering Summary: Exposures/Releases	**Release**	**Exposure**	**Exposure**
Scenario	[redacted]	[redacted]	[redacted]
Sites	[redacted]	[redacted]	[redacted]
Media	[redacted]	[redacted]	[redacted]
Descriptor A	Output 2	Typical	Typical
Quantity A (kg/site/day)	[redacted]	[redacted]	[redacted]
Frequency A (day/year)	[redacted]	[redacted]	[redacted]
Descriptor B		Worst Case	Worst Case
Quantity B (kg/site/day)		[redacted]	[redacted]
Frequency B (day/year)		[redacted]	[redacted]
From	[redacted]	[redacted]	[redacted]
Workers		[redacted]	[redacted]
Exposure Type		[redacted]	[redacted]

V. Summary of Exposures/Releases

Engineering Summary: P-09-0398

Exposures/Releases	**Exposure**	**Exposure**	**Exposure**
Scenario	[redacted]	[redacted]	[redacted]
Sites	[redacted]	[redacted]	[redacted]
Media	[redacted]	[redacted]	[redacted]
Descriptor A	Typical	Typical	Typical
Quantity A (kg/site/day)	[redacted]	[redacted]	[redacted]
Frequency A (day/year)	[redacted]	[redacted]	[redacted]
Descriptor B	Worst Case	Worst Case	Worst Case
Quantity B (kg/site/day)	[redacted]	[redacted]	[redacted]
Frequency B (day/year)	[redacted]	[redacted]	[redacted]
From	[redacted]	[redacted]	[redacted]
Workers	[redacted]	[redacted]	[redacted]
Exposure Type	[redacted]	[redacted]	[redacted]

Engineering Summary: Exposures/Releases	**Exposure**	**Exposure**	**Exposure**
Scenario	[redacted]	[redacted]	[redacted]
Sites	[redacted]	[redacted]	[redacted]
Media	[redacted]	[redacted]	[redacted]
Descriptor A	Typical	Typical	Low End of Range
Quantity A (kg/site/day)	[redacted]	[redacted]	[redacted]
Frequency A (day/year)	[redacted]	[redacted]	[redacted]
Descriptor B	Worst Case	Worst Case	High End of Range
Quantity B (kg/site/day)	[redacted]	[redacted]	[redacted]
Frequency B (day/year)	[redacted]	[redacted]	[redacted]
From	[redacted]	[redacted]	[redacted]
Workers	[redacted]	[redacted]	[redacted]
Exposure Type	[redacted]	[redacted]	[redacted]

V. Summary of Exposures/Releases

Engineering Summary: P-09-0398

Exposures/Releases	Exposure	Exposure	
Scenario	[redacted]	[redacted]	
Sites	[redacted]	[redacted]	
Media	[redacted]	[redacted]	
Descriptor A	Typical	Typical	
Quantity A (kg/site/day)	[redacted]	[redacted]	
Frequency A (day/year)	[redacted]	[redacted]	
Descriptor B	Worst Case	Worst Case	
Quantity B (kg/site/day)	[redacted]	[redacted]	
Frequency B (day/year)	[redacted]	[redacted]	
From	[redacted]	[redacted]	
Workers			
Exposure Type	[redacted]	[redacted]	

VI. Focus Decision and Rationale

Regulatory Actions

Regulatory Decision: PMN Ban Pending Upfront Testing Decision Date: 06/21/2009

Type of Decision:

Rationale: P09-0398 will be regulated under the TSCA 5(e) category polyanionic polymers under the exposure and risk based authorities for ecotoxicity concerns. Human health concerns were low-moderate and risks were mitigated by adequate dermal and respiratory protection. It should be noted that the inhalation concerns listed for the PMN substances as a vapor are inaccurate. The PMN submission has a very minute vapor pressure thereby eliminiating any inhlation exposure from vapor. The following CEB exposure based criteria were met: [redacted]). The following EAB exposure base criteria were met: [redacted]) and [redacted]). No human health exposure based testing is required. Enviornmental concerns are from releases to water where the chronic COC of 340 ppb was exceeded [redacted] during manufacturing [redacted] during processing 1 [redacted] during processing 2, 3, and 4 [redacted] during use 1 [redacted] during use 1 [redacted] during use 2 [redacted] during use 3 [redacted]. Many of these releases also exceed the acute COC of 1325 ppb. Ecotoxicity testing will be the acute base set, Fish acute toxicity test (OPPTS: 850.1075), Aquatic Invertebrate acute toxicity test freshwater daphnid (OPPTS: 850.1010), and algal toxicity tiers I and II (OPPTS: 850.5400). Fish and daphnia testing will be done using the flow-through method and the static method will be used for algal. A cirtificate of analysis of the test substance is required of the submitter and it is recommended that a RAD representative approve all protocols before beginning testing. Fate testing will be the Activated sludge sorption isotherm (OPPTS: 835.1110). The submitter can choose which PMN substance to do ecotoxicity testing (either P09-0398 or P09-0399) however, fate testing must be done on both substances.

Summary of Exposures and Releases:

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

OR Incineration OR Landfill

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

P2 Rec Comments:

Testing:

Final Recommended:

Health:

Eco: Fish acute toxicity test (OPPTS: 850.1075), Aquatic Invertebrate acute toxicity test freshwater daphid (OPPTS: 850.1010), and algal toxicity tiers I and II (OPPTS: 850.5400)

Fate: Activated sludge sorption isotherm (OPPTS: 835.1110)

Other:

SAT Report

PMN Number: **P-09-0398**
SAT Date: **6/12/2009**
Print Date: **3/10/2015**

Related cases: [redacted]

Health related cases: [redacted]
Ecotox related cases: [redacted]

Concern levels:

Type of Concern:	**Health**	**Eco**	**Comments**
Level of Concern:	1-2	2	

Persistence	**Bioaccum**	**Toxicity**	**Comments**
3	1	1 Awaiting Human Health Entry Awaiting Human Health Entry Awaiting Human Health Entry	

Exposure Based Review:

Health: No
Ecotox: Yes

Routes of exposure:

Health: Inhalation
Ecotox: All releases to water
Fate: ;

Keywords:

Keywords:

Summary of Assessment:

Fate:

Fate Summary: P-09-0398

FATE: [redacted]
Solid
S > 800 g/L at 25℃ (M)

VP < 1.0E-6 torr at 25 EC (E)
BP > 400 EC (E)
H < 1.00E-8 (E)
POTW removal (%) = 0
Time for complete ultimate aerobic biodeg > mo
Sorption to soils/sediments = low - moderate
PBT Potential: P3B1
*CEB FATE: Migration to ground water = moderate

Health:

Health Summary: Absorption is nil all routes (pchem). Uncertain concern for irritation to eyes, mucous membranes and lung based on the pH of the material (5.3 - 5.4).

Ecotox:

Test Organism	Test Type	Test End Point	Predicted	Measured	Comments
fish	**96-h**	**LC50**	>100		
daphnid	**48-h**	**LC50**	>100		
green algal	**96-h**	**EC50**	5.3		
fish	**_**	**chronic value**	>10		
daphnid	**_**	**chronic value**	>10		
algal	**_**	**chronic value**	3.4		
Sewage Sludge	**3-h**	**EC50**	**_**		
Sewage Sludge	**_**	**Chronic Value**	**_**		

Ecotox Values Comments:

Factors	Values	Comments
Assessment Factor	10	
Concentration of Concern (ppb)	340	
SARs	polyanionic polymers	
SAR Class	polymer-anionic-chelator	
Ecotox Category		

Ecotox Factors Comments:

SAT Chair: L Keifer 564-8916

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

April 30, 2012

MEMORANDUM

SUBJECT: Response to Comments from [redacted] and Review of Ecotoxicity Tests for PMN P-09-0398/0399

FROM: Jeffrey Gallagher
Toxicologist
New Chemicals and Assessment Branch
Risk Assessment Division (7403M)

TO: Virginia Lee
Program Manager
New Chemicals Branch
Chemical Control Division (7405M)

THRU: Jennifer Seed
Acting Branch Chief
New Chemicals and Assessment Branch
Risk Assessment Division (7403M)

This Memorandum Contains
TSCA Confidential Business Information (CBI)

Conclusions

Based on additional information provided by sponsor [redacted], EPA accepts [redacted] as an analog for P-09-0398. In addition, [redacted] demonstrated that "[redacted]" complexed all of the carboxylic acid content of the polymer in the algal toxicity test. Furthermore, the additional information clarified the results from the aquatic invertebrate toxicity test concerning why the results from the second *D. magna* definitive toxicity test (as compared to the first definitive test showing toxicity) were used to calculate the submitted ecotoxicity test values.

From the acceptable aquatic invertebrate toxicity results, the *D. magna* 48-hr EC_{50} for P-09-0398 is > 850 mg a.i./L. Both of the algal toxicity tests (with and without calcium amendments) were considered acceptable. Based on the algal toxicity test (without calcium amendments), the 96-hr EC_{50} for P-09-0398 is 65.25 mg a.i./L. The algal 96-hr EC_{50} for P-09-0398 is 130.50 mg a.i./L for the algal toxicity test with calcium

amendments, which is used for concentration of concern (COC) calculations. From both algal toxicity tests, the NOEC and LOEC were 34 mg/L and 68 mg/L, respectively, for P-09-0398. Hence, the algal ChV (or MATC) for P-09-0398 is 48.11 mg/L. The revised acute COC, based on the algal 96-hr EC_{50} of 130.50 mg/L, is 20,000 µg/L (rounded down from 32,625 µg/L). The chronic COC, based on the algal ChV of 48.11 mg/L is 1,000 µg/L (rounded down from 4,811 µg/L). The acute and chronic COCs for P-09-0398 are 20,000 µg/L and 1,000 µg/L, respectively. As a result of the lack of ecological hazard, the ecological risk to P-09-0398 and P-09-0399 is low.

Background

On June 22, 2009, P-09-0398 and P-09-0399 (polyanionic polymers) were reviewed at FOCUS as a consolidated case. The decision at the FOCUS meeting was to ban the PMNs pending up front testing due to their predicted *algal-only* toxicity. The acute and chronic concentrations of concern (COC) for both P09-398 and P09-399 were 1,325 ppb and 340 ppb, respectively (based on algae). For both PMNs, most of the surface water concentrations [redacted] exceeded the chronic concern concentration by greater than 20 days. Many of the predicted surface water concentrations also exceeded the acute concern concentration (1,325 ppb).

Since June 22, 2009, EPA and the sponsor [redacted] have had discussions about algal testing and other PMN-specific concerns (i.e., measured vs. nominal concentrations). Due to the physical / chemical characteristics, EPA agreed with [redacted] that reporting nominal concentrations were sufficient when testing P-09-0398 and P-09-0399. In addition, during the correspondence with the [redacted], EPA recommended that the testing laboratory conduct two algal toxicity tests: 1) one traditional algal toxicity test following the OCSPP 850.5400 test guideline and 2) one modified algal toxicity test with the addition of CaCl2*2H2O, which "should be based on the calculated carboxylic acid content of the polymer." In a modified algal toxicity test, additional calcium amendments help to account for the potential PMN-specific toxicity following cationic binding of the polyanionic polymers.

In January 2012, [redacted] submitted an acute *Daphnia magna* toxicity study and a modified (with calcium amendment) algal (*Selenastrum capricornutum*) toxicity study. In both studies, [redacted] (the testing laboratory) exposed the testing organisms to [redacted] Questions arose from [redacted] submission. EPA requested that [redacted] provide:

1) The standard chemical characteristics of [redacted], such as the ratio of monomers and its molecular weight, so that EPA can determine whether it is an appropriate analog for P-09-0398 and P-09-0399;
2) Verify whether the "40% equivalent calcium loading dose" complexed all of the carboxylic acid content of the polymer in the algal toxicity test; and
3) Explain why the results from the second *D. magna* definitive toxicity test (as compared to the first definitive test showing toxicity) were used to calculate the submitted ecotoxicity test values.

On April 4, 2012, EPA received a letter from [redacted]. [redacted] letter responded to questions from EPA about their submitted acute aquatic invertebrate and algal toxicity test (with calcium amendments). Based on additional information provided by sponsor, EPA accepts [redacted] as an analog for P-09-0398. In addition, [redacted] demonstrated that "[redacted]" complexed all of the carboxylic acid content of the polymer in the algal toxicity test. Furthermore, the additional information clarified the results from the aquatic invertebrate toxicity test concerning why the results from the second *D. magna* definitive toxicity test (as compared to the first definitive test showing toxicity) were used to calculate the submitted ecotoxicity test values. [redacted] also included a second algal toxicity test (with calcium amendments). As a result, the aquatic invertebrate and algal toxicity tests are reviewed below.

Review of Aquatic Invertebrate and Algal Ecotoxicity Tests

Between 2011 and 2012, [redacted] exposed aquatic invertebrates (*Daphnia magna*) and algae (*Selenastrum capricornutum*) to [redacted], a close analog of P-09-0398, in ecotoxicity tests. In the *D. magna* toxicity test and in one of the *S. capricornutum* toxicity tests, [redacted] added calcium amendments to each of the respective test concentrations prior to test initiation. The calcium amendments [redacted] were used to complex all of the carboxylic acid content of the polyanionic polymer, [redacted]. The second *S. capricornutum* toxicity test was conducted without calcium amendments at the same test concentrations. In each of the reports, [redacted] was identified as being 85% active.

In a 48-hour aquatic invertebrate toxicity test, *D. magna* were exposed to [redacted] at nominal test concentrations of 0 (control), 62.5, 125, 250, 500, and 1,000 mg/L. Based on an active ingredient of 85%, the adjusted nominal test concentrations are 0 (control), 53.1, 106.3, 212.5, 425, and 850 mg a.i./L. The test substance, calcium amendment, and dilution water were combined at appropriate amounts and homogenized for 15 minutes prior to test initiation. The definitive test concentrations were based on a range – finding test. EPA agreed with [redacted] that nominal concentrations were acceptable for this PMN set (P-09-0398/0399) due to the PMN's physical/chemical properties. Two definitive tests were conducted with *D. magna* on [redacted]. The results of the first definitive toxicity test were not used due to inconsistent immobilization of the *D. magna*. In the second definitive test, the temperature ranged from 21 to 22ºC. The pH ranged from 5.9 to 7.9. The percent dissolved oxygen ranged from 89 to 94. Three replicates of ten *D. magna* were exposed to either the test concentrations or the dilution water controls. From the acceptable aquatic invertebrate toxicity results, the second definitive test resulted in a 48-hr EC_{50} of > 850 mg a.i./L, which is consistent with ECOSAR predictions of greater than 100 mg/L for aquatic invertebrates under acute exposure conditions.

In two independent 96-hour algal toxicity tests, *S. capricornutum* ($5x10^4$ cells/mL) were exposed to [redacted] at nominal test concentrations of either 0 (control), 20, 40, 80, 160, and 320 mg/L in the test without calcium amendments or 0 (control), 5, 10, 20, 40, 80, and 160 mg/L in the test with calcium amendments. Based on an active ingredient of 85%, the adjusted nominal test concentrations for the algae without calcium amendments are 0 (control), 17, 34, 68, 136, and 272 mg a.i./L. Based on an active ingredient of 85%,

the adjusted nominal test concentrations for the algae with calcium amendments are 0 (control), 4.25, 8.5, 17, 34, 68, and 136 mg a.i./L. Three replicates of *S. capricornutum* were used for each of the test concentrations. Six replicates were used for the dilution water controls in the toxicity tests. Between the two tests, temperature ranged from 22 to 24º C. For both tests, pH ranged from 6.4 to 9.7. The algal results for both tests are based on growth rate. Both of the algal toxicity tests (with and without calcium amendments) were considered acceptable. Based on the algal toxicity test (without calcium amendments), the 96-hr EC_{50} for P-09-0398 is 65.25 mg a.i./L. The algal 96-hr EC_{50} for P-09-0398 is 130.50 mg a.i./L for the algal toxicity test with calcium amendments, which is used for concentration of concern (COC) calculations. From both algal toxicity tests, the NOEC and LOEC were 34 mg/L and 68 mg/L, respectively, for P-09-0398. Hence, the algal ChV (or MATC) for P-09-0398 is 48.11 mg/L. For comparative purposes, the ECOSAR generated algal 96-hr EC_{50} and algal ChV was 5.3 and 3.4 mg/L, respectively. The revised acute COC, based on the algal 96-hr EC_{50} of 130.50 mg/L, is 20,000 µg/L (rounded down from 32,625 µg/L). The chronic COC, based on the algal ChV of 48.11 mg/L is 1,000 µg/L (rounded down from 4,811 µg/L). The acute and chronic COCs for P-09-0398 are 20,000 µg/L and 1,000 µg/L, respectively.

Briefing Paper

Case Number: **P-09-0398**

Part I: Background Data

Program Manager: Virginia Lee
Technical Integrator:
Review Team:
Meeting Date:
Day In Process: 90
Day 90: 05/14/2012

A. CBI Claims:
B. Submitter: [redacted]
C. Chemical Identity: [redacted]
D. Chemical Class:
Ecotox: polyanionic polymers ; polymer-anionic-chelator

E. Structure:

[redacted]

F. Physical/Chemical properties:
VP: Measured Torr @ 25 C
Est. < 0.001 Torr @ 25 C
s-H2O: Measured g/L
MW: [redacted] [redacted] %<500 [redacted] %<1000
Phys State: Neat: Solid
Manufacturing: [redacted]
Process/Form: [redacted]
End Use: [redacted]

G. Volume: [redacted]
H. Use: Anti-scaling agent for water treatment ([redacted]); co-builder (cation sequestrant) for detergents ([redacted]); viscosity modifier for drilling muds ([redacted]); dispersant in water-based coatings [redacted]). [redacted]
I. Test Data Submitted:
J. MSDS:
MSDS: Yes
Label: No
General equipment: compatible chemical-resistant gloves, chemical safety glasses
Respirator: wear respirators and components tested and approved under appropriate government standards such as NIOSH or CEN; where risk assessment shows air-purifying respirators are appropriate use a dust mask type N95 or type P1 respirator
Health Effects: may cause skin or eye irritation, may be irritating to mucous membranes and upper respiratory tract; may be harmful by inhalation, ingestion, or skin absorption

K. SAT Ratings:

Human Health: 1-2 ; Environment: 2 ;

L. Focus Results: P09-0398 will be regulated under the TSCA 5(e) category polyanionic polymers under the exposure and risk based authorities for ecotoxicity concerns. Human health concerns were low-moderate and risks were mitigated by adequate dermal and respiratory protection. It should be noted that the inhalation concerns listed for the PMN substances as a vapor are inaccurate. The PMN submission has a very minute vapor pressure thereby eliminiating any inhlation exposure from vapor. The following CEB exposure based criteria were met: [redacted]. The following EAB exposure base criteria were met: [redacted] and [redacted]. No human health exposure based testing is required. Enviornmental concerns are from releases to water where the chronic COC of 340 ppb was exceeded [redacted] during manufacturing [redacted] during processing 1 [redacted] during processing 2, 3, and 4 [redacted] during use 1 [redacted] during use 1 [redacted] r during use 2 [redacted] during use 3 [redacted] use 4 [redacted] Many of these releases also exceed the acute COC of 1325 ppb. Ecotoxicity testing will be the acute base set, Fish acute toxicity test (OPPTS: 850.1075), Aquatic Invertebrate acute toxicity test freshwater daphnid (OPPTS: 850.1010), and algal toxicity tiers I and II (OPPTS: 850.5400). Fish and daphnia testing will be done using the flow-through method and the static method will be used for algal. A cirtificate of analysis of the test substance is required of the submitter and it is recommended that a RAD representative approve all protocols before beginning testing. Fate testing will be the Activated sludge sorption isotherm (OPPTS: 835.1110). The submitter can choose which PMN substance to do ecotoxicity testing (either P09-0398 or P09-0399) however, fate testing must be done on both substances.

Summary of Exposures and Releases:

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

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[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

Part II: New Information

The submitter provided daphnid and algal acute toxicity data which RAD (J. Gallagher) reviewed. RAD concluded that the acute and chronic COCs are 20,000 ppb and 1,000 ppb, respectively based on the measured algal data. RAD also recommended, "as a result of the lack of ecological hazard, the ecological risk to P-09-0398 and P-09-0399 is low."

Part III: Recommendation and Rationale

The program manager recommends P-09-398 and P-09-399 be dropped from further review with voluntary testing based on the lack of hazard and low ecological and human health risk expected from exposure to the PMN substances.

Part IV: Risk Summary

A. Health Effects:

Absorption is nil all routes (pchem). Uncertain concern for irritation to eyes, mucous membranes and lung based on the pH of the material (5.3 - 5.4).

B. Environmental Effects:

Ecotox: predicted (P) and measured (M) toxicity value is mg/L (ppm) are:

Fish 96-h LC50:	>100(P)
Daphnid 48-h LC50:	>100(P)
Green algal 96-h EC50:	5.3(P)
Fish Chronic Value:	>10(P)

Daphnid ChV: >10(P)
Algal ChV: 3.4(P)

C. Environmental Releases and Exposures:

D. Risk Estimates:

Part V: Exposure Criteria Met

Exposure Based Review (Chemistry):	○ Yes ● No	**Exposure Based Review (Health):**	○ Yes ● No
Exposure Based Review (Ecotox):	● Yes ○ No	**Exposure Based Review (Occupational):**	● Yes ○ No
Exposure Based Review (Non-Occupational):	○ Yes ● No	**Exposure Based Review (Environmental):**	○ Yes ○ No

[redacted]

Part VI: Tests

Final Testing Recommendation

Health:
Eco: Fish acute toxicity test (OPPTS: 850.1075), Aquatic Invertebrate acute toxicity test freshwater daphid (OPPTS:
Fate: Activated sludge sorption isotherm (OPPTS: 835.1110)
Other:

Comments:

Part VII: Other Factors

A. Substitutes:

B. Benefits:

C. Other Uses: [redacted]

D. Other:

Part VIII: Regulatory History

Comments:

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