SAT Report

PMN Number: **P-09-0085**
SAT Date: **12/9/2008**
Print Date: **11/26/2014**

Related cases: [redacted]

Concern levels:

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

Persistence	Bioaccum	Toxicity	Comments
1	1	2 Awaiting Human Health Entry Awaiting Human Health Entry Awaiting Human Health Entry	

Exposure Based Review:

Health: Yes
Ecotox: No

Routes of exposure:

Health: Inhalation and drinking water
Ecotox: No releases to water
Fate: ;

Keywords:

Keywords:

Summary of Assessment:

Fate:

Fate Summary: P-09-0085

FATE: [redacted]
[redacted] MP = 256 EC (E)
[redacted]
S > 10 g/L at 25 EC (E)

VP < 1.0E-6 torr at 25 EC (E)
BP > 400 EC (E)
H < 1.00E-8 (E)
log Koc = 1.09 (E)
log Fish BCF = 0.50 (E)
POTW removal (%) = 90 via biodeg
Time for complete ultimate aerobic biodeg = wk
Sorption to soils/sediments = low
PBT Potential: P1B1
*CEB FATE: Migration to ground water = negl due to biodeg

Health:

Health Summary: Absorption is nil through the skin based on physical/chemical properties and good through the lungs and GI tract based on analogs. There is concern for neurotoxicity based on the [redacted]. Low moderate concern.

Test data for an analog, [redacted]
rat acute oral LD0 = 2.0 g/kg with no toxic signs
a potential for only mild eye irritation based on the HET-CAM test
no skin irritation in humans
Ames test was negative, however, an inconclusive test because only one dose was tested once (Cimino)

Ecotox:

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

Ecotox Values Comments:

Factors	Values	Comments
Assessment Factor	10	
Concentration of Concern (ppb)	1000	

SARs		
SAR Class		
Ecotox Category		

Ecotox Factors Comments:

SAT Chair: Becky Jones

Focus Report

New Chemicals Program

PMN Number: **P-09-0085**

Focus Date:	12/15/2008 12:00:00 AM	Report Status:	Completed
Consolidated Set:			
Focus Chair:	Ken Moss	Contractor:	Paul Sohi

I. Notice Information

Submitter: Champion Technologies

CAS Number: [redacted]

Chemical Name: [redacted]

Use: [redacted] Analog, [redacted] . P2REC: CRSS forward [redacted].

Other Uses: [redacted].

PV-Max: [redacted]

Manufacture: X

Import:

II. SAT Results

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

Occupational: 1B **Non-Occupational:** 3 **Environmental:**

(1) **PBT:** 1 1 2 **Comments:**

III. OTHER FACTORS

Categories:

Health Chemical Category:

Ecotox Category:

Related Cases/Regulatory History:

Health related Cases: [redacted]

Ecotox Related Cases: Analogs: [redacted]

Regulatory History:

[redacted] FOCUS DROP

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

MSDS/Label Information:

MSDS: Yes Label: No

General Equipment: chemical-resistant gloves / chemical splash goggles, safety glasses and/or face shield / general and/or local exhaust ventilation, process enclosures, or other engineering controls to control airborne levels below exposure guidelines

Respirator: approved air-purifying respirator or positive-pressure supplied-air respirator depending on potential airborne concentration

Health Effects: Irritating to skin / Irritating to eyes / Repeated or prolonged exposure to product mist, aerosol, or vapor may be irritating to respiratory system / May be harmful if swallowed.

TLV/PEL (PMN or raw material): - [redacted] -

Exposure Based Information:

Exposure Based Review: Y

Exposure Based Review (Health): Y

Exposure Based Review (Eco): N

Exposure Based (Occupational): No

Exposure Based Review (Non Occupatuional):

Exposure Based (Environmental):

IV. Summary of SAT Assessment

Fate:

Fate Summary:

P-09-0085
FATE: Estimations for [redacted]
Solid with MP = 256 EC (E)
log Kow = [redacted] (M);
S > 10 g/L at 25 EC (E)
VP < 1.0E-6 torr at 25 EC (E)
BP > 400 EC (E)
H < 1.00E-8 (E)
log Koc = 1.09 (E)
log Fish BCF = 0.50 (E)
POTW removal (%) = 90 via biodeg
Time for complete ultimate aerobic biodeg = wk
Sorption to soils/sediments = low
PBT Potential: P1B1
*CEB FATE: Migration to ground water = negl due to biodeg

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Low moderate concern.

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rat acute oral LD0 = 2.0 g/kg with no toxic signs
a potential for only mild eye irritation based on the HET-CAM test
no skin irritation in humans
Ames test was negative, however, an inconclusive test because only one dose was tested once (Cimino)

Ecotox:

Ecotox Values:

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

Ecotox values comments:

Predictions are based on SARs for [redacted]; SAR chemical class = [redacted] pH7; S > 1000 g/L (P); effective concentrations based on 100% active ingredients and nominal concentrations; hardness <150.0 mg/L as CaCO3; and TOC <2.0 mg/L;

Evaluation of three ecotoxicity studies with PMN submission:
Evaluator S. Cragg
See attached spreadsheet for more details
Conclusion: Results from the three limit tests are considered valid. No effects were detected (mortality, behavior, morphology, or growth) in the acute fish test at the highest concentration tested of 1,000 mg/L. In daphnia, the 48-hr EC50 was 186 mg/L with a LOEC of 148 mg/L, a NOEC of 114 mg/L, and a calculated chronic values (geom mean of LOEC & NOEC) of 130 mg/L. In algae, EC50's, LOECs and NOECs also were established at concentrations exceeding those in daphnia. As the most sensitive species, the ChV of daphnia is used to derive a concentration of concern (CoC). The daphnid ChV of 130 mg/l yeilds a CoC of 13 mg/L or 13,000 ppb. The maximum designated CoC is 1,000 ppb for PMN purposes. PMN is of low concern for ecotoxicity.

Ecotox Factors:

Assessment Factor:	10
Concern Concentration:	1000

V. Summary of Exposures/Releases

Engineering Summary: P-09-0085

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

V. Summary of Exposures/Releases

Engineering Summary: P-09-0085

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

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

VI. Focus Decision and Rationale

Regulatory Actions

Regulatory Decision: PMN Consent Order Decision Date: 12/15/2008
Type of Decision:

Rationale: P09-0085 will be regulated under TSCA section 5(e) exposure-based authority for human health, fate and ecotoxicity concerns. There is a concern for neurotoxicity based on the [redacted]. Exposure based criteria met were drinking water and total releases. With the very high production volume, all exposure based testing is being required. The required testing will be the combined repeated dose toxicity study (OECD 422), reproduction/developmental toxicity screening test (OPPTS: 870.3650), an acute oral study in rats (OPPTS 870.1100) and Ames assay (40 CFR 799.9510). The FATE testing requested is the ready biodegradability study (OPPTS: 835.3110). Eco testing will be the base set Flow-through method, analytical measurement of test substance for Fish 96-hr LC50 (OPPTS 850.1075) and Acute Daphnia (OPPTS 850.1010) and the static analytical measurement of Algae (OPPTS 850.5400).

Summary of Exposures/Releases:

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

P2 Rec Comments: Test data was submitted to support a claim that the PMN compound is less toxic than [redacted] to the aquatic environment, but no comparison can be done for potential for human effects. The focus participants agreed not to forward the P2REC claim.

Testing:

Final Recommended:

Health:

Eco:

Fate:

Other:

QA-QC:
· KC 5/11/09
· TK 5/12/09

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF POLLUTION PREVENTION AND TOXICS

REGULATION OF A NEW CHEMICAL SUBSTANCE

PENDING DEVELOPMENT OF INFORMATION

In the matter of:	)	Premanufacture Notice Number:
	)	
	)	
	)	
	)	
	)	
Champion Technologies, Inc.	)	P-09-85
	)	
	)	EPA SANITIZED
	)	
	)	CONTAINS NO CBI
	)	

Consent Order and Determinations Supporting Consent Order

TABLE OF CONTENTS

PREAMBLE

I. INTRODUCTION

Under the authority of § 5(e) of the Toxic Substances Control Act ("TSCA") (15 U.S.C. 2604(e)), the Environmental Protection Agency ("EPA" or "the Agency") issues the attached Order, regarding premanufacture notice ("PMN") P-09-85 for the chemical substance [

] ("the PMN substance") submitted by Champion Technologies, Inc. ("the Company"), to take effect upon expiration of the PMN review period. The Company submitted the PMN to EPA pursuant to § 5(a)(1) of TSCA and 40 CFR Part 720.

Under § 15 of TSCA, it is unlawful for any person to fail or refuse to comply with any provision of § 5 or any order issued under § 5. Violators may be subject to various penalties and to both criminal and civil liability pursuant to § 16, and to specific enforcement and seizure pursuant to § 17. In addition, chemical substances subject to an Order issued under § 5 of TSCA, such as this one, are subject to the § 12(b) export notice requirement.

II. SUMMARY OF TERMS OF THE ORDER

The Consent Order for this PMN substance requires the Company to maintain certain records and submit to EPA certain toxicity testing at least 14 weeks before manufacturing or importing a total of [ ], [ ], and [ ] of the PMN substance or within [ ], [ ], and [ ] years after commencing manufacture of the PMN substance for domestic use, whichever of the respective volumes or time limits come later.

III. CONTENTS OF PMN

Confidential Business Information Claims (Bracketed in the Preamble and Order): Chemical identity information; production, import, and use information; process and operation descriptions; formulation percentages; physical-chemical property information.

Chemical Identity:

Specific: [ ]

Generic: 1,3-propane diaminium-2-substituted, -hexaalkyl-, di halide.

Use:

Specific: [ ]

Generic: Formation stabilizer and drilling mud additive.

Maximum 12-Month Production Volume: [ ].

Test Data Submitted with PMN:

Results from the three limit tests were considered valid.

Acute Daphnia – 48-hr EC50 = 186 mg/l.

Acute Fish – 96-hr LC50 = >1,000 mg/l. No effects were detected (mortality, behavior, morphology, or growth) in the acute fish test at the highest concentration tested of 1,000 mg/L.

Algae – 72-hr ErC50 = 1,505 mg/l.

IV. EPA'S ASSESSMENT OF EXPOSURE

The following are EPA's predictions regarding the probable human exposure and environmental release of the PMN substance, based on the information currently available to the Agency.

Exposure and Environmental Release Summary:

	Manufacture	**Use 1 – [ ]**	**Use 2 – [ ]**	**Exposure Criteria Met**
# Sites	1	[ ]	[ ]	
Releases (days/year)	[ ]	[ ]	[ ]	
Post Treatment Release to Water (kg/day)	[ ]	[ ]	[ ]	
Surface Water Concentration (ppb)	3,495	1,038	462	
Drinking Water Exposure (mg//kg/day)	0.17	0.05	0.02	> 0.003
Surface Water Release After Treatment (kg/yr)	2,250	1,410	2,060	> 1,000

V. EPA'S CONCLUSIONS OF LAW

The following findings constitute the basis of the Consent Order:

(a) EPA is unable to determine the potential for neurotoxicity (based on the quaternary amines) from exposure of humans to the PMN substance and for chronic aquatic toxicity from exposure of aquatic organisms to the PMN substance. EPA therefore concludes, pursuant to § 5(e)(1)(A)(i) of TSCA, that the information available to the Agency is insufficient to permit a reasoned evaluation of the fate, human health, and environmental effects of the PMN substance.

(b) In light of the estimated production volume of, environmental release of, and human exposure to the PMN substance, EPA has further concluded, pursuant to § 5(e)(1)(A)(ii)(II) of TSCA, that the PMN substance will be produced in substantial quantities and may reasonably be anticipated to enter the environment in substantial quantities, and there may be significant (or substantial) human exposure to the substance.

VI. INFORMATION REQUIRED TO EVALUATE HUMAN HEALTH AND ENVIRONMENTAL EFFECTS

Triggered Testing. The Order prohibits the Company from exceeding specified production volumes or time periods after commencing manufacture of the PMN substance for domestic use unless the Company submits the information described in the Testing section of this Order in accordance with the conditions specified in the Testing section.

CONSENT ORDER

I. SCOPE OF APPLICABILITY AND EXEMPTIONS

(a) Scope. The requirements of this Order apply to all commercial manufacturing, processing, distribution in commerce, use and disposal of the chemical substance [ ] (P-09-85)("the PMN substance") in the United States by Champion Technologies, Inc. ("the Company"), except to the extent that those activities are exempted by paragraph (b).

(b) Exemptions. Manufacturing, processing, distribution in commerce, use and disposal of the PMN substance is exempt from the requirements of this Order (except the requirements in the Recordkeeping and Successor Liability Upon Transfer Of Consent Order sections) only to the extent that (1) these activities are conducted in full compliance with all applicable requirements of the following exemptions, and (2) such compliance is documented by appropriate recordkeeping as required in the Recordkeeping section of this Order.

(1) Completely Reacted (Cured). The requirements of this Order do not apply to quantities of the PMN substance after they have been completely reacted (cured).

(2) De Minimis Concentrations. The requirements of this Order do not apply to quantities of the PMN substance that are (1) present in the work area only as a mixture and (2) at a concentration not to exceed 1.0 percent by weight or volume (0.1 percent by weight or volume if the PMN substance is identified as a potential carcinogen in paragraph (f) of the Hazard Communication Program section of this Order). This exemption is not available if the Company has reason to believe that, during intended activities, the PMN substance in the mixture may be reconcentrated above the 1.0 or 0.1 percent level, whichever applies. If his Order contains New Chemical Exposure Limits provisions or Release to Water provisions that, respectively, specify a NCEL concentration ("TWA") or in-stream concentration ("N") less than the de minimis concentration specified here, then this de minimis exemption does not apply to those provisions.

(3) Export. Until the Company begins commercial manufacture of the PMN substance for use in the United States, the requirements of this Order do not apply to manufacture, processing or distribution in commerce of the PMN substance solely for export in accordance with TSCA §12(a) and (b), 40 CFR 720.3(s) and 40 CFR Part 707. However, once the Company begins to manufacture the PMN substance for use in the United States, no further activity by the Company involving the PMN substance is exempt as "solely for export," even if some amount of the PMN substance is later exported. At that point, the requirements of this Order apply to all activities associated with the PMN substance while in the territory of the United States. Prior to leaving U.S. territory, even those quantities or batches of the PMN substance that are destined

for export are subject to terms of the Order, and count towards any production volume test triggers in the Testing section of this Order.

(4) Research & Development ("R&D"). The requirements of this Order do not apply to manufacturing, processing, distribution in commerce, use and disposal of the PMN substance in small quantities solely for research and development in accordance with TSCA §5(h)(3), 40 CFR 720.3(cc), and 40 CFR 720.36. The requirements of this Order also do not apply to manufacturing, processing, distribution in commerce, use and disposal of the PMN substance when manufactured solely for non-commercial research and development per 40 CFR 720.30(i) and TSCA §5(i).

(5) Byproducts. The requirements of this Order do not apply to the PMN substance when it is produced, without separate commercial intent, only as a "byproduct" as defined at 40 CFR 720.3(d) and in compliance with 40 CFR 720.30(g).

(6) No Separate Commercial Purpose. The requirements of this Order do not apply to the PMN substance when it is manufactured, pursuant to any of the exemptions in 40 CFR 720.30(h), with no commercial purpose separate from the substance, mixture, or article of which it is a part.

(7) Imported Articles. The requirements of this Order do not apply to the PMN substance when it is imported as part of an "article" as defined at 40 CFR 720.3(c) and in compliance with 40 CFR 720.22(b)(1).

(c) Automatic Sunset. If the Company has obtained for the PMN substance a Test Market Exemption ("TME") under TSCA §5(h)(1) and 40 CFR 720.38 or a Low Volume Exemption ("LVE") or Low Release and Exposure Exemption ("LoREX") under TSCA §5(h)(4) and 40

CFR 723.50(c)(1) and (2) respectively, any such exemption is automatically rendered null and void as of the effective date of this Consent Order.

II. TERMS OF MANUFACTURE, IMPORT, PROCESSING, DISTRIBUTION IN COMMERCE, USE, AND DISPOSAL PENDING SUBMISSION AND EVALUATION OF INFORMATION

PROHIBITION

The Company is prohibited from manufacturing the PMN substance in the United States, for any nonexempt commercial purpose, pending the development of information necessary for a reasoned evaluation of the fate, human health, and environmental effects (including biodegradability, neurotoxicity, and chronic aquatic toxicity) of the substance, and the completion of EPA's review of, and regulatory action based on, that information, except in accordance with the conditions described in this Order.

MANUFACTURING

(a)(1) Prohibition. The Company shall not cause, encourage, or suggest the manufacture or import of the PMN substance by any other person.

(2) Sunset Following SNUR. Subparagraph (a)(1) shall expire 75 days after promulgation of a final significant new use rule ("SNUR") governing the PMN substance under section 5(a)(2) of TSCA unless the Company is notified on or before that day of an action in a Federal Court seeking judicial review of the SNUR. If the Company is so notified, subparagraph (a)(1) shall not expire until EPA notifies the Company in writing that all Federal Court actions involving the SNUR have been resolved and the validity of the SNUR affirmed.

(3) Notice of SNUR. When EPA promulgates a final SNUR for the PMN substance and subparagraph (a)(1) expires in accordance with subparagraph (a)(2), the Company shall notify each person whom it causes, encourages or suggests to manufacture or import the PMN substance of the existence of the SNUR.

TESTING

(a) Section 8(e) Reporting. Reports of information on the PMN substance which reasonably supports the conclusion that the PMN substance presents a substantial risk of injury to health or the environment, which is required to be reported under EPA's section 8(e) policy statement at 43 Federal Register 11110 (March 16, 1978) as amended at 52 Federal Register 20083 (May 29, 1987), shall reference the appropriate PMN identification number for this substance and contain a statement that the substance is subject to this Consent Order. Additional information regarding section 8(e) reporting requirements can be found in the reporting guide referenced at 56 Federal Register 28458 (June 20, 1991).

(b) Notice of Study Scheduling. The Company shall notify, in writing, the EPA Laboratory Data Integrity Branch (2225A), Office of Enforcement and Compliance Assurance, U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, N.W., Washington, D.C. 20460, of the following information within 10 days of scheduling any study required to be performed pursuant to this Order, or within 15 days after the effective date of this Order, whichever is later:

(1) The date when the study is scheduled to commence;

(2) The name and address of the laboratory which will conduct the study;

(3) The name and telephone number of a person at the Company or the laboratory whom EPA may contact regarding the study; and,

(4) The appropriate PMN identification number for each substance and a statement that the substance is subject to this Consent Order.

(c) Good Laboratory Practice Standards and Test Protocols. Each study required to be performed pursuant to this Order must be conducted according to TSCA Good Laboratory Practice Standards at 40 CFR Part 792 and using methodologies generally accepted in the relevant scientific community at the time the study is initiated. Before starting to conduct any study, the Company must obtain approval of test protocols from EPA by submitting written protocols. EPA will respond to the Company within 4 weeks of receiving the written protocols. Published test guidelines specified in paragraph (d) provide general guidance for development of test protocols, but are not themselves acceptable protocols. Approval of the test protocol does not mean pre-acceptance of test results.

(d) Triggered Testing Requirements. The Company is prohibited from manufacturing or importing the PMN substance beyond the following aggregate manufacture and import volumes or time periods after commencing manufacture of the PMN substance for domestic use ("the production or time limits"), unless the Company conducts the following studies on the PMN substance and submits all final reports and underlying data in accordance with the conditions specified in this Testing section.

Production Limit	Study	Guideline
[ ] after commencement, whichever comes later	Ready Biodegradability	OPPTS 835.3100
	Acute Oral Toxicity Study	OPPTS 870.1100 or OECD 425
	Bacterial Reverse Mutation Test	OPPTS 870.5100
[ ] after commencement, whichever comes later	Combined Repeated Dose Toxicity Study with the Reproductive/Developmental Toxicity Screening Test	OPPTS 870.3650 or OECD 422
[ ] after commencement, whichever comes later	Fish Early-Life Stage Toxicity Test	OPPTS 850.1400
	Daphnid Chronic Toxicity Test	OPPTS 850.1300

Any test data submitted shall include protocols, raw data, and results. The Company will also provide a certificate of analysis for the test article that gives the percent purity of the PMN substance as well as levels of all impurities in the test article. The fish and daphnid tests shall use flow-through methods and measured concentrations with analytical monitoring.

(e) Test Reports. The Company shall: (1) conduct each study in good faith, with due care, and in a scientifically valid manner; (2) promptly furnish to EPA the results of any interim phase of each study; and (3) submit, in triplicate (with an additional sanitized copy, if confidential business information is involved), the final report of each study and all underlying data ("the report and data") to EPA no later than 14 weeks prior to exceeding the applicable production or time limit. The final report shall contain the contents specified in 40 CFR 792.185. Underlying data shall be submitted to EPA in accordance with the applicable "Reporting," "Data and Reporting," and "Test Report" subparagraphs in the applicable test guidelines. However, for

purposes of this Consent Order, the word "should" in those subparagraphs shall be interpreted to mean "shall" to make clear that the submission of such information is mandatory. EPA will require the submission of raw data such as slides and laboratory notebooks only if EPA finds, on the basis of professional judgment, that an adequate evaluation of the study cannot take place in the absence of these items.

(f) Testing Waivers. The Company is not required to conduct a study specified in paragraph (d) of this Testing section if notified in writing by EPA that it is unnecessary to conduct that study.

(g) Equivocal Data. If EPA finds that the data generated by a study are scientifically equivocal, the Company may continue to manufacture and import the PMN substance beyond the applicable production limit. To seek relief from any other restrictions of this Order, the Company may make a second attempt to obtain unequivocal data by reconducting the study under the conditions specified in paragraphs (b), (c), and (e)(1) and (2). The testing requirements may be modified, as necessary to permit a reasoned evaluation of the risks presented by the PMN substance, only by mutual consent of EPA and the Company.

(h) EPA Determination of Invalid Data.

(1) Except as described in subparagraph (h)(2), if, within 6 weeks of EPA's receipt of a test report and data, the Company receives written notice that EPA finds that the data generated by a study are scientifically invalid, the Company is prohibited from further manufacture and import of the PMN substance beyond the applicable production or time limit.

(2) The Company may continue to manufacture and import the PMN substance beyond the applicable production or time limit only if so notified, in writing, by EPA in response to the Company's compliance with either of the following subparagraphs (h)(2)(i) or (h)(2)(ii).

(i) The Company may reconduct the study in compliance with paragraphs (b), (c), and (e)(1) and (2). If there is sufficient time to reconduct the study and submit the report and data to EPA at least 14 weeks before exceeding the production or time limit as required by subparagraph (e)(3), the Company shall comply with subparagraph (e)(3). If there is insufficient time for the Company to comply with subparagraph (e)(3), the Company may exceed the production or time limit and shall submit the report and data in triplicate to EPA within a reasonable period of time, all as specified by EPA in the notice described in subparagraph (h)(1). EPA will respond to the Company, in writing, within 6 weeks of receiving the Company's report and data.

(ii) The Company may, within 4 weeks of receiving from EPA the notice described in subparagraph (h)(1), submit to EPA a written report refuting EPA's finding. EPA will respond to the Company, in writing, within 4 weeks of receiving the Company's report.

(i) Company Determination of Invalid Data.

(1) Except as described in subparagraph (i)(2), if the Company becomes aware that circumstances clearly beyond the control of the Company or laboratory will prevent, or have prevented, development of scientifically valid data under the conditions specified in paragraphs (c) and (e), the Company remains prohibited from further manufacture and import of the PMN substance beyond the applicable production or time limit.

(2) The Company may submit to EPA, within 2 weeks of first becoming aware of such circumstances, a written statement explaining why circumstances clearly beyond the control of the Company or laboratory will cause or have caused development of scientifically invalid data. EPA will notify the Company of its response, in writing, within 4 weeks of receiving the Company's report. EPA's written response may either:

(i) allow the Company to continue to manufacture and import the PMN substance beyond the applicable production or time limit, or

(ii) require the Company to continue to conduct, or to reconduct, the study in compliance with paragraphs (b), (c), and (e)(1) and (2). If there is sufficient time to conduct or reconduct the study and submit the report and data to EPA at least 14 weeks before exceeding the production or time limit as required by subparagraph (e)(3), the Company shall comply with subparagraph (e)(3). If there is insufficient time for the Company to comply with subparagraph (e)(3), the Company may exceed the production or time limit and shall submit the report and data in triplicate to EPA within a reasonable period of time, all as specified by EPA in the notice described in subparagraph (i)(2). EPA will respond to the Company, in writing, within 6 weeks of receiving the Company's report and data, as to whether the Company may continue to manufacture and import beyond the applicable production or time limit.

(j) Unreasonable Risk.

(1) EPA may notify the Company in writing that EPA finds that the data generated by a study are scientifically valid and unequivocal and indicate that, despite the terms of this Order, the PMN substance will or may present an unreasonable risk of injury to human health or the environment. EPA's notice may specify that the Company undertake certain actions concerning

further testing, manufacture, import, processing, distribution, use and/or disposal of the PMN substance to mitigate exposures to or to better characterize the risks presented by the PMN substance. Within 2 weeks from receipt of such a notice, the Company must cease all manufacture, import, processing, distribution, use and disposal of the PMN substance, unless either:

(2) within 2 weeks from receipt of the notice described in subparagraph (j)(1), the Company complies with such requirements as EPA's notice specifies; or

(3) within 4 weeks from receipt of the notice described in subparagraph (j)(1), the Company submits to EPA a written report refuting EPA's finding and/or the appropriateness of any additional requirements imposed by EPA. The Company may continue to manufacture, import, process, distribute, use and dispose of the PMN substance in accordance with the terms of this Order pending EPA's response to the Company's written report. EPA will respond to the Company, in writing, within 4 weeks of receiving the Company's report. Within 2 weeks of receipt of EPA's written response, the Company shall comply with any requirements imposed by EPA's response or cease all manufacture, import, processing, distribution, use and disposal of the PMN substance.

(k) Other Requirements. Regardless of the satisfaction of any other conditions in this Testing section, the Company must continue to obey all the terms of this Consent Order until otherwise notified in writing by EPA. The Company may, based upon submitted test data or other relevant information, petition EPA to modify or revoke provisions of this Consent Order pursuant to Part VI. of this Consent Order.

RISK NOTIFICATION

(a) If as a result of the test data required under the terms of this Order, the Company becomes aware that the PMN substance may present a risk of injury to the human health or environment (or is so notified by EPA), the Company must incorporate this new information, and any information on methods for protecting against such risk, into a Material Safety Data Sheet ("MSDS"), as described in 40 CFR section 721.72(c), within 90 days from the time the Company becomes aware of the new information. If the PMN substance is not being manufactured, imported, processed, or used in the Company's workplace, the Company must add the new information to an MSDS before the PMN substance is reintroduced into the workplace.

(b) The Company must ensure that persons who will receive the PMN substance from the Company, or who have received the PMN substance from the Company within 5 years from the date the Company becomes aware of the new information described in paragraph (a) of this section, are provided an MSDS containing the information required under paragraph (a) within 90 days from the time the Company becomes aware of the new information.

III. RECORDKEEPING

(a) Records. The Company shall maintain the following records until 5 years after the date they are created and shall make them available for inspection and copying by EPA in accordance with section 11 of TSCA:

(1) Exemptions. Records documenting that the PMN substance did in fact qualify for any one or more of the exemptions described in Section I, Paragraph (b) of this Order. Such records must satisfy all the statutory and regulatory recordkeeping requirements applicable to the

exemption being claimed by the Company. Any amounts or batches of the PMN substance eligible for the Export exemption in Section I, Paragraph (b)(1) of this Order are exempt from all the requirements in this Recordkeeping section, if the Company maintains, for 5 years from the date of their creation, copies of the export label and export notice to EPA, required by TSCA sections 12(a)(1)(B) and 12(b), respectively. Any amounts or batches of the PMN substance eligible for the Research and Development exemption in Section I, Paragraph (b)(2) of this Order, are exempt from all the requirements in this Recordkeeping section, if the Company maintains, for 5 years from the date of their creation, the records required by 40 CFR 720.78(b). For any amounts or batches of the PMN substance claimed to be eligible for any other exemption described in Section I, Paragraph (b) of this Order, the Company shall keep records demonstrating qualification for that exemption as well as the records specified in paragraphs (2) and (3) below, but is exempt from the other recordkeeping requirements in this Recordkeeping section;

(2) Records documenting the manufacture and importation volume of the PMN substance and the corresponding dates of manufacture and import;

(3) Records documenting the names and addresses (including shipment destination address, if different) of all persons outside the site of manufacture or import to whom the Company directly sells or transfers the PMN substance, the date of each sale or transfer, and the quantity of the substance sold or transferred on such date;

(4) Records documenting the address of all sites of manufacture, import, processing, and use;

(5) Copies of Material Safety Data Sheets required by the Risk Notification section of this Order;

(6) Copies of any Transfer Documents and notices required by the Successor Liability section of this Order, if applicable; and,

(7) The Company shall keep a copy of this Order at each of its sites where the PMN substance is manufactured, imported, processed, or used.

(b) Applicability. The provisions of this Recordkeeping Section are applicable only to activities of the Company and its Contract Manufacturer, if applicable, and not to activities of the Company's customers.

(c) OMB Control Number. Under the Paperwork Reduction Act and its regulations at 5 CFR Part 1320, particularly 5 CFR 1320.5(b), the Company is not required to respond to this "collection of information" unless this Order displays a currently valid control number from the Office of Management and Budget ("OMB"), and EPA so informs the Company. The "collection of information" required in this TSCA §5(e) Consent Order has been approved under currently valid **OMB Control Number 2070-0012.**

IV. REQUESTS FOR PRE-INSPECTION INFORMATION

(a) EPA's Request for Information. Pursuant to section 11 of TSCA and 40 CFR 720.122, EPA may occasionally conduct on-site compliance inspections of Company facilities and conveyances associated with the PMN substance. To facilitate such inspections, EPA personnel may contact the Company in advance to request information pertinent to the scheduling and conduct of such inspections. Such requests may be written or oral. The types of information that EPA may request include, but are not limited to, the following:

(i) Expected dates and times when the PMN substance will be in production within the subsequent 12 months;

(ii) Current workshift schedules for workers who are involved in activities associated with the PMN substance and may reasonably be exposed to the PMN substance;

(iii) Current job titles or categories for workers who are involved in activities associated with the PMN substance and may reasonably be exposed to the PMN substance;

(iv) Existing exposure monitoring data for workers who are involved in activities associated with the PMN substance and may reasonably be exposed to the PMN substance;

(v) Records required by the Recordkeeping section of this Order; and/or

(vi) Any other information reasonably related to determining compliance with this Order or conducting an inspection for that purpose.

(b) Company's Response. The Company shall respond to such requests within a reasonable period of time, but in no event later than 30 days after receiving EPA's request. When requested in writing by EPA, the Company's response shall be in writing. To the extent the information is known to or reasonably ascertainable to the Company at the time of the request, the Company's response shall demonstrate a good faith effort to provide reasonably accurate and detailed answers to all of EPA's requests.

(c) Confidential Business Information. Any Confidential Business Information ("CBI") that the Company submits to EPA pursuant to paragraph (b) shall be protected in accordance with §14 of TSCA and 40 CFR Part 2.

V. SUCCESSOR LIABILITY UPON TRANSFER OF CONSENT ORDER

(a) Scope. This section sets forth the procedures by which the Company's rights and obligations under this Order may be transferred when the Company transfers its interests in the PMN substance, including the right to manufacture the PMN substance, to another person outside the Company (the "Successor in Interest").

(b) Relation of Transfer Date to Notice of Commencement ("NOC").

(1) Before NOC. If the transfer from the Company to the Successor in Interest is effective before EPA receives a notice of commencement of manufacture or import ("NOC") for the PMN substance from the Company pursuant to 40 CFR 720.102, the Successor in Interest must submit a new PMN to EPA and comply fully with Section 5(a)(1) of TSCA and 40 CFR part 720 before commencing manufacture or import of the PMN substance.

(2) After NOC. If the transfer from the Company to the Successor in Interest is effective after EPA receives a NOC, the Successor in Interest shall comply with the terms of this Order and shall not be required to submit a new PMN to EPA.

(c) Definitions. The following definitions apply to this Successor Liability section of the Order:

(1) "Successor in Interest" means a person outside the Company who has acquired the Company's full interest in the rights to manufacture the PMN substance, including all ownership rights and legal liabilities, through a transfer document signed by the Company, as transferor, and the Successor in Interest, as transferee. The term excludes persons who acquire less than the full interest of the Company in the PMN substance, such as a licensee who has acquired a limited license to the patent or manufacturing rights associated with the PMN substance. A Successor in

Interest must be incorporated, licensed, or doing business in the United States in accordance with 40 CFR 720.22(a)(3).

(2) "Transfer Document" means the legal instrument(s) used to convey the interests in the PMN substance, including the right to manufacture the PMN substance, from the Company to the Successor in Interest.

(d) Notices.

(1) Notice to Successor in Interest. On or before the effective date of the transfer, the Company shall provide to the Successor in Interest, by registered mail, a copy of the Consent Order and the "Notice of Transfer" document which is incorporated by reference as Attachment B to this Order.

(2) Notice to EPA. Within 10 business days of the effective date of the transfer, the Company shall, by registered mail, submit the fully executed Notice of Transfer document to: U.S. Environmental Protection Agency, New Chemicals Branch (7405), 1200 Pennsylvania Avenue, N.W., Washington, D.C. 20460.

(3) Transfer Document. Copies of the Transfer Document must be maintained by the Successor in Interest at its principal place of business, and at all sites where the PMN substance is manufactured or imported. Copies of the Transfer Document must also be made available for inspection pursuant to Section 11 of TSCA, must state the effective date of transfer, and must contain provisions which expressly transfer liability for the PMN substance under the terms of this Order from the Company to the Successor in Interest.

(e) Liability.

(1) The Company shall be liable for compliance with the requirements of this Order until the effective date of the transfer described above.

(2) The Successor in Interest shall be liable for compliance with the requirements of this Order effective as of the date of transfer.

(3) Nothing in this section shall be construed to prohibit the Agency from taking enforcement action against the Company after the effective date of the transfer for actions taken, or omissions made, during the time in which the Company manufactured, processed, used, distributed in commerce, or disposed of the PMN substance pursuant to the terms of this Consent Order.

(f) Obligations to Submit Test Data under Consent Order. If paragraph (d) of the Testing section of this Consent Order requires the Company to submit test data to EPA at a specified production volume or time period ("test trigger"), the aggregate volume of the PMN substance manufactured and imported by the Company up to the date of transfer, or the aggregate time period after commencing manufacture of the PMN substance for domestic use, shall count towards the test trigger applicable to the Successor in Interest.

VI. MODIFICATION AND REVOCATION OF CONSENT ORDER

The Company may petition EPA at any time, based upon new information on the health or environmental effects of, or human exposure to, or environmental releases of the PMN substance, to modify or revoke substantive provisions of this Order. The exposures and risks identified by EPA during its review of the PMN substance and the information EPA determined

to be necessary to evaluate those exposures and risks are described in the preamble to this Order. However, in determining whether to amend or revoke this Order, EPA will consider all relevant information available at the time the Agency makes that determination, including, where appropriate, any reassessment of the test data or other information that supports the findings in this Order, an examination of new test data or other information or analysis, and any other relevant information.

EPA will issue a modification or revocation if EPA determines that the activities proposed therein will not present an unreasonable risk of injury to health or the environment and will not result in significant or substantial human exposure or substantial environmental release in the absence of data sufficient to permit a reasoned evaluation of the health or environmental effects of the PMN substance.

In addition, the Company may petition EPA at any time to make other modifications to the language of this Order. EPA will issue such a modification if EPA determines that the modification is useful, appropriate, and consistent with the structure and intent of this Order as issued.

VII. EFFECT OF CONSENT ORDER

By consenting to the entry of this Order, the Company waives its rights to file objections to this Order pursuant to section 5(e)(1)(C) of TSCA, to receive service of this Order no later than 45 days before the end of the review period pursuant to section 5(e)(1)(B) of TSCA, and to challenge the validity of this Order in any subsequent action. Consenting to the entry of this Order, and agreeing to be bound by its terms, do not constitute an admission by the Company as to the facts or conclusions underlying the Agency's determinations in this proceeding. This waiver does not affect any other rights that the Company may have under TSCA.

5/1/09
Date

Jim Willis, Director
Chemical Control Division
Office of Pollution Prevention and Toxics

7 May 2009
Date

Kevin D Dake
Name:

Title: Manager, Product Stewardship - Americas

Company: Champion Technologies, Inc.

ATTACHMENT A

DEFINITIONS

[Note: The attached Order may not contain some of the terms defined below.]

"Chemical name" means the scientific designation of a chemical substance in accordance with the nomenclature system developed by the International Union of Pure and Applied Chemistry or the Chemical Abstracts Service's rules of nomenclature, or a name which will clearly identify a chemical substance for the purpose of conducting a hazard evaluation.

"Chemical protective clothing" means items of clothing that provide a protective barrier to prevent dermal contact with chemical substances of concern. Examples can include, but are not limited to: full body protective clothing, boots, coveralls, gloves, jackets, and pants.

"Company" means the person or persons subject to this Order.

"Commercial use" means the use of a chemical substance or any mixture containing the chemical substance in a commercial enterprise providing saleable goods or a service to consumers (e.g., a commercial dry cleaning establishment or painting contractor).

"Common name" means any designation or identification such as code name, code number, trade name, brand name, or generic chemical name used to identify a chemical substance other than by its chemical name.

"Consumer" means a private individual who uses a chemical substance or any product containing the chemical substance in or around a permanent or temporary household or residence, during recreation, or for any personal use or enjoyment.

"Consumer product" means a chemical substance that is directly, or as part of a mixture, sold or made available to consumers for their use in or around a permanent or temporary household or residence, in or around a school, or in recreation.

"Container" means any bag, barrel, bottle, box, can, cylinder, drum, reaction vessel, storage tank, or the like that contains a hazardous chemical. For purposes of this section, pipes or piping systems, and engines, fuel tanks, or other operating systems in a vehicle, are not considered to be containers.

"Contract Manufacturer" means a person, outside the Company, who is authorized to manufacture and import the PMN substance under the conditions specified in Part II. of this Consent Order and in the Consent Order for Contract Manufacturer.

"Identity" means any chemical or common name used to identify a chemical substance or a mixture containing that substance.

"Immediate use." A chemical substance is for the "immediate use" of a person if it is under the control of, and used only by, the person who transferred it from a labeled container and will only be used by that person within the work shift in which it is transferred from the labeled container.

"Impervious." Chemical protective clothing is "impervious" to a chemical substance if the substance causes no chemical or mechanical degradation, permeation, or penetration of the chemical protective clothing under the conditions of, and the duration of, exposure.

"Manufacturing stream" means all reasonably anticipated transfer, flow, or disposal of a chemical substance, regardless of physical state or concentration, through all intended operations of manufacture, including the cleaning of equipment.

"MSDS" means material safety data sheet, the written listing of data for the chemical substance.

"NIOSH" means the National Institute for Occupational Safety and Health of the U.S. Department of Health and Human Services.

"Non-enclosed process" means any equipment system (such as an open-top reactor, storage tank, or mixing vessel) in which a chemical substance is manufactured, processed, or otherwise used where significant direct contact of the bulk chemical substance and the workplace air may occur.

"Non-industrial use" means use other than at a facility where chemical substances or mixtures are manufactured, imported, or processed.

"PMN substance" means the chemical substance described in the Premanufacture notice submitted by the Company relevant to this Order.

"Personal protective equipment" means any chemical protective clothing or device placed on the body to prevent contact with, and exposure to, an identified chemical substance or substances in the work area. Examples include, but are not limited to, chemical protective clothing, aprons, hoods, chemical goggles, face splash shields, or equivalent eye protection, and various types of respirators. Barrier creams are not included in this definition.

"Process stream" means all reasonably anticipated transfer, flow, or disposal of a chemical substance, regardless of physical state or concentration, through all intended operations of processing, including the cleaning of equipment.

"Scientifically invalid" means any significant departure from the EPA-approved protocol or the Good Laboratory Practice Standards at 40 CFR Part 792 without prior or subsequent Agency approval that prevents a reasoned evaluation of the health or environmental effects of the PMN substance.

"Scientifically equivocal data" means data which, although developed in apparent conformity with the Good Laboratory Practice Standards and EPA-approved protocols, are inconclusive, internally inconsistent, or otherwise insufficient to permit a reasoned evaluation of the potential risk of injury to human health or the environment of the PMN substance.

"Sealed container" means a closed container that is physically and chemically suitable for long-term containment of the PMN substance, and from which there will be no human exposure to, nor environmental release of, the PMN substance during transport and storage.

"Use stream" means all reasonably anticipated transfer, flow, or disposal of a chemical substance, regardless of physical state or concentration, through all intended operations of industrial, commercial, or consumer use.

"Waters of the United States" has the meaning set forth in 40 CFR 122.2.

"Work area" means a room or defined space in a workplace where the PMN substance is manufactured, processed, or used and where employees are present.

"Workplace" means an establishment at one geographic location containing one or more work areas.

ATTACHMENT B

NOTICE OF TRANSFER
OF
TOXIC SUBSTANCES CONTROL ACT
SECTION 5(e) CONSENT ORDER

Champion Technologies, Inc.	P-09-85
Company (Transferor)	PMN Number

1. Transfer of Manufacture Rights. Effective on _____, the Company did sell or otherwise transfer to _____, ("Successor in Interest") the rights and liabilities associated with manufacture of the above-referenced chemical substance, which was the subject of a premanufacture notice ("PMN") and is governed by a Consent Order issued by the U.S. Environmental Protection Agency ("EPA") under the authority of §5(e) of the Toxic Substances Control Act ("TSCA," 15 U.S.C. §2604(e)).

2. Assumption of Liability. The Successor in Interest hereby certifies that, as of the effective date of transfer, all actions or omissions governed by the applicable Consent Order limiting manufacture, processing, use, distribution in commerce and disposal of the PMN substance, shall be the responsibility of the Successor in Interest. Successor in Interest also certifies that it is incorporated, licensed, or doing business in the United States in accordance with 40 CFR 720.22(a)(3).

3. Confidential Business Information. The Successor in Interest hereby:

___ reasserts,

___ relinquishes, or

___ modifies

all Confidential Business Information ("CBI") claims made by the Company, pursuant to Section 14 of TSCA and 40 CFR part 2, for the PMN substance(s). Where "reasserts" or "relinquishes" is indicated, that designation shall be deemed to apply to all such claims. Where "modifies" is indicated, such modification shall be explained in detail in an attachment to this Notice of Transfer. Information which has been previously disclosed to the public (e.g., a chemical identity that was not claimed as CBI by the original submitter) would not subsequently be eligible for confidential treatment under this Notice of Transfer.

TOXIC SUBSTANCES CONTROL ACT
SECTION 5(e) CONSENT ORDER

NOTICE OF TRANSFER
(continued)

Champion Technologies, Inc.
Company (Transferor)

P-09-85
PMN Number

_____
Signature of Authorized Official

_____
Date

_____
Printed Name of Authorized Official

_____
Title of Authorized Official

_____
Successor in Interest

_____
Signature of Authorized Official

_____
Date

_____
Printed Name of Authorized Official

_____
Title of Authorized Official

_____
Address

_____
City, State, Zip Code

TOXIC SUBSTANCES CONTROL ACT
SECTION 5(e) CONSENT ORDER

NOTICE OF TRANSFER
(continued)

_____
Successor's Technical Contact

_____
Address

_____
City, State, Zip Code

_____
Phone