

Lima, 29 de febrero de 2024

**CARTA N° 075-2024-FSR CONSULTORES**

Señor:  
Blgo. Rafael Guillen Encinas  
Director  
Sub-Dirección de Insumos Agrícolas  
Ministerio de Desarrollo Agrario y Riego

**Asunto: SOLICITUD DE ADICIÓN DE NUEVA PLANTA DE FORMULACIÓN Y ORIGEN DEL PRODUCTO CONSENTO 450 SC (PQUA N° 224-SENASA)**

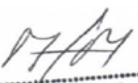
Estimado Señor Director:

Es grato dirigirnos a usted para solicitarle la modificación de registro del producto **CONSENTO 450 SC (PQUA N° 224-SENASA)** en cuanto a la planta de formulación y al origen del mismo.

Es preciso señalar que **los fabricantes de los ingredientes activos no se modificarán**, es por ello que se adjunta una declaración del nuevo formulador SARASWATI AGRO CHEMICALS (India) PVT. LTD. (**por encargo y siguiendo las especificaciones de Gowan Crop Protection Limited**), señalando que los ingredientes activos de grado técnico usado en la formulación del producto **CONSENTO 450 SC (PQUA N° 224-SENASA)** mantienen su mismo fabricante.

Sin otro particular, quedo de Ud.

Atentamente,



Manuel Martín Fasabi Espinar  
GERENTE GENERAL  
FSR CONSULTORES

Manuel Fasabi Espinar  
Representante Legal  
FSR CONSULTORES EIRL

Para cualquier consulta, por favor contactarse con:  
FSR CONSULTORES  
E-mail: [tramites@grupofsr.com](mailto:tramites@grupofsr.com)  
Teléfono: +51 920 534 766

ADICION DE FORMULADOR - ORIGEN  
**PRODUCTO CONSENTO 450 SC**  
PQUA N° 224 - SENASA

**IDENTIDAD**

**Nuevo formulador:**

Nombre del formulador : SARASWATI AGRO CHEMICALS (India) PVT. LTD.  
(Por encargo y siguiendo las especificaciones de  
GOWAN CROP PROTECTION LIMITED)  
Dirección : Lane No. 2, Phase-I, SIDCO Industrial Complex, Bari Brahmana,  
Distt. Samba, PIN: 181133, Jammu & Kashmir, India  
Origen : India  
Teléfono : 01923-221433, 221914

**Especificaciones técnicas del producto formulado**

**1. Contenido del ingrediente activo expresado en %, g/kg o g/L**

Fenamidone	75 g/L
Propamocarb HCL	375 g/L

**2. Contenido y naturaleza de los demás componentes incluidos en la formulación**

El certificado de análisis y de composición del PQUA CONSENTO 450 SC, ha sido ingresado como información CONFIDENCIAL el día 01.03.2024 (Expediente: 1273)

**3. Método o Métodos de análisis para determinación del contenido del ingrediente activo dentro del formulado**

**DETERMINACIÓN DE FENAMIDONA MEDIANTE CROMATOGRAFÍA LÍQUIDA DE ALTA RESOLUCIÓN**

**Ámbito de aplicación**

Este método se utiliza para la determinación cuantitativa del principio activo Fenamidona en Consent 450 SC.

**Principio**

La muestra se diluye en acetonitrilo y se analiza mediante cromatografía líquida de alta resolución con un detector UV. La muestra se cuantifica mediante calibración de patrón externo utilizando mediciones de área de pico y comparación con un patrón conocido de Fenamidona.

### Aparatos

- Cromatógrafo de líquidos de alta resolución: equipado con un detector UV y un auto muestreador.
- Software de cromatografía
- Nucleosil C18 de 3 mm x 125 mm x 5 µm (o equivalente)
- Balanza analítica
- Material de vidrio de laboratorio
- Baño ultrasónico

### Productos químicos y reactivos

- a. Acetonitrilo, grado HPLC o mejor
- b. Fenamidona, estándar analítico
- c. Agua desionizada ultrapura

### Procedimiento

#### *Preparación de los Estándares de Calibración*

Por duplicado, pese aproximadamente 25 mg de estándar analítico de Fenamidona en un matraz aforado de 100 mL. Llene el matraz hasta aproximadamente la mitad del volumen (~50 mL) con acetonitrilo y sonique la solución durante 10 minutos para asegurar la disolución. Deje que la solución vuelva a la temperatura ambiente y luego añada volumétricamente 10.0 mL de agua, lleve el matraz a volumen con acetonitrilo y mezcle bien.

#### *Preparación de la muestra*

Pesar aproximadamente 375 mg de Consentro 450 SC en un matraz aforado de 100 mL. Añadir volumétricamente 10,0 mL de agua, agitar suavemente y sonicar durante 5 minutos. Llenar el matraz hasta aproximadamente la mitad del volumen (~45 mL) con acetonitrilo y sonicar la solución durante 10 minutos. Dejar que la solución vuelva a la temperatura ambiente y, a continuación, llevar el matraz a su volumen con acetonitrilo y mezclar bien. Filtrar una alícuota a través de un filtro de jeringa de PTFE de 0,45 micras en un vial de automuestreador.

### Cálculo del factor de respuesta

$$RF = \frac{\text{Area (i.s)} \times \text{mg Active}}{\text{Area (Active)}}$$

Donde:

RF = Factor de respuesta para fenamidona

Área (i.s) = Área del pico para el estándar interno en la solución de calibración

mg Activo = Peso de Fenamidona en la solución de calibración

Área (activa) = Área del pico de Fenamidona en la solución de calibración

### Cálculo del % en peso de Fenamidona en la muestra

$$\text{Fenamidone} = \frac{\text{Area Sample} \times \text{Analytical Standard Weight} \times \text{Purity}}{\text{Area Analytical Standard} \times \text{Sample Weight}}$$

Donde:

Área sample = Área de Señal del cromatograma de Muestra de Consentido 450 SC.

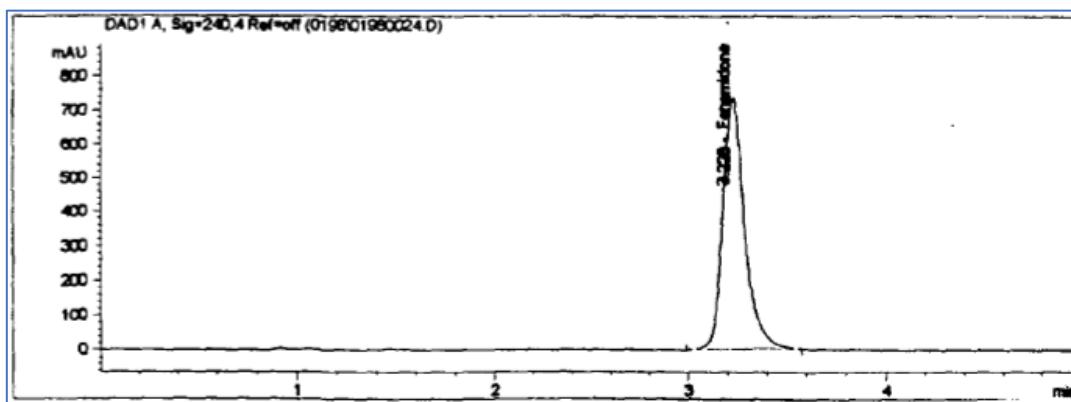
Area Analytical standard = Área de Señal del cromatograma del estándar de referencia.

Purity = Estándar Analítico.

Analytical standard weight = Peso del estándar analítico en mg.

Sample weight = Peso de la muestra del Consentido 450 SC en mg.

### Cromatograma típico



### Registro de revisiones

Version	Changes	Date	Author/ Editor	Reviewer
001	Original	10/19/2021	W. Grimm	C. Waid
002	Include revision log, typical chromatogram, and references	09/16/2022	A. Ortegón	M. Lopez
003	Add calculations	01/17/2023	A. Ortegón	M. Lopez

### Referencia:

DETERMINATION OF FENAMIDONE BY HIGH PERFORMANCE LIQUID CHROMATOGRAPHY.  
CONSENTO 450 SC. Gowan Company. AM\_FEA\_GWN12041\_1068\_003

### DETERMINACIÓN DE PROPAMOCARB HYDROCHLORIDE MEDIANTE CROMATOGRAFÍA LÍQUIDA DE ALTA RESOLUCIÓN

#### Ámbito de aplicación

Este método se utiliza para la determinación cuantitativa del ingrediente activo Propamocarb hydrochloride en Consentido 450 SC.

### Principio

La muestra se diluye en agua y se analiza mediante cromatografía líquida de alta resolución con un detector UV. La muestra se cuantifica mediante calibración de patrón externo utilizando mediciones de área de pico y comparación con un patrón conocido de Propamocarb HCl.

### Aparatos

- Cromatógrafo de líquidos de alta resolución: equipado con un detector UV y un auto muestreador.
- Software de cromatografía
- Xterra RP18 de 3 mm x 50 mm x 3,5 µm (o equivalente).
- Balanza analítica
- Material de vidrio de laboratorio
- Baño ultrasónico

### Productos químicos y reactivos

- Acetonitrilo, grado HPLC o mejor
- Clorhidrato de propamocarb, patrón analítico
- Agua, desionizada ultrapura
- Solución de amoníaco, pureza mínima del 28% grado reactivo

### Procedimiento

#### *Preparación de la fase móvil A*

Preparar una solución de amoníaco de 15 g/L en agua mili-q.

#### *Preparación de los Estándares de Calibración*

Por duplicado, pese aproximadamente 40 mg de estándar analítico Propamocarb HCl en un matraz aforado de 50 mL. Llene el matraz con agua hasta aproximadamente la mitad del volumen (~25 mL) y sonique la solución durante 15 minutos para asegurar la disolución. Deje que la solución vuelva a la temperatura ambiente y luego llene el matraz hasta el volumen con agua y mezcle bien.

#### *Preparación de la muestra*

Pesar aproximadamente 180 mg de Consentro 450 SC en un matraz aforado de 100 mL. Llene el matraz con agua hasta aproximadamente la mitad del volumen (~50 mL) y sonique la solución durante 15 minutos. Deje que la solución vuelva a la temperatura ambiente y luego lleve el matraz a volumen con agua y mezcle bien. Filtrar una alícuota a través de un filtro de jeringa de PTFE de 0,45 micras en un vial de automuestreador.

### Cálculo del factor de respuesta

$$RF = \frac{\text{Area (i.s)} \times \text{mg Active}}{\text{Area (Active)}}$$

Donde:

RF = Factor de respuesta para Propamocarb HCl

Área (i.s) = Área del pico para el estándar interno en la solución de calibración

mg Activo = Peso de Propamocarb HCl en la solución de calibración

Área (activa) = Área del pico de Propamocarb HCl en la solución de calibración

#### Cálculo del % en peso de Propamocarb HCl en la muestra

$$\text{Propamocarb HCl} = \frac{\text{Area Sample} \times \text{Analytical Standard Weight} \times \text{Purity}}{\text{Area Analytical Standard} \times \text{Sample Weight}}$$

Donde:

Área sample = Área de Señal del cromatograma de Muestra de Consentro 450 SC.

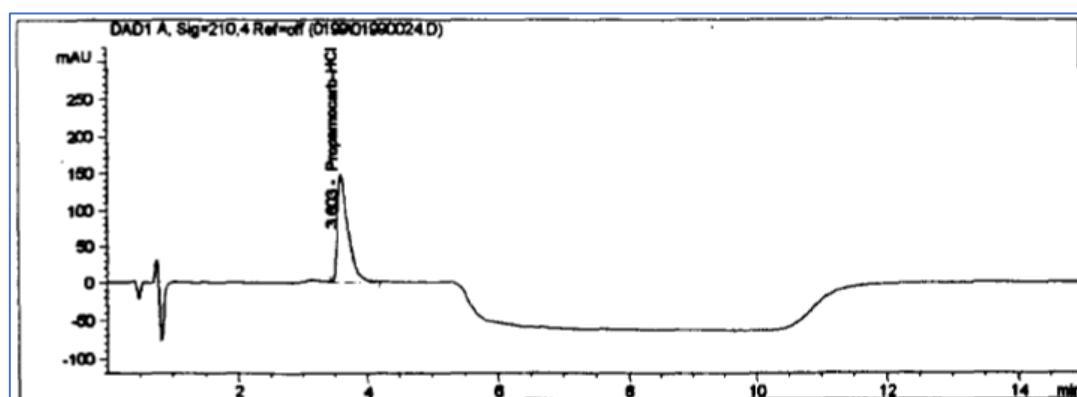
Analytical standard weight = Peso del estándar analítico en mg.

Purity = Estándar Analítico

Area Analytical standard = Área de Señal del cromatograma del estándar de referencia.

Sample weight = Peso de la muestra del Consentro 450 SC en mg.

#### Cromatograma típico



#### Registro de revisiones

Version	Changes	Date	Author/ Editor	Reviewer
001	Original	10/19/2021	W. Grimm	C. Waid
002	Include revision log and references	09/16/2022	A. Ortegón	M. Lopez
003	Add calculations	01/17/2023	A. Ortegón	M. Lopez

#### Referencia:

DETERMINATION OF PROPAMOCARB HYDROCHLORIDE BY HIGH PERFORMANCE LIQUID CHROMATOGRAPHY. CONSENTO 450 SC. Gowan Company.

AM\_PRA\_GWN12041\_1069\_003

#### **4. Estado físico**

Líquido

Referencia: Declaración de propiedades fisicoquímicas del formulador

#### **5. Color**

Blanco a beige ligero

Referencia: Declaración de propiedades fisicoquímicas del formulador

#### **6. Olor**

Ligero, característico

Referencia: Declaración de propiedades fisicoquímicas del formulador

#### **7. Estabilidad en el almacenamiento**

Se llevó a cabo una prueba acelerada de estabilidad durante el almacenamiento de la sustancia de ensayo en recipientes de almacenamiento. Se analizó el nivel de ingrediente activo de la sustancia de ensayo al inicio del ensayo. Se almacenaron dos submuestras de la sustancia de ensayo en una incubadora a 54 °C y se analizaron tras un periodo de almacenamiento de 14 días. Las concentraciones de principio activo se determinaron mediante cromatografía líquida de alta resolución (HPLC). Se realizaron pruebas de linealidad, precisión y exactitud para validar los métodos. En el análisis inicial y al final de la fase de almacenamiento de 14 días, se examinaron visualmente la sustancia de ensayo y los recipientes para detectar cualquier cambio físico y se registraron las observaciones. La sustancia de ensayo estuvo en contacto con los recipientes de almacenamiento durante todo el período de almacenamiento.

Se observó que la sustancia de ensayo conservaba su nivel de ingredientes activos cuando se almacenó a 54 °C durante 14 días; por lo tanto, se consideró que el producto era estable. Se observó separación de fases en la sustancia de ensayo el día 14, aunque volvió a ser una suspensión homogénea tras mezclarla. No se observaron cambios de peso significativos en los recipientes. No se observó corrosión de los recipientes de almacenamiento.

Se concluyó que CONSENTO 450 SC fue estable cuando se almacenaba a 54 °C durante 14 días, que corresponde a un tiempo de 24 meses.

Referencia:

Consento 450 SC: Accelerated Storage Stability and Corrosion Characteristics. Study Number 61576. Sponsor: Gowan Company

**8. Densidad**

1100 - 1140 g/L (1.10 - 1.14 g/ml) a 20 °C

Referencia: Declaración de propiedades fisicoquímicas del formulador

**9. Inflamabilidad****9.1 Para los líquidos, punto de inflamación**

No es inflamable

Referencia: Declaración de propiedades fisicoquímicas del formulador

**9.2 Para los sólidos aclarar si el producto es inflamable**

No aplica

**10. pH**

6.9 a 24 °C

CIPAC MT 75

Referencia: Declaración de propiedades fisicoquímicas del formulador

**11. Explosividad**

No explosivo

Referencia: Declaración de propiedades fisicoquímicas del formulador

**12. Humedad y humectabilidad**

No aplica

**13. Persistencia de espuma**

A una concentración de 1.4 g/L espuma

inicial → 0 ml

después de 14 días → 0 ml

A una concentración de 28 g/L espuma

inicial → 0 ml

después de 14 días → 0 ml

Referencia: Declaración de propiedades fisicoquímicas del formulador

**14. Suspensibilidad**

No aplica

**15. Análisis granulométrico en húmedo/tenor del polvo**

No aplica

**16. Análisis granulométrico en seco**

No aplica

**17. Estabilidad de la emulsión**

No aplica

**18. Corrosividad.**

No se conocen propiedades corrosivas

Referencia: Declaración de propiedades fisicoquímicas del formulador

**19. Incompatibilidad conocida con otros productos (fitosanitarios y fertilizantes)**

El producto es compatible con los plaguicidas de uso común

Referencia: Declaración de propiedades fisicoquímicas del formulador

**20. Densidad a 20°C en g/ml**

1.10 - 1.14 g/ml (1100 - 1140 g/L) a 20 °C

Referencia: Declaración de propiedades fisicoquímicas del formulador

**21. Punto de inflamación**

No aplica

**22. Viscosidad**

64 mm<sup>2</sup>/s (inicial)

Referencia: Declaración de propiedades fisicoquímicas del formulador

**23. Índice de sulfonación**

No aplica

**24. Dispersión**

No aplica

**25. Desprendimiento de gas**

No aplica

**26. Soltura o fluidez para polvos secos**

No aplica

**27. Índice de yodo e índice de saponificación**

No aplica

# CARGO

## SOLICITUD DE TRATAMIENTO CONFIDENCIAL DE INFORMACION TECNICA DE PLAGUICIDA USO AGRICOLA REGISTRADO

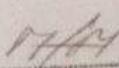
SR. DIRECTOR DE LA SUBDIRECCIÓN DE INSUMOS AGRÍCOLAS

PARTE I. INFORMACIÓN DE LA EMPRESA SOLICITANTE					
1	NOMBRE O RAZÓN SOCIAL	FSR CONSULTORES E.I.R.L.			2 R.U.C. N° 20600788753
3	DOMICILIO LEGAL	Av./Calle/Jr. Jr. Luis N. Saenz 348, Int. 101			
4	URBANIZACIÓN	5 DISTRITO		6 PROVINCIA LIMA	
7	DEPARTAMENTO	8 TELÉFONO	9 FAX	10 EMAIL	tramites@grupofsr.com
11	NOMBRE DEL REPRESENTANTE LEGAL	MANUEL MARTÍN FASABI ESPINAR			12 N° DNI: 40714570
13	ACTIVIDAD	14 N° DE REGISTRO 0046-MINAGRI-SENASA			
PARTE III. DE LA INFORMACION QUE SEA SOLICITADA COMO CONFIDENCIAL					
1	NOMBRE DEL PRODUCTO: CONSENTO® 450 SC				
2	LISTA Y DESCRIPCION DE LA INFORMACION A CONSIDERAR CONFIDENCIAL  CERTIFICADO DE COMPOSICIÓN DEL PRODUCTO FORMULADO CONSENTO® 450 SC CERTIFICADO DE ANÁLISIS DEL PRODUCTO FORMULADO CONSENTO® 450 SC				
ESTA SOLICITUD DE CONFIDENCIALIDAD PERTENECE AL TRAMITE DE ADICION DE FORMULADOR GESTIONADO EN FEBRERO DE 2024					
 <p>Ministerio de Desarrollo Agrario y Riego Servicio Nacional de Sanidad Agraria ATENCIÓN AL USUARIO  01 MAR 2024  Expediente: 1273</p>					

Adjuntar información según artículo 23 del Reglamento del Sistema Nacional de Plaguicidas de Uso Agrícola

Declaro bajo juramento que los datos consignados y adjuntados en la presente solicitud son verídicos y me someto a las sanciones de orden jurídico-técnico-administrativo por el incumplimiento, inexactitud o falsedad de lo declarado

Lima 29 de Febrero del 2024



Manuel Martín Fasabi Espinar  
GERENTE GENERAL  
FSR CONSULTORES

REPRESENTANTE LEGAL  
MANUEL MARTÍN FASABI ESPINAR



# SARASWATI AGRO CHEMICALS (INDIA) PVT. LTD.

Lane-2, Phase-1, Near ESI Hospital

SIDCO Industrial Complex Bari Brahmana, Distt. Samba, Jammu (J&K) - 181133

ISO 14001 : 2004, OHSAS 18001 : 2007 & ISO 9001:2008

Ph. : 01923-221433, 221914 E-mail : saraswatiagro@gmail.com

GSTIN : 01AAFC2290A1Z1 CIN : U24211PB1999PTC022404

## PROPIEDADES FÍSICAS Y QUÍMICAS CORRESPONDIENTES AL PRODUCTO FORMULADO CONSENTO® 450 SC

### 3.1 Aspecto

#### 3.1.1 Estado físico

Líquido

#### 3.1.2 Color

Blanco a beige ligero

#### 3.1.3 Olor

Ligero, característico

### 3.2 Estabilidad en el almacenamiento (respecto de su composición y a las propiedades físicas relacionadas con el uso)

En un estudio de estabilidad de almacenamiento acelerada se concluyó que Consent 450 SC fue estable cuando se almacenaba a 54°C durante 14 días que corresponden a un tiempo de 24 meses.

Ref.: *Gowan Company. Consent 450 SC: Accelerated Storage Stability and Corrosion Characteristics*

### 3.3 Densidad relativa

1.10 – 1.14 g/ml a 20°C

### 3.4 Inflamabilidad:

#### 3.4.1 Para líquidos, punto de inflamación

No es inflamable

#### 3.4.2 Para sólidos, debe aclararse si el producto es o no inflamable

No aplica.

### 3.5 pH

6.9 a 24°C

### 3.6 Explosividad

No explosivo



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REGD. OFFICE :- VILLAGE DAO MAJRA, KHARAR KURALI ROAD, DISTT. MOHALI (PB.)  
Ph.: 0160-2285060, 2281940

- 4. PROPIEDADES FÍSICAS DEL PRODUCTO FORMULADO, RELACIONADAS CON EL USO**
- 4.1 Humedad y humectabilidad (para los polvos dispersables)**  
No aplica.
- 4.2 Persistencia de espuma (para los formulados que se aplican en el agua)**
- A una concentración de 1.4 g/L espuma                      inicial → 0 ml  
     después de 14 días → 0 ml
- A una concentración de 28 g/L espuma                      inicial → 0 ml  
     después de 14 días → 0 ml
- 4.3 Suspensibilidad (para los polvos dispersables y los concentrados en suspensión)**  
No aplica.
- 4.4 Análisis granulométrico en húmedo /tenor de polvo (para los polvos dispersables y los concentrados en suspensión)**  
No aplica.
- 4.5 Análisis granulométrico en seco (para gránulos y polvos)**  
No aplica.
- 4.6 Estabilidad de la emulsión (para los concentrados emulsionables)**  
No aplica.
- 4.7 Corrosividad**  
No se conocen propiedades corrosivas.
- 4.8 Incompatibilidad conocida con otros productos (Ej.: fitosanitarios y fertilizantes)**  
El producto es compatible con los plaguicidas de uso común.
- 4.9 Densidad a 20°C en g/ml (para formulaciones líquidas)**  
1.10 – 1.14 g/ml a 20°C
- 4.10 Punto de inflamación (aceites y soluciones)**  
No aplica.
- 4.11 Viscosidad (para suspensiones y emulsiones)**  
64mm<sup>2</sup>/s (inicial)



**4.12 Índice de sulfonación (aceites)**

No aplica.

**4.13 Dispersión (para gránulos dispersables)**

No aplica.

**4.14 Desprendimiento de gas (solo para gránulos generadores de gas u otros productos similares)**

No aplica.

**4.15 Soltura o fluidez para polvos secos**

No aplica.

**4.16 Índice de yodo e índice de saponificación (para aceites vegetales)**

No aplica.

For Saraswati Agro Chemicals (India) Pvt. Ltd.

(Suraj Kumar Bansal)  
Managing Director



# **Product Safety Labs**

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## **STUDY TITLE**

Consento 450 SC:  
Accelerated Storage Stability and Corrosion Characteristics

## **TEST GUIDELINE(S)**

U.S. EPA Product Properties Test Guidelines, OPPTS 830.6317 and 830.6320

## **AUTHOR**

Catherine Wo, PhD

## **STUDY COMPLETED ON**

2023.05.11 14:40:09  
-04'00'  


## **PERFORMING LABORATORY**

Product Safety Labs

## **LABORATORY STUDY NUMBER**

61576

## **SPONSOR**

Gowan Company  
370 S Main Street  
Yuma, AZ 85364

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## NO CLAIM OF CONFIDENTIALITY

No claim of confidentiality, on any basis whatsoever, is made for any information contained in this document. I acknowledge that information not designated as within the scope of FIFRA sec. 10(d)(1)(A), (B), or (C) and which pertains to a registered or previously registered pesticide is not entitled to confidential treatment and may be released to the public, subject to the provisions regarding disclosure to multinational entities under FIFRA 10(g).

Submitter:\_\_\_\_\_

Date:\_\_\_\_\_

Name of Signer:\_\_\_\_\_

Name of Company: Gowan Company

## GOOD LABORATORY PRACTICE COMPLIANCE STATEMENT

Consento 450 SC

This study meets the requirements of U.S. EPA GLP: Pesticide Programs (FIFRA): 40 CFR Part 160, 1989, with the following exception:

Characterization of the Propamocarb HCl reference substance(s) was not documented according to GLP, but was characterized by an ISO accredited vendor. Characterization of the Fenamidone reference substance(s) was not documented according to GLP; however, the purity of the material(s) used was certified by a reputable supplier.

Other than analyses conducted at Product Safety Labs, specific information related to the characterization of the test substance as received and tested is the responsibility of the study Sponsor (see Test Substance section).



Digitally signed by Catherine Wo

Reason: I attest to the GLP  
compliance of this study

Date: 2023.05.11 14:37:01 -04'00'

---

Catherine Wo, PhD  
Study Director  
Product Safety Labs

Sponsor: \_\_\_\_\_

Date: \_\_\_\_\_

Name of Signer: \_\_\_\_\_

Name of Company: Gowan Company

Submitter: \_\_\_\_\_

Date: \_\_\_\_\_

Name of Signer: \_\_\_\_\_

Name of Company: Gowan Company

## QUALITY ASSURANCE STATEMENT

The Product Safety Labs' Quality Assurance Unit has reviewed this final study report to assure the report accurately describes the methods and standard operating procedures, and that the reported results accurately reflect the raw data of the study.

QA activities for this study:

QA Activity	Performed By	Date Conducted	Date Findings Reported To Study Director And Management
Protocol review	R. Krick; K. Hobson	Sep 1, 2017 <sup>1</sup> ; Mar 27, 2023	Sep 1, 2017; Mar 27, 2023
Critical phase inspection: <i>Sample preparation for Day 14 analysis</i>	K. Hobson	Feb 28, 2023	Feb 28, 2023
Raw data audit	K. Hobson	Mar 27, 2023	Mar 27, 2023
Draft report review	K. Hobson	Mar 27, 2023	Mar 27, 2023

Final report reviewed by:



Digitally signed by Edward  
Hyman  
Reason: I have reviewed this  
document  
Date: 2023.05.05 16:59:27 -04'00'

---

Quality Assurance  
Product Safety Labs

<sup>1</sup> PSL's "generic" protocol used for this study was reviewed by the Quality Assurance group on this date.

## SIGNATURE

Consento 450 SC

I, the undersigned, declare that the methods, results and data contained in this report faithfully reflect the procedures used and raw data collected during the study.



Digitally signed by Catherine  
Wo  
Reason: I am the author of this  
document  
Date: 2023.05.11 14:38:43  
-04'00'

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Catherine Wo, PhD  
Study Director  
Product Safety Labs

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## CONSENTO 450 SC: ACCELERATED STORAGE STABILITY AND CORROSION CHARACTERISTICS

<b>PROTOCOL NO.:</b>	P802
<b>STUDY NUMBER:</b>	61576
<b>SPONSOR:</b>	Gowan Company 370 S Main Street Yuma, AZ 85364
<b>TEST SUBSTANCE IDENTIFICATION:</b>	Consento 450 SC Batch #: SARAM2001/ Lot - 7
<b>DATE RECEIVED:</b>	January 4, 2023
<b>PSL REFERENCE NO.:</b>	230104-9G
<b>STUDY INITIATION DATE:</b>	February 13, 2023
<b>DATES OF TEST:</b>	February 14 - February 28, 2023
<b>NOTEBOOK NO.:</b>	61576: pages 1-383

### 1. PURPOSE

The objective of this study was to determine the product stability by accelerating the aging of Consento 450 SC by heating. The corrosive effect of the test substance on the containers was also assessed.

### 2. SUMMARY

An accelerated storage stability test was carried out on the test substance in storage containers. The test substance was analyzed for the level of active ingredient at test initiation. Two sub-samples of the test substance were stored in a 54°C incubator and tested following a 14-day storage period. The active ingredient concentrations were determined by High Performance Liquid Chromatography (HPLC). Linearity, precision, and accuracy were performed to validate the methods. At the initial analysis and at the end of the 14-day storage phase, the test substance and containers were visually examined for any physical changes and the observations were recorded. The test substance was in contact with the storage containers throughout the storage period.

The test substance was found to retain its level of active ingredients when stored at 54°C for 14 days; therefore, the product was found to be stable. Phase separation was observed in the test substance on Day 14, however it returned to a homogenous suspension after mixing. No significant weight change in the containers were observed. No corrosion of the storage containers was observed.

## 3. MATERIALS

### A. Test Substance

The test substance, identified as Consento 450 SC, Batch #: SARAM2001/ Lot - 7, was received on January 4, 2023, and further identified with PSL Reference Number 230104-9G. The test substance was stored at room temperature prior to initiation of the study. Documentation of the methods of synthesis, fabrication, or derivation of the test substance is retained by the Sponsor.

The following information related to the characterization of the test substance was provided by the Sponsor unless otherwise noted (see also Appendix B):

Composition: Fenamidone – 6.66% (w/w)<sup>1</sup>, CAS #161326-34-7  
Propamocarb HCl – 34.01% (w/w)<sup>1</sup>, CAS #25606-41-1

Physical Description: Beige, Opaque liquid<sup>1</sup>

pH: 7.74 (as a 1% w/w mixture)<sup>1</sup>

Stability: Test substance was expected to be stable for the duration of testing.

Expiration Date: February 13, 2024<sup>1</sup>

### B. Reference Standard(s)

Name: Fenamidone PESTANAL™, analytical standard  
Lot No.: BCCG3735  
Purity: 99.5%  
Expiration Date: August 2025  
Supplier: Sigma-Aldrich

Name: Propamocarb HCl  
Lot No.: 14089500  
Purity: 99.5%  
Expiration Date: November 30, 2026  
Supplier: Chem Service Inc.

## 4. PROCEDURE

### A. Storage Container Selection

The container selected for the storage period was a 50 mL high-density polyethylene (HDPE) container. The size of the container was adequate for all chemical analysis and visual observations of the test substance integrity throughout the study.

### B. Sample Storage

The test substance was put into an incubator at 54°C for 14-days following initial characterization of the active ingredients. Temperature during the storage period ranged from 53.6-55.8°C.

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<sup>1</sup> As determined by Product Safety Labs (from PSL study numbers 61576 for the active ingredient(s), and 61577 for the physical description and pH, respectively). Preliminary composition information was provided by the Sponsor prior to study initiation.

## C. Testing Intervals

The Sponsor selected the study duration. For this 14-day study, chemical analysis and observations were conducted at Time 0 and on Day 14.

## D. Chemical Analysis

The test substance was analyzed for active ingredient concentrations at the initiation of the study. At Day 14 one container was withdrawn from storage and analyzed for active ingredients. A detailed description of the analytical test methods was documented at the time of initial characterization. Procedures used were consistent with the Sponsor supplied analytical test method with approved modifications.

### 4.D.1 Procedure for the Determination of Fenamidone

#### (a) Standard Preparation:

Linearity Solution Preparation: Six linearity solutions were prepared, as shown below, by accurately pipetting appropriate amounts of the reference standard into volumetric flasks, bringing to volume with diluent (ACN: DI H<sub>2</sub>O (900:100)) and mixing well. The solutions were sonicated for 10 minutes.

Standard ID	STD Weight Added (g)	Final Volume (mL)
Lin 1	0.0034	50
Lin 2	0.0036	25
Lin 3	0.0048	25
Lin 4	0.0122	50
Lin 5	0.0037	10
Lin 6	0.0041	10

#### (b) Test Substance and Accuracy Sample Preparation:

Sample Preparation: At each analysis, replicate sample solutions were prepared by accurately weighing approximately 0.38 gram of the test substance into separate 100 mL volumetric flasks, adding 10 mL of DI water and sonicating for 5 minutes. The solutions were brought to volume with acetonitrile, sonicated for 10 minutes, allowed to cool to room temperature, and mixed well. Aliquots of 3 mL were filtered through 0.45 µm syringe filters and transferred to the appropriate auto-sampler vial for analysis.

Accuracy Solution Preparation: Appropriate amounts of the standard and test substance solutions were transferred into volumetric flasks, as shown below. The samples were diluted to volume with diluent and mixed well.

Sample ID	Sample ID	Weight Used (g)	Vol. of DI Water Added (mL)	Final Vol. (mL)
Low Spike	Test substance	0.1905	10	100
	Reference standard	0.0098		
High Spike	Test substance	0.2678	10	100
	Reference standard	0.0130		

#### (c) Method Performance:

Linearity: Injections of the linearity solutions, as described in Section 4.D.1(a), were performed. The peak area responses were recorded using the

chromatography software. Linear regression analysis of the resultant peak area response was performed as a function of the standard solution concentration.

Precision: Precision was evaluated using the results obtained from duplicate injections of five preparations of the test substance, as described in Section 4.D.1(b). The Relative Standard Deviation (RSD) of the active ingredient concentration was determined.

Accuracy: Accuracy was assessed via spike recovery. The spike solutions, as described in 4.D.1(b), were injected in duplicate. The amount of active ingredients in the spike sample preparations was determined and compared to the expected amount.

(d) Analysis:

Instrument conditions are presented in Table 1. Aliquots of each solution were transferred to auto-sampler vials for analysis. Prior to analysis, the instrument was equilibrated until stable operating conditions were obtained. An analysis sequence containing solvent blanks, standards, and test substance was prepared and injections of the solutions were performed. The peak area responses were recorded. The amount of active ingredients found was calculated as shown below.

(e) Calculations:

All calculations were performed using Excel (or equivalent) with full precision. Minor differences may be found between the values reported and those obtained if calculated manually.

$$\% \text{AI (w/w)} = \text{Calc. Amount (mg/mL)} / \text{Sample Conc (mg/mL)} * 100$$

Where:

$$\text{Calc. Amount (mg/mL)} = \text{Peak Area} / \text{Average Response Factor}$$

$$\text{Response Factor} = \text{Ave. Peak Area} / (\text{Adjusted Standard concentration by purity} / \text{mg/mL})$$

$$\text{Sample Conc. (mg/ml)} = \text{Sample Wt. (g)} * 1000 / \text{Final Vol. (mL)}$$

$$\text{Standard Conc. (mg/ml)} = \text{Standard Wt. (g)} * \text{Purity of STD} * 1000 / \text{Final Vol. (mL)}$$

## 4.D.2 Procedure for the Determination of Propamocarb HCl

(a) Standard Preparation:

Linearity Solution Preparation: Six linearity solutions were prepared, as shown below, by accurately pipetting appropriate amounts of the reference standard into volumetric flasks, bringing to volume with DI water and mixing well. The solutions were sonicated for 15 minutes.

Standard ID	STD Weight Added (g)	Final Volume (mL)
Lin 1	0.0034	20
Lin 2	0.0030	10
Lin 3	0.0040	10
Lin 4	0.0110	20
Lin 5	0.0030	5
Lin 6	0.0059	5

(b) Test Substance and Accuracy Sample Preparation:

Sample Preparation: At each analysis, replicate sample solutions were prepared by accurately weighing approximately 0.16 gram of the test substance into separate 100 mL volumetric flasks, adding DI water to volume, stoppering the vessels and sonicating for 15 minutes. The solutions were allowed to cool to room temperature and mixed well. Aliquots of 3 mL were filtered through 0.45  $\mu\text{m}$  syringe filters and transferred to the appropriate auto-sampler vial for analysis.

Accuracy Solution Preparation: Appropriate amounts of the standard and test substance solutions were transferred into volumetric flasks, as shown below. The samples were diluted to volume with DI water and swirled to dissolve. The solutions were sonicated for ~15 minutes, allowed to cool to room temperature and mixed well.

Sample ID	Sample ID	Weight Used (g)	Final Vol. (mL)
Low Spike	Test substance	0.1000	100
	Reference standard	0.0094	
High Spike	Test substance	0.1130	100
	Reference standard	0.0265	

4.D.3 Method Performance:

Linearity: Injections of the linearity solutions, as described in Section 4.D.2(a), were performed. The peak area responses were recorded using the chromatography software. Linear regression analysis of the resultant peak area response was performed as a function of the standard solution concentration.

Precision: Precision was evaluated using the results obtained from duplicate injections of five preparations of the test substance, as described in Section 4.D.2(b). The Relative Standard Deviation (RSD) of the active ingredient concentration was determined.

Accuracy: Accuracy was assessed via spike recovery. The spike solutions, as described in 4.D.2(b), were injected in duplicate. The amount of active ingredients in the spike sample preparations was determined and compared to the expected amount.

4.D.4 Analysis:

Instrument conditions are presented in Table 1. Aliquots of each solution were transferred to auto-sampler vials for analysis. Prior to analysis, the instrument was equilibrated until stable operating conditions were obtained. An analysis sequence containing solvent blanks, standards, and test substance was prepared and injections of the solutions were performed. The peak area responses were recorded. The amount of active ingredients found was calculated as shown below.

4.D.5 Calculations:

All calculations were performed using Excel (or equivalent) with full precision. Minor differences may be found between the values reported and those obtained if calculated manually.

%AI (w/w)= Calc. Amount (mg/mL)/Sample Conc (mg/mL) 100

Where:

Calc. Amount (mg/mL) = Peak Area/Average Response Factor

Response Factor = Ave. Peak Area/Standard Conc. (mg/mL)

Sample Conc. (mg/ml) = Sample Wt. (g)\*1000/Final Vol. (ml)

Standard Conc. (mg/ml) = Standard Wt. (g)\*Purity of STD\*1000/Final Vol. (mL)

## E. Observations

Upon initiation of storage, visual observations of the test substance and the storage containers were recorded. At Day 14, the stored sample was visually examined for any physical changes in the product such as clumping, phase separation or discoloration, and in particular any changes which would interfere with the usefulness or safe handling of the product if used according to label directions. The sample container was also evaluated for effects of corrosion such as cracking, distortion, discoloration, pitting, fogging, perforations, darkening, leaking, or rust at the seam, etc. All observations were documented.

## F. Monitoring of Container Weight

Total container weight was monitored throughout the study. At the beginning and end of the testing interval, the weight of all storage containers was determined. The change in weight of the container(s) (excluding sampling) was determined.

## 5. STATISTICAL ANALYSIS

Calculation of a mean, standard deviation, relative standard deviation, and correlation coefficient (r) were the only statistical methods employed for analyzing the data.

## 6. STUDY CONDUCT

This study was conducted at Product Safety Labs (PSL), 2394 US Highway 130, Dayton, New Jersey 08810. This study was conducted to comply with the Good Laboratory Practice (GLP) regulations as defined in:

- U.S. EPA GLP: Pesticide Programs (FIFRA): 40 CFR Part 160, 1989

and based on the following testing guidelines:

- U.S. EPA Product Properties Test Guidelines, OPPTS 830.6317 and 830.6320

and additional guidance from:

- EPA Memorandum "Accelerated Storage Stability and Corrosion Characteristics Study Protocol", R. Keigwin, J. Harrigan-Farrelly, L. Rossi and J. Housenger. November 16, 2012.
- "MT 46 Accelerated Storage Tests by Heating," Hatching Green, Harpenden, Hertfordshire, England (1970).

## 7. QUALITY ASSURANCE

The final report was audited for agreement with the raw data records and for compliance with the protocol, Product Safety Labs Standard Operating Procedures and appropriate Good Laboratory Practice Standards. Dates of inspections and audits performed during the study and the dates of reporting of the inspection and audit findings to the Study Director and Facility Management are presented in the Quality Assurance Statement.

## 8. AMENDMENTS TO THE PROTOCOL

None.

## 9. DEVIATIONS FROM THE PROTOCOL

None.

## 10. FINAL REPORT AND RECORDS TO BE MAINTAINED

Information on care of the equipment maintenance and calibration, storage, usage, and disposition of the test substance, and all other records that would demonstrate adherence to the protocol will be maintained. Facility records, which are not specific to the subject study, will be maintained by the testing facility and archived according to PSL SOP.

The original, signed final report will be forwarded to the Sponsor. A copy of the signed report, together with the protocol and all raw data generated at Product Safety Labs, will be maintained in the Product Safety Labs' Archives. PSL will maintain these records for a period of at least five years. After this time, the Sponsor will be offered the opportunity to take possession of the records or may request continued archiving by PSL.

## 11. RESULTS

HPLC operating conditions are presented in Table 1. Linearity results are presented in Table 2. Results of test sample analyses for fenamidone and propamocarb are presented in Tables 3 and 4, respectively. Monitoring of container weights is presented in Table 5. Representative chromatograms for fenamidone and propamocarb are presented in Appendices A and B, respectively. The Certificate of Analysis is presented in Appendix C. PSL's GLP qualification is presented in Appendix D.

Method validation criteria and results are summarized below.

Fenamidone			
Parameter Evaluated	Acceptance Criteria	Result	Acceptable (Yes/No)
Linearity Linearity Range: 0.0677-0.4080 mg/mL	$r \geq 0.995$	1.000	Yes
Accuracy	98-102%	99.65%	Yes
Precision	RSD $\leq 5\%$	0.45%	Yes

Propamocarb HCl			
Parameter Evaluated	Acceptance Criteria	Result	Acceptable (Yes/No)
Linearity Linearity Range: 0.1692-1.1741 mg/mL	$r \geq 0.995$	0.999	Yes
Accuracy	98-102%	99.65%	Yes
Precision	RSD $\leq 2\%$	0.47%	Yes

Consento 450 SC was observed to be a beige liquid suspension at test initiation and throughout the course of the study. During the storage period, phase separation was observed, however the test

substance returned to a homogenous suspension after mixing. No changes to the storage containers were observed. The average total weight change observed in the test containers was -0.12.

The average active ingredient concentrations for each testing interval is presented below.

Test Substance	Consento 450 SC Batch #: SARAM2001 / Lot - 7					
	Fenamidone			Propamocarb HCl		
Active Ingredient	% w/w	g/L	% w/v	% w/w	g/L	% w/v
Initial	6.66	74.9	7.49	34.01	382.6	38.26
Day 14	6.58	74.0	7.40	33.93	381.7	38.17

## 12. CONCLUSIONS

As summarized above, the test substance was found to retain its level of active ingredients when stored at 54°C for 14 days; therefore, the product was found to be stable. Phase separation was observed in the test substance on Day 14, however it returned to a homogenous suspension after mixing. No significant weight change in the containers were observed. No corrosion of the storage containers was observed.

**TABLE 1: HPLC OPERATING CONDITIONS**

Fenamidone

<b>HPLC System</b>	Agilent HPLC #20, UV Detector
<b>Column</b>	Nucleosil C 18, 5 µm, 125 x 3 mm
<b>Column Temp. (°C)</b>	35
<b>Injection volume (µL)</b>	10
<b>Wavelength (nm)</b>	240
<b>Mobile Phase</b>	ACN:DI H <sub>2</sub> O (900:100)
<b>Flow Rate (mL/min)</b>	0.5
<b>Run Time (min)</b>	15

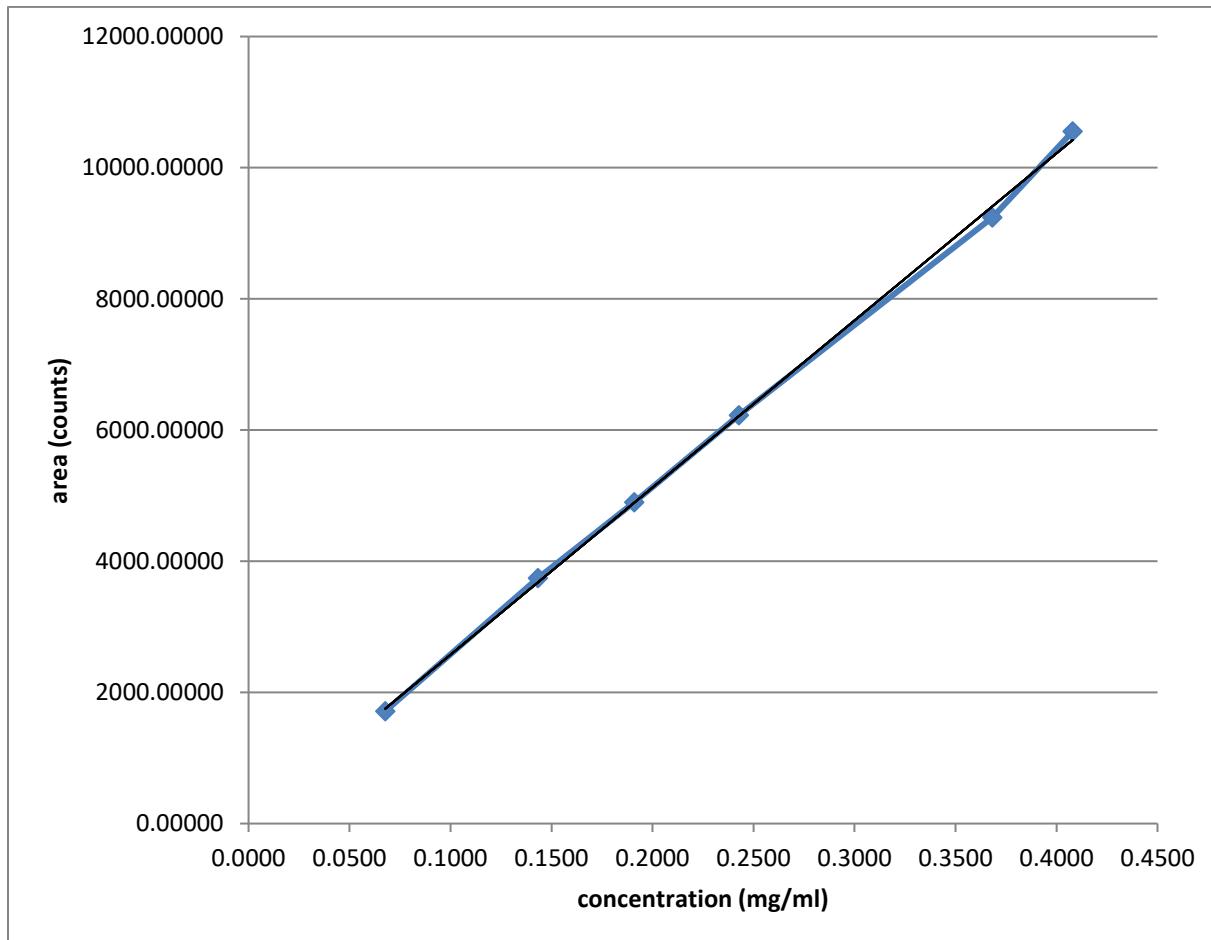
Propamocarb HCl

<b>HPLC System</b>	Agilent HPLC #13, UV Detector
<b>Column</b>	Waters Xterra RP18, 3.5 µm, 50 x 3 mm
<b>Column Temp. (°C)</b>	35
<b>Injection volume (µL)</b>	10
<b>Wavelength (nm)</b>	210
<b>Mobile Phase</b>	ACN:Prepared 15 g/L ammonium (300:700)
<b>Flow Rate (mL/min)</b>	0.5
<b>Run Time (min)</b>	15

**TABLE 2: LINEARITY RESULTS**

Fenamidone

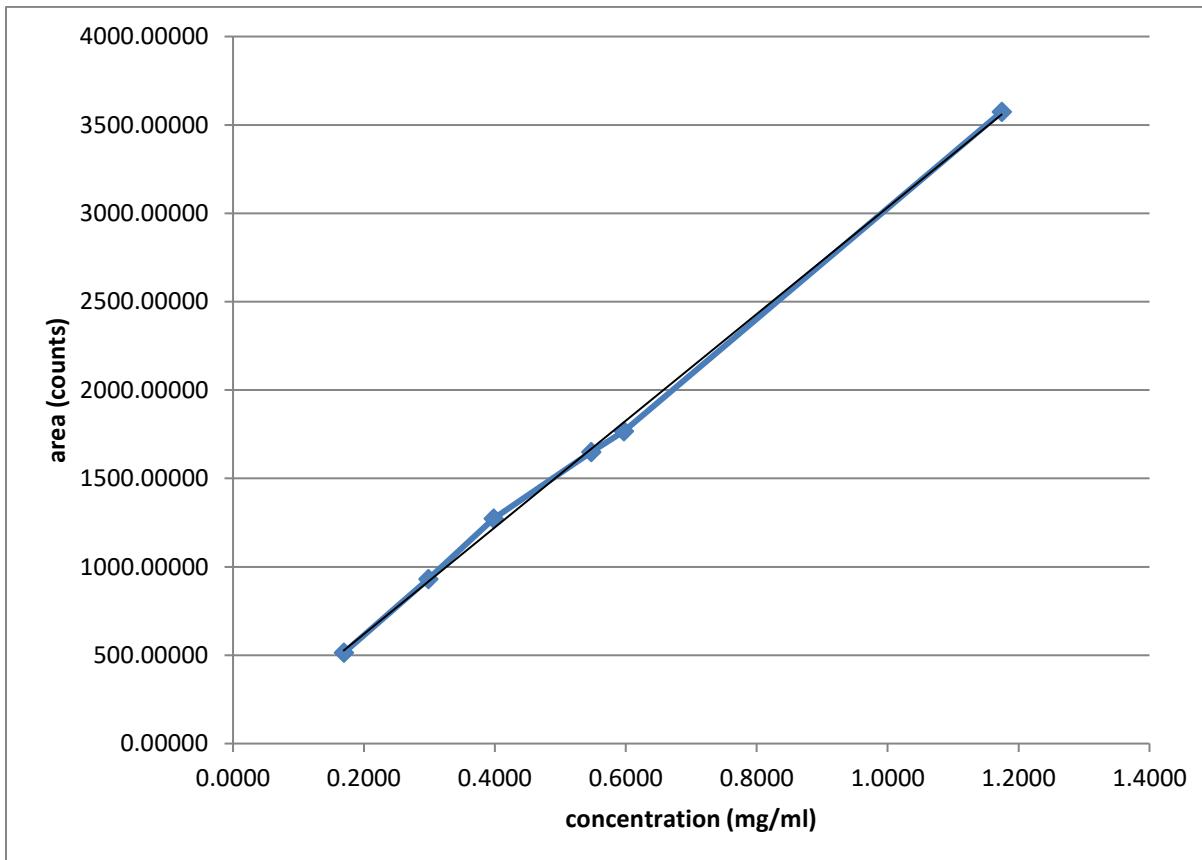
Sample Name	Standard Concentration (mg/mL)	Response Area
Lin 1	0.0677	1714.30481
Lin 2	0.1433	3742.84692
Lin 3	0.1910	4896.77148
Lin 4	0.2428	6223.53076
Lin 5	0.3682	9240.01172
Lin 6	0.4080	10551.2
	<b>Slope</b>	2.548E+04
	<b>Intercept</b>	2.677E+01
	<b>Correlation Coefficient (r)</b>	1.000



**TABLE 2 (cont.): LINEARITY RESULTS**

Propamocarb HCl

Sample Name	Standard Concentration (mg/mL)	Response Area
Lin 1	0.1692	513.15686
Lin 2	0.2985	930.97986
Lin 3	0.3980	1271.99463
Lin 4	0.5473	1648.54163
Lin 5	0.5970	1766.10315
Lin 6	1.1741	3573.61841
	<b>Slope</b>	3.018E+03
	<b>Intercept</b>	1.605E+01
	<b>Correlation Coefficient (r)</b>	0.999



**TABLE 3: RESULTS OF TEST SAMPLE ANALYSIS FOR FENAMIDONE**

**Initial Analysis**

Container #	Sample Name	Sample Conc. (mg/mL)	Response Area	Calc. AI Conc. (mg/mL)	%AI (w/w)	
2 of 3	9G-1-1	3.8350	6551.11865	0.2549	6.65	
	9G-1-2		6522.51611	0.2538	6.62	
	9G-2-1	3.8090	6551.31299	0.2549	6.69	
	9G-2-2		6528.93066	0.2540	6.67	
<b>Average</b>					6.66	
<b>%RSD</b>					0.45	

Average Response Factor = 25703.8122

Result expressed as g/L = 6.66% \* 1.125 g/ml \* 1000ml/1L = 74.9 g/L  
1.125 g/ml = density value, as provided by client

**Day 14 Analysis**

Container #	Sample Name	Sample Conc. (mg/mL)	Response Area	Calc. AI Conc. (mg/mL)	%AI (w/w)	
2A	9G-1-1	3.8450	6394.59375	0.2520	6.55	
	9G-1-2		6395.53027	0.2521	6.56	
	9G-2-1	3.8710	6466.59619	0.2549	6.58	
	9G-2-2		6467.69287	0.2549	6.58	
	9G-3-1	3.8150	6395.47510	0.2521	6.61	
	9G-3-2		6396.27979	0.2521	6.61	
<b>Average</b>					6.58	
<b>%RSD</b>					0.30	

Average Response Factor = 25370.8661

Result expressed as g/L = 6.58% \* 1.125 g/ml \* 1000ml/1L = 74.0 g/L  
1.125 g/ml = density value, as provided by client

**TABLE 4: RESULTS OF TEST SAMPLE ANALYSIS FOR PROPAMOCARB HCI**

**Initial Analysis**

Container #	Sample Name	Sample Conc. (mg/mL)	Response Area	Calc. AI Conc. (mg/mL)	%AI (w/w)	
2 of 3	9G-1-1	1.6180	1669.72717	0.5538	34.23	
	9G-1-2		1646.65552	0.5462	33.76	
	9G-2-1	1.6290	1675.72131	0.5558	34.12	
	9G-2-2		1665.25439	0.5524	33.91	
<b>Average</b>					34.01	
<b>%RSD</b>					0.62	

Average Response Factor = 3014.7954

Result expressed as g/L = 34.01% \* 1.125 g/ml \* 1000ml / 1L = 382.6 g/L  
1.125 g/ml = density value as provided by client

**Day 14 Analysis**

Container #	Sample Name	Sample Conc. (mg/mL)	Response Area	Calc. AI Conc. (mg/mL)	%AI (w/w)	
2A	9G-1-1	1.6680	1559.61584	0.5654	33.90	
	9G-1-2		1544.63245	0.5600	33.57	
	9G-2-1	1.6150	1502.50879	0.5447	33.73	
	9G-2-2		1507.35242	0.5465	33.84	
	9G-3-1	1.6580	1562.11670	0.5663	34.16	
	9G-3-2		1572.41296	0.5701	34.38	
<b>Average</b>					33.93	
<b>%RSD</b>					0.85	

Average Response Factor = 2758.3108

Result expressed as g/L = 33.93% \* 1.125 g/ml \* 1000ml / 1L = 381.7 g/L  
1.125 g/ml = density value as provided by client

**TABLE 5: MONITORING OF TEST CONTAINER WEIGHTS**

Test Substance Identification		Consento 450 SC				
Lot #		Batch #: SARAM2001 / Lot - 7				
Container #		2A		2B		
Empty Container weight (g)		11.24		11.15		
Initial Container + Test Substance Weight (g)		46.90		43.43		
Time Period (days)	Initial weight <sup>1</sup> (g)	Final weight <sup>2</sup> (g)	Difference <sup>3</sup> (g)	Initial weight <sup>1</sup> (g)	Final weight <sup>2</sup> (g)	Difference <sup>3</sup> (g)
0-14	46.90	46.85	-0.05	43.43	43.38	-0.05
% Total weight change <sup>4</sup>	-0.11		-0.12			
Average ± SD	$-0.12 \pm 0.01$					

<sup>1</sup> Initial weight = Container weight + weight of test substance after sampling for the test period.

<sup>2</sup> Final weight = Container weight + weight of test substance prior to sampling for the next test period.

<sup>3</sup> Difference = Weight change observed during the storage period = Final weight - Initial weight observed.

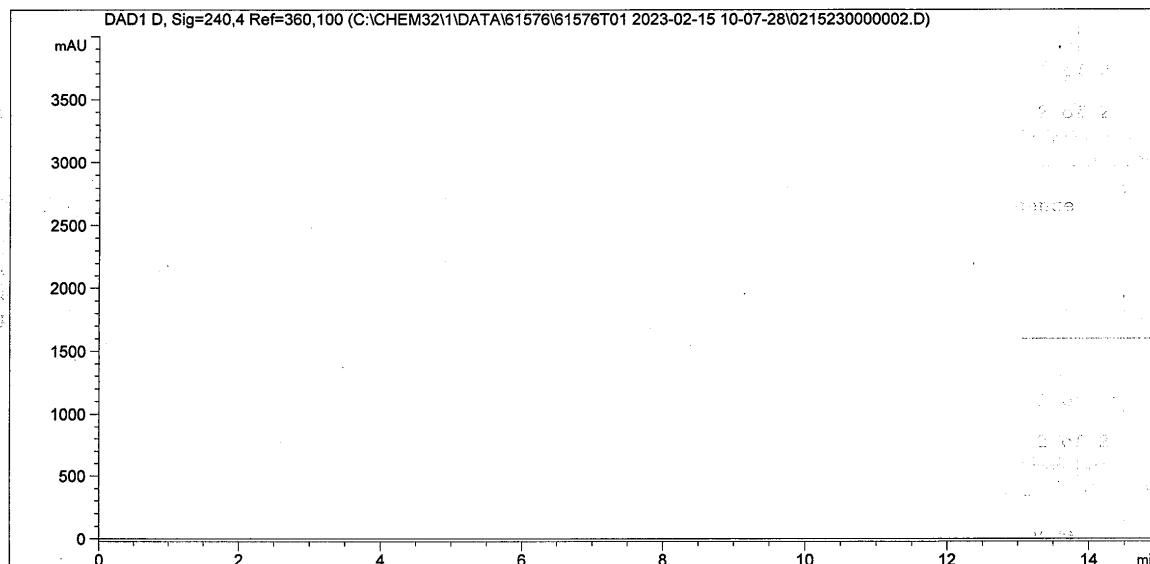
<sup>4</sup> % Total weight change = Sum of differences observed during the storage phase period / initial weight observed x 100.

## APPENDIX A: REPRESENTATIVE CHROMATOGRAMS FOR FENAMIDONE

### BLANK (INITIAL)

Batch Run # 2 of 31  
Data File C:\CHEM32\1\DATA\61576\61576T01 2023-02-15 10-07-28\0215230000002.D  
Sample Name: Blank-Diluent

```
=====
Acq. Operator   : CO          Seq. Line : 1
Acq. Instrument : Instrument 2 Location : Vial 1
Injection Date  : 2/15/2023 10:26:41 AM Inj : 2
                                                Inj Volume : 10.0 µl
Acq. Method    : C:\CHEM32\1\DATA\61576\61576T01 2023-02-15 10-07-28\61576.M
Last changed    : 2/15/2023 9:52:59 AM by CO
Analysis Method : C:\CHEM32\1\DATA\61576\61576T01 2023-02-15 10-07-28\61576.M (Sequence
Method)
Last changed    : 2/16/2023 5:28:10 AM
                   (modified after loading)
Method Info     : Acc storage stab of 230104-9G
```



```
=====
Area Percent Report
```

```
Sorted By      : Signal
Calib. Data Modified : 2/16/2023 5:28:10 AM
Multiplier     : 1.0000
Dilution       : 1.0000
Use Multiplier & Dilution Factor with ISTDs
```

Signal 1: DAD1 D, Sig=240,4 Ref=360,100

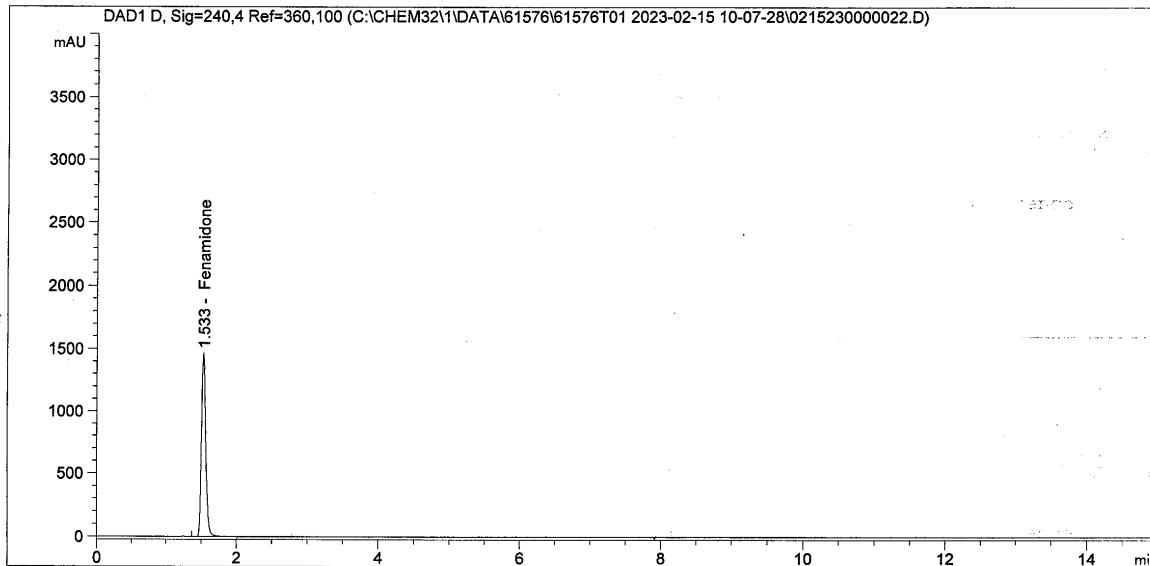
Peak #	RetTime [min]	Type	Width [min]	Area [mAU*s]	Area %	Name
1	1.530		0.0000	0.00000	0.00000	Fenamidone

Totals : 0.00000

## APPENDIX A (cont.): REPRESENTATIVE CHROMATOGRAMS FOR FENAMIDONE STANDARD (INITIAL)

Batch Run # 22 of 31  
Data File C:\CHEM32\1\DATA\61576\61576T01 2023-02-15 10-07-28\0215230000022.D  
Sample Name: Lin 4

```
=====
Acq. Operator : CO                               Seq. Line : 17
Acq. Instrument : Instrument 2                 Location : Vial 17
Injection Date : 2/15/2023 4:08:17 PM           Inj : 1
                                                Inj Volume : 10.0 µl
Acq. Method : C:\CHEM32\1\DATA\61576\61576T01 2023-02-15 10-07-28\61576.M
Last changed : 2/15/2023 9:52:59 AM by CO
Analysis Method : C:\CHEM32\1\DATA\61576\61576T01 2023-02-15 10-07-28\61576.M (Sequence
Method)
Last changed : 2/16/2023 5:28:10 AM
(modified after loading)
Method Info : Acc storage stab of 230104-9G
```



### Area Percent Report

```
=====
Sorted By : Signal
Calib. Data Modified : 2/16/2023 5:28:10 AM
Multiplier : 1.0000
Dilution : 1.0000
Use Multiplier & Dilution Factor with ISTDs
```

Signal 1: DAD1 D, Sig=240,4 Ref=360,100

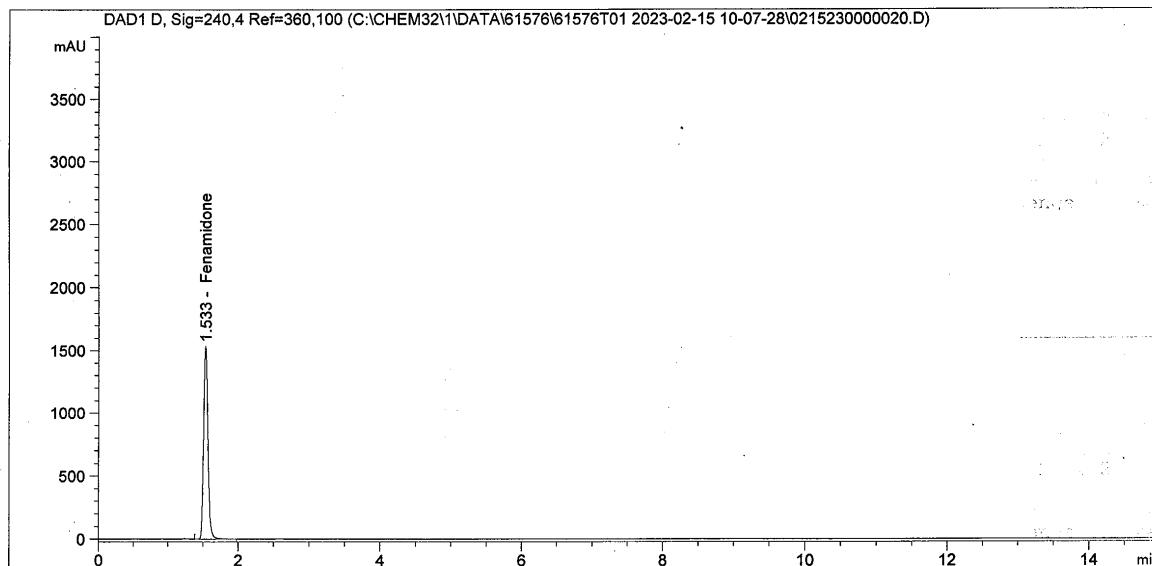
Peak #	RetTime [min]	Type	Width [min]	Area [mAU*s]	Area %	Name
1	1.533	VB	0.0657	6246.09131	100.0000	Fenamidone

Totals : 6246.09131

## APPENDIX A (cont.): REPRESENTATIVE CHROMATOGRAMS FOR FENAMIDONE SAMPLE (INITIAL)

Batch Run # 20 of 31  
Data File C:\CHEM32\1\DATA\61576\61576T01 2023-02-15 10-07-28\0215230000020.D  
Sample Name: A 2

```
=====
Acq. Operator   : CO                               Seq. Line : 16
Acq. Instrument : Instrument 2                 Location : Vial 16
Injection Date  : 2/15/2023 3:34:13 PM           Inj       : 1
                                                Inj Volume : 10.0 µl
Acq. Method    : C:\CHEM32\1\DATA\61576\61576T01 2023-02-15 10-07-28\61576.M
Last changed    : 2/15/2023 9:52:59 AM by CO
Analysis Method : C:\CHEM32\1\DATA\61576\61576T01 2023-02-15 10-07-28\61576.M (Sequence
Method)
Last changed    : 2/16/2023 5:28:10 AM
(modified after loading)
Method Info     : Acc storage stab of 230104-9G
```



### Area Percent Report

```
=====
Sorted By      : Signal
Calib. Data Modified : 2/16/2023 5:28:10 AM
Multiplier     : 1.0000
Dilution       : 1.0000
Use Multiplier & Dilution Factor with ISTDs
```

Signal 1: DAD1 D, Sig=240,4 Ref=360,100

Peak RetTime	Type	Width	Area	Area %	Name
#	[min]	[min]	[mAU*s]	%	
1	1.533 BB	0.0657	6551.31299	100.0000	Fenamidone

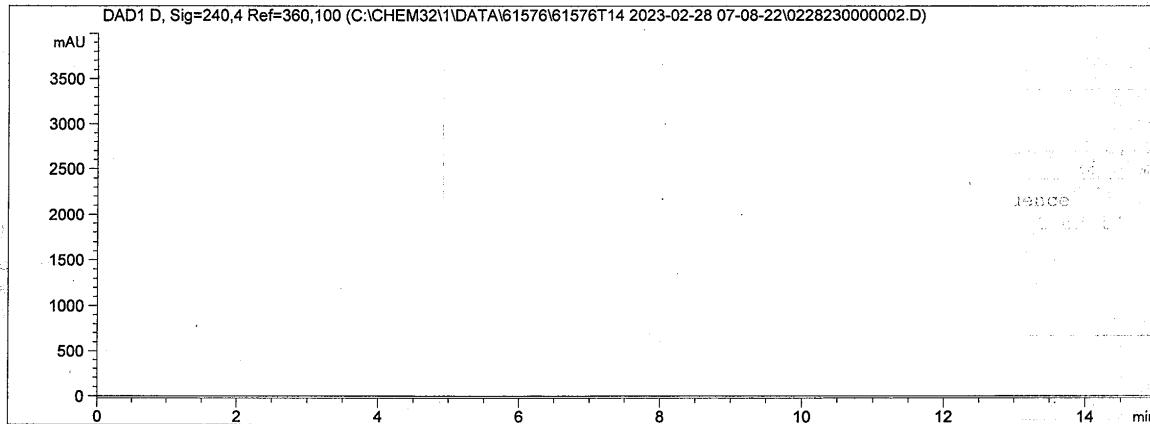
Totals : 6551.31299

## APPENDIX A (cont.): REPRESENTATIVE CHROMATOGRAMS FOR FENAMIDONE

### BLANK (DAY 14)

Batch Run # 2 of 16  
Data File C:\CHEM32\1\DATA\61576\61576T14 2023-02-28 07-08-22\0228230000002.D  
Sample Name: Blank-Diluent

```
=====
Acq. Operator : CO                               Seq. Line : 1
Acq. Instrument : Instrument 2                 Location : Vial 1
Injection Date : 2/28/2023 7:27:20 AM           Inj : 2
                                                Inj Volume : 10.0 µl
Acq. Method : C:\CHEM32\1\DATA\61576\61576T14 2023-02-28 07-08-22\61576.M
Last changed : 2/15/2023 9:52:59 AM by CO
Analysis Method : C:\CHEM32\1\DATA\61576\61576T14 2023-02-28 07-08-22\61576.M (Sequence
Method)
Last changed : 2/28/2023 11:50:14 AM
(modified after loading)
Method Info : Acc storage stab of 230104-9G
```



#### Area Percent Report

```
=====
Sorted By : Signal
Calib. Data Modified : 2/28/2023 11:50:14 AM
Multiplier : 1.0000
Dilution : 1.0000
Use Multiplier & Dilution Factor with ISTDs
```

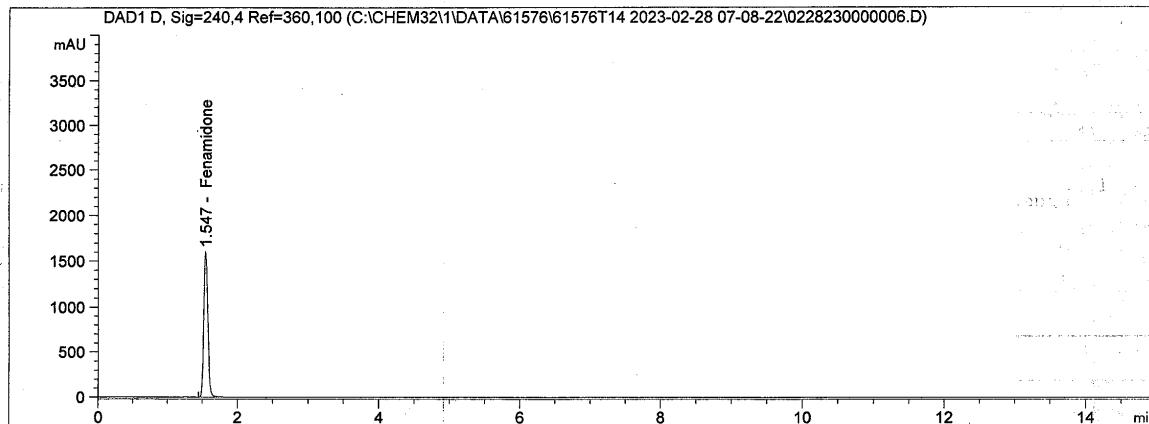
Signal 1: DAD1 D, Sig=240,4 Ref=360,100

Peak #	RetTime [min]	Type	Width [min]	Area [mAU*s]	Area %	Name
1	1.540		0.0000	0.00000	0.00000	Fenamidone
				Totals :	0.00000	

## APPENDIX A (cont.): REPRESENTATIVE CHROMATOGRAMS FOR FENAMIDONE STANDARD (DAY 14)

Batch Run # 6 of 16  
Data File C:\CHEM32\1\DATA\61576\61576T14 2023-02-28 07-08-22\022823000006.D  
Sample Name: Std

```
=====
Acq. Operator : CO                               Seq. Line : 3
Acq. Instrument : Instrument 2                 Location : Vial 3
Injection Date : 2/28/2023 8:35:59 AM           Inj : 2
                                                Inj Volume : 10.0 µl
Acq. Method : C:\CHEM32\1\DATA\61576\61576T14 2023-02-28 07-08-22\61576.M
Last changed : 2/15/2023 9:52:59 AM by CO
Analysis Method : C:\CHEM32\1\DATA\61576\61576T14 2023-02-28 07-08-22\61576.M (Sequence
Method)
Last changed : 2/28/2023 11:50:14 AM
(modified after loading)
Method Info : Acc storage stab of 230104-9G
```



### Area Percent Report

```
=====
Sorted By : Signal
Calib. Data Modified : 2/28/2023 11:50:14 AM
Multiplier : 1.0000
Dilution : 1.0000
Use Multiplier & Dilution Factor with ISTDs
```

Signal 1: DAD1 D, Sig=240,4 Ref=360,100

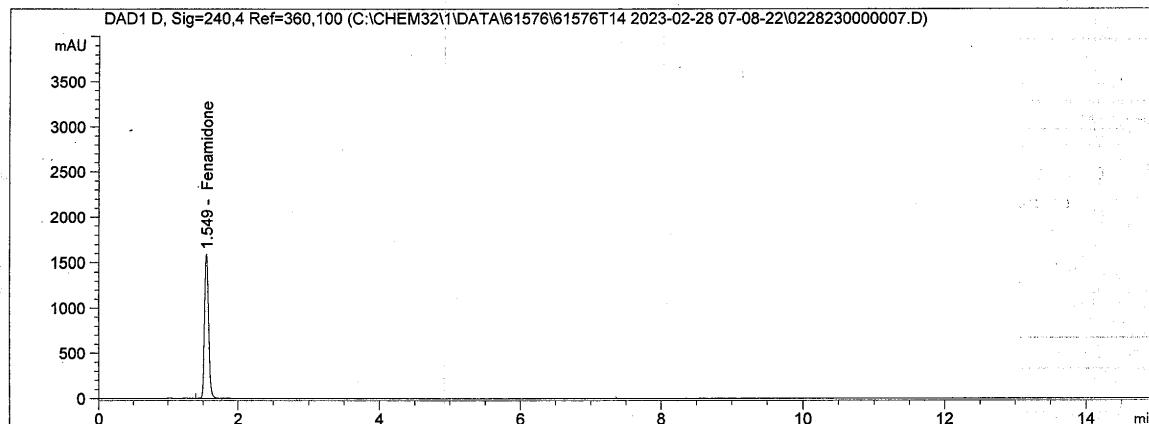
Peak #	RetTime [min]	Type	Width [min]	Area [mAU*s]	Area %	Name
1	1.547	BB	0.0627	6436.64355	100.0000	Fenamidone

Totals : 6436.64355

## APPENDIX A (cont.): REPRESENTATIVE CHROMATOGRAMS FOR FENAMIDONE SAMPLE (DAY 14)

Batch Run # 7 of 16  
Data File C:\CHEM32\1\DATA\61576\61576T14 2023-02-28 07-08-22\0228230000007.D  
Sample Name: A 1

```
=====
Acq. Operator   : CO          Seq. Line : 4
Acq. Instrument : Instrument 2 Location : Vial 4
Injection Date  : 2/28/2023 8:53:04 AM    Inj : 1
                                         Inj Volume : 10.0 µl
Acq. Method     : C:\CHEM32\1\DATA\61576\61576T14 2023-02-28 07-08-22\61576.M
Last changed    : 2/15/2023 9:52:59 AM by CO
Analysis Method : C:\CHEM32\1\DATA\61576\61576T14 2023-02-28 07-08-22\61576.M (Sequence
Method)
Last changed    : 2/28/2023 11:50:14 AM
                  (modified after loading)
Method Info     : Acc storage stab of 230104-9G
```



### Area Percent Report

```
=====
Sorted By      : Signal
Calib. Data Modified : 2/28/2023 11:50:14 AM
Multiplier     : 1.0000
Dilution       : 1.0000
Use Multiplier & Dilution Factor with ISTDs
```

Signal 1: DAD1 D, Sig=240,4 Ref=360,100

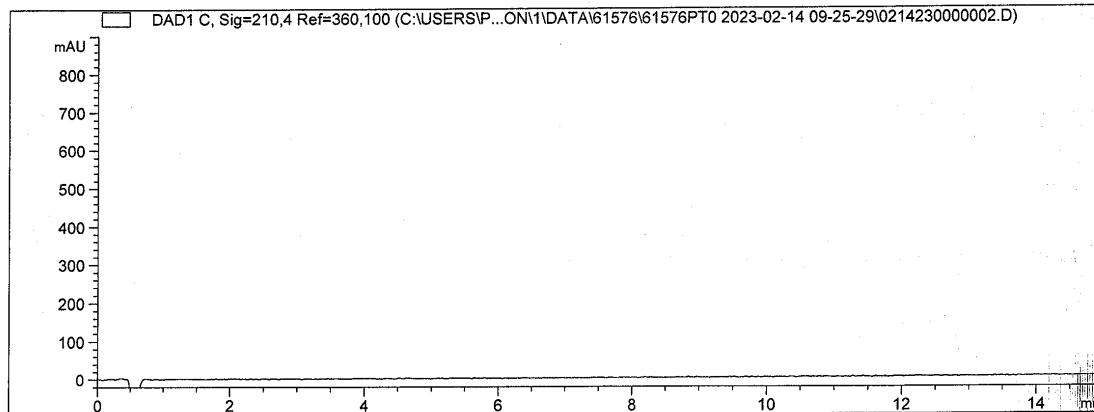
Peak #	RetTime [min]	Type	Width [min]	Area [mAU*s]	Area %	Name
1	1.549	VV	0.0626	6394.59375	100.0000	Fenamidone
Totals :				6394.59375		

## APPENDIX B: REPRESENTATIVE CHROMATOGRAMS FOR PROPAMOCARB HCI

### BLANK (INITIAL)

Batch Run # 2 of 31  
Data File C:\USERS\P...EMSTATION\1\DATA\61576\61576PT0 2023-02-14 09-25-29\021423000002.D  
Sample Name: Blank-H2O

```
=====
Acq. Operator   : SYSTEM          Seq. Line :  2
Sample Operator : SYSTEM
Acq. Instrument : LC-13          Location  :  1
Injection Date  : 2/14/2023 9:45:44 AM    Inj       :  2
                                                Inj Volume : 10.000 µl
Acq. Method     : C:\Users\Public\Documents\ChemStation\1\Data\61576\61576PT0 2023-02-14
                   09-25-29\61576P.M
Last changed    : 2/14/2023 9:23:18 AM by SYSTEM
Analysis Method : C:\Users\Public\DOCUMENTS\ChemStation\1\Data\61576\61576PT0 2023-02-14
                   09-25-29\61576P.M (Sequence Method)
Last changed    : 2/15/2023 5:03:53 AM by SYSTEM
                   (modified after loading)
Method Info     : Stability of 230104-9G
=====
```



### Area Percent Report

```
=====
Sorted By        : Signal
Calib. Data Modified : 2/15/2023 5:03:53 AM
Multiplier       : 1.0000
Dilution         : 1.0000
Do not use Multiplier & Dilution Factor with ISTDs
=====
```

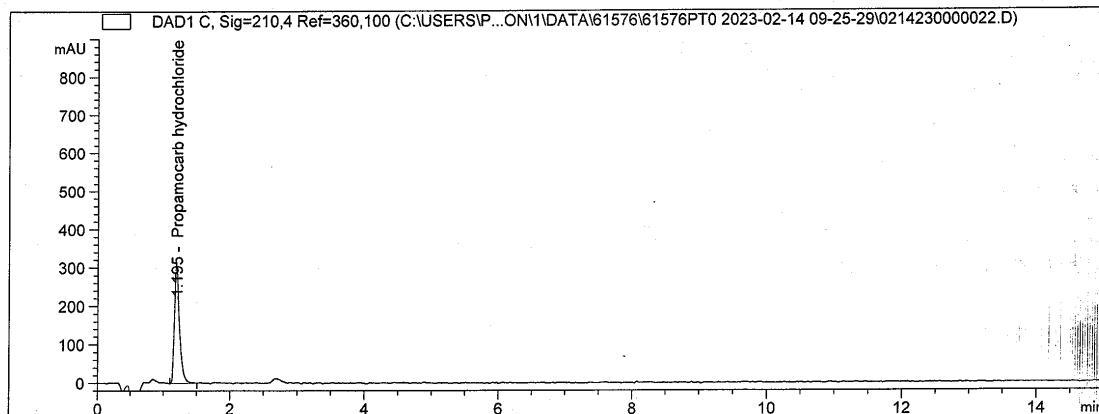
Signal 1: DAD1 C, Sig=210,4 Ref=360,100

Peak #	RetTime [min]	Type	Width [min]	Area [mAU*s]	Area %	Name
1	1.203		0.0000	0.00000	0.00000	Propamocarb hydrochloride
Totals :				0.00000		

## APPENDIX B (cont.): REPRESENTATIVE CHROMATOGRAMS FOR PROPAMOCARB HCI STANDARD (INITIAL)

Batch Run # 22 of 31  
Data File C:\USERS\P...EMSTATION\1\DATA\61576\61576PT0 2023-02-14 09-25-29\0214230000022.D  
Sample Name: Lin 4

```
=====
Acq. Operator   : SYSTEM                      Seq. Line : 22
Sample Operator : SYSTEM
Acq. Instrument : LC-13                     Location  : 17
Injection Date  : 2/14/2023 3:54:30 PM        Inj       : 1
                                                Inj Volume : 10.000 µl
Acq. Method    : C:\Users\Public\Documents\ChemStation\1\Data\61576\61576PT0 2023-02-14
                  09-25-29\61576P.M
Last changed    : 2/14/2023 9:23:18 AM by SYSTEM
Analysis Method : C:\Users\Public\DOCUMENTS\ChemStation\1\DATA\61576\61576PT0 2023-02-14
                  09-25-29\61576P.M (Sequence Method)
Last changed    : 2/15/2023 5:03:53 AM by SYSTEM
                  (modified after loading)
Method Info     : Stability of 230104-9G
=====
```



### Area Percent Report

```
=====
Sorted By      : Signal
Calib. Data Modified : 2/15/2023 5:03:53 AM
Multiplier     : 1.0000
Dilution       : 1.0000
Do not use Multiplier & Dilution Factor with ISTDs
=====
```

Signal 1: DAD1 C, Sig=210,4 Ref=360,100

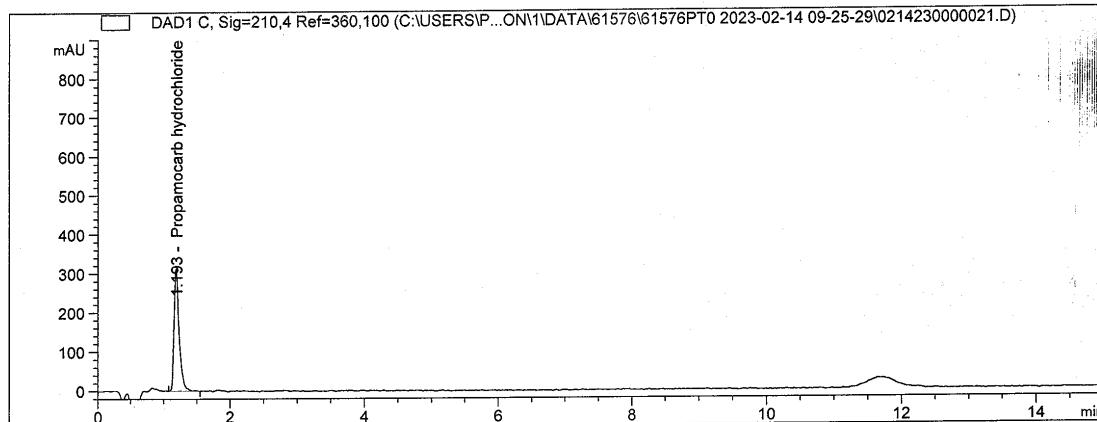
Peak	RetTime	Type	Width	Area	Area	Name
#	[min]		[min]	[mAU*s]	%	
1	1.195	BB	0.0827	1639.88965	100.0000	Propamocarb hydrochloride

Totals : 1639.88965

## APPENDIX B (cont.): REPRESENTATIVE CHROMATOGRAMS FOR PROPAMOCARB HCI SAMPLE (INITIAL)

Batch Run # 21 of 31  
Data File C:\USERS\...\EMSTATION\1\DATA\61576\61576PT0 2023-02-14 09-25-29\0214230000021.D  
Sample Name: A 2

```
=====
Acq. Operator : SYSTEM           Seq. Line : 21
Sample Operator : SYSTEM
Acq. Instrument : LC-13          Location : 16
Injection Date : 2/14/2023 3:36:07 PM   Inj : 2
                                         Inj Volume : 10.000 µl
Acq. Method : C:\Users\Public\Documents\ChemStation\1\Data\61576\61576PT0 2023-02-14
                           09-25-29\61576B.M
Last changed : 2/14/2023 9:23:18 AM by SYSTEM
Analysis Method : C:\Users\Public\DOCUMENTS\ChemStation\1\Data\61576\61576PT0 2023-02-14
                           09-25-29\61576B.M (Sequence Method)
Last changed : 2/15/2023 5:20:02 AM by SYSTEM
Method Info : Stability of 230104-9G
=====
```



```
=====
Area Percent Report
=====
```

```
Sorted By : Signal
Calib. Data Modified : 2/15/2023 5:03:53 AM
Multiplier : 1.0000
Dilution : 1.0000
Do not use Multiplier & Dilution Factor with ISTDs
=====
```

Signal 1: DAD1 C, Sig=210,4 Ref=360,100

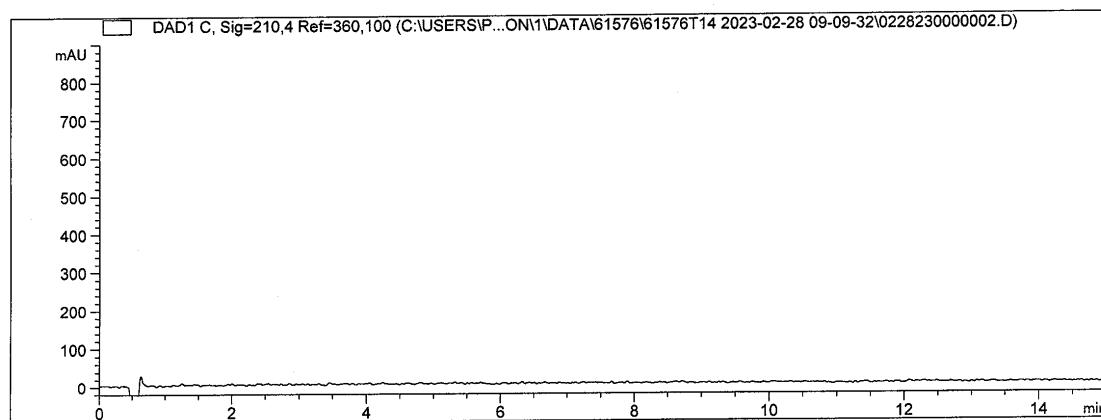
Peak #	RetTime [min]	Type	Width [min]	Area [mAU*s]	Area %	Name
1	1.193	BBA	0.0827	1665.25439	100.0000	Propamocarb hydrochloride

Totals : 1665.25439

## APPENDIX B (cont.): REPRESENTATIVE CHROMATOGRAMS FOR PROPAMOCARB HCI BLANK (DAY 14)

Batch Run # 2 of 16  
Data File C:\USERS\P...EMSTATION\1\DATA\61576\61576T14 2023-02-28 09-09-32\0228230000002.D  
Sample Name: Blank-H2O

```
=====
Acq. Operator   : SYSTEM          Seq. Line : 2
Sample Operator : SYSTEM
Acq. Instrument : LC-13          Location  : 1
Injection Date  : 2/28/2023 9:29:45 AM    Inj       : 2
                                                Inj Volume : 10.000 µl
Acq. Method     : C:\Users\Public\Documents\ChemStation\1\Data\61576\61576T14 2023-02-28
                   09-09-32\61576P.M
Last changed    : 2/28/2023 9:09:26 AM by SYSTEM
Analysis Method : C:\Users\Public\DOCUMENTS\ChemStation\1\DATA\61576\61576T14 2023-02-28
                   09-09-32\61576P.M (Sequence Method)
Last changed    : 3/1/2023 5:40:51 AM by SYSTEM
                   (modified after loading)
Method Info     : Stability of 230104-9G
```



### Area Percent Report

```
=====
Sorted By      : Signal
Calib. Data Modified : 3/1/2023 5:40:51 AM
Multiplier      : 1.0000
Dilution        : 1.0000
Do not use Multiplier & Dilution Factor with ISTDs
```

Signal 1: DAD1 C, Sig=210,4 Ref=360,100

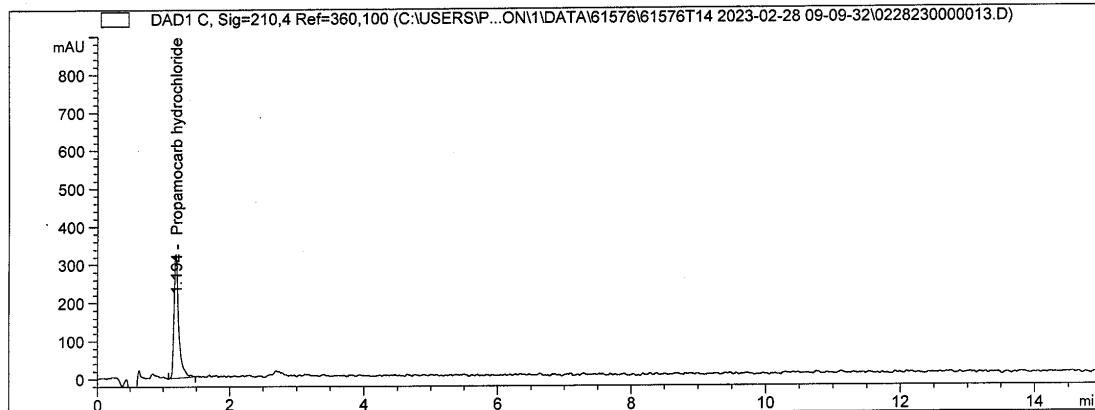
Peak #	RetTime [min]	Type	Width [min]	Area [mAU*s]	Area %	Name
1	1.190		0.0000	0.00000	0.00000	Propamocarb hydrochloride
Totals :				0.00000		

## APPENDIX B (cont.): REPRESENTATIVE CHROMATOGRAMS FOR PROPAMOCARB HCI STANDARD (DAY 14)

Batch Run # 13 of 16  
Data File C:\USERS\P...EMSTATION\1\DATA\61576\61576T14 2023-02-28 09-09-32\0228230000013.D  
Sample Name: Std

```
=====
Acq. Operator : SYSTEM           Seq. Line : 13
Sample Operator : SYSTEM
Acq. Instrument : LC-13          Location : 7
Injection Date : 2/28/2023 12:52:13 PM   Inj : 1
                                         Inj Volume : 10.000 µl
Acq. Method      : C:\Users\Public\Documents\ChemStation\1\Data\61576\61576T14 2023-02-28
                     09-09-32\61576P.M
Last changed     : 2/28/2023 9:09:26 AM by SYSTEM
Analysis Method  : C:\Users\Public\DOCUMENTS\ChemStation\1\Data\61576\61576T14 2023-02-28
                     09-09-32\61576P.M (Sequence Method)
Last changed     : 3/1/2023 5:40:51 AM by SYSTEM
                     (modified after loading)
Method Info      : Stability of 230104-9G
```

---



---

### Area Percent Report

---

```
Sorted By       : Signal
Calib. Data Modified : 3/1/2023 5:40:51 AM
Multiplier      : 1.0000
Dilution        : 1.0000
Do not use Multiplier & Dilution Factor with ISTDs
```

---

Signal 1: DAD1 C, Sig=210,4 Ref=360,100

Peak #	RetTime [min]	Type	Width [min]	Area [mAU*s]	Area %	Name
1	1.194	BBA	0.0767	1585.16235	100.0000	Propamocarb hydrochloride

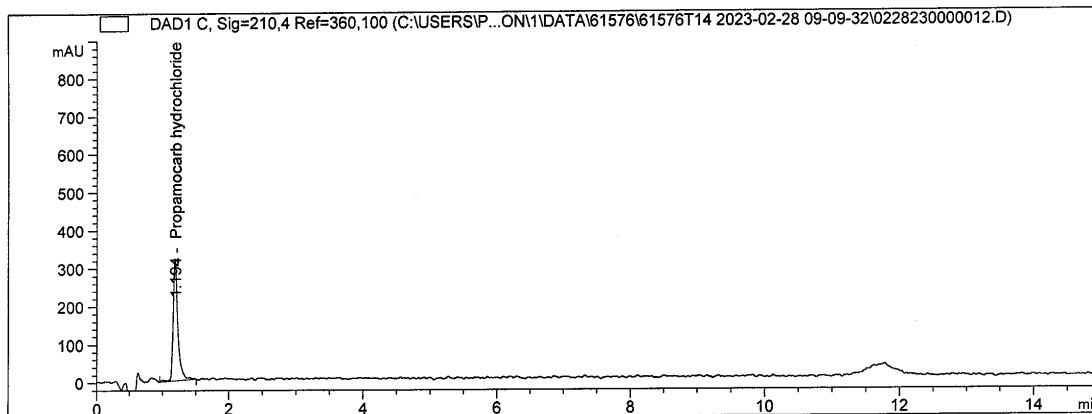
---

Totals : 1585.16235

## APPENDIX B (cont.): REPRESENTATIVE CHROMATOGRAMS FOR PROPAMOCARB HCI SAMPLE (DAY 14)

Batch Run # 12 of 16  
Data File C:\USERS\P...EMSTATION\1\DATA\61576\61576T14 2023-02-28 09-09-32\0228230000012.D  
Sample Name: A 3

```
=====
Acq. Operator      : SYSTEM          Seq. Line : 12
Sample Operator   : SYSTEM
Acq. Instrument  : LC-13           Location  : 6
Injection Date    : 2/28/2023 12:33:50 PM     Inj       : 2
                                                Inj Volume : 10.000 µl
Acq. Method       : C:\Users\Public\Documents\ChemStation\1\Data\61576\61576T14 2023-02-28
                      09-09-32\61576P.M
Last changed      : 2/28/2023 9:09:26 AM by SYSTEM
Analysis Method   : C:\Users\Public\DOCUMENTS\ChemStation\1\Data\61576\61576T14 2023-02-28
                      09-09-32\61576P.M (Sequence Method)
Last changed      : 3/1/2023 5:40:51 AM by SYSTEM
                      (modified after loading)
Method Info       : Stability of 230104-9G
=====
```



### Area Percent Report

```
=====
Sorted By          : Signal
Calib. Data Modified : 3/1/2023 5:40:51 AM
Multiplier        : 1.0000
Dilution          : 1.0000
Do not use Multiplier & Dilution Factor with ISTDs
=====
```

Signal 1: DAD1 C, Sig=210,4 Ref=360,100

Peak	RetTime	Type	Width	Area	Area	Name
#	[min]		[min]	[mAU*s]	%	
1	1.194	BBA	0.0774	1572.41296	100.0000	Propamocarb hydrochloride
Totals :						
1572.41296						

## APPENDIX C: CERTIFICATES OF ANALYSIS

### Product Safety Labs

## CERTIFICATE OF ANALYSIS

**Product:** Consento 450 SC

**Batch #:** SARAM2001/ Lot - 7

**PSL Reference No.:** 230104-9G

**Date of Analysis:** Feb. 14, 2023

**Expiration Date:** Feb. 13, 2026

### Result\* %w/w:

**Fenamidone** 6.66%

**Propamocarb HCL** 34.01%

Approval:



  
Date

Catherine Wo, PhD  
Analytical Services  
Product Safety Labs

QA Release:



  
Date

Quality Assurance  
Product Safety Labs

*This material was analyzed in compliance with Good Laboratory Practice (40 CFR 160) standards.  
Data are reported in PSL GLP Study No. 61576*

\*74.9 g/L for Fenamidone and 382.6 g/L for Propamocarb HCL respectively.



SARASWATI AGRO CHEMICALS (INDIA) PVT. LTD.

Lane-2, Phase-1, Near ESI Hospital

SIDCO Industrial Complex Bari Brahma, Distt. Samba, Jammu (J&K) - 181133

ISO 14001 : 2004, OHSAS 18001 : 2007 & ISO 9001:2008

Ph. : 01923-221433, 221914 E-mail : saraswatiagro@gmail.com

GSTIN : 01AAFC52290A1Z1 CIN : U24211PB1999PTC022404

280104-9G

## Certificate of Analysis

Product: Consent 450 SC

Issue Date: 20/10/2022

Testing Date: 19/09/2022

Batch No.: SARAM2001/Lot-7

Mfg.: 19/09/2022

Exp.: 18/09/2024

Sr. No.	Tests Description	Release Limits	Observations
1	Description	White to light beige liquid suspension	Complies
2	Assay (g/L) Fenamidone	71.30 - 78.80	75.66
3	Assay (g/L) Propamocarb HCL	363.8 - 386.3	378.22
4	Particle size in micron (d 0.50)	1.5 – 7.0	3.80
	(d 0.90) max	15	11.60
5	Viscosity (cp) @ 20°C, Shear rate 20/s, Measuring Cone - CP-50 Rheometer (Antonpaar MCR-92)	270 - 700	605
6	Density @ 20°C (g/ml)	1.100 – 1.140	1.1250
7	pH (Neat)	6.0 - 7.5	6.53
8	Wet sieve (75µm sieve), Ret. % 150 micron sieve %m/m, max 45 micron sieve %m/m, max	0.01 1.0	Nil Nil
Remarks : Sample Complies w.r.t. above tests only.			

Mr. Amitpal

(Chemist)

Dr. Gopal Rathore

(Manager QC)

## APPENDIX D: GLP QUALIFICATION

### Product Safety Labs

#### Good Laboratory Practice Qualification

Product Safety Labs subscribes to the principles of the Good Laboratory Practice Standards and the respective Quality Systems as defined in the following:

US FDA GLP; 21 CFR Part 58 / US EPA FIFRA GLP; 40 CFR Part 160 / US EPA TSCA GLP; 40 CFR Part 792

Which are compatible with:  
OECD GLP; EC Directive 2004/10/EC & JMAFF GLP: No. 76, 30 Nov 2018

As a contract research organization, we are mandated to comply with the Good Laboratory Practices (GLP) as contracted by the Sponsor. The United States Food and Drug Administration (FDA) and the United States Environmental Protection Agency (EPA) do not "certify" laboratories as GLP compliant. These agencies conduct periodic inspections to monitor laboratories for compliance with Good Laboratory Practice standards. GLP compliance is study specific and driven by the requirements of individual study protocols, which are approved by the Sponsor, and signed by the Study Director. The GLP Compliance Statement is provided within individual study reports attesting to the regulatory status of the work performed.

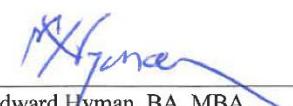
There have been some various iterations of our corporate identity. Establishment Inspection Reports have been logged under the following names:

Product Safety Labs; Product Safety Labs Inc; Eurofins, Product Safety Labs; Product Safety Laboratories

Our facility is located in Dayton, NJ. Our previous facility was located in East Brunswick, NJ.

These are the dates of our GLP inspections:

  
Dan Merkel, BS, MBA  
President

  
Edward Hyman, BA, MBA  
Director, Quality Assurance

Inspectional History			
EPA		FDA	
July	1988	August	2005
January	1990	October	2009
February	1990	August	2013
September	1993	September	2016
January	1995	July	2022
July	1997		
September	1997		
October	2000		
July	2001		
March	2005		
January	2007		
January	2011		
August	2014		
December	2019		

Issued: 08/22/2022



**SARASWATI AGRO CHEMICALS (INDIA) PVT. LTD.**

Lane-2, Phase-1, Near ESI Hospital

SIDCO Industrial Complex Bari Brahmana, Distt. Samba, Jammu (J&K) - 181133

ISO 14001 : 2004, OHSAS 18001 : 2007 & ISO 9001:2008

Ph. : 01923-221433, 221914    E-mail : saraswatiagro@gmail.com

GSTIN : 01AAFC2290A1Z1    CIN : U24211PB1999PTC022404

## **STATEMENT**

### **TO WHOM IT MAY CONCERN:**

We, SARASWATI AGRO CHEMICALS (INDIA) PVT. LTD. (on behalf of and according to the specifications of GOWAN CROP PROTECTION LIMITED, located at Lane No. 2, Phase-I, SIDCO Industrial Complex, Bari Brahmana, Distt. Samba, PIN: 181133, Jammu & Kashmir, India, declare that we take the services of the manufacturers of the technical material Fenamidone and Propamocarb HCl. Both technical materials used for the formulation of the product CONSENTO 450 SC (i.a. Fenamidone + Propamocarb HCl).

Yours sincerely,

For Sarawati Agro Chemicals (India) Private Limited

**(Suraj Kumar Bansal)**  
**Managing Director**









