Reconhecimento BPL

BPL 0002

Study Title
Physical State, Appearance, Color, and Odor of
S-2200 43% SC

Methodology Reference
USEPA OPPTS 830.6302, 1996
USEPA OPPTS 830.6303, 1996
USEPA OPPTS 830.6304, 1996
ASTM D 1535/2008

Study Director
Viviane C. Hilário

Study Concluded
20/Aug/2015

Translated Copy n° 01 realized in
20/Aug/2015

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São Paulo/SP, Zip Code: 01310-913
Phone: (11) 3174-0355

Study #
12986.001.045.14

Study Compliance Statement

Copy n° 01 Authorized and Translated of the Final Report

The study described in this Final Report was performed under my supervision, according to the Study Plan and procedures described in the USEPA OPPTS 830.6302 (1996), USEPA OPPTS 830.6303 (1996), USEPA OPPTS 830.6304 (1996), and ASMT D 1535/2008 and following the Principles of Good Laboratory Practice (GLP) as established by Norma Nº NIT-DICLA-035-(Rev. 02). PRINCÍPIOS DAS BOAS PRÁTICAS DE LABORATÓRIO – BPL. CGCRE – Coordenação Geral de Acreditação – Set/2011 and the OECD (Organisation for Economic Co-operation and Development) Number 1. OECD Principles on Good Laboratory Practice. (as revised in 1997). ENV/MC/CHEM(98)17.

This report represents an accurate and true recording of the results obtained.

Study plan, an original Final Report, all the data, raw data and observations referent to this study will be archived at BIOAGRI for a period of 10 years.

Viviane C. Hilário

Viviane C. Hilário
Study Director
Telephone: +55 (19) 3429-7700

20/Aug/2015
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Study #: 12986.001.045.14
Study Title: Physical State, Appearance, Color, and Odor of S-2200 43% SC.

Quality Assurance Statement

This Final Report has been inspected by the Quality Assurance (QA) – BIOAGRI. The dates and phases of the inspections in the study are given below:

Inspection		***Information Date***	
Date	**Phase**	**Study Director**	**Test Facility Manager**
01/Sep/2014	**Study Plan**	01/Sep/2014	01/Sep/2014
13/Mar/2015	**RAS 0033/15 (Weighing, acclimatization, assessment of physical condition, appearance, color and odor - Munsell scale)**	16/Mar/2015	17/Mar/2015
25/Jun/2015	**DRAFT Report**	25/Jun/2015	25/Jun/2015
20/Aug/2015	**Final Report**	20/Aug/2015	20/Aug/2015

The most recent process inspection prior to the completion of the laboratory phase of this class of study was performed between March 11th and 13th, 2015. This inspection has been recorded in the internal Quality Assurance document identified as **RAS 0033/15**. The Study Director and The Facility Manager were reported and the dates are described on table above.

The results and observations presented in this Final Report are an accurate representation of the raw data generated during the conduct of this study, all the raw data, study plan amendment, and study plan deviation generated during the conduction of this study was inspected.

The translation/copy of this Final Report was verified and represents a precise translated copy of the original Final Report.

Carlos Alberto Goia
Quality Assurance Officer
Quality Assurance
Telephone: +55 (19) 3429-7700

20 / AUG / 2015
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Index

Page #

Study Compliance Statement 2
Quality Assurance Statement 3
Index 4
Summary 5
1. General Information 5
2. Technical Staff 5
3. Definitions 5
4. Objective 6
5. Material and Methods 6
5.1 Test Item Information 6
5.2 Reference Information 6
5.3 Equipment 6
5.4 Experimental Procedure 7
5.4.1 Physical State and Appearance 7
5.4.2 Color 7
5.4.3 Odor 7
6. Results 7
7 Conclusion 7
8. References 8

Table

Table 1 - Physical State, Appearance, Color, and Odor of S-2200 43% SC. 7

Annexes

Annex 1 - Recognition of Compliance with the OECD Principles on Good Laboratory Practice 9
Annex 2 - Analysis Certificate (Bioagri) 10
Annex 3 - Analysis Certificate (Sumitomo) 11

Summary

The physical state, appearance, color and odor of S-2200 43% SC were established from observations carried out under controlled laboratory conditions at a temperature 24.9 to 25.1°C. On the basis of the evaluations performed, the test substance was classified liquid, with a milky appearance, white (N9.5/) color and characteristic odor.

1. General Information

Study Initiation Date:	01/Sep/2014
Experimental Starting Date:	14/May/2015
Experimental Completion Date:	14/May/2015
Draft Report Date:	25/Jun/2015
Study Completion Date:	20/Aug/2015

2. Technical Staff

Study Director:	Viviane C. Hilário
Laboratory Technicians:	Rafaela P. Vicente
	Renata C. de Almeida
Laboratory Auxiliary:	Renata A. Arruda

3. Definitions

Tight definitions of physical state, appearance, color, and odor are difficult, since the outcome of determinations of these properties of a test substance are dependent on the observer's experience and training, rather than on quantitative testing. In addition, it is difficult to separate these four aspects to the description of a test substance. It is easier to indicate the scheme which the observer uses to determine "values" for the following properties:

Physical state: This property is mainly related to the ability of the test substance to maintain its shape, irrespective of its container. The first level of classification is then into gas, liquid, and solid, or mixtures of two or more of these three. For solids, useful sub-categories include crystalline solid, granular solid, semi-solid, and powder. Liquids may be further categorized as, for instance, solutions, aqueous solutions, emulsions, and volatile.

Appearance: This property requires further sub-divisions to get a more complete description of the test substance beyond that contained within the classification of its physical state. For example, powders may be classified as dry or wet. Other physical properties which have a strong influence on the description of the test substance and fall within the boundaries of appearance include viscosity (viscous or mobile), and light transmission (opaque, transparent, translucent, milky).

Color: Test substances exhibit colors due to the relative probabilities with which they reflect, absorb, emit, and transmit light of different wavelengths. The color of a substance is the observer's subjective summary of these complex wavelength-dependent spectroscopic properties, which is necessarily drawn from the experience and training of the observer. The subjectivity of the classification can be greatly reduced by comparing the color against a set of standard colors, and performing the test under a standard set of viewing conditions.

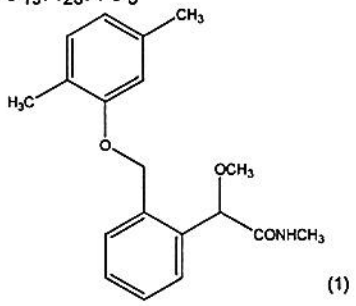
Odor: It is the olfactive characterization for perception of characteristic odors. It is associated to known aromas, if necessary. The odors can be classified as: ethereal, alcoholic, acid, sulphurous, unsaturated, odorless and characteristic of the test substance.

4. Objective

The determination of the physical state, appearance, color and odor of S-2200 43% SC at temperature of 25 ± 1°C.

5. Material and Methods

5.1 Test Item Information

Test item:	S-2200 43% SC
Received on:	04/Aug/2014
BIOAGRI code:	AGR-0693/14
Common name of the active ingredient (a.i.):	mandestrobin [1]
Chemical name (IUPAC) of a.i.:	(*RS*)-2-methoxy-*N*-methyl-2-[α-(2,5-xylyloxy)-*o*-tolyl]acetamide [1]
CAS number of a.i.:	173662-97-0 [1]
Declared Concentration of a.i. (Sponsor):	430.0 g L^{-1} [1]
Analyzed Concentration of a.i. (BIOAGRI):	435.7 g L^{-1}
Analysis Certificate (CA):	CA-0456/14R1
Batch number:	AQ13-9F302 [1]
Homogeneity data:	homogeneous sample (TH-0044/15)
Manufacture date:	21/Aug/2013 [1]
Expiry date:	20/Aug/2015 [1]
Formulation type:	Suspension concentrate [1]
Molecular weight of a.i.:	313.39 [1]
Molecular formula of a.i.:	$C_{19}H_{23}NO_3$ [1]
Structural Formula of a.i.:	 [1]
Physical state:	Liquid [1]
Test item sent by:	Sumitomo Chemical do Brasil Representações Ltda.
[1] Source:	Information provided by the sponsor

5.2 Reference Information

Munsell Scale of Colors.

5.3 Equipment

Analytical Balance;.
Luminous Chamber (Fluorescent);
Digital Timer;
Petri dish;
Temperature Monitoring System;
Common laboratory glassware.

5.4 Experimental Procedure

5.4.1 Physical State and Appearance

An aliquot of 11.6230 g of the test substance was weighed into a beaker, and taken to the observation room, which was maintained at a temperature of 25 ± 1 °C. Thermal equilibrium of the sample to the room temperature was assured by leaving the sample in the room for a period of 2 hours before the observations were made. The observer's perceptions of the physical state and appearance of the test substance were compared against locally devised classification tables, presented to the observer as a set of check boxes.

5.4.2 Color

The test substance above weighed (section 5.4.1), was transferred into a Petri dish, which was taken to the observation room at a temperature of 25 ± 1°C. The Petri dish was placed into a luminous chamber, with white walls and a fluorescent lamp. The walls and lamp define the standard viewing conditions for the assessment of color. After an initial subjective assessment, the color of the test substance was compared against a set of standard colors (Munsell scale), and the best match was identified.

5.4.3 Odor

An aliquot of the test substance (section 5.4.1), was placed in a beaker and the odor was felt and identified by 2 analysts. The test was carried out in an acclimatized room, free of odorous interference, and carefully keeping an approximate interval of 15 minutes between each analyst.

6. Results

Table 1 - Physical State, Appearance, Color, and Odor of S-2200 43% SC.

Property	Results	Temperature (°C)
Physical State	Liquid	24.9 to 25.1
Appearance	Milky	24.9 to 25.1
Definitive color	White (N9.5/)	24.9 to 25.1
Odor	Characteristic	24.9 to 25.1

7 Conclusion

According to the results obtained, the test substance was classified liquid, with a milky appearance, white (N9.5/) color and characteristic odor.

8. References

ASTM (American Society for Testing and Materials). 2008. *Standard Practice for Specifying Color by the Munsell System.* D 1535-08. 37 p.

Norma Nº NIT-DICLA-035-(Rev. 02). PRINCÍPIOS DAS BOAS PRÁTICAS DE LABORATÓRIO – BPL. CGCRE – Coordenação Geral de Acreditação – Rio de Janeiro. p 19. Set/2011.

OECD (Organisation for Economic Co-operation and Development) SERIES ON PRINCIPLES OF GOOD LABORATORY PRACTICE AND COMPLIANCE MONITORING. Number 1. OECD Principles on Good Laboratory Practice. (as revised in 1997). ENV/MC/CHEM(98)17. OLIS : 21-Jan-1998. Dist. : 26-Jan-1998.

USEPA (United States Environmental Protection Agency). 1996. *Product Properties Test Guidelines. Color.* OPPTS 830.6302. 2 p.

USEPA (United States Environmental Protection Agency). 1996. *Product Properties Test Guidelines. Physical State.* OPPTS 830.6303. 1 p.

USEPA (United States Environmental Protection Agency). 1996. *Product Properties Test Guidelines. Odor.* OPPTS 830.6304. 1 p.

Annex 1 - Recognition of Compliance with the OECD Principles on Good Laboratory Practice

Federal Republic of Brazil
Ministry of Development, Industry and Foreign Trade
National Institute of Metrology, Quality and Technology - INMETRO

General Coordination for Accreditation

Brazilian Compliance Monitoring Authority for the Principles of Good Laboratory Practice – GLP

Statement of GLP Compliance

GLP Recognition No. GLP 0002

Initial Recognition: May 25th 2000

BIOAGRI LABORATÓRIOS LTDA.
RODOVIA SP 127 - KM 24 – GUAMIUM
PIRACICABA - SP

The General Coordination for Accreditation of Inmetro grants to the above mentioned test facility the recognition of compliance with the OECD Principles of Good Laboratory Practice as part of the Brazilian GLP Monitoring Program to carry out non-clinical health and environmental safety studies, as describe in the scope below:

Areas of expertise	Categories of Test Items
Physical-chemical testing; Toxicity studies; Mutagenicity studies; Environmental toxicity studies on aquatic and terrestrial organisms; Studies on behavior in water, soil and air and bioaccumulation; Residue studies.	- Pesticides, Their Components and Suchlike; - Pharmaceutical Products; - Cosmetics; - Veterinary Products; - Disinfectants; - Industrial Chemical Products; - Genetically Modified Organisms or derived from GMOs or genetically modified living organisms.

Note: Categories of test items "pesticides" and "industrial chemical" are covered by Brazil's full adherence to the OECD Council Acts related to the Mutual Acceptance of Data (MAD) on Good Laboratory Practice.

Issue Date: May 27th 2014

Expiration date: May 25th 2016

Marcos Aurélio Lima de Oliveira
General Coordinator for Accreditation

The recognition status shall be checked at the address http://www.inmetro.gov.br/monitoramento_BPL/certificados/

MOD-CGCRE-027 – Rev. 02 – Apr. JAN/14 – Pg. 01/01

Cópia Digitalizada do Documento Original
Scanned Copy of Original Document

Annex 2 - Analysis Certificate (Bioagri)

BIOAGRI
a Mérieux NutriSciences Company

Certificado de Análise
Certificate of Analysis

CA – 0456/14 R1

Empresa: Company	Sumitomo Chemical do Brasil Representações Ltda.
Nome comercial da Amostra: Sample Comercial Name	S-2200 43% SC
Ingrediente Ativo: Active Ingredient	Mandestrobina Mandestrobin
Lote: Batch	AQ13 - 9F302
Data de fabricação: Manufacture date	21/Ago/2013 21/Aug/2013
Data de validade: Expiry date	20/Ago/2015 20/Aug/2015
Código Bioagri: Bioagri Code	AGR-0693/14
Finalização do ensaio: Finish of analysis	10/Abr/2015 10/Apr/2015
Data de emissão do certificado: Issue date of certificate	12/Jun/2015 12/Jun/2015
Metodologia utilizada: Employed Methodology	CLAE/UV RF 12986.003.114.14 HPLC/UV

Objetivo: Determinar o teor do ingrediente ativo.
Objective: Determine the concentration of the active ingredient.

RESULTADOS
RESULTS

Concentração de ingrediente ativo: 435,7 $g \cdot L^{-1}$
Concentration of active ingredient: 435.7 g L-1

Obs.: A análise refere-se exclusivamente à amostra analisada, não sendo extensivo a outros lotes e/ou produtos.
Os documentos e registros deste certificado serão arquivados na BIOAGRI por um período de 10 anos.
The analysis refers only to the sample tested and not be extended to other lots and / or products
The documents and records of the certificate is filed in BIOAGRI for a period of 10 years

João Márcio V. Kuppe
Analista Responsável
Analyst responsible

Carla Santos
Responsável Técnico
Technical responsible

Este Certificado de análise CA-0456/14 R1 cancela e substitui o certificado de análise CA-0456/14 emitido anteriormente.
This Certificate of Analysis CA-0456/14 R1 cancels and replaces the certificate of analysis CA-0456/14 previously issued

SQB 0074/Q – Registro da Qualidade (Elaborado em 15/Agosto/2014)
BQS 0074/Q – Quality Records (Elaborated in August 15, 2014)

Bioagri Laboratórios Ltda
Piracicaba - SP / Rodovia SP 127, km 24 / Guamium - Caixa postal: 573 / CEP: 13.412-000
Fone: (19) 3429 7700 / com.agroquimicos@bioagri.com.br / com.biocombustiveis@bioagri.com.br / com.farmacos@bioagri.com.br | bioagri.com.br

Test Facility Recognized to be in Compliance with the Principles of
Good Laboratory Practice – GLP

Annex 3 - Analysis Certificate (Sumitomo)

SUMITOMO CHEMICAL
http://www.sumitomo-chem.co.jp
27-1, Shinkawa 2-Chome, Chuo-ku, Tokyo 104-8260, Japan

August 1, 2014

CERTIFICATE OF ANALYSIS

To whom it may concern:

We hereby certify that SUMITOMO CHEMICAL COMPANY, LIMITED has manufactured the following commodities and that the relative statements below are true and correct.

1. COMMODITY :

Name of product, quantity	Lot No.	Purity /content	Date of Manufacturing	Date of Expiration
S-2200 43%SC, 0.1 L x 5 0.8 L x 1 1.7 L x 1	AQ13-9F302	43%	21/08/2013	20/08/2015

2. Country of origin: Japan
3.
4. Indication of condition for storage:
Keep in a cool, dry and dark place.

SUMITOMO CHEMICAL CO., LTD.
CROP PROTECTION DIVISION
-International

Ippei Uemura

Ippei Uemura
Marketing Dept.