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Susan Stanton 4/29/98

DATE: 09/JUN/1998

SUBJECT: PRODUCT CHEMISTRY REVIEW OF MP [ ] TGAI[X]
DP BARCODE No.:D245940 REG./File Symbol No.: 2217-455
PRODUCT NAME: 2,4-Dichlorophenoxy acetic acid
COMPANY: PBI/Gordon Corporation

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INTRODUCTION

The registrant PBI/Gordon Corporation has submitted an application for an amended registration for the product, using A.H.Marks produced compound as an alternate source of technical 2,4-D acid. The A.H.Marks and Company Ltd, has submitted the CSF and the manufacturing process & the composition of the product(a confidential information of A.H.Marks))and must not be revealed to personal employed by PBI/Gordon Incorporation. When Marks agreed with PBI/Gordon to be an alternate source for PBI/Gordon's registered 2,4-D acid, it was decided to develop five batch constituents data extracting the 2,4-D acid intermediate for ongoing production of 2,4-D 2-EHE, rather than analyzing ten year old samples of 2,4-D acid.

SUMMARY OF FINDINGS

1. The five batch analyses was carried out on the recently prepared samples of the 2,4-D acid by HPLC method. The study was conducted under GLP and was performed at A.H.Marks facility in U.K. The five selected batches of 2,4-D acid were analyzed for purity, impurity profile, sulphated ash and water content. The results of five batches of 2,4-D give a closure of at least 99%; the linearity obtained for the 2,4-D content by HPLC was 0.99995.[MRID No. 445435-02 & -03]

2. The chemical composition of two technical are substantially similar with similar purity & impurity profiles. The nominal concentration was 98%(for A.H.Marks; Basic CSF dated 4-18-98) which is very close to 97.9%(PBI/Gordon; Basic CSF dated 10-01-92, EPA Reg. No. 2217-455).

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3. The registrant provided the existing manufacturing process used by A.H.Marks at UK facility. This process is intended to be superseded in 1998 by a revised process to be known as the New Manufacturing Process. The registrant described the complete experimental procedure and reaction conditions for each step of the manufacturing process. [MRID No. 445479-01]

4. The registrant has provided the following Physical-Chemical properties for 2,4-D acid: Color (830.6302), Physical state (830.6303), odor(830.6304), Stability(830.6313), pH(830.7000), UV/Visible absorption(830.7050), MP(830.7200), Density(830.7300), Dissociation constant(830.7370), $K_{o/w}$(830.7550), water solubility (830.7840), and Vapor pressure(830. 7950). [MRID No. 445435-04].

CONCLUSION

1. Since the 2,4-D acid produced by A.H.Marks and 2,4-D of PBI/Gordon(EPA Reg. No. 2217-455) has similar purity & impurity profile, same nominal concentration, and similar Physical-Chemical Properties, the Agency concludes that A.H.Mark's 2,4-D acid can be used as an alternate source of the active ingredient in PBI/Gordon's EPA Reg. No. 2217-455.

2. The alternate formulation CSF(dated 04-18-98)for 2,4-D acid produced as an alternate for EPA Reg. No. 2217-455 is filled out correctly and completely in compliance with PR Notice 91-2 and agree with the label claim nominal concentration. The alternate formulation CSF is acceptable. [Satisfy 40CFRSec.158.155 & 158.175].

3. The data submitted for five batch analysis(830. 1700) satisfy the data requirements of 40CFRSec.158.170 and is acceptable.

4. The data submitted for manufacturing process(830.1620)& discussion on the formation of impurities(830.1670)satisfy the data requirements of 40CFRSc.158.165 and 158.167 respectively and are acceptable.

5. the data submitted for Color (830.6302), Physical state (830.6303), odor(830.6304), Stability(830.6313), pH(830.7000), UV/Visible absorption(830.7050), MP(830.7200), Density(830.7300), Dissociation constant(830.7370), $K_{o/w}$(830.7550), water solubility (830.7840), and Vapor pressure(830. 7950)satisfy the data requirements of 40CFRSec.158.190 and are acceptable.

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Physical-Chemical characteristics of 2,4-D acid produced by A.H.Marks & Company: [MRID No. 445435-04]

Color (830.6302):	White
Physical state (830.6303):	Solid Powder
odor(830.6304):	Slightly Phenolic
Stability(830.6313):	(A). Stable under warehouse conditions for 14 days (B). Stable at 54±2°C for 14 days (C). Stable in presence of metals iron, aluminum,& tin at 54±2°C For 14 days.

Full Experimental details are provided.

pH(830.7000):	2.78 at 20°C saturated solution
UV/Visible absorption(830.7050):	maxima at 208, 228.3, & 283.3 nm
MP(830.7200):	139.5°C
Density(830.7300):	1.508 at 20°C
Dissociation constant(830.7370):	2.73 at 25°C
$K_{o/w}$(830.7550):	The n-octanol/water partition Coefficient was determined as Follows(Shake Flask method:

pH	Molar Concentration	Log $P_{o/w}$
1	0.001	2.58
1	0.0001	2.83
5	0.01	0.04
5	0.001	0.33
7	0.01	-0.91
7	0.001	-0.75
9	0.01	-1.04
9	0.001	-0.99

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Water solubility(830.7840): Column elution method; shake flask method:

Solution	solubility of 2,4-D mg/l at 25°C
pH 1 buffered	311
pH 5 buffered	20031
pH 7 buffered	23180
pH 9 buffered	34196
pH 5 buffered	29934
pH 7 buffered	44558
pH 9 buffered	41314

Vapor pressure(830. 7950): 1.4×10^{-7} mm Hg at 25°C

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830.1700.Preliminary analysis: (MRID No. 445435-02 & -03)

The registrant provided following information on this topic: this study was performed at A.H.Mark's facility in UK and was carried out under GLP conditions in compliance with 40CFRSec.160.

A. 2,4-D content:

The five samples were analyzed for 2,4-D content by an internal standard HPLC method. The GLC was operating under following conditions:

HPLC Column:	ZORBAX ODS 5µm, 25 cm x 4.6 mm i.d.
Mobile Phase:	35% acetonitrile:65% (0.1M acetic acid) v/v
Flow rate:	1.0 ml/min
Injection volume:	10 µl
Detector UV:	280 nm
Column temperature:	50^{0}C

The concentration of each test sample was calculated using the response factor which was then used in the following equation:

$$\% \text{ w/w } 2,4\text{-D} = \frac{PAR(Sample)\ P}{RF1 \times \text{Sample weight}}$$

Where, PAR(sample) = peak area ratio
RF1 = relative response factor
P = purity of analytical standard
The resukts were calculated using validated Unicam 4880 software

B. Water content: The water content of each batch was determined using karl Fischer instrument, calibrating the instrument with water before.

C. Sulphated Ash Content: was determined by gravimetric method; the difference in weight method after treatment first with MeoH and then with sulfuric acid following by burning.

$$\text{Sulfated Ash}(\% \text{ w/w}) = \frac{(W3-W1) \times 100}{(W2-W1)}$$

Where, W1 = wight of empty crucible
W2 = wight of crucible + weight of sample
W3 = weight of crucible containing ash.

CONFIDENTIAL APPENDIX
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D. Impurity Profile: The following compounds were analyzed using an HPLC method. These impurities were chosen as being the most likely impurities that would be present on the basis of the known chemistry of 2,4-D; the analyses were carried out by HPLC method:

M1 = 4-chlorophenoxyacetic acid
M2 = 2-chlorophenoxy acetic acid
M3 = 2,4-dichlorophenol
M4 = 2,6-dichlorophenol
M5 = 2,6-dichlorophenoxy acetic acid
M6 = 2,4,6-trichlorophenoxy acetic acid
M7 = 2,4-dichlorophenol ester of 2,4-D

HPLC conditions: the standard solutions were injected into the HPLC followed by the test sample solutions. The HPLC conditions used are described below:

HPLC Column:	Partisil ODS 3, 10 µm, 25 cm x 4.6 mm i.d.
Flow rate:	1.0 ml/min
Injection volume:	10 µl
Detector UV:	280 nm
Column temperature:	50°C
Organic phase:	Acetonitrile
Aqueous Phase:	0.005 M Sulphuric acid

Gradient Program:

Time (min)	%Organic Phase (%v/v)	% Aq. Phase (%v/v)
0	30	70
20	30	70
40	100	0
50	100	0
55	30	70

Page _____ is not included in this copy.

Pages 7 through 14 are not included in this copy.

The material not included contains the following type of information:

_____ Identity of product inert ingredients.

_____ Identity of product impurities.

__X__ Description of the product manufacturing process.

_____ Description of quality control procedures.

_____ Identity of the source of product ingredients.

_____ Sales or other commercial/financial information.

_____ A draft product label.

_____ The product confidential statement of formula.

_____ Information about a pending registration action.

_____ FIFRA registration data.

_____ The document is a duplicate of page(s) _____.

_____ The document is not responsive to the request.

_____ Proprietary information pertaining to the chemical composition of an inert ingredient provided by the source of the ingredient.

_____ Attorney-Client Privilege.

_____ Claimed Confidential by submitter upon submission to the Agency.

_____ Internal Deliberative Information.

* The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.