DP BARCODE: D329417, 329527; **EPA REG. No.**: 62719-LLO; **PRODUCT**: Florasulam Wet Cake Technical

January 12, 2007

SUBJECT: FEE. Secondary Product Chemistry Review on Florasulam Wet Cake Technical

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SBMathur 01/12/07

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Herbicide Branch / RD (7505P)

DP BARCODE: D329417, 329527
DECISION No.: 366687
EPA REG. No.: 62719-LLO
PRODUCT: Florasulam Wet Cake Technical
PCC: 129108
REGISTRANT: DOW Agrosciences
USE: Herbicide

INTRODUCTION:

The registrant DAS has submitted an application for the new registration for Florasulam Wet Cake Technical produced in USA. The registrant has submitted CSF for basic formulation (dated 03-20-06) and supporting product chemistry data under MRID Nos. 468279-01 & 468080-02. According to the registrant florasulam was first registered in Israel (1998) and is also registered in Canada & Europe. DAS has provided the product chemistry review conducted on the technical by PMRA, Canada. TRB has been asked to perform the secondary review of the PMRA report and determine if the data submitted to PMRA will support its registration with the Agency.

SUMMARY OF FINDINGS:

1. The CSF for basic formulation (dated 03-20-06) is filled out completely and correctly. The nominal concentration (NC) of the active ingredient (99.2%) concurs with the product label claim nominal concentration. The CSF is in compliance with PR Notice 91-2. The proposed certified limits for the AI are in compliance with standard certified limit table set-forth in 40CFR §158.175(b)(2). The proposed upper certified limits of the impurities are based on preliminary analysis and the expected production variability. The product chemistry data submitted corresponding to guideline reference 830.1550 (product identity & composition) and 830.1750 (certified limits) satisfy the data requirements of 40CFR§158.155 and 158.175 respectively [MRID No. 468279-01].

2. The product chemistry data submitted corresponding to guideline 830.1600 (description of materials use to produce the product) satisfy the data requirements of 40CFR§158.160. The registrant has provided the MSDS for all the starting materials used to produce the active ingredient [MRID No. 468279-01].

3. The product chemistry data submitted corresponding to guideline reference 830.1620 (description of production process) do not satisfy the data requirements for 40CFR§158.162. The active ingredient was produced in three step integrated batch process. The production process has been described in details. Each production process steps included the reaction conditions, amounts of each chemical used and production yield [MRID No. 468279-01].

4. The product chemistry data submitted corresponding to guideline reference 830.1670 (Discussion on the formation of impurities) satisfy the data requirements for 40CFR§158.167. The registrant has provided the mechanisms of formation and identification of all impurities identified in the 5-batch analysis at ≥0.1% and the potential impurities. In the CSF is also listed two impurities of toxicological concern (0.1% each) [MRID No. 468279-01].

5. The data submitted corresponding the guideline reference 830.1700 (Preliminary analysis) satisfy the data requirements of 40CFR§158.170. Five representative batches of the technical, produced at pilot plant scale, were analyzed for percent AI and the impurities. The active ingredient contents of analyzed batches were determined by means of HPLC-UV (260 nm) method. The five-batch analysis supports the CSF. However, the registrant is required to submit the five batch analysis of the technical samples produced on commercial scale. Based on the 5 batch analysis, a revised supporting CSF might be required [MRID No. 468279-01].

6. The data submitted corresponding the guideline reference 830.1800 (Enforcement Analytical method) satisfy the data requirements of 40CFR§158.180. The HPLC/UV (260 nm) method was used to determine the active ingredient content [MRID No. 468279-01].

7. The product chemistry data submitted corresponding to guideline reference 830 Series Subgroup B (physical/chemical properties) for the Florasulam wet cake technical satisfy the data requirements of 40CFR§158.190, except for one year storage stability (830.6320) and corrosion characteristics (830.6320) studies [MRID No. 468080-02].

CONCLUSIONS

TRB has reviewed the product chemistry data submitted for 830 series Subgroup A & Subgroup B for florasulam wet cake technical (produced on pilot plat scale) and has concluded that:

1. The CSF for basic formulation (dated 03-20-06) is acceptable.

2. The product chemistry data submitted corresponding to guidelines 830 series subgroup A are acceptable.

3. The registrant is required to provide 5 batch analysis on the samples produced on commercial scale and based on the analytical results a revised basic CSF must be submitted.

4. The product chemistry data submitted corresponding to guidelines 830 series subgroup B are acceptable, except for the guidelines 830.6314 (oxidation/reduction), one year storage stability (830.6317), and 830.6320 (corrosion characteristics).

5. The registrant must submit the results of one year storage stability (830.6317) and corrosion characteristics (830.6320) to the Agency on completion. It is recommended that the observations must be made at 0, 3, 6, 9, & 12 month intervals. The results must be submitted in a hard copy and an electronic format is also requested.

Note: The PMRA report is attached below

CONFIDENTIAL APPENDIX
Toxic impurities: [redacted]

Manufacturing process information may be entitled to confidential treatment

Part 2. Chemistry data for the registration of a technical grade of active ingredient (TGAI) or an integrated system product (ISP).

Florasulam

Submission Number: 1999-0441 (formerly Sub. # 99-0009 for research permit application)PCP Number:

Not yet assignedSource Code: FRA-DOWS-1Guarantee: 99.2% nominal (limits: 96.2 - 100%)Data

Submission and Review History:

Table 1. Correspondence Dates, LSS # and Content for Technical Florasulam

Date Received	Sub. #	LSS #	Content Summary	Reviewer
98-12-10	99-0009	98474	Initial submission of Part 1 (label) and Part 2 (Chemistry) as submission for a Research Permit	R. Scharfe
1999/07/20	1999-0441	99266	Correspondence, product specification form, comprehensive data summaries, Parts 0 (index), 1 (label) and 2 (chemistry for TGAI).	Y. Wigfield
1999/12/14	1999-0441	99421	Revised CPSF and schedule for batch data for industrial scale TGAI to confirm data in CPSF.	Y. Wigfield
2000/02/16	1999-0441	00,081	Parts 0 (index), 12.7 [final EU (Belgium) monograph for DE-570 and updated Tier III Overall Summary & Assessmetm for DE-570 and EF-1343.	Y. Wigfield
2001/05/24	1999-0441	01244	Response from Dow indicating that the batch data to support / confirm the specifications will be provided as soon as they become available.	Y. Wigfield

Product Identification

Documentation: M.Stewart (1998) "Chemistry requirement for the registration of a technical grade active (TGAI) or an integrated system product", Dow AgroSciences Canada Inc. Part 2, Vol. 5. (LSS 99266)

2.1 Applicant's Name & Office Address

Dow AgroSciences Canada Inc.
Suite 201, 1144 - 29th Avenue, N.E.
Calgary, Alberta T2E 7P1

2.2 Manufacturer's Name & Office Address & Manufacturing Plant's Name & Address

The Dow Chemical Company
969 Building

Midland, MI 48667, U. S. A.

2.3 Trade Name: Florasulam Technical Herbicide

2.3.1 Other Names: DE-570, XDE-570, XR-570

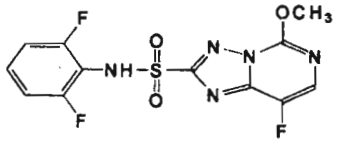
2.4 Common Name: Florasulam (ISO proposed)

2.5 Chemical Name: IUPAC: 2**N**,6**N**,8-trifluoro-5-methoxy-s-triazolo[1,5-c]pyrimidine-2-sulphonanilide CAS: N-(2,6-diflurophenyl)-8-fluoro-5-methoxy[1,2,4]triazolo[1,5-c]pyrimidine-2

sulfonamide

2.6 CAS Number: 145701-23-1

2.7 Structural Formula



2.8 Molecular Formula: $C_{12}H_8O_3N_5F_3S$

2.9 Molecular Weight: 359.3

2.11 Manufacturing Methods:

Documentation:

1 M. Stewart, (1998), "Manufacturing Summary", Vol 1, Tab 2.11.1. (LSS #98474)
2 S. Madsen (1998), "Description of Starting Materials", Study GH-C4749. (LSS #98474)
3 M. Stewart, (1998), "Detailed Production Process Description", Vol 1, Tab 2.11.3. (LSS #98474)

2.11.1 Manufacturing Summary:

[redacted]

2.11.2 Description of Starting Materials

Specifications and suppliers and MSDS's of the starting materials were provided.

2.11.3 Detailed Production Process Description

Manufacturing process information may be entitled to confidential treatment

Page _____ is not included in this copy.

Pages 6 through 20 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.

_____ Internal deliberative information.

_____ Attorney-client communication.

_____ Claimed confidential by submitter upon submission to the Agency.

_____ Third party confidential business 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.