

## Evaluation Report for Category B, Subcategory 1.1, 1.3, 4.6 Application

**Application Number:** 2009-4946  
**Application:** B.1.1 Changes to TGAI: New site, same registrant  
B.1.3 Changes to TGAI: Chemistry-specifications  
B.4.6 Fulfill Conditions of Registration on a Product with Full Registration  
**Product:** Everest Technical Herbicide  
**Registration Number:** 26446  
**Active ingredients (a.i.):** flucarbazone (present as flucarbazone-sodium) [FLS]  
**PMRA Document Number English PDF:** 2010809

### Purpose of Application

The purpose of this application was to add a new manufacturing site with changes in the specifications for Everest Technical Herbicide and to fulfill the conditions of registration on a product with full registration for the initially registered site/source.

### Chemistry Assessment

**Common Name:** Flucarbazone (present as flucarbazone-sodium)  
**IUPAC Chemical Name:** Sodium 4,5-dihydro-3-methoxy-4-methyl-5-oxo-*N*-[[2-(trifluoromethoxy)phenyl]sulfonyl]-1*H*-1,2,4-triazole-1-carboximidate  
**CAS Chemical Name:** 4,5-dihydro-3-methoxy-4-methyl-5-oxo-*N*-[[2-(trifluoromethoxy)phenyl]sulfonyl]-1*H*-1,2,4-triazole-1-carboxamide, sodium salt

Everest Technical Herbicide has the following properties:

Property	Result										
Colour and physical state	Colourless crystalline solid										
Nominal concentration	89.2 % Flucarbazone										
Odour	Odourless										
Density @ 20°C	1.34 g/mL										
Vapour pressure @ 20°C	$< 1 \times 10^{-6}$ mPa										
pH	6.2 (1% solution)										
Solubility in water	44 g/L (pH 4-9)										
n-Octanol/water partition coefficient ( $K_{ow}$ )	<table border="0"> <tr> <td><u>pH</u></td> <td><u>Log <math>K_{ow}</math></u></td> </tr> <tr> <td>4</td> <td>-0.89</td> </tr> <tr> <td>7</td> <td>-1.85</td> </tr> <tr> <td>9</td> <td>-1.89</td> </tr> <tr> <td>Unbuffered</td> <td>-2.80</td> </tr> </table>	<u>pH</u>	<u>Log <math>K_{ow}</math></u>	4	-0.89	7	-1.85	9	-1.89	Unbuffered	-2.80
<u>pH</u>	<u>Log <math>K_{ow}</math></u>										
4	-0.89										
7	-1.85										
9	-1.89										
Unbuffered	-2.80										

The chemistry requirements for the initially registered site/source of Everest Technical Herbicide have been completed and the conditions of full registration have been satisfied.

For the new site, as a condition of full registration, the registrant must provide five-batch data showing the results of the analysis of the active ingredient and all impurities from commercial scale production for the new site/source.

#### Health Assessments

The request to add a new manufacturing site/source and to change the specifications of Everest Technical Herbicide is not expected to alter the residues in food and feed crops treated with end-use products containing flucarbazone-sodium. Therefore, no increase in dietary exposure to flucarbazone-sodium is anticipated.

As chemical equivalence was established between Everest Technical Herbicide manufactured at the registered site and that at the new site, the toxicological profiles were not expected to be different. No new toxicological data were required.

#### Environmental and Value Assessments

Environmental and value assessments were not required in this application.

#### Conclusion

The PMRA has completed an assessment of the subject application and found the addition of a new manufacturing site/source, with changes in specifications for Everest Technical Herbicide and with the condition that five-batch data are provided from commercial scale production, is acceptable. Also, the information is sufficient to address the conditions of full registration for the initial registered site/source.

## References List

PMRA#	Title
1074949	2004, Flucarbazone in Flucarbazone Technical: Analytical Method Validation by High Performance Liquid Chromatography., DACO: 2.13.1 CBI
1074950	2004, Impurities in Flucarbazone Technical: Analytical Method Validation by High Performance Liquid Chromatography., DACO: 2.13.1 CBI
1266867	1998, Chemistry Requirements for the Registration of MKH 6562 Technical., DACO: 2.1,2.11,2.12.1,2.13,2.14,2.15,2.2,2.3,2.4,2.5,2.6,2.7,2.8,2.9 CBI
1266870	2004, U.S. EPA Product Properties Test Guidelines- Group A and B of Everest Technical Herbicide., DACO: 2.12.1,2.13.1,2.13.2,2.13.3,2.13.4,2.14,2.7,2.8,2.9 CBI
1431380	2007, Flucarbazone-Sodium Coupling Process Description, DACO: 2.11.1 CBI
1431388	2007, Analysis of Flucarbazone-Sodium Technical Grade Active Ingredient, Impurities and Water in Pilot Batches: KHD 1-24LW, KHD 1-27LW, KHD 1-29LW, KHD 1-30LW, KHD 1-32LW & KHD 1-34LW, DACO: 2.13.1, 2.13.2, 2.13.3 CBI
1659971	2004, Safety Data Sheet, DACO: 2.11.2
1621465	2008, Product Chemistry Data to Support the Registration of New Sources of Everest Technical Herbicide - Volume 2, DACO: 2.11.2, 2.13.3, 2.13.4, 2.15 CBI
1659973	2008, Analysis of [CBI Removed] Impurity in Everest Technical Herbicide Pilot Batches: 14/2007, 15/2007, 16/2007, 17/2007, 18/2007, 19/2007, 20/2007., DACO: 2.13.4 CBI
1866397	2010, Product Chemistry Data to Support the Registration of [CBI Removed] Source of Everest Technical Herbicide, DACO: 2.2 CBI
1831214	2009, Quantitation of [CBI Removed] in Six Batches of Flucarbazone-Sodium, DACO: 2.13.4 CBI
1971947	2010, Method Validation for Flucarbazone-Sodium, DACO: 2.0, 2.13.1 CBI
1971948	2010, Group A Product Chemistry Analysis for Flucarbazone-sodium Final Report Preliminary Analysis Enforcement Analytical Method, DACO: 2.0, 2.13, 2.13.2, 2.13.3, 2.13.4, 2.2 CBI

- 2010264 2011, DACO 2.0 Everest Technical Herbicide Product Chemistry Data to Support the Requirements for the Registration of the Registered Technical Grade Active Ingredient [CBI Removed] Source, DACO: 2.0, 2.13, 2.13.1, 2.13.3 CBI
- 2013019 2011, DACO 2.13.1 Everest Technical Herbicide Product Chemistry Data to Support the Requirements for the Registration of the Registered Technical Grade Active Ingredient [CBI Removed] Source, DACO: 2.13, 2.13.1

ISSN: 1911-8082

© Her Majesty the Queen in Right of Canada, represented by the Minister of Public Works and Government Services  
Canada 2011

All rights reserved. No part of this information (publication or product) may be reproduced or transmitted in any form or by any means, electronic, mechanical photocopying, recording or otherwise, or stored in a retrieval system, without prior written permission of the Minister of Public Works and Government Services Canada, Ottawa, Ontario K1A 0S5.