

Evaluation Report for Category B, Subcategory 2.1, 2.3, 2.4, 2.5, 3.1, 3.13 Application

Application Number: 2009-0759
Application: New product chemistry: guarantee, identity of formulants, proportion of formulants, formulation type
New product label: application rate increase, precautions
Product: Ziram Granuflo
Registration Number: 29685
Active ingredient (a.i.): Ziram
PMRA Document Number : 1883058

Purpose of Application

The purpose of this application was to register a new end-use product, Ziram Granuflo, based on the precedent products, Ziram 85W (historical Registration Number 14773) and Ziram 85W Fungicide (current Registration Number 29140). The active ingredient, ziram, is currently under re-evaluation.

Chemistry Assessment

Ziram Granuflo is formulated as wettable granules containing ziram at a nominal concentration of 76.0%. This end-use product has a density between 0.563 and 0.621 g/mL and a pH of 5.29. The chemistry requirements for Ziram Granuflo are complete.

Health Assessment

Ziram Granuflo is of high acute toxicity in the rat by the oral ($LD_{50} = 478$ mg/kg bw in females) and inhalation routes ($LC_{50} = 0.06$ mg/L for technical grade active). It is of low dermal toxicity ($LD_{50} > 2000$ mg/kg) in rabbits, and it is extremely irritating to the eye and non-irritating to the skin of rabbits. It is a dermal sensitizer in guinea pigs.

Based on a comparison to the use pattern of the registered precedent product, the use of Ziram Granuflo is not considered to represent an increase of potential occupational exposure over registered uses.

Based on a comparison to the formulation of the registered precedent product, there is no indication that Ziram Granuflo will have an impact on the magnitude of the residues of ziram in/on treated crops when used according to the label as the use directions are identical. Therefore, no increase in dietary exposure is anticipated.

Environmental Assessment

Based on a comparison to the use pattern of the registered precedent product, Ziram Granuflo is not expected to pose an unacceptable risk to the environment.

Value Assessment

The proposed pest/crop combinations and rates for Ziram Granuflo are the same as the precedent products; however, the formulation type has been changed from wettable powder to water dispersible granules. The change in product formulation is not expected to decrease efficacy or increase phytotoxic effects on the crops.

Conclusion

The PMRA conducted an evaluation of the subject application and found the information sufficient to support full registration of Ziram Granuflo. The regulatory status of Ziram Granuflo may be affected by the outcome of the re-evaluation of the active ingredient, ziram.

References

PMRA Document Number: 1726228

Reference: 2009, Chemistry Part 3 EP, Data Numbering Code: 3.1.1, 3.1.2, 3.1.3, 3.1.4

PMRA Document Number: 1726230

Reference: 2009, Chemistry Part 3 EP, Data Numbering Code: 3.2.1 Confidential Business Information

PMRA Document Number: 1726231

Reference: 2009, Ziram Granuflo, Annex I formulation process, Data Numbering Code: 3.2.2 Confidential Business Information

PMRA Document Number: 1726232

Reference: 2009, Ziram Granuflo, Annex II specifications, Data Numbering Code: 3.3.1 Confidential Business Information

PMRA Document Number: 1726233

Reference: 2006, Suitability of the CIPAC CS₂ method for the determination of the active ingredient content in ziram 76WG, Data Numbering Code: 3.4.1 Confidential Business Information

PMRA Document Number: 1726234

Reference: 2000, Ziram 76 WG physical state, aspect, colour, odour, Data Numbering Code: 3.5.1, 3.5.2, 3.5.3, 3.5.4

PMRA Document Number: 1726235

Reference: 2007, Ziram 76DF/WG one year storage stability and corrosion characteristics, Data Numbering Code: 3.5.10, 3.5.14

PMRA Document Number: 1726236

Reference: 2000, Ziram 76WG: determination of flammability - solids, Data Numbering Code: 3.5.11

PMRA Document Number: 1726237

Reference: 2009, Chemistry requirements, Ziram 76, Data Numbering Code: 3.5.12, 3.5.13, 3.5.15, 3.5.5, 3.5.8, 3.5.9

PMRA Document Number: 1726238

Reference: 1998, Ziram 76WG bulk (tap) density, Data Numbering Code: 3.5.6

PMRA Document Number: 1726239

Reference: 1986, Ziram 76 WDG: pH, Data Numbering Code: 3.5.7

PMRA Document Number: 1726240

Reference: 1989, Acute oral toxicity to rats of Ziram 76 WG, Data Numbering Code: 4.6.1

PMRA Document Number: 1726241

Reference: 1989, Acute dermal toxicity to rabbits of Ziram 76 WG, Data Numbering Code: 4.6.2

PMRA Document Number: 1726242

Reference: 2009, Acute inhalation - waiver, Data Numbering Code: 4.6.3

PMRA Document Number: 1726243

Reference: 2006, Particle size assessment for Ziram 76 WG, Data Numbering Code: 4.6.3

PMRA Document Number: 1726244

Reference: 1989, Eye irritation to rabbits of Ziram 76 WG, Data Numbering Code: 4.6.4

PMRA Document Number: 1726245

Reference: 1989, Skin irritation to rabbits of Ziram 76 WG, Data Numbering Code: 4.6.5

PMRA Document Number: 1726246

Reference: 1989, Skin sensitization to Ziram 76 WG in the albino guinea pig, Data Numbering Code: 4.6.6

PMRA Document Number: 1735877

Reference: 2009, Value Part 10 EP, Data Numbering Code: 10.2.3.1, 10.2.3.3(d), 10.3.1, 10.3.2

PMRA Document Number: 1745789

Reference: 2009, Exposure, Ziram 76 WDG, Data Numbering Code: 5.2

PMRA Document Number: 1827650

Reference: 2009, Chemical and physical properties, Data Numbering Code: 3.5.1, 3.5.12, 3.5.13, 3.5.15, 3.5.2, 3.5.3, 3.5.4, 3.5.5, 3.5.6, 3.5.7, 3.5.8, 3.5.9

ISSN: 1911-8082

© Her Majesty the Queen in Right of Canada, represented by the Minister of Public Works and Government Services Canada 2010

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.