

## Evaluation Report for Category L, Subcategory 1.2 Application

**Application Number:** 2023-2805  
**Application:** Application Subject to the Protection of Proprietary Interests in Pesticide Data (PIIP) Policy-Equivalency/Data Compensation Assessment  
**Applicant:** Zhejiang Xinan Chemical Industrial Group Co. Ltd.  
**Product:** WYNCA SUNS-MET HERBICIDE  
**Registration Number:** 35334  
**Active ingredient (a.i.):** S-metolachlor and R-enantiomer  
**PMRA Document Number:** 3625281

### Purpose of Application

The purpose of this application was to register the end-use product WYNCA SUNS-MET HERBICIDE, based on a registered precedent product.

### Chemistry Assessment

WYNCA SUNS-MET HERBICIDE is formulated as an emulsifiable concentrate containing S-metolachlor and R-enantiomer at a concentration of 960 g/L. This end-use product has a density of 1.103 – 1.108 g/mL and a pH of 5.25. The required chemistry data have been provided, reviewed and found to be acceptable.

### Health Assessments

WYNCA SUNS-MET HERBICIDE was considered toxicologically equivalent to the registered precedent product; therefore, no toxicology data were submitted or were required. WYNCA SUNS-MET HERBICIDE is considered to be of low acute toxicity via the oral, dermal and inhalation routes of exposure. It is considered to be minimally irritating to the eyes, non-irritating to the skin, and is not considered to be a skin sensitizer.

The use pattern of WYNCA SUNS-MET HERBICIDE is comparable to the registered use pattern of the registered precedent product. Therefore, potential exposures for mixers, loaders, applicators, bystanders, and postapplication workers are not expected to exceed the current exposures to the registered products of this active ingredient. No health risks of concern are expected for workers and bystanders when label directions, precautions and restrictions are followed.

No new residue data for S-metolachlor and R-enantiomer were submitted or were required to support the registration of WYNCA SUNS-MET HERBICIDE. Previously reviewed residue data were re-assessed in the framework of this application. The use directions on the WYNCA SUNS-MET HERBICIDE label, including the target crops, method (ground), rates and timing of application, geographic restrictions, preharvest intervals, feeding restrictions, and crop rotation restrictions are comparable to those on the label of the registered precedent end-use product.

Based on this assessment, residues are not expected to be greater than those from the currently registered uses and will be covered by the established maximum residue limits (MRLs). Consequently, dietary exposure to residues of S-metolachlor and R-enantiomer is not expected to increase with the registration of WYNCA SUNS-MET HERBICIDE and will not pose health risks of concern to any segment of the population, including infants, children, adults and seniors.

### **Environmental Assessment**

The use pattern for WYNCA SUNS-MET HERBICIDE is within the registered use pattern of the registered precedent product, therefore, no additional risk is expected from the use of WYNCA SUNS-MET HERBICIDE.

When used according to the directions for use and in accordance with the risk mitigation measures, the risks to non-target organisms from the use of WYNCA SUNS-MET HERBICIDE were determined to be acceptable.

### **Value Assessment**

Registration of a generic product may increase product competition, which may in turn reduce purchasing costs of similar products.

The formulation of WYNCA SUNS-MET HERBICIDE was compared to the formulations of the registered precedent product. The differences between the formulations were considered minor, and are unlikely to result in any significant impacts on product performance, in terms of efficacy and/or crop tolerance. Therefore, all uses and claims found on the registered precedent product label are supported for inclusion on the WYNCA SUNS-MET HERBICIDE label.

### **Conclusion**

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found the information acceptable to support the registration of WYNCA SUNS-MET HERBICIDE.

### **References**

#### **PMRA**

#### **Document**

#### **Number**

#### **Reference**

3473801	2015, Chemical and Physical Characterization of S-metolachlor 960 g/L EC: Color, Physical State, Odor, Miscibility, pH, Density, Surface Tension, Corrosion, Accelerated Storage Stability, Flash Point, Viscosity, Emulsion Stability and Re-emulsification, Persistent Foam and Low Temperature Stability, DACO: 3.5.1,3.5.10,3.5.11,3.5.13,3.5.14,3.5.2,3.5.3,3.5.6,3.5.7,3.5.9
3476805	2023, Formulation Type, DACO: 3.5.4
3476806	2023, Container Material and Description, DACO: 3.5.5
3496463	2023, Explanation of the Oxidative Property of S-metolachlor 960g/L EC, DACO: 3.5.8

3476797 2023, Description of Manufacturing S-metolachlor 960 EC, DACO: 3.2.2  
CBI  
3476798 2023, Description of the formulation of impurities of toxicological concern,  
DACO: 3.2.3

© His Majesty the King in Right of Canada, as represented by the Minister of Health Canada, 2024

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 Health Canada, Ottawa, Ontario K1A 0K9.