

Evaluation Report for Category B, Subcategory 2.1, 2.3, 2.4, 2.5, 3.10, 3.12 Application

Application Number: 2014-6050

Application:

- B.2.1 New / Changes EP or MA Product Chemistry-Guarantee
- B.2.3 New / Changes EP or MA Product Chemistry-Identity of Formulants
- B.2.4 New / Changes EP or MA Product Chemistry-Proportion of Formulants
- B.2.5 New / Changes EP or MA Product Chemistry-Formulation Type
- B.3.10 New or Changes to Product Labels-Tank Mixes
- B.3.12 New or Changes to Product Labels-New Site or Host

Product: Solo ADV

Registration Number: 32066

Active ingredients (a.i.): Imazamox

PMRA Document Number : 2502871

Purpose of Application

The purpose of this application was to register a new end use product, Solo ADV, based on the registered product Solo WDG Herbicide (Reg. No. 25496), for post emergence control or suppression of broadleaf weeds, grasses, and volunteer grain cereals in Clearfield (CL) canola, CL canola quality *Brassica juncea*, CL lentils, CL sunflowers, and soybeans.

Chemistry Assessment

Solo ADV is a solution containing the active ingredient imazamox at a nominal concentration of 25.0 g/L. This product has a density of 1.126 g/mL and pH of 3.7. The chemistry requirements for Solo ADV have been fulfilled.

Health Assessments

The uses of Solo ADV as a post emergent treatment on CL canola, CL canola quality *Brassica juncea*, CL lentils, CL sunflowers, and soybeans, do not represent an expansion of use for imazamox. Food residues for these crop commodities are not expected to exceed the established MRLs for imazamox. The residues of imazamox in/on 1) CL canola and CL canola quality *Brassica juncea* are covered under the MRL of 0.05 ppm established for crop subgroup 20A; 2) CL lentils are covered under the established MRL of 0.25 ppm for dry lentils; 3) CL sunflowers are covered under the established MRL of 0.3 ppm for sunflower seeds; and 4) soybeans are covered under the established MRL of 0.1 ppm for dry soybeans.

Consequently, the dietary exposure to imazamox is not expected to increase as a result of the

registration of Solo ADV and will not pose an unacceptable risk to any segment of the consumer population, including infants, children, adults and seniors.

The use of Solo ADV on CL canola, lentils, sunflower and soybeans is not expected to result in potential occupational or bystander exposure over the registered use of imazamox. No health risks of concern are expected when workers follow label directions and wear personal protective equipment as stated on the label.

Solo ADV is of low acute oral, dermal and inhalation toxicity in rats. It is minimally irritating to the eyes and mildly irritating to the skin of rabbits. It is not a dermal sensitizer in mice.

Environmental Assessment

No new environmental data were provided with this application, nor were any required. Solo WDG Herbicide is fully registered for use in identified agricultural crops. There are no outstanding data required for the technical active ingredient imazamox.

As the use pattern for Solo ADV Herbicide is identical to that of Solo WDG Herbicide, there is no change to the environmental exposure or risk profile for the TGAI imazamox. The addition of soybeans to the Solo ADV Herbicide label is not expected to result in an increase in environmental risk over other uses on registered field crops at the same rate (i.e., canola). Imazamox is toxic to aquatic organisms and non-target terrestrial plants. Environmental mitigation requirements for Solo WDG Herbicide, including spray buffer zones, are required for the proposed new end use product. Solo ADV Herbicide is not expected to contain any formulants or impurities of concern to the environment.

Value Assessment

Solo ADV is a new formulation that may replace Solo WDG Herbicide in the marketplace. A water-soluble concentrate formulation with a built in adjuvant will be more easily and conveniently handled by users of the product. Value information submitted demonstrated that the efficacy and crop safety of Solo ADV were comparable to those of Solo WDG Herbicide. Therefore, all labelled uses and claims for Solo WDG Herbicide are supported for Solo ADV.

Information also supported (1) the inclusion of soybean as a new host crop and a rotational crop that can be seeded in the year following an application of Solo ADV, (2) the substitution of Lontrel 360 Herbicide for Lontrel Dry Herbicide in a tank mixture with Solo ADV, and (3) the inclusion of Poast Ultra Herbicide as a tank mix partner for additional grass control. The information included data from ten combined efficacy and crop tolerance trials, eight dedicated crop tolerance trials, and a scientific rationale.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found the information sufficient to support the registration of the new end-use product Solo ADV.

References

PMRA Document Number	Reference
2486227	2014, Group A - Product identity, composition, and analysis of BAS 720 16 H (Imazamox SL), DACO: 3.2.1,3.2.2,3.2.3,3.3.1 CBI
2486228	2012, Analytical Method AFL0867/01 - HPLC Method for the Determination of Active Ingredient Content in BAS 720 10 H, DACO: 3.4.1
2486229	2012, Validation of Analytical Method AFL0867/01: HPLC Method for the Determination of Active Ingredient Content in BAS 720 10 H, DACO: 3.4.1
2486230	2014, Additional validation of Analytical Method AFL0867/01 for the Determination of Active Ingredient in BAS 720 16 H, DACO: 3.4.1
2486233	2014, Physical and Chemical Properties of BAS 720 16 H: Storage Stability for 2 weeks at 54°C stored in a fluorinated high-density polyethylene (F-HDPE) bottle., DACO: 3.5.1,3.5.10,3.5.14,3.5.2,3.5.3,3.5.6,3.5.7,3.5.9 CBI
2486234	2014, Physical and Chemical Properties of BAS 720 16 H: Storage Stability for 8 weeks at 40°C stored in a fluorinated high-density polyethylene (F-HDPE) bottle., DACO: 3.5.1,3.5.10,3.5.14,3.5.2,3.5.3,3.5.6,3.5.7 CBI
2486235	2014, Determination of physico-chemical properties according to Directive 94/37/EC (Regulation (EC) No. 440/2008), DACO: 3.5.11,3.5.12,3.5.8
2486240	2014, Formulation Type of SOLO ADV (BAS 720 16H), DACO: 3.5.4
2486241	2014, Container Material and Description, DACO: 3.5.5
2486224	2014, Application to register SOLO ADV, a formulation replacement for SOLO WDG Herbicide, DACO: 10.1, 10.2, 10.2.1, 10.2.2, 10.2.3, 10.2.3.1, 10.2.3.3, 10.3, 10.3.1, 10.3.2, 10.3.3, 10.4, 10.5, 10.5.1, 10.5.2, 10.5.3, and 10.5.4.
2486243	2014, Acute Toxicology Summaries, DACO: 4.1
2486244	2012, BAS 720 10 H: Acute oral toxicity study in rats, DACO: 4.6.1
2486245	2012, BAS 720 10 H - Acute dermal toxicity study in rats, DACO: 4.6.2
2486246	2013, BAS 720 10 H - Acute inhalation toxicity study (nose-only) in the rat, DACO: 4.6.3
2486247	2013, BAS 720 13 H - Acute eye irritation in rabbits, DACO: 4.6.4
2486248	2014, BAS 720 13 H - Acute dermal irritation / corrosion in rabbits, DACO: 4.6.5
2486249	2013, BAS 720 10 H - Murine local lymph node assay (LLNA), DACO: 4.6.6
2565602	2015, BASF Response: Submission for Solo ADV (2014-6050), DACO: 4.6.1,4.6.2,4.6.4,4.6.5,4.6.6 CBI

ISSN: 1911-8082

**8 Her Majesty the Queen in Right of Canada, represented by the Minister of Public Works and Government Services
Canada 2016**

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.