Health Canada Santé Canada

Evaluation Report for Category B, Subcategory 2.1, 2.3 & 2.4 Application

Application Number: 2012-5694
Application: New EP Product Chemistry-Guarantee, Identity and Proportion of Formulants
Product: Intake Adjuvant
Registration Number: 31243
Active ingredients (a.i.): Mineral Oil-Paraffin Base (Adjuvants)(MOA), Surfactant Blend (XXX)
PMRA Document Number: 2380208

Purpose of Application

The purpose of this application was to register the new product, Intake Adjuvant (Registration Number 31243; guarantee 586 g/L paraffinic oil and 242 g/L alkoxylated alcohol non-ionic surfactant), to be used in combination with a variety of registered herbicide products.

Chemistry Assessment

Intake Adjuvant is fomulated as an emulsifiable concentrate containing the active ingredients paraffinic oil and alkoxylated alcohol non-ionic surfactants at nominal concentrations of 586 g/L and 242 g/L, respectively. This product has a density of 0.888 g/mL and pH of 7.8 for a 10% dilution. The chemistry data requirements for Intake Adjuvant have been fulfilled.

Health Assessments

Intake Adjuvant was of low acute toxicity via the oral, dermal or inhalation routes of exposure in rats. It was mildly irritating to the skin and the eyes of rabbits. It was not considered to be a potential skin sensitizer in mice.

Alkoxylated alcohol non-ionic surfactants and mineral oil are currently registered for use in Canada in other adjuvants, and the proposed use is not expected to result in an expansion of use over the currently registered use pattern.

No new residue data were submitted to support the registration of Intake Adjuvant containing paraffinic oil and alkoxylated alcohol non-ionic surfactants. The new adjuvant is similar to previously registered surfactant blends and has a similar use pattern. When it is used together with end-use products containing various active ingredients on cereals, or on rangeland and pasture, no change in the magnitude of residues is expected in the treated crops. Therefore, dietary exposure to these active ingredients is not expected to increase, and will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

Canada

Environmental Assessment

Intake Adjuvant contains aromatic petroleum distillates, which are known to be toxic to aquatic organisms. Based on the proposed rate of application of Intake Adjuvant, no environmental mitigative measures are required at this time. A hazard label statement explicitly stating the presence of petroleum distillates in the product and the potential risk to aquatic organisms will, however, be required. No track-1 substances (as per the Toxic Substances Management Policy) or micro-contaminants of concern were noted. The use of Intake Adjuvant is not expected to result in an expansion of use or an increase in environmental risk over the currently registered use patterns for either the alkoxylated alcohol non-ionic surfactants or paraffinic mineral oil.

Value Assessment

Data from 18 field trials conducted in small grain cereals demonstrated that efficacy of Achieve Liquid (containing tralkoxydim) applied with Intake Adjuvant for wild and tame oat control was agronomically similar to that applied with Turbocharge. Therefore, herbicides that contain the active ingredient of tralkoxydim and require use of Turbocharge, including Achieve Liquid, Liquid Achieve, Challenger, and Marengo, are supported for labeling.

Data from four field trials conducted in small grain cereals demonstrated that Intake Adjuvant may be applied in a rate range of 0.5-1.0% v/v with tralkoxydim containing herbicides with slight improvement in treatment efficacy at the higher rate of the adjuvant.

Data from one trial conducted in spring wheat demonstrated that efficacy of Refine SG, Simplicity, Florasulam, and Everest 70DF applied with Intake Adjuvant for broadleaf weed control was agronomically similar to these herbicides applied with Agral 90. Therefore, herbicides that contain one or more of the active ingredients, including thifensulfuron methyl, tribenuron methyl, pyroxsulam, florasulam, and flucarbazone, and require use of a NIS (non-ionic surfactant) or MSO (methylated seed oil) are supported for labeling.

Data from three field trials conducted in rangeland and pasture demonstrated that efficacy of Sightline A applied with Intake Adjuvant for Canada thistle and dandelion control was agronomically similar to that applied with Agral 90 or other comparable adjuvant. Data from the same trials also supported that efficacy of Tordon 101 applied with Intake Adjuvant for Canada thistle control was comparable to the herbicide applied without an adjuvant. Therefore, herbicides that contain aminopyralid, metsulfuron methyl, and 2,4-D Amine, and require use of a NIS or MSO are supported for labeling.

Data from field trials demonstrated that Intake Adjuvant can be used as an alternative of a NIS or MSO adjuvant when applied in tank mix with Group 4 herbicides. Therefore, XRM-571 (originally named as Curtail M) and Lontrel are supported for labeling.

Glyphosate herbicides are also supported for labeling since (1) Intake Adjuvant has been determined to be similar to other registered NIS or MSO adjuvants when applied in tank mix with Group 1, 2, and 4 herbicides, (2) glyphosate-containing herbicides have been registered for use with a NIS for years in Canada, and (3) a glyphosate-containing product (i.e. Ripper 480) is registered for application with Uptake Spray Oil (i.e. Intake Adjuvant) in Australia.

Other listed herbicides, which are not currently registered for use with an adjuvant, are not supported for labeling from a value standpoint.

Conclusion

The PMRA has reviewed all available information for Intake Adjuvant and found the information sufficient to support a full registration of the product.

References

PMRA Document Number	Reference
2260682	2012, Product Identification, DACO: 3.1.1, 3.1.2, 3.1.3, 3.1.4 CBI
2260683	2012, MSDS [CBI removed], DACO: 3.2.1 CBI
2260684	2012, MSDS [CBI removed], DACO: 3.2.1 CBI
2260685	2011, MSDS [CBI removed], DACO: 3.2.1 CBI
2260686	2011, MSDS [CBI removed], DACO: 3.2.1 CBI
2260687	2012, MSDS [CBI removed], DACO: 3.2.1 CBI
2260688	2010, MSDS [CBI removed], DACO: 3.2.1 CBI
2260689	2012, Formulation Process for GF-303 Adjuvant, DACO: 3.2.2 CBI
2260690	2012, Establishing Certified Limits, DACO: 3.3.1 CBI
2260691	2012, Product Analysis, DACO: 3.4.1,3.4.2 CBI
2260692	2012, Physical Chemical Properties Summary, DACO: 3.5.1, 3.5.10, 3.5.11, 3.5.12, 3.5.13, 3.5.14, 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 CBI
2260693	2000, Accelerated Storage Stability of Uptake Spraying Oil (GF-303), DACO: 3.5.10 CBI
2260694	2012, Storage Stability Data, DACO: 3.5.10 CBI
2260697	1999, Packaging Storage Stability Trial for [CBI removed], DACO: 3.5.10 CBI
2260700	2012, Dielectric Breakdown, DACO: 3.5.15 CBI
2351702	2013, COA for Intake Adjuvant, DACO: 3.5 CBI
2260670	2012, GF-303 Adjuvant - Value summary, DACO 10.1
2260675	2012, GF-303 Adjuvant Submission ARM 7 Trial Reports1, DACO 10.2.3.3
2260676	2012, GF-303 Adjuvant Submission ARM 7 Trial Reports2, DACO 10.2.3.3

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