Health Canada Santé Canada

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

Application Number: 2008-0224
Application: New / Changes to Product Chemistry-Guarantee and Identity of Formulants; New / Changes to Product Chemistry-Proportion of Formulants
Product: ADDIT Adjuvant
Registration Number: 29263
Active ingredients (a.i.): Surfactant blend (XXX)
PMRA Document Number: 1722238

Purpose of Application

Makteshim Agan of North America Inc. (MKC) has submitted an application for a new adjuvant, MANA Tralkoxydim Adjuvant (label guarantee: 36.9% surfactant blend) to be used with the proposed new products, MANA Tralkoxydim 400 SC (Sub. No. 2008-0218) and IPCO Tralkoxydim 400 SC (Sub. No. 2008-0217).

Chemistry Assessment

MANA Tralkoxydim Adjuvant is an emulsifiable concentrate containing surfactant at a nominal concentration of 36.9%. The formulation has a density of 0.867 g/mL and pH of 5-7. With the exceptions of the storage stability and corrosion characteristics studies that are currently being conducted, the chemistry requirements for MANA Tralkoxydim Adjuvant are complete.

Health Assessments

MANA Tralkoxydim Adjuvant is of low toxicity to rats via the oral (LD_{50} > 5000 mg/kg), dermal (LD_{50} > 2000 mg/kg), and inhalation routes (LC_{50} > 2.07 mg/L). It is minimally irritating to the eye and moderately irritating to the skin of rabbits. It is not a dermal sensitizer in guinea pigs (Buehler method).

No new residue data were submitted for this application. The use of MANA Tralkoxydim Adjuvant with end-use products, IPCO Tralkoxydim 400 SC and MANA Tralkoxydim 400 SC, is not expected to impact on the magnitude of residues of tralkoxydim. Consequently, no increase in dietary exposure is anticipated.

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Environmental Assessment

MANA Tralkoxydim Adjuvant is comparable to a currently registered adjuvant with a similar use pattern. None of the formulants in the MANA Tralkoxydim Adjuvant are of concern for the intended uses. As a result, there was no need to perform a risk assessment for this adjuvant.

Value Assessment

Data from 25 trials conducted in Alberta (8 trials), Saskatchewan (10 trials), and Manitoba (7 trials), during a 3 year period (2005-2007), were submitted to support the registration of MANA Tralkoxydim Adjuvant, which is only to be used in a tank-mix with the post-emergence herbicide MANA Tralkoxydim 400SC (submission number 2008-0218) or IPCO Tralkoxydim 400SC (submission number 2008-0217) for control of annual grasses in small grain cereals and in selected forage grasses grown for seed. Efficacy and crop safety of MANA Tralkoxydim 400SC applied with MANA Tralkoxydim Adjuvant were directly compared to that of the cited precedent treatment, Achieve Liquid Herbicide (Reg. No. 27011) + Turbocharge (Reg. No. 23135), and as well as Achieve Liquid Herbicide + MANA Tralkoxydim Adjuvant and MANA Tralkoxydim 400SC + Turbocharge in these trials.

Control of wild oats and green foxtail was visually assessed from 2 to 3 times during the growing season. Mean control of these weeds following the application of MANA Tralkoxydim 400SC + MANA Tralkoxydim Adjuvant was comparable to that of Achieve Liquid Herbicide + either Turbocharge or MANA Tralkoxydim Adjuvant and MANA Tralkoxydim 400SC + Turbocharge.

The tolerance of spring wheat, durum wheat, and spring barley was visually assessed from 3 to 4 times during the growing season. Mean crop injury following the application of MANA Tralkoxydim 400SC + MANA Tralkoxydim Adjuvant was comparable to that of Achieve Liquid Herbicide + either Turbocharge or MANA Tralkoxydim Adjuvant and MANA Tralkoxydim 400SC + Turbocharge. Data for final grain yield further supported the crop tolerance observations.

The efficacy and crop tolerance data support the use of MANA Tralkoxydim Adjuvant when applied with MANA Tralkoxydim 400SC and IPCO Tralkoxydim 400SC.

Conclusion

The PMRA has evaluated all of the data submitted in support of this application and has determined that sufficient information is available to support full registration of MANA Tralkoxydim Adjuvant. However, submission and review of the storage stability and corrosion characteristics studies will be required as conditions of full registration.

References

PMRA 1538622 2007, 3.1.1-3.1.4, DACO: 3.1.1,3.1.2,3.1.3,3.1.4

PMRA 1538623 2007, 3.4.1, 3.4.2, DACO: 3.4.1,3.4.2 CBI

PMRA 1538624 2007, 3.5.3, DACO: 3.5.3 CBI

PMRA 1538625 2007, 3.5.4, 3.5.5, DACO: 3.5.4,3.5.5 CBI

PMRA 1538626 2007, 3.5.15, DACO: 3.5.15 CBI

PMRA 1538627 2007, AG-ADJ1-SL Physical and Chemical Characteristics: Oxidation/ Reduction, 22598, DACO: 3.5.8 CBI

PMRA 1538628 2007, Adjuvant AG-ADJ1-SL Determination of Storage Stability and Shelf Life Specification of Adjuvant: AG-ADJ1-SL Stored at 54 C for 14 Days, F07-06/3, DACO: 3.5.1,3.5.10,3.5.11,3.5.12,3.5.14, 3.5.2,3.5.6,3.5.7,3.5.9 CBI

PMRA 1560816 2008, Waiver in Lieu of a Miscibility Study, DACO: 3.5.13 CBI

PMRA 1538630. Acute Oral Toxicity Up and Down Procedure in Rats. Safety Laboratories. Laboratory report number 22599. Study report date: 05-October-2007. DACO 4.6.1.

PMRA 1538631. Acute Dermal Toxicity Study in Rats – Limit Test. Laboratory report number 22600. Study report date: 08-October-2007. DACO 4.6.2.

PMRA 1538632. Acute Inhalation Toxicity Study in Rats – Limit Test. Laboratory report number 22601. Study report date: 05-October-2007. DACO 4.6.3.

PMRA 1538633. Primary Eye Irritation Study in Rabbits. Laboratory report number 22602. Study report date: 05-October-2007. DACO 4.6.4.

PMRA 1538634. Primary Skin Irritation Study in Rabbits. Laboratory report number 22603. Study report date: 05-October-2007. DACO 4.6.5.

PMRA 1538635. Dermal Sensitization Study in Guinea Pigs (Buehler Method). Laboratory report number 22604. Study report date: 05-October-2007. DACO 4.6.6.

PMRA 1538394 to 1538418 Trial reports. Makhteshim Agan of North America. DACO: 10.2.3.3. and 10.3.2. A total of 556 pages.

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