

Evaluation Report for Category A, Subcategory 1.1 Application

Application Number: 2007-2054
Application: New Adjuvant (A.1.1)
Product: Enhance
Registration Number: 29157
Active ingredients (a.i.): Ethoxylated triglycerides (TXR)
PMRA Document Number: 1678216

Purpose of Application

Norac Concepts Inc. has applied to register Enhance, a non-ionic spray adjuvant based on soybean oil containing ethoxylated triglyceride at 80%, with Master Product Status. This product is proposed to be used with 59 herbicides, 2 plant growth regulators, 1 plant desiccant, 3 insecticides, and 1 fungicide, for control of the listed pests on the respective pesticide labels. The applicant cited Agral 90 (Reg. No. 24725), owned by the same company, as a registered precedent which has a guarantee of 90% nonylphenoxy polyethoxy ethanol. Enhance was proposed as a replacement for Agral 90, to be used at the same application rate.

Chemistry Assessment

Enhance is formulated as an emulsifiable concentrate containing triglyceride ethoxylate 10 POE at a nominal concentration of 80% w/w. This end-use product has a specific gravity of 0.987 and pH range of 6-7.5. The chemistry requirements for Enhance are complete.

Health Assessments

Enhance exhibits low oral and dermal toxicity with an $LD_{50} > 2000$ mg/kg bw in the rat. It is considered to be of low toxicity by the inhalation route. It is minimally irritating to the eye (MAS = 4.63/110) and mildly irritating (MAS = 2.76/8) to the skin of the rabbit. It is not dermal sensitizer in the guinea pig.

No residue data were submitted to support Enhance as an alternate adjuvant. The mode of action of Enhance Adjuvant (which was determined to be agronomically equivalent to Agral 90, a commonly used registered adjuvant) involves the reduction of surface tension of the aqueous solution containing the active ingredient. Thus, it is unlikely that the use of Enhance Adjuvant will lead to increased residues of the pesticides with which it is proposed to be used in/on targeted crops. As such, an increase in dietary exposure is not anticipated.

Environmental Assessment

This product is an adjuvant and as such does not have any inherently pesticidal properties. The main ingredient, ethoxylated soybean oil, is already used as a formulant in other products, is not considered hazardous to the environment and is not expected to persist once applied. The use of Enhance instead of many of the petroleum- or nonylphenylethoxylate-based adjuvants currently registered for the same uses will result in a decreased release of petroleum distillates and nonylphenol ethoxylates to the environment.

Value Assessment

The equivalence of Enhance and Agral 90 was demonstrated with herbicides, and is expected with insecticides as well; therefore, the use of Enhance with insecticides is acceptable for products registered for use with Agral 90.

Efficacy and crop tolerance data from 10 herbicide field trials conducted on corn at 6 locations in Ontario during a 2-year period (2004-2005) were accepted for critical review. Weed control was visually assessed following application of the tank mixture of Ultim + Distinct + 28% UAN applied with Enhance at 0.25% v/v versus that applied with Enhance at the same rate for barnyard grass, green foxtail, lamb's-quarters, redroot pigweed, quackgrass, and common ragweeds. Trial data indicated that the tank mixture of Ultim + Distinct + 28% UAN applied with Enhance at 0.25% v/v were agronomically equivalent to that applied with Agral 90 at the same rate.

Crop tolerance, expressed as % crop injury, and corn grain yield, expressed as % of the untreated weedy check, were assessed in these trials. It was concluded that the crop safety following the application of the tank mixture of Ultim + Distinct + 28% UAN applied with Enhance at 0.25% v/v were agronomically equivalent to that applied with Agral 90 at the same rate.

Based on the data made available and similarity of formulations between Enhance and the precedent product, Agral 90, the registered uses that pertain to herbicides, plant growth regulators, and plant desiccant on the Agral 90 label are acceptable to appear on the Enhance label.

The currently registered label for Agral 90 also recommends that Ambush 500EC, Cymbush 250EC, and Pounce 384 EC insecticides should be applied in combination with Agral 90 to cole crops and Elevate 50WDG fungicide should be applied in combination with Agral 90 to grapes. The uses also appear on the respective pesticide labels. As herbicide trials demonstrated that efficacy and crop tolerance were equivalent with either Enhance or Agral 90 used at the same rate, equivalence is, therefore, expected with insecticides and fungicides as well. The registered uses that pertain to insecticides and fungicide on the Agral 90 label are also acceptable to appear on the Enhance label.

Conclusion

The Agency has completed an assessment of available information for Enhance, a non-ionic spray adjuvant based on soybean oil containing ethoxylated triglyceride and has found the information sufficient to support full registration.

References

A. List of Studies/Information Submitted by Applicant

Chemistry Assessment

<u>PMRA No.</u>	<u>Title</u>
1389290	2005, Physico-chemical tests on the test item S002, 05-919038-001, DACO: 3.5.10, 3.5.6, 3.5.9 CBI
1389291	2007, DACO: 3.1.1, 3.1.2, 3.1.3, 3.1.4
1389292	2005, Flash point of Ethoxylated Triglyceride, 05-919038-005, DACO: 3.5.11, 3.5.12 CBI
1389293	2005, Analytical method validation of ethoxylated triglycerides in S002, 05-919038-004, DACO: 3.4.1 CBI
1389294	2006, Emulsion Stability of NCF-050, DACO: 3.5.13 CBI
1389295	2005, Appearance of Blend Of Ethoxylated Triglyceride and Non-Ionics, 1067, DACO: 3.5.1 CBI
1389296	2007, Discussion of Impurities, DACO: 3.2.3, 3.4.2 CBI
1389306	2006, Manufacturing Procedure, DACO: 3.2.2 CBI
1389307	2007, Physical State & Formulation Type, DACO: 3.5.2, 3.5.4 CBI
1389308	2006, Odour Assessment of NCF-050, DACO: 3.5.3 CBI
1389309	2007, Container Material and Description, DACO: 3.5.5 CBI
1389310	2007, Certified Limits, DACO: 3.3.1 CBI
1389311	2007, Dielectric Breakdown Voltage, DACO: 3.5.15 CBI
1389313	2005, Relative density of liquids of Ethoxylated Triglyceride, 05-919038-006, DACO: 3.5.6 CBI
1389314	2005, Accelerated storage procedure for 14 days at 54 +/- 2 degrees Celsius and physico-chemical tests after the storage procedure on the test item S002, 05-919038-002, DACO: 3.5.10 CBI
1389315	2007, Storage Stability and Corrosion Characteristics, DACO: 3.5.10, 3.5.14 CBI
1389316	2005, Water content (Karl Fischer) of Ethoxylated Triglyceride, 1023, DACO: 3.7 CBI
1389317	2005, UV/Visible Spectrum of Ethoxylated Triglyceride, 1078, DACO: 3.7 CBI
1389318	2005, Saponification Value of Ethoxylated Triglyceride, 1024, DACO: 3.7 CBI
1389319	2005, Acid Value of Ethoxylated Triglyceride, 1026, DACO: 3.7 CBI
1389320	2005, Hydroxyl Value of Ethoxylated Triglyceride, 1027, DACO: 3.7 CBI
1389321	2005, Infrared Spectrum of Ethoxylated Triglyceride, 1063, DACO: 3.4.1 CBI
1389322	2005, Chromatograph of Agnique SBO 10, 1029, DACO: 3.4.1 CBI
1389323	2005, Chromatograph of Agnique SBO 10, DACO: 3.4.1 CBI
1389324	2005, pH-Value of Ethoxylated Triglyceride, 1022, DACO: 3.5.7 CBI
1389325	2006, Rationale in Lieu of Oxidizing Action Study in Support of Enhance, DACO: 3.5.8 CBI

1421735 2007, Product Information - Category G Submitted in Confidence by Cognis to the PMRA, DACO: 2.11.1 CBI

1421736 2007, Product Information - Category G Submitted in Confidence by Cognis to the PMRA, DACO: 2.11.2, 2.11.3 CBI

1423508 2007, Agnique SBO 10 Data Submission, DACO: 2.1, 2.11.4, 2.12.1, 2.2,2.3, 2.3.1, 2.4, 2.5,2.6, 2.7, 2.8, 2.9 CBI

1617285 2008, Agnique SBO 10 (technical substance), DACO: 2.14.11, 2.14.7, 2.14.8, 2.14.9 CBI

1628464 2008, Storage Stability and Corrosion Characteristics , DACO: 3.5.10, 3.5.14 CBI

1628465 2008, Storage Stability and Corrosion Characteristics-Certification Of Composition, DACO: 3.5.10, 3.5.14 CBI

Health Assessment

<u>PMRA No.</u>	<u>Title</u>
1389326	2005, Primary Skin Irritation Study in Rabbits, 17570, DACO: 4.6.5 CBI
1389327	2005, Primary Eye Irritation Study in Rabbits, 17569, DACO: 4.6.4
1389328	2005, Acute Dermal Toxicity Study in Rats - Limit Test, 17568, DACO: 4.6.2
1389329	2007, Acute Inhalation Study (LC50) in Rats, Enhance Spray Adjuvant, DACO 4.6.3, DACO: 4.6.3
1389330	2005, Acute Oral Toxicity Up And Down Procedure in Rats, 17567, DACO: 4.6.1
1389331	2005, Skin Sensitization Test in Guinea Pigs, 29944 TSG, DACO: 4.6.6

Value Assessment

<u>PMRA No.</u>	<u>Title</u>
1389269	2005, 2005 Surfactants Field Trials NCF 050, TS-1, DACO: 10.2.3.3 & 10.3.2
1389270	2005, 2005 Surfactants Field Trials NCF 050, TS-2, DACO: 10.2.3.3 & 10.3.2
1389271	2005, 2005 Surfactants Field Trials NCF 050, TS-4, DACO: 10.2.3.3 & 10.3.2
1389272	2005, 2005 Surfactants Field Trials NCF 050, TS-5, DACO: 10.2.3.3 & 10.3.2
1389274	2004, 2004 Surfactants Field Trials NCF 050, TS-6, DACO: 10.2.3.3 & 10.3.2
1389275	2004, 2004 Surfactants Field Trials NCF 050, TS-7, DACO: 10.2.3.3 & 10.3.2
1389276	2004, 2004 Surfactants Field Trials NCF 050, TS-8, DACO: 10.2.3.3 & 10.3.2
1389277	2004, 2004 Surfactants Field Trials NCF 050, TS-9, DACO: 10.2.3.3 & 10.3.2
1389278	2004, 2004 Surfactants Field Trials NCF 050, TS-10, DACO: 10.2.3.3 & 10.3.2
1389279	2005, 2005 Surfactants Field Trials NCF 050, TS-3, DACO: 10.2.3.3 & 10.3.2

B. Additional Information Considered

I) Published Information

Merck Index, 1983, 10th ed. Merck & Co. Inc., Rahway, New Jersey, USA. Entry 8574, p. 1249.

Environmental Assessment

<u>PMRA No.</u>	<u>Title</u>
1677985	Federle, Thomas W. and Nina R. Itrich, 2005, Fate of free and linear alcohol-ethoxylate-derived fatty alcohols in activated sludge. Ecotoxicol. Environ, Saf. 64 (2006) 30-41, DACO: 8.6
1677986	National Biodiesel Board, Soybean methyl ester formula and molecular weight, DACO: 8.6
1677994	Periera, M. Glória and Stephen M. Mudge, 2004, Cleaning oiled shores: laboratory experiments testing the potential use of vegetable oil biodiesels, Chemosphere: 54 (3): 297-304. DACO: 8.6
1678001	Peterson, C. L. and Gregory Möller, Biodegradability, BOD, COD and toxicity of biodiesel fuels, Department of Food Science and Toxicology, University of Idaho, DACO: 8.6. & 9.9
1678002	von Wedel, Randall, 1999, Technical handbook for marine biodiesel in recreational boats, 2 nd ed. CytoCulture International, Inc. Point Richmond, CA, DACO: 8.6. & 9
1678005	Zhang, Xiulin, Charles L. Peterson, Daryl Reece, Gregory Möller and Randall Haws, Biodegradability of biodiesel in the aquatic environment, DACO: 8.6

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