

## Evaluation Report for Category B, Subcategory 2.1, 2.3, 2.4 & 3.13 Application

**Application Number:** 2007-8927  
**Application:** B.2.1, B.2.3, B.2.4 and B.3.13: Changes EP Product Chemistry-Guarantee, Identity and Proportion of Formulants and Changes to Product Labels-Precautions  
**Product:** MSO Concentrate with Leci-Tech  
**Registration Number:** 28385  
**Active ingredients (a.i.):** Methylated Seed Oil of Soybean and Surfactant Blend  
**PMRA Document Number:** 1751707

### Background

MSO Concentrate (Reg. No. 28385) is an adjuvant, registered since October 27, 2006, for use with selected post-emergent herbicides in soybeans, canola and peas (USC 13/14). For specific details of uses, application rates and methods, precautions, restrictions, and personal protective equipment requirements, refer to the product label.

### Purpose of Application

Loveland Industries Inc. has applied to amend the registration of the adjuvant MSO Concentrate (Reg. No. 28385). The purpose of this application is to change the product name from MSO Concentrate to MSO Concentrate with Leci-Tech, to amend the product formulation to include additional sources and alternate formulation and to update the label precautionary statements to remove inhalation warnings.

### Chemistry Assessment

MSO Concentrate with Leci-Tech is a liquid adjuvant containing methylated seed oil of soybean at a nominal concentration of 70 %. This product has a density of 0.90 g/mL and a pH of 6.9 for a 1 % solution in water. The product contains the allergen soy. The chemistry requirements for MSO Concentrate with Leci-Tech have been completed.

## **Health Assessments**

MSO Concentrate with Leci-Tech is of low acute oral dermal and inhalation toxicity. It is minimally irritating to the eye and non to slightly irritating to rabbit skin. It is not a dermal sensitizer in the guinea pig.

The four formulation variants of MSO Concentrate with Leci-Tech are toxicologically equivalent.

The proposed changes to the product MSO Concentrate with Leci-Tech will not result in an increase in occupational exposure. Further, the addition of 'Avoid breathing vapours or mist.' to the label precautions will only help to decrease exposure to MSO Concentrate. No changes to the personal protective equipment or directions for use are needed on the label.

MSO Concentrate with Leci-Tech is registered as an adjuvant to be used at 1% v/v with various herbicides. Since MSO Concentrate with Leci-Tech is not a pesticide active ingredient, no MRL is required. No new residue data were submitted for the present submission. The three additional formulations when used as an adjuvant with herbicides are unlikely to impact the magnitude of residues; therefore, no increase in dietary exposure is anticipated.

## **Environmental Assessment**

This product is registered as an adjuvant for use with selected post-emergent herbicides in soybeans, canola and peas. None of the ingredients in the adjuvant are of environmental concern and therefore no environmental risk assessment was performed nor was any additional environmental data requested.

## **Value Assessment**

A rationale was provided to support the amendment of the registration of MSO Concentrate for the three alternate formulations. Based on the information provided, it is expected that the alternate MSO Concentrate with Leci-Tech formulations would be agronomically equivalent to that of the currently registered MSO Concentrate formulation. As such, the proposed alternate formulations are acceptable from a value perspective.

## **Conclusion**

The Agency has completed an assessment of available information for the subject application and has found it sufficient to amend the product name to MSO Concentrate with Leci-Tech. Amendments to include additional sources and alternate formulation, and to update the label precautionary statements to remove inhalation warnings can also be supported.

## References

### A. List of Studies/Information Submitted by Registrant

#### Health Assessment

<u>PMRA No.</u>	<u>Reference</u>
1526148	2007. Acute Inhalation Toxicity Study in Rats-Limit Test. 21635. Unpublished. DACO. 4.6.3

#### Chemistry Assessment

<u>PMRA No.</u>	<u>Reference</u>
1574612	mso concentrate reg. no. 28385, DACO: 3.1.1,3.1.2 CBI
1574613	material safety data sheet, DACO: 3.2,3.2.1 CBI
1574614	material data sheet, DACO: 3.2,3.2.1 CBI
1574615	material data sheet, DACO: 3.2,3.2.1 CBI
1574616	material safety data sheet, DACO: 3.2,3.2.1 CBI
1574617	mso concentrate reg no 28385, DACO: 3.2,3.2.1 CBI
1574618	certificate of quality and analysis, DACO: 3.3.1
1574619	standard test method for density and relative density of liquids by digital density meter, DACO: 3.4,3.4.1
1574620	standard test method for ph of aqueous solutions with the glass electrode, DACO: 3.4,3.4.1
1574621	standard test methods for surface and interfacial tension of solutions of surface-active agents, DACO: 3.4,3.4.1
1587711	DACO: 3.5.10,3.5.11,3.5.12,3.5.13,3.5.14,3.5.15,3.5.6,3.5.7,3.5.8,3.5.9 CBI

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