MEMORANDUM

Subject: **Reg. #:** 42964-17
DPBarcode: D233564
Chemical #: 001501
Chemical Name: Ethanol
Action Code: 674
Type of Data: Toxicology, acute
PRS Bean #: 6013

TO: Marion Johnson, PM # 31; Attn: N. Tompkins
Antimicrobial Program Branch
Registration Division (7505C)

FROM: David Ritter, Toxicologist
Precautionary Review Section
Registration Support Branch
Registration Division (7505C)

DLR 4-7-97

Registrant: Ecolab
370 N. Wabasha Street
St. Paul MN 55102

Action Requested:

Eight month response. Review acute toxicity data and precautionary labeling.

PRS Response:

The acute dermal and dermal sensitization studies were waived in the T. Levine 5/7/96 note to B. Kapner.

The acute oral, inhalation and eye and skin irritation studies have been reviewed and the DERs are attached. The acute oral and inhalation studies were placed in TOX category IV while the eye and skin irritation studies were placed in TOX category II.

All studies were classified as acceptable.

The studies are summarized below:

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Acute Toxicity Data Requirements (40 CFR §158.340). Pesticide Assessment Guidelines, Subdivision F. Hazard Evaluation: Human and Domestic Animals. (1982; revised 1984).

Data Required	MRID #	Toxicity Category	Classification
Acute Oral (§81-1)	440157-04	IV	A
Acute Dermal (81-2)		Requirement waived.	
Acute Inhal. (81-3)	" -05	IV	A
Eye Irr. (§81-4)	" -06	II	A
Dermal Irr. (§81-5)	" -07	II	A
Dermal Sens. (§81-6)		Requirement waived.	

These data support reregistration of the product.

Precautionary Labeling Review:

See the attached LRS sheet.

(2)

DATA EVALUATION RECORD FOR ACUTE ORAL TOXICITY TESTING §81-1

(PM): 31 EPA Reg. No.: 42964-17 Reviewer: D. Ritter
MRID No.: 440157-04 Lab. No.: 96-8019-21
Testing Laboratory: Hilltop Biolabs, Inc.
Title Of Report: Acute Oral Toxicity in Rats - Limit Test
Date of Report: 2/2/96 Author(s): T. D. Morris
Species: Sprague Dawley rat Sex: 5/sex Wt.: 208 - 264 gm
Source: Harlan Sprague Dawley, Inc.
Test Material: Asepticare Aerosol
Dosage: 5000 mg/kg by gavage
Quality Assurance (40 CFR, Section 160.12): Acceptable

Summary: LD_{50} Males & Females > 5000 mg/kg

Toxicity Category: IV Classification: Acceptable

Procedure (Deviation From Series 81-1):

Standard laboratory animal husbandry and GLP were observed.

Animals were weighed initially, on day 7 and at termination.

Test Article was administered as a single gavage dose of 5000 mg/kg to a group of 5M + 5F.

Observations for effects and mortality were made frequently on day one, then twice daily thereafter for 14 days.

Animals dying during the observation period and those surviving to termination were subjected to gross necropsy.

Results:

Except for slight depression on day one, clinical signs were absent.
Body weight gain was not affected.
There was no mortality.

REPORTED MORTALITY

	No. Killed/No. Exposed		
Dose mg/kg	Males	Females	Combined
5000	0/5	0/5	0/10

Conclusions: See summary above.

(3)

DATA EVALUATION RECORD ACUTE INHALATION TOXICITY TESTING §81-3
(PM): 31 EPA Reg. No.: 42964-17 Reviewer: D. Ritter
MRID No.: 440157-05 Lab. No.: 2710-96
Testing Laboratory: Stillmeadow
Title Of Report: Acute Inhalation Toxicity Study in Rats
Date of Report: 5/3/96 Author(s): J. Bennick
Species: Sprague Dawley rat Sex: 5/sex Wt.: 201 - 294 gm
Source: Harlan Sprague Dawley
Test Material: Asepticare Aerosol
Dosage: 2.48 mg/l
Quality Assurance (40 CFR, Section 160.12): Acceptable

Summary: LC_{50}M&F > 2.48 mg/l MMAD ± GSD = 1.156 ± 3.100 μm
Toxicity Category: IV Classification: Acceptable
Procedure (Deviation From Series 81-3):

Standard laboratory animal husbandry and GLP were observed.
Animals were weighed initially, on day 7 and at termination.
Test Article was administered as an aerosol dose of 2.48 mg/l.
Observations for effects and mortality were made frequently on day one, then daily thereafter for 14 days.
Animals dying during the observation period and those surviving to termination were subjected to gross necropsy.

Generation of Test Atmosphere:

Spraying System Co. 1/4 JSS atomizer followed by elutriation.

Measurement of Particle Size:

Andersen Cascade Impactor from the breathing zone.

Results:

Clinical signs included piloerection, crusting around nose and ptosis in males only.
Body weight gain was not affected.
There was no mortality.

REPORTED MORTALITY

	No. Killed/No. Exposed		
Dose mg/l	Males	Females	Combined
2.48 mg/l	0/5	0/5	0/10

Conclusions: See summary above.

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DATA EVALUATION RECORD FOR EYE IRRITATION TOXICITY TESTING §81-
(PM): 31 EPA Reg. No.: 42964-17 Reviewer: D. Ritter
MRID No.: 440157-06 Lab. No.: 96-8021-21
Testing Laboratory: Hilltop Biolabs, Inc.
Title Of Report: Primary Eye Irritation Study in Rabbits Without Rinsing
Date of Report: 2/2/96 Author(s): T. D. Morris
Species: NZW rabbit Sex: 3/sex Wt.: 2.485 - 2.774 kg
Source: Myrtle's Rabbitry Inc.
Test Material: Asepticare Aerosol
Dosage:
Quality Assurance (40 CFR, Section 160.12): Acceptable

Summary: Irritation or corneal involvement clearing in 8 -21 days.
Toxicity Category: II Classification: Acceptable
Procedure (Deviation From Series 81-4):

Standard laboratory animal husbandry and GLP were observed.
Eyes were examined with sodium fluorescein 24 hours prior to application. Undiluted Test Article was administered as a single one second blast from 10 cm to the opened eye.
Observations for effects were made at 1, 24, 48 and 72 hours, and days 4, 7, 14 and 21.

Irritancy scores were made after Draize (1959).

Results:

EYE IRRITATION SCOREBOARD

	No. affected/No. exposed in days								
Ocular Effects	1hr	1	2	3	4	7	14	21	
Cornea	5/6	1/6	1/6	1/6	1/6	1/6	0/6	0/6	
Iris	5/6	3/6	3/6	2/6	1/6	0/6	0/6	0/6	
Conjunctivae									
Redness	2/6	5/6	5/6	2/6	2/6	0/6	0/6	0/6	
Chemosis	6/6	6/6	3/6	2/6	2/6	0/6	0/6	0/6	
Discharge	4/6	2/6	1/6	1/6	0/6	0/6	0/6	0/6	

Conclusions:

See summary above.

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DATA EVALUATION RECORD DERMAL IRRITATION TOXICITY TESTING §81-5
(PM): 31 EPA Reg. No.: 42964-17 Reviewer: D. Ritter
MRID No.: 440157-07 Lab. No.: 96-8020-21
Testing Laboratory: Hilltop Biolabs, Inc.
Title Of Report: Primary Skin Irritation in Rabbits
Date of Report: 2/2/96 Author(s): T. D. Morris
Species: NZW rabbit Sex: 3/sex Wt.: 2.486 - 2.743 kg
Source: Myrtle's Rabbitry Inc.
Test Material: Asepticare Aerosol
Dosage: 0.5 ml applied topically
Quality Assurance (40 CFR, Section 160.12): Acceptable
Summary: Moderate to severe erythema at 72 hours.
Toxicity Category: II Classification: Acceptable
Procedure (Deviation From Series 81-5):

Standard laboratory animal husbandry and GLP were observed. Fur was clipped from the dorsal trunk one day prior to exposure. Article was administered as a single topical dose of Test Article from which the propellant had been removed. 0.5 ml was applied under a 1 in^2 gauze patch which was then secured with occlusive dressings. Animals were fitted with Elizabethan collars. After 4 hours the dressings were removed and the test sites cleansed.

Observations for dermal irritation were made on days 1, 24, 48 and 72 hours. Further observations were made on days 7 and 14 as necessary.

Results:

DERMAL IRRITATION SCOREBOARD

Rab.#	Eschar/Erythema											Edema											Score
	OBSERVATION TIMES IN DAYS																						
	30m	1	2	3	4	5	6	7	10	14	21	30m	1	2	3	4	5	6	7	10	14	21	
12M	2	2	2	2				2		0		2	1	2	2				1		0		3.75
13M	1	2	3	3				2		1		1	1	2	2				1		1		3.75
14M	2	2	3	3				2		0		3	2	2	2				1		0		4.75
18F	1	2	2	3				1		0		1	1	1	2				1		0		2.75
19F	1	1	2	3				2		0		2	1	2	2				1		0		3.50
20F	1	2	3	3				2		0		2	2	2	2				1		0		4.25

Score = sum of numerical grades/no. observation periods at 1, 24, 48 and 72 hours.

PII = Sum of scores/No. animals = 22.75/6 = 3.80
Slight < 2.0; Moderate 2 - 5; Severe > 5

Conclusions: See summary above.

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ACUTE TOX ONE-LINER

1. PC CODE: 001501; EtOH

2. CURRENT DATE: 4/7/97

3. TEST MATERIAL: Asepticare

4. EPA Reg. #: 42964-17

Study/Species/Lab/ Study#/Date	MRID No.	Results	Tox. Cat.	Core Grade
Acute oral/rat/HB*/ 96-8019-21/2-2-96	440157-04	LD_{50}M+F > 5000 mg/kg	IV	A
Acute inhal./rat/ Stillmeadow/2710-96/ 5-3-96	" -05	LC_{50}M+F = 2.48 mg/l MMAD $\pm$ GSD = 1.16 $\pm$ 3.1 μm	IV	A
Eye irr./rabbit/HB/ 96-8021-21/2-2-96	" -06	Irr. or corneal inv. clearing 8 - 21 days.	II	A
Skin irr./rabbit/HB/ 96-8020-21/2-2-96	" -07	Mod. to severe erythema @ 72 hrs.	II	A

Core Grade Key:

A = Acceptable
U = Unacceptable
S = Supplementary

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