US EPA ARCHIVE DOCUMENT

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: EPA Reg. No./File Symbol 862-20
SUNSPRAY 9N

FROM: William S. Woodrow WSW 5-23-89
Precautionary Review Section
Registration Support Branch
Registration Division (H75-05C)
E 5/23/89

TO: Dennis Edwards (PM 12)
Insecticide-Rodenticide Branch
Registration Division (TS-767C)

APPLICANT: Sun Refining and Marketing Co.
Ten Penn Center
1801 Market St.
Philadelphia, PA 19103

FORMULATION FROM LABEL:

Active Ingredient(s):	% by wt.
Refined Petroleum Distillate	100.00
Inert Ingredient(s):	0.00
Total	100.0%

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1 of 6

BACKGROUND:

The Sun Refining and Marketing Co. submitted documents stated to contain acute toxicity evaluations of their fungicide product, SUNSPRAY-9 MRID NO. 402812-01, reported to contain acute ora acute dermal, eye irritation, dermal irritation, and dermal sensitization studies.

MRID NO. 402812-02 was reported to contain an acute dermal study.

~~RECOMMENDATION:~~

MRID NO. 402708-06 is entitled "Eye irritation in rabbits (SUNSPRAY 6N)."

MRID NO. 402708-07 is entitled "Primary dermal irritation in albino rabbits (SUNSPRAY 6N)."

RECOMMENDATION:

~~LABELING:~~

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1) MRID NOS. 402812-01, and 402812-02; reported to contain supporting acute toxicity studies:

a. A number of hydrocarbons were tested - it was not clear which chemical represented SUNSPRAY 9N.

b. Summary test results only were presented for the acute oral, acute dermal, eye irritation, derma irritation, and dermal sensitization studies (402812-402812-02).

P.M. Note: The Agency will not accept summary data only; positive identification of all materials tested, and complete experiments, including all raw data must be submitted.

2) MRID NO. 402708-06 "Eye irritation in Rabbits (SUNSPRAY 6N)".
MRID NO. 402708-07 "Primary dermal irritation in Albino rabbits (SUNSPRAY 6N).
NOTE TO PM: Both the eye and dermal irritation studies are acceptable to RSB/PRS - tentatively; providing the registrant can satisfactorily clarity and establish that the materials tested are identical to SUNSPRAY 9N.
Specifically, identify: SUNSPRAY 6N, and "test article # 8601507".

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3) An acute oral, dermal, inhalation toxicity, and dermal sensitization studies must be submited. If the Registrant can prove that the eye and dermal irritation studies discussed under 2) above employed SUNSPRAY 9, additional eye and dermal irritation studies will not be required.

LABELING: NOTE: The following Precautionary labeling statements may require revision, upon submission of the requested acute toxicity studies:

1) The CAUTION label signal word is appropriate.
2) Under Precautionary Statements, following Avoid breathing of spray mists or vapors, add "Avoid contact with skin or clothing".

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3) Under Statements of Practical Treatment, following ~~both~~ both the skin and the eye statements, add "Get medical attention if irritation persists."

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DATA REVIEW FOR ACUTE EYE IRRITATION TESTING (§81-4)

Product Manager: (12)
MRID No.: 402708-06
Testing Laboratory: MB Res. Labs., PA
Author(s): O.M. Morene
Species: rabbit
Sex: not given
Weight: not given
Source: Acc animals
Dosage: 0.1ml undiluted
Test Material: #8601507, SENSPRAY 6N liquid undiluted
Quality Assurance (40 CFR §160.12): satisfactory

Reviewer: ~~M. Waller~~ Woodrow
Report Date: 5-23-89
Report No. MB87-3649D

Summary: (identify test material)

Tox. Category: IV Classification: Core Minimum

Procedure ~~(Deviation From §81-4)~~: 0.1ml undiluted test material to conjunctival sac of 1 eye of each of 6 rabbits; eyes held closed briefly (approx). Eyes examined and scored according to Draize on days 1, 2 & 3.

Results:

	Observations (number "positive"/number tested)							
	Hour	Days						
	1	1	2	3	4	7	14	21
Cornea Opacity		0/6	0/6	0/6				
Iris		0/6	0/6	0/6				
Conjunctivae Redness		0/6	0/6	0/6				
Chemosis		0/6	0/6	0/6				
Discharge		0/6	0/6	0/6				

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Comments: No irritation in any of 6 test rabbits was observed.

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DATA REVIEW FOR SKIN IRRITATION TESTING (§81-5)

Product Manager: (12)
MRID No.: 402708-07
Testing Laboratory: MB Res. Labs. PA
Author(s): O.M. Morrine
Species: Rabbit
Age: not given
Sex: not given
Weight: not given
Dosage: 0.5ml undiluted
Test Material: #860/607 SUNSPRAY 6N liquid
Quality Assurance (40 CFR §160.12): Satisfactory

Reviewer: ~~Mr Walter~~ Woodrow
Report Date: 5-23-89
Report No.: MB 87-8649 c

Summary:

The Primary Irritation Index = P.I. Index = 2.62

Toxicity Category: III

Classification: Core minimum data (should have continued experiment)

Procedure (~~Deviations From §81-5~~): 0.5ml to 1 intact and 1 abraded dorsal test sites on clipped backs of 6 rabbits (total of 1ml) Each test site covered c̄ 2.5cm sq gauze/adhesive tape. Torso wrapped c̄ plastic/adhesive tape. 24hr contact. Test sites scored for irritation at 24 & 72 hrs post treatment, according to Draize.

Results:

Time	Av. irritation scores Erythema/Eschar	Edema
intact -24	1.83	1.50
-72	1.50	0.50
abraded -24	1.83	1.50
-72	1.33	0.50

P.I. Index = 2.62 - (a slight irritant)

Special Comments:

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