



5-16-89

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

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: EPA Reg. No./File Symbol 59820-R
ARCOSAN MOIST POWDER

FROM: William S. Woodrow WSW 5-16-89
Precautionary Review Section E 5/16/89
Registration Support Branch
Registration Division (H75-05C)

TO: Philip Hutton (PM 17)
Insecticide-Rodenticide Branch
Registration Division (TS-767C)

APPLICANT: Werner & Mertz GmbH
Engelheim Strasse 13
16500 Mainz
West Germany

FORMULATION FROM LABEL:

<u>Active Ingredient(s):</u>	<u>% by wt.</u>
<u>Benzyl Benzoate</u>	<u>5.0</u>
_____	_____
_____	_____
<u>Inert Ingredient(s):</u>	<u>95.0</u>
Total	100.0%

BACKGROUND:

Werner & Mertz GmbH, submitted Acute oral, dermal, inhalation, Primary eye and dermal irritation, and Dermal sensitization studies in support of ARCOBAN Registration. MRID NOS. used were 408453-04 through 408453-09

RECOMMENDATION:

- 1) The 6 Acute studies submitted by Fisons are acceptable to RSB/PPS.
- 2) Got minimum designations for eye & skin irritation studies: only 3 animals employed, instead of 6 animals.

LABELING:

- 1) The CAUTION label hazard word is acceptable.
- 2) Change Precautionary Statements, as follows:
 - a. Following Harmful if swallowed, add "Harmful if absorbed through skin. Harmful if inhaled. Causes (moderate) eye injury (irritation)."
- 3) Change Statements of Practical Treatment, as follows:

After the skin statement, add "Get medical attention."

DATA REVIEW FOR ACUTE INHALATION TOXICITY TESTING (S81-3)

Product Manager: (17) Reviewer: W. Woodrow
 MRID No.: 408453-06 Report Date: 5-15-89
 Testing Laboratory: Res. & Consulting Co. Report No. 057802
 Author(s): L. Ullman
 Species: Rat, Wistar
 Sex: 5M + 5F Weight: M255-293, F197-226g
 Source: Kicintlerfarm Madocin AG
 Test Material: Atcosan Moist Powder
 Quality Assurance (40 CFR \$160.12): Satisfactory

Summary:

1. LC50 (mg/kg): Males = _____; Females = _____; Combined = _____
2. The estimated LC50 is $> 2.02 \text{ mg/L}$
3. Mean Concentration: _____
4. Tox. Category: III. Classification: Guidelines

Procedure (~~Deviations from S81-2~~): 4hr exposure to $2020 \text{ mg}^5/\text{m}^3$ liter exposure chambers (now only) - Aerosol generation - nozzle to high velocity air stream (test powder into air stream) - Extraneous concentrations on selection filters (pore size < 0.2

Results:

Exposure Concentration (mg/L)	Reported Mortality (NUMBER KILLED/NUMBER TESTED)		
	Males	Females	Combined
2.02 mg/L	0/5	0/5	0/10

Symptomology & ~~Gross Necropsy~~ Findings:

μ , $\neq 50 \text{ mg}$ india - Particle size: 4 stage cascade impactor (Casella Ltd., London) \rightarrow on selection filters, pore size 0.2μ
 $\neq 25 \text{ mm}$ india - 17.5 l/min air flow - Animals observed for mortality & toxic symptoms; 4x days, 1x daily. All animals gained weight.

Results - No toxic signs or symptoms. One female showed a dark, mottled lung, during necropsy, no other organ or tissue alteration observed at necropsy.

Mean geometric aerosol chamber concentration = $2020 \text{ mg/m}^3 = 2.02 \text{ mg/L}$

Particle size analysis

dry particles (generated from dry aerosol)

$> 7 \mu$	99.6%
3-7 μ	0.39%
1-3 μ	0.14%
$< 1 \mu$	0.09%

The particles were in a respirable range.

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

Product Manager: (17) Reviewer: Woodrow M. Walter
 MRID No.: 408453-07 Report Date: 5-15-89
 Testing Laboratory: Res. & Consulting Co. AG Report No. 057791
 Author(s): L. Ullman
 Species: Rabbit, N2 white
 Sex: 2M & 1F Weight: 1.9-2.5 kg
 Source: Klein Tier Farm Madison AG
 Dosage: 0.1 gram
 Test Material: Atcosan Moist Powder
 Quality Assurance (40 CFR §160.12): Satisfactory

Summary:

Tox. Category: III Classification: Cose Minimum

only 3 chemos - about 1 hr used 6 animals.

Procedure (~~Deviation from §81-4~~): 0.1 gram of test material to left eyes of 2 male and 1 female rabbits. Eyes examined at 1, 24, 48, 72 hrs after eye instillation. Irritation scored according to Drury

Results:

Observations

(number "positive"/number tested)

	Hour	Days							
		1	1	2	3	4	7	14	21
Cornea Opacity	0/3	0/3	0/3	0/3					
Iris	0/3	0/3	0/3	0/3					
Conjunctivae Redness	3/3	1/3	0/3	0/3					
Chemosis	0/3	0/3	0/3	0/3					
Discharge	-	-	-	-					

Comments: No iris or Corneal involvement. All irritation (redness) absent by Day 2.

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

Woodrow

Product Manager: (17)

Reviewer: M. Waller

MRID No.: 408453-08

Report Date: 5-15-89

Testing Laboratory: Res. & Consulting Co. AG

Report No. 057780

Author(s): L. Ullman

Species: Rabbit, M 2 white

Age: (5-6 weeks)

Sex: 1 m & 2 F

Weight: 2.3-2.5 kg

Dosage: 0.5g

Test Material: Atcosan Moist Powder

Quality Assurance (40 CFR §160.12): satisfactory

Summary:

The Primary Irritation Index = P. Irritation Index = 0.00

Toxicity Category: IV

Classification: Core minimum (should have used 6 animals)

Procedure (~~Deviations From §81-5~~): 4ht app. 0.5g to clipped backs of 1m & 2F rabbits (shaved also). 3x3cm² gauze patch/gauze covered Aluminum foil/occlusive dressing. Body weights. Dressings removed, test sites washed. Irritation scored at 1, 24, 48 & 72 hts.

Results:

No irritation was observed, for any animal, at any of the examination periods.

Special Comments:

DATA REVIEW FOR SKIN SENSITIZATION TESTING (§81-6)

Product Manager: (17)
 MRID No.: 408453-09
 Testing Laboratory: Res. & Consulting Co. AG
 Author(s): L. Ullman
 Species: Guinea pig; Dunkin Hartley
 Sex: _____ Weight: M 345-449, F 316-338g
 Source: Kleintierfarm Madocum AG
 Test Material: Arcozan Moist Powder
 Positive Control Material: _____
 Quality Assurance (40 CFR §160.12): Satisfactory
 Method: Modified Buehler

Reviewer: ~~M. Waller~~ Woodrow
 Report Date: 5-15-85
 Report No. 057778

Summary:

1. This product is / is not a dermal sensitizer
2. Classification: Guidelines

Procedure (~~Deviation From §81-6~~): A preliminary study was conducted to determine non-irritating concentrations; ^A 0.1 ml injections of 5, 3, 1, 0 % of test compound in saline. Reaction read 24 hrs later. B- 2 cm² filter paper patches saturated \bar{c} 25, 10, 5 + 3% of test mat. in

Results: Saline applied to clipped & shaved flanks of g.p., covered \bar{c} aluminum foil/plaster/tape. Exposure 24 hrs.

Induction: Intradermal: 6 x 8 cm area clipped free of hair. 3 pairs of intradermal injections (0.1 ml/site) made:

- 1) Freund's Complete adjuvant 50:50 \bar{c} saline
- 2) Test material diluted to 1.0% \bar{c} saline.
- 3) Test material at conc. used in NO. 2, emulsified in 50:50 mix of Freund's Complete adjuvant + saline.

Topical applications: One week after injections, same test sites clipped & shaved. 4x4 cm patch of filter paper saturated \bar{c} test material & placed over injection sites/aluminum foil/tape/wrapping \bar{c} placed in place 48 hours. Control group g.p. received same treatment, without test material.

Test and control guinea pig challenge 2 weeks after topical induction.

Challenge: Hair clipped & shaved, 2x2 cm patch of filter paper applied to same test (induction) sites, and a similarly treated patch applied to the opposite (unexposed site) side of each g.p. 24 hours later, dressing removed & test sites assessed. Control animals treated & vehicle alone.

Re-challenge: A second challenge performed 2 weeks after the 1st challenge. (Same as the first challenge, except that the unexposed sites only tested). Control animals similarly treated - without test material.

Results: All animals gained weight.
Control groups - all negative.

1st challenge:	24 hrs	48 hrs
	1/19	0/20
2nd challenge:	0/20	0/20

The animal positively responding at 1st challenge was believed not to represent a true sensitizing response.

Conclusion: Arcason print powder did not sensitize guinea pigs in the present experiment.