

US EPA ARCHIVE DOCUMENT



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 DERMAL TOXICITY TESTING (§81-2)

Product Manager: (17) Woodrow
 MRID No.: 408453-05 Reviewer: H. Waller
 Testing Laboratory: Res. & Consulting AG Report Date: 5-15-89
 Author(s): L. Wilman Report No. 057767
 Species: Rat, Wistar
 Sex: 5M & 5F Wt.: M 240-251g, F 209-218g
 Test Material: ARCOsan moist Powder
 Quality Assurance (40 CFR §160.12): satisfactory

Summary:

1. LD50 (mg/kg): Males = _____; Females = _____; Combined = _____;
2. The estimated LD50 is > 2000 mg/kg
3. Tox. Category: III. Classification: Guidelines

Procedure (~~Deviations from §81-2~~): 4% soln in CMC & distilled water.
 2000 mg/kg to clipped backs of 5M & 5F rats. Occlusive Dressing 24h contact.
 Irritation assessed according to Neaks & Sanderson. Mortality starting 4x
 day 1, 1x daily to 15 days + necropsy. Poly-uto

Results:

Reported Mortality

DOSAGE (mg/kg)	(NUMBER KILLED/NUMBER TESTED)		
	Males	Females	Combined
2.0g/kg	0/5	0/5	0/10

Symptomology & Gross Necropsy Findings:

All animals gained weight. No clinical symptoms were observed for males or females. No treatment related tissues or organ changes were noted during necropsies.

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 Madocrin 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, NZ 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 wrapped \bar{c} tape; dressing left 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: Arason print powder did not sensitize guinea pigs in the present experiment.