

US EPA ARCHIVE DOCUMENT

8-10-94



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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: **SULFLURAMID** - Amount of A.I. in Raid Max Roach Bait

TO: Mike Mendelsohn
PM Team Reviewer (18)
Registration Division (7505C)

FROM: Linda L. Taylor, Ph.D. *Linda Taylor 8/10/94*
Toxicology Branch II, Section II,
Health Effects Division (7509C)

THRU: K. Clark Swentzel *K. Clark Swentzel 8/10/94*
Section II Head, Toxicology Branch II
Health Effects Division (7509C)

and

Marcia van Gemert, Ph.D. *Marcia van Gemert 8/10/94*
Chief, Toxicology Branch II/HED (7509C)

Registrant: SC Johnson & Son, Inc.
Chemical: N-ethyl perflurorooctanesulfonamide
Synonym: GX-071; Sulfluramid
Caswell No.: 454E
Shaughnessey No.: 128992
DP Barcode: D205949
Submission: 455933

Action Requested: Please define what constitutes human exposure to an amount of Sulfluramid via this product that may produce serious personal injury or illness to a 25 lb child.

Comment: Based on the available toxicology data on Sulfluramid, TB II has determined that the contents of one bait cannot be considered harmless if ingested by a 25 pound [11.4 kilograms] child in that the amount of active ingredient in one bait on a per kg basis exceeds the NOEL for all but one of the studies [see appended Table A].

In the classical sense, Sulfluramid is not an acute toxin; however, some of the endpoints observed in the developmental toxicity studies may result from a one-time exposure; e.g., the amount of Sulfluramid in one bait ingested by a child has the potential to cause adverse reproductive and/or developmental effects as the



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child develops. Since the calculated dose to a child is comparable to the LEL's and greater than all but one NOEL in the oral toxicity studies, no margin of safety exists in this case.

CALCULATIONS: Several assumptions were made, based on available information supplied by RD, as modified by R. Gross and TB II, in calculating the amount of Sulfluramid in each bait: (1) 0.84 ounce/12 baits; (2) active ingredient level in each bait is 1%; (3) child weight is 11.4 kg [25 pounds]. Using the conversions: one ounce \Rightarrow 30 grams; grams \times 1000 = # mg, each bait is calculated to contain 21 mg a.i. [$0.84 \text{ ounce} \div 12 \times 1\% \text{ a.i.} = 0.0007 \text{ oz a.i./bait}$; $0.0007 \text{ oz} \times 30 \text{ g} = 0.021 \text{ g/bait}$; $0.021 \times 1000 = 21 \text{ mg/bait}$]. Therefore, the dose to a 25 pound child ingesting the entire contents of one bait is 1.84 mg/kg [$21 \text{ mg/bait} \div 11.4 \text{ kg} = 1.84 \text{ mg/kg}$]. Table A, which provides a comparison of the NOEL's [no-observed-effect levels] and LEL's [lowest-effect levels] from pertinent toxicology studies to the calculated dose of Sulfluramid a 25 pound child could be exposed to if the entire contents of one bait were ingested, is set up as a series of columns. Column 1: study type; Column 2: NOEL's; Column 3: LEL's; Column 4: effect(s) on which the LEL is based; Column 5: comparison of the NOEL to the calculated dose to a child {NOEL \div dose}; Column 6: comparison of LEL to the calculated dose to a child {LEL \div dose}.

Table A. Sulfuramid - Comparison of NOEL's and LEL's to the Calculated Dose of Sulfuramid to a 25-Pound Child Ingesting the Entire Contents of One Bait

Study	NOEL	LEL	LEL based on	NOEL vs Dose in one bait	LEL vs Dose in one bait
90-day dog*	33 ppm [0.825 mg/kg]	100 ppm [2.5 mg/kg]	↑ epididymal & testicular lesions affecting seminiferous tubules in testes	0.825 vs 1.84 (0.45)*	2.5 vs 1.84 (1.36)
90-day rat	10 ppm [0.5 mg/kg]	50 ppm [2.5 mg/kg]	↓ BW & FC, ↑ liver weight, centrilobular hepatocellular hypertrophy/vacuolation	0.5 vs 1.84 (0.27)	2.5 vs 1.84 (1.36)
3-week dermal	100 mg/kg/day	300 mg/kg/day	↓ BW & FC, ↑ emaciation, ↑ liver vacuolation & necrosis, ↑ testicular & epididymal atrophy, aspermia (epididymides), seminal vesicle distension	100 vs 1.84 (54.3)	300 vs 1.84 (163.0)
developmental tox. - rat	Maternal 0.8 mg/kg/day Developmental 3.3 mg/kg/day	Maternal 3.3 mg/kg/day Developmental 13.3 mg/kg/day	Maternal: ↓ BW/BWG Developmental: ↓ fetal weight, ↑ in cleft palate, incomplete ossification [3 ^d /4 th sternbrae/skull, enlarged fontanelle	Maternal 0.8 vs 1.84 (0.43) Developmental 3.3 vs 1.84 (1.8)	Maternal 3.3 vs 1.84 (1.79) Developmental 13.3 vs 1.84 (7.2)
developmental tox. - rabbit	Maternal: no effects at 1.5 mg/kg/day Developmental: no effects at 1.5 mg/kg/day	Maternal 3.0 mg/kg/day Developmental 3.0 mg/kg (range-finding study)	Maternal: ↓ BW/BWG, FC, deaths/abortions/premature deliveries Developmental: abortions/premature deliveries	Maternal 1.5 vs 1.84 (0.82) Developmental 1.5 vs 1.84 (0.82)	Maternal 3.0 vs 1.84 (1.63) Developmental 3.0 vs 1.84 (1.63)

* ↑ mortality, renal hyperemia and nephrosis in 1500 ppm; ↓ BW & FC, epididymides & testes weights, % motile sperm & epididymal sperm & testicular spermatid concentrations, increased liver weight at 500 and 1500 ppm; a direct acting testicular toxin in dog affecting late spermatids and possibly Sertoli cells

* (#) NOEL or LEL ÷ Calculated Dose (1.84 mg/kg)

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CHILD-RESISTANT PACKAGING REVIEW

Registration Support and Emergency Response Branch

IN 8/9/94 OUT 8/10/94

Reviewed by Rosalind L. Gross Date 8/10/94 *R L Gross*

EPA Reg. No. or File Symbol 4822-355

EPA Petition or EUP No. _____

Date Division Received 8/9/94

Type Product(s) Insecticide

Data Accession No(s). 430364-00, 430364-01

Product Mgr. No. PM 18

Product Name(s) Raid Max Roach Bait

Company Name(s) S. C. Johnson & Son, Inc.

Submission Purpose Addendum to 4/25/94 review for child-resistant packaging, question of bait accessibility based on Health Effects Division determination of a toxic amount of the product/active ingredient.

Chemical & Formulation

Active Ingredient(s)

3

Sulfloramid (12/13/91 accepted label)

13

4

Background

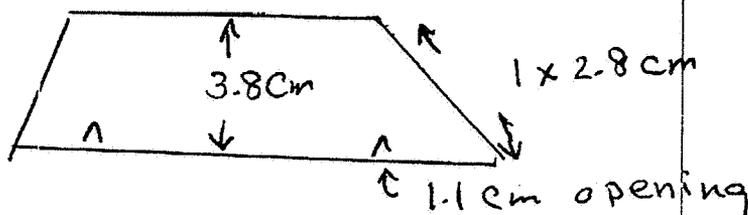
EPA Registration Number 4822-355 was registered initially as EPA Registration Number 1812-329. EPA Registration Number 1812-329 was conditionally registered in a letter dated March 23, 1989¹. The decision to register EPA Registration Number 1812-329 included an assumption of no human exposure to the active ingredient (memorandum D. Camp/A. Lindsay March 22, 1989). A February 15, 1994 facsimile from the registrant confirms that EPA Registration Number 4822-355 was registered with data waivers based on the assumption the product was in CRP.

Company Data

MRID number 430364-00 and 430364-01 consists of a CRP certification and summary of the CRP test procedures and data upon which the certification is based. MRID number 430364-01 reports bait station # 40150 and disc bait station # 40151 were tested, the data does not show the design of these stations. MRID number 430364-01 states the "station was observed specifically for the child resistance of the outer shell of the station....". The summary of results defines a failure as opening or damaging eight bait stations in a manner that exposes the center of the bait station. The report concludes that none of the 200 children tested were able to damage or open eight bait stations in a way to expose the center and therefore the station tested is 100% child-resistant. Table 2 in the report indicates 73 children opened or exposed the center of the bait station for one or more bait stations.

Package Description

The product label for Raid Max Roach Bait Plus Egg Stoppers consists of two parts, EPA Registration Number 4822-355 and 4822-400. EPA Registration Number 4822-355 the sulfluramid part is the only part addressed in this review. The package contains 12 sulfluramid bait stations net weight 0.84 ounces (0.07 ounces of product per bait station). The sample bait station is a plastic trapezoid 5 cm on top, 7.3 cm on bottom, 3.8 cm long, 1.4 cm high with a small round disc of wood in it. The bait station has two trapezoid shaped 1.1 cm openings on the bottom, and a 1 cm by 2.8 cm opening on each end. There is a 1.7 by 2.1 cm indentation in the bottom of the bait station where the wood disc, which represents the bait, fits. The wood disc is about 3.6 cm in from either end of the trapezoid.



¹The registration FR Notice appeared on June 14, 1989.

Analysis of Data and Conclusion

The Toxicology Branch of Health Effects Division (memorandum Mendelsohn/Taylor et. al. August 10, 1994) indicates that a one-time exposure to one bait station has the potential to cause adverse reproductive and/or developmental effects as the child develops. Therefore, a child failure is defined as access to the contents of one bait station in a manner that permits it to be potentially ingested.

The company's data in MRID number 430364-01 states the package was 63.5% child resistant, which is substantially below the 80% minimum level of child-resistance required by our regulations.² In conclusion, this package is not child-resistant packaging.

²It is unclear from the test data whether access through the aperture of 1 cm by 2.8 cm on each end was measured. The anthropometric data for 2.5-5.5 year old children (CPSC Contract CPSC-C-76-0119 Final Report September 1977 "Gripping Strength Measurements of Children for Product Safety Design" by Owings, C.L., Norcutt, R.H., Snyder, R.G., Golomb, D. H., and Lloyd, K.Y., University of Michigan, Ann Arbor, MI.) suggest a child could easily contact the bait and possibly dislodge it through the aperture.