

February 14, 2005

Stephen L. Johnson  
Acting Administrator  
U.S. Environmental Protection Agency  
Ariel Rios Bldg. (1101A)  
1200 Pennsylvania Ave. NW  
Washington, DC 20460

Re: Public comments on the Rohm and Haas HPV test plan for Hexaoxatricosane



PEOPLE FOR THE ETHICAL  
TREATMENT OF ANIMALS

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Rohm and Haas submitted an HPV test plan for hexaoxatricosane (CAS No. 143-29-03), a substance used to increase flexibility in rubber products. These comments are submitted on behalf of People for the Ethical Treatment of Animals, the Physicians Committee for Responsible Medicine, the Humane Society of the United States, the Doris Day Animal League, and Earth Island Institute. These health, animal, and environmental protection organizations have a combined membership of more than ten million Americans.

It appears as though Rohm and Haas is deliberately attempting to mislead the public when it states on the first page of its test plan that “it is the intent of our company to use existing data ...in conjunction with predictive computer models to adequately fulfill the SIDS ...endpoints. We believe that in total these data are adequate to fulfill all the requirements of the HPV program *without need for the conduct of any new or additional tests*” (emphasis added). Otherwise the company is shockingly oblivious to the commitments it made regarding the basic requirements of the HPV program.

A review of Rohm and Haas’ robust summaries reveals that acute toxicity testing, acute dermal toxicity, rabbit skin irritation testing, rabbit eye irritation testing, guinea pig skin sensitization testing, repeat dose, reproductive, and developmental toxicity testing, *in vivo* micronucleus toxicity testing, and acute fish toxicity testing were all conducted by the company in either 2003 or 2004.

Beyond the fact that the animal welfare principles the EPA set forth in October 1999 require the use of thoughtful toxicology, the original HPV framework agreement to which all companies agreed when they signed on to participate in the HPV program stated that companies were to allow 120 days for public comments following the posting of their test plans prior to initiating testing. Not only did Rohm and Haas completely flout this provision but the testing they conducted went far beyond anything required in the HPV program. Rohm and Haas conducted repetitive tests for the same endpoints, even when the earlier tests had been conducted according to “good laboratory practices” (GLP).

Rohm and Haas conducted the following tests prior to submitting its HPV test plan for comment:

1. An oral LD-50 in 2003 when a prior oral LD-50 and six acute inhalation studies had been conducted, three of which were rated (2), valid with restrictions.

2. An acute dermal toxicity test in 2004 when it had already conducted an acute dermal toxicity test in 1977 which was rated (2), valid with restrictions. Dermal toxicity testing is specifically excluded from the HPV program.
3. A rabbit skin irritation test in 2003 when it had already conducted a GLP rabbit skin irritation test in 1991. Dermal testing is specifically excluded from the HPV program.
4. A rabbit eye irritation (Draize) test in 2003 when it had already conducted Draize tests in 1966 and in 1991, the latter of which was GLP. Eye irritation testing is specifically excluded from the HPV program.
5. A skin sensitization test on guinea pigs in 2004 when it had already conducted a skin sensitization test on guinea pigs according to GLP in 1991. Skin sensitization is not a part of the HPV program.
6. An *in vivo* mouse micronucleus test in 2003 when it had negative results from a prior *in vitro* genetic toxicity test. The HPV program specifically encourages the use of *in vitro* genetic toxicity testing, unless known chemical properties preclude its use, in which case justification must be provided. Furthermore, no authority, including the Organization for Economic Cooperation and Development (OECD), calls for *in vivo* testing as a follow-up to negative *in vitro* results.
7. A repeated dose, reproductive, and developmental toxicity test in 2004.

Given the facts that nos. 1-6 above were clearly unnecessary based on pre-existing tests, it is obvious that Rohm and Haas has made no attempt to critically evaluate, or conduct a thoughtful analysis of, the toxicity of this chemical based on existing data. One can only conclude that animal experimenters at the Rohm and Haas laboratory in Spring House, PA, have nothing better to do than cause the type of misery described in their test results. There is no other earthly reason to have conducted these repetitive tests as they make neither scientific nor financial sense. This is what the animals endured in the mammalian acute oral test:

*“Animal 2 exhibited convulsions, lachrymation, and salivation approximately 30 minutes after dosing. Death had occurred within approximately one hour. Animal 3 exhibited lethargy on Day 1. Reduced activity and hunched posture were then noted on days 2 and 3. Recovery occurred by day 4. Animal 4 was unconscious within approximately 30 minutes of dosing. Some recovery was apparent within 24 hours of dosing, when piloerection was noted. Full recovery had occurred within 48 hours. Animal 5 appeared moribund within approximately 30 minutes of dosing, remaining so for the remainder of the day. It was cold to the touch and exhibited a hunched posture on days 2 and 3. Recovery had occurred within 72 hours.*

*At 550 mg/kg: Convulsions were apparent within approximately 6 minutes of dosing. A degree of recovery soon occurred with the animal remaining lethargic*

*from approximately 11 minutes after dosing and continuing for the remainder of the day.”*

The suffering of the animals used in the completely unnecessary genetic toxicity test is described as follows by Rohm and Haas:

*“ Animals from the high treatment group showed ataxia, hunched posture, ungroomed appearance, reduced activity and three female animals were found moribund approximately 20 minutes after treatment. Animals from the intermediate group showed reduced activity and hunched posture, and one male animal was found moribund approximately 25 minutes after treatment. A full recovery was observed for all animals, the day after treatment. A female animal was found dead at the low dose level 24 hours after treatment. Reduced activity and hunched posture were also observed in a female animal from the vehicle control group, 24 hours and 48 hours after treatment.”*

In a 2-10-05 phone conversation, James McLaughlin of Rohm and Haas told PETA that the company had conducted these tests for “product stewardship” reasons and because “employees are exposed.” This is clearly a disingenuous excuse for the company’s complete disregard for public comments on its testing plan since Rohm and Haas obviously had employees working with this material prior to 2003. If Rohm and Haas felt it needed this information to protect its employees in 2003 then, by the same token, the company was clearly negligent in protecting its employees prior to this time and in violation of the Occupational Safety and Health Administration’s hazard communications standard.

In conclusion, the Rohm and Haas test plan for hexaoxatricosane is among the worst examples we have seen to date of thoughtless toxicology and duplicative testing in the HPV program. It is a disgrace. The EPA should make it clear to this company that its participation in the program is contingent upon its abiding by both the original HPV framework agreement and the animal welfare principles laid out in the agency’s October 14, 1999, letter and December 2000 *Federal Register* notice.

Sincerely,

Jessica Sandler  
Federal Agency Liaison