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Public Information and Records Integrity Branch (PIRB) (7502C)
Office of Pesticide Programs (OPP)
U.S. Environmental Protection Agency
1200 Pennsylvania Ave., N.W.
Washington, DC 20460
Attn: Docket ID Number OPP-2005-0043

Submitted via electronic mail

To Whom It May Concern:

Docket No. OPP-2005-0043- Pyrethrins Risk Assessments

The purpose of this letter is to comment on EPA's risk assessments for pyrethrins, which were made available for public comment on April 27, 2005 (70 FR 21754). Tri-TAC is concerned that the risk assessments do not evaluate the potential adverse water quality impacts associated with sewer discharges of pyrethrins, particularly pyrethrins used in pet shampoos, head lice shampoos, and other indoor-use products. As background, Tri-TAC is a technical advisory group for Publicly Owned Treatment Works (POTWs) in California. It is jointly sponsored by the California Association of Sanitation Agencies, the California Water Environment Association, and the League of California Cities. The constituency base for Tri-TAC collects, treats, and reclaims more than two billion gallons of wastewater each day and serves most of the sewered population of California.

Comments on Indoor Uses, Including Pet Shampoos

While the EPA risk assessments for pyrethrins consider potential adverse water quality impacts arising from agricultural and mosquito abatement uses, they do not consider such impacts from pyrethrins usage in pet shampoos and other indoor use products. The vast majority of pyrethrins are used in indoor settings, including pet shampoos. According to EPA, 85% of pyrethrins are used in indoor settings.[1] Only 9% are used on agricultural commodities and 6% on terrestrial non-food areas (including mosquito

[1] EPA, Overview of the Pyrethrins Risk Assessments, April 27, 2005.

abatement applications).[2] EPA should not ignore potential adverse water quality impacts from the largest uses of pyrethrins. Note that normal usage of pet shampoos includes a direct pathway to sewers, from rinsing of the shampoo after application. Even when pets are rinsed outdoors, the rinse water can enter storm drains or flow directly to creeks and rivers.

Because pyrethrins bind well to solids, the majority of pyrethrins discharged to sewers are expected to be removed during wastewater treatment. However, not all solids are removed during treatment so some pyrethrins will pass through such treatment. In receiving waters, the pyrethrins are expected to bind to sediments and can potentially impact benthic communities. Such water quality impacts would then come under the jurisdiction of the Clean Water Act, and POTWs could be impacted, either through more stringent discharge limitations or through the Total Maximum Daily Load process designed to address waters not attaining their assigned water quality standards.

EPA's Environmental Fate and Effects Division (EFED) recommends that the label on pyrethrins for end use products contain the language "Do not contaminate water when disposing of equipment wash-waters or rinsate." This proposed language does not offer any suggestions for disposal of shampoo rinse water that is generated during normal usage of pet shampoos. The rinse water must either be allowed to run off to storm drains or put down sewers; in either case there is a pathway for water contamination.

Because of these concerns, Tri-TAC requests that EPA evaluate potential adverse water quality impacts from sewer discharges of pyrethrins, and develop appropriate label language or take other actions to ensure that no adverse impacts occur.

Comments on Head Lice Treatment (Pediculicide) Uses

Additionally, pyrethrins are commonly used in head lice shampoos that are applied directly to humans. For example, RID Lice Killing Shampoo and RID Lice Killing Mousse both contain 0.33% pyrethrins. When these shampoos are rinsed after use, they will flow directly to sewers. Although pediculicide uses of pesticides are not currently subject to regulation under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), they were subject to such regulation until 1979. Since pediculicides are considered to be drugs, they are also subject to the Federal Food, Drug and Cosmetic Act (FFDCA). On November 5, 1979 (44 Federal Register, 63749), EPA decided to exempt pediculicides from the requirements of FIFRA. The regulation of these products under both FIFRA and FFDCA was felt to be duplicative, as stated in the announcement of the exemption, "EPA and FDA concluded that the dual review of pesticide/new drug products offered solely for human use represents an expensive duplication of time and resources for both the Agencies and the sponsors of these products without any significant increase in benefits to public health and/or the environment. It is further concluded that regulations of these products solely by FDA under the FFDCA would adequately serve the intent of FIFRA."

[2] Ibid.

Regulation under the FIFRA and the FFDCA is no longer duplicative. Since 1979, the degree of regulation under FIFRA has changed considerably, most notably with passage of the Food Quality and Protection Act of 1996 (FQPA). This statute requires EPA to review all pesticide registrations on at least a fifteen-year cycle (7 U.S.C. §136a(g)(1)(A)). The goal of this requirement is to ensure that all pesticides continue to meet up-to-date standards for safety, public health, and environmental protection. EPA has the authority to require data and take action if needed between registration cycles (7 U.S.C. §136a(c)(2)(B); §136a-1(d)(3)). No similar provisions exist under the FFDCA. Additionally, EPA has emergency suspension authority, which means a pesticide registration can be canceled immediately if there is an emergency, imminent threat to public health or the environment. (7 U.S.C. §136d(c)) This appears to be a much more direct and powerful tool to regulate pesticides when compared to the FDA's authority to simply require an Environmental Assessment in such circumstances.

Tri-TAC believes that EPA should reassert its control over pediculicides under FIFRA. As such action is beyond the scope of the action EPA is currently considering, EPA should, at minimum, consider the environmental impacts of these treatments in its current risk assessments. Under FIFRA, EPA has a statutory responsibility to ensure that pesticides are safe and effective for their intended uses and to prevent unreasonable adverse effects to man, other animals, and the environment from their usage (7 U.S.C. §136(bb), §136a(a), §136a(d)(2); §136d(b)). By ignoring the risks posed by pyrethrins-containing head lice treatments, EPA is not fulfilling its statutory responsibility.

Contact Information

Tri-TAC appreciates this opportunity to comment on the risk assessments for pyrethrins. If you have any questions about this letter or require additional information, please contact Ann Heil by phone at 562/699-7411, extension 2950, or by e-mail at aheil@lacsd.org.

Sincerely,

Sharon N. Green

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