



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

OFFICE OF
PREVENTION, PESTICIDES
AND
TOXIC SUBSTANCES

August 18, 1999

MEMORANDUM

SUBJECT: Incidents and Adverse Effects Regarding EPA Registration Number 65331-1, 65331-2, and 65331-3

FROM: Rosalind L. Gross *R L Gross*
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TO: Ann Sibold
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Merial reported 131 human incidents (6)(a)(2) in the United States for EPA Registration Number 65331-1, 65331-2, and 65331-3 from April-June 1999. All 131 human incidents were classified as minor effects. Approximately 12 of the incidents involved children under 5 years old and four of the incidents were ingestions. While all the incidents were classified as minor the number of incidents for a 3 month period raise concerns because the packaging for EPA Registration Number 65331-1, 65331-2, and 65331-3 is relatively new to the marketplace and is CRP.

A review of the CRP data for EPA Registration Number 65331-1, 65331-2, and 65331-3 reveals that for 65331-2 and 65331-3 small pipette 5 children out of 50 accessed a pipette during testing. According to the sequential child test in 16 CFR 1700.20 a maximum of 5 out of 50 children can access a unit package for it to be considered a pass rather than having to continue testing to another 50 children.

Some questions that should be answered for the 12 of the incidents involved children under 5 years old are:

1. How do the number of incidents involving children under 5 years old for the time period December 1998 - June 1999 compare to the year before CRP was used?
2. How many of the incident involving children under 5 years old involved the child accessing an unopened package, specifically the blister containing the pipettes? What size pipettes were involved?
3. For those incidents involving the spray bottle did the children activate the sprayer or was it left in the nonchild-resistant position by the adult?
4. Were the dermal incidents a result of the children under 5 years old touching the dog, coming into contact with an unopened pipette out of the blister, a previously opened pipette, or liquid on the outside of the sprayer/bottle? Be as specific as possible including the size pipettes involved.
5. How many packages were sold and/or what percentage of the packages sold do these 12 incidents involving children under 5 years old represent?
6. Case 2026396 involves a 5 year old and an ocular injury involving gas. Please explain what the gas is and the details surrounding the incident.