6(b) CLEAR 6/6/96
MFR/PRVLBR NOTIFIED
No Comments made
Comments attached
Excisions/Revisions
Firm has not requested further notice

LOG OF MEETING

SUBJECT: Meeting with Brigid Klein, staff attorney for the Chemical Specialties Manufacturers Association (CSMA), and industry members to discuss ammonia.

DATE OF MEETING: April 4, 1996

DATE OF LOG ENTRY: April 5, 1996

LOCATION: 4330 East West Highway, Bethesda, MD, Room 714

CPSC ATTENDEE(S): See Attached list.

NON-CPSC ATTENDEE(S): See Attached list.

SUMMARY OF MEETING: CSMA members described how they ensure consumer safety and satisfaction through product safety evaluations and surveillance of poisoning data through contracts with poison control centers. Additionally, Dr. Ed Krenzelok presented data from the American Association of Poison Control Centers relating to exposures to ammonia-containing all purpose household cleaners (see attached report).

CPSC Staff Meeting with CSMA on Ammonia

April 4, 1996
10:30 A.M., Room 715

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Charles J. Wilbur	CPSC-EHPS	301-504-0477 Ext 1204
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Marcia Robins	CPSC/ECON	301. 504-0962 x132
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Martha Mary-Rule	Procter & Gamble	513- 626-3652
Mary F. Doro	CPSC/CE	
Harleigh Ewell	CPSC/OGC	301-504-0980 x 2217
Maureen Cisko	PRODUCT SAFETY LETTER	703-247-3423

EVALUATION OF THE TOXICITY ASSOCIATED WITH HUMAN EXPOSURE TO AMMONIA-CONTAINING ALL PURPOSE HOUSEHOLD CLEANERS

Property of the Dial Corporation

Prepared By:

Edward P. Krenzelok, PharmD, FAACT, ABAT
Consulting Clinical Toxicologist

April 2, 1996

EXECUTIVE SUMMARY

An examination of the data from the American Association of Poison Control Centers Toxic Exposures Surveillance System (AAPCC TESS) reveal that no fatalities or major (*serious*) effects were reported in 8,763 children less than six years of age who were exposed to ammonia-containing all purpose household cleaners. Poisindex®, the leading reference used by poison information centers, indicates that the accidental exposure to household ammonia is not associated with serious injury. According to 16 CFR § 1700.3 *"...serious personal injury or serious illness..."* must occur to warrant the use of child-resistant closures. Based upon AAPCC TESS and Poisindex®, there is no evidence that such claims can be made about ammonia-containing all purpose household cleaners. Therefore, the mandated use of child-resistant closures on ammonia-containing all purpose houshold cleaners cannot be justified.

INTRODUCTION

The word *accident* means "an unintended and usually sudden and unexpected happening or change occurring through carelessness or ignorance or from unavoidable causes..." (Webster's New Ideal Dictionary). Poisonings are one of the most common and long-standing accidents in the pediatric population. Like other accidents, poisonings are largely preventable. One of the first efforts to prevent poisonings was the enactment of the Hazardous Substances Labeling Act of 1960. This Act provided a means to ban unusually toxic substances from commercial trade, but its major focus was to dictate precautionary labeling. Labeling is a passive poison prevention tool. More active measures were necessary to reduce the morbidity and mortality associated with accidental poisonings. To acknowledge the importance of poison prevention and active intervention, Congress passed the Poison Prevention Packaging Act (PPPA) in 1970. While caregivers of children could control influential environmental factors (i.e., keeping products out of reach), the purpose of the PPPA was to control the agents that were responsible for poisoning exposures in children. The PPPA has had a major impact on reducing both the morbidity and mortality associated with pediatric exposure to aspirin, furniture polish, prescription medications, lye, methanol, ethylene glycol, iron and a host of other agents associated with significant toxicity when used improperly.

The U.S. Food and Drug Administration was initially charged with the administration of the PPPA, but in 1973 the jurisdiction was changed to the U.S. Consumer Product Safety Commission. In accordance with the provision of the PPPA, "the Commission may establish...by regulation, standards for the special packaging of any household substance if it finds that":

- The degree or nature of the hazard to children in the availability of such substance, by reason of its packaging, is such that special packaging is required to protect children from serious injury or serious illness resulting from handling, using, or ingesting such substance.

- The special packaging to be required by such standard is technically feasible, practicable, and appropriate for such substance.

"In establishing a standard under this section, the Commission shall consider:"

- The reasonableness of such standard.

- Available scientific, medical, and engineering data concerning special packaging and concerning childhood accidental ingestions, illness, and injury caused by household substances.

- The manufacturing practices of industries affected by this Act.

- The nature and use of the household substance.

The purpose of this report is twofold: 1) To examine the degree or nature of the hazard that ammonia-containing all purpose household cleaners present to children less than six years of age by examining human exposure data from the American Association of Poison Control Centers Toxic Exposure Surveillance System; 2) To determine if the reported pediatric exposures to ammonia-containing all purpose household cleaners justify the use of child-resistant closures on those products.

METHODOLOGY

The American Association of Poison Control Centers Toxic Exposure Surveillance System (AAPCC TESS) is a poison exposure data collection system which represents the collective experience of American poison information centers that voluntarily submit their case exposure data to the AAPCC. The database represents exposures reported on a standardized patient documentation/data entry form which is used by participating centers and tabulated on an annual basis. The contributing centers are a combination of AAPCC certified regional poison information centers and noncertified centers. Only data which meets specific quality control parameters are included in the database.

AAPCC TESS utilizes a unique seven digit code which is provided on Poisindex®, the computerized poison information resource which is utilized by all poison information centers that contribute to AAPCC TESS. Since the cases include product-specific codes, the system may be searched to identify exposures to specific products or groups of products with similar applications or characteristics. The cases for the years 1991-1994 were categorically searched to identify all exposures to *ammonia-containing all purpose household cleaners.* These data were further stratified to identify all exposures to these products (which would include exposure to multiple substances) and those that solely involved ammonia-containing all purpose household cleaners. The data were selectively extracted and entered into a computer graphics database to compare all exposures to cases with no concomitants in both the general population and children less than six years of age. The following data fields were extracted as a subsets: patient demographics such as age, reason for the exposure, acute vs. chronic, location of the exposure, route of exposure, management site, decontamination therapy and patient outcome.

The outcome parameters are those defined by the AAPCC TESS:

No effect--the patient developed no symptoms as a result of the exposure.

Minor effect--the patient exhibited some symptoms as a result of the exposure, but they were minimally bothersome to the patient.

Moderate effect--the patient exhibited symptoms as a result of the exposure which are more pronounced, more prolonged or more of a systemic nature than minor symptoms. The symptoms are not life-threatening.

Major effect--the patient exhibited some symptoms as a result of the exposure. The symptoms were life-threatening or resulted in significant residual disability or disfigurement.

Unknown nontoxic--the final patient outcome was unknown, but the case was deemed to be a nontoxic exposure.

Unknown potentially toxic-- the final patient outcome was unknown and it was deemed as a potentially toxic exposure.

Unrelated effect--the effects were unrelated to the exposure.

The data were analyzed using descriptive statistics.

RESULTS

Profile of Exposures

Number of Exposures

The search identified 17,569 exposures to ammonia-containing all purpose household cleaners (ammonia-containing all purpose household cleaners). In 13,760 cases the exposures were solely to ammonia-containing all purpose cleaners and no concomitants were involved. During the same time period, 7,380,041 exposures (involving all substances) were reported to AAPCC TESS and 0.24% of all reported cases involved exposure to ammonia-containing all purpose household cleaners (patient exposed to one or more substances) and 0.19% were sole exposures to ammonia-containing all purpose household cleaners.

Number of Substances/Exposure

The data were stratified into two groups--*all exposures* involving ammonia-containing all purpose household cleaners ($\geq$ 1 substance/exposure) and those with *no concomitants*. In the all exposure category, 77.76% involved only one substance.

Acute vs Chronic Exposure

The majority (> 99%) of cases were acute exposures (Table 1, Figure 1).

Location

Ammonia-containing all purpose household cleaners are marketed for sale in the home and the domestic residence was the most common location where exposures occurred. There was a relatively even distribution of exposures occurring in the residence between the *all exposure* category (92.71%) and the *no concomitant* category (94.96%) (Figure 2).

Age

Children less than 6 years of age accounted for 50.04% of all exposures to ammonia-containing all purpose household cleaners. Putting that into perspective, 61% of all exposures to cleaning products (1991-1994) occurred in children less than 6 years of age. (Table 2)[1,2,3,4] The median percentage of the 88 category list occurred at 66% (Spot. Dry Clean-Glycol) and ammonia-containing all purpose household cleaners occurred at position 64 in the lower 27% of this list. Therefore, the frequency of exposures to ammonia-containing all purpose household cleaners by children less than 6 years of age is not an unusual occurrence. Exposures in the *no concomitant* group in children less than age 6 years accounted for 47.78% of the exposures. 95.48% of all exposures by children less than 6 years of age were to ammonia-containing all purpose household cleaners alone. Approximately 75% of the exposures (children < 6) in both categories involved children aged 12-35 months (Figure 3). Furthermore, 37.40% of all exposures to ammonia-containing all purpose household cleaners involved children in the 12-35 month age bracket (Figure 3).

Unintentional

Most exposures were unintentional--88.05% of the *all exposure* group vs 97.25% of the *no concomitant* group (Figure 4). In excess of 99% of the exposures in children less than 6 years of age were unintentional (Table 3). Within the unintentional category, there is a *misuse* subcategory which represents the accidental but improper use of a product, such as the admixture of an ammonia all purpose cleaner with a bleach (hypochlorite)-containing product. 13.06% of all unintentional exposures were secondary to misuse (Figure 4). 90.77% of the

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[1] Litovitz TL, Holm KC, Bailey KM, et al. 1991 Annual Report of the American Association of Poison Control Centers National Data Collection System. *Am J Emerg Med* 1992;10:452-505.

[2] Litovitz TL, Holm KC, Clancy C, et al. 1992 Annual Report of the American Association of Poison Control Centers Toxic Exposure Surveillance System. *Am J Emerg Med* 1993;11:494-555.

[3] Litovitz TL, Clark LR, Soloway RA. 1993 Annual Report of the American Association of Poison Control Centers Toxic Exposure Surveillance System. *Am J Emerg Med* 1994;12:546-584.

[4] Litovitz TL, Felberg L, Soloway RA, et al. 1994 Annual Report of the American Association of Poison Control Centers Toxic Exposure Surveillance System. *Am J Emerg Med* 1995;13:551-597.

misuse cases involved exposure to a combination of an all purpose ammonia cleaner and a hypochlorite-containing product

Route of Exposure

The routes of exposure were ingestion 52.93%, inhalation 25.15%, ocular 12.81% and dermal 8.80%. The frequency of exposure by all routes is illustrated in Figure 5. For comparision, the routes of exposure for all reported poisoning exposures are ingestion 74.3%, dermal 7.9%, inhalation 6.7% and ocular 6.2%.[5]

Treatment

Management Site

In excess of 80% (*all exposures* 80.61% vs *no concomitants* 85.86%) of the exposures were managed at the site of exposure (nonhealthcare facility) and the remainder were treated in a healthcare facility (Figure 6). Specifically, in children less than 6 years of age, approximately 90% were not hospitalized (Figure 7).

Examining the subset of patients who were treated at a healthcare facility, over 60% were treated and released (Figure 8). In children less than 6 years of age, approximately 10% were poison center-referred or self-referred for evaluation in a healthcare facility. Approximately 82% of the children treated at a healthcare facility were treated and released (Figure 9). **Therefore, only 1.8% of all children less than six years of age were admitted for observation or treatment after exposure to ammonia-containing all purpose household cleaners, compared to 11.0% of all poisonings involving nonpharmaceuticals and 18.4% of poisoning exposures involving pharmaceuticals in children less than 6 years of age.**[6]

Specific Therapy

No specific interventional therapy was utilized in approximately 8% of the cases (Figure 10). Dilution or irrigation (skin or eyes) were used in 74.63% of the *all exposure* category patients and 78.05% of the *no concomitant* group (Figure 10). The remainder of therapies involved a variety of interventions and unknown therapies.

Patient Outcome

There were no fatalities reported in the 17,569 exposures to ammonia-containing all purpose household cleaners (Table 4). No effects developed in 21.25% of *all exposures* and in 25.09% of the *no concomitant* group. An additional 20% of

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[5] Litovitz TL, Felberg L, Soloway RA, et al. 1994 Annual Report of the American Association of Poison Control Centers Toxic Exposure Surveillance System. *Am J Emerg Med* 1995;13:551-597.

[6] Litovitz TL, Holm KC, Clancy C, et al. 1992 Annual Report of the American Association of Poison Control Centers Toxic Exposure Surveillance System. *Am J Emerg Med* 1993;11:494-555.

cases had an unknown outcome, but they were assessed by the specialist in poison information to be nontoxic exposures. Approximately 20% of the patients from each category were in the unknown potentially toxic group--these represented cases where no symptoms were initially apparent, but follow-up was not completed and the specialist in poison information categorized the case as potentially toxic.

Minor or moderate effects developed in 36.55% (minor 33.03%, moderate 3.52%) of the *all exposure* group and in 31.53% (minor 29.07%, moderate 2.46%) of the *no concomitant* group (Table 4). Minor or moderate effects occurred in approximately 20% of the exposures involving children less than 6 years of age (*all exposures*-minor 19.98%, moderate 1.01%, total = 20.99% vs *no concomitants* minor 19.89%, moderate 1.00%, total = 20.89%) (Table 5).

Major effects occurred in only 0.09% of *all exposures* (16 patients) (Table 5). Adults accounted for 15 cases and there was one pediatric case in a six year old (Table 6). 56.25% (9/16) of the exposures with a major outcome were intentional and not accidental exposures (Table 7).

When household ammonia cleaners were mixed with hypochlorite, only 3.42% (vs 21.25% of *all exposures*) of the cases experienced no effects, 50.68% (vs 33.03% of all exposures) developed minor symptoms and 8.50% (vs 1.01% of all exposures) experienced moderate effects (Table 8).

Symptoms

The incidence of symptoms experienced by children less than six years of age who were categorized as having a moderate outcome are profiled in Table 9. The presence of one of these symptoms does not automatically categorize the patient as having a moderate outcome. The moderate outcome is assigned by the specialist in poison information if the seriousness of the symptom(s) or the development of a constellation of symptoms warrants the assignment of that category.

DISCUSSION

Pediatric exposures to ammonia-containing all purpose household cleaners occur, but far less frequently than exposures to other household cleaning products.[7] However, the number of exposures does not dictate the degree of concern about the product. Morbidity and mortality, or as stated in 16 CFR § 1700.3 the incidence of *"...serious personal injury or serious illness..."* should drive decisions about the necessity of using child-resistant safety closures on a product to protect a child. The operative word is *serious*. Do the AAPCC TESS data reveal that ammonia-containing all purpose household cleaners constitute a serious hazard to children and are there serious sequelae?

[7] Litovitz TL, Felberg L, Soloway RA, et al. 1994 Annual Report of the American Association of Poison Control Centers Toxic Exposure Surveillance System. *Am J Emerg Med* 1995;13:551-597.

In AAPCC TESS symptomatic patient outcomes are categorized as minor effect, moderate effect, major effect and death. Among the 17,569 exposures to ammonia-containing all purpose household cleaners reported over the period of 1991-1994, there were no fatalities, either unintentional or intentional. Furthermore, there were only 16 major outcomes (life-threatening, residual disability or disfigurement) reported. Adults accounted for 15 of the major outcomes and 9 of the 15 were intentional exposures (generally suicide gestures). There was one pediatric exposure (6 year old male) resulting from the ingestion of an unknown ammonia-containing all purpose household cleaner of unknown strength. Since the actual case records were not reviewed, the specific circumstances surrounding this exposure are unknown. The case is documented as an accidental exposure and may have occurred when the product was poured into an alternative container such as a measuring cup or coffee cup. Furthermore, child-resistant packaging probably would not protect a six year old male child since the standard for child-resistance is established in younger children who have undeveloped motor skills and reduced strength. The child-resistance protocol itself (16 CFR § 1700.20) specifies the use of children between the ages of 42 and 51 months. Fatalities and major effects constitute serious events and based upon the AAPCC TESS data, only one pediatric case would meet that definition and that case can be dismissed due to the age of the child. As illustrated in Figure 3, this child falls outside of the most poison-prone age groups that child-resistant packaging is designed to protect.

Moderate outcomes do not represent life-threatening or disfiguring problems and are not associated with any permanent sequelae They reflect a symptom or constellation of symptoms where the patient exhibits more prolonged, pronounced or systemic manifestations. The incidence of moderate outcomes in children less than 6 years of age was only 1%. It would be inappropriate to categorize moderate outcomes as being reflective of *"...serious personal injury or serious illness..."*.

Labeling an outcome as moderate is a judgment made by the specialist in poison information via the telephone. This category could be assigned without hospitalization or confirmation of the symptoms by a healthcare professional. The actual incidence of moderate exposures may actually be lower than reported due to limitations inherent to the collection of poison exposure data. The cases which were categorized as moderate were not available for review. Therefore, it cannot be determined if symptoms such as oral burns were confirmed by a physician or if they were merely the impression of a nonmedical caller to a poison information center. For example, it is not unusual for a caller to state "my child's skin was burned" when minor irritation, expressed as erythema, was present. Five patients were classified as having esophageal injury--without reviewing the specific cases it is not possible to make an informed decision regarding the significance of this finding. The only way to confirm this finding is to review the endoscopy data from the actual cases. If endoscopy is performed and minor inflammation is observed, the only way to document the finding on the AAPCC TESS form is to indicate that esophageal injury occurred--the degree of the injury is not reflected and should not be misinterpreted to indicate serious injury unless the actual case is reviewed. Similarly, oral burns were reported in 20 pediatric patients. This may have been confirmed in an emergency department or could have been the impression of a parent. The assignment of that symptom does not mean that the integrity of the skin on the lips or the mucosa of the oral pharynx were compromised.

The number of moderate outcomes is very small. Moderate outcomes do not constitute *"...serious personal injury or serious illness..."*. However, if it is the opinion of the Commission that this very limited number of moderate events is significant, the only way to make an informed decision regarding the impact of the moderate outcomes on the safety of children is to examine each and every case. As described above, limitations inherent to the documentation and interpretation of poison center data mandate careful review of each case.

Ninety percent (90%) of the exposures to ammonia-containing all purpose household cleaners by children less than 6 years of age were treated in the home--hospitalization was unnecessary. In approximately 10% of the cases the child was treated in a healthcare facility. The decision for healthcare facility referral may have been self-motivated by an individual without poison information center consultation or could have been secondary to referral by the the poison center. That is an important distinction to make and that data field was not present in the version of the AAPCC TESS data that was analyzed. Over 82% of the children that were treated in a healthcare facility were treated and released without admission to a hospital. Therefore, in excess of 98% of all pediatric cases were resolved without admission for actual medical care or precautionary observation.

Some poison information centers use customized protocols to treat the most common poisoning exposures as well as those associated with significant morbidity and mortality. However, the standard among poison information centers is to utilize the computerized database Poisindex® to direct the management of poisoning exposure victims. While Poisindex® is a commercial product information and toxicology treatment database, it is written and peer-reviewed by practicing clinical toxicologists and represents science-based evidence and consensus opinion. Poisindex® clearly states that *"household ammonia (5-10% ammonia) rarely causes burns..."* and that only *"...deliberate suicidal ingestion has resulted in esophageal burns"*. Three cases involving the ingestion of household ammonia for suicidal purposes are cited as the only evidence of significant toxicity from the ingestion of household ammonia.[8] All other reference to ammonia-related toxicity occurred as a consequence of industrial and agricultural exposures to concentrated forms of ammonia. Poisindex® clearly supports the position that household ammonia exposures are not associated with serious injury. This is further evidence that the use of child-resistant closures on ammonia-containing all purpose household cleaners is unjustified and is consistent with the AAPCC TESS data which reveals that no major (*serious*) effects occurred in 8,763 children less than six years of age who were exposed to these products.

As a standard of care among poison information centers, the ingestion of a small amount of an ammonia-containing all purpose household cleaner would be treated with simple dilution ("a glass of milk for the child and a tincture of reassurance for the parent"). In nearly approximately 20% of the cases, the poison information center did not place follow-up calls to determine the ultimate outcome of the patient. This is the standard for cases that are deemed nontoxic. In my personal experience of 21 years as a clinical toxicologist and Director of an AAPCC Certified Regional Poison Information Center, I am unaware of any

[8] Klein J, Olson KR, McKinney HE. Caustic Injury from Household Ammonia. *Am J Emerg Med* 1985;3:320.

pediatric accidental exposures to ammonia-containing all purpose household cleaners that have resulted in serious outcomes.

CONCLUSIONS

Based upon my experience as a clinical toxicologist and the Director of an AAPCC Certified Regional Poison Information Center and the data from AAPCC TESS, accidental exposures to ammonia-containing all purpose household cleaners are not associated with *"...serious personal injury or serious illness..."*. Therefore, there is no persuasive evidence that justifies the use of child-resistant closures on ammonia-containing all purpose cleaners.

AMMONIA-CONTAINING ALL PURPOSE HOUSEHOLD CLEANERS
ALL EXPOSURES vs EXPOSURES WITHOUT COMCOMITANTS
ACUTE EXPOSURES

	ALL EXPOSURES	NO CONCOMITANTS
ACUTE	17398	13673
TOTAL	17569	13760
% ACUTE	99.03%	99.37%

TABLE 1

EXPOSURES TO CHILDREN <6 YEARS OF AGE CALCULATED AS A PERCENTAGE OF TOTAL EXPOSURES

Data Recovered from AAPCC Annual Reports: 1991 - 1994

TABLE 2

Substance	Total No. of Exposures	Exposures to Children <6	Calculated % Exposures to Children <6
LndryPrewash (Other/unknown surf.)	1446	1375	95%
Auto. dish (rinse agents)	2890	2669	92%
LndryPrewash (Dry surfactant based)	2389	2167	91%
Auto dish. detergents (granules)	20290	17951	88%
Fabric...(Solid/sheet)	1607	1392	87%
LndryPrewash (Dry solvent-base)	59	51	86%
Laundry detergent(Granules)	35627	30708	86%
LndryPrewash (liquid surfactant based)	7423	6354	86%
LndryPrewash (Spray surfactant based)	1143	955	84%
Starch/fabric	4653	3848	83%
Auto. dish (liquids)	8027	6624	83%
Auto. dish (other/unknown)	3899	3198	82%
Glass cleaners (Other/unknown)	21045	17201	82%
Glass cleaners (Isopropanol)	10167	8238	81%
Glass cleaners (Ammonia)	11252	8842	79%
Cleansers (anionic/nonionic)	34267	26921	79%
Toilet Bowl Clnr.(Other/unknown)	8806	6913	79%
Fabric...(Liquids)	3794	2974	78%
Carpet/upholstery cleaners	12827	10022	78%
Laundry additives (Bluing/brighten)	261	202	77%
LndryPrewashLiq (Spray solvent-base)	2418	1858	77%
Spot..DryClean Isopropanol	194	146	75%
Laundry detergent(Liquids)	14089	10590	75%
LndryPrewash (Liquid solvent-base)	945	710	75%
Disinfectants (Pine oil)	44,344	33051	75%
Laundry additives (Other/unknown)	850	628	74%
Misc. Cleaner (Ethanol)	1425	1045	73%
Misc. Cleaner (Isopropanol)	4408	3201	73%

Substance	Total No. of Exposures	Exposures to Children <6	Calculated % Exposures to Children <6
Misc. Cleaner (Methanol)	191	137	72%
Wall floor/tile (Glycols)	2842	2036	72%
Wall floor/tile (Anionic/nonionic)	2462	1744	71%
Wall floor/tile (Cationic)	4032	2852	71%
Misc. Cleaner (Anionic/nonionic)	31559	22258	71%
Laundry detergent (Other/unknown)	886	623	70%
Spot Removers (Anionic/nonionic)	1179	828	70%
Wall floor/tile (Isopropanol)	238	166	70%
Laundry detergent (Soap)	556	384	69%
Disinfectants (Phenol)	15651	10728	69%
Hand dishwashing (Anionic/nonionic)	35381	24214	68%
Misc. Cleaner (Glycols)	4697	3211	68%
Fabric...(Other/unknown)	106	72	68%
Glass cleaners (Anionic/nonionic)	130	88	68%
Fabric..(Dry powder)	9	6	67%
t..Dry Clean (Glycol)	385	255	66%
..dryPrewashLiq (Other solvent-base)	830	545	66%
Toilet Bowl Clnr. (Alkali)	1509	972	64%
Hand dishwashing (Other/unknown)	6722	4206	63%
Spot..DryClean (Other nonhalo.hydro)	718	445	62%
LndryPrewash (Other/unknown)	184	114	62%
Cleansers (Other/unknown)	8710	5383	62%
Laundry additives (Enzyme additive)	164	100	61%
Misc. Cleaner (Other/unknown)	12552	7599	61%
Misc. Cleaner (Cationic)	13435	7838	58%
Laundry additives (Detergent booster)	169	98	58%
Bleaches (Borate)	2753	1589	58%
Wall floor/tile (Alkali)	28097	16160	58%
Bleaches (Nonhypochlorite)	4350	2469	57%
Wall floor/tile (Other/unknown)	2118	1159	55%
Bleaches (Other/unknown)	1469	798	54%
Misc. Cleaner (Alkali)	27696	14690	53%
Disinfectants (Other/unknown)	7713	4081	53%
Fab.soft./antistatic (Aerosol/spray)	217	110	51%
Spot..Dry Clean (Other/unknown)	560	283	51%
Ammonia all-purpose cleaners	17576	8801	50%
ist Remover (Anionic/nonionic)	6	3	50%
Rust Remover (Acid other)	1014	501	49%

Substance	Total No. of Exposures	Exposures to Children <6	Calculated % Exposures to Children <6
Spot..Dry CleanPerchloroethylene	333	160	48%
Wall floor/tile (Acid)	12959	6157	48%
Bleaches (Hypochlorite)	167,343	76,162	46%
Toilet Bowl Clnr. (Acid)	13307	5366	40%
Misc. Cleaner (Acid)	2984	1199	40%
Disinfectants (Hypochlorite)	18183	7283	40%
Laundry additives (Water softener)	235	94	40%
Spot/Dry Clean (Other halo.hydrocarb)	648	256	40%
Misc. Cleaner (Phenol)	55	20	36%
Rust Remover (Alkali)	214	77	36%
Oven Cleaner (Detergent type)	35	10	29%
Oven Cleaner (Alkali)	13057	3589	27%
Oven Cleaner (Other/unknown)	1427	366	26%
Wall floor/tile (Methanol)	13	3	23%
Drain cleaners (Other/unknown)	1233	283	23%
Drain cleaners (Alkali)	11320	2422	21%
Rust Remover (Other/unknown)	1165	224	19%
Wall floor/tile (Ethanol)	23	4	17%
Oven Cleaner (Acid)	39	5	13%
Drain cleaners (Acid)	3660	433	12%
Rust Remover (Hydrofluoric acid)	6178	594	10%
Spot Removers (Carbon Tet.)	2	0	0%
Category Total	753,824	462,087	61%

HOUSEHOLD AMMONIA EXPOSURES
% OF UNINTENTIONAL EXPOSURES IN CHILDREN < 6 YR

	ALL EXPOSURES	NO CONCOMITANTS
UNINTENTIONAL EXPOSURES	8718	8361
ALL EXPOSURES	8763	8382
% UNINTENTIONAL	99.49%	99.75%

TABLE 3

HOUSEHOLD AMMONIA EXPOSURES
PATIENT OUTCOME

OUTCOME	ALL EXPOSURES	NO CONCOMITANTS
NO EFFECT	21.25%	25.09%
MINOR	33.03%	29.07%
MODERATE	3.52%	2.46%
MAJOR	0.09%	0.04%
DEATH	0.00%	0.00%
DEATH UNRELATED	0.00%	0.00%
UNKNOWN NONTOXIC	19.10%	21.64%
UNKNOWN POT. TOXIC	20.70%	19.53%
UNRELATED	2.31%	2.17%

TABLE 4

HOUSEHOLD AMMONIA EXPOSURES
PATIENT OUTCOME CHILDREN < 6 YR

OUTCOME	ALL EXPOSURES	NO CONCOMITANTS
NO EFFECT	35.35%	35.02%
MINOR	19.98%	19.89%
MODERATE	1.01%	1.00%
MAJOR	0.00%	0.00%
DEATH	0.00%	0.00%
DEATH UNRELATED	0.00%	0.00%
UNKNOWN NONTOXIC	26.38%	38.34%
UNKNOWN POT. TOXIC	16.17%	4.64%
UNRELATED	1.09%	1.11%

TABLE 5

HOUSEHOLD AMMONIA EXPOSURES
PROFILE OF MAJOR OUTCOMES

ALL EXPOSURES	NO CONCOMITANTS
15 ADULTS	5 ADULTS
1 CHILD	1 CHILD

TABLE 6

HOUSEHOLD AMMONIA EXPOSURES

MEDICAL OUTCOME BY REASON

	ALL EXPOSURES	NO CONCOMITANTS
UNINTENTIONAL		
MODERATE	89.18% (552/619)	89.64% (303/338)
MAJOR	37.50% (6/16)	40.00% (2/5)
INTENTIONAL		
MODERATE	9.59% (59/619)	9.76% (33/338)
MAJOR	56.25% (9/16)	60.00% (3/5)

TABLE 7

HOUSEHOLD AMMONIA EXPOSURES
OUTCOME--MIXTURE WITH HYPOCHLORITE PRODUCTS

OUTCOME	MIXTURE WITH HYPOCHLORITE
NO EFFECT	3.42%
MINOR	50.68%
MODERATE	8.50%
MAJOR	0.12%
DEATH	0.00%
DEATH UNRELATED	0.00%
UNKNOWN NONTOXIC	9.51%
UNKNOWN POT. TOXIC	25.83%
UNRELATED	1.93%

TABLE 8

TABLE 9

HOUSEHOLD AMMONIA EXPOSURES*

Incidence of Symptoms, Moderate Exposures, Children < 6 Years

SYMPTOM	ALL EXPOSURES	NO CONCOMITANTS
Dermal		
Burns Superficial	5	5
Burns 2^{O} & 3^{O}	4	4
Edema	2	2
Erythema/Flushed	2	2
Hives/Welts	1	1
Irritation/Pain	7	7
Rash	1	1
Gastrointestinal		
Abdominal Pain	1	1
Diarrhea	2	2
Dysphagia	8	8
Esophageal Injury	5	5
Hematemesis	2	2
Nausea	4	3
Oral Burns (includes lips)	20	20
Oral Irritation	16	15
Throat Irritation	8	7
Vomiting	18	18
Neurologic		
Agitation/Irritable	1	1
Coma	1	0
Ocular		
Burns	6	6
Corneal Abrasion	6	5
Irritation/Pain	16	15
Lacrimation	2	2
Respiratory		
Bronchospasm	2	2
Cough/Choke	8	7
Cyanosis	1	1
Dyspnea	3	2
Miscellaneous		
Diaphoresis	1	1
Bleeding (other)	1	4
Excess Secretions	4	2
Fever/Hyperthermia	1	1
Other	2	2

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Some patients had multiple symptoms. Therefore, these data do not reflect the number of patients, only the number of times that a symptom occurred.

ACUTE HOUSEHOLD AMMONIA ... ALL EXPOSURES vs EXPOSURES WITHOUT CONCOMITANTS

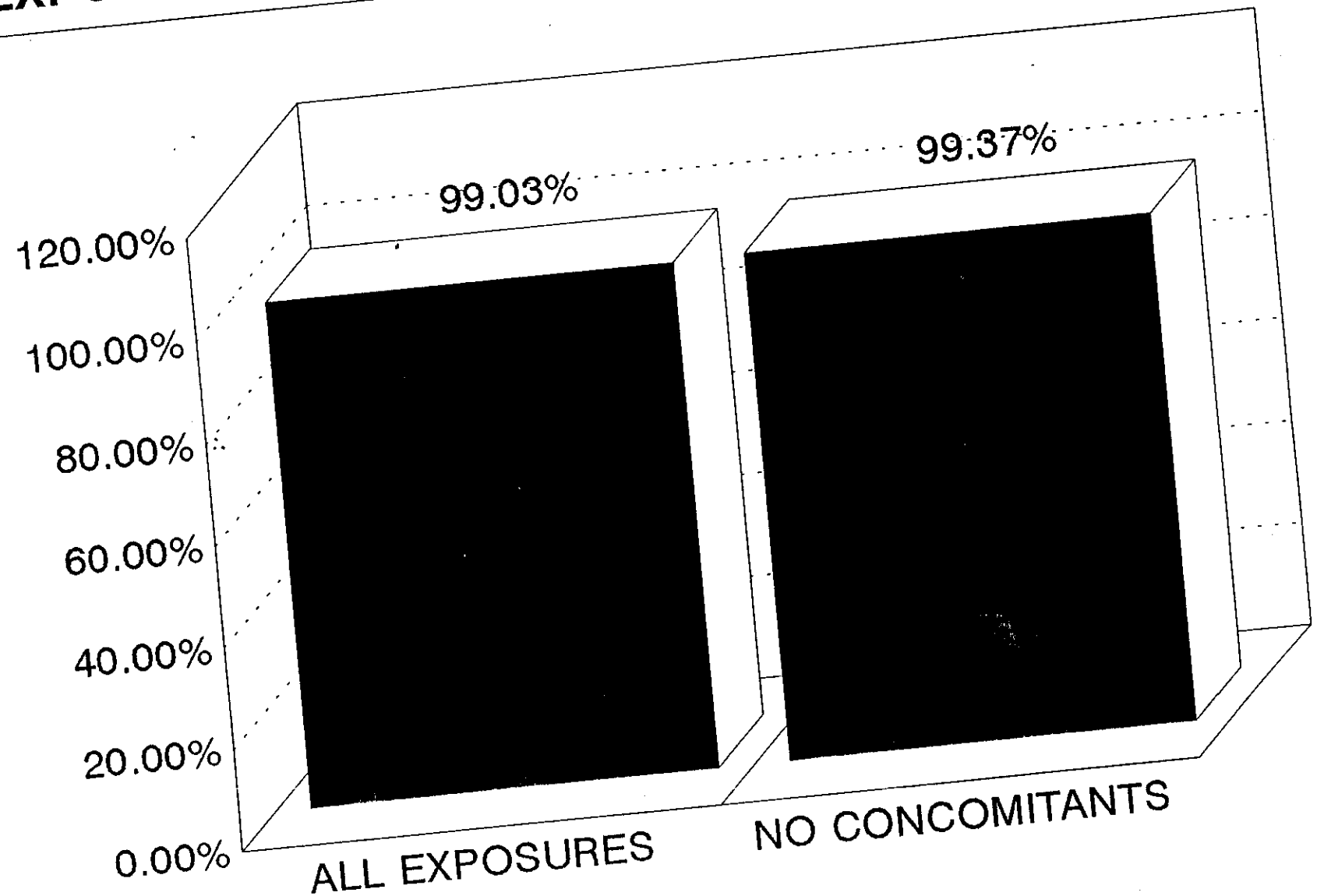


FIGURE 1

HOUSEHOLD AMMONIA EXPOSURES*

LOCATION OF EXPOSURES

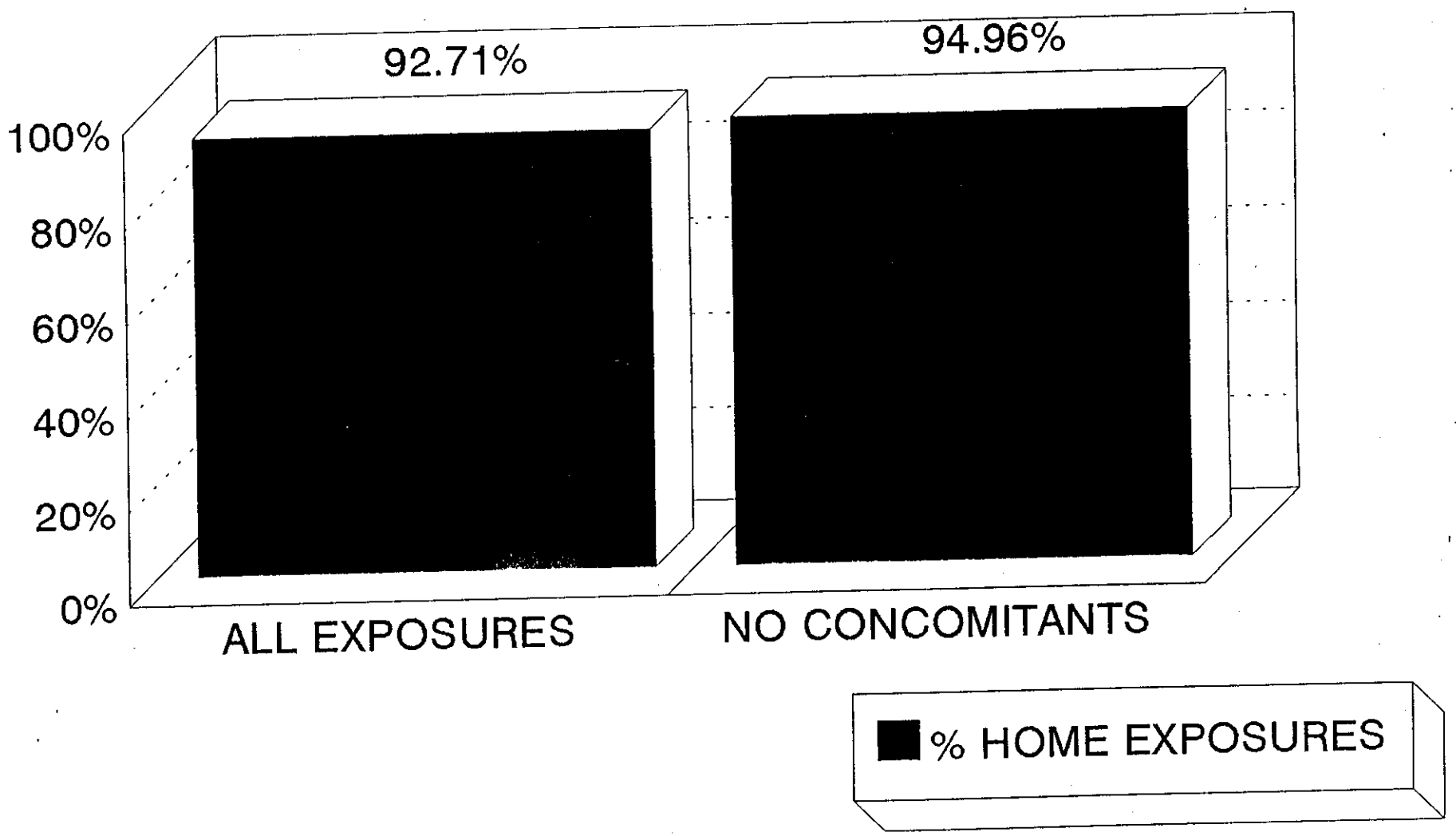
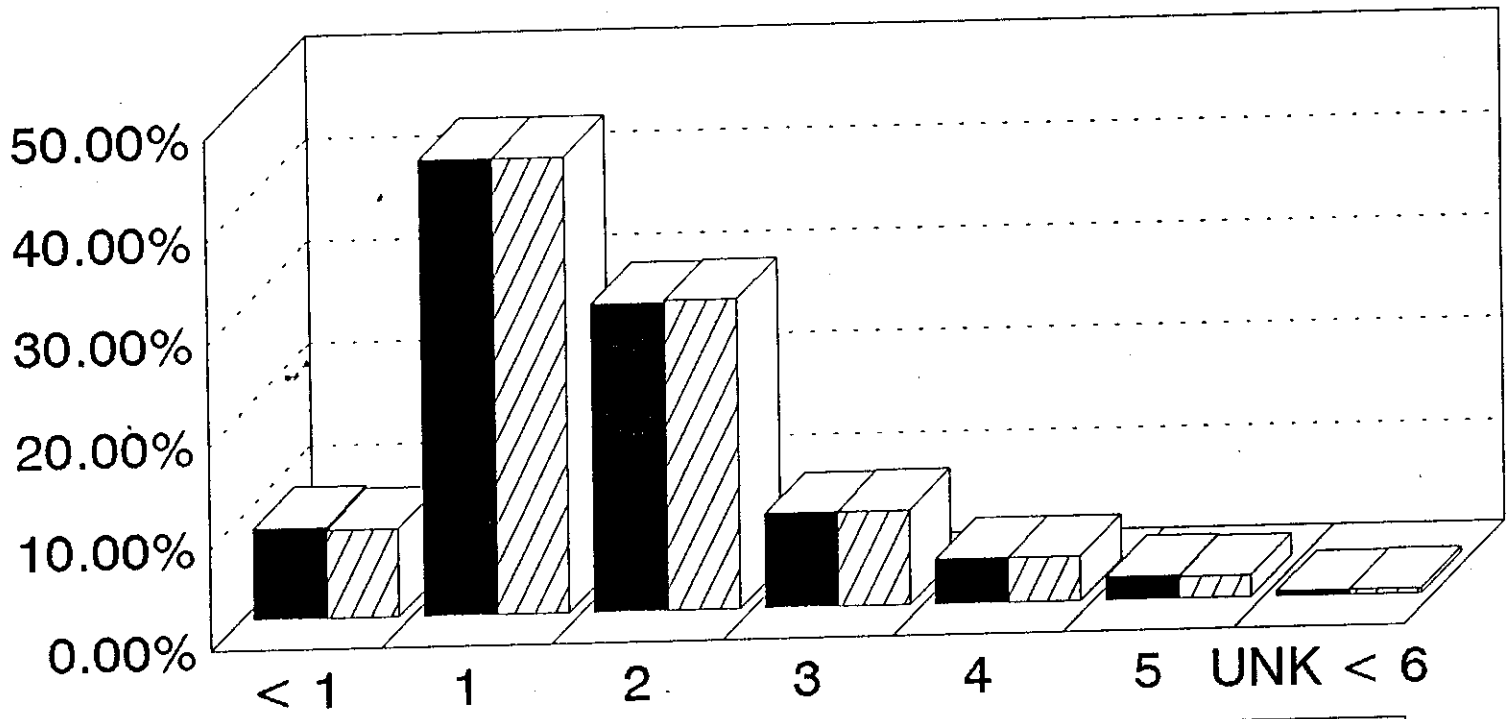


FIGURE 2

*A high percentage is expected since the products are designed for use in the home.

HOUSEHOLD AMMONIA EXPOSURES
FREQUENCY BY AGE (1-5 Yr)



ALL EXPOSURES	8.91%	44.59%	30.15%	9.24%	4.44%	2.24%	0.43%
NO CONCOMITANTS	8.67%	44.63%	30.36%	9.33%	4.37%	2.18%	0.45%

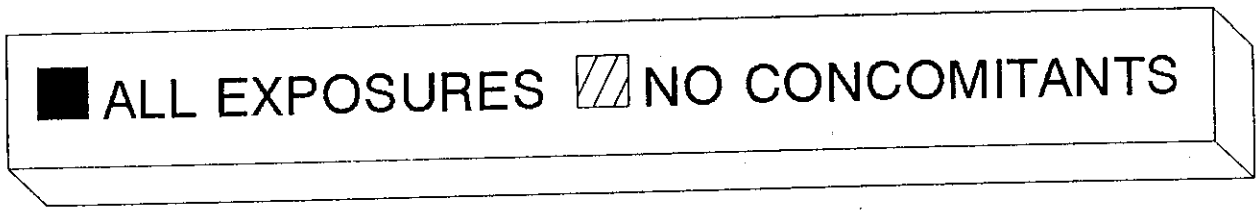


FIGURE 3

HOUSEHOLD AMMONIA EXPOSURES
UNINTENTIONAL EXPOSURES & MISUSE

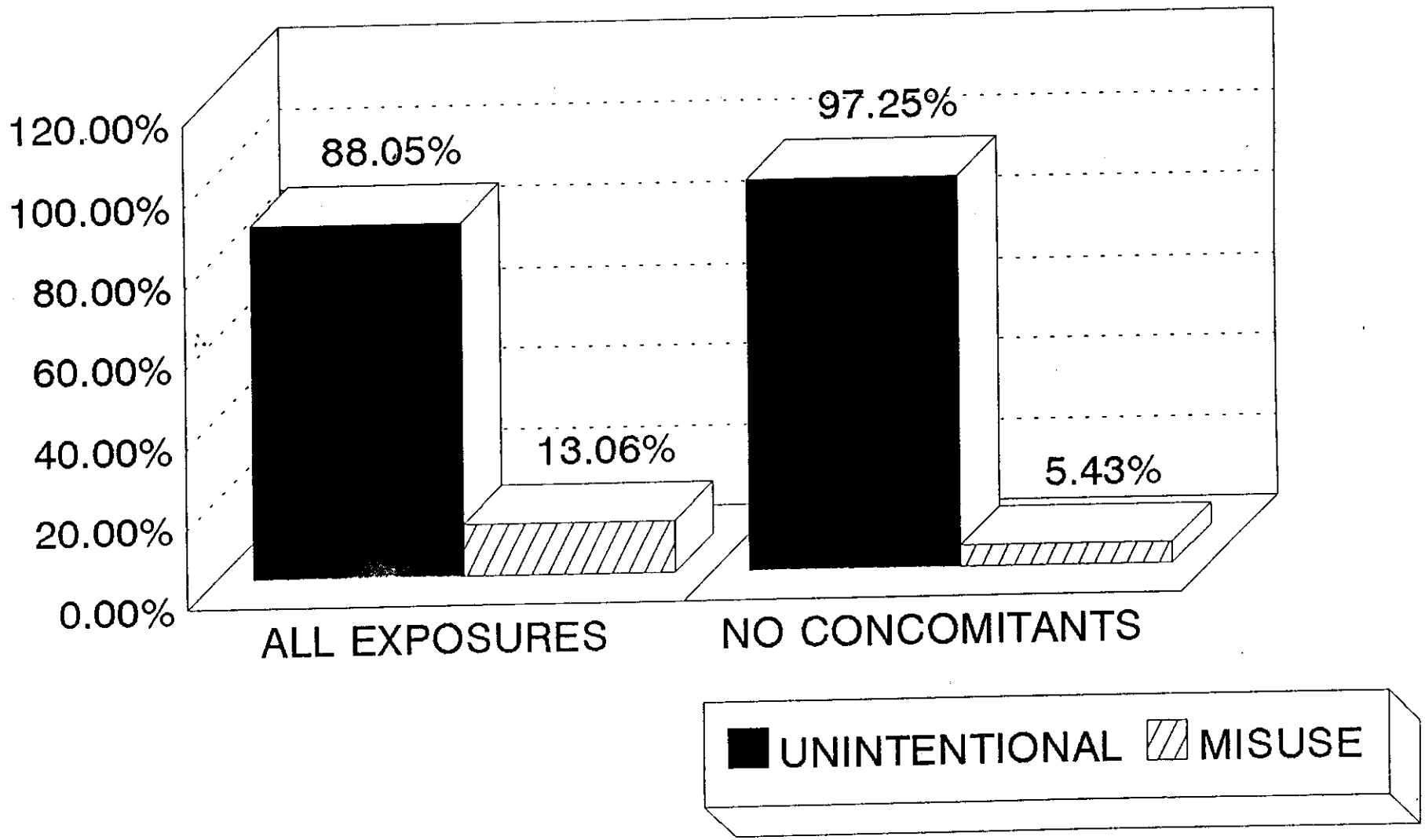


FIGURE 4

HOUSEHOLD AMMONIA EXPOSURE
ROUTE OF EXPOSURE

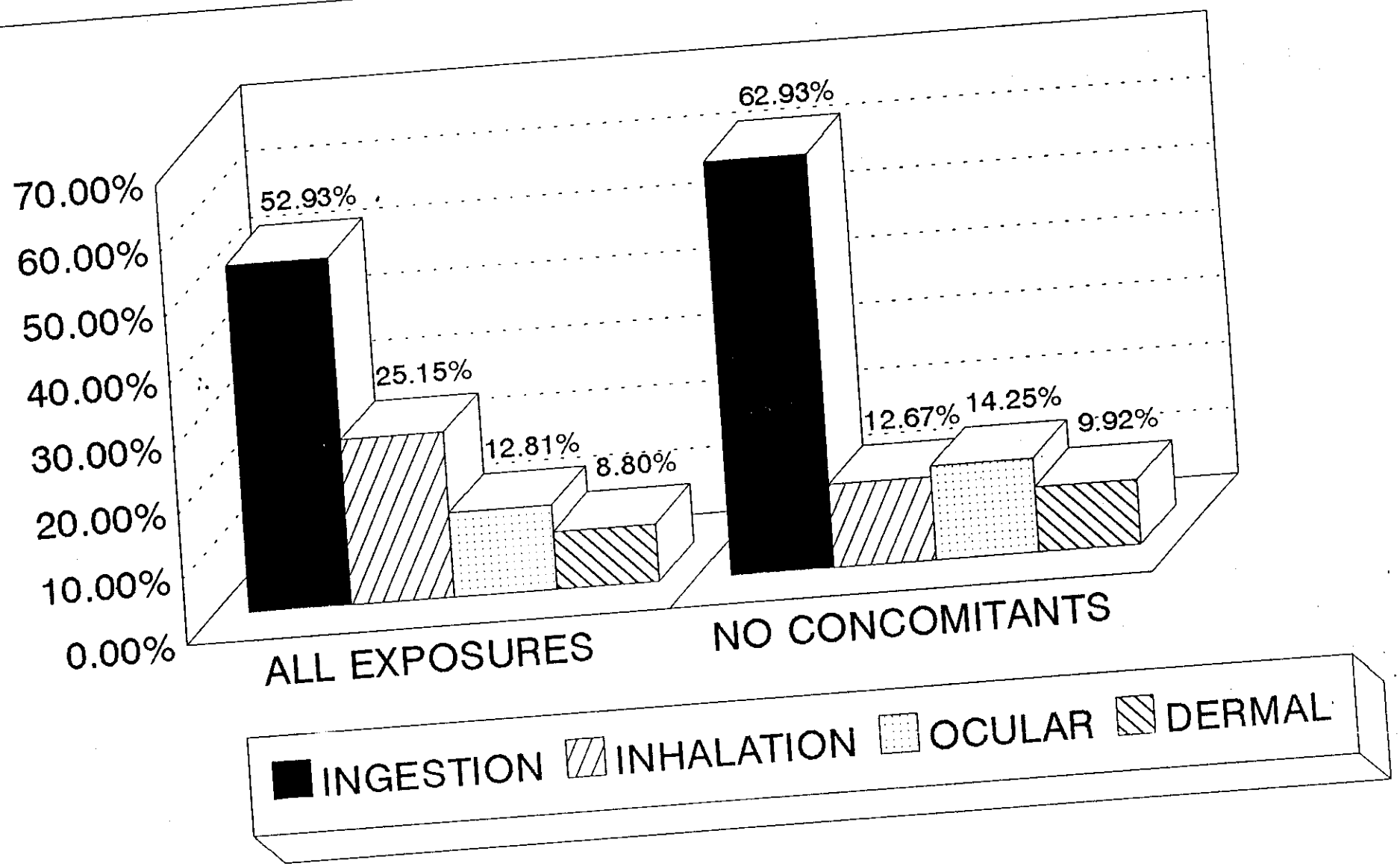
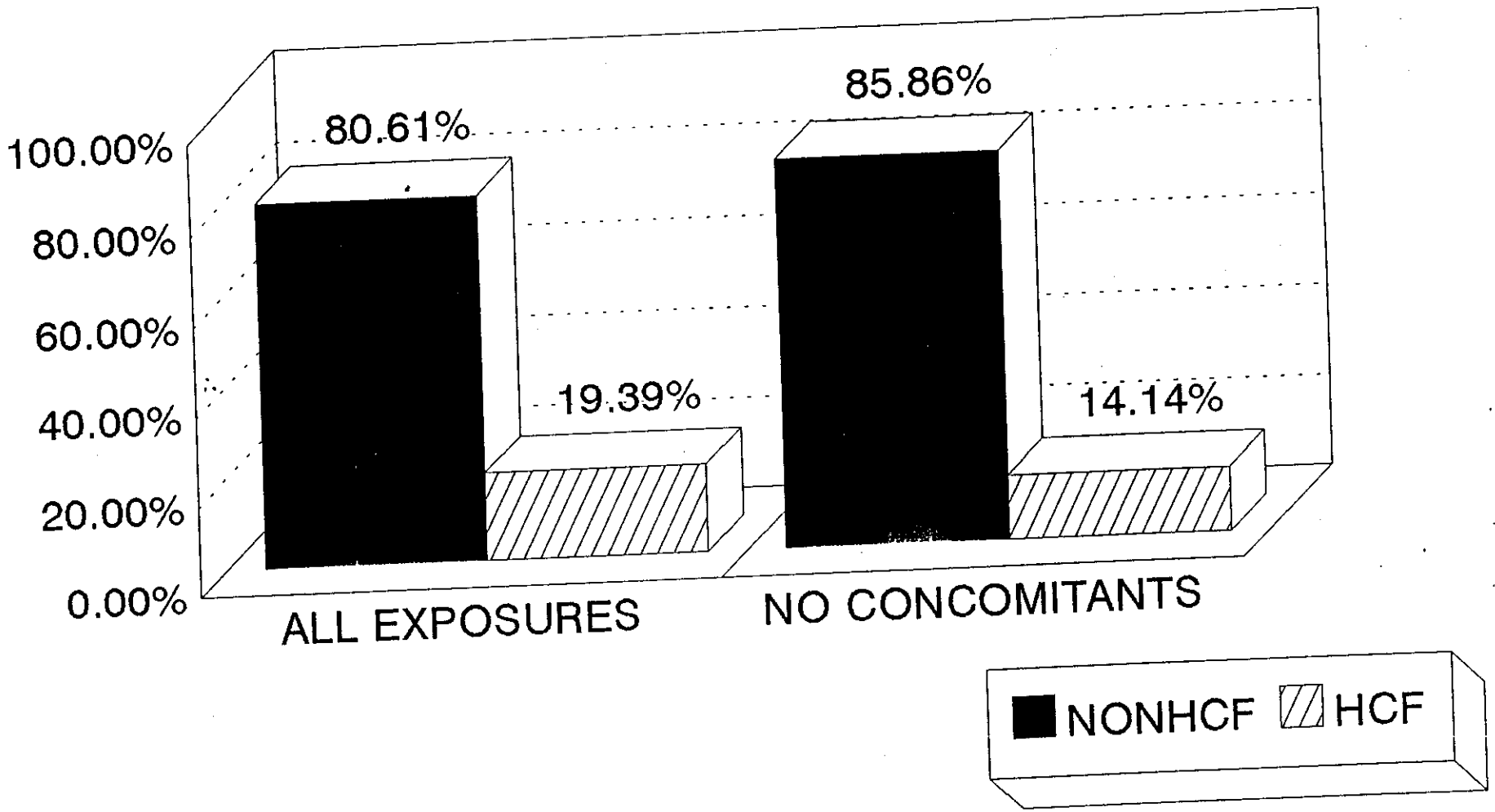


FIGURE 5

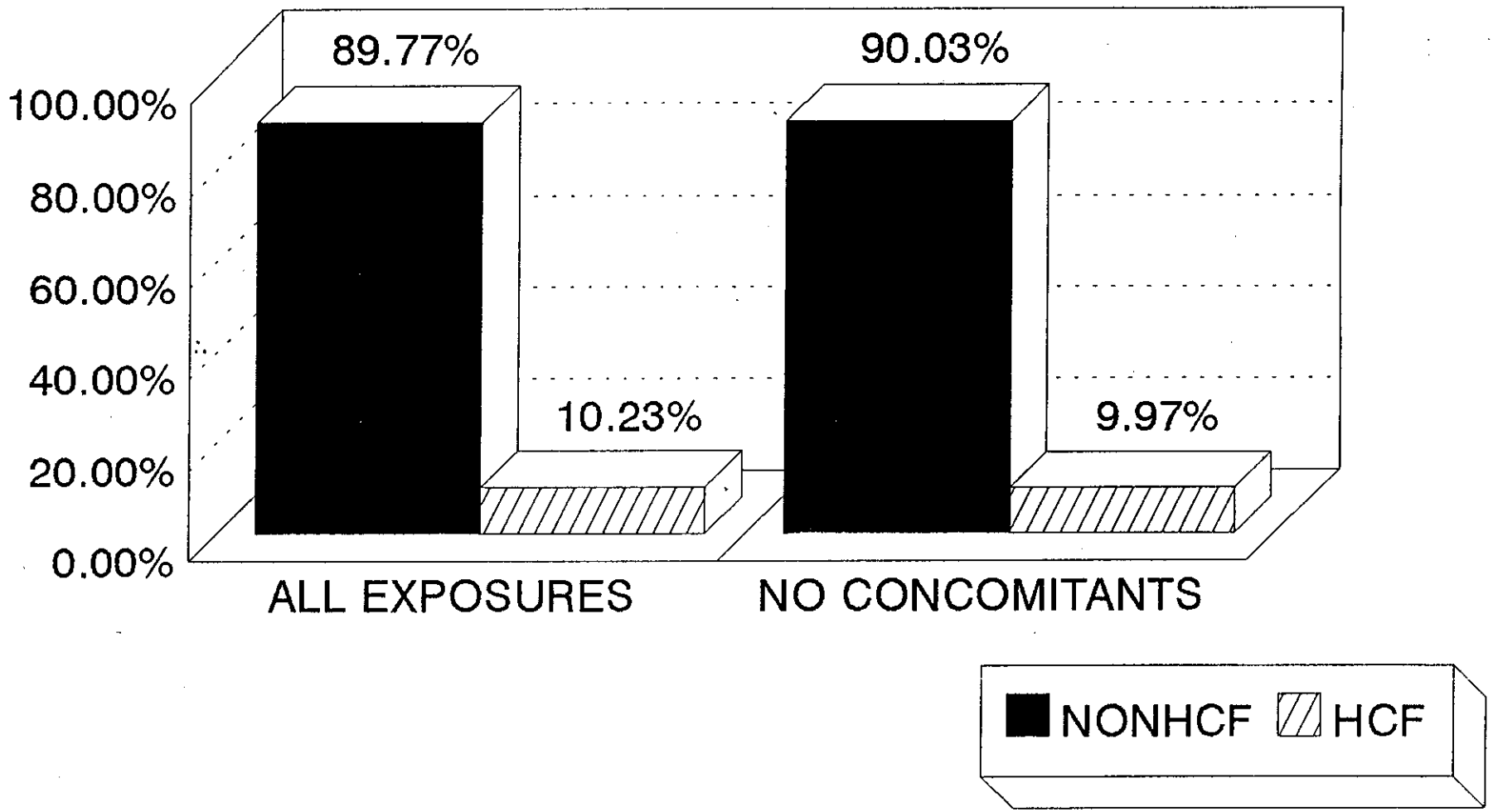
HOUSEHOLD AMMONIA EXPOSURES
MANAGEMENT SITE



HCF = HEALTHCARE FACILITY

FIGURE 6

HOUSEHOLD AMMONIA EXPOSURES
MANAGEMENT SITE IN CHILDREN < 6 YR



HCF = HEALTHCARE FACILITY

FIGURE 7

HOUSEHOLD AMMONIA EXPOSURES
% HOSPITALIZED PATIENTS TREATED AND RELEASED

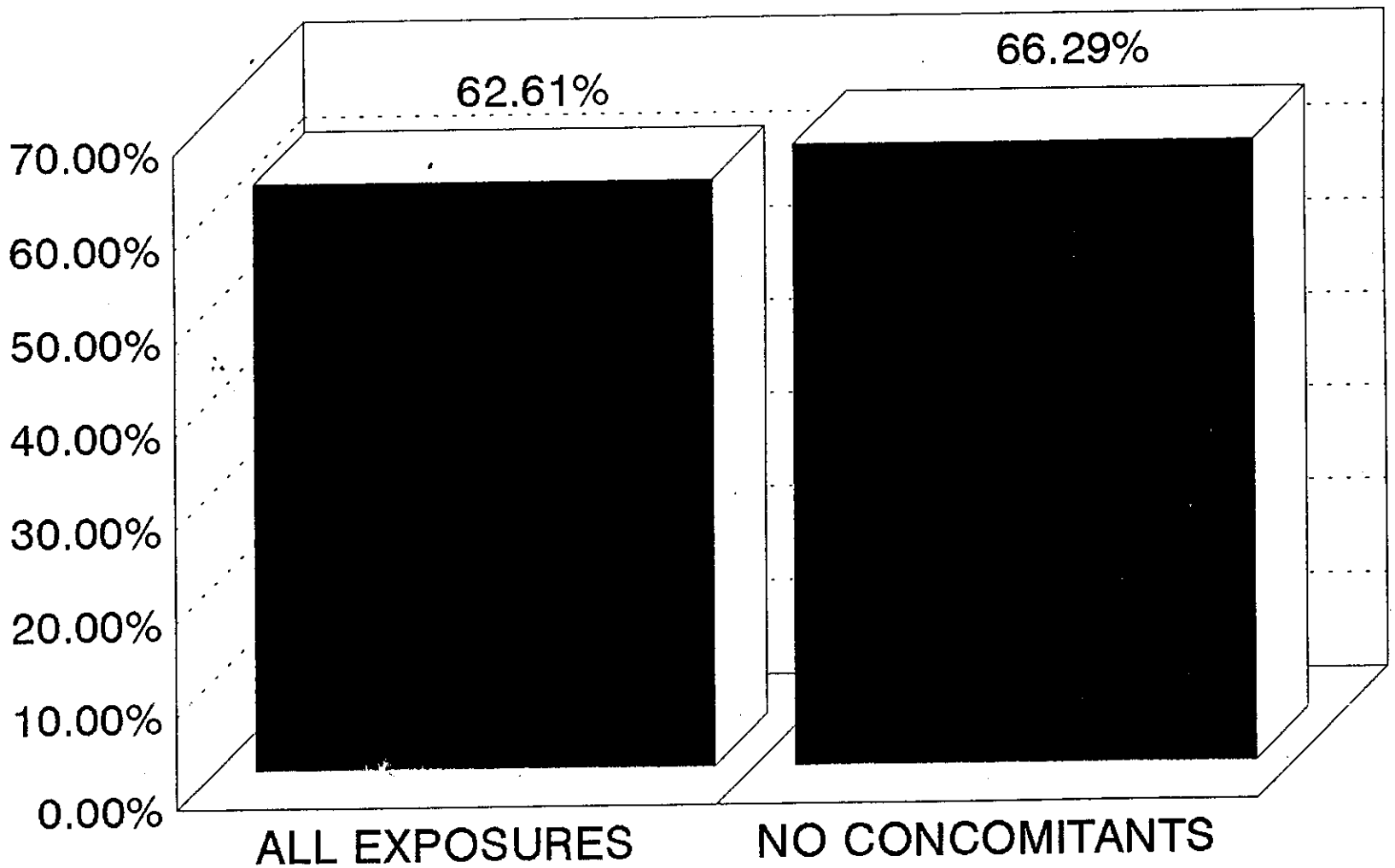


FIGURE 8

HOUSEHOLD AMMONIA EXPOSURES
% OF CHILDREN < 6 YR--TREATED AND RELEASED

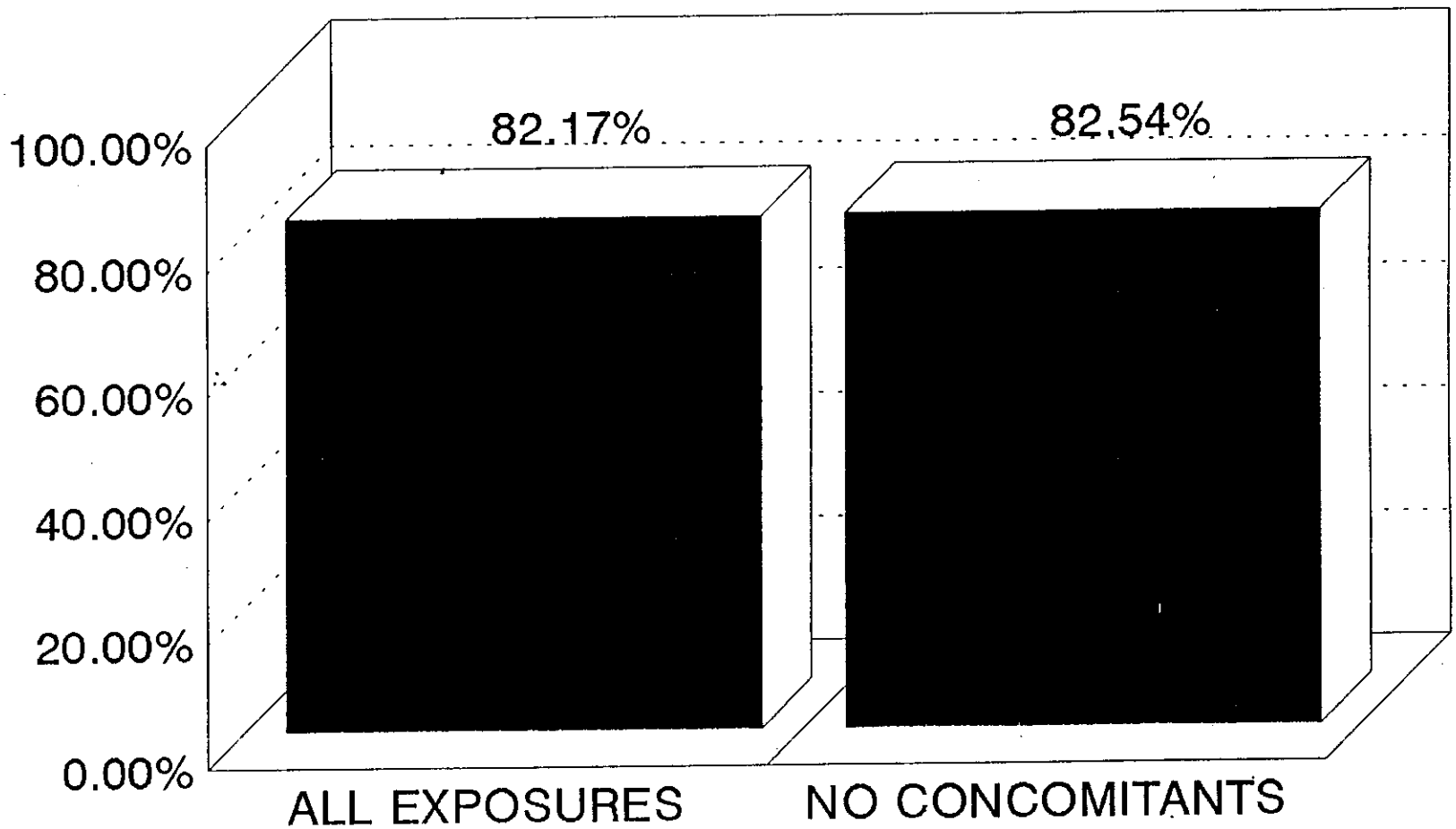


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FIGURE 9

HOUSEHOLD AMMONIA EXPOSURES
TREATMENT TRENDS

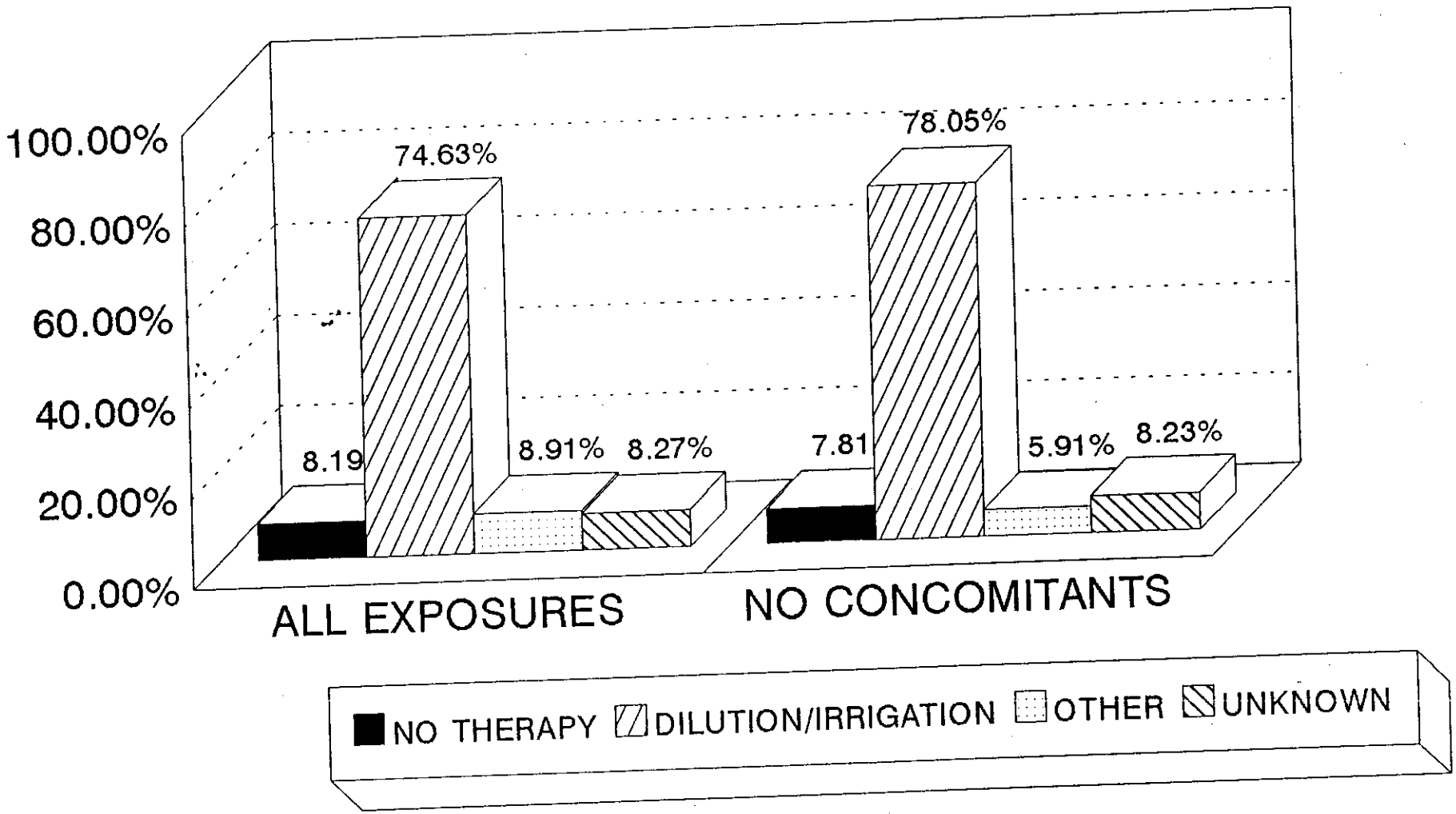

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FIGURE 10