

UNITED STATES GOVERNMENT
Memorandum

U.S. CONSUMER PRODUCT
SAFETY COMMISSION
WASHINGTON, D.C. 20267

To: Bert G. Simson

Through: Andrew G. Ulsamer, HS

Through: Rita A. Orzel, HSHE

Through: Lakshmi C. Mishra, HSHE

From: Murray S. Cohn, HSHE MSC

Subject: Commissioner Statler's request for carcinogen hazard comparisons

APR 19 1985

As requested by Commissioner Statler, attached is a table ranking consumer products containing carcinogens of present or previous concern to CPSC. Rankings of four factors are provided for each product:

1. Potency - defined as the milligrams (mg) per kilogram (kg) body weight per day for life, of a carcinogen, leading to an estimated 10% chance of developing cancer. The methodology for calculating potency and the uncertainties inherent in this methodology are described in the paper on potency previously provided at Commissioner Statler's request (see attachment).
2. Exposure - defined as the estimated total number of mg of carcinogen to which a consumer is exposed from use of a product. *per yr?*
3. Number of Persons Exposed per Year's Sale - defined either as:
 - a) the estimated total number of units sold per year, with the assumption that each unit is used, and that the exposure per use leads to the mg value for exposure in (2), or
 - b) the estimated total number of persons who, in a particular year, are added to that population which is exposed to a carcinogen due to manufacture of a product. Once a person becomes a member of this population, the exposure is assumed to last for a certain period of time, depending on the product, which may exceed a year. The total exposure in mg for the duration of use of the product is the value in (2).

The difference between categories "a" and "b" is illustrated by the following examples. In the case of benzene in paint removers, it is assumed that each unit of product sold will, upon use, result in a particular exposure in mg to the person using the product. In other words, one unit of product sold leads to one person exposed to the number of mg in (2). Thus, method (a) would be applied. In the case of urea-formaldehyde foam insulation (UFFI), the number of persons newly exposed per year is different from the number of units of product (installations) sold per year, since more than one person resides in a home. Also, the exposure is estimated to last over a nine year period, based on data from UFFI homes. Thus, method (b) would be applied, with the total number of mg being that to which a person living in a UFFI home is exposed over the nine year period.

AP00019885

By utilizing the two procedures described, the total number of persons exposed per year's sale, and thus the estimated number of cases of cancer per year's sale of the different types of products (with respect to usage and exposure pattern) can be directly compared. One thus does not have to worry about how many years the products have been sold in the past, or will be sold in the future, to compare their estimated adverse effects on the population.

4. Cases per year - defined as the number of cases of cancer estimated to result due to one year's sale of a product.

For each of the categories, potency information was taken from, or calculated in the same fashion as the values in, the table of potencies previously provided at Commissioner Statler's request (see attachment). The exposure was directly taken from previous CPSC materials, or calculated from preliminary data for methylene chloride; if necessary, conversion from the units of exposure previously used to mg was made for purposes of consistency. The number of persons exposed per year's sale was again either taken directly from previous CPSC materials, or estimated by Economics staff in the case of methylene chloride. Finally, the number of cases of cancer per year's sale was taken from previous CPSC materials as well, or calculated in the case of methylene chloride. Basically, the estimated number of cases per year's sale is directly proportional to the exposure and number of persons exposed as defined in (2) and (3). Factoring in the effect of potency into projecting the number of cancer cases per year also depends upon the shape of the dose-response curve, and other characteristics of the particular chemical as described in the paper on potency (see attachment).

For methylene chloride, the preliminary estimates will change as more data become available. For other chemicals, information from previous CPSC materials, which reflects the exposure generally occurring when CPSC initiated its investigation, was used, although use of different techniques and more recent data might change the results if reevaluated today.

It can be seen from the table that, except for benzidine-based dyes, where the exposure is virtually zero, a predominant factor in formulating the final rankings is the estimated number of persons exposed per year's sale. Potency alone has little bearing on the overall magnitude of the adverse effect on the consumer population as a whole, and it must be considered together with the other factors.

These rankings are to be considered as a guide only, and for this reason rankings, rather than numerical values, are displayed in the table. Numerical values upon which these rankings are based are, of course, subject to the uncertainties inherent in the data from which they are derived.

Table of Estimated Potency, Exposure, Number Exposed, and Cases of Cancer/Year
Rankings Due to Use of Products Evaluated by the Consumer Product Safety Commission

Chemical/Product	Potency ¹	Exposure ²	Number Exposed Per Year's Sale ³	Cases/Year ⁴
Benzidine Based Dyes/Home Dying	Medium	Low	High ^a	Low
Asbestos/Hairdryers	High	Low	Medium ^a	Low
DEHP/Pacifiers	Low	Medium	Medium ^b	Medium
Formaldehyde/UFPI	High	High	Low ^b	Medium
Nitrosamines/Pacifiers	High	Low	Medium ^b	Medium
Benzene/Paint Removers	Medium	High	Low ^a	Medium
Vinyl Chloride/Aerosols	Medium	High	Low ^a	Medium
Methylene Chloride/Aerosol Paints	Low	Medium	High ^a	High
Tris/Sleepwear	Medium	Low	High ^a	High
Asbestos/Patching Compounds	High	Low	High ^a	High
Methylene Chloride/Paint Removers	Low	High	High ^a	High
	mg/kg/day	mg/use	number/year	cases/year
High	< 1	> 1000	> 10,000,000	> 100
Medium	1 - 100	100 - 1000	1,000,000 - 10,000,000	10 - 100
Low	> 100	< 100	< 1,000,000	< 10

¹ mg/kg/day to give a risk of 0.1, by the methodologies described, and subject to the uncertainties expressed, in the paper on potency comparisons; the higher the number, the lower the potency.

² mg/use calculated by either estimating the total exposure of a newly exposed person to a product over the product's lifetime, or by the total exposure per use of one unit of product sold.

³ number of newly exposed people per year's sale of a product, or number of units of product sold per year, assuming all units sold per year are used. "a" indicates the basis was number of units sold per year; "b" indicates the basis was number of people exposed per year. See text (section 3) for details.

⁴ all data leading to this final ranking are the result of estimates, and thus these final rankings are subject to uncertainty. The final ranking is a result of consideration of the data from which potency, exposure, and number of persons exposed as ranked in the first three columns is derived.