



DUKE UNIVERSITY SCHOOL OF MEDICINE

**Department of Community & Family Medicine
Division of Occupational & Environmental Medicine
Box 3834, Durham, NC 27710
May 12, 2005**

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I enclose the evaluation of your ink(s) for use in writing instruments listed under Product # BLACKBOARD and the following brand names:

BLACKBOARD MARKER INKS

This evaluation was conducted in conformance with the chronic health hazard labeling practice, ASTM D-4236 as adopted by into law as part of the Federal Hazardous Act administered by the Consumer Product Safety Commission (CPSC). The toxicological procedures I have used for the evaluation of your products have been reviewed by the California Department of Health Services (CDHS) and are on file with CPSC. CDHS has found that the exposure presumptions I use are conservative. My assessment presumes that an individual will absorb 25 cm of line, either through skin contact or ingestion, each day and that 2 cm of line can get into the eye.

If default values for chronic toxicity have been published by the California Office of Health Hazard Assessment (Proposition 65), these are incorporated into my risk assessment. We have completed market surveys to determine writing instrument use patterns. Information from these surveys is used to modify our exposure presumptions. Survey data has been shared with CPSC.

I use the following safety factors or limits in determining whether or not a writing instrument would require acute or chronic hazard labeling:

<u>Effect</u>	<u>Safety Factor</u>
Acute effects from ink absorption	10-100x
Eye irritation (Draize testing or equivalent)	less than mild
Skin irritation (Draize testing)	mild
Chronic health effects	100-1000x

For potential carcinogenic contaminants I use a quantitative risk assessment approach using 10^{-6} risk at the 95% upper bound of a multistage model as being acceptable.

I require bioaccessibility testing of inks or ingredients of concern for potential toxins. Synthetic intestinal or gastric juice is used for solubility testing. If no bioaccessibility test method has been developed, quantitative testing is used (such as for PCBs and hexachlorobenzene).

For markers, I assume that the ink laydown is 600 micrograms/cm, the maximum ink laydown for marking instruments using these types of inks. Using this evaluation, I have found no hazardous component or contaminant level or effect of the products themselves that would require acute or chronic hazard labeling to conform with ASTM D4236.

Further, assuming that the maximum marker reservoir size in which these inks are used is 17ml., I find that the inks are not a toxic or hazardous substance as defined by 16 CFR 1500.3 of the Federal Hazardous Substances Act nor does it contain components that would require special labeling under 16 CFR 1500.14. It requires no labeling under the Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65). My evaluation is in accord with the 1984 CPSC Policy Statement on Animal Testing.

Sincerely,



Woodball Stopford, MD, MSPH
Consulting Toxicologist

CONFIDENTIAL
TRADE SECRET INFORMATION

2200 West Main Street Suite 600A

ACTION: NEW PRODUCT
FACILITATED

MEG# COMPANY NAME	PRODUCT #	PRODUCT CATEGORY	APPROVAL STATUS	APPLICABILITY
	BLACKBOARD	MARKER/INK	1 NO LABELING REQMT	Adults & Children


BRAND NAME	ALTERNATE BRAND NAME (1)	ALTERNATE BRAND NAME (2)
BLACKBOARD MARKER INKS		

PRODUCT SIZES	#COLORS	APPROVAL	SUBMITTED BY	SUB.DATE	WGT	FACTOR	PROD.TYPE
NO.	21	05/12/2005		11/01/2002	17.0	600	6 MARKER

NO LABELING REQUIRED

LABELING CONFORMS TO ASTM D-4236. Writing instruments using these inks do not require hazard labeling under 16CFR1500.3 or 16CFR1500.14 and do not require testing under 16CFR1500.83 of the Federal Hazardous Substances Act Regulations.

TOXICOLOGIST'S ACTION: NO LABELING REQMT


Woodhall Stopford MD, MSPH
Toxicologist

DATE: 05/12/2005