TELEPHONE NATIONAL 8-2588

L-260

Manufacturing Chemists' Association, Inc.

(FOUNDED 1872)
1625 EYE STREET, N. W.
WASHINGTON 6, D. C.

Meeting of
LABELS AND PRECAUTIONARY INFORMATION COMMITTEE
Room Number 546
Sheraton Hotel
Thursday, November 13, 1958
Philadelphia, Pennsylvania

The meeting came to order at 9:30 A.M. on Thursday, November 13, 1958.

MEMBERS PRESENT

Nicholas M. Walker (Chairman), Pennsalt Chemicals Corporation
S. J. Hill, E. I. du Pont de Nemours & Co., Inc.
H. H. McIntyre, The Dow Chemical Company
J. A. Mooney (for Frank Low), Food Machinery and Chemical Corporation
Thomas W. Nale, M.D., Union Carbide Corporation
John F. Osterritter, M.D., Celanese Corporation of America
Richard F. Philpitt, Olin Mathieson Chemical Corporation
F. D. Sparre (for Dr. Foulger), E. I. du Pont de Nemours & Co., Inc.
John B. Tuttle, Esso Standard Oil Company
L. J. Waldbauer, General Aniline & Film Corporation
N. E. Wendt, American Potash & Chemical Corporation
J. B. Williamson, American Cyanamid Company
James D. Kittelton, Manufacturing Chemists' Association, Inc.

MEMBERS ABSENT

Robert H. Dewey, Commercial Solvents Corporation
Chester L. French, Mallinckrodt Chemical Works
J. T. Fuess, Eastman Organic Chemicals Dept., Distillation Products Industries
Edward J. Hogan, Barrett Division, Allied Chemical Corporation
Edward J. Masek, Diamond Alkali Company
R. G. Troup, J. T. Baker Chemical Co.
N. G. White, Shell Chemical Corporation

1.3 ALLIED COMMITTEE ACTIVITIES

1.3.8 AMA

Discussions on Compromise AMA-Industry Precautionary Labeling Bill.

Mr. Walker reviewed for the committee the meeting which had been held in Ohio on November 5, 1958 and which was attended by representatives of AMA and interested trade associations. Mr. Walker said that those in attendance carefully considered the bill and areas of agreement were noted. A compromise bill was then drafted and has been sent to those who attended.

In addition to the bill, there will be a set of notes which will discuss certain points needing elaboration and will also indicate the areas of disagreement. This bill would then be presented to jurisdictions interested in precautionary labeling as a joint AMA-Industry bill. The LAPI Committee then considered this proposed compromise bill. The following discussion is listed under the items of the bill discussed.

Scope of Bill

The first matter considered was the scope of the bill and Mr. Walker pointed out that it was proposed to carry a note which would enable a state to have a choice regarding coverage. Committee members discussed this and deferred consideration of the scope of the bill until other parts were considered.

Section 2(d)

The committee next discussed the definition of the term "hazardous chemical substances" and Mr. Walker said that the word chemical had been added to the term and also that "radioactive" had been deleted from the bill. The LAPI Committee agreed with this action.

Section 2(e)

The committee next considered the definition of "toxic" and agreed with the wording.

Section 2(f)

The committee next considered the definition of the term "corrosive" and also agreed with this wording. In the compromise bill there would be a statement in a note, that inhalation also includes aspiration.

Section 2(g)

The committee next considered the term "irritant" and agreed with this wording which now states that an irritant ----- "will induce a local inflammatory reaction." Mr. Sparre said that Dr. Foulger especially liked that wording.

Section 2(h)

The committee next considered the definition of the term "strong sensitizer" and Drs. Nale and Osterritter agreed that the term needed revision from a technical standpoint. The Chairman appointed the two Doctors to a subcommittee to work out acceptable wording and this subcommittee later recommended the following wording:

> "The term strong sensitizer means a chemical substance which will cause on normal living tissue through an allergic or photodynamic process evidence of hypersensitivity on reapplication of the same chemical substance and which is designated as such by the Commissioner. The Commissioner shall consider the frequency and severity of the sensitization reaction in determining whether a sensitizing material offers a significant potentiality for causing such a reaction."

After discussion of the wording proposed,

It was moved, seconded and voted

THAT, The LAPI Committee recommends that the definition of "strong sensitizer" be that developed by Drs. Nale and Osterritter, as stated above.

Messrs. Tuttle and Williamson voted no on this motion.

Mr. Walker said that he would write Mr. Trichter of New York City a letter concerning this definition.

Section 2(i)

The committee next considered the terms "extremely flammable" and "flammable" and agreed that it would be desirable to join the two definitions with the word "and", and to insert a semicolon after the phrase "Tagliabue Open Cup Tester" in line 6.

After this discussion,

It was moved, seconded and voted

THAT, The LAPI Committee agrees that the definitions for "extremely flammable" and "flammable" should be as follows:

> "The term 'extremely flammable' shall apply to any chemical substance which has a flash point at or below twenty degrees Fahrenheit as determined by the Tagliabue Open Cup Tester; and the term 'flammable' shall apply to any chemical substance which has a flash point of above twenty degrees to and including eighty degrees Fahrenheit, as determined by the Tagliabue Open Cup Tester; except

that the flammability of the contents of self-pressurized containers shall be determined by methods generally applicable to such containers and established by regulations issued by the Commissioner."

Messrs. McIntyre and Tuttle voted no on this motion.

Section 2(1)

The committee next considered the term "label" and were critical of that portion of it which would require precautionary statements on all accompanying literature "which contains any written or printed graphic matter." The committee agreed that if there were accompanying placards containing illustrations or directions for use that they should have a warning label.

After this discussion,

It was moved, seconded and voted

THAT, Items 1 and 2 in the definition of "label" be consolidated so that they would read, "(2) on all accompanying literature where there are directions for use, written or otherwise."

The committee directed that MCA representatives at the next meeting with AMA, take a strong position on this matter.

Section 2(l)

The committee next considered the definition of the term "misbranded package" and agreed that the present wording which now reads "the common or usual name, and the chemical name" should be changed so that it reads, "the common or usual name or chemical name." Committee members believe that any one of the three names would be sufficient to enable a Doctor to treat a patient.

The committee next considered the use of the signal word "DANGER" and

It was moved, seconded and voted

THAT, The term "explosive" be deleted from the list of substances requiring the use of the signal word "DANGER."

The committee's reasons for this action are that the term "explosive" is not covered by the act, and substances of this type are already adequately regulated by the ICC.

The committee next considered the matter of the number of days of testing which would be required for accurate results on test animals. Dr. Nale reported on data which he had obtained

from Dr. H. Smyth, Jr. of Mellon Institute. This indicated that in a single oral dose to rats, 99.7% of the rats who would eventually die, died within seven days. Dr. Nale's report is attached as Appendix A to these Minutes. The committee agreed that in view of these facts, a seven day period for testing would be adequate and suggested that MCA representatives take this position in negotiations with AMA.

The committee at this time also considered the matter of the one gram dosage and concluded that such an amount would be logical for household chemicals, but would not be for industrial chemicals. The reason for this is that a ten kilogram (22 lb.) child might be expected to ingest an amount which this test would indicate.

Dr. Nale also suggested that three milligrams be used for inhalation purposes and a dosage of one gram for skin contact purposes. The Chairman inquired of Dr. Nale as to what would be an acceptable figure if AMA does not agree to the three milligrams for inhalation purposes. Dr. Nale replied that he would not go much above four milligrams.

After this discussion,

It was moved, seconded and voted

THAT, The limits suggested by Dr. Nale for dosages be adopted together with a seven day period of testing.

Scope of Bill

At this point, the committee again discussed the scope of the bill, and concluded that the dosage concentrations to be used in ascertaining the use of the signal word "DANGER" are only acceptable in the case of household products.

It was moved, seconded and voted

THAT, The LAPI Committee's position is that the proposed bill be limited to hazardous chemical substances intended or suitable for household use.

This motion was passed unanimously.

The committee then discussed the use of the other two signal words "WARNING" and "CAUTION" and agreed that these two signal words should be used on all other chemical substances.

After this discussion,

It was moved, seconded and voted

THAT, The LAPI Committee recommends to its representatives that the signal word "WARNING" or "CAUTION" be required on all other hazardous chemical substances covered by the proposed bill.

Definition of Poison

At this point, the committee discussed its position in regard to the use of the word "poison" in the bill and concluded that it was absolutely essential that a bill contain a definition of poison.

After this discussion,

It was moved, seconded and voted

THAT, The MCA definition of poison be placed in the proposed act itself, and not simply in a footnote to the act.

This motion was passed unanimously.

It was agreed that in negotiations with AMA, MCA representatives are authorized to increase the period of testing for poison from 48 hours to seven days.

Section 2(1)(2)

A point was raised about the requirement that statements must be "in English in legible type." It was thought that this might be somewhat misleading and it would be preferable to say, "in the English language in legible type."

Mr. Sparre raised a point about the wording of the Proviso in Section 2(1)(2). This states, "Provided further that the Commissioner may provide for less . . . ." Mr. Sparre suggested that the wording be changed as follows, "Provided further that the Commissioner may permit less." It was the consensus of the committee that this was a desirable change and should be made.

In preparing the conference draft, the Secretary inadvertently left out the fact that the proposed bill would not apply to cosmetics. Therefore, the wording of this Section would read, "the term 'misbranded package' shall not apply to . . . . packages of foods, drugs, and cosmetics subject to the Federal Food, Drug and Cosmetic Act."

3.0 LABELS--SAFETY DATA SHEETS

3.38 Sulfur

The Chairman said that MCA was preparing a Safety Data

Sheet on Sulfur and he asked the opinion of the committee whether a precautionary label was needed for Sulfur. This question was given consideration and it was decided that Sulfur would not require a precautionary label.

4.0 NEW LABELS

4.7 Diethylenetriamine

The Chairman stated that he had also received a draft on Diethylenetriamine and that he believed the label in Manual L-1 for this chemical needed some revision. The Secretary was instructed to ascertain if the draft contained the final medical section. When this is available, Mr. Walker will appoint a subcommittee to draft a new label for the chemical.

MISCELLANEOUS

Letter from Mr. A. Winterle of Florida

The committee discussed a letter which had been received from Mr. Winterle of the State of Florida, a copy of which is attached as Appendix B to these Minutes.

Dr. Nale pointed out that under the MCA definition of poison, there was no justification for the use of the word poison on the label for Paraformaldehyde. Some state pharmacy laws require the word poison on Paraformaldehyde and this is the reason for placing it on the suggested label.

The Secretary was instructed to answer Mr. Winterle's letter, pointing out the reason why the word poison appears on the suggested MCA warning label. The Secretary should also indicate that LAPI is concerned about the use of a shakertop container from the standpoint of danger to children. Directions for use of this product should be very carefully drawn up.

It was also suggested that the Secretary emphasize that MCA is primarily concerned with industrial chemicals and that this problem might be referred to the Chemical Specialties Manufacturers Association. Another suggestion made was that Mr. Winterle contact the U. S. Department of Agriculture and ask their opinion as to what labeling they would require if asked to register the product.

James D. Kittelton
Secretary
Labels and Precautionary
Information Committee

Minutes Subject to Approval
November 28, 1958

JDK/jmb

ATTACHMENTS (2)

November 6, 1958

Chemical samples picked at random from records of Chemical Hygiene Fellowship, Mellon Institute, and compiled by Dr. Henry F. Smyth, Jr.

	Number of Chemicals	Animals	Time Distribution of Deaths: Number of Deaths within 14 Days	Deaths within 48 Hours	Deaths within 7 Days
Single oral dose to rats	105	711	314	86%	99.7%
Single skin penetration to rabbits	90	720	306	64%	94% *
Single inhalation by rats	54	274	136	77%	88.5%

* After seven days the deaths were chiefly secondary bacterial pneumonia.

Thomas W. Nale, M. D.

APPENDIX B

COPY

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STATE OF FLORIDA
DEPARTMENT OF AGRICULTURE
CHEMICAL DIVISION

J. J. Taylor
State Chemist

Post Office Box 408

T A L L A H A S S E E

29 October 1958

Manufacturing Chemists' Association, Inc.
1625 Eye Street, N. W.
Washington 6, D. C.

Gentlemen:

It will be appreciated if you will give us any information that you may have developed regarding paraformaldehyde and the recommended warning statements as shown on page 62 of your 1956 edition of Warning Labels.

The reason behind our request is the distribution of a 100% paraformaldehyde product in a shakertop can for household use and which shows no active ingredient statement or warning statement.

I feel sure that we can obtain proper labeling of this product but we cannot justify the use of a shakertop can for dispensing the 100% product under mattresses, under cushions on overstuffed furniture, etc.

We of course recognize the danger of a formaldehyde solution and the likelihood of someone drinking it by mistake but do you think there is the danger present in the case of paraformaldehyde to warrant the use of the same warning statement and symbols on the granular product as on a liquid solution.

We will certainly be glad to have any help you can give us on the above matter.

Yours truly,

J. J. TAYLOR
State Chemist

E. R. Winterle
Director, Pesticide Lab.

ERW:wg