

Manufacturing Chemists' Association

OF THE UNITED STATES

(FOUNDED 1873)

608 WOODWARD BUILDING

WARREN N. WATSON
SECRETARY

WASHINGTON 5, D. C.

L-162

MINUTES OF MEETING LABELS AND PRECAUTIONARY INFORMATION COMMITTEE Hotel Chalfonte, Atlantic City, N.J. Thursday and Friday, October 30 and 31, 1947

The meeting of the Labels and Precautionary Information Committee was called to order by Chairman W. N. Watson on Thursday, October 30, 1947, at 10:00 A.M. The following were present:

W. N. Watson, Chairman
T. R. Aalto
Carl Anderson
A. Q. Butler
A. G. Cranch
J. H. Foulger
J. T. Fuess
S. J. Hill

A. W. Hopton, alt. for J.S. Coey
W. A. Knapp
Frank S. Low
Robert D. Minter
J. A. Noone
W. W. Sunderland, alt. for D.D. Irish
J. B. Williamson, alt. for R. W. Lahey

Guests: J. S. Walker, Hooker Electrochemical Co.
G. E. Hinds, Sharples Chemical Co.
F. E. Shook, J. T. Baker Chemical Co.
R. W. Miller, Pittsburgh Plate Glass Co.
R. A. Bradley, The Sherwin-Williams Co.
C. S. Heath, Carbide & Carbon Chemical Corp.
Thomas W. Nale, Union Carbide & Carbon Corp.
Albert R. Jasuta, Westvaco Chlorine Products Corp.
M. H. Arvison, Standard Oil Co. (Ind.)
F. D. Sparre, E. I. duPont de Nemours & Co.
R. H. Long, Harshaw Chemical Co.
E. G. Fenrich, Mathieson Alkali Works
L. A. Helfrich, U.S. Industrial Chemicals, Inc.

PLAINTIFF'S
EXHIBIT
CMA-275

I. LABELS

I-1. Warning Statement. Reference was made to Dr. Irish's April 21 revision of a list of products for which application of the warning statement "Remove all contaminated clothing at once" had been suggested. An item-by-item review was made of these products as well as those in the manual "Warning Labels" and it was voted to add this phrase to labels for the following products:

Allyl Alcohol
Arsenic Trichloride

Aniline
Hydrofluoric Acid, Aqueous

The following items were referred to the subcommittees indicated with the request that a report be submitted at the next meeting of the LAPI Committee:

Ethylene Dibromide - Bromine - Dr. Irish and Frank Low
Mohonitrophenol - R. D. Minter
Sodium Fluoride - W. A. Knapp

I-2. Paradichlorobenzene. Reference was made to labels now in use by nine repackaging firms. It was the feeling of the committee that the caution label used by Merck & Co. is the most effective and accurate warning, based on available information.

Following a review of the published information on medical injuries, the subcommittee recommended that procedures be set up to obtain accurate medical information by complete examinations, at periodic intervals, of employees engaged in producing this product, such information to be obtained by the producers and submitted to the LAPI Committee through chairman Coey.

I-3. Labeling of Bulk Chemicals. Chairman Anderson referred to his report to the LAPI Committee dated May 16, concerning a conference with C. W. Crawford, Assoc. Commissioner of Food and Drugs on the question of exemption, under the regulations, of drugs intended for repackaging. The following letter from Mr. Crawford, dated July 3, was read, and it was felt that under these conditions current practices may be continued, and that exemption agreements under Section 503 were not indicated for any shipment of a drug intended for repackaging.

"When you and Messrs. Groening and Anderson visited the Administration on April 24, 1947, to discuss the revision of regulations under section 502 (f) (1) of the Federal Food, Drug, and Cosmetic Act, I informed you that some decision would probably be forthcoming from this office within a few weeks.

"At that time our consideration of the question was based on the assumption that the Federal Government had jurisdiction over the labeling of drugs not only while they were moving in interstate commerce but also between the time that they reached their interstate destination and the time that they came into the hands of the ultimate consumer. However, the Fifth Circuit Court of Appeals on May 12, 1947, rendered a decision against the Government in the case of Jordan James Sullivan, trading as Sullivan's Pharmacy, versus United States of America, which casts serious doubt upon the application of the Federal law to the labeling of drugs which are no longer in the hands of the original interstate importer. The Department of Justice has asked the Supreme Court to review this decision.

"Question has also been cast upon the extent to which the Federal law applies after merchandise has completed its interstate journey by the decision of the Ninth Circuit Court of Appeals in the case of Phelps Dodge Mercantile Company versus U.S. Government. As you know, proposed amendatory legislation designed to correct the apparent flaw in the law which was revealed by the latter Court decision is now in the hands of the Congress.

"Pending clarification of the extent to which this Administration has jurisdiction over foods and drugs subsequent to their shipment in interstate commerce, we would be loath to undertake any revision of the regulation under section 502 (f). When we have an expression from the Supreme Court in this regard, or if action by Congress serves to clarify the situation, we shall be glad to give further consideration to the proposal you left on April 24."

I-4. Synthetic Resin Adhesives. The Chairman referred to a letter dated June 27 from F. H. Carman, general manager of the Plastics Materials Manufacturers' Association, copy of which was sent to each member of the LAPI Committee. This letter advised of the Plastics Association's conclusion that any further action in the way of precautionary labeling should be handled as an individual proposition, and that no further association action was deemed desirable at this time.

Subject removed from docket.

I-5. Reagent Chemicals. J. T. Fuess, chairman, submitted the following preliminary report, which was approved:

General Principles Only

Each label must be considered individually.

Definition: Reagent chemicals are those chemicals of controlled quality sold primarily in small packages for laboratory, experimental and control use.

1. The majority of the subcommittee feels that, for reagent chemicals, a condensation of the LAPI labels as described in Manual L-1 and shown in L-2 should be permitted when such condensation is necessary for purposes of adequate legibility.

2. Condensation.

- a. The signal word should always be retained.
- b. The statement of hazards is, as a general rule, sufficient additional warning in consideration of the type of consumer of these chemicals. The statement of hazards should be retained as in L-2 when possible.

- c. Precautionary measures may be omitted unless indicating a hazard not mentioned in the statement of hazards, in which case such hazard should be included with the statement of hazards.

The subcommittee requests that it be continued at least until the next meeting of the LAPI Committee. A group of chemicals has been selected as samples for each member of the subcommittee to label in order to test the principles set up.

It was agreed that the work of the subcommittee should be continued.

I-6. Perchloric Acid Solution. The caution label for perchloric acid solution was approved as printed in Chemical Safety Data Sheet SD-11, except that the phrase "when hot" was deleted in the statement beginning with the word "Danger." The approved label follows:

Perchloric Acid Solution
DANGER. Strong Oxidant
Corrosive Liquid
Contact with Combustible Material May Cause
Fire or Explosion, Especially if Heated

Keep containers closed and away from combustible material, dehydrating agents and heat.

In case of spillage, flush with plenty of water and remove contaminated articles.

In case of contact, remove and wash clothing at once.
Immediately flush skin or eyes with water for at least 15 minutes; for eyes, get medical attention.

I-7. Aqua Ammonia. The committee reviewed a query from a member of the General Safety Committee concerning whether the caution relative to getting medical attention in case of injury to the eyes should not include a reference to medical attention in injuries other than the eyes. It was concluded that a revision to this effect is not necessary.

I-8. Trichloroethane. By request of Mr. Williamson, the query from the Jefferson Chemical Company, concerning a label for 1,1,2-trichloroethane, was withdrawn.

I-9. Rubber Chemicals. The meeting of the subcommittee on rubber chemicals, held in New York on October 16, was reviewed. Another meeting of the subcommittee is anticipated in the near future and its final recommendations will be submitted to the LAPI Committee.

I-10. Phosphorus. The committee reviewed the query of Carl Anderson of the legal committee concerning inclusion, on dry shipments of phosphorus, of the label phrase "Contents packed under water and will ignite if water is removed." It was pointed out that this might create a possible inconsistency with ICC authorization of dry shipments. The conclusion

as that dry shipments are not actually used, and it was agreed that the label for phosphorus should carry in the upper left corner the phrase "for wet shipments."

I-10a. Phosphorus. The committee referred to Mr. Minter for review the comment of the Monsanto member of the General Safety Committee questioning use of the caution that the operator wear rubber gloves, his point being that rubber gloves may be dangerous due to difficulty of removal in case of spillage and fire.

I-10b. Phosphorus. The committee also referred to Mr. Minter the suggestion of a member of the General Safety Committee that the semi-colon be substituted by the conjunction "and" in the phrase "Flush with plenty of water (and) keep the skin wet."

I-11. Aniline. A member of the legal advisory committee raised the question of the use of the phrase "do not take internally" in all cases where the word "poison" is used on a label. The chairman agreed to tabulate all items which carry the word "poison" showing whether the phrase in question is used in each case, and also the items which carry the phrase but not the word "poison." This tabulation is to be reviewed at the next meeting of the committee.

I-12. Rubber Cements. Consideration was given to an inquiry from the U.S. Rubber Company concerning a caution for one and two ounce tubes of rubber cement containing solvent naphtha but in which no benzol is used. The committee pointed out that there is ample precedent for use of the current phrase "Caution -- inflammable mixture - do not use near fire or flame." They agreed that the size of type used would depend upon the size of the package but that in any event the caution should be clear and legible.

I-13. Ethyl Ether. Dr. Butler submitted the following revision of the special caution in the ethyl ether label, his reason being that the iodine test is extremely sensitive and unless carefully conducted would give positive results:

CAUTION. Ether, especially when dry, readily forms explosive peroxides. Do not allow to evaporate to near dryness. Old ethers are particularly dangerous.

The suggested revision was referred to a committee consisting of Dr. Butler, Dr. Cranch, and Mr. Anderson.

I-14. Labeling of Repackaged Products. Mr. Low reported on the need for a method to insure transfer of required caution labels to subdivided packages in order to protect the ultimate consumer, and suggested that modified cautions might be prepared for this purpose. The subject was referred for recommendation to the Carbon Tetrachloride Committee of which Mr. Low is chairman.

I-16. Labeling of Small Packages. It was the feeling of the committee that developments in the past year point toward the need and desirability of caution labels patterned on the LAPI recommendations, for use on small packages going to the ultimate consumer.

I-17. Picric Acid. Mr. Sparre reviewed the USP picric acid caution label which introduces the phrase "hazardous explosives."

I-18. Nitrocellulose. The committee authorized the organization of a subcommittee including Mr. Sparre and a representative of Hercules and Atlas Powder companies on the subject of nitrocellulose containing less than 12.4% nitrogen.

I-19. Labeling of New Products - Toxicological Tests. Dr. Foulger submitted a report on minimum tests needed for the labeling of new products. He suggested that the number of animal tests be revised in accordance with the provisions of the Class B poison report under Minute V. The report follows:

Minimum Toxicological Tests to Give Information
For Labeling New Products

The following tests comprise the minimum needed for labeling new products with respect to toxicological hazards. They do not give adequate information for plant control of operations making or using the chemicals tested. They must necessarily ignore any species differences in toxicity, especially the difference between laboratory animals and men. Nevertheless, even minimum information is better than none, and upon it an adequate label can often be based.

1. Acute Oral Toxicity. Determine the fatal dosage on rats by the method of Deichmann and Leblanc. Give the chemical, in solution if necessary, by stomach tube. Commence with dosage level of 60 mg. per kilo. If this kills rapidly (10 minutes or less), the substance should be labeled, "Poison," according to M.C.A. definition.

2. Toxicity by Inhalation. Expose two rats in a bell jar for 10 to 20 minutes to an estimated vapor or gas concentration of 200 p.p.m. by volume. If this kills rapidly or causes serious disturbance, the material should be labelled, "Poison," according to M.C.A. definition.

This test may be repeated at higher concentrations; e.g., 500, 1,000, 2,000 p.p.m., to decide the degree of hazard below that of "poison."

3. Contact Irritation of the Skin. Use rabbits. Shave back over a circular area of about 10 cm. in diameter between shoulders.

Apply to each animal 3 concentrations of material to be tested (e.g., undiluted, 50%, one other concentration), and observe over 24 hours. If lowest concentration irritates, wait 24 hours and retest with lower concentration.

Tests for contact irritation do not disclose the possibility of allergy. Allergy tests are much more complicated.

4. Irritation of Eyes. This test can be made on the same rabbits as used above. Instill a drop of test material into one eye and observe for at least 24 hours.

Dr. Foulger gave each member of the committee a photostat copy of "Determination of the Approximate Lethal Dose with About Six Animals," by Wm. B. Deichmann and T. J. LeBlanc, appearing in the "Journal of Industrial Hygiene and Toxicology," Vol. 25, No. 9, pages 415-417, Nov. 1943.

I-20. Company Product Labels. Sets of labels were submitted from the Westvaco Chlorine Products Co., Heyden Chemical Corp., Dow Chemical Co., Hooker Electrochemical Co., and Monsanto Chemical Co. Review was not completed due to shortage of time, and it was agreed that these labels should be taken up at the February meeting for detailed discussion.

I-21. Type and Size of Caution Labels. Mr. Fuess submitted a report on this subject, concluding with the following recommendation:

"In the preparation of the sample labels shown in the M.C.A. Manual L-2, the layouts, the type and the type size relationships among the various portions of the label were selected to provide the maximum in warning. It is realized that individual label design precludes in many instances adherence to any such arbitrary standards. An equal effect may be obtained by judicious use of color contrast and placement.

"The LAPI Committee of the M.C.A. suggests that the layout and relationships shown in Manual L-2 be followed to the extent permitted by the design of the individual label. It should be stressed that the warning portion of the label be so placed that it cannot be overlooked under normal and expected examination of the product label."

Following a discussion, it was agreed that absolute rules cannot be established for the size of type on a label; that size depends to a large extent on the size of the package. The relationships set up in L-2 nevertheless serve as a valuable guide, the objective being to have clearly legible cautions with good contrast. Members of the committee gave examples of several consumer goods products, citing the negative effect of cautions in fine type placed at the end of text.

I-22. "Warning Labels" Supplement. The chairman advised the committee that current inventory of the manual "Warning Labels" shows a total of 700 copies out of the original print of 3,000. Orders for the past six months have averaged 40 copies per month, thus indicating that the supply will last until April 1949.

I-22a. Insecticide Labels. In reviewing the "Warning Labels" supplement, the committee agreed that failure to place a signal word in the labels for arsenicals, fluorine compounds, and paris green, was an oversight and inconsistent with the LAPI Committee pattern. The subject was referred to the insecticide subcommittee for recommendation.

I-22b. Hexaethyl Tetraphosphate. Mr. Minter proposed the addition of a phrase on the hexaethyl tetraphosphate label to the effect that a worker having any of the symptoms mentioned in the label should leave or be transferred. The subject was referred back to Mr. Minter and to Mr. Low on two points, namely, that additional toxicological information is not available, and that the interpretation of symptoms by the worker involves doubtful safety procedure.

I-23. Ethylene Chlorhydrin. Dr. Cranch recommended a revision of the ethylene chlorhydrin label, and also reported that accidents had resulted from failure of repackers to label this product. No exceptions were taken to the recommended revision, which follows, but it was suggested that Dr. Irish be invited to submit his comments to Dr. Cranch and the chairman.

For Technical Use Only

Ethylene Chlorhydrin
Anhydrous

DANGER./ EXTREMELY HAZARDOUS LIQUID AND VAPOR
MAY BE FATAL IF INHALED, SWALLOWED OR
ABSORBED THROUGH SKIN

Do not get on skin, on clothing, or in eyes.

(Ordinary rubber gloves will not prevent skin absorption).

Do not breathe vapor.

Do not take internally.

In case of contact, (clothing) remove all contaminated clothing at once, wash clothing before re-use; (skin) immediately wash skin with soap and plenty of water; (eyes) flush eyes with water for at least 15 minutes. Get medical attention.

⊗ POISON ⊗

First Aid Treatment

If swallowed, make patient vomit immediately, finger down throat or give warm mustard water or salt water freely.

General: Keep patient warm; if conscious, give black coffee.

Call physician. Do not give adrenalin.

Note: Use same label for Ethylene Chlorhydrin 38%

I-24. Ammonium Nitrate. The committee reviewed the following draft of a label prepared by the M.C.A. Ammonium Nitrate Technical Committee, although no final action was taken:

Ammonium Nitrate
Fertilizer

Keep away from heat and open flame -- do not smoke.
Store away from combustible materials.
In case of fire, flood with water.
Burn empty bags promptly in open and in small quantities.
Rebag or remove all spilled material immediately.

However, the following suggestions were made:

1. Add a signal word.
2. Put "do not smoke" in capital letters.
3. Change line 2 to read "Store away from materials which will burn."
4. In line 4 replace the phrase "in small quantities" by "a few at a time."
5. In line 5 separate the rebag caution if possible so as to differentiate between rebagging contaminated material and that which is uncontaminated.

I-25. Methanol. The chairman was requested to canvass methanol producers to determine their attitude toward a revision of the label covered under the USPHS agreement.

II. TOXICITY

The committee reviewed an inquiry from the Agricultural Insecticide and Fungicide Association concerning the toxic effect on warm-blooded animals of copper and zinc compounds, and particularly sulfates. It was the committee's informal opinion that these products would not fall within the definition "highly toxic to man" as set forth in the new Federal Insecticide Act regulations, and that these products have relatively low toxicity. The chairman was requested to draft a reply for clearance with Dr. Foulger.

III. MODEL STATE BILL

Dr. Knapp reported that the press of work had prevented Mr. Hansen from completing the redraft of the model state label bill. It was suggested that the chairman offer to get assistance for Mr. Hansen if the latter should be able to use this aid.

It was the feeling of the committee that it is of the utmost importance that this model bill be completed, as a call for it may come without warning. It was also suggested that the redraft be completed, if possible, prior to the next meeting in order that committee members may come prepared with their specific and final comments.

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The question was raised as to whether the current model bill would cover the repacker, and it was the understanding of the committee that both producers and repackers were covered.

The chairman advised the committee that the model state poison bill was being redrafted for the National Drug Trade Conference and that a copy would be sent to the committee following the conference in Washington on November 3. (Mailed to committee members on November 3.)

IV. LABEL ADHESIVES

Mr. Minter gave a detailed review of the results of preliminary 65-day weather tests with various label adhesives, now on the market, on metal. He advised the committee that he expected to have a final report ready for the committee at the next meeting, and also invited committee members to send a one-pint sample of any adhesive found to be satisfactory, in order that it may be included in his pending test program.

V. DEFINITION OF CLASS B POISONS

Dr. Cranch submitted draft of a definition of Class B Poisons which, after extensive discussion, was agreed upon as follows:

"Class B Poison. Class B Poisons are liquid or solid (including semi-solid) substances, other than Class A Poisons, which fall within any one of the following categories, when tested on two species of laboratory animals.

"Category 1. Oral toxicity. Those which produce death in half or more than half the animals of any species within 24 hours at a dosage of 50 milligrams or less per kilogram of body weight at a single dose, when administered orally to ten or more such animals of each species.

"Category 2. Toxicity on inhalation. Those which produce death within 24 hours in half or more than half of the animals of any species at a dosage of 200 parts or less by volume of gas or vapor per million parts by volume of air by continuous inhalation for one hour or less to ten or more animals of each species, provided such concentration is likely to be encountered by man when the material is handled in any reasonably foreseeable manner.

"Category 3. Toxicity by skin absorption. Those which produce death within 48 hours in half or more than half of the animals (rabbits only) tested at a dosage of 200 milligrams or less per kilogram of body weight when administered by continuous contact with the bare skin for 24 hours or less to ten or more animals."

The draft of this definition is to be submitted to the other M.C.A. Technical Committees for study, and is patterned after the definition in the new Federal

Insecticide Act regulations. Information available indicated that the scope of this definition would be less than the scope of the current list of Class B poisons in the I.C.C. regulations.

VI. MISCELLANEOUS

VI-1. Army-Navy Labeling. The attention of the committee was called to the requirement of the Joint Army-Navy Purchase Description for drugs and fine chemicals reading as follows:

"Precautionary labeling currently recommended by the Manufacturing Chemists' Association in their publication 'Warning labels' shall apply."

It was suggested that the chairman send to the appropriate official a copy of the recommendation on the labeling of reagent chemicals, explaining that this group is under active study.

VI-2. N.Y. Fire Regulations. The chairman was requested to send a letter to the appropriate official in New York City recommending the use of the term "flammable" instead of "inflammable" in their label regulations.

VI-3. Federal Insecticide Act Regulations. Reference was made to the oral statement made on behalf of the M.C.A., and the support of various witnesses, concerning regulations under the Federal Insecticide Act at hearings held August 25, 1947, and also to the supplemental statement filed with the administrator of the act.

Following a discussion of the requirements for caution labels for insecticides and other products under the act, it was agreed that the following special committee should be set up on this subject:

Chairman - ~~J.A. Noone~~; S. J. Hill, W.W. Sunderland, W. A. Knapp, Frank S. Low, R. D. Minter, A. G. Cranch, J. S. Coey, ~~Carl Anderson~~, and ~~F.E. Sheek~~.

The chairman of the committee was authorized to make such additions to the committee as might be desirable.

VI-4. Shoes. It was pointed out that plant experience is usually satisfactory in the prompt removal of clothing in case of product spillage involving danger through skin contact. Frequently, however, the shoes are overlooked and spillage remains in the porous leather and may be absorbed through the skin with bad results.

It was therefore suggested that the chairman run an item in the General Bulletin on removal of shoes, and that "Warning Labels" when and if republished, should contain a caution to this effect.

VI-5. Policy. A review of committee policy developed the following points: (1) that the manual "Warning Labels" contains a sufficient variety of labels to serve as a guide for the preparation of labels for new products, and that the committee does not need to emphasize the preparation of additional labels; (2) new groups, such as rubber chemicals, should be handled according to present procedure, namely, through subcommittees which in turn report their recommendations to the full committee for final approval, and could be incorporated in a supplement to "Warning Labels"; (3) the review of company labels should be continued because of the great value of round table comment on caution phrases and label arrangement; (4) while it appeared a year ago that the committee's work was substantially completed, later developments point to two significant trends: first, the extension of LAPI labels to small packages and end products, and second, prospects of legislative or regulatory requirements on caution labels; (5) a six months' interval between meetings has resulted in an excessive accumulation of items for discussion and insufficient time for their consideration.

VI-6. Next Meeting. It was agreed that the next meeting of the committee should be held at the New Yorker on Thursday and Friday, February 5 and 6, 1948.

VII. ADJOURNMENT

The meeting adjourned Friday, October 31, 1947.

W. N. WATSON
CHAIRMAN

Minutes subject to approval.