Therefore, based upon the available toxicity data, the small amount of the color additive added to the contact lens, and the agency's exposure calculation, FDA finds that the color additive chromium-cobalt-aluminum oxide is safe for use in contact lenses. FDA further concludes that the safety margin is sufficiently large that a limitation on the amount of the color additive that may be present in the lens is not required beyond the limitation that only the amount necessary to accomplish the intended technical effect may be used. Batch certification is not required to ensure safety.

V. Conclusions

Based on data contained in the petition and other relevant material, FDA concludes that there is a reasonable certainty that no harm will result from the petitioned use of chromium-cobalt-aluminum oxide for coloring contact lenses, and that this color additive is safe for its intended use. In addition, based upon the data it considered, the agency finds that chromium-cobalt-aluminum oxide is suitable for use in coloring contact lenses and is adding new § 73.3110a to Subpart D of the color additive regulations.

VI. Inspection of Documents

In accordance with § 71.15 (21 CFR 71.15), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above. As provided in § 71.15, the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

VII. Environmental Impact

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday. This action was considered under FDA's Final rule implementing the National Environmental Policy Act (21 CFR Part 25).

VIII. Objections

Any person who will be adversely affected by this regulation may at any time on or before November 21, 1988 file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday. FDA will publish a notice of the objections that the agency has received or lack thereof in the Federal Register.

List of Subjects in 21 CFR Part 73

Color additives, Cosmetics, Drugs, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, Part 73 is amended as follows:

PART 73—LISTING OF COLOR ADDITIVES EXEMPT FROM CERTIFICATION

1. The authority citation for 21 CFR Part 73 continues to read as follows:

Authority: Secs. 701, 706, 52 Stat. 1055–1056 as amended, 74 Stat. 399–407 as amended (21 U.S.C. 371, 376); 21 CFR 5.10.

2. New § 73.3110a is added to Subpart D to read as follows:

§ 73.3110a Chromium-cobalt-aluminum oxide.

(a) *Identity.* The color additive chromium-cobalt-aluminum oxide (Pigment Blue 36) (CAS Reg. No. 68187–11–1, Colour Index No. 77343) shall conform in identity and specifications to the requirements of § 73.1015 (a) and (b).

(b) *Uses and restrictions.* (1) The substance listed in paragraph (a) of this section may be used as a color additive in contact lenses in amounts not to exceed the minimum reasonably required to accomplish the intended coloring effect.

(2) Authorization for this use shall not be construed as waiving any of the requirements of sections 510(k), 515, and 520(g) of the Federal Food, Drug, and Cosmetic Act (the act) with respect to the contact lens in which the color additive is used.

(c) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore the color additive is exempt from the certification requirements of section 706(c) of the act.

Dated: October 18, 1988.

John M. Taylor,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 88–24458 Filed 10–20–88; 8:45 am]

BILLING CODE 4160–01–M

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21 CFR Part 172

[Docket No. 82F–0185]

Direct Food Additives; Food Additives Permitted for Direct Addition to Food for Human Consumption; Dimethyl Dicarbonate

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of dimethyl dicarbonate as a yeast inhibitor in wines. This action responds to a petition filed by Mobay Chemical Corp.

DATES: Effective October 21, 1988; written objections and requests for a hearing by November 21, 1988. The Director of the Office of the Federal Register approves the incorporation by reference of certain publications at 21 CFR 172.133(a)(2), effective October 21, 1988.

ADDRESSES: Written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: JoAnn Ziyad, Center for Food Safety and Applied Nutrition (HFF–334); Food

and Drug Administration, 200 C Street SW., Washington, DC 20204, 202–426–9463.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of July 13, 1982 (47 FR 30291), FDA announced that a petition (FAP 2A3636) has been filed by Mobay Chemical Corp., Penn Lincoln Parkway West, Pittsburgh, PA 15205, proposing that the food additive regulations be amended to provide for the safe use of dimethyl dicarbonate as a cold sterilant in beverages and fruit juices. Subsequently, the petition was amended to request the use of dimethyl dicarbonate to prevent the growth of yeasts in wines only.

Dimethyl dicarbonate is unstable in aqueous solution and breaks down almost immediately after addition to beverages. In wine and aqueous liquids, the principal breakdown products are methanol and carbon dioxide. Dimethyl carbonate and methylethl carbonate, as well as carbomethoxy amino and hydroxy adducts of amines, sugars, and fruit acids, are also formed in minor amounts. Dimethyl dicarbonate also may react with traces of ammonia or ammonium ions in wines to form trace quantities of methyl carbamate. Methyl carbamate has been shown to cause cancer in laboratory animals.

In accordance with 21 CFR 171.1, FDA has reviewed the safety of the food additive dimethyl dicarbonate, as well as that of the by-products formed during hydrolysis and reaction of the food additive with other constituents found in wines. The results of that review are discussed below.

I. Determination of Safety

Under section 409(c)(3)(A) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348(c)(3)(A)), the so-called "general safety clause" of the statute, a food additive cannot be approved for a particular use unless a fair evaluation of the data available to FDA establishes that the additive is safe for that use. Under section 409(c)(5)(A) of the act (21 U.S.C. 348(c)(5)(A)), in determining whether a proposed use of a food additive is safe, among the relevant factors to be considered is the probable consumption of the additive and of any substance formed in or on food because of the use of the additive. The concept of safety embodied in the Food Additives Amendment of 1958 is explained in the legislative history of the provision: "Safety requires proof of a reasonble certainty that no harm will result from the proposed use of an additive. It does not—and cannot—require proof beyond any possible doubt that no harm will result under any conceivable circumstance." (H. Rept. 2284, 85th Cong., 2nd Sess. 4 (1958)). This concept of safety has been incorporated into FDA's food additive regulations (21 CFR 170.3(i)). The anticancer or Delaney clause of the Food Additives Amendment (section 409(c)(3)(A) of the act (21 U.S.C. 348(c)(3)(A))) provides further that no food additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal.

In the past, FDA often refused to approve a use of an additive that contained even minor amounts of a carcinogenic chemical, even though the additive as a whole had not been shown to cause cancer. The agency now believes that the Delaney or anticancer clause is applicable only when the food additive as a whole is found to cause cancer. An additive that has not been shown to cause cancer but that contains a carcinogenic constituent, or whose use will lead to the formation of trace amounts of a carcinogenic substance in or on food, may be properly evaluated under the general safety clause of the statute.[1] Risk assessment procedures are used to determine whether there is a reasonable certainty that no harm will result from the proposed use of the additive. Developments in scientific technology and experience with risk assessment procedures make it possible for FDA to establish the safety of such additives.

The agency's position on additives that contain a carcinogenic constituent but that have themselves not been shown to cause cancer is supported by *Scott* v. *FDA*, 728 F. 2d 322 (6th Cir. 1984). That case involved a challenge to FDA's decision to approve the use of D&C Green No. 5, which contains a carcinogenic chemical but has itself not been shown to cause cancer. Relying heavily on the reasoning in the agency's decision to list the above color additive, the United States Court of Appeals for the Sixth Circuit rejected the challenge to FDA's action and affirmed the listing regulation. The agency believes that it is consistent with the *Scott* decision to interpret the constituents policy to include the current situation, which relates to the possible formation of trace amounts of a carcinogenic substance from the use of a food additive in food but in which the additive itself has not been shown to cause cancer.

II. Safety of Petitioned Use of Dimethyl Dicarbonate

FDA finds that the petitioned use level of 100 to 200 parts per million (ppm) of dimethyl dicarbonate will result in virtually no exposure of consumers to the additive itself. Dimethyl dicarbonate is unstable in aqueous solution and breaks down almost immediately after addition to the food (beverages) to form primarily carbon dioxide and methanol. The instability of dimethyl dicarbonate is confirmed by data submitted by the petitioner showing that dimethyl dicarbonate cannot be detected by analysis of food to which it has been added.

To establish that dimethyl dicarbonate is safe for use as an inhibitor of yeast in wine, the petitioner submitted data from acute, subchronic, and chronic toxicity studies. In the subchronic and chronic toxicity studies, rats received either water, orange juice, or wine treated with 4,000 (ppm) of dimethyl dicarbonate (20 times the proposed use level in wine) as the drinking fluid while the controls received water, orange juice, or wine. These studies revealed no adverse effects from water, orange juice, or wine treated with dimethyl dicarbonate.

In other chronic toxicity studies, dogs received either water or orange juice treated with 4,000 ppm of dimethyl dicarbonate as the drinking fluid. These studies also revealed no adverse effects from the water or orange juice treated with dimethyl dicarbonate.

The petitioner also submitted a 2-generation rat study in which rats received drinking fluids that were treated with dimethyl dicarbonate (4,000 ppm). This study revealed no adverse effects. These chronic and multigeneration studies of dimethyl dicarbonate did not produce any evidence that it is a carcinogen.

III. Safety of Substances That May be Present in Wine Due to Use of the Additive

Because dimethyl dicarbonate decomposes into other chemical species when added to aqueous solutions such as wine, FDA has also evaluated the safety of the chemicals formed as a result of the addition of dimethyl dicarbonate to wine.

A. Minor Reaction Products

The minor reaction products formed in wine from the use of dimethyl

[1] However, the statute calls for a different treatment from compounds whose use as a food additive, color additive, or new animal drug administered to food-producing animals results in the formation of carcinogenic metabolites in the animal. Such compounds and their metabolites are subject to the relevant Delaney Clause and DES proviso (21 U.S.C. 348(c)(3)(A) (food additives); 376(b)(5)(B) (color additives); 360b(d)(1)(H)(ii) (new animal drugs)); as well as the general safety clause. See the Commissioner's decision on the withdrawal of approval of new animal drug applications for diethylstilbestrol (44 FR 54852 at 54868–54869; September 21, 1979).

dicarbonate include methylethyl carbonate and carbomethoxy amino- and hydroxy-adducts of amines, sugars, and naturally occurring fruit acids such as lactic acid, citric acid, and ascorbic acid (vitamin C). Dimethyl carbonate, an impurity in dimethyl dicarbonate, is also found in wine in minor amounts as a result of the use of the additive.

The petitioner presented data to show that the addition of 100 to 200 ppm of dimethyl dicarbonate to wine is effective in inhibiting the growth of most species of yeast found in wine. Based on this level of addition, for a wine intake of 232 grams per person per day (the 90th percentile consumption level for "drinkers only"—Most recent USDA Food Consumption Survey, 1977–78), and based on data submitted by the petitioner, the agency estimates that the maximum daily consumption of the minor reaction products resulting from the addition of dimethyl dicarbonate to wine is from 2 to 5 milligrams per person per day. Because these reaction products were formed in the dimethyl dicarbonate-treated fluids (water and wine) used in the subchronic and chronic rat and dog studies submitted by the petitioner, the safety of the reaction products is evidenced by the findings of no-adverse effects in these studies.

The safety of methylethyl carbonate was further evaluated in a subchronic toxicity study in rats in which this substance was added to the drinking water at levels of 0, 1,000, 3,000 and 10,000 ppm for 3 months. The average daily consumption of methylethyl carbonate ranged from approximately 0.1 milligram per kilogram to 1 gram per kilogram body weight per day. No adverse effects in rats from drinking the water treated with methylethyl carbonate were seen in this study.

A teratogenicity study was conducted with pregnant female rats of the Long-Evans FB30 strain. The animals were fed diets containing methylethyl carbonate at levels of 0, 100, 1,000 and 10,000 ppm. No signs of toxicity were noted in the study report. However, there was a dose-related reduction in fluid intake and a slight decrease in body weight gain in pregnant females receiving methylethyl carbonate throughout the gestational period. The reduced fluid intake appears to be attributable to the bad taste and smell of the water containing the methylethyl carbonate. All test and control females were sacrificed at day 20 (Cesarean sections were performed), and the fetuses were examined. No embryotoxic or teratogenic effects were found in this examination.

To establish the safety of dimethyl carbonate the petitioner submitted a subchronic study in which dimethyl carbonate was incorporated into the drinking water at levels of 0, 1,000, 3,000 and 10,000 ppm. An increase in body weight gain was observed in male rats at all treated levels. No adverse effects were found in this study at 10,000 ppm or at lower levels.

B. Carbon Dioxide

Carbon dioxide, one of the principal hydrolysis products of dimethyl dicarbonate, is a natural product of animal metabolism. Prolonged exposure to concentrations of carbon dioxide (in inhaled air) at levels higher than 5 volume per cent may lead to unconsciousness and death (Ref. 7). Carbon dioxide is present in solution as the carbonate and bicarbonate anions, however, and is routinely used to carbonate beverages (Ref. 8). The levels of carbon dioxide present in wine as a result of the use of dimethyl dicarbonate are well below the levels found in carbonated beverages. Thus, the agency has no evidence that carbon dioxide would be harmful under the intended conditions of use.

C. Methanol

Methanol is the principal reaction product of concern resulting from addition of dimethyl dicarbonate to wine. Theoretically, complete hydroloysis of dimethyl dicarbonate would yield 2 moles of methanol and 2 moles of carbon dioxide from each mole of dimethyl dicarbonate added to wine. On a weight basis, this yield corresponds to approximately 48 milligrams of methanol for each 100 milligrams of the additive added to a liter of wine. In aqueous/alcoholic solutions such as wine, the theoretical level of methanol is not achieved because dimethyl dicarbonate may also react with naturally occurring minor constituents of the solution to form other chemicals in trace amounts. However, to estimate a worst case exposure of consumers to methanol from the proposed use of the additive, the agency assumed complete hydrolysis of dimethyl dicarbonate to methanol and carbon dioxide. Based on the addition of 100 to 200 mg dimethyl dicarbonate to one liter of wine and on a wine intake of 232 grams per person per day (90th percentile consumption level), the agency estimates that the daily intake of methanol from this use of dimethyl dicarbonate would range from 11 to 22 milligrams per person per day (0.18 to 0.36 milligram per kilogram body weight for a 60 kilogram person) (Ref. 1).

The agency considers the daily intake of methanol from the addition of dimethyl dicarbonate to wine, even when added to the amount of methanol naturally present in other foods such as fresh fruits and vegetables and grain alcohol, to be safe. An adult human can metabolize up to 1500 milligrams of methanol per hour with no adverse symptoms or effects (Ref. 2). The levels of methanol that occur in wine and fruit juices average up to 140 milligrams per liter and an additional 50 to 100 milligrams per liter may result from the use of dimethyl dicarbonate, assuming a wine intake of 232 grams per person per day (Ref. 1). The total methanol exposure from these sources would be up to 50 to 60 milligrams per person per day. There is, therefore, a large margin of safety between the methanol intake and the amount which can be safely ingested.

D. Methyl Carbamate

1. Carcinogenicity. Reaction of dimethyl dicarbonate with naturally occurring ammonia or ammonium ions in wine may result in the formation of trace amounts of methyl carbamate which has been shown to be carcinogenic in rats (Ref. 3). FDA has evaluated the safety of this reaction by-product using risk assessment procedures to estimate the upper-bound limit of risk presented by the presence of this chemical as an impurity in wine treated with dimethyl dicarbonate. Based on this evaluation, the agency has concluded that under the proposed conditions of use, dimethyl dicarbonate is safe.

2. Basis for evaluation. The risk assessment procedures that FDA used in this evaluation are similar to the methods that it has used to examine the risk associated with the presence of minor carcinogenic impurities in various food and color additives (see, e.g., 49 FR 13018; April 2, 1984). This evaluation of the risk from the use of dimethyl dicarbonate has two aspects: (1) Assessment of the probable exposure to methyl carbamate produced in food from the use of dimethyl dicarbonate; and (2) extrapolation of the risk observed in the animal bioassay to the conditions of probable exposure to humans.

Based on the level of methyl carbamate produced from the addition of dimethyl dicarbonate to wine as a yeast inhibitor, as well as the estimated lifetime consumption of wine, FDA estimated the worst case exposure to methyl carbamate to be 2.4 micrograms per person per day (Refs. 1, 4, and 5). The agency used data in a carcinogenesis bioassay report on methyl carbamate conducted by the National Toxicology Program (NTP)

(Ref. 4) to estimate the upper-bound level of lifetime human risk from exposure to this chemical stemming from the proposed use of dimethyl dicarbonate.

The bioassay report consisted of results from studies of methyl carbamate in both rats and mice. The bioassay in B6C3F1 mice was reported by NTP to be negative. The bioassay of methyl carbamate in F344/N rats consisted of a 2-year chronic study and a parallel study with sacrifices at 6, 12, and 18 months. The 2-year study employed a high dosage level of 200 milligrams per kilogram body weight. The parallel study employed one dosage level of 400 milligrams per kilogram body weight. An increase in hepatocellular neoplasms was found at the high dose in female F344/N rats of the 2-year study. In the parallel study, hepatocellular neoplasms were found at 6 months in both sexes, and the sacrifices at the later times revealed a classic picture of progression from benign to highly malignant neoplasms dependent upon the length of time of exposure. The NTP concluded that "there was clear evidence of carcinogenic activity for male and female F344/N rats given methyl carbamate as indicated by incidences of hepatocellular neoplastic nodules and hepatocellular carcinoma" (Ref. 3).

3. Results of evaluation. Using the NTP bioassay report, the Center for Food Safety and Applied Nutrition's Quantitative Risk Assessment Committee (QRAC) estimated the human cancer risk from the potential exposure to methyl carbamate stemming from the proposed use of dimethyl dicarbonate as a yeast inhibitor in wine (Refs. 4 and 5).

The QRAC used a quantitative risk assessment procedure (linear proportional model) to extrapolate from the dose used in the animal experiment through zero to cover the very low doses expected to be encountered under the proposed conditions of use of the additive. This procedure is not likely to understimate the actual risk from the very low doses and may, in fact, exaggerate it because the extrapolation models used are designed to estimate the maximum risk consistent with the data. For this reason, the estimate can be used with confidence to determine to a reasonable certainty whether any harm will result from the proposed conditions and a level of use of 200 ppm of the food additive.

Based on a worst case exposure to methyl carbamate (2.4 micrograms per person per day), FDA estimated, using a simple linear model, that the upper-bound limit of individual lifetime risk from potential exposure to methyl carbamate is 2.4×10^{-8} or less than 1 in 42 million. Because of numerous conservatisms in the exposure estimate, lifetime avaraged individual exposure to methyl carbamate is expected to be substantially less than the estimated daily intake, and, therefore, the calculated upper-bound risk would be less. Thus, the agency concludes that there is a reasonable certainty of no harm from the exposure to methyl carbamate that results from the use of up to 200 ppm of dimethyl dicarbonate in wine.

4. Need for specifications. The agency has also considered whether a specification is necessary to control the amount of methyl carbamate that may be formed in wine treated with the additive. The agency finds that the amount of methyl carbamate formed in wine may be controlled by limiting the amount of dimethyl dicarbonate that can be added to the wine to 200 ppm or less rather than by setting a specification for the level of methyl carbamate impurity in wine. The petitioner submitted data to show that the maximum level of methyl carbamate impurity formed in commercial wine is less than 10 parts per billion (ppb) for each 100 ppm of dimethyl dicarbonate added to wine. A 200 ppm level of dimethyl dicarbonate is sufficient to control the growth of all significant genera and species of yeast in wine that has been adequately pasteurized or ultra/filtered according to current good maufacturing practices to reduce the microbial count to 500 per milliliter (ml) or less.

E. Ethyl Carbamate

The petitioner submitted studies in which gas chromatography/mass spectroscopy was used to measure the formation of ethyl carbamate (urethane) in dimethyl dicarbonate-treated wine and model wine solutions, in the presence of high concentrations of ammonium ions. These studies, conducted over a 12-month period, failed to show the formation of ethyl carbamate in excess of endogenous levels found in wine. These studies also did not show evidence of formation of ethyl carbamate by transesterification of methyl carbamate. Thus there is no indication that the use of dimethyl dicarbonate affects the level of ethyl carbamate in wine.

The agency is aware that ethyl carbamate, an animal carcinogen, occurs as a contaminant in wine. The agency is in the process of obtaining as much information as possible about the levels of such ethyl carbamate contamination. In addition, in cooperation with the wine industry, a program, has been instituted to find and control the formation of ethyl carbamate so as to reduce it to the extent possible. (Agreement Between the Association of American Vintners, the Wine Institute, and FDA, "Ethyl Carbamate Voluntary Program," Jan. 7, 1988) (Ref. 6).

IV. Conclusion on Safety

FDA has evaluated all of the data in the petition pertaining to the use of dimethyl dicarbonate in wine and has determined that the additive is safe for its proposed use.

To ensure the safe to the additive, FDA, under 21 U.S.C. 348(c)(1)(A), finds that it is necessary to require that the label of the package containing the additive contain, in addition to other information required by the Federal Food, Drug, and Cosmetic Act, (1) the name of the additive, "dimethyl dicarbonate," and (2) directions to provide that not more than 200 ppm of dimethyl dicarbonate will be added to the wine.

In accordance with 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above. As provided in 21 CFR 171.1(h), the agency will delete from the documents any materials that are are not available for public disclosure before making the documents available for inspection.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday. Under FDA's regulations implementing the National Environmental Policy Act (21 CFR Part 25), an environmental assessment is required for an action of this type under 21 CFR 25.31a(a).

V. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday:

1. Memorandum dated January 14, 1987, Regulatory Food Chemistry Branch to GRAS Review Branch, "Dimethyl Dicarbonate

(DMDC) in Wine. Submission of September 5, 1986; Exposure Estimate for Methyl Carbamate (MC) and Methanol in Wine."

2. Letter of A.J. Lehman, February 12, 1963, in Food Additive Petition No. 0A0043 (FAP 0A0043).

3. NTP Technical Report on the Toxicology and Carcinogensis Studies of Methyl Carbamate in F344/N Rats and B6C3F1 Mice, National Toxicology Program U.S. Department of Health and Human Service, Reprt No. 328, 1986.

4. Memorandum dated October 28, 1986, Quantitative Risk Assessment Committee to Office of Toxicological Sciences, "Methyl Carbamate in Wine."

5. Memorandum dated November 20, 1987, Quantitative Risk Assessment Committee to Office of Toxicological Sciences, "Methyl Carbamate in Wine."

6. "Ethyl Carbamate Voluntary Program," Final Agreement Between the Wine Institute, the Association of American Vintners and the Food and Drug Administration, January 7, 1988.

7. Ballou, W. Robert, "Carbon Dioxide," *Encyclopedia of Chemical Technology*, 4:725–742, 1978

8. Mones, Martha, "Carbonated Beverages," *Encyclopedia of Chemical Technology*, 4:710–725, 1978.

Any person who will be adversely affected by this regulation may at any time on or before November 21, 1988 file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 172

Food additives, Reporting and recordkeeping requirements, Incorporation by reference.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under the authority delegated to the Commissioner of Food and Drugs, Part 172 is amended as follows:

PART 172—FOOD ADDITIVES PERMITTED FOR DIRECT ADDITION TO FOOD FOR HUMAN CONSUMPTION

1. The authority citation for 21 CFR Part 172 continues to read as follows:

Authority: Secs. 201(s), 409, 72 Stat. 1784–1788 as amended (21 U.S.C. 321(s), 348); 21 CFR 5.10 and 5.61.

2. Section 172.133 is added to Subpart B to read as follows:

§ 172.133 Dimethyl dicarbonate.

Dimethyl dicarbonate (CAS Reg. No. 4525–33–1) may be safely used in wine in accordance with the following prescribed conditions:

(a) The additive meets the following specifications:

(1) The additive has a purity of not less than 99.8 percent as determined by the following titration method:

Principles of Method

Dimethyl dicarbonate (DMDC) is mixed with excess diisobutylamine with which it reacts quantitatively. The excess amine is backtitrated with acid.

Apparatus

250-milliliter (mL) Beaker
100-mL Graduate cylinder
25-mL Pipette
10-mL Burette (automatic, eg., Metrohm burette)
Stirrer
Device for potentiometric titration
Reference electrode
Glass electrode

Reagents

Acetone, analytical-grade
Solution of 1 *N* diisobutylamine in chlorobenzene, distilled
1 *N* Acetic Acid

Procedure

Accurately weigh in about 2 grams of the sample (W) and dissolve in 100 mL acetone. Add accurately 25 mL of the 1 *N* diisobutylamine solution by pipette and allow to stand for 5 minutes. Subsequently, titrate the reaction mixture potentiometrically with 1 *N* hydrochloric acid (consumption = *a* mL) while stirring. For determining the blank consumption, carry out the analysis without a sample (consumption = *b* mL).

Calculation

$$\frac{(b-a)\times 13.4}{W} = \%\ \text{DMDC}$$

Note.—For adding the diisobutylamine solution, always use the same pipette and wait for a further three drops to fall when the flow has stopped.

(2) The additive contains not more than 2,000 ppm (0.2 percent) dimethyl carbonate as determined by a method entitled "Gas Chromatography Method for Dimethyl Carbonate Impurity in Dimethyl Dicarbonate," which is incorporated by reference in accordance with 5 U.S.C. 552(a). Copies are available from the Division of Food and Color Additives, Center for Food Safety and Applied Nutrition (HFF–334), 200 C Street SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L Street NW., Washington, DC 20408.

(b) The additive is used or intended for use as an inhibitor of yeast in wine under normal circumstances of bottling where the viable yeast count has been reduced to 500 per milliliter or less by current good manufacturing practices such as flash pasteurization or filtration. The additive may be added to wine in an amount not to exceed 200 parts per million (ppm).

(c) To ensure the safe use of the food additive, the label of the package containing the additive shall bear, in addition to other information required by the Federal Food, Drug, and Cosmetic Act:

(1) The name of the additive "dimethyl dicarbonate."

(2) Directions to provide that not more than 200 ppm of dimethyl dicarbonate will be added to the wine.

Dated: October 17, 1988.

John M. Taylor,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 88–24417 filed 10–20–88; 8:45 am]

BILLING CODE 4160–01–M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of the Assistant Secretary for Community Planning and Development

24 CFR Part 570

[Docket No. R–88–1204; FR–1895]

Community Development Block Grants; Final Rule; Corrections

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Final rule; corrections.

SUMMARY: The purpose of this document is to make editorial corrections to a final rule published September 6, 1988 (53 FR 34416), that amended substantial portions of its Community Development

Block Grants (CDBG) regulation at 24 CFR Part 570.

FOR FURTHER INFORMATION CONTACT: James R. Broughman, Director, Entitlement Cities Division, Office of Block Grant Assistance, Room 7280, Department of Housing and Urban Development, 451 Seventh Street SW., Washington, DC 20410–5000, telephone (202) 755–5977. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: On September 6, 1988 (53 FR 34416), the Department amended substantial portions of its Community Development Block Grants (CDBG) regulation at 24 CFR Part 570 in order to update and make more efficient the CDBG program. The rule also incorporated legislative changes to Title I of the Housing and Community Development Act of 1974 contained in the Housing and Urban-Rural Recovery Act of 1983 and the Housing and Community Development Act of 1987.

Accordingly, the following corrections are made in FR Doc. 88–20101 published in the **Federal Register** on September 6, 1988 at 53 FR 34416:

§ 570.3 [Corrected]

1. In § 570.3(j), on page 34437, third column, correct "1970" to read "1960".

2. In § 570.3(v)(3)(i), on page 34438, second column, line 8, correct the word "act" to read "Act".

3. In § 570.3(w), on page 34438, third column, in lines 5 and 7, correct "section" to read "Section", and in line 8, correct "program" to read "Program".

4. In § 570.3(x), on page 33438, third column, in lines 5 and 10, correct the word "section" to read "Section", and in line 11, correct "program" to read "Program".

5. On page 34439, third column, in the table of contents, in § 570.204, correct the word "subrecipients".

§ 570.200 [Corrected]

6. In § 570.200(j)(2) concluding text, on page 34442, first column, line 11, correct "(j)(3)x" to read "(j)(3)".

§ 570.202 [Corrected]

7. § 570.202(b)(6), on page 34443, third column, line 2, correct "of" to read "or".

8. In § 570.202(d), on page 34444, first column, top of page, line 6, correct "of" to read "or".

§ 570.206 [Corrected]

9. In § 570.206(c), on page 34445, third column, line 14, correct "high proposition of lower income" to read "high proportion of low and moderate income".

10. In § 570.206(g) introductory text, on page 34445, third column, line 15, correct "by lower income households," to read "by low and moderate income households," and in line 19, correct "affordable rents/costs by lower income" to read "affordable rents/costs by low and moderate income".

11. In § 570.206(g)(3), on page 34446, column one, line 7, correct "program" to read "Program".

12. In § 570.206(g)(6), on page 34446, column one, line 5, correct "lower income persons" to read "low and moderate income persons".

§ 570.207 [Corrected]

13. In § 570.207(b)(2)(ii), on page 34446, third column, correct "work" to read "works".

§ 570.208 [Corrected]

14. In § 570.208(a)(3)(i)(A), on page 34448, first column, correct "non-elderly housing project;" to read "non-elderly rental housing project;".

15. In § 570.208(d)(1), on page 34449, first column, in last sentence, correct "§ 570.505" to read "§ 570.505".

§ 570.301 [Corrected]

16. In § 570.301(b)(1)(i), on page 34449, second column, correct "recieved" to read "received", and omit close parenthetical after the word "use", and insert close parenthetical after the word "activities" and before the semi-colon.

§ 570.303 [Corrected]

17. § 570.303(h), on page 34450, second column, last line, correct "105(1)(11)" to read "105(a)(11)".

§ 570.506 [Corrected]

18. In § 570.506(b), on page 34454, second column, line 10, correct "used in the definition of "low and moderate income person" at § 570.3;" to read "used in the definitions of "low and moderate income person" and low and moderate income household" (as applicable) at § 570.3;".

19. Section 570.506(b)(2)(ii), on page 34454, second column, is correctly revised to read "The income characteristics of families and unrelated individuals in the service area; and".

20. In § 570.506(g)(5), on page 34456, first column, correct "the hiring and training of lower income residents and the use of local businesses." to read "the hiring and training of low and moderate income persons and the use of local businesses."

§ 570.606 [Corrected]

21. In § 570.606(b)(1)(iii)(B), on page 34459, third column, line 3, correct by removing "a" at end of line.

22. In § 570.606(d), on page 34461, second column, line 18 is corrected by removing the citation reference, "(see 24 CFR 570.201(i))".

§ 570.608 [Corrected]

23. In § 570.608(c), on page 34462, second column, in the introductory paragraph, correct by removing the last sentence, "These requirements shall be implemented not later than September 21, 1987."

24. In § 570.608(c)(2), on page 34462, third column, the definition for "Elevated blood lead level or EBL." is corrected to read, "Excessive absorption of lead, that is, a confirmed concentration of lead in whole blood of 25 μg/dl (micrograms of lead per deciliter of whole blood) or greater."

§ 570.609 [Corrected]

25. In § 570.609, on page 34463, second column, line 4, correct the word, "service" to read "services".

§ 570.610 [Corrected]

26. In § 570.610, on page 34463, second column, correct section heading to read, "Uniform administrative requirements and cost principles".

§ 570.611 [Corrected]

27. In § 570.611(a)(2), on page 34463, third column, in the parenthetical phrase on line 12, correct the word "of" to read "or".

§ 570.904 [Corrected]

28. In § 570.904(c)(2)(iv), on page 34469, first column, line 8, correct "(C)(1)" to read "(c)(1)".

Authority: Title I, Housing and Community Development Act of 1974 (42 U.S.C. 5301–20); and sec. 7(d), Department of Housing and Urban Development Act (42 U.S.C. 3535(d)).

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Grady J. Norris,

Assistant General Counsel for Regulations.

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24 CFR Part 570

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Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments; Technical Amendment

AGENCY: Department of Housing and Urban Development.