

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

> OFFICE OF Prevention, pesticides and Toxic substances

April 1, 2004

<u>Memorandum</u>

Subject:	Lower Risk Pesticide Chemical Focus Group's Assessment for Carbon Dioxide Tolerance Reassessment
From:	Mark Perry Product Reregistration Branch Special Review and Reregistration Division (7508C)
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The following is the Lower Risk Pesticide Chemical Focus Group's science assessment for carbon dioxide (PC Codes 016601, 800029). The purpose of this review is a reassessment of the exemption from the requirement of a tolerance under 40CFR 180.1049. This assessment summarizes available information on carbon dioxide. In performing this assessment, EPA has relied on a peer-reviewed evaluation performed by the Food and Drug Administration (FDA).

Carbon Dioxide (CO_2) is an odorless, colorless, noncombustible gas. Under ordinary conditions of temperature and pressure, the gas is one and one half times as dense as air, and is moderately soluble in water, dissolving at about a 1:1 ratio by volume. At 0.03%, it is the fourth most abundant gas in the Earth's atmosphere and is an essential component of plant and animal respiration. Animals exhale carbon dioxide as a metabolic byproduct, and plants use carbon dioxide by converting it to sugars and other forms of energy through photosynthesis. In the human body, carbon dioxide is involved in several vital functions, including the regulation of

respiration, the maintenance of acid-base balance, the liberation of oxygen to tissue and is an end-product of carbohydrate and fat metabolism. The average adult produces more than 500 grams of carbon dioxide per day, under resting conditions.

Carbon dioxide has many commercial uses. Its most well known use is in the production of carbonated beverages. It is also used in water softening, manufacturing of aspirin, as a propellant in aerosol cans and in the coffee packaging process. Solid carbon dioxide, or dry ice, is used as a refrigerant. Carbon dioxide is obtained for commercial use from chemical fermentation, from the burning of limestone or carbonaceous fuels, and from natural springs and wells. As a pesticide active ingredient, carbon dioxide is used indoors as a fumigant to control insects in stored food and feed by displacing oxygen in the container's atmosphere. It does not accumulate in treated raw agricultural commodities, but rather diffuses into the atmosphere following application. Currently there are four registered end-use products containing carbon dioxide as the active ingredient, as well as one experimental-use and one Special Local Needs registration. As a pesticide inert ingredient carbon dioxide is used as an aerosol propellant.

The Office of Pesticide Programs published its Carbon and Carbon Dioxide Reregistration Eligibility Decision (RED) Document in September of 1991. The RED considers the many vital functions which carbon dioxide performs in the human body as well as the available acute, sub-chronic and chronic studies performed on carbon dioxide. That document acknowledged that exposure to relatively high levels of carbon dioxide may result in serious health effects and even death through asphyxiation.

The Food and Drug Administration (FDA) has classified carbon dioxide as Generally Recognized As Safe (21CFR 184.1240) as a direct food additive. The 1979 FDA evaluation of carbon dioxide, entitled "Evaluation of the Health Aspects of Carbon Dioxide as a Food Ingredient," also considers the essential role of carbon dioxide in the human body and the available toxicity data. This evaluation found that although data relating directly to carbon dioxide safety as a food ingredient were not available, "there is substantial evidence that the amount of carbon dioxide ingested with foods is negligible compared with that produced normally by the body." The Evaluation also states that "[c]arbon dioxide also has been administered experimentally without ill effects in amounts orders of magnitude greater than from possible food sources." The FDA evaluation goes on to conclude that "there is no evidence in the available information on carbon dioxide that demonstrates, or suggests reasonable grounds to suspect, a hazard to the public when it is used at levels that are now current or that might reasonably be expected in the future."

Based on the available information on carbon dioxide, its expected use pattern, its safe history of use as a food additive, and its essential role in human metabolism and respiration, there is a reasonable certainty of no harm from exposure to carbon dioxide through its use in pesticides. Furthermore, there is no concern for potential sensitivity to infants and children. As with all chemicals, carbon dioxide must be used safely according to good manufacturing or good agricultural practices. The Agency believes that exposure to levels of concern of carbon dioxide are unlikely as a result of its use in pesticide products, and would be most appropriately addressed through the use of protective equipment, adequate ventilation, and labeling, not through the establishment of tolerance exemptions. References:

U.S. Environmental Protection Agency (EPA), 1991. Reregistration Eligibility Document (RED), Carbon and Carbon Dioxide.

U.S. Food and Drug Administration (FDA), 1979. Evaluation of the Health Aspects of Carbon Dioxide as a Food Ingredient. Prepared by Life Sciences Research Office, Federation of American Societies for Experimental Biology.