INFO #: 50707234

CustID: 3638
Fonterra Co-operative Group Limited
Interloans Librarian
Library
Private Bag 11029
Palmerston North , New Zealand .

Customer No:	**3638 / 87054**
Date of Order:	**04/03/2011**
Date of Shipping:	**09/03/2011**
Orderer:	**Interloans Librarian**
Department:	
Bill Ref:	**Sinclair, Sue**
Order No:	
Shipping method:	**eMail**
	interloans.pda@fonterra.com

Standard

Journal:	Prepared by the Select Committee of GRAS substances (SCOGS) Life Sciences
Citations:	(): 1979
Author:	Bethesda, M D
Title:	Evaluation of the health aspects of hydrogen peroxide as a food ingredient
ISSN:	

$60ill

Infotrieve Australia Pty
344 Ferntree Gully Road
Notting Hill VIC 3168
AUSTRALIA

Ph: +61-3-9544 4911
Fax: +61-3-9544 3277
Email: status@infotrieve.com.au
www.infotrieve.com

SCOGS-113

EVALUATION OF THE HEALTH ASPECTS OF HYDROGEN PEROXIDE AS A FOOD INGREDIENT

1979

Prepared for

Bureau of Foods
Food and Drug Administration
Department of Health, Education, and Welfare
Washington, D.C.

Contract No. FDA 223-75-2004

Life Sciences Research Office
Federation of American Societies
for Experimental Biology
9650 Rockville Pike
Bethesda, Maryland 20014

The Select Committee on GRAS Substances of LSRO is making its evaluation of these substances in full recognition of the foregoing provisions. In reaching its conclusions on safety, the Committee, in accordance with FDA's guidelines, is relying primarily on the absence of substantive evidence of, or reasonable grounds to suspect, a significant risk to the public health. While the Committee realizes that a conclusion based on such reasoned judgment is expected even in instances where the available information is qualitatively or quantitatively limited, it recognizes that there can be instances where, in the judgment of the Committee, there are insufficient data upon which to base a conclusion. The Committee is aware that its conclusions will need to be reviewed as new or better information becomes available.

In this context, the LSRO Select Committee on GRAS Substances has reviewed the available information on hydrogen peroxide and submits its interpretation and assessment in this report, which is intended for the use of FDA in determining the future status of this substance under the Federal Food, Drug, and Cosmetic Act.

I. INTRODUCTION

This report concerns the health aspects of using hydrogen peroxide as a food ingredient. It has been based partly on the information contained in a scientific literature review (monograph) furnished by FDA (1), which summarizes the world's scientific literature from 1920 through 1973.* To ensure completeness and currency as of the date of this report this information has been supplemented by searches of over 30 scientific and statistical reference sources and compendia that are generally available; use of new, relevant books and reviews and the literature citations contained in them; consideration of current literature citations obtained through computer retrieval systems of the National Library of Medicine; searches for relevant data in the files of FDA; and by the combined knowledge and experience of members of the Select Committee and the LSRO staff. In addition, an announcement was made in the Federal Register of April 6, 1979 (44 FR 20797-20800) that opportunity would be provided for any interested person to appear before the Select Committee at a public hearing to make oral presentation of data, information and views on the health aspects of using hydrogen peroxide as a food ingredient. The Select Committee received no requests for such a hearing on hydrogen peroxide.

As indicated in the Food, Drug, and Cosmetic Act [21 USC 321(s)], GRAS substances are exempt from the premarketing clearance that is required for food additives. It is stated in the Act and in the Code of Federal Regulations (2) [21 CFR 170.3 and 170.30] that GRAS means general recognition of safety by experts qualified by scientific training and experience to evaluate the safety of substances on the basis of scientific data derived from published literature. These sections of the Code also indicate that expert judgment is to be based on the evaluation of results of credible toxicological testing or, for those substances used in food prior to January 1, 1958, on a reasoned judgment founded in experience with common food use, and is to take into account reasonably anticipated patterns of consumption, cumulative effects in the diet, and safety factors appropriate for the utilization of animal experimentation data. FDA (2) recognizes further that it is impossible to provide assurance that any substance is absolutely safe for human consumption.

---

*The document (PB-241 957/0WF) is available from the National Technical Information Service, U.S. Department of Commerce, P.O. Box 1553, Springfield, Virginia 22161.

CONTENTS

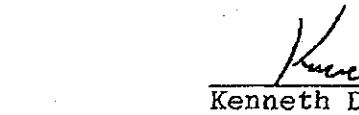
NOTICE

This report is one of a series concerning the health aspects of using the Generally Recognized as Safe (GRAS) or prior-sanctioned food substances as food ingredients, being made by the Federation of American Societies for Experimental Biology (FASEB) under contract no. 223-75-2004 with the Food and Drug Administration (FDA), U.S. Department of Health, Education, and Welfare. The Federation recognizes that the safety of GRAS substances is of national significance, and that its resources are particularly suited to marshalling the opinions of knowledgeable scientists to assist in these evaluations. The Life Sciences Research Office (LSRO), established by FASEB in 1962 to make scientific assessments in the biomedical sciences, is conducting these studies.

Qualified scientists were selected as consultants to review and evaluate the available information on each of the GRAS substances. These scientists, designated the Select Committee on GRAS Substances, were chosen for their experience and judgment with due consideration for balance and breadth in the appropriate professional disciplines. The Select Committee's evaluations are being made independently of FDA or any other group, governmental or nongovernmental. The Select Committee accepts responsibility for the content of each report. Members of the Select Committee who have contributed to this report are named in Section VII.

Tentative reports are made available to the public for review in the Office of the Hearing Clerk, Food and Drug Administration, after announcement in the Federal Register, and opportunity is provided for any interested person to appear before the Select Committee at a public hearing to make oral presentation of data, information, and views on the substances covered by the report. The data, information, and views presented at the hearing are considered by the Select Committee in reaching its final conclusions. Reports are approved by the Select Committee and the Director of LSRO, and subsequently reviewed and approved by the LSRO Advisory Committee (which consists of representatives of each constituent society of FASEB) under authority delegated by the Executive Committee of the Federation Board. Upon completion of these review procedures the reports are approved and transmitted to FDA by the Executive Director of FASEB.

While this is a report of the Federation of American Societies for Experimental Biology, it does not necessarily reflect the opinion of all of the individual members of its constituent societies.



Kenneth D. Fisher, Ph.D., Director
Life Sciences Research Office
FASEB

III. CONSUMER EXPOSURE DATA

On the basis of surveys conducted by the National Research Council (NRC), the amount of hydrogen peroxide used in foods in 1975 was reported to be 630,000 kg (98). This was approximately sixty percent more than the amount used in 1970 (13), based on reports from those respondents providing information for both years. The quantity reported in 1975 is equivalent to a per capita daily "intake" of 8 mg. However, this is an illusory value, for only traces, if any, of the added hydrogen peroxide would survive food processing. The ingestion of hydrogen peroxide from foods is almost certainly miniscule. Man's exposure to hydrogen peroxide from other sources is also very slight under normal conditions. Small amounts may be absorbed from common pharmaceutical preparations (dentifrices, mouthwashes, deodorants) and from contaminated atmospheres. From 40 to 180 parts per billion of hydrogen peroxide have been reported in the atmosphere during smog formation, corresponding to a potential daily respiratory intake of 0.5 to 2.5 mg (14).

Because of these uses, the FDA requested that the Select Committee evaluate the health aspects of employing hydrogen peroxide as an antimicrobial agent in cheese and whey processing, as well as using it as a bleaching agent (12).

TABLE I

Authorized Uses of Hydrogen Peroxide

Use	Limitations	Authorization	Comment
GRAS			
Bleaching agent	Good manufacturing practice	21 CFR 182.1366	
In dry food packaging	Cotton and cotton fabrics	21 CFR 182.70	
To produce bleached lecithin	No residual unreacted hydrogen peroxide		Unpublished GRAS (5)
Treatment of wine:			
To reduce aldehydes in distilling materials	Not to exceed 200 ppm	27 CFR 240.1051	Deemed GRAS for these uses by Department of the Treasury (6)
To facilitate secondary fermentation in production of sparkling wines	Not to exceed 3 ppm, with no residual amount		
OTHER USES			
A. Standards of identity:			
Cheese production			
Cheddar	Not to exceed 0.05 percent by weight and must not contain preservative	21 CFR 133.113	Excess H_2O_2 must be destroyed by catalase
Colby		21 CFR 133.118	
Washed and soaked curd		21 CFR 133.136	
Swiss and Emmentaler		21 CFR 133.195	
Dried egg treatment			
Whole eggs	H_2O_2 must comply with USP specifications	21 CFR 160.105	Treated with glucose oxidase-catalase preparation to remove glucose
Egg whites		21 CFR 160.145	
Egg yolks		21 CFR 160.185	
Bleaching of tripe	H_2O_2 must be removed after use, by rinsing with water	9 CFR 318.7	(7)
B. Food additives, direct:			
Modification of food starch	0.45 percent	21 CFR 172.892	Bleaching agent
Production of hydroxylated lecithin	"...separated fatty acid fractions...has an acetyl value of 30 to 38."	21 CFR 172.814	
C. Food additives, indirect:			
Component of adhesives		21 CFR 175.105	

II. BACKGROUND INFORMATION

Hydrogen peroxide (H_2O_2) is a strong oxidizing agent that is used extensively in industry and medicine. It is usually available as aqueous solutions in concentrations of 3, 30, or 90 percent by weight. The 3 percent solution is used as a topical antiseptic and cleansing agent, and as a constituent in mouthwashes, dentifrices, and sanitary lotions; the 30 percent as an effective bleaching agent and for other industrial uses; and the 90 percent as a vigorous oxidizer of rocket fuels. The anhydrous form is a colorless, bitter-tasting liquid with an ozone-like odor. In the absence of stabilizing agents (e.g., phosphates, tin), hydrogen peroxide solutions are unstable and decompose upon standing, agitation, exposure to light, or heating. Hydrogen peroxide reacts vigorously with many oxidizing as well as reducing agents. Concentrated solutions are highly caustic to the skin (3).

The Food Chemicals Codex (4) specifies that the composition of solutions of hydrogen peroxide used in foods must be within the range stated on the label or contain not less than the stated amount. The limits of impurity in parts per million are as follows: acidity (as H_2SO_4), 300; arsenic (as As), 3; heavy metals (as Pb), 10; iron, 0.5; phosphate, 50; tin, 10; and residue on evaporation, 60. It should be stored in a cool place in containers with vented stoppers.

The Code of Federal Regulations (2) lists hydrogen peroxide as a multiple purpose GRAS food substance specifically listed as GRAS when used as a bleaching agent in accordance with good manufacturing practice [21 CFR 182.1366]. It is also considered GRAS as a substance migrating to food from cotton and cotton fabrics used in dry food packaging [21 CFR 182.70]. It has been accorded unpublished GRAS status for bleaching of lecithin, provided that no residual hydrogen peroxide remains after treatment (5). Additional authorized uses are summarized in Table I.

In addition to its effectiveness as a bleach, hydrogen peroxide has proved to be a useful antimicrobial agent. This latter property has been utilized in some countries as a preservative of milk (8) and whey (9). Thus, treatment of milk with hydrogen peroxide is officially recognized in Italy as a substitute for pasteurization (10). The Joint FAO/WHO Expert Committee on Food Additives has approved the use of hydrogen peroxide in milk as an emergency measure when other methods of microbiological control, such as pasteurization, are not available (11). In the United States hydrogen peroxide cannot be used as a substitute for pasteurization (10), but it is used in the manufacture of certain cheeses (Table I) and in whey processing (12).