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Safety challenged

FDA may act on claims that excessive use of sugar substitutes threatens health

by Barbara J. Culliton

Americans consume 8,000 tons of artificial sweeteners every year—in pop, coffee, dietary foods, candy and the like—confident that the chemical sweeteners are safe. Manufacturers insist that they are; the sugar industry—watching a \$300 million inroad into its market—insists they are not. Each side presents evidence to support its claim; both sides' arguments purport to be scientific, and conclusive.

As recently as 1965, manufacturers of the nonnutritive, noncaloric sweet-eners chemically known as cyclamates, had the Food and Drug Administration on their side. "There is no evidence," FDA stated then, "that cyclamates, at present use levels, are a hazard to health." But that position rested largely on old data, submitted when cyclamates were first approved as food additives in the early 1950's, when common use was a drop or two to sweeten coffee and only one company sold diet cola.

On another look, last year FDA noted the boom in diet drinks, saw that cyclamates were added to innumerable foods and quietly modified its stand. "There is no evidence, yet," it hedged.

Then both camps swamped FDA with detailed evidence pro and con, and now there are indications that within a few months FDA, armed with its own data, will change its tune again.

At present there is no law or regulation about labeling cyclamates. There are cautionary warnings, in fine print on many products, that artificial sweeteners are for persons who "must restrict" their dietary intake of sugar. Although they appear to apply to cyclamates, they technically are required only for the saccharin in common cyclamate-saccharin combinations.

Both cyclamate, which is 30 times as sweet as sugar, and saccharin, which is 300 times as sweet, leave a bitter taste if used singly. Together, in a mixture of 10 parts cyclamate and one part saccharin, they leave no bitter aftertaste. Cyclamates, chemical salts, are produced from cyclohexylamine, a material also used in the manufacture of corrosion inhibitors and rubber chemicals.

The major issue in what both cyclamate manufacturers and sugar people



The warning is only in fine print.

see as potentially a billion-dollar battle rests on the quantity consumed. There is no doubt that in large doses cyclamates cause softening of the stools, sometimes diarrhea. Pediatricians reportedly prescribe diet colas as laxatives.

Scientists for Abbott Laboratories, Chicago, the largest cyclamate producer, claim that people simply do not consume enough of the chemical to cause any trouble. Five grams (that contained in eight 16-ounce bottles of pop) is considered a large dose. Their statistics show that even among teenagers, who consume more than any other group, three and a half grams a day is unusual. Researchers supported by sugar interests dispute this.

They cite evidence of more serious cyclamate-induced effects. In studies on rats, Drs. Paul Nees and Philip Derse of the Wisconsin Alumni Research Foundation, found tissue changes in the testes, kidneys, adrenals and pancreas. Their work is supported by the Sugar Research Foundation, New York.

French researchers report structural changes in the intestines of animals ingesting cyclamates. In April, a team of Austrian scientists showed liver changes in four guinea pigs fed cyclamates and impaired coagulation of the blood in rabbits.

To respond to these challenges to the safety of their product, Abbott scientists recently called a press conference "to set the record straight." They charged

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. . . sweeteners

excessive cyclamate levels, "far out of line with any possible human consumption," as a cause of adverse experimental effects, and said, "over the past 18 years, millions of persons have used cyclamate without ill effects." The Wisconsin researchers admittedly tested very large doses.

But the argument does not end there. When cyclamates were first approved, scientists believed they were excreted unchanged from the body. But testing within the last four years indicates that some individuals do metabolize the chemical, breaking it down into its original cyclohexylamine.

Dr. Derse recently found four others in animal urine but does not know yet if they are toxic.

Abbott scientists claim only about 10 percent of individuals metabolize cyclamates. Others put the figure closer to 50 percent.

Within the last three months, two groups of researchers studying cyclohexylamine have shown that in animals it increases blood pressure and speeds heart rates. One team was headed by Dr. Robert L. Dixon of the University of Washington, Seattle; the other by Dr. Frederick Coulston of Albany Medical College in New York. (Dr. Dixon's research is supported by the SRF. He hopes soon to get a grant from FDA to investigate the action of cyclamates on drugs. Dr. Coulston has funds from Abbott, the SRF and a \$46,000 grant from the FDA.) "Cyclohexylamine, injected directly into an animal, acts like amphetamine," Dr. Dixon says, "but it has a much milder effect on the sympathetic nervous system."

Abbott scientists, studying this effect in humans in whom the metabolite occurs only as a by-product, found no such response.

A more serious threat may exist for diabetics, who must avoid sugar. Unpublished, preliminary evidence exists that cyclamates may interfere with the pharmacologic action of a class of diabetic drugs called hypoglycemics. These drugs are prescribed for adult diabetics to facilitate their release of insulin.

Last March Dr. James L. Goddard, then FDA commissioner, asked the National Academy of Sciences to take on the role of arbiter among the interests by forming a committee to evaluate the data. Originally, the judges' decision was expected to reach FDA by Oct. 1, but the time has been extended to Thanksgiving. An FDA spokesman pegs St. Valentine's Day as the time it will be released to the public.

Meanwhile, NAS committee members and FDA spokesmen are hinting that the cyclamate manufacturers will not be pleased with the decision.

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