

The Lactaid Story 39

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Dairy products are an important part of a healthy diet. Millions of Americans have difficulty digesting milk and other dairy products. In fact, it is estimated that more than one-third of the U.S. population has some form of lactose intolerance—an inability to digest lactose, the principal sugar of almost all mammal milk. Cow's milk contains about 4.8 percent lactose. The degree of intolerance varies with a person's race or ethnic group (see table 1). Lactose intolerance arises because the human body has stopped producing an intestinal enzyme called lactase, which hydrolyzes lactose (breaks it down to the simple sugars glucose and galactose) during digestion. In the absence of the enzyme, sensitive people may suffer uncomfortable gastrointestinal symptoms such as bloating, cramps, diarrhea, gas, and nausea.

Dairy products are the best sources of calcium and are also rich in protein, magnesium, phosphorus, vitamins A and D, and the B vitamins. These nutrients are needed for development of strong bones and maintenance of good health, especially in children, teenagers, and the elderly. Lactose-intolerant people need to avoid milk as a beverage, although they may be able to tolerate small amounts of milk products such as yogurt or ice milk, especially if they are part of a meal.

In the 1950's, it was thought that it might be possible to modify lactose in milk by adding an enzyme. But this became possible only with the development of commercial processes that provide lactase from nonhuman sources. The enzymes most widely used to break down lactose are taken from yeasts such as *Kluyveromyces marxianus* var. *lactis* (formerly *K. lactis*) and *Kluyveromyces fragilis* and from fungi such as *Aspergillus niger* and *Aspergillus oryzae*.

Table 1. Estimated rate of lactose intolerance in various U.S. population groups

Population group	Intolerance (Percent)
African-American	45 - 81
Mexican-American	47 - 74
Asian-American	65 - 100
Native-American	50 - 75
North European	6 - 25

Source: Houts, S.S., 1988, "Lactose Intolerance," *Food Technology*, 42:110.

Research Developments

To evaluate the use of lactase in product manufacture, scientists at the Eastern Regional Research Center (ERRC), ARS, USDA, first evaluated the properties of the available enzymes, because the properties of lactase depend on its source. Lactase

from fungal sources was shown to function most efficiently under acid conditions (such as in the digestive tract), whereas lactase preparations from the *Kluyveromyces* yeasts were best suited for the treatment of milk and sweet whey, a byproduct of cheesemaking.

In a series of test products made from lactase-treated milk, 87-95 percent of the lactose was broken down. The enzyme used was isolated from *K. marxianus* var. *lactis* in the form of a colorless, free-flowing powder. In this process, freshly pasteurized whole or skim milk was preheated to 32 °C, and then treated with 300 parts per million (ppm) lactase for about 3 hours with continuous stirring; another method was to treat refrigerated milk with 150 ppm lactase for 16-18 hours. Gener-

ally, about the only change in flavor noticed in the lactase-treated beverage was increased sweetness (glucose and galactose are sweeter than lactose). Taste-panel studies showed that the sweeter taste of the milk was acceptable and, in some cases, enhanced the milk's desirability.

Commercialization

The SugarLo Company (progenitor of Lactaid Inc.) of Pleasantville, NJ, contacted ARS after the first publication of ERRC, ARS research results in October 1974. The company first obtained an exclusive license for the *K. marxianus* var. *lactis* lactase enzyme, manufactured by Gist-Brocades, Inc., Delft, Netherlands. After the safety and effectiveness of this enzyme were thoroughly analyzed, a Generally Rec-



Lactose-free products are commercially available in supermarkets. Agricultural Research Service scientists at the Eastern Regional Research Center first evaluated

the properties of the available enzymes to produce lactose-free products.
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ognized as Safe (GRAS) Affirmation Petition was filed and subsequently granted.

SugarLo first marketed the enzyme in single-dose packets for the lactose-intolerant consumer to use to break down about 70 percent of the lactose in 1 quart of milk in 24 hours in the refrigerator. The powder was phased out in 1981 in favor of a sterile liquid form that is much easier to use. The liquid is sold in sizes to treat 75 quarts, 30 quarts, or 12 quarts of milk. Cost to the consumer is about 5 cents per glass of milk.

The availability of the liquid form of the enzyme made possible the commercial-scale production and marketing of a fluid milk already treated with lactase. In a milk processing plant, the sterile liquid (lactase) is added to previously pasteurized milk and held for 24 hours. After about 70 percent of the lactose has broken down, the milk is pasteurized again to stop further breakdown. Then the milk is packaged for retail sale. At present, the treated fluid milk is available as lactase-treated chocolate, nonfat, 1-percent-fat, 2-percent-fat, or calcium-fortified milk.

Further products developed by Lactaid Inc. include cottage cheese and pasteurized-process American cheese. Lactase-treated cottage cheese contains 50 percent less salt, with minimum effect on flavor.

Because treating milk with the liquid form of the enzyme may be inconvenient, Lactaid Inc. developed lactase capsules, which they began marketing to health professionals in 1985. Previous research had shown that if lactase is delivered to the small intestine, symptoms in lactose-intolerant persons are reduced. In addition, if the right dose is taken, milk lactose can be broken down in the body even in the presence of solid food. Tablets are now available for both consumers and health professionals. Each tablet contains lactase from the fungus *Aspergillus oryzae*; one to two tablets taken with a meal will usually handle the lactose in a glass of milk. In 1990, Sterling Drug Co. introduced a chewable tablet called Dairy-Ease.

This successful transfer of information between ARS scientists and Lactaid Inc. has resulted in assorted lactose-modified dairy foods and in lactase in liquid or tablet form for home use. Research and development activities are also continuing, for example in the development of new sources of lactase and in the development of new food products such as a low-lactose, low-fat, milk-based beverage powder. Because the total elimination of lactose-containing foods from the diet is nutritionally unwise, these new products have helped to make the nutrients of milk available to everyone. □