



Charles Denby, Ph.D.
Berkeley Fermentation Science Inc.
15555 E 14th Street, Suite 525
San Leandro, CA 94578

Re: GRAS Notice No. GRN 001285

Dear Dr. Denby:

The Food and Drug Administration (FDA, we) completed our evaluation of GRN 001285. We received Berkeley Fermentation Science Inc. (Berkeley Fermentation Science)'s GRAS notice on June 9, 2025, and filed it on November 5, 2025. Berkeley Fermentation Science submitted an amendment to the notice on February 6, 2026, providing additional information and clarifications regarding the batch analyses, dietary exposure, and the identity, taxonomy, and characterization of the parent and notified yeast strains.

The subject of the notice is *Saccharomyces cerevisiae* "BY-927" (*S. cerevisiae* "BY-927") expressing a gene encoding an a-acetolactate decarboxylase (ALDC) enzyme from *Acetobacter aceti* for use in beer brewing at a level of $7.5 \times 10^5 - 1.5 \times 10^6$ cells per mL per degree Plato of wort to improve beer flavor by preventing the formation of diacetyl.^{1,2} The notice informs us of Berkeley Fermentation Science's view that this use of *S. cerevisiae* "BY-927" is GRAS through scientific procedures.

Berkeley Fermentation Science describes *S. cerevisiae* "BY-927" as a liquid slurry of the strain and states that *S. cerevisiae* "BY-927" prevents formation of diacetyl (an off-flavor compound) by expressing ALDC that converts a-acetolactate, the chemical precursor of diacetyl, directly into acetoin, which is then converted to butane-2,3-diol. Berkeley Fermentation Science describes the identity and construction of *S. cerevisiae* "BY-927" and states that the strain is non-pathogenic and non-toxicogenic. The host organism (parent strain) is an industrial brewing strain of *S. cerevisiae* (Chico Ale Yeast) with a long history of use in commercial beer production. Berkeley Fermentation Science states that the genetic modification is the integration of a synthesized gene encoding ALDC, along with promoter and terminator sequences from *S. cerevisiae* "S288C", into the genome of the parent strain at a single locus. Successful integration was confirmed by diagnostic polymerase chain reaction and sequencing. Berkeley Fermentation Science states that an antibiotic resistance gene used for selection during strain development

¹Degrees Plato is used in the brewing industry to quantify the concentration of extract (mainly fermentable sugars but also other soluble solids) in wort as a percentage of weight.

²Berkeley Fermentation Science states that the intended use level is consistent with standard brewing industry practice.

was subsequently removed from *S. cerevisiae* “BY-927”.

Berkeley Fermentation Science states that *S. cerevisiae* “BY-927” is manufactured by fermentation of a pure culture under controlled conditions. After fermentation the yeast cell mass is separated from the fermentation medium by flocculation and settling and is collected as a concentrated liquid slurry. Berkeley Fermentation Science states that *S. cerevisiae* “BY-927” is manufactured in accordance with current good manufacturing practices and that all raw materials and processing aids are food-grade, are used in accordance with applicable U.S. regulations, are GRAS for the intended use, or are the subject of an effective food contact notification. Berkeley Fermentation Science states that none of the materials used in the manufacture of *S. cerevisiae* “BY-927” is or is derived from a major food allergen.

Berkeley Fermentation Science provides specifications for *S. cerevisiae* “BY-927” that include viable yeast cells (> 95%) and limits for lead (<10 µg/kg). Berkeley Fermentation Science provides the results from the analyses of five non-consecutive batches to demonstrate that *S. cerevisiae* “BY-927” can be manufactured to meet these specifications.

Berkeley Fermentation Science states that the intended use of *S. cerevisiae* “BY-927” is substitutional for other *S. cerevisiae* strains currently used in commercial beer production and, therefore, dietary exposure to *S. cerevisiae* is not expected to increase. Berkeley Fermentation Science states that the dietary exposure to *S. cerevisiae* from the intended uses will be extremely limited because the yeast is removed from beer as part of the standard brewing process. Berkeley reports the levels of the flavoring compounds (diacetyl and acetoin) and their metabolite butane-2,3-diol present in beer produced by *S. cerevisiae* “BY-927” and states that these levels are similar to or less than the levels in commercial beers currently consumed. Therefore, there is no change in the dietary exposure to these compounds from the intended uses of *S. cerevisiae* “BY-927”.

Berkeley Fermentation Science discusses the safety of *S. cerevisiae* “BY-927” by addressing the safe use of the *S. cerevisiae* parent strain and donor organisms (*A. aceti* and *S. cerevisiae* “S288C”) and the ALDC enzyme in the food industry. Berkeley Fermentation Science incorporates into their notice and provides summaries of the information pertaining to the safety of genetically engineered *S. cerevisiae* strains used in fermented beverages discussed in GRNs 000120, 000175, 000350, 000798, 001062, 001094, and 001096.³ Berkeley Fermentation Science evaluated the ALDC enzyme for toxigenic and allergenic potential using bioinformatic analyses and concluded it does not pose a safety concern. Furthermore, untargeted metabolomic analyses did not identify any unexpected metabolic products that would warrant a safety assessment.

Based on the totality of the data and information, Berkeley Fermentation Science concludes that *S. cerevisiae* “BY-927” is GRAS for its intended use.

³ Various *S. cerevisiae* strains were the subjects of GRNs 000120, 000175, 000350, 000798, 001062, 001094, and 001096. We evaluated these notices and responded in letters dated June 30, 2003, January 6, 2006, February 4, 2011, August 13, 2019, April 5, 2023, November 28, 2023, and July 5, 2023, respectively, stating that we had no questions at the time regarding the notifiers’ GRAS conclusions.

Section 301(ll) of the Federal Food, Drug, and Cosmetic (FD&C Act)

Section 301(ll) of the FD&C Act prohibits the introduction or delivery for introduction into interstate commerce of any food that contains a drug approved under section 505 of the FD&C Act, a biological product licensed under section 351 of the Public Health Service Act, or a drug or a biological product for which substantial clinical investigations have been instituted and their existence made public, unless one of the exemptions in section 301(ll)(1)-(4) applies. In our evaluation of Berkeley Fermentation Science’s notice concluding that *S. cerevisiae* “BY-927” is GRAS under its intended conditions of use, we did not consider whether section 301(ll) or any of its exemptions apply to foods containing *S. cerevisiae* “BY-927”. Accordingly, our response should not be construed to be a statement that foods containing *S. cerevisiae* “BY-927”, if introduced or delivered for introduction into interstate commerce, would not violate section 301(ll).


Conclusions

Based on the information that Berkeley Fermentation Science provided, as well as other information available to FDA, we have no questions at this time regarding Berkeley Fermentation Science’s conclusion that *S. cerevisiae* “BY-927” is GRAS under its intended conditions of use. This letter is not an affirmation that *S. cerevisiae* “BY-927” is GRAS under 21 CFR 170.35. Unless noted above, our review did not address other provisions of the FD&C Act. Food ingredient manufacturers and food producers are responsible for ensuring that marketed products are safe and compliant with all applicable legal and regulatory requirements.

In accordance with 21 CFR 170.275(b)(2), the text of this letter responding to GRN 001285 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

**Susan J.
Carlson -S**

 Digitally signed by Susan J.
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Susan J. Carlson, Ph.D.
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