

# Red Yeast Rice: A Review

As early as the first century, red yeast rice was used as a food color, preservative, and flavoring in many East Asian countries. An ancient Chinese pharmacopoeia, the Ben Cao Gang Mu of Li Shi-zhen, cited fermented rice as a medication that was helpful for improving digestion and revitalizing the blood. In 1590, a Chinese medical book included a red yeast rice monograph which described the fermented product's medical properties.<sup>1</sup> Today, red yeast rice is manufactured with modern technology, and sold globally as a dietary supplement.

Red yeast rice derives its name from the distinct red color it acquires after fermentation. The process involves cultivating *Monascus purpureus* mold on a rice substrate under tightly controlled time, pH, and temperature conditions. The process results in red yeast rice with trace amounts of fatty acids and minerals along with monacolin K, dihydromoncolin, and monacolin I to VI.<sup>1</sup>

Monocolin compounds are believed to inhibit the production of cholesterol by blocking HMG-CoA reductase, a key liver enzyme responsible for manufacturing cholesterol. One of the compounds, monacolin K, is assumed to be the compound which helps maintains healthy LDL cholesterol levels.<sup>2</sup>

## Manufacturing Process

Producing impurity-free, high-quality red yeast rice requires tight control of incoming raw



materials and precise management of the fermentation process. Sylvan uses state of the art processing equipment to craft high-quality, pure, USDA-certified, organic, all natural, GMO-free Synastat Red Yeast Rice, and in fact since 1998, Sylvan Bio has been the sole Red Yeast Rice manufacturer in the U.S.

The Sylvan process starts with organic, 100% USA-sourced rice substrate. Inoculation takes place under aseptic conditions in stainless steel blenders. The red yeast rice is then transferred into specialized growing bags in a class 100 clean room. Sylvan's drying, milling, and blending process allows for a controlled method to insure uniform drying and sterilization.

Sylvan's Quality Assurance Program insures that Synastat is manufactured under Good

Manufacturing Practices (GMP). The procedures assure that Synastat is coliform, heavy metal, and citrinin free. This cannot be said of all imported red yeast rice.

## About Citrinin

Citrinin is a naturally occurring mycotoxin which may appear in *Monascus purpureus*. Research has shown citrinin to cause kidney failure in animals at concentrations of 35 mg/kg, and while its exact effect on humans is unknown, it is suspected to be hepatotoxic and nephrotoxic even at low levels.<sup>3</sup>

Citrinin may develop during red yeast rice fermentation if the process is poorly controlled. In a 2010 survey of 12 red yeast rice products purchased online, four products were found with elevated citrinin levels, one of which totaled 288.3 ug/day of citrinin if the daily dose were taken.<sup>4</sup>

Sylvan's manufacturing process, along with carefully managed quality control procedures and batch testing, assures that citrinin is not present in Sylvan products. Products are tested for citrinin at 200 ppb (parts per billion). Since citrinin is not detectable at 1 ppm, Synastat Red Yeast Rice is extremely safe to use.

## Side Effects and Counter-Indications

Side effects of red yeast rice are reported to be rare, and include headache, stomach ache or bloating, gas, dizziness, heartburn, muscle aches and weakness.<sup>5</sup> Red yeast rice has been studied as an option for patients with cholesterol problems who cannot take statins.<sup>7</sup>

The lack of research and safety data among children and adolescents under the age of 18 as well as among pregnant or breastfeeding

women indicates that red yeast rice should not be used by these groups.<sup>4</sup>

Red yeast rice should not be taken by people taking cholesterol medication or anticoagulants. Grapefruit juice and grapefruit may increase the probability of side effects.

Red yeast rice may lower Coenzyme Q10 levels, leading to fatigue or muscle aches and pains.<sup>5</sup> For this reason, some dietary supplement companies combine red yeast rice with CoQ10. Synastat is available with CoQ10 sourced in the USA.

## Research

A randomized, placebo-controlled study in the

Extensive research has been conducted with red yeast rice. These studies were part of the more than 20 submitted to the European Food Safety Administration (EFSA) as part of Sylvan Bio's opinion application.<sup>6</sup>

*Annals of Internal Medicine* in 2009 examined the combination of Sylvan Red Yeast Rice and therapeutic lifestyle changes among participants who had discontinued statin use.

Sixty-two people with dyslipidemia and a pattern of discontinuing statin therapy were randomly assigned either 1,800 mg of Sylvan Red Yeast Rice or a placebo taken twice daily for 24 weeks. Participants also were enrolled in a 12-week therapeutic lifestyle program. LDL cholesterol (LDL-C) blood serum levels were measured at the 12- and 24 week intervals. LDL-C levels were found to be significantly lower among the red yeast rice group.

Within the intervention group, LDL-C decreased an average of 43 mg/dL from baseline at week 12 and 35 mg/dL at week 24. In comparison, LDL-C decreases in the placebo group were 11 mg/dL at week 12 and 15 mg/dL at week 24. While limited, the study concluded that the combination of red yeast rice and a therapeutic lifestyle decreased LDL-C without increasing pain levels.<sup>8</sup>

A study published in the *American Journal of Cardiology* in 2010 assigned 43 adults with dyslipidemia and a history of statin discontinuation either 2,400 mg twice daily of red yeast rice or 20 mg of pravastatin twice daily for 12 weeks. During the same period, subjects were enrolled in a 12-week therapeutic lifestyle program. The primary outcome included treatment discontinuation because of myalgia, and a daily pain severity score. The incidence of withdrawal was 5% (1 of 21) in the red yeast rice group and 9% (2 of 22) in the pravastatin group ( $p = 0.99$ ).

There was no significant difference in muscle strength between the groups ( $p = 0.61$  at week 4,  $p = 0.81$  at week 8, and  $p = 0.82$  at week 12). LDL-C decreased 30% in the red yeast rice group and 27% in the pravastatin group.<sup>9</sup>

A randomized, double-blind, placebo-controlled, unpublished, proprietary study was performed with Sylvan Red Yeast Rice in 2006. A total of 85 people with hypercholesterolemia who were not taking lipid-lowering medications were randomly assigned one of three daily regimens. One group received 2.4 g of red yeast rice, the second group received 1.2 g, and the third group received a placebo. The regimens were followed for 12 weeks. LDL-cholesterol concentrations were measured at baseline, and weeks 4, 8 and 12. There was a statistically significant change in LDL-cholesterol concentrations from baseline to week 12. Pair-wise comparisons between

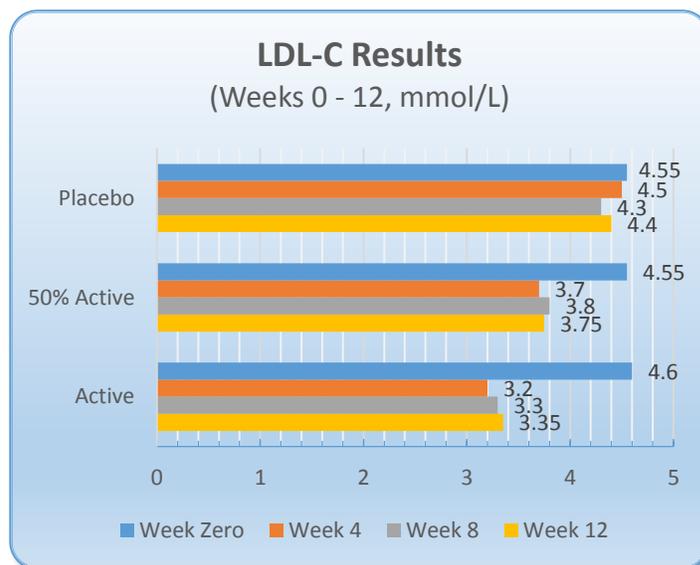


Figure 1. Starting and ending LDL-C levels for each of the three arms of an Australian study<sup>10</sup> after 12 weeks

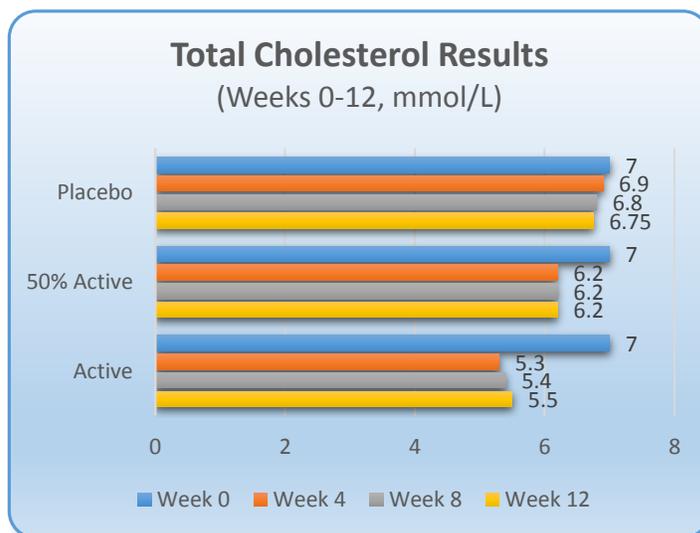


Figure 2. Starting and ending Total Cholesterol levels for each of the three arms of an Australian study<sup>10</sup> after 12 weeks. Note the decrease in the active group.

groups, adjusted by the Bonferroni correction, showed a significant reduction in LDL-C in the 2.4 g group compared to placebo ( $p < 0.0001$ ). No differences were observed between the 1.2 g and placebo groups. Total cholesterol only decreased in the active group.<sup>10</sup>

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