Stay Informed: Understanding the Impact of the Red Dye No. 3 Ban on Pregnancy and Breastfeeding

You may have heard recently that the Food and Drug Administration (FDA) has banned Federal Food, Drug, and Cosmetic Act (FD&C) Red No. 3. In this blog, we will review details about the ban, including why it was enacted, and the timeline for removing FD&C Red No. 3 from products. Our goal is to equip you with information to help make informed decisions. Be sure to check back, as we'll continue updating this post with the latest developments.

All food dyes, called color additives, must be approved for use by the FDA before manufacturers can use them. Color additives can be synthetic (lab made) or naturally derived from plants, animals and minerals. Manufacturers submit information about safety and manufacturing to the FDA in order to receive approval.

What is Red No. 3?

FD&C Red No. 3., also found on food labels as Red 3 or Red No. 3, is a synthetic food dye that gives foods and drinks a bright, cherry-red color. Red No. 3 can be found in some cake icing, candies, and other food items. Red No. 3 is also used in some oral medications and supplements.

Red No. 3 is a complicated formula for those of us not in the food manufacturing business. Specifically, the FDA reports that the color additive FD&C No. 3 is monohydrate of 9-6-hydroxy-2,4,5,7-tetraiodo-3H-xanthen-3-one, disodium salt, with smaller amounts of lower imdinated fluoresceins.

Why is Red No. 3 being banned?

Red No. 3 food dye is being banned because studies found that at high doses, the dye caused cancer in male laboratory rats. Studies in other animals or in humans did not show an increased chance for cancer.

The way that the food dye causes cancer in laboratory rats involves a mechanism not present in humans, so it is not known if this could also be a risk for humans.

Has Red No. 3 been associated with birth defects or problems with breastfeeding?

Studies have not been done to research this.

When is the ban taking effect?

On January. 15, 2025, the FDA announced that Red No. 3 will be banned from all products, including medications and foods. However, this ban allows manufacturers time to phase out the use of Red No. 3. Manufacturers who use Red No. 3 in food will have until January 15, 2027 to remove it from their products. Manufacturers of oral medications and supplements will have until January 18, 2028 to remove it.

Is FD&C Red No. 3 used in cosmetics or topical medications?

Red No. 3 has not been allowed in cosmetics, or topical medications, by the FDA since at least 1990.

How can I confirm if my food has Red No. 3?

To learn if your food has Red No. 3, look at nutrition facts on the product's label. The nutrition facts label lists calories and serving size, as well as other information. Below the nutrition facts, you will find an ingredients list. Ingredients are listed in order of those found in highest amounts to those found in smallest amounts in the product. For example, if the first ingredient is water, this means that most of the product is water, and each ingredient listed after that is found in the product in smaller amounts.

Here is a sample of a products' ingredients. Red No.3 is listed as less than 2% of the product.



You can learn more from the FDA announcement here: FDA Consumer Announcement

FDA Red No 3

FDA Red No 3 composition

FDA Color Additives for Consumers

Questions? Call 866.626.6847 | Text 855.999.3525 | Email or Chat at MotherToBaby.org.

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