



The Honorable Edith Ramirez, Chairwoman
Federal Trade Commission
600 Pennsylvania Ave, NW
Washington, DC 20580

January 21, 2014

Dear Chairwoman Ramirez:

This week, Consumer Reports, an independent non-profit research and testing organization, is releasing the results of its testing of sodas and soft drinks for the presence of 4-MeI, a potentially-carcinogenic chemical byproduct of the production of certain types of caramel color. Caramel color is added to many foods and beverages consumers buy every day, primarily to make these products brown in color. Twelve brands of sodas and soft drinks from five manufacturers – including Coca-Cola, Pepsi, and Goya – were tested. The full findings will be featured online on January 23, 2014 at www.ConsumerReports.org.

As a result of these findings, Consumer Reports and its policy and advocacy arm, Consumers Union, submitted a Citizen Petition with the U.S. Food and Drug Administration's Office of Food Additive Safety on January 21, 2014 regarding the color additive "caramel color."

Along with our concerns outlined in the Citizen Petition, related to the presence of 4-MeI in certain types of caramel color and a request for the specific labeling of caramel colors, we are writing today to share our concerns with your office regarding the false representation and deceptive marketing practices by caramel color manufacturers.

Two leading caramel color manufacturers, D. D. Williamson and Sethness, represent caramel color as Generally Recognized as Safe (GRAS) by the Food and Drug Administration (FDA). The American Beverage Association (ABA), the trade association representing the beverage industry, also states on several of its webpages that caramel color is considered Generally Recognized as Safe by the FDA (see enclosed screenshots).

This representation is false and misleading, since the Federal Food, Drug and Cosmetic Act's (FFDCA) Color Additive Amendment of 1960 states that food color additives (caramel color meets the definition of a food color additive), must be specially regulated. Caramel color is therefore not considered Generally Recognized as Safe by the FDA.

We believe the practice by color manufacturers and the ABA of representing caramel color as Generally Recognized as Safe to its customers (food and beverage manufacturers) and to the general public violates the Federal Trade Commission Act's prohibition on deceptive practices in commerce. 15 U.S.C. 45(a)(1) states: "Unfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices in or affecting commerce, are hereby declared

unlawful.” The Act also empowers and directs the FTC to prevent corporations from using “unfair or deceptive acts or practices in commerce” (15 U.S.C. 45(a)(2)).

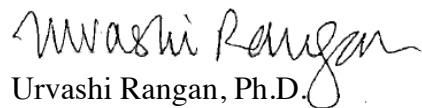
FDA regulations governing caramel color are confusing, in large part due to the fact that “caramel,” the ingredient with a similar name, is considered Generally Recognized As Safe. We are concerned that caramel color manufacturers and the ABA are adding to this confusion by falsely representing their caramel color additives - with a similar name - as the same substance.

The distinction between “caramel” as a Generally Recognized as Safe substance (21 CFR 82.1235) and “caramel color” as a food color additive (21 CFR 73.85) is important. Color additives are used primarily for the purpose of imparting color to foods and beverages and confer no nutritional, preservative or other functional benefits to foods or beverages. Since their use is purely aesthetic and unnecessary, color additives must meet a higher threshold for safety than substances that are regulated as Generally Recognized as Safe.

This representation of caramel color as Generally Recognized as Safe is also misleading to consumers who are interested in learning more about caramel color and its safety, and who read materials posted on the ABA or the caramel color manufacturers’ websites. For example, Sethness advertises on Google, including for the keywords “caramel color safety,” which brings consumers to their website with several webpages representing caramel color as “listed as Generally Recognized as Safe by the FDA.”

We ask that your office investigate this matter and take appropriate enforcement action to stop the deceptive representation of caramel color as “Generally Recognized as Safe.” We have apprised FDA of our findings as well.

Sincerely,



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American Beverage Association



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February 16, 2011

Caramel Coloring: The Tall Tale for Today

It's getting ridiculous out there. Today, yet another outrageous and egregious attempt to dupe and scare the public was made, this time by an activist group called CSPI. This is a group that makes its living bashing the food and beverage industry. So what do they have to do to stay afloat? Find new ways to bash the food and beverage industry: Facts be damned!

Their latest attempt at "science-by-press-release" tried to whip up a scare that caramel coloring is harmful to consumers via a byproduct called 4-MEI. First, 4-MEI is virtually ubiquitous. It's found in a wide variety of foods and beverages, from baked goods and breads to molasses and coffee. It forms during the heating, roasting or cooking process. Caramel color is not a threat to human health even when it contains minute amounts of 4-MEI. **Studies show that and FDA has agreed by classifying caramel color as generally recognized as safe.** And that's the affirmed position of the federal government's health agencies, as well as regulatory agencies around the world.

Even the National Toxicology Program, the very group CSPI tries to cite in making its case, has not classified 4-MEI as a cancer causing agent, a fact which actually throws cold water all over the activists' zealotry.

The National Toxicology Program (NTP) does not identify 4-MEI as even "[reasonably anticipated to be a human carcinogen](#)." Click on the hyperlink for the details. Furthermore, Dr. Ernest McConnell, former NTP Director of NTP's Toxicology Research and Testing Program, wrote that "4-MEI does not have sufficient evidence of carcinogenicity to be placed on the list."

But there's real world evidence as well. Consumers can take confidence in the fact that people have been

safely drinking colas for more than a century, as well as consuming the wide variety of foods and beverages containing caramel coloring. This petition is not based on sound science and is unnecessarily raising the fears of consumers.

Common sense would seem to also tell folks that our companies – some of which have been successfully in business for more than 100 years – would never put the safety of their consumers at risk. Safety is always their top priority.

Maybe some need to start taking a long, hard look at groups like CSPI, the misinformation they continue to peddle and the pecuniary interests they maliciously protect at the expense of the public's interest. These folks should have to answer for the mud they sling.

These baseless and reckless attacks are beyond getting old. It's to the point that the public doesn't know what health news to believe thanks to the sensational "study of the day" that promises to doom us all.

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March 5, 2012

CSPI: Scaring People for No Reason...Again.

Are they really at it again?

You might have read today about how the Center for Science in the Public Interest (CSPI) is unjustifiably alerting people to the alleged dangers of colas and the caramel used to color and flavor it, as well as a host of other foods and beverages. And this time they're overreaching with even more outrageous claims that are not based in science or fact.

The science simply doesn't show that caramel coloring in foods or beverages is a threat to human health. But, of course the folks over at CSPI are playing fast and loose with the facts and would have you believe that a shaky-at-best California ruling should carry enough weight to have you running for the hills. Here's where things really stand, as referenced in [our media statement released today](#): California added 4-MEI to its list of carcinogens with no studies showing that it causes cancer in humans. California's listing was based on a single study in lab mice and rats. A person would need to drink more than 2,900 cans of cola every day for 70 years to reach the lowest dose levels mice received in the single study upon which California based its decision. And, to boot, the study showed a reduction of tumors in the lab rats tested.

Yet time and again, and even very recently, leading public health organizations have reaffirmed that caramel coloring, including the trace amounts of 4-MEI found in it, is safe for use in colas and countless other foods. Most relevant to today's coverage, the **U.S. Food and Drug Administration (FDA) has approved caramel as a color additive and lists it as a "generally recognized as safe" food ingredient.** And just today in [a Bloomberg article](#), a representative from FDA was quoted as saying:

“A person would have to drink more than a thousand cans of soda in a day to match the doses administered in studies that showed links to cancer in rodents, Douglas Karas, a U.S. Food and Drug Administration spokesman, said in a statement....The FDA has no reason to believe consumers are in danger, the FDA’s Karas wrote in an e-mail.”

As recently as last November, [Health Canada](#) said that 4-MEI, including that found in certain caramel colors, does “not represent a risk” to consumers. In March 2011, following a comprehensive review of the scientific literature, the [European Food Safety Authority \(EFSA\)](#) reaffirmed the safety of 4-MEI and stated that the presence of 4-MEI in caramel coloring is not a health concern. And the [National Toxicology Program \(NTP\)](#) does not even list 4-MEI as “reasonably anticipated to be a human carcinogen” in its Report on Carcinogens (Source: Report on Carcinogens, Twelfth Edition. <http://1.usa.gov/iId3qz>)

The fact of the matter is that 4-MEI forms in foods, such as caramel, during the heating, roasting and cooking process and is virtually ubiquitous – found in small amounts in foods and beverages that have been commonly consumed for decades, including some soft drinks, baked goods, coffee, breads, molasses, soy sauce, gravies and some beers.

The foremost priority of our member companies is the safety of their products; it makes no sense for the sake of our consumers or our business to put anyone’s health at risk. It’s unfortunate for a group like CSPI to claim to be operating in the interest of the public’s health when it is clear its only motivation is to scare the American people – and attempt to impugn our industry’s products.

So, seriously. Give it up.

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DDW is a world leader in caramel color and natural coloring sources for food and beverage applications.

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The Truth About Caramel Colour



Caramel color results from the process of caramelization, or the carefully controlled heating of carbohydrates (nutritive sweeteners). The use of caramel colouring in food products is nothing new; in fact, caramel colour has been used for centuries. Caramel colour in food and beverage products is not a health risk.

What is Caramel Color?

Caramel colour is naturally derived. Sugars are cooked to produce a brown colour that is used in a wide variety of soft drinks, baked goods, pet foods, alcoholic beverages, sauces and other food and beverage products that have a brown hue.

Learn more about caramel color in the following video interview with food industry expert [Margaret Lawson](#), Chief Science Officer, DDW “The Color House”:



4-Mel is ubiquitous in foods in the food supply and is a common trace element commonly created in the natural heat processing of many foods — including roasted coffee, chocolate, baked goods and class 3 and 4 caramel colors. However, it was still listed on Prop 65, despite all this use. Caramel class III and IV have been tested for rodent toxicity and have been found not carcinogenic.

Furthermore, on March 8, 2011, EFSA released its report that assessed the safety of caramel colors. Based on all available data, including the NTP report that formed the basis of the 4-Mel Prop 65 listing, the EFSA panel concluded that caramel colors “are neither genotoxic nor carcinogenic and there is no evidence of any adverse health effects on human reproduction or the developing child.”

In addition, DDW also offers multiple low 4-Mel versions of class III and IV caramel colors in both liquid and powder form. Although conventional Class I caramels do not contain 4-methylimidazole, Class I caramels are not traditionally stable at low pH. DDW 520 is an acid-proof class one caramel color.



What is 4-Mel?

Margaret Lawson, Chief Science Officer at DDW and a leading expert in the food & beverage industry, explains the naturally formed 4-Methylimidazole (4-Mel, sometimes incorrectly referred to as “4-MI” by CSPI) appearing in many foods:



Video – “What is 4-Mel”



Video – “Caramel Colors are safe”

Is Caramel Color Safe?

Caramel colour has undergone complete food safety testing more than 20 times in the past 35 years, and caramel colour meets rigorous food safety standards around the world. According to the European Food Safety Authority (EFSA):

“Based on all available data, the Panel concluded that these caramel colours are neither genotoxic, nor carcinogenic.”

On 26th June, 2012, the British Soft Drink Association issued a statement saying:

“The 4-MI [4-Mel] levels found in food and drink products pose no health or safety risks. Outside the State of California, no regulatory agency around the world considers the exposure of the public to 4-MI [4-Mel] as present in caramels as an issue. ... The presence of 4-MI [4-Mel] in caramel colouring is not a health concern.”

Caramel colouring has been tested extensively in the 1970s and 1980s and was found to be safe. Caramel colour does not cause cancer and has Generally Recognized as Safe (GRAS) status with the American Food and Drug Administration (FDA).

Industry expert Margaret Lawson, Chief Science Officer, DDW, has this to say about caramel colouring in food and beverage products:

"Caramel colors are extremely safe. There's never been any evidence to show that caramel color causes cancer." Citing studies including the Ontario Research Foundation's study on Caramel Toxicity (1979 – 1981) and Bio Research Laboratories Bioassay of Caramels Consumed By Rats (1978), Lawson points out that caramel colouring for food and beverage products has gone through "extensive toxicological testing" and the colours "were proven to be extremely safe to consume."

Historically, caramel colour has been produced for years and can be found in soft drinks, pet foods, alcoholic beverages, sauces, and more.

"There's never been any issue with caramel colors," Lawson adds.



There has never been a study that showed any health risk from caramel colour. See the facts

The American Beverage Association states that:

"Caramel color is not a threat to human health. ... Studies show that and the FDA has agreed by classifying caramel color as Generally Recognized as Safe. [That's] the affirmed position of the federal government's health agencies as well as regulatory agencies around the world."

In 2012, the Southern California Institute of Food Technologists Section (SCiFTS) released the following statement in preparation for the Southern California Food Industry Conference. This includes a presentation by Jim Coughlin, Ph.D., world-renowned Sane Science Food Consultant with over 35 years of experience in food and nutritional toxicology, diet and health, risk communication and scientific regulatory affairs. In his presentation — entitled *Prop 65: Foods and Dietary Supplements Under Siege!* — Coughlin will be discussing scientific and regulatory issues in the food and beverage industry under California's Proposition 65. More information is available here. Coughlin had the following to say about Prop 65:

"Foods and supplements have become major targets of regulatory enforcement and litigation activities in the past several years. ...

Unfortunately, [California's Proposition 65] and its regulations focus only on the presence of trace levels of individual, listed chemicals in products, but not on the safety or benefits of the whole food or supplement product, nor about real harm to California consumers.

The stakes remain very high for agriculture, foods and supplements, since our products will be under increasing regulatory and legal pressure from Prop 65."

40 years of caramel safety studies have all indicated that caramel is of no health threat to humans. DDW, for example, has participated in millions of dollars of safety studies over the past forty years, all of which have concluded that caramel colour is safe and harmless. Ted Nixon, President and CEO of DDW, says, "There has never been a study showing any health risk from caramel coloring."



Video – "Ted Nixon on Caramel Safety"

**My hope is that people truly get the idea that caramel color is and always has been a safe ingredient."
- Ted Nixon, Chairman and CEO, DDW**

Caramel is Safe, Science Shows

from *Soft Drinks International*, April 2012:

"In response to a release issued by the US Center for Science in the Public Interest regarding the safety of 4-Mel, which forms in foods such as caramel used by the beverage industry, the [American Beverage Association](#) stated that:

"This is nothing more than CSPI scare tactics, and their claims are outrageous. The science simply does not show that 4-Mel in foods or beverages is a threat to human health. In fact, findings of regulatory agencies worldwide, including the US Food and Drug Administration, European Food Safety Authority and Health Canada, consider caramel colouring safe for use in foods and beverages. CSPI fraudulently claims to be operating in the interest of the public's health when it is clear its only motivation is to scare the American people."

The [European Food Safety Authority \(EFSA\)](#) reaffirmed the safety of caramel colouring back in March 2011 following a comprehensive review of the scientific literature. It stated that the presence of 4-Mel in caramel colouring is not a health concern.

Leading regulatory authorities around the world also judge caramel colouring as safe for use in food and beverages. In November 2011, Health Canada said that 4-Mel, including that found in certain caramel colours, **does "not represent a risk" to consumers**, and the US Food and Drug Administration (FDA) has approved caramel as a colour additive and lists it as a "generally recognized as safe" food ingredient.

Commenting on the CSPI study linking caramel to cancer in rodents, an FDA spokesperson noted that:

"A consumer would have to drink more than 1,000 cans a day to reach the doses administered in the study."

And these numbers would be for an entire lifetime!

Scientific Information & Resources

See the following resources for more information about caramel colouring in food and beverage products.

Articles and Additional Information:

[British Soft Drink Association Rejects Calls to Ban Caramel Colouring](#)

[Caramel Color is Safe & Harmless](#)

[Questions and Answers about Caramel Coloring and 4-methylimidazole \(4-MEI or 4-MI\)](#)

[2-Mel is Not Present in Caramel Colors](#)

[REUTERS: US regulators dispute finding of cancer-causing soda](#)

[Generally Recognized as Safe \(GRAS\)](#)

[The Truth About Caramel Color](#)

[Caramel Coloring: The Tall Tale for Today](#)

[California Proposition 65 at Twenty-five. What's Happening to Foods, Beverages and Dietary Supplements Now?](#)

["Prop 65: Foods and Dietary Supplements Under Siege!" from SCiftS \(2012\)](#)

[What is Caramel Colour?](#)

[CSPI Scare Tactics on Caramel Coloring](#)

Studies on Caramel Colour Safety:

[EFSA Reviews Safety of Caramel Colours](#)

FDA Department of Health and Human Services

Ontario Research Foundation's study on Caramel Toxicity (1979 – 1981)

Bio Research Laboratories Bioassay of Caramels Consumed By Rats (1978)

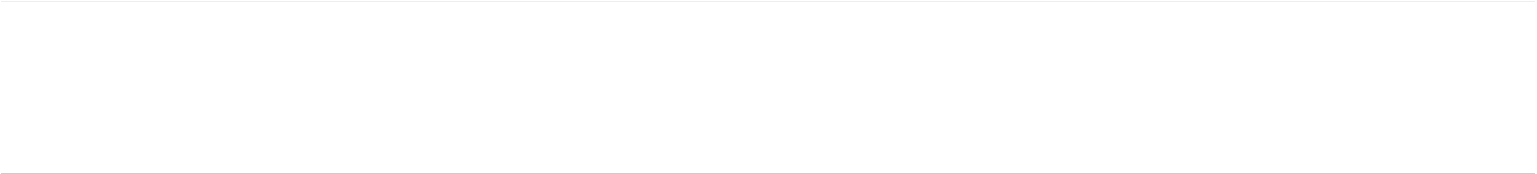
Official Statements

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[DDW's Official Statement](#)

[Caramel Color is Not a Health Risk](#)

US FDA Q&A on Caramel Coloring and 4-Mel



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DDW is a world leader in caramel color and natural coloring sources for food and beverage applications.

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Caramel Color

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DDW (D.D. Williamson) is the world leader in caramel color for food and beverage products, with over 140 years of innovation in the development and supply of caramel colouring. Caramel color results from the controlled heat treatment or cooking of carbohydrates (nutritive sweeteners, such as glucose and sucrose, derived from natural carbohydrate sources including corn, wheat and sugar). This process is called "caramelization." Caramel color can be created at home during the cooking, boiling or baking process. Caramel color ingredients are the world's most widely consumed food coloring by weight and can be commercially produced for food and beverage products.



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Regulations and Compliance

Click one of the following links for more information about regulations, compliance and standards for caramel color and naturally derived colorings for food and beverage product applications:

[Compliance Certifications](#) | [Regulatory Standards](#) | [Health and Safety Regulations Certifications](#)

Studies on Caramel Colour



Caramel colouring is commonly found in many food and beverage products and is considered to be safe and harmless according to leading food ingredient authorities worldwide. Here at DDW, our products go into over two billion servings of foods and drinks each day — so we take food safety and product quality very seriously. Over the past 40 years, we've been part of extensive food safety studies at the cost of millions of dollars.

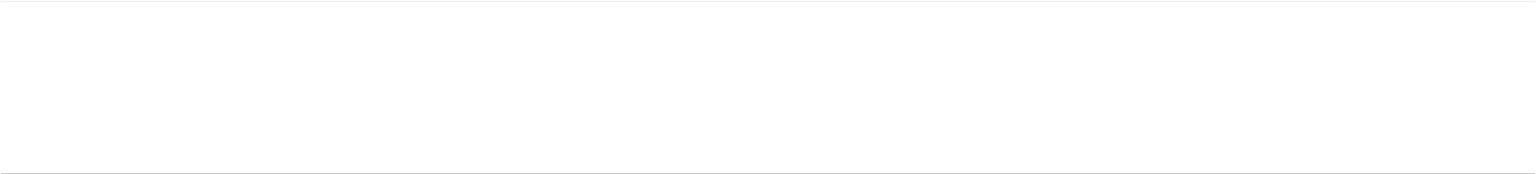
A caramel color safety review completed by the European Food Safety Authority (EFSA) in March 2011 found that caramel colors are “neither genotoxic, nor carcinogenic.” In the United States, the Food and Drug Administration (FDA) lists all four classes of caramel color listed on the Generally Recognized as Safe (GRAS) list of food ingredients.

For more facts about the safety of caramel color in food and beverage products, visit <http://www.ddwcolor.com/carameltruth>

Food product developers can [contact a DDW sales representative](#) for a customized product recommendation. You can also [buy a jar for home use](#).

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Frequently Asked Questions About Caramel Color

Caramel Color Facts

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5. [Does Caramel Color have an ingredient list?](#)
6. [Are Caramel Colors oil soluble?](#)
7. [What are the Caramel Color Classes?](#)
8. [What is the caloric value of Caramel Color?](#)
9. [What about GMO's?](#)
10. [Are Sethness Caramel Colors Kosher and Halal?](#)
11. [Do Caramel Colors contain allergens such as peanuts, gluten, dairy, seafood, or soy?](#)
12. [Do Caramel Colors contain sulfites?](#)
13. [What are the most common test methods for Caramel Color?](#)

What is Caramel Color?

Caramel Color is the world's most widely used food colorant. It is used to impart color in numerous foods and beverages including colas, soy sauce, seasonings, breads, pet foods, cereals etc.

Caramel Color is not a flavor but simply a coloring agent. When Caramel Color is used at the usual low concentrations required in most food coloring applications, it generally has no significant effect on the flavor profile of the finished product.

Caramel Color, according to the [Code of Federal Regulations \(CFR 21 73.85\)](#) (<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=73.85>) is the dark-brown liquid or solid resulting from the carefully controlled heat treatment of food grade carbohydrate. Certain food-grade acids, alkalis and salts may be employed to assist the caramelization of the carbohydrate. **The resulting Caramel Colors are very safe additives, and are GRAS (Generally Regarded as Safe) according to 21 CFR 182.1235.**

Caramel Color's most commonly used carbohydrate is High Dextrose Corn Syrup; however invert sugar and sucrose are also starting materials. High Dextrose Corn Syrup is the preferred carbohydrate, as the resulting Caramel Color is more stable over time and less viscous. In addition, Sethness Liquid Caramel Color is spray dried to produce a high quality Powdered Caramel Color.

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Are Caramel Colors the same as caramels?

The term "caramel" is often used to describe confections and flavors made from caramelized sugar. The term

"Caramel Color" only describes the color additive.

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Are Caramel Colors "Natural"?

Numerous Sethness customers, including some of the world's largest food companies, utilize our Caramel Colors to color their "all natural" products, but Caramel Color can be labeled simply as Caramel Color. There is still no legal definition of "natural", which makes this a difficult topic to address.

[Natural Status Statement \(/certifications_statements/\)](/certifications_statements/)

Unlike FD&C dyes, Caramel Color does not require certification. Caramel Color is in the same category as other "natural colorants" such as annatto, beta carotene, beet juice, etc. Therefore, technically speaking, Caramel Color is considered "natural".

In addition, Sethness produces various Certified Organic Caramel Colors that meet the most stringent "natural" requirements.

[Learn more about how the FDA refers to Caramel Color as a "Natural" food coloring.
\(http://www.labelwatch.com/addinfo.php?aid=161\)](http://www.labelwatch.com/addinfo.php?aid=161)

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Are Caramel Colors Safe?

[Learn more about the safety of Caramel Color \(/certifications_statements/\)](/certifications_statements/)

Does Caramel Color have an ingredient list?

Caramel Color does not have an "ingredient list" because it is a single color additive. Sethness Caramel Color is 100% Caramel Color.

[Ingredient and Label Statement \(/certifications_statements/\)](/certifications_statements/)

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Are Caramel Colors oil soluble?

All Caramel Colors are water soluble, but there is no such thing as oil-soluble Caramel Color. However, all Caramel Color can be dispersed in an oil system resulting in pastes or emulsions.

[Learn how to disperse Caramel Colors in a non-aqueous \(fat\) system \(/certifications_statements/\)](/certifications_statements/)

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What are the Caramel Color Classes?

Internationally the FAO/WHO Joint Expert Committee on Food Additives (JECFA) has divided Caramel Color into **four** classes depending on if the food grade reactants are used in its manufacturing. Tests on all of these classes have supported the safety of the product, and all classes of Caramel Color are GRAS.

Class I, or Plain Caramel Colors, carry the European designation E150a. Class I Caramel Colors are often considered the most "natural" of the four classes. The carbohydrate is heated simply, and approved food-grade acids or bases may be used in the process. No ammonium or sulfite compounds are allowed in Class I production. The resulting Caramel Color carries a neutral to slightly negative ionic charge.

Class II, Caustic Sulfite Caramel Colors, or E150b. The carbohydrate is heated in the presence of sulfite compounds. The resulting Caramel Color carries a negative ionic charge. RT80 is the only Class II Liquid Caramel Color produced in the United States.

Class III, Ammonia Caramel Colors, or E150c. The carbohydrate is heated with or without acids or alkalis in the presence of ammonia compounds. The resulting low-sulfite Caramel Color carries a positive ionic charge.

Class IV, Sulfite Ammonia Caramel Colors, or E150d. The carbohydrate is heated in the presence of both sulfite and ammonium compounds. The resulting Caramel Color carries a negative ionic charge. These are the most widely produced Caramel Colors.

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What is the caloric value of Caramel Color?

Although high dextrose corn syrup is the main component in the manufacture of Caramel Colors, the resulting material generally has a low caloric value. This is so because during the manufacturing process the dextrose polymerize with the reactants to form color. The color components are virtually unabsorbed in the gastrointestinal tract and are thus not biologically available. The remaining caloric value of Caramel Colors can be attributed to unreacted sugars that remain after manufacture.

Specific caloric values are listed on the Sethness Nutritional Composition Data sheets.

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What about GMO's?

[Absence of GMOs \(/certifications_statements/\)](#)

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Are Sethness Caramel Colors Kosher and Halal?

All of Sethness Caramel Colors are Kosher and Halal, and we produce small amounts of Kosher for Passover Caramel Color. Our Kosher and Halal statements can be found at:

[Kosher Certification Letter \(/certifications_statements/\)](#)

[Halal Certificate \(/certifications_statements/\)](#)

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Do Caramel Colors contain allergens such as peanuts, gluten, dairy, seafood, or soy?

No, those ingredients are not allowed in Caramel Colors manufacturing. However, some Caramel Color may contain traces of sulfites (see [Do Caramel Colors contain sulfites? \(#sulfites\)](#))

[Absence of Allergen Statement \(/certifications_statements/\)](#)

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Do Caramel Colors contain sulfites?

[Sulfite Statement \(/certifications_statements/\)](#)

Sulfite is used along with ammonia as reactants in making Class IV Caramel Colors. The sulfite gives the Class II and Class IV products their negative charge. The combination of the two reactants allows Class IV products to generate much higher color strengths while maintaining lower viscosity. The higher color strength means more color strength per pound and therefore lower total cost for equivalent color. The lower viscosity allows for easier handling and for longer shelf life. Sulfite in Caramel Color is reacted into the polymer and is therefore not "free sulfite."

"Free" sulfite is a preservative that acts as an oxygen scavenger and is often used for this purpose on foods such as lettuce in salad bars. Sulfite scavenges the oxygen and keeps the lettuce green and slows down wilting. The negative aspect of sulfite is that it is a sensitizing agent. Some people can become sick when exposed to sulfite. Some countries include sulfite on the allergens list. While sulfite is not a true allergen, it is a sensitizing agent.

"Free" sulfite also means that the sulfite does not react with the food, but remains as the free sulfite and it is available to react with oxygen from the air. **In Caramel Color the sulfite is a reactant.** It actually combines with the various molecules and become an integral part of the polymer that makes up the color bodies in Carmel Color. When we have analyzed Class II or IV Caramel Colors in the past for free sulfite, we found the level is almost undetectable. However, the FDA requires that Caramel Colors be analyzed using the Monier Williams test. This test requires boiling the Caramel Color in a strong acid for 110 minutes. The strong acidic condition and high temperature breaks down the polymer and releases the sulfite.

The FDA considers a sulfite level of less than 10 ppm to be insignificant (21CFR.101.100 (a)(4)) Typically we

recommend that our customers use the maximum level when calculating the final level in their product. For example: Assuming your use level of RT240 is 1.0% then the sulfite from the Caramel Color would amount to $0.01 \times 1500 \text{ ppm} = 15 \text{ ppm}$. This would exceed the 10 ppm limit, and the product would be labeled as containing sulfite. If the usage level was 0.1% the calculation would be $0.01 \times 1500 \text{ ppm} = 1.5 \text{ ppm}$. This product is under the 10 ppm limit and the sulfite would not have to be reported. Please note that the above calculation assumes that the Caramel Color is the only source of sulfite.

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What are the most common test methods for Caramel Color?

Caramel Color undergoes strict laboratory testing to assure product quality. The three major laboratory tests to standardize a production lot of Caramel Color are:

1. **Color Strength (Tinctorial Power):** defined as the absorbance of a 0.1% solution (weight/volume) in water, measured using a 1 cm light path at a wavelength of 560 nanometers.
2. **Baumé:** measures density or specific gravity at a given temperature.
3. **pH:** for Liquid Caramel Color it is measured on an "as is basis", and for Powdered Caramel Color is measured on a 1% basis.

Several other parameters are important in the measurement of Caramel Color including Viscosity, Hue Index, Resinification, Haze & Gel, Alcohol Solubility, Salt Stability, and Beer Test.

- **Viscosity** is the flow ability of a liquid. Thick products carry a high viscosity. This often reflects the quality and the shelf life of a Caramel Color but is not related to a Caramel Color's Color Strength.
- **Hue Index** is a measure of Caramel Color's red tones, and is calculated as a function of the absorbance of two wavelengths, 510 and 610 nanometers. Higher hue index products are generally more reddish.
- **Resinification** is an accelerated stability test. The Caramel Color is sealed in an airtight ampule and heated at 100°C. Time in hours is measured until the material no longer flows. One hour is said to represent approximately one month of shelf life. The normal shelf life of Caramel Color made from High Dextrose Corn Syrup is usually 2 years from the date of manufacture.
- **Haze and Gel** test is used to demonstrate the product stability in strong phosphoric acid solutions. This test is mainly for the soft drink industry.
- **Alcohol Stability** as well as **Salt Stability Tests** are designed for the compatibility of the Caramel Color in different concentrated solutions.
- **The Beer Test** measures the compatibility of a Caramel Color in beer.

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Sethness is always here to help you...

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Class IV Low 4MeI Caramel Colors

Effective January 7, 2012 California Prop 65 began enforcing the listing of 4 Methylimidazole (4MeI) as a possible carcinogen in Caramel Color. Sethness Products Company has been diligently monitoring the events in California and we feel California's decision is based on poor science.

In order to be proactive, we have spent more than three years developing these low 4MeI alternatives for our Class IV liquid and powdered Caramel Colors. All classes of Caramel Colors have been safely used for hundreds of years and have been listed as GRAS (Generally Regarded as Safe) by the U.S. Food and Drug Administration.

Class IV Low 4MeI Caramel Color Specifications and Nutritionals

Liquid Caramel Color Powder Caramel Color

Class IV Low 4MeI

RTL4 (low 4MeI)	spec	nutr	LF320 (Low 4MEI)	spec	nutr
DSL4 (low 4MeI)	spec	nutr	LF740 (low 4MeI)	spec	nutr

Read FDA's Question and Answers regarding the safety of Caramel Color and 4MeI
(<http://www.fda.gov/Food/IngredientsPackagingLabeling/FoodAdditivesIngredients/ucm364184.htm>)

Caramel Color Products

- Class I
- Class II
- Class III
- Class IV
- Class IV Low 4MeI
- Organic/Non-GMO
- Caramelized Sugar Syrups



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