

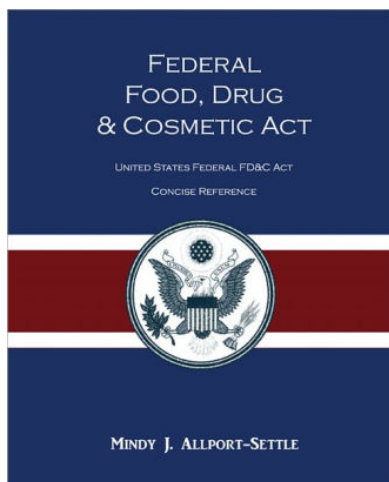
Activated Charcoal in Food

Ellen Anderson
Consumer Safety Officer
US Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Food Additive Safety

May 9, 2019
Central Atlantic States Association of Food and Drug Officials
2019 Annual Seminar
Annapolis, MD

Overview

- What is activated charcoal?
- How are food ingredients regulated?
 - Food additives, color additives, GRAS, dietary ingredients
- What is the regulatory status of activated charcoal?



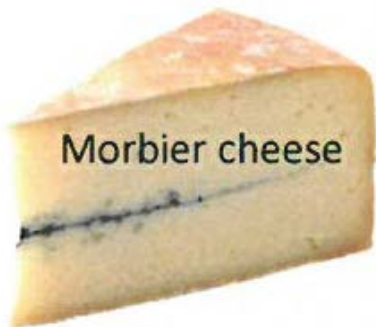
What is activated charcoal?

- Vegetable ash, vegetable carbon, vegetable black, activated carbon...
- **E153** : *“Vegetable carbon is produced by the carbonization of vegetable material such as wood, cellulose residues, peat and coconut and other shells...”*
- High temperature processing with steam
- Finely milled
- Highly adsorptive



How is activated charcoal used?

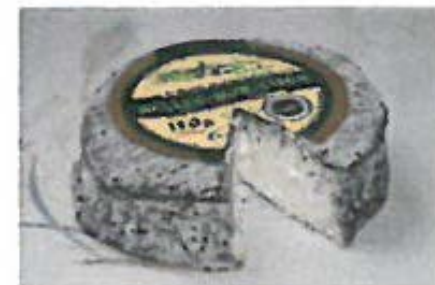
- Medicinal use to treat poisonings and overdoses
- Environmental uses to filter water, purify air
- Historical uses in cheesemaking
 - pH control agent/acidity regulator
 - Preservation barrier
 - Cheese layer separation



Morbier cheese



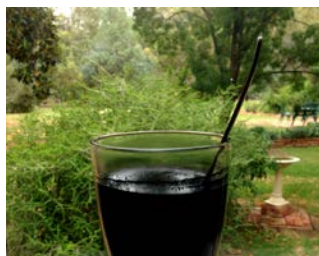
Italian cheese Sottocenere
(buried under the ash)



Selles Sur Cher

How is activated charcoal *marketed*?

- A “detox”
 - Beverages
 - Capsules



Scientific support for these claims ?

- Skin cleanser
- Pillow cases



Global market projected to be \$6.2 billion by 2022
(Source: Business Insider, Oct. 2, 2018; <https://www.businessinsider.com/is-activated-charcoal-safe-for-eat-drink-teeth-whitening-2018-9>)

THE WALL STREET JOURNAL.

JAPAN REAL TIME

Popular Burger King Japan Offering Back, Black

By Jun Hongo

Sep 11, 2014 3:45 pm JST



Press Release

2014年9月10日

株式会社バーガーキング・ジャパン

～あの『黒バーガー』がプレミアムに進化～
『KURO Pearl』『KURO Diamond』
 9月19日(金)より期間限定で発売!!

株式会社バーガーキング・ジャパン(本社:東京都渋谷区、代表取締役社長:村尾 泰幸、以下:BKJ)は、黒いバンズを使用したハンバーガー『KURO Pearl(KURO パール)』と、『KURO Diamond(KURO ダイヤモンド)』を2014年9月19日(金)よりBK各店*にて期間限定で販売いたします。*一部店舗を除く。



『KURO Pearl』



『KURO Diamond』

BKJは、2012年に“非常識”をコンセプトに今までのファストフード業界の概念を覆す、「KUROバンズ」を使用した『黒バーガー』を初めて発売し、その年の日本におけるBKで発売した新商品の中で最大の販売個数を記録するなど、大変ご好評をいただきました。

そして、2014年は、この『黒バーガー』をプレミアムに進化させ、選べる楽しさをプラスして、“二つの非常識”をコンセプトとした『KURO Pearl』、『KURO Diamond』を発売いたします。

『KURO Pearl』、『KURO Diamond』の最大の特徴は、徹底的に黒を追求して新たに開発した具材にあり、ブラックペッパーを配合した『KURO パール』(牛乳でできた『KURO チーズ』)、『KURO ダイヤモンド』(黒いソースを配合した『KURO チーズ』)が特徴です。

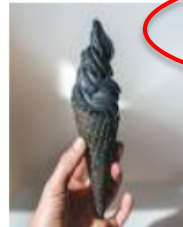
In the United States...

EATS LIFESTYLE

Ice cream that tastes like ash is the summer's latest food craze



By JEANETTE SETTEMBRE | NEW YORK DAILY NEWS | JUL 06, 2016 | 6:00 AM



Top 10 Food and Restaurant Trends of 2017

Forbes - Nov 29, 2017

Bret Thorn is Senior Food & Beverage Editor of Nation's Restaurant News with responsibility ... Activated charcoal turns just about any food into something highly ...



topfoodmelbourne • Follow
Long Story Short

topfoodmelbourne • LONG STORY SHORT
~ Port Melbourne • [Activated Charcoal Fish n Chips ~ Apple Cider Batter, Beetroot Labneh, Chips & Salad. \$19.00] ✓✓✓✓
Despite what it may look like this dish was OUTSTANDING!!!!!! Thanks @longstoryshortcafe !!

Load more comments

kristinastevens_ hahahaha wtf @ray.ha.nah
rosepericandoc @timofortiz
deadlifts_and_pizza @waynes_burgers
jojocrane_ @kiefersutherland4
raminayounan LMAOOOO @julideeee
@aahhhmmmeett27 bruh
julideeee @raminayounan daaaaafu is dat

larahajaig
jackshort_

673 likes



little.damage
Little Damage

Follow

4,269 likes

5d

little.damage The @little.damage Black Roses is ssssoooooo deliciousss! We use charcoal in our cones & ice cream so it gets its coloring naturally! 🍷 @lfoodiebitch

load more comments

abing184 Thx! @little.damage!
brizz_1994 @micheladuhhh that looks bomb. I'm down
tatiana @juditawignall @cooperativesalon guys. My goth heart needs this @jeffreydavidharvey
tamiterrell_ @mynamerond
n.hel @hbluewe اسم قوت ايس كريم
baalakayy @adamushell take me here bc I'm goth and should eat goth food 🍷
adamushell @baalakayy this is right



boozybubs • Follow
Olivella Restaurant

boozybubs Olivella in North Bergen is now serving activated charcoal pizza, pasta and mozzarella. Would you try a pie with charcoal in the crust? :
@olivellarestaurant #nj #olvellarj #northbergen #pizza #woodoven #pizzatime #charcoal
boozybubs #nom #foodgasm #foodporn #foodstagram #infatation #instadaily #eater #eeeeeats #foodie #sogood #trytordiet #foodbeast #buzzfeed #buzzfeedfood #devourpower #foreyah

287 likes
MAY 25, 2017

Log in to like or comment.



darksidcharcoal • Follow

darksidcharcoal Halloween Throwback 🍷

Terkenang kreasi Ibu @yoear | | |

#repost from @yoear

BLACK POISON 🍷

Masih dengan edisi halloween. Pagi ini coconut water + raw activated charcoal @darksidcharcoal. . A refreshing hydration. Kickstarts metabolism dan bisa curing hangovers. .

Photo: @mpyhoudini

32 likes

NOVEMBER 1, 2018

Log in to like or comment.

Charcoal Food Festival San Francisco, CA, July 2018

"...come taste the dark side..."



**What is the regulatory status of
activated charcoal?**

Is it permitted in food?

***It depends...what is its intended
use in food?***

Definition of Food Additive (FD&C Act Sections 201(s) and 409)



- Any substance that is reasonably expected to become a component of food, *except...*
 - Ingredients whose use is Generally Recognized As Safe (GRAS)
 - Color additives
 - Dietary ingredients in dietary supplements
 - Prior sanctioned ingredients (substance whose use was approved by FDA or USDA prior to 1958)
 - Pesticide chemicals or pesticide chemical residue (EPA)
 - Animal drugs that may remain in food
 - Inherent components of the food
 - Contaminants not added intentionally to food
- Requires FDA premarket review and approval via petition process
 - Approval results in a regulation listed in Title 21 Code of Federal Regulations (21 CFR)

Food Additive Exemption – Dietary Ingredients (FD&C Act Section 201(ff))



- A dietary supplement contains one or more *dietary ingredients*:
 - Vitamins
 - Minerals
 - Herbs or other botanical
 - Amino acids
 - Dietary substances used to supplement the diet by increasing total dietary intake
 - A concentrate, metabolite, constituent, or extract of a dietary ingredient
- Not intended to treat diseases
- FDA premarket review required only for “**new**” dietary ingredients via a notification program
 - Dietary ingredients not sold in supplements before October 15, 1994



Food Additive Exemption - **GRAS**

(FD&C Act Section 201(s))

- The use of the ingredient is generally recognized as safe (GRAS), not the ingredient itself
- GRAS status requires
 - Scientific consensus by qualified experts that the use is safe
 - Based on scientific procedures (e.g., published data) or a history of common use in food before 1958
- Must meet same safety standard as food additives, but FDA premarket review and approval is **not** required
- Voluntary GRAS notification program

FDA safety standard (21 CFR 170.3(i)):

“...there is a reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use...”

Food Additive Exemption – Color Additives

(FD&C Act Sections 201(t) and 721)



- A dye, pigment, or other substance that is capable of imparting color to a food, drug, cosmetic or to the human body
- Requires FDA premarket review and approval via petition process; listing in 21 CFR
 - Uses cannot be GRAS
- *Possible exemption*: if a substance is used for a purpose other than coloring and any color imparted is unimportant to the appearance, value, marketability, or consumer acceptance (21 CFR 70.3(g))



Example: Tomato Lycopene



GRAS Notice #119 (2003)

- **Synthetic lycopene**
- GRAS for use as an ingredient in specific foods.
- FDA had no questions; noted some uses may require a color additive listing.

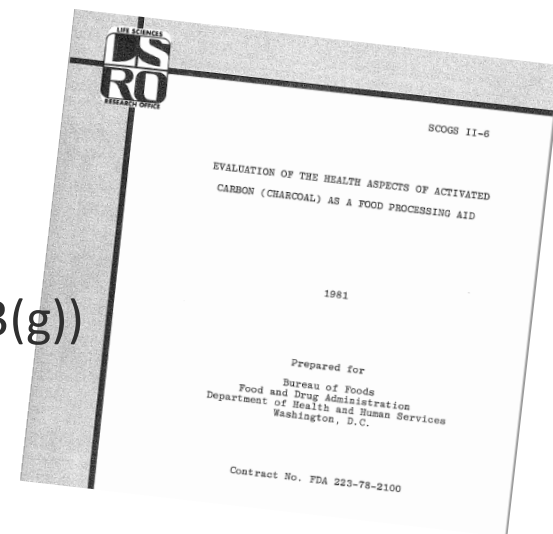


Color Additive Petition 1C0273 (2005)

- **21 CFR 73.585 Tomato lycopene extract/concentrate**
- May be safely used for coloring foods generally in amounts consistent with GMP
- Petition approved by FDA

What is the regulatory status of activated charcoal in food in the U.S.?

- GRAS as a processing aid only
 - Based on 1981 report by Select Committee on GRAS Substances (SCOGS)
 - Purification of water and various foods
 - Decolorization and clarification of wine
- Historical uses in cheesemaking
 - Some uses could be GRAS (see 21 CFR 70.3(g))
 - No GRAS notices submitted to FDA



What is the regulatory status of activated charcoal in food in the U.S.?



- Not considered a valid dietary ingredient
 - No food additive or color additive regulation
 - FDA's current thinking summarized in "Guidance for Industry: Colored Sea Salt"
- If used to impart color, it is an unapproved color additive
 - Food is adulterated under section 402(c) FD&C Act



For Industry

Home > For Industry > Color Additives > Laws, Regulations, and Guidance

Laws, Regulations, and Guidance

[Color Additive Guidance](#)

[Color Additive Regulations](#)

Resources for You

- [Ingredients, Additives, GRAS, & Packaging Guidance Documents & Regulatory Information](#)

Guidance for Industry: Colored Sea Salt

[f](#) SHARE [t](#) TWEET [in](#) LINKEDIN [p](#) PIN IT [e](#) EMAIL [p](#) PRINT

September 2015

[Print-Friendly PDF \(77KB\)](#)

Contains Nonbinding Recommendations

This guidance represents the current thinking of the Food and Drug Administration (FDA or we) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

You may submit written comments regarding this guidance at any time. Submit written comments on the guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the title of the guidance document.

I. Introduction

This guidance document is intended for manufacturers of colored sea salt products. This document describes the regulatory requirements for the use of color additives to color sea salt.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe our current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in FDA guidances means that something is suggested or recommended, but not required.

II. Discussion

Safety concerns?

Charcoal Food Trend is Lit, But Is It Safe?

August 10, 2018

AP NEWS

EAT & DRINK

Charcoal is trendy ingredient at Twin Cities restaurants, but comes with risk

Welcome to the dark side of cocktails and lattes.

By Amelia Rayno Star Tribune | JUNE 15, 2018 — 11:53AM



Doctors Warn Activated Charcoal Food Craze Might Not Be Healthy

By Stephanie Stahl | March 8, 2019 at 6:46 pm | Filed Under: HealthWatch, Local TV

Safety concerns?



- Unknown source material
 - Wood, bone, coconut shells, other materials?
 - Presence of heavy metals, other impurities?
- Potential for the presence of polycyclic aromatic hydrocarbons (PAHs)
 - Created during combustion process
 - Known carcinogens
- Particle size distribution; nano?
- Unknown effects of chronic consumption

FDA safety standard (21 CFR 170.3(i)):
“...there is a reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use...”

Take-aways

- The intended use of activated charcoal determines its regulatory status
 - Certain uses may be GRAS
- Activated charcoal is not an approved color additive
 - There is no listing for activated charcoal in 21 CFR
 - Foods containing activated charcoal as an unapproved color additive may be deemed adulterated (section 402(c) FD&C Act)
- Case-by-case assessment if use meets the definition of a color additive, based on 21 CFR 70.3(g)
- End of a trend?
 - Recent media reports questioning safety
 - Increased enforcement (e.g., NYC, Portland)



