Safety Assessment of Plant-Derived Charcoal Ingredients as Used in Cosmetics

Status:	Draft Final Report for Panel Review
Release Date:	November 9, 2023
Panel Meeting Date:	December 4-5, 2023

The Expert Panel for Cosmetic Ingredient Safety members are: Chair, Wilma F. Bergfeld, M.D., F.A.C.P.; Donald V. Belsito, M.D.; David E. Cohen, M.D.; Curtis D. Klaassen, Ph.D.; Allan E. Rettie, Ph.D.; David Ross, Ph.D.; Thomas J. Slaga, Ph.D.; Paul W. Snyder, D.V.M., Ph.D.; and Susan C. Tilton, Ph.D. The Cosmetic Ingredient Review (CIR) Executive Director is Bart Heldreth, Ph.D., and the Senior Director is Monice Fiume. This safety assessment was prepared by Christina L. Burnett, M.S., Senior Scientific Analyst/Writer, CIR.

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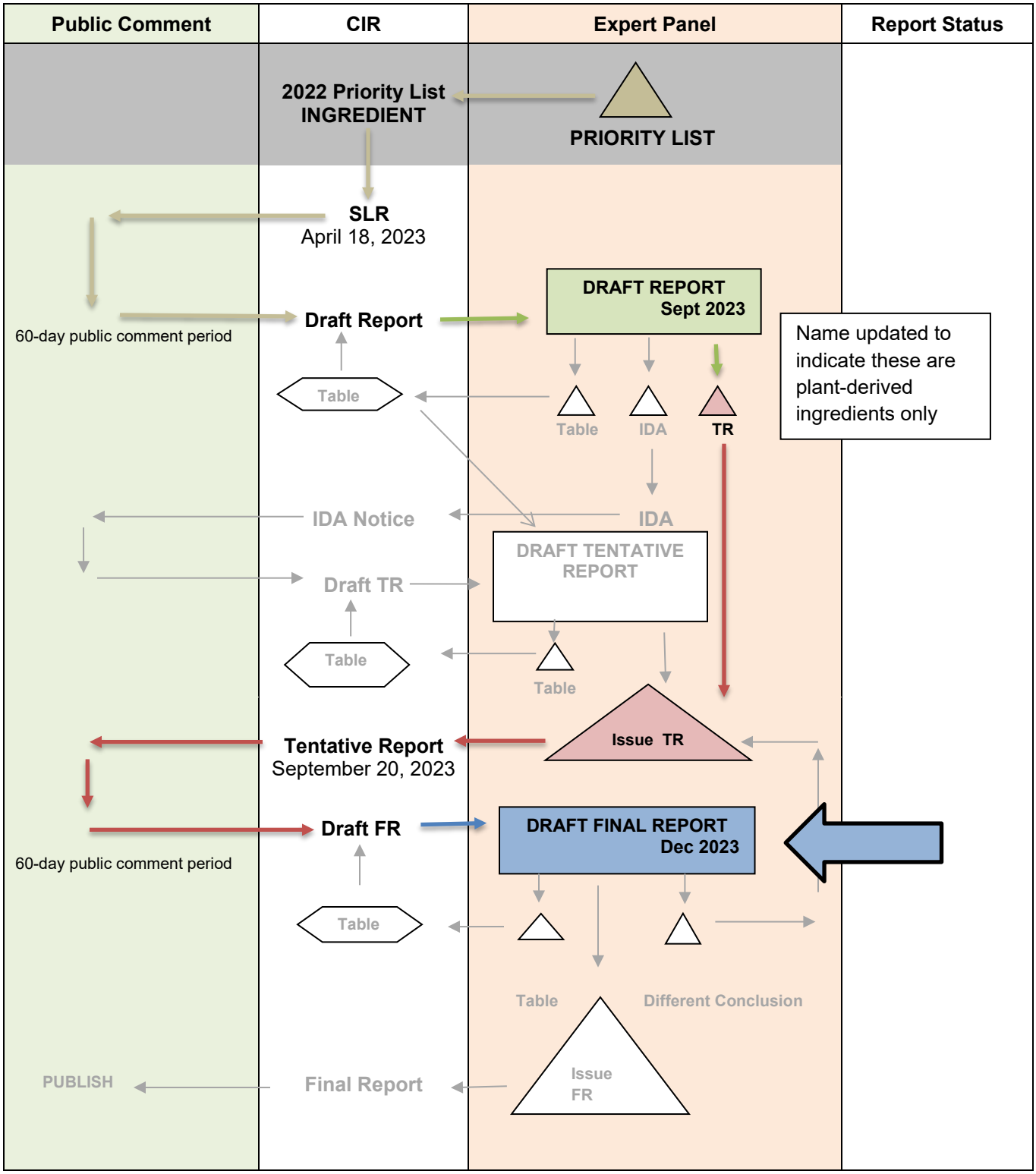
SAFETY ASSESSMENT FLOW CHART

INGREDIENT/FAMILY Plant-Derived Charcoal Ingredients

MEETING December 2023



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Memorandum

To: Expert Panel for Cosmetic Ingredient Safety Members and Liaisons
From: Christina L. Burnett, M.S., Senior Scientific Analyst/Writer, CIR
Date: November 9, 2023
Subject: Safety Assessment of Plant-Derived Charcoal Ingredients as Used in Cosmetics

Enclosed is the Draft Final Report on the Safety Assessment of Plant-Derived Charcoal Ingredients as Used in Cosmetics. (It is identified as *report_Charcoal_122023* in the pdf document.) At the September 2023 meeting, the Panel concluded that Charcoal, Charcoal Extract, Charcoal Powder, and activated charcoal are safe in cosmetics in the present practice of use and concentration described in this safety assessment. Only plant-derived charcoal ingredients are included in this assessment; accordingly, charcoal derived from petroleum or other mineral sources are excluded from this review.

Following the September meeting, the International Nomenclature Committee informed CIR staff that activated charcoal is a synonym of Charcoal Powder and is now described as such in the *Dictionary*. (An additional CAS No. associated with Charcoal Powder (64365-11-3) has also been added to this entry.) However, because activated charcoal is the more commonly known name in published literature and the medical community, it will be referred to as such herein in the appropriate studies but described under the ingredient heading Charcoal Powder.

CIR staff noted a suggestion to mention D&C Black No. 2 in the Use section of this safety assessment. This colorant does not pertain to any of the ingredients in this report, thus it was not included in this section. The Introduction does inform the reader that colorants are not under the purview of the Panel and the use of such ingredients are not addressed in the safety assessment.

No other unpublished data have been received for this report. Comments provided by the Council on the Tentative Report have been addressed (*PCPCcomments_Charcoal_122023* and *response-PCPCcomments_Charcoal_122023*).

Other supporting documents for this report package include a flow chart (*flow_Charcoal_122023*), report history (*history_Charcoal_122023*), a search strategy (*search_Charcoal_122023*), meeting transcripts (*transcripts_Charcoal_122023*), and a data profile (*dataprofile_Charcoal_122023*).

Items that have been added to the safety assessment since the last meeting have been highlighted to aid in the Panel's review. The Panel should carefully review the Abstract, Discussion, and Conclusion, and issue a Final Report.

Personal Care Products Council
Committed to Safety, Quality & Innovation

Memorandum

TO: Bart Heldreth, Ph.D.
Executive Director - Cosmetic Ingredient Review

FROM: Alexandra Kowcz, MS, MBA
Industry Liaison to the CIR Expert Panel

DATE: October 2, 2023

SUBJECT: Tentative Report: Safety Assessment of Plant-Derived Charcoal Ingredients as Used in Cosmetics (release date: September 20, 2023)

The Personal Care Products Council respectfully submits the following comments on the Tentative Report Safety Assessment of Plant-Derived Charcoal Ingredients as Used in Cosmetics.

Chemical Properties – It would be helpful to note that particle size distribution was tested in three samples.

Method of Manufacture, Charcoal – Please correct: “to produce differ quality charcoals” (“differ” should be “different”)

Dermal Irritation and Sensitization – It would be helpful to state in the text that 3 LLNA’s were completed on Charcoals with different C-fix values.

Other Clinical Reports, Activated Charcoal – Please state the endpoints that were studied. The abstract of reference 50 indicates they completed standard laboratory serum values including lipids, alkaline phosphatase, phosphate, and calcium.

Charcoal Ingredients - December 2023 – Christina Burnett	
Comment Submitter: Alexandra Kowcz, Personal Care Products Council **Date of Submission: October 2, 2023**	
Comment	**Response/Action**
Chemical Properties – It would be helpful to note that particle size distribution was tested in three samples.	Suggested edit made.
Method of Manufacture, Charcoal – Please correct: "to produce differ quality charcoals" ("differ" should be "different")	Correction made.
Dermal Irritation and Sensitization – It would be helpful to state in the text that 3 LLNA's were completed on Charcoals with different C-fix values.	Suggested edit made.
Other Clinical Reports, Activated Charcoal – Please state the endpoints that were studied. The abstract of reference 50 indicates they completed standard laboratory serum values including lipids, alkaline phosphatase, phosphate, and calcium.	Additional detail added.

Charcoal Ingredients History

April 18, 2023– The Scientific Literature Review was issued for public comment.

September 12, 2023 – The Panel issued a Tentative Report for public comment with the conclusion that the following 4 plant-derived Charcoal ingredients are safe in cosmetics in the present practices of use and concentration described in the safety assessment:

Charcoal	Charcoal Powder
Charcoal Extract	Activated Charcoal *

**Not in the web-based International Cosmetic Ingredient Dictionary and Handbook (wINCI; Dictionary)*

Both the *Dictionary* and communications with the International Nomenclature Committee (INC) indicate that the source material for these cosmetic ingredients is plant-based, while carbon black (not an ingredient in this report) is sourced from minerals (e.g., petroleum). Clarification on the ingredient source for Activated Charcoal is being sought; however, the data in the report indicate it is also sourced from plants (e.g., bamboo). Carbon black and ingredients derived from mineral sources are not produced in the same manner (e.g., sourced from petroleum instead of plants) and are likely to have different compositions and impurities. The data in the report are specific to the plant-based materials and do not include carbon black.

The Panel discussed the issue of incidental inhalation exposure that may occur from the use of these ingredients in cosmetic formulations (i.e., Charcoal Powder is used in a hair spray at 0.001%). Limited data available from inhalation studies, including an acute rat study with Charcoal and an intratracheal rat carcinogenicity study with Charcoal Powder, suggest little potential for respiratory effects at relevant doses. The Panel considered other data available to characterize the potential for plant-derived Charcoal ingredients to cause systemic toxicity, irritation, sensitization, and genotoxicity. They noted the lack of systemic toxicity in acute and repeated dose studies at up to 11,240 mg/kg bw, a lack of irritation and sensitization in tests of dermal exposure, and the absence of genotoxicity in *in vitro* and *in vivo* test systems. Thus, based on all these findings, the Panel determined that plant-derived Charcoal ingredients are safe as used in cosmetics in the present practices of use and concentration described in the safety assessment.

September 26, 2023 – CIR staff were notified by the INC that the monograph for Charcoal Powder had been updated to include Activated Charcoal as a synonym.

Charcoal Ingredient Data Profile* – December 2023 – Christina Burnett																																
				Toxicokinetics			Acute Tox			Repeated Dose Tox			DART		Genotox		Carci			Dermal Irritation			Dermal Sensitization				Ocular Irritation		Clinical Studies	
	Reported Use	Method of Mfg	Impurities	log P/log K_{ow}	Dermal Penetration	ADME	Dermal	Oral	Inhalation	Dermal	Oral	Inhalation	Dermal	Oral	In Vitro	In Vivo	Dermal	Oral	Other	In Vitro	Animal	Human	In Vitro	Animal	Human	Phototoxicity	In Vitro	Animal	Retrospective/ Multicenter	Case Reports
Charcoal	X	X		X					X						X					X	X			X			X	X		
Charcoal Extract	X																													
Charcoal Powder CAS No. 7440-44-0; 16291-96-6	X							X			X				X	X			X											X
activated charcoal**	X	X	X																											

* "X" indicates that data were available in a category for the ingredient

** Synonym for Charcoal Powder in the *Dictionary*

Charcoal

Ingredient	CAS #	INCIpedia	PubMed	FDA	EU	ECHA	SCCS	SIDS	ECETOC	HPVIS	AICIS	NTIS	NTP	WHO	FAO	NIOSH	FEMA	Web
Charcoal	16291-96-6	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
Charcoal Extract		√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
Charcoal Powder	16291-96-6; 7440-44-0 (generic)	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
Activated Charcoal	64365-11-3	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√

Search Strategy
PubMed

(charcoal) OR (16291-96-6) = 24,099 hits; modified with NOT (activated) = 12,684 hits; modified with AND (toxicity) = 897 hits, 38 relevant
(charcoal) AND (extract) = 2523 hits; modified with NOT (activated) = 1385, 4 relevant
(((charcoal) AND (powder)) OR (16291-96-6[EC/RN Number])) OR (7440-44-0[EC/RN Number]) = 82,629 hits; modified with NOT (activated) = 57,477 hits
Further modifications: AND (dermal) = 42 hits, 0 relevant; AND (cosmetic) = 487 hits, 6 relevant; AND (genotoxicity) = 67 hits, 1 relevant
(activated charcoal) OR (64365-11-3[EC/RN Number]) = 24,060 hits; modified with AND (dermal) = 51 hits, 0 relevant; modified with AND (cosmetic) = 261 hits, 12 relevant; modified with AND (genotoxicity) = 45 hits, 2 relevant

Typical Search Terms

- INCI names
- CAS numbers
- chemical/technical names
- additional terms will be used as appropriate

LINKS

Search Engines

- Pubmed (- http://www.ncbi.nlm.nih.gov/pubmed)

appropriate qualifiers are used as necessary
search results are reviewed to identify relevant documents

Pertinent Websites

- wINCI - http://webdictionary.personalcarecouncil.org
- FDA databases http://www.ecfr.gov/cgi-bin/ECFR?page=browse
- FDA search databases: http://www.fda.gov/ForIndustry/FDABasicsforIndustry/ucm234631.htm;,
- Substances Added to Food (formerly, EAFUS): https://www.fda.gov/food/food-additives-petitions/substances-added-food-formerly-eafus
- GRAS listing: http://www.fda.gov/food/ingredientspackaginglabeling/gras/default.htm
- SCOGS database: http://www.fda.gov/food/ingredientspackaginglabeling/gras/scogs/ucm2006852.htm
- Indirect Food Additives: http://www.accessdata.fda.gov/scripts/fdcc/?set=IndirectAdditives
- Drug Approvals and Database: http://www.fda.gov/Drugs/InformationOnDrugs/default.htm
- FDA Orange Book: https://www.fda.gov/Drugs/InformationOnDrugs/ucm129662.htm
- (inactive ingredients approved for drugs: http://www.accessdata.fda.gov/scripts/cder/iig/

Last updated October 2023.

- HPVIS (EPA High-Production Volume Info Systems) - https://iaspub.epa.gov/oppthpv/public_search.html_page
- NIOSH (National Institute for Occupational Safety and Health) - http://www.cdc.gov/niosh/
- NTIS (National Technical Information Service) - http://www.ntis.gov/
    - technical reports search page: https://ntrl.ntis.gov/NTRL/
- NTP (National Toxicology Program) - http://ntp.niehs.nih.gov/
- Office of Dietary Supplements https://ods.od.nih.gov/
- FEMA (Flavor & Extract Manufacturers Association) GRAS: https://www.femaflavor.org/fema-gras
- EU CosIng database: http://ec.europa.eu/growth/tools-databases/cosing/
- ECHA (European Chemicals Agency – REACH dossiers) – http://echa.europa.eu/information-on-chemicals;jsessionid=A978100B4E4CC39C78C93A851EB3E3C7.live1
- ECETOC (European Centre for Ecotoxicology and Toxicology of Chemicals) - http://www.ecetoc.org
- European Medicines Agency (EMA) - http://www.ema.europa.eu/ema/
- OECD SIDS (Organisation for Economic Co-operation and Development Screening Info Data Sets)- http://webnet.oecd.org/hpv/ui/Search.aspx
- SCCS (Scientific Committee for Consumer Safety) opinions: http://ec.europa.eu/health/scientific_committees/consumer_safety/opinions/index_en.htm
- AICIS (Australian Industrial Chemicals Introduction Scheme)- https://www.industrialchemicals.gov.au/
- International Programme on Chemical Safety http://www.inchem.org/
- FAO (Food and Agriculture Organization of the United Nations) - http://www.fao.org/food/food-safety-quality/scientific-advice/jecfa/jecfa-additives/en/
- WHO (World Health Organization) technical reports - http://www.who.int/biologicals/technical_report_series/en/
- www.google.com - a general Google search should be performed for additional background information, to identify references that are available, and for other general information

Last updated October 2023.

SEPTEMBER 2023 PANEL MEETING – INITIAL REVIEW/DRAFT REPORT

Belsito Team – September 11, 2023

DR. BELSITO: Okay, Charcoal. Here we've got Wave 2 with Women's Voice for the Earth. And the major issue here is whether we're talking about mineral charcoal or botanical-derived charcoal. And my understanding is we're talking about plant-derived charcoal. So we need to make that very clear in the report. I think, if we do that, that takes away the concerns that were raised by Women's Voice for the Earth. Is that what everyone else is --

DR. RETTIE: Yep. Organic matter, bamboo, and coconut shells, they're prominently in this report.

MS. BURNETT: When you look it up, there is the potential that other types of charcoal are produced from coal or petroleum products. But, based on the entry in the dictionary, it listed bamboo charcoal as an alternate name. So I assume that that's the source.

DR. BELSITO: So should we change the title of this report to the Safety Assessment of --

DR. SNYDER: Organic-Derived Charcoal.

DR. BELSITO: -- or Plant-Derived --

DR. SNYDER: Plant-derived.

DR. BELSITO: -- Charcoal Ingredients as Used in Cosmetics? Also, I think, in the Introduction, we need to make the point that carbon black as a petrol-derived charcoal and is not included in this report.

DR. EISENMANN: And don't say it's the approved color because it's not. There's a specific name for the approved color.

MS. BURNETT: Yes.

DR. EISENMANN: It's Carbon 2. I mean Black 2.

MS. BURNETT: Black 2, yes.

DR. BELSITO: Carbon Black 2?

DR. EISENMANN: It's Black 2, is the official.

DR. SNYDER: Really?

DR. EISENMANN: It has specific specifications and specific way it's made and then --

DR. BELSITO: But we don't look at colorants.

DR. EISENMANN: Right. Put in her comments to call carbon black as a colorant.

MS. BURNETT: Mm-hmm.

DR. EISENMANN: But it's not. The approved colorant in the United States is a specific carbon black called D&C Black 2.

DR. BELSITO: So maybe that should be -- colorants can be used in foods as well as in cosmetics. Or is it only cosmetics?

DR. EISENMANN: Well, this is just a D&C. So this is Drugs and Customs.

DR. BELSITO: Okay. So that would be a cosmetic use, but not under our purview.

DR. EISENMANN: Correct, but it's made from the hydrocarbon.

DR. BELSITO: I understand, but I think that the question is, where in the report do we reference this? So I think under cosmetic use, there should perhaps be a paragraph that says whatever is an approved colorant. The safety of use of colorants in cosmetic products is not under the purview of the CIR Panel, but rather under the purview of FDA. And, therefore, we are not assessing the safety of this colorant, to make it very clear.

MS. BURNETT: Let me clarify. In my introduction when I list the functions, charcoal powder has the additional reported function as colorant.

DR. EISENMANN: Not in US.

MS. BURNETT: That is not as --

DR. SNYDER: But she also brings up is the charcoal powder being used in a dry shampoo, and that's not colorant use, right?

DR. BELSITO: Right.

MS. BURNETT: Right.

DR. BELSITO: But, again, she was concerned about mineral.

DR. SNYDER: Petroleum based.

DR. BELSITO: Petroleum based, right.

DR. SNYDER: So I think we just need to clarify what this is.

DR. BELSITO: Right.

DR. SNYDER: What it is and what it isn't is just the most important.

DR. BELSITO: And that's why, I think, up front we need to say that plant -- maybe even change the title, again, to plant-based charcoals.

MS. BURNETT: Okay.

DR. BELSITO: And, again, in the cosmetic section, I think, since carbon black is Black 2 as a colorant that has very specific manufacturing, we need to mention that that is used as a cosmetic ingredient, as a colorant, and that the regulation of colorants is under the guidance of the FDA and not the purview of this Panel. So we're not assessing the safety. Carbon black has been totally removed from this report in any of its iterations.

MS. FIUME: I'm sorry. Carol, what you said is the actual colorant, is not a technical name for carbon black, though, right? Or it is? I mean, I know she mentioned it in her comments.

DR. EISENMANN: If it's a specific type of carbon black.

MS. FIUME: Okay.

DR. SNYDER: Yeah. I think we're using it too generalized. We need to be more specific in what we're -- yeah.

DR. EISENMANN: If you have a product that says carbon black, FDA should get after it?

DR. BELSITO: So it's called Black 2?

DR. SRINIVASAN: That is correct.

DR. SNYDER: D&C Black #2.

DR. SRINIVASAN: That is correct. D&C Black 2 is a specific type of carbon black.

DR. SNYDER: Yeah.

MS. FIUME: Okay. Thank you.

DR. BURNETT: But carbon black is not --

DR. SNYDER: D&C Black #2.

DR. SRINIVASAN: A generic carbon black.

DR. KLAASSEN: Which comes from petroleum.

DR. SNYDER: Correct.

DR. EISENMANN: And it has to be certified by FDA in order for you to use it.

DR. RETTIE: Because it's a colorant.

MS. BURNETT: (Inaudible) impurities test.

DR. KLAASSEN: Is white a color or lack of color?

DR. SNYDER: So have we addressed the dry shampoo use?

DR. BELSITO: Not yet.

DR. SNYDER: Okay.

DR. BELSITO: Yeah. We haven't even gotten there yet.

DR. SNYDER: Okay. All right.

DR. BELSITO: We're just trying to sort out, get rid of the fact that we're not looking at petrol derived. We've done that by changing the title. We're recommending a change in the title of the document and then a mention under cosmetic use that carbon black, manufactured under specific conditions as defined by the FDA, is an approved colorant. D&C Black #2, the safety of colorants is not in the purview of this Panel, but rather under FDA regulations, and therefore we are not assessing this specific material in this report.

DR. SNYDER: So, having said all of that, if we go to the Introduction.

DR. BELSITO: The Introduction. Okay.

DR. SNYDER: After this assessment, it says charcoal, charcoal extract, charcoal powder, and activated charcoal are all carbonaceous materials for the use of this report they're all -- but they could be petroleum, couldn't they? Is that statement true?

DR. BELSITO: Where are you?

DR. SNYDER: The first sentence, right underneath -- right there where you're at.

DR. BELSITO: So this says pyrolysis of organic matter.

DR. RETTIE: Specifies pyrolysis.

DR. SNYDER: No, but there are charcoals, there are charcoal powders and activated charcoals that are petroleum derived, right?

DR. BELSITO: Yes.

DR. BURNETT: But I don't know if they're cosmetic ingredients.

DR. BELSITO: But I requested that a statement be added that we are not assessing carbon black or other petroleum-derived charcoal.

DR. SNYDER: Well, that's what I thought. I said here, The ingredients under review in this document are charcoal, charcoal extracts, are all carbonaceous. After that front statement in there saying that the ones that were considered here for safety, because they can be produced by other methods.

DR. BELSITO: Right.

MS. FIUME: Christina, we checked with the International Nomenclature Committee representative, correct?

MS. BURNETT: Mm-hmm.

MS. FIUME: And we received an email saying that they're only plant based? Is that correct? Do I remember correctly?

MS. BURNETT: I'm pulling up her email. No, she said it should be plant as charcoal is made from wood, or the ingredients that are in the dictionary. They can be produced in the matter from other things, but I don't think they'd be considered to be an INCI ingredient, then, if they're not produced from the plant, if I'm understanding correctly.

DR. SNYDER: Right.

MS. BURNETT: Right. In this report, it's --

DR. SNYDER: But I'm saying that that statement is not necessarily true. Because there are charcoals that are produced by other methods other than organic.

DR. BELSITO: Yeah. What Paul is saying is that you're not saying the --

DR. SNYDER: Ingredients under review.

DR. BELSITO: -- ingredients in cosmetics.

DR. SNYDER: Cosmetics.

DR. BELSITO: I think you have to add charcoal, charcoal extract, charcoal powder, and activated charcoal --

MS. BURNETT: Derived.

DR. BELSITO: -- as used in cosmetics are all --

DR. SNYDER: Are all carbonaceous. Then it's fine because you can source them from Don. Yeah.

MS. BURNETT: Yeah, got you.

DR. RETTIE: Do you want to beat it to death by just adding a sentence really specifying that --

DR. BELSITO: What we also will have -- I think we need to really beat it to death by putting it in our title as well.

MS. BURNETT: Yep.

DR. SNYDER: Well, it's addressing the Women's Voices for the Earth concern that appears to be that you could use petroleum-based, and that's not true.

MS. BURNETT: Right.

DR. BELSITO: Okay. Then that gets rid of the need for my addition here, so let me delete that. And then, in the cosmetic-use section we'll go into the D&C Black #2.

DR. SNYDER: More specifics.

DR. BELSITO: Right. That we're not reviewing it, it's a colorant.

DR. SNYDER: Correct.

DR. RETTIE: I had a couple of comments on the chemistry section.

MS. BURNETT: Okay.

DR. BELSITO: Chemistry being chemical properties? What chemistry section?

DR. RETTIE: After the introduction.

DR. BELSITO: Yeah. Okay. Go ahead.

DR. RETTIE: Yeah. I was just wondering about the use of absorb and adsorb. Do we care about this?

DR. KLAASSEN: Yes, very much so.

DR. RETTIE: One's a surface phenomenon, and the other is not a surface phenomenon.

DR. KLAASSEN: Go through on every place where it says absorb in this. This is not absorption, it's adsorption, a very important difference.

DR. RETTIE: In the chemistry paragraph.

MS. BURNETT: Yeah. Okay. Yeah. I double checked that and all these places use it incorrectly.

DR. KLAASSEN: They maybe do, but it's incorrect.

MS. BURNETT: Okay.

DR. BELSITO: So where are we here?

DR. RETTIE: Third paragraph. We're changing absorb to adsorb. Maybe absorb somewhere else in the document as well.

DR. KLAASSEN: Yeah, there's a few places.

MS. BURNETT: Yeah.

DR. BELSITO: I'm not seeing that. Third paragraph under chemistry definition?

DR. SNYDER: Chemical properties, second paragraph.

DR. BELSITO: Chemical properties.

DR. SNYDER: Charcoal ingredients absorbed.

DR. RETTIE: I was reading through them all for you.

MS. BURNETT: Yeah, yeah. Okay. Thank you. I can do a search.

DR. RETTIE: I had a nitpicky thing as well in the first paragraph.

MS. BURNETT: Mm-hmm.

DR. RETTIE: So, all through the document, every time we seem to say activated charcoal, it's always followed by which is not listed in the dictionary. So after a while, it gets a bit redundant.

MS. BURNETT: Okay.

DR. BELSITO: Okay. And method of manufacturing for the activated charcoal, you go through all of this, “which may include sawdust, peat, lignite, coal, cellulose residues, coconut shells and petroleum coke.” Again, I think, if you're going to say that, which is true according to your reference, I would add the sentence, “however, the cosmetic charcoals are manufactured from plant-based and not mineral sources.”

DR. SNYDER: So activated charcoal is not in the dictionary, but it's reported to be used in 53 formulations.

DR. EISENMANN: And I have brought this up with the person, Joanne (phonetic), who is in charge of it, and they're going to have a discussion about it with the INCI Committee whether or not --

DR. SNYDER: So it will be mis-categories again?

DR. EISENMANN: Well whether or not it needs a separate name. It’s a really different -- I mean, it has greater surface area. I mean, there's a little bit of difference in method of manufacture. But they're going to have a discussion as whether it's --

DR. BELSITO: Okay.

MS. BURNETT: It's treated with something in order to increase the surface area. Yeah.

DR. EISENMANN: Treated in higher temperature or things like that. But they're going to have that discussion. So we might hear that, yeah, they've decided to add it in. And I also looked up the Unicode (phonetic) and there wasn't a separate one for activated charcoal.

DR. SNYDER: I think there needs to (inaudible) discussion (inaudible).

DR. EISENMANN: It's like all -- activated carbon and activated charcoal is all under one. So I don't know.

MS. BURNETT: Yeah.

DR. EISENMANN: So they're going to have the discussion.

MS. BURNETT: Potentially, as I was maybe interpreting it, charcoal powder is actually activated charcoal. And they need to either merge the data or come up with a separate listing.

DR. SNYDER: Since you're reporting -- nope, you're not. We want clarification of the --

DR. RETTIE: But powder is different from activated charcoal, right?

MS. BURNETT: By definition, it should be. How it's defined by the people that are using it, I don't know. They might be using activated charcoal, but just calling it charcoal powder.

DR. KLAASSEN: It's a big deal in poison control that you use activated charcoal.

DR. BELSITO: Activated charcoal. Yeah.

DR. KLAASSEN: I don't know how it's made either.

DR. RETTIE: Apparently you can just throw some citric acid in there and heat it up. How does that work? That's what I read, anyway.

MS. BURNETT: I have the basic understanding of it.

DR. SNYDER: Yeah. I mean, we have lots of data on powder, tox data. And it was a control in a carci study, and it was negative.

DR. BELSITO: So we have this ingredient, activated charcoal, but we don't have a definition because it's not a cosmetic ingredient.

DR. SNYDER: Clear definition.

DR. BELSITO: Clear definition. We don't have the method of manufacture. We don't know how that differs from just charcoal.

MS. BURNETT: Right. Because I assume the charcoal has to be a powder, too. Because no one's actually rubbing a piece of charcoal on their face.

DR. BELSITO: Well we never know how people are --

MS. BURNETT: Well, I know. But it has to be a powderized form too.

DR. BELSITO: Right.

MS. BURNETT: So what the difference between charcoal powder and activated charcoal is, is not clear.

DR. RETTIE: Well, we have method of manufacture for activated charcoal.

MS. BURNETT: Correct.

DR. RETTIE: And for charcoal.

MS. BURNETT: Again, yeah, but that also doesn't say whether it's powderized.

DR. SNYDER: I'm guessing all that powdered charcoal is actually activated charcoal. 53 uses.

MS. BURNETT: And if it's misclassified --

DR. EISENMANN: That's what I would assume, they're all the same, that it's pretty much the same.

DR. SNYDER: Yeah. I think it probably is.

MS. BURNETT: If it's misclassified, because then the charcoal powder has the actual highest frequency of use of 231. So it's probably close to 300 uses total for a charcoal product.

DR. SNYDER: Yeah, exactly. And the powder is the highest concentration at 4.8 percent.

DR. BELSITO: So, based upon the method of manufacturing that we have, despite the fact that this hasn't been added to the INCI dictionary yet, are we all comfortable keeping activated charcoal in this report?

DR. SNYDER: I have no problem with safety issues. It's a matter of clarification of exactly what we're calling stuff.

DR. BELSITO: Right.

DR. SNYDER: It matters because it's the use and concentration of use that I always default to.

DR. RETTIE: If we've moved onto Uses, I just had a comment.

DR. BELSITO: Yes.

DR. RETTIE: One the one, two, three, fourth paragraph, which says something about airbrush delivery. And, then, the first paragraph under cosmetic section also has info relevant to airbrush delivery. Are they consolidatable?

DR. BELSITO: Airbrush is mentioned twice in the first paragraph.

DR. RETTIE: And again in the fourth.

MS. BURNETT: Oh, that's part of their boilerplate language.

MS. FIUME: Yeah. The first paragraph is an identification of where all the information comes from. The fourth paragraph is defining that the Panel, without this information, cannot -- that the data are insufficient to evaluate without parameters needed.

DR. RETTIE: Okay. So it's appropriate the way that you've worded it.

DR. BELSITO: In the third paragraph, Women's Voices for the Earth present the data that charcoal used in dried shampoo could be respirable.

DR. SNYDER: But there was an inhalation. Let's see, I had to write it down because I went back to the data that we had.

MS. BURNETT: There was an acute inhalation study for charcoal.

DR. SNYDER: Well, there was a carci study, too, with 3, 4-benzopyrene and no lung tumors in those that received powder, is what I had.

DR. BELSITO: But I think we need to correct that statement, assuming that we agree that the data presented by Women's Voices for the Earth is indeed correct, and bring that into the report. And say that it could be respirable, however, based upon --

DR. SNYDER: LC50 was almost five grams for inhalation.

DR. BELSITO: Right. The acute inhalation data and the --

DR. SNYDER: There's no -- yeah.

DR. BELSITO: -- the genotox data are radar concerns.

MS. FIUME: It currently does state that it's in products that could possibly be inhaled, but it's referring to the hair sprays.

DR. BELSITO: Yeah, but we dismissed that inhalation based upon particle size. And the information that Women's Voice for the Earth gave with dry shampoos was the particle sizes could be respirable.

DR. RETTIE: Yes. I've got a note to that effect here.

DR. BELSITO: So I don't think that our respiratory boilerplate, assuming that we agree with the data being presented by WVE, covers dry shampoos.

DR. SNYDER: Well, charcoal powder anyway, because we have a carci study along with --

DR. BELSITO: Right. That's what I mean. But we can't say --

DR. SNYDER: Oh, particle size? Oh, I see. Yeah, I agree. I agree.

DR. BELSITO: Particle size based exclusion --

DR. SNYDER: I got you. I agree.

DR. BELSITO: -- because we have data that they provided saying that it could be respirable in the dry shampoo, right? So, then, we have to come up with data as to why this is safe and the current respiratory boilerplate doesn't cover that.

DR. SNYDER: I agree.

DR. BELSITO: I think that, in the third paragraph, we need to say something to the effect that data on particle size in some dry shampoos indicate that there could be respirable levels of charcoal.

DR. SNYDER: However, point of delivery, intratracheally --

DR. BELSITO: Right.

DR. SNYDER: -- it did not induce any lung tumors.

DR. BELSITO: Right. Go ahead, Allan.

DR. RETTIE: Under Toxicological studies, PDF 14, second paragraph is inhalation, charcoal. They talk about 50 percent of the particles generated being less than four micromolar, then says considered the inhalable fraction. Shouldn't that be respirable fraction less than four micromolar?

DR. BELSITO: Yeah. Yeah.

DR. RETTIE: Okay.

DR. BELSITO: And where was that exactly, Allan?

DR. RETTIE: PDF 14, second paragraph, inhalation, fourth line.

DR. BELSITO: PDF 14.

DR. RETTIE: Yeah, PDF 14, Tox Studies, inhalation.

DR. BELSITO: That's not the second paragraph. Oh, tox studies, second paragraph.

DR. RETTIE: Says considered the inhalable fraction. It should be respirable.

DR. BELSITO: What line was that?

DR. SNYDER: Fourth.

MS. BURNETT: Fourth line.

DR. RETTIE: Fourth one.

DR. KLAASSEN: In parentheses.

DR. SNYDER: Probably captured from that publication. That's probably what they said.

DR. RETTIE: You guys ever considered adding line numbers to use?

MS. FIUME: We have not. We can.

DR. RETTIE: I don't want to make more work, but we're always going around, where is it.

MS. BURNETT: I think it's a setting.

MS. FIUME: Yeah, we can look at it and see.

DR. SNYDER: I'm glad to know that Adobe Pro because I find it frustrating editing.

MS. BURNETT: I think we can do it in Word, and then see if it captures it in PDF. I'm not sure.

MS. FIUME: Right. We'd have to make sure that it transfers to the PDF.

MS. BURNETT: Our conversion. That would cause a problem.

DR. RETTIE: Well, when you put the line numbers in, you don't actually land on the line. You land between the line.

MS. FIUME: Yeah. Yep.

DR. RETTIE: But it gets it down to --

MS. FIUME: Understand.

DR. KLAASSEN: So maybe we can conclude. In 2023, we have concluded that a chemical that has been used for centuries to treat poisoning is not very toxic.

DR. RETTIE: It's a good thing, all the way back to the Egyptians.

DR. KLAASSEN: In cosmetics at minute doses.

DR. BELSITO: Carcinogenicity study, I'm just (inaudible) particle size not given in 1980 publication. So checking with manufacturer not helpful. Was that in response to -- this is the third paragraph.

MS. BURNETT: What page?

DR. BELSITO: PDF Page 15, on charcoal powder, carcinogenicity. I guess that was just probably in reference to Women's Voices for the Earth, but this was given --

DR. SNYDER: Half a milligram intratracheally.

DR. BELSITO: Right. Yeah. So let me strike that comment. Okay. So, in the discussion, just one other thing. In the dermal irritation, where we have the LLNA in mice, it just says was not sensitizing when tested at a concentration up to 10 percent. I mean, that's true, but that almost implies that above 10 percent it is sensitizing, and that's not true. Basically, they couldn't come up with an EC3 value because they didn't get the stimulation index above three with any of these.

So I think it would be better saying that -- how to phrase it. But, in an LLNA using charcoal, up to ten percent sensitization index of greater than 3 --

DR. SNYDER: Was not achieved.

DR. BELSITO: -- was not achieved. And not make a statement that it was not sensitizing at 10 percent because, again, it almost implies that, at 15 percent, it is sensitizing and that's probably not the case.

MS. BURNETT: Okay.

DR. BELSITO: So, in our discussion, we really have great endpoints for absorption and for sensitization, irritation, ocular toxicity. We're restricting it to plant based. We have an intratracheal carcinogenicity study that I think covers the inhalation endpoint. And I think we can go ahead and say safe as used.

DR. SNYDER: I agree. You had a slug of work this time, Christina.

MS. BURNETT: The finals were easy.

DR. SNYDER: Yeah, but you had these documents, too, these guidance documents.

MS. BURNETT: Yeah. I'll have to say that this is the first ingredient in a long time that has gone to the next stage without any hiccups. So I'm kind of pleased here.

DR. BELSITO: Yeah.

MS. BURNETT: Don't want to jinxed myself. We don't know yet.

DR. BELSITO: So everyone's happy with the safe as used?

DR. SNYDER: I am.

DR. RETTIE: Yes.

DR. BELSITO: Okay.

DR. SNYDER: Guidance, FDA.

DR. BELSITO: So, Table 2, I just had a comment. Particle size, I said the extracts and powders are used in aerosols. Can we generalize these particle sizes to the materials used in aerosols, question to the team. But I guess they're simply giving chemical properties here. We've already discussed this.

DR. SNYDER: Yeah.

DR. BELSITO: Let me delete that comment. Okay. That was it for me. Any other comments on this document?

DR. RETTIE: No.

Cohen Team – September 11, 2023

DR. COHEN: Okay. Moving on to Charcoal. So, this is a draft report on Charcoal ingredients. Activated Charcoal is currently not listed in the dictionary, however, it has reported use. And the extract is reported to function as an opacifying agent and skin conditioning agent. According to the 2023 VCRP, charcoal powder has the highest frequency of use in 231 formulations. Charcoal powder has the highest concentration of use at up to 4.8 percent in eye liners and four percent in a paste mask.

So, we're looking at four derived ingredients, Charcoal extract, powder, and activated charcoal. For additional discussion, we have a second wave discussion. I think this is from Women's Voices for the Earth, to consider the inclusion of carbon black. And I'd like to hear what everyone has to say.

One of my notes was that -- and our method of manufacturing we only have bamboo sourcing. Carbon black could come from other sources and perhaps the impurities would be different from other sources of the carbon. So, I'll open it up and then I can summarize after. Tom, you want to open? Tom, you're on mute.

DR. SLAGA: Yeah, I agree with what you said, that I would not add it even though the voice of women wanted the carbon charcoal black. But overall, the way it's used it's really not an irritant or doesn't bring about sensitization and it's not genotoxic.

So, in general, I don't have any problems there on the skin, but I don't know if this is potentially inhalable. That's my only concern. Because of the different particle sizes in it.

DR. ROSS: Do you want me to?

DR. COHEN: Go ahead.

DR. ROSS: So, I had a few comments on this one. If I go through the dermal irritation and sensitization data, all the in vitro and the animal tests were done with charcoal, and there was no human studies at all with any of the four products. So, I felt we needed both irritation and sensitization for charcoal powder, which was 163 uses up to 4.8 percent. You know, Tom, I was sort of differentiating between charcoal and charcoal powder. In activated charcoal we've got 44 dermal uses in up to half percent.

So, I felt we needed some dermal irritation and sensitization with the powder and the activated charcoal at max; so that was the first thing. I can go on. Ocular. There were no ocular studies with the powder, even though there was only three uses, but it's up to 4.8 percent. I thought we needed a molecular test, maybe a HET-CAM on the powder.

DR. COHEN: What do we need?

DR. ROSS: On ocular?

DR. COHEN: No. For ocular I got. You said something after that.

DR. ROSS: Oh, the HET-CAM test? There's some in there already for charcoal itself I believe. I think the genotox is okay. I think the oral, there's nothing on activated charcoal but it's used at high doses in emergency situations, in the clinical study in 6 grams per day for eight weeks to 11 hemodialysis patients. So, I think the oral's okay.

DR. COHEN: Yeah, the charcoal powder in male and female rats the LD50 was 11,240 milligrams per kilo. I couldn't help but notice that. I don't know if you could eat anything else.

DR. ROSS: Yeah, and there was some black residues in there. We'll leave it at that. And just other things, we need a particle size distribution on the powder. That wasn't in there. At least I didn't see it. Maybe I missed it.

DR. SLAGA: I didn't see it either.

MS. BURNETT: I did want to note that it's not entirely clear that charcoal, charcoal powder, and activated charcoal aren't all one in the same. Just based on what I've read, and what I understand about the ingredients and how they behave, I don't think anyone's using it like -- I'm sure someone might be. But in the industry, they're not using a charcoal briquette and rubbing it on their face so it has to be powderized form.

And so, I -- just based on the definitions, I'm not sure that charcoal and charcoal powder are really different. And then we are still waiting to hear back from the INC Committee to see if they're going to prepare a monograph on the activated charcoal to see if it was actually different from the charcoal powder and the charcoal ingredient.

DR. ROSS: What was in the method of manufacture? I think it just said -- in that table it just said it was a finely --

MS. BURNETT: Yeah.

DR. COHEN: That it was cooked at a certain temperature --

MS. BURNETT: So, yeah. So, to make activated charcoal they do a special process.

DR. ROSS: Activated is very different.

MS. BURNETT: Right. They treat it to get more surface area.

DR. ROSS: Yeah. You add things to it also. So, it's clear that's a different product.

MS. BURNETT: Correct. But it's unclear what industry is currently using. If it's all the same or if it's two different, three different ingredients.

DR. COHEN: And depending on the source, perhaps.

MS. BURNETT: Right. As far as what we've been told, the source is -- for this purpose, in the dictionary it is a wood-based or bamboo-based.

DR. ROSS: I went after that little bit, it seems to be most of it is bamboo.

MS. BURNETT: Correct.

DR. ROSS: I dug in to that a little bit.

DR. COHEN: We have to put that in the Discussion, because it's very easy to confuse this with charcoal from other sources.

MS. BURNETT: Correct.

DR. ROSS: Yeah, but there's no method of manufacture on the extract, for example. And there's no powder particle size. I mean, some of the respiratory stuff was a micronized prep of charcoal.

MS. BURNETT: Right.

DR. COHEN: So, we have method of manufacturing on activated charcoal and charcoal. We need it on extract and powder?

DR. ROSS: We need the method of manufacture for the extract, I believe. And we need a particle size distribution for the powder. I think we have the method of manufacture for the activated.

DR. COHEN: We have activated.

DR. ROSS: So, I think that's okay.

DR. COHEN: We have charcoal, but we don't have --

DR. ROSS: Extract.

DR. COHEN: Extract and powder. Well, we don't know if there the same or different, right?

DR. ROSS: Table 1 says charcoal powder is finely ground charcoal.

DR. COHEN: Table?

DR. ROSS: One. But I think we need some sort of definition of particle size. But anyway, I tracked them as different and that was why I came up with those recommendations for dermal irritation and sensitization.

DR. COHEN: Yeah, I had the same thing. We didn't have anything.

DR. TILTON: I mean, I think that makes sense until we get additional clarification.

DR. COHEN: Is the rest of the composition it's just all carbon? Just carbon?

MS. BURNETT: Yes. I mean, there could be some kind of --

DR. COHEN: I went back and forth on this. I don't know if we need sensitization data on carbon.

DR. ROSS: Which one?

MS. BURNETT: I mean, your impurities are probably going to be whatever the combustion --

DR. COHEN: Right. I mean, if it's just carbon and it's got some impurities, I don't know if I need sensitization. I went back and forth on it. Carbon's not going to be a sensitizer.

DR. ROSS: So, we have that on charcoal, right? At least in animal in vitro.

DR. COHEN: Yeah. It's just to -- this is one of those case-by-case basis things. It's like carbon is not going to fulfill any the criteria for being a sensitizer. Yeah, we could talk about this.

DR. ROSS: Activated is clearly different. Okay. So the derivation of the different products from charcoal, yeah, it's a bit vague. And is it the same? I mean --

DR. COHEN: But even activated charcoal, it's a different method of manufacturing but it still winds up being --

DR. ROSS: Yeah, it's different.

DR. COHEN: -- carbon and they add -- you got zinc in there.

DR. ROSS: Ammonia. I mean, it's just different stuff in there. And there's different solubility characteristics, it's different stuff. But, I mean, I don't think we need too much with that activated. So the issue becomes how does charcoal powder relate to charcoal, which I think is exactly the issue Christina brought up.

DR. TILTON: Or we discussed it might just be a particle size difference.

DR. ROSS: Could be, Susan, could be.

DR. COHEN: So, we discussed the sensitization. Not sure we need that, but the ocular tox, right?

DR. ROSS: Yeah. I still say you need some sort of irritation/sensitization with activated charcoal because it's a different product and you don't have it. Right?

DR. COHEN: I'm making notes. I'm just not sure -- I'm just trying to go through what we would form in that that could be a problem. But genotox is okay. We need particle size, distribution, method of manufacturing on the extract and powder. Any other data needs? We'll have an IDA on this? Susan?

DR. TILTON: No, I think that sounds good. I mean, from the data that's presented there are not a lot of toxicological concerns but there are insufficiencies.

DR. COHEN: Okay. Got it. We're good with an IDA?

DR. ROSS: Yeah.

DR. SLAGA: Yeah.

DR. COHEN: All right.

Full Panel – September 12, 2023

DR. COHEN: So, this is a draft report of Charcoal Ingredients. Activated charcoal is not listed in the dictionary, however, it is reported to be used according to the VCRP and a concentration of use survey. Charcoal extract is reported to function as an opacifying agent, skin conditioning agent, abrasive absorbent and deodorant agent. In 2023, the VCRP survey data showed that charcoal powder had the highest frequency of use and it was present in 231 formulas. Activated charcoal also had several uses and charcoal powder had the highest concentration of use at 4.8 percent in eyeliner and 4 percent in a paste mask.

Our motion is for an Insufficient Data Announcement. Our asks are for method of manufacturing of the extract and the powder, and we'd like clarification if all of these other than the extract are the same -- are these similar things? We understand activated charcoal is processed differently.

We'd like particle size distribution of the powder since it's used in spray formulation. We'd like some ocular tox data since it's used near the eyes. And we had a discussion about irritation and sensitization. It wasn't a high concern about sensitization, but perhaps irritation, particularly, since the activated charcoal is prepared in a different method. So that's our motion. And we can have a discussion a little bit afterwards about some correspondence we got.

DR. BERGFELD: Is there a second or a comment?

DR. BELSITO: We actually went with safe as used. In terms of the inhalation, there was an acute oral study on charcoal that was negative. And we noted that the absorption was low, there was no sensitization, irritation. We just felt that you could read across from the different components.

DR. SNYDER: Changed the name, plant-derived.

DR. BELSITO: Yes. We've also -- I mean, getting into very specifics, we changed the name of the ingredient to plant-derived to make sure that it is not mineral, or not petroleum-based charcoal. We noted that carbon black is considered D&C Black No. 2. It's a colorant. It's not under our purview, it's under the purview of the FDA as a colorant. And what other specifics did we have? We noted that there was no sensitization in studies.

DR. COHEN: You reconciled that just based on the chemistry of the product, right?

DR. BELSITO: Right. Not absorbed, sensitization and irritation, ocular toxicity. We also had an intratracheal carcinogenicity study, two years, that was negative. And so, we felt we had enough data.

DR. RETTIE: Yeah, we just know there's ocular irritation data for charcoal itself.

DR. BELSITO: Yeah, that's what I said. Not absorbed, sensitization and irritation, ocular toxicity okay, two year intratracheal carcinogenicity study was negative. We're restricting it to plant-based, not petroleum-based.

DR. BERGFELD: What about inhalation?

DR. BELSITO: Two-year intratracheal.

DR. BERGFELD: Oh, okay.

DR. BELSITO: Installation of charcoal was negative for carcinogenicity.

DR. BERGFELD: I'm not a tox- --

DR. BELSITO: They sprayed the charcoal into the trachea.

DR. BERGFELD: Oh, they sprayed it, they didn't implant it.

DR. COHEN: Yeah, I know, but other than carcinogenicity, anything else we have to think about?

DR. ROSS: Could I ask the question how you dealt with the dermal irritation and sensitization? We felt that the studies were with charcoal, and this gets at David's question, differentiating between these different products. The studies were with charcoal but not with the charcoal powder or the activated charcoal.

And we can have a discussion about the powder, but I think from the method of manufacture, the activated charcoal looks a little different. I mean, there are more additions there, it's a different process. I mean, okay, you heat it to 1200 degrees so your question is, well, is there anything left? But it actually is a different product. I wondered how you got around that issue?

DR. BELSITO: Well first of all, we assume that no one's going to take a piece of charcoal and be using that as a product on their face. And that what's called charcoal is at the least a charcoal powder and not a whole block of charcoal. We thought -- I mean Allan can comment, but the activated charcoal was just an increase to surface area.

DR. RETTIE: Yeah, that's kind of how we were approaching the activated charcoal. I mean, it just increases the surface area right up to about 500 millimeters per square centimeter. But I thought that the processing would've got rid of all the things that you put in there like citric acid to activate it. So I was less enthused by that.

DR. COHEN: There's also zinc chloride now in the composition and impurities. I didn't see the zinc hanging around there, but it is added. And zinc is an irritant, zinc chloride is an irritant. But I don't know if that would be considered an impurity if that's part of the method of manufacturing. That's kind of where -- zinc chloride can be irritating.

DR. RETTIE: I mean in some theaters, people use charcoal to make things up, right.

DR. COHEN: Yes.

DR. RETTIE: So, people have been putting charcoal on their faces forever.

DR. COHEN: Well, and don't forget this is put on as a mask at 4 percent.

DR. BELSITO: But we have irritation at 100 percent that's negative.

DR. COHEN: For?

DR. BELSITO: Charcoal.

DR. ROSS: For charcoal, yeah.

DR. COHEN: Yeah, but we're talking about activated charcoal.

DR. BELSITO: So, do you think just because the surface area is larger, it would be less likely to get absorbed, no?

DR. COHEN: No, no, not for sensitization so much, for irritation and whether there's any residual zinc chloride in there.

DR. RETTIE: So you're concerned about carryover of other things in the activated charcoal? And we don't have clarity on that, I guess, in terms of impurities in the activated charcoal or composition of the activated charcoal.

DR. ROSS: I mean the prep is adding nitric acid, ammonia, other materials not specified, and then of course you bake it to a 500 degrees and up -- oh sorry. Yeah, I can repeat that. The method is adding nitric acid, ammonia, other materials not specified and then you bake it 500 degrees and upwards. And then there are some misuses David has pointed out with the impurity. So, we just felt that was a different product. We didn't have many other issues with it apart from the irritation and sensitization.

DR. KLAASSEN: Activated charcoal, as we know, is a very important ingredient used in poison control centers, and they don't use it by the micrograms, they use it by the grams and tens of grams. So, I don't really think that there must be much irritation with it, otherwise it wouldn't be used in the way that it's been used for the last two centuries.

DR. ROSS: Kurt, yeah, you raise a good point. I mean, it was used in the hemodialysis patients, I think, which is why we cleared it systemically. Didn't have any issues with that. It was a study using it, I think, 6 to 8 grams a day and it was clear. I think systemically there is not an issue. It was just application.

DR. KLAASSEN: Yeah.

DR. COHEN: I mean, I think the fact that it could be copiously swallowed doesn't mean it can't be irritating, right. On skin. Tabasco sauces on your eyelids is going to be pretty rough, but it may taste pretty good going down.

DR. BELSITO: But it's going to be irritating.

DR. COHEN: Going down you mean?

DR. BELSITO: Yeah. It's going to be irritating in the mouth. It's going to be irritating on the lips.

DR. COHEN: What about poison ivy?

DR. BERGFELD: Can we come to some conclusion here? We have two opposing views here.

DR. COHEN: Thank you, Wilma.

DR. ROSS: I'm fine with moving ahead with it.

DR. COHEN: Let me poll the team. Susan, Tom? Susan, why don't you go first? What are your thoughts on our IDA versus the Belsito, safe as used?

DR. TILTON: Yeah. In our discussions, we did not have a lot of concerns about the toxicity as we've reviewed and gone through a lot of negative toxicity data. Discussion was primarily about the relationship between the ingredients and we were

possibly going to be receiving some clarification on activated charcoal since it's not in the dictionary as to whether or not it's used in cosmetics. But outside of that, it sounds like maybe there's a lot of similarity between these ingredients. So, I don't have any concerns around toxicity.

DR. COHEN: Tom?

DR. SLAGA: Yes, I really had no problem with irritation, sensitization, genotox. I had some little concern about particle size for some of the charcoal products. But there was, as Don pointed out, an inhalation study and it was negative for cancer in the laryngeal area. So, I don't think -- I mean, I could actually go with safe like Don pointed out.

DR. BERGFELD: So, Dr. Cohen?

DR. COHEN: So, Don, you don't feel irritation is going to be much of an issue? Okay, we'll second the Belsito motion.

DR. BERGFELD: Okay. And you'll rescind your first motion?

DR. COHEN: Oh yes, I'm sorry. I'll rescind my motion.

DR. BERGFELD: Right.

DR. COHEN: And we will propose a new motion as safe as used in present practices and concentrations.

DR. BERGFELD: And, Don, you're seconding then?

DR. BELSITO: Yeah. And you're agreeing with the change in the name of the report to plant-derived or plant-based?

DR. COHEN: Yeah. Thank you. Because we excluded carbon black for the exact reasons that you mentioned, and I think the clarification that they made in the title was perfect.

DR. BERGFELD: Thank you. I guess we'll call the question now. All those in favor of safe for charcoal? Thank you. Unanimous.

Safety Assessment of Plant-Derived Charcoal Ingredients as Used in Cosmetics

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The Expert Panel for Cosmetic Ingredient Safety members are: Chair, Wilma F. Bergfeld, M.D., F.A.C.P.; Donald V. Belsito, M.D.; David E. Cohen, M.D.; Curtis D. Klaassen, Ph.D.; Allan E. Rettie, Ph.D.; David Ross, Ph.D.; Thomas J. Slaga, Ph.D.; Paul W. Snyder, D.V.M., Ph.D.; and Susan C. Tilton, Ph.D. The Cosmetic Ingredient Review (CIR) Executive Director is Bart Heldreth, Ph.D., and the Senior Director is Monice Fiume. This safety assessment was prepared by Christina L. Burnett, M.S., Senior Scientific Analyst/Writer, CIR.

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ABBREVIATIONS

C-fix	carbon content
CIR	Cosmetic Ingredient Review
Council	Personal Care Products Council
CPSC	Consumer Product Safety Commission
D_{50}	size distribution for 50% of particles
DART	developmental and reproductive toxicity
Dictionary	web-based *International Cosmetic Ingredient Dictionary and Handbook* (wINCI)
DMSO	dimethyl sulfoxide
EC_3	effective concentration inducing a stimulation index of 3
ECHA	European Chemicals Agency
EU	European Union
FAO	Food and Agriculture Organization of the United Nations
FDA	Food and Drug Administration
HET-CAM	hen's egg test-chorioallantoic membrane
INC	International Nomenclature Committee
LLNA	local lymph node assay
MTT	3-(4,5-dimethylthiazol-2-yl)-2,5-diphenyltetrazolium bromide
NOAEL	no-observable-adverse-effect level
NR	not reported
OECD	Organisation for Economic Co-Operation and Development
OTC	over-the-counter
Panel	Expert Panel for Cosmetic Ingredient Safety
SI	stimulation index
TG	test guideline
US	United States
VCRP	Voluntary Cosmetic Registration Program
WHO	World Health Organization

ABSTRACT

The Expert Panel for Cosmetic Ingredient Safety (Panel) assessed the safety of Charcoal, Charcoal Extract, and Charcoal Powder (including activated charcoal), all of which are reported to function as opacifying agents and two of which are reported to function as abrasives and absorbents in cosmetic products. The Panel reviewed the available data to determine the safety of these ingredients. The Panel concluded that these 3 plant-derived charcoal ingredients are safe in cosmetics in the present practices of use and concentration described in this safety assessment.

INTRODUCTION

This assessment reviews the safety of Charcoal, Charcoal Extract, and Charcoal Powder (including activated charcoal) as used in cosmetic formulations. These ingredients, as used in cosmetics, are all carbonaceous materials produced by the pyrolysis of plant-derived organic matter. Only plant-derived charcoal ingredients are included in this assessment; accordingly, charcoal derived from petroleum or other mineral sources are excluded from this review.

According to the *Dictionary*, all three ingredients are reported to function in cosmetics as opacifying agents (Table 1).[1] Charcoal is also reported to function as a deodorant agent, both Charcoal and Charcoal Powder as abrasives and absorbents, and Charcoal Extract as a skin-conditioning agent – miscellaneous in cosmetics. Additionally, Charcoal Powder is reported to function as a colorant; however, Charcoal Powder is not listed as an approved colorant by the United States (US) Food and Drug Administration (FDA) and therefore not allowed to be used as such in cosmetics in the US. Additionally, colorants (with the exclusion of so called "coal tar exemption" hair dyes) are not under the purview of the Panel and use as such in not addressed in this assessment.

The International Nomenclature Committee (INC) has determined that activated charcoal is a synonym for Charcoal Powder, and is listed as such in the *Dictionary*.[1] However, because activated charcoal is the more commonly known name in published literature and the medical community, it will be referred to as such herein in the appropriate studies but categorized under the ingredient heading Charcoal Powder.

This safety assessment includes relevant published and unpublished data that are available for each endpoint that is evaluated. Published data are identified by conducting an extensive search of the world's literature; the search was last conducted October 2023. A listing of the search engines and websites that are used and the sources that are typically explored, as well as the endpoints that the Panel typically evaluates, is provided on the Cosmetic Ingredient Review (CIR) website (https://www.cir-safety.org/supplementaldoc/preliminary-search-engines-and-websites; https://www.cir-safety.org/supplementaldoc/cir-report-format-outline). Unpublished data are provided by the cosmetics industry, as well as by other interested parties.

Much of the data included in this safety assessment was found on the European Chemicals Agency (ECHA) website.[2] Please note that the ECHA website provides summaries of information generated by industry, and it is those summary data that are reported in this safety assessment when ECHA is cited.

CHEMISTRY

Definition

The definitions of the charcoal ingredients included in this review are provided in Table 1.[1] Charcoal is the dried, carbonaceous material obtained from the heating of organic substances, and Charcoal Extract and Charcoal Powder are the extract and the dried powder, respectively, of Charcoal. The INC has determined that activated charcoal is a synonym for Charcoal Powder.[1]

Chemical Properties

Available chemical properties for activated charcoal and Charcoal are summarized in Table 2. Charcoal has low water solubility.[2] In 3 samples of Charcoal with carbon content (C-fix) ranging from 73.3% to 88.7%, particle size distribution smaller than 100 µm was reported in 0.53 - 0.87% of samples tested, and only < 0.3% of the particles of the samples tested were smaller than 10 µm. Activated charcoal is insoluble in water and in organic solvents.[3,4]

Charcoal ingredients adsorb chemicals and substances from air and water, with the activation of charcoal increasing material volume, breaking turbo-static carbon structures that form surface functional groups, and removing non-crystallized carbons.[5] Surface area-to-mass ratios and van der Waals force contribute to adsorption properties of these ingredients.

Method of Manufacture

The following methods of manufacturing are general to the production of charcoal ingredients, and it is unknown whether these methods are used in the manufacture of charcoal ingredients for use in cosmetics.

Charcoal

Charcoal sourced from bamboo is manufactured by cutting bamboo into small pieces, washing through boiling in distilled water, and then drying at nearly 110°C to remove moisture.[5] The bamboo is then carbonized in an oven at 800 - 1200°C for several hours. Lower temperatures may be utilized to produce different quality charcoals. From here, the charcoal may undergo activation to increase adsorption properties.

Charcoal Powder

According to *the Food Chemicals Codex*, activated charcoal is prepared by carbonizing and activating organic substances, which may include sawdust, peat, lignite, coal, cellulose residues, coconut shells, and petroleum coke.[3] However, cosmetic charcoal ingredients are manufactured from plant-derived products only, such as bamboo. The raw materials may be carbonized and activated at a high temperature with or without the addition of inorganic salts in a stream of activating gases such as steam or carbon dioxide. Alternatively, the raw material may be treated with a chemical-activating agent such as phosphoric acid or zinc chloride, with the mixture then carbonized at an elevated temperature followed by removal of the chemical-activating agent by water washing.

Activated charcoal sourced from bamboo (see above) is produced by mixing the bamboo charcoal with carbon dioxide, nitric acid, ammonia, or other materials (not specified) before it is heated to 500 - 1200°C for several hours.[5] The annealed bamboo charcoal is then cooled.

Composition and Impurities

Charcoal Powder

According to the *Food Chemicals Codex*, activated charcoal may not contain more than 3 mg/kg arsenic, 10 mg/kg lead, or 0.004% heavy metals (as lead).[3] Testing specifications were also provided for organic impurities such as cyanogen compounds and higher aromatic hydrocarbons, but quantifiable limits were not described.

USE

Cosmetic

The safety of the cosmetic ingredients addressed in this assessment is evaluated based on data received from the US FDA and the cosmetics industry on the expected use of these ingredients in cosmetics and does not cover their use in airbrush delivery systems. Data are submitted by the cosmetic industry via the US FDA Voluntary Cosmetic Registration Program (VCRP) database (frequency of use) and in response to a survey conducted by the Personal Care Products Council (Council) (maximum use concentrations). The data are provided by cosmetic product categories, based on 21CFR Part 720. For most cosmetic product categories, 21CFR Part 720 does not indicate type of application and, therefore, airbrush application is not considered. Airbrush delivery systems are within the purview of the US Consumer Product Safety Commission (CPSC), while ingredients, as used in airbrush delivery systems, are within the jurisdiction of the FDA. Airbrush delivery system use for cosmetic application has not been evaluated by the CPSC, nor has the use of cosmetic ingredients in airbrush technology been evaluated by the FDA. Moreover, no consumer habits and practices data or particle size data are publicly available to evaluate the exposure associated with this use type, thereby preempting the ability to evaluate risk or safety.

Use for Charcoal Powder and activated charcoal has been reported separately to both the VCRP and in the concentration of use survey conducted by the Council, and accordingly, are presented separately in this safety assessment. According to 2023 VCRP survey data, Charcoal Powder has the highest frequency of use; it is reported to be used in 231 formulations, with a majority of uses in rinse-off formulations, such as skin cleansing preparations (Table 3).[6] Activated charcoal is reported to be used in 53 formulations, also with the majority of uses in rinse-off formulations. The results of the concentration of use survey conducted by the Council in 2021 indicate that Charcoal Powder has the highest concentration of use; it is used at up to 4.8% in eyeliners and at up to 4% in paste masks (mud packs).[7]

Some charcoal ingredients may be incidentally ingested or used near the eye or mucous membranes. For example, Charcoal Powder is reported to be used in lipstick (0.25%), eyeliners (4.8%), and bath soaps and detergents (3%).[7] Additionally, some of the ingredients are used in cosmetic sprays and could possibly be inhaled; for example, Charcoal Powder is reported to be used in a hair spray at 0.001%.[7] It has been noted that Charcoal Powder may be used in dry shampoos; although the VCRP and Council survey data do not specify use in dry shampoos, Charcoal Powder is reported to be used in 24 formulations at a maximum use concentration of 0.03%. Please refer to the Panel's respiratory exposure resource document for information regarding exposures from incidental inhalation (https://www.cir-safety.org/cir-findings).

Although products containing some of these ingredients may be marketed for use with airbrush delivery systems, this information is not available from the VCRP or the Council survey. Without information regarding the frequency and concentrations of use of these ingredients (and without consumer habits and practices data or particle size data related to this use technology), the data are insufficient to evaluate the exposure resulting from cosmetics applied via airbrush delivery systems.

The charcoal ingredients named in the report are not restricted from use in any way under the rules governing cosmetic products in the European Union (EU).[8]

Non-Cosmetic

Charcoal has been used since ancient Egyptian times, initially for metallurgy and cooking.[9,10] The first recorded use in oral hygiene was reported by Hippocrates in ancient Greece.[9,11] Medicinal use to treat the ingestion of poisons was first reported in the early 1800s.[9,10]

Charcoal (non-activated) has been studied as a treatment for irritable bowel syndrome,[12] and in tattoo localization in surgical procedures (peat-derived).[13] Wood charcoal has been present in over-the-counter (OTC) digestive aids; however, there are inadequate data to establish general recognition of the safety and effectiveness of this ingredient for the specified use (21CFR Part 310.545). Nano charcoal (derived from bamboo) has been studied as a drug delivery carrier.[14,15] Charcoal (derived from bamboo) also has been studied for use in water treatment to adsorb heavy metals, such as cadmium,[16] and fluorinated compounds, such as perfluorooctanoic acid.[17] Charcoal is also reported to be used in the filters of some types of cigarettes.[18] Charcoal has been reported to be a food ingredient in China, Taiwan, South Korea, and Japan.[19]

Per the *Food Chemicals Codex*, activated charcoal functions as a decolorizing agent, a taste- and odor-removing agent, and a purification agent in food processing.[3] The FDA allows the use of activated charcoal for purification in the production of synthetic paraffin that is used in direct and indirective food additives (21CFR Part 172.250 and Part 172.615). Activated charcoal has been present in OTC digestive aids and antidiarrheal drug products; however, there are inadequate data to establish general recognition of the safety and effectiveness of this ingredient for the specified uses (21CFR Part 310.545). The FDA lists activated charcoal as beneficial in the treatment of aspirin overdose, but only after emesis and lavage, and if less than 3 h has passed since ingestion (21CFR Part 343.80). Activated charcoal is used in emergency medicine and veterinary medicine as an oral and hemoperfusion adsorbent of ingested poisons.[20-28] The World Health Organization (WHO) has listed activated charcoal as an essential medicine for its use as an antidote used in poisonings.[29] Dressings and treatments using up to 98% activated charcoal have been studied for use in controlling foul odor associated with severe skin disorders and chronic wounds.[30,31] Activated charcoal has also been studied for use in tattoo localization in surgical procedures,[32] in topical drug-delivery systems,[33] as a treatment for intrahepatic cholestasis of pregnancy,[34] as a treatment for high cholesterol,[35] and as a treatment for uremia in patients with renal disease.[10,36]

TOXICOKINETIC STUDIES

No toxicokinetic studies were reported for charcoal ingredients in the published literature and unpublished data were not submitted. However, a summary of toxicity data under "Basic Toxicokinetics" in the ECHA dossier for Charcoal concluded that there is low potential for absorption by oral ingestion and dermal application.[2]

TOXICOLOGICAL STUDIES

Acute Toxicity Studies

Oral

Charcoal Powder

An acute oral study of Charcoal Powder (bamboo-sourced) was performed in accordance with Organisation for Economic Co-Operation and Development (OECD) test guideline (TG) 420.[37] Groups of 10 male and 10 female Sprague-Dawley rats received a single dose by gavage of 11,240 mg/kg bw of one of 2 kinds of Charcoal Powder with either 93.5% purity (size distribution of 50% of particles (D_{50}) = 2.175 µm) or 95.5% purity (D_{50} = 10.514 µm) in ultrapure deionized water. Control groups received only the vehicle. Mortality and clinical signs of toxicity were assessed at 30 min, 4 h, and daily up to 14 d post-treatment, and body weights were recorded on observation days 1, 7, and 14. The animals were killed at the end of the observation period, and organs were analyzed. No mortalities were observed. All rats exposed to Charcoal Powder had black colored feces, which resolved after 2 d. One rat given the Charcoal Powder with 93% purity had diarrhea, which abated after 2 d. No other clinical signs were observed. No significant differences were found in the body weights in the groups treated with either Charcoal Powder when compared to the controls. No treatment-related histological changes in the organs were observed. The LD_{50} of both types of Charcoal Powder in both male and female rats was greater than 11,240 mg/kg bw.

Inhalation

Charcoal

In an acute inhalation study performed in accordance with OECD TG 403, 5 male and 5 female Wistar Crl:(WI) BR rats were exposed to a mean concentration of 4.97 mg/l air of Charcoal (carbon content (C-fix) = 80.5%; the test article was micronized powder milled to 150 µm).[2] During testing, 52.3% of the particles generated in the chamber were < 4 µm (considered the respirable fraction); the mass median aerodynamic diameter/geometric standard deviation was 3.523 µm/2.46 µm. The rats were exposed nose-only for 4 h, and then observed for 14 d. No mortality occurred during the exposure period. Clinical signs, specifically decreased activity, general reactions, and dyspnea, were observed between the third hour of inhalation exposure and the first hour of the observation period in both males and females. All animals were symptom-free starting day 1 of the observation period. No toxicologically-relevant findings were noted at necropsy. The LC_{50} was greater than 4.97 mg/l.

Short-Term Toxicity Studies

Oral

Charcoal Powder

In a short-term oral study performed in accordance with OECD TG 407, groups of 5 male and 5 female Sprague Dawley rats received 1 of 2 kinds of Charcoal Powder (93.5% purity; D_{50} = 2.175 µm or 95.5% purity; D_{50} = 10.514 µm) in ultrapure deionized water daily for 28 d via gavage.[37] The Charcoal Powder was sourced from bamboo. The dose levels for both types of Charcoal Powder were 2810, 5620, or 11,240 mg/kg bw. Control groups received only the vehicle. Mortality and clinical signs of toxicity were assessed daily. Feed consumption was recorded once per week. Surviving animals were killed at the end of the treatment period following an 18 h fast. Blood samples and organs were analyzed.

No mortalities or obvious signs of toxicity were observed in the rats in any dose group. A dose-related change in the color of the feces was observed, with increased doses producing darker colored feces. No significant changes were observed in body weight gains or feed consumption. No significant differences were noted in relative weights of the organs or hematological and biochemical parameters of the treated animals when compared to the controls. In the treated rats, the gastrointestinal tract content was black. No other treatment-related macroscopic findings were observed. There were no treatment-related microscopic findings. The no-observed-adverse-effect level (NOAEL) was greater than 11,240 mg/kg bw/d for both Charcoal Powder types in both sexes.[37]

Subchronic Toxicity Studies

Oral

Charcoal Powder

In a 90-d study performed in accordance with OECD TG 408 by the same research group, Charcoal Powder (bamboo-sourced; 93.5% pure; D_{50} = 2.175 µm) was administered orally to groups of 10 male and 10 female Sprague Dawley rats at 0, 2810, 5620, or 11,240 mg/kg bw/d.[19] The test material was mixed in ultrapure water and administered via gavage (2 ml/kg bw). The rats were observed for clinical signs of toxicity, and feed consumption, body and organ weights, and hematological and biochemical parameters were measured. Additional satellite groups (5 males and 5 females each) from the control group and the high dose group were observed for a 28-d recovery period. At the end of the treatment and recovery periods, the rats were killed, blood samples were collected, and the brain, thymus, heart, liver, kidneys, adrenal gland, spleen, testes, epididymides, uterus, and ovaries were weighed. Macroscopic and microscopic examinations were performed.

No mortalities were observed during the dosing period or the recovery period. No clinical signs of toxicity were observed other than a dose-related change in the color of feces in the treated groups, which returned to normal color in the recovery group. No significant differences ($p > 0.05$) were observed in feed consumption or organ weights among the rats in the treatment and recovery periods. All treated rats gained weight normally during the dosing and recovery periods. No significant differences were observed in hematology parameters or other biochemical parameters of the treated rats compared to the controls. After 90 d of treatment, the gastrointestinal tracts of the treated rats were black. No other macroscopic findings were reported at necropsy. Slight inflammatory cell infiltration in the bronchium and cardiac muscles of 5% of the male rats was observed without intergroup differences, and hepatic steatosis, mineralization of the kidney medulla, and eosinophilic granulocyte infiltration of the uterus were observed in 8% of female rats, without difference in severity among all groups. These microscopic findings were not considered treatment-related in any of these rats. The NOAEL was determined to be 11,240 mg/kg bw/d in both sexes.[19]

DEVELOPMENTAL AND REPRODUCTIVE TOXICITY (DART) STUDIES

DART studies for charcoal ingredients were not found in the published literature, and unpublished data were not submitted.

GENOTOXICITY STUDIES

In vitro and in vivo genotoxicity data on Charcoal and Charcoal Powder are summarized in Table 4. Charcoal (C-fix 73.3 to 88.7%) and Charcoal Powder were not mutagenic in Ames tests at up to 5000 µg/plate.[2,19] No clastogenic activity was observed in chromosome aberration tests with V79 Chinese hamster lung cells or human peripheral blood lymphocytes exposed to Charcoal (C-fix 75.75 to 83.3%; up to 5000 µg/ml).[2] No genotoxicity was observed to Charcoal in gene mutation assays with mouse lymphoma cells (C-fix 80.5%; tested up to 2400 µg/ml) or in an in vitro micronucleus test with human peripheral blood lymphocytes (C-fix 83.3%; up to 2000 µg/ml). No mutagenicity was reported in a Comet assay or an erythrocyte micronucleus study of Charcoal Powder (up to 11,240 mg/kg orally) conducted in mice.[19]

CARCINOGENICITY STUDIES

Charcoal Powder

In lung tumor induction studies, Charcoal Powder was given to male C57BL/6 andC3H/He mice with and without the carcinogen 3,4-benzopyrene.[38] Groups of mice (number not reported) received intratracheally 1.0 mg benzopyrene with 0.5 mg of Charcoal Powder or 0.5 mg of benzopyrene with 0.5 mg Charcoal Powder in 0.025 ml of 0.9% sodium chloride

solution once a week for 4, 8, or 16 wk. Control mice (34 for strain C57Bl/6 and 33 for strain C3H/H3) received 0.5 mg of Charcoal Powder in 0.025 ml of 0.9% sodium chloride solution once a week for 8 wk. The mice were examined daily and weighed weekly during the observation period of 120 wk. Animals that died naturally or were killed for humane reasons prior to study end were necropsied. Lungs with trachea and mediastinal organs, liver, spleen, kidneys, adrenals and stomach were examined. For histological examination of early changes of the epithelium of the respiratory tract, 5 mice were killed sequentially 1, 3, 5, 7, and 10 wk after receiving 8 high doses of benzopyrene.

During the study, some of the control mice died of pneumonia without tumors. The mean body weights of the animals that received just Charcoal Powder were observed to increase up until week 30 of the observation period before gradually decreasing until study end. In macroscopic observations, Charcoal Powder was observed to be distributed almost equally in each lobe of the lung after a single instillation of benzopyrene and Charcoal Powder. In the mice that received 8 doses of the high dose of benzopyrene, many tiny nodular lesions were observed on the surface of the lung as early as 2 wk after the last instillation: these lesions were always surrounded by charcoal deposits. In microscopic findings, sections of stained lung showed Charcoal Powder evenly distributed in the periphery of the lung along with the benzopyrene, especially in the terminal bronchioles and alveoli. Occasionally the Charcoal Powder was phagocytosed by alveolar macrophages. In the animals that received both benzopyrene and Charcoal Powder, tumors of various sizes were observed after week 10, with some being highly keratinized squamous cell carcinomas. In the controls (those just receiving Charcoal Powder in solution), no tumors were observed in the C57BL/6 mice within 110 wk and only 1 alveolar-type adenoma was observed in C3H/He mice within 100 wk.[38]

OTHER RELEVANT STUDIES

Cytotoxicity

Charcoal Powder

The effects of highly-porous activated charcoal (coconut-shell sourced; 1 μm) on cell viability was studied in an 3-(4,5-dimethylthiazol-2-yl)-2,5-diphenyltetrazolium bromide (MTT) assay on human corneal epithelial cells, human foreskin fibroblasts, vaginal epithelial cells, and HeLa cell lines.[33] Activated charcoal was tested at up to 10 mg/ml for 24 h. At the end of incubation, MTT (0.5 mg/ml in whole media) was added and incubated for an additional 3 h. Cell viability was greater than 75% in all cell types. It was concluded that highly porous activated charcoal was not cytotoxic.

DERMAL IRRITATION AND SENSITIZATION STUDIES

Dermal irritation and sensitization data on Charcoal are summarized in Table 5. Charcoal (C-fix 73.3, 80.5, and 88.7%) was not predicted to be irritating in reconstructed human epidermis model tests, nor was it irritating in a rabbit primary skin irritation test when tested under occlusion at a concentration of 100%.[2] In 3 different local lymph node assays (LLNAs) in mice with up to 10% Charcoal (C-fix 73.3, 80.5, and 88.7%), an effective concentration inducing a stimulation index of 3 (EC_3) could not be calculated.

OCULAR IRRITATION STUDIES

Ocular irritation data on Charcoal are summarized in Table 6. Charcoal (C-fix 73.3, 80.5, and 88.7%) was not predicted to be an ocular irritant when tested neat in hen's egg test-chorioallantoic membrane (HET-CAM) studies, nor was Charcoal (C-fix 80.5%) irritating in rabbit eyes according to EU criteria when instilled undiluted; slight to severe conjunctival irritant effects that were observed were fully reversible within 1 wk.[2]

CLINICAL STUDIES

Case Report

A 52-yr-old woman presented with intermittent mild loose stool with no other specific medical comorbidities.[39] A colonoscopy revealed numerous small and medium-sized irregular grayish black pigmentations mostly on the background of geographic light grayish discolored mucosa and some on the normal-looking mucosa on the terminal ileum. Microscopic examination of the biopsy specimen taken from the pigmented mucosa showed black, coarse, and dust-like particles with irregular borders freely dispersed or focally aggregated in the lamina propria and submucosa. A review of the patient's medication history after endoscopy revealed she had ingested Charcoal Powder (approximately 10 g) with a glass of water daily for 2 yr. A colonoscopy 5 yr prior revealed no melanosis of the terminal ileum at that time. The pigmented particles were considered exogenous, and the pigmentation was likely due to the Charcoal Powder. The patient was advised to stop ingesting Charcoal Powder. A follow-up colonoscopy 10 mo later found no significant change to the pigmentation of the terminal ileum.

Other Clinical Reports

Charcoal

In a study with irritable bowel syndrome patients, Charcoal (non-activated) in a formulation and as a control was evaluated in 284 patients.[12] The patients orally received at minimum 180 mg Charcoal daily for 12 wk. Endpoints monitored

were overall well-being, decrease in irritable bowel syndrome severity score, other irritable bowel syndrome characteristics, self-assessed gastrointestinal events (e.g., abdominal pain, bloating, stool, etc.), safety/tolerability, and number of patients withdrawn for treatment failure. Mild or moderate adverse events, which mainly affected the gastrointestinal tract, were reported in 21% of the patients that received the formulation and 17% that received the control. No serious, unusual, or unexpected adverse events were observed.

In another study, 26 patients with chronic stasis leg ulcers and 13 patients with suppurating post-operative wounds received a single layer of Charcoal cloth (50 - 800 cm^2).[40] Treatment sites were monitored for wound odor, wound healing, and wound cleansing. No adverse effects to the material were observed.

Charcoal Powder

Several studies have been conducted to investigate whitening, remineralization, and anti-caries claims in dentifrice and mouthwash products.[11,41-49] In one double-blind clinical trial for remineralization and anti-caries effects with 12 subjects using a toothpaste containing activated charcoal (concentration not reported) twice daily for 90 d, no adverse events or side effects were reported or observed.[42]

Activated charcoal was given orally (6 g/d for 8 wk) to 11 stable hemodialysis patients with idiopathic generalized pruritus.[50] Self-assessed itching intensity was recorded by the patients, and changes in skin lesions and serum chemistry, including lipids, alkaline phosphatase, phosphorus, and calcium, were examined during the study. No adverse effects from activated charcoal were noted.

In an efficacy study of an inhaled asthma drug, activated charcoal (suspension; 50 g in 250 ml tap water) was given orally to 33 healthy subjects to prevent gastrointestinal absorption of the test drug.[51] The subjects received the activated charcoal as a 10 g dose prior to inhalation of the test drug and as a 30 g dose during the 1.5 h after inhalation or oral ingestion of the test drug in 4 different treatment scenarios (4 single treatments total). The subjects rinsed their mouths with 2 x 25 ml of activated charcoal-water suspension and with 25 ml tap water prior to swallowing the activated charcoal suspension and water. This rinsing procedure was performed immediately before and after drug administration and repeated after 45 min and 1.5 h. No further details were provided on the dosing of activated charcoal. The efficacy of the activated charcoal was determined via venous blood samples measuring the concentration of the asthma drug. Thirty subjects completed the study; one subject withdrew due to an adverse event (stomatitis; no further details). The most frequently reported adverse events were headache and respiratory tract infection; the adverse events were not specifically attributed to use of activated charcoal.

SUMMARY

The safety of 3 plant-derived charcoal ingredients as used in cosmetics is assessed herein; only plant-derived charcoal ingredients, and not those derived from petroleum or other mineral sources, are included in this assessment. According to the *Dictionary*, all three ingredients are reported to function in cosmetics as opacifying agents and two are reported to function as abrasives and absorbents. Additional functions are reported for each as well; specifically, Charcoal Powder is reported to function as a colorant in cosmetics. However, Charcoal Powder is not listed as an approved colorant by the US FDA and therefore not allowed to be used as such in cosmetics in the US. Furthermore, colorants (with the exception of coal tar hair dyes) are not under the purview of the Panel and use as such in not addressed in this assessment. Per the INC, activated charcoal is a synonym of Charcoal Powder; however, because activated charcoal is the more commonly known name in published literature and the medical community, it will also be referred to as such herein in the appropriate studies but described under the ingredient heading Charcoal Powder.

According to 2023 VCRP survey data, Charcoal Powder has the highest frequency of use; it is reported to be used in 231 formulations, with a majority of uses in rinse-off formulations, such as skin cleansing preparations. Activated charcoal (reported separately from Charcoal Powder even though these 2 names are synonyms) is reported to be used in 53 formulations, also with the majority of uses in rinse-off formulations. The results of the concentration of use survey conducted by the Council in 2021 indicate that Charcoal Powder has the highest concentration of use; it is used at up to 4.8% in eyeliners and up to 4% in paste masks (mud packs).

Charcoal has been used since ancient Egyptian times, initially for metallurgy and cooking. Charcoal ingredients have been studied for many medical treatments, are used as food ingredients in several Asian countries, and are used in filtration. Activated charcoal is used in purification of paraffin used in direct and indirect food additives and is well known for its use in emergency medicine for poisoning treatment.

In an acute oral study, the LD_{50} for Charcoal Powder in male and female rats is greater than 11,240 mg/kg bw. The LC_{50} in an acute rat inhalation study of Charcoal (C-fix 80.5%; 52.3% of particles < 4 μm; mass median diameter/geometric standard deviation = 3.523 μm/2.46 μm) was greater than 4.97 mg/l. The NOAEL for Charcoal Powder in an oral 28-d and 90-d study in rats was 11,240 mg/kg bw/d, which was the maximum dose tested in both studies.

Charcoal (C-fix 73.3 to 88.7%) and Charcoal Powder were not mutagenic in Ames tests at up to 5000 μg/plate. No clastogenic activity was observed in chromosome aberration tests with V79 Chinese hamster lung cells or human peripheral blood lymphocytes exposed to Charcoal (C-fix 75.75 to 83.3%; up to 5 mg/ml). No genotoxicity was observed to Charcoal

(C-fix 80.5%) in gene mutation assays with mouse lymphoma cells (tested up to 2400 μg/ml) or in a cell micronucleus test (C-fix 83.3%) with human peripheral blood lymphocytes (up to 2000 μg/ml). No mutagenicity was reported in a Comet assay and an erythrocyte micronucleus study of Charcoal Powder (up to 11,240 mg/kg orally) conducted in mice.

In a lung tumor induction study using two strains of mice, controls received Charcoal Powder only. No tumors were observed in the C57BL/6 strain of mice during a 110-wk observation period, and only one alveolar-type adenoma was observed in C3H/He mice during a 100-wk observation period.

The cytotoxicity of a highly-porous activated charcoal was studied in an MTT assay on human corneal epithelial cells, human foreskin fibroblasts, vaginal epithelial cells, and HeLa cell lines. Activated charcoal was not cytotoxic in any of the cells.

Charcoal (C-fix 73.3, 80.5, and 88.7%) was predicted to be not irritating in reconstructed human epidermis model tests and was not irritating in a rabbit primary skin irritation test when tested at a concentration of 100%. In 3 different mouse LLNAs with up to 10% Charcoal (C-fix 73.3, 80.5, and 88.7%), an EC_3 could not be calculated. In ocular irritation studies, Charcoal (C-fix 73.3 to 88.7%) was not predicted to be an ocular irritant when tested neat in HET-CAM studies, and it was not irritating in rabbit eyes according to EU criteria.

Clinical studies have been conducted using charcoal ingredients. A clinical study was performed with a toothpaste containing activated charcoal, in which 12 subjects used the test material twice daily for 90 d. No adverse events or side effects were reported or observed. No adverse effects were reported with charcoal ingredients when used as treatments for irritable bowel syndrome, leg ulcers, and idiopathic generalized pruritus. Although adverse events were observed in a study of an inhaled drug comprising in part activated charcoal, to prevent gastrointestinal absorption, those events were not considered attributable to the activated charcoal

DISCUSSION

The Panel reviewed the safety of 3 plant-derived charcoal ingredients and concluded that these ingredients are safe as used in cosmetics in the present practices of use and concentration described in this safety assessment. The charcoal ingredients reviewed in this safety assessment are derived from plant sources (e.g. bamboo); accordingly, charcoal derived from petroleum and other mineral sources are excluded from this safety assessment.

The Panel concluded that the available data are sufficent for determining the safety of these ingredients for use in cosmetic products. They noted the lack of systemic toxicity in acute and repeated-dose studies at up to 11,240 mg/kg bw and the safe use of activated charcoal (synonymous with Charcoal Powder) as an oral treatment for poisioning. The Panel also noted negative results in irritation and sensitization in tests of dermal exposure, and in genotoxicity using in vitro and in vivo test systems.

Furthermore, the Panel discussed the issue of incidental inhalation exposure that may result from the use of formulations containing these ingredients (i.e., Charcoal Powder is used in a hair spray at 0.001%). Data available from inhalation studies, including an acute rat study with Charcoal and an intratracheal rat carcinogenicity study with Charcoal Powder, suggest little potential for respiratory effects at doses relevant to cosmetic use. A detailed discussion and summary of the Panel's approach to evaluating incidental inhalation exposures to ingredients in cosmetic products is available at https://www.cir-safety.org/cir-findings.

The Panel's respiratory exposure resource document (see link above) notes that airbrush technology presents a potential safety concern, and that no data are available for consumer habits and practices thereof. As a result of deficiencies in these critical data needs, the safety of cosmetic ingredients applied by airbrush delivery systems cannot be assessed by the Panel. Therefore, the Panel has found the data insufficient to support the safe use of cosmetic ingredients applied via an airbrush delivery system.

CONCLUSION

The Expert Panel for Cosmetic Ingredient Safety concluded that the following 3 plant-derived charcoal ingredients are safe in cosmetics in the present practice of use and concentration described in this safety assessment:

Charcoal
Charcoal Extract
Charcoal Powder

TABLES

Table 1. Definitions and reported functions of the ingredients in this safety assessment.[1,3]

Ingredient & CAS No.	Definition	Function(s)
Charcoal 16291-96-6	Charcoal is the dried, carbonaceous material obtained from the heating of organic substances.	abrasive; absorbent; deodorant agent; opacifying agent
Charcoal Extract	Charcoal Extract is the extract of Charcoal.	opacifying agent; skin-conditioning agent – miscellaneous
Charcoal Powder 7440-44-0; 64365-11-3; 16291-96-6	Charcoal Powder is finely ground Charcoal. *The chemical name, "activated charcoal" is considered to be a synonym for Charcoal Powder.*	abrasive; absorbent; colorant; opacifying agent

Table 2. Chemical properties.

Property	Value	Reference
Charcoal Powder (reported as activated charcoal)		
Physical Form	black powder or granules	4
Density (g/ml @ 25 ºC)	1.8 - 2.1	52
Melting Point (ºC)	3550	52
Vapor Pressure (mm Hg @ 25 ºC)	0.750	52
Water Solubility	insoluble	2
Organic Solvent Solubility	insoluble	2
Charcoal		
Physical Form	black, porous solid, coarse granules or powder	2
Specific Gravity (@ 20 ºC)	1.41 - 1.50	2
Particle Size Distribution (%) < 100 µm < 10 µm	 0.53 – 0.87 < 0.3	2
Melting Point (ºC)	> 300	2
log K_{ow} (@ 20 ºC)	1.474	2
Water Solubility	low	2

Table 3. Frequency (2023)[6] and concentration (2021)[7] of use according to likely duration and exposure and by product category.

	Charcoal†		Charcoal Extract		Charcoal Powder		activated charcoal	
	# of Uses	Max Conc of Use (%)	# of Uses	Max Conc of Use (%)	# of Uses	Max Conc of Use (%)	# of Uses	Max Conc of Use (%)
Totals*	**9**	**NR**	**15**	**0.0004-0.5**	**231**	**0.0001-4.8**	**53**	**0.2-0.5**
summarized by likely duration and exposure**								
Duration of Use								
Leave-On	*3*	*NR*	*3*	*0.0004-0.0038*	*71*	*0.001-4.8*	*11*	*0.2*
Rinse-Off	*6*	*NR*	*12*	*0.0004-0.5*	*157*	*0.0001-4*	*38*	*0.35-0.5*
Diluted for (Bath) Use	*NR*	*NR*	*NR*	*NR*	*3*	*0.005*	*4*	*NR*
Exposure Type*								
Eye Area	NR	NR	NR	NR	3	4.8	1	NR
Incidental Ingestion	NR	NR	NR	NR	28	0.13-0.25	9	NR
Incidental Inhalation-Spray	1[b]	NR	1[a]; 2[b]	0.0004[a]	1; 10[a]; 36[b]	0.001	1[a]; 2[b]	NR
Incidental Inhalation-Powder	1[b]	NR	2[b]	0.0019-0.0038[c]	36[b]	0.0028[c]	2[b]	NR
Dermal Contact	9	NR	10	0.0004-0.5	163	00.001-4.8	44	0.2-0.5
Deodorant (underarm)	NR	NR	NR	NR	2[a]	0.0062	NR	NR
Hair - Non-Coloring	NR	NR	5	0.0004-0.005	38	0.0001-0.7	NR	NR
Hair-Coloring	NR	NR	NR	NR	1	NR	NR	NR
Nail	NR	NR	NR	NR	NR	NR	NR	NR
Mucous Membrane	NR	NR	4	0.0004-0.5	58	0.001-3	21	NR
Baby Products	NR	NR	NR	NR	NR	NR	NR	NR
as reported by product category								
Bath Preparations (diluted for use)								
Bath Oils, Tablets, and Salts					1	0.001-0.005	3	NR
Other Bath Preparations					2	NR	1	NR
Eye Makeup Preparations								
Eyeliner					NR	4.8		
Mascara					1	NR		
Other Eye Makeup Preparations					2	NR	1	NR
Hair Preparations (non-coloring)								
Hair Conditioner			3	0.0019-0.005	9	0.0005-0.7		
Hair Spray (aerosol fixatives)					1	0.001		
Rinses (non-coloring)			1	NR	1	NR		
Shampoos (non-coloring)			1	0.0004-0.002	24	0.0001-0.03		
Tonics, Dressings, and Other Hair Grooming Aids					1	NR		
Other Hair Preparations					2	NR		
Hair Coloring Preparations								
Hair Bleaches					1	NR		
Makeup Preparations								
Lipstick					NR	0.25		
Makeup Bases					1	NR		
Oral Hygiene Products								
Dentifrices					22	0.13	8	NR
Mouthwashes and Breath Fresheners					2	NR		
Other Oral Hygiene Products					4	NR	1	NR
Personal Cleanliness Products								
Bath Soaps and Detergents			4	0.0019-0.5	20	0.005-3	7	NR
Deodorants (underarm)					2	0.0062		
Other Personal Cleanliness Products			NR	0.0004	7	NR	1	NR
Shaving Preparations								
Shaving Cream					1	0.005		
Other Shaving Preparations			NR	0.0006				

Table 3. Frequency (2023)[6] and concentration (2021)[7] of use according to likely duration and exposure and by product category.

	Charcoal†		Charcoal Extract		Charcoal Powder		activated charcoal	
	# of Uses	Max Conc of Use (%)	# of Uses	Max Conc of Use (%)	# of Uses	Max Conc of Use (%)	# of Uses	Max Conc of Use (%)
Skin Care Preparations								
Cleansing	3	NR	2	0.0038-0.05	45	0.0063-0.1	15	0.35
Face and Neck (exc shave)	1	NR	2	0.0038	32	0.0028	2	NR
Body and Hand (exc shave)			NR	0.0019	4	NR		
Moisturizing			1	NR	1	NR	1	NR
Night					4	NR		
Paste Masks (mud packs)	3	NR	1	NR	21	0.037-4	6	0.5
Skin Fresheners			NR	0.0004	2	NR		
Other Skin Care Preparations	2	NR			18	0.01-0.3	7	0.2

†Listed as Bamboo Charcoal in the VCRP database.
NR – not reported
*Because each ingredient may be used in cosmetics with multiple exposure types, the sum of all exposure types may not equal the sum of total uses.
**Likely duration and exposure is derived based on product category (see Use Categorization https://www.cir-safety.org/cir-findings)
[a] It is possible these products are sprays, but it is not specified whether the reported uses are sprays.
[b] Not specified whether a spray or a powder, but it is possible the use can be as a spray or a powder, therefore the information is captured in both categories
[c] It is possible these products are powders, but it is not specified whether the reported uses are powders.

Table 4. Genotoxicity studies.

Test Article	Concentration/Dose	Vehicle	Test System	Procedure	Results	Reference
			IN VITRO			
Charcoal (batch with C-fix = 73.3%)	50 - 5000 µg/plate with plate incorporation method; 313 - 5000 µg/plate with pre-incubation method	ethanol	*Salmonella typhimurium* TA97a, TA98, TA100, TA102, and TA1335	Bacterial reverse mutation assay, with and without S9 metabolic activation; in accordance with OECD TG 471; positive and negative controls used	Not mutagenic, with or without metabolic activation, in all tester strains	[2]
Charcoal (batch with C-fix = 80.5%)	50 - 5000 µg/plate with plate incorporation method; 313 - 5000 µg/plate with pre-incubation method	ethanol	*S. typhimurium* TA97a, TA98, TA100, TA102, and TA1335	Bacterial reverse mutation assay, with and without S9 metabolic activation; in accordance with OECD TG 471; positive and negative controls used	Not mutagenic, with or without metabolic activation, in all tester strains; controls yielded expected results	[2]
Charcoal (batch with C-fix – 88.7%)	50 - 5000 µg/plate with plate incorporation method; 313 - 5000 µg/plate with pre-incubation method	ethanol	*S. typhimurium* TA97a, TA98, TA100, TA102, and TA1335	Bacterial reverse mutation assay, with and without S9 metabolic activation; in accordance with OECD TG 471; positive and negative controls used	Not mutagenic, with or without metabolic activation, in all tester strains; controls yielded expected results	[2]
Charcoal (batch with C-fix = 83.26%)	50 - 5000 µg/plate with plate incorporation method	dimethyl sulfoxide (DMSO)	*S. typhimurium* TA98, TA100, TA1535, and TA153 and *Escherichia coli* WP2 uvrA	Bacterial reverse mutation assay, with and without S9 metabolic activation; in accordance with OECD TG 471; positive and negative controls used	Not mutagenic, with or without metabolic activation, in all tester strains; controls yielded expected results	[2]
Charcoal (total carbon 83.11%, C-fix = 75.72%)	50 - 5000 µg/plate with plate incorporation method and pre-incubation method	DMSO	*S. typhimurium* TA97a, TA98, TA100, TA102, and TA1335	Bacterial reverse mutation assay, with and without S9 metabolic activation; in accordance with OECD TG 471; positive and negative controls used	Not mutagenic, with or without metabolic activation, in all tester strains; controls yielded expected results	[2]
Charcoal (batch with C-fix = 80.5%)	1250, 2500, or 5000 µg/ml	Dulbecco's Modified Eagle medium	V79 male Chinese hamster lung cells	Mammalian chromosome aberration test in accordance with OECD TG 473, with and without S9 metabolic activation; positive and negative controls used	Not clastogenic; test material did not induce structural chromosome aberrations, with or without metabolic activation; controls yielded expected results	[2]

Table 4. Genotoxicity studies.

Test Article	Concentration/Dose	Vehicle	Test System	Procedure	Results	Reference
Charcoal (batch with C-fix = 83.3%)	3-h exposure with and without S9: 150, 500, 1500, or 5000 µg/ml mg/ml 24-h exposure without S9: 500, 1000, 2500, or 5000 µg/ml	Dulbecco's Modified Eagle medium	V79 male Chinese hamster lung cells	Mammalian chromosome aberration test in accordance with OECD TG 473, with and without S9 metabolic activation; positive and negative controls used	Not clastogenic; test material did not induce structural chromosome aberrations, with or without metabolic activation; controls yielded expected results	[2]
Charcoal (total carbon 83.11%, C-fix = 75.75%)	3-h exposure with and without S9 100, 300, or 1000 µg/ml 24-h exposure without S9 100, 300, or 1000 µg/ml	DMSO	human peripheral blood lymphocytes	Mammalian chromosome aberration test in accordance with OECD TG 473, with and without S9 metabolic activation; positive and negative controls used	Not mutagenic; test material did not induce any biologically significant or concentration-related increase in the incidence of chromosome aberrations, with or without metabolic activation; controls yielded expected results	[2]
Charcoal (batch with C-fix = 80.5%)	128, 320, 800, 2000 µg/ml	acetone/n-hexane 50:50 (v:v)	mouse lymphoma L5178Y $TK^{+/-}$ cells	Mammalian cell gene mutation assay in accordance with OECD TG 476; with and without S9 metabolic activation; positive and negative controls used	Not mutagenic; test material did not induce gene mutations, with or without metabolic activation; controls yielded expected results	[2]
Charcoal (no further details)	up to 2400 µg/ml	not reported	mouse lymphoma L5178Y TK+/- cells	Mammalian cell gene mutation assay in accordance with OECD TG 476; with and without S9 metabolic activation; positive and negative controls used	Not mutagenic; test material did not induce gene mutations, with or without metabolic activation; controls yielded expected results	[2]
Charcoal (batch with C-fix = 83.3%)	125 - 2000 µg/ml	DMSO	human peripheral blood lymphocytes	Mammalian cell micronucleus test in accordance with OECD TG 487; with and without metabolic activation; positive and negative controls used	Not genotoxic, with or without metabolic activation; controls yielded expected results	[2]
Charcoal Powder (bamboo sourced)	8-5000 µg/plate with plate incorporation method	ultrapure water	*S. typhimurium* TA97, TA98, TA100, and TA102	Bacterial reverse mutation assay, with and without S9 metabolic activation; in accordance with OECD TG 471; positive and negative controls used	Not mutagenic, with or without metabolic activation, in all tester strains; controls yielded expected results	[19]
IN VIVO						
Charcoal Powder (bamboo-sourced)	0, 2810, 5620, or 11,240 mg/kg bw/d	ultrapure water	Groups of 5 male and 5 female Kunming mice	Comet assay in accordance with OECD draft guideline for the Testing of Chemicals – In Vivo Mammalian Alkaline Comet Assay; animals received test material for 4 d at 24-h intervals via gavage (2 ml/kg); clinical signs of toxicity and mortality were assessed; mice were killed 3 h after last dose; positive and negative controls used; liver cells analyzed in assay	Not mutagenic; no statistically significant differences in % tail DNA, tail length, and Olive tail moment indices between the negative control and the groups treated with the test material; no clinical signs of toxicity, including the positive control; positive control yielded expected results in assay	[19]
Charcoal Powder (bamboo-sourced)	0, 2810, 5620, or 11,240 mg/kg bw/d	ultrapure water	Groups of 5 male and 5 female Kunming mice	Mammalian erythrocyte micronucleus test in accordance with OECD TG 474; animals received test material for 4 d at 24-h intervals via gavage (2 ml/kg); clinical signs of toxicity and mortality were assessed; mice were killed 3 h after last dose; positive and negative controls used; bone marrow cells analyzed; 2000 polychromatic erythrocytes per animal evaluated for the presence of micronuclei and the ratio of polychromatic erythrocytes in 1000 normochromatic erythrocytes per animal were evaluated	Not mutagenic; no increase of micronuclei in the groups treated with the test material, comparable to negative control; no clinical signs of toxicity, including the positive control; positive control yielded expected results	[19]

Table 5. Dermal irritation and sensitization studies.

Test Article	Vehicle	Concentration/Dose	Test Population	Procedure	Results	Reference
IRRITATION						
IN VITRO						
Charcoal (batch with C-fix = 73.3%)	none	100%	Reconstructed human epidermis	Reconstructed human epidermis model test; positive and negative controls used	Not irritating; controls yielded expected results	[2]
Charcoal (batch with C-fix = 80.5%)	none	100%	Reconstructed human epidermis	Reconstructed human epidermis model test; positive and negative controls used	Not irritating; controls yielded expected results	[2]
Charcoal (batch with C-fix = 88.7%)	none	100%	Reconstructed human epidermis	Reconstructed human epidermis model test; positive and negative controls used	Not irritating; controls yielded expected results	[2]
ANIMAL						
Charcoal (bath with C-fix = 80.5%)	none	100%	3 male New Zealand White rabbits	Primary skin irritation test in accordance with OECD TG 404; single dose of 0.5 g applied moistened to test site and occluded; test material removed by rinsing with water after 4 h; signs of irritation were assessed at 1, 24, 48, and 72 h post-patch removal; untreated skin was negative control	Not irritating; no signs of erythema or edema observed	[2]
SENSITIZATION						
ANIMAL						
Charcoal (batch with C-fix = 73.3%)	propylene glycol	0, 2.5, 5, or 10% w/w	Groups of 4 female CBA/CaOlaHsd mice	LLNA in accordance with OECD TG 429; positive and negative controls used	Not sensitizing; stimulation indices (SI) for 2.5, 5, and 10% test material were 0.65, 0.72, and 1.11, respectively; an effective concentration inducing a stimulation index of 3 (EC_3) could not be calculated; controls yielded expected results	[2]
Charcoal (batch with C-fix = 80.5%)	propylene glycol	0, 2.5, 5, or 10% w/w	Groups of 4 female CBA/CaOlaHsd mice	LLNA in accordance with OECD TG 429; positive and negative controls used	Not sensitizing; SI for 2.5, 5, and 10% test material were 1.04, 0.87, and 1.30, respectively; an EC_3 could not be calculated; controls yielded expected results	[2]
Charcoal (batch with C-fix = 88.7%)	propylene glycol	0, 2.5, 5, or 10% w/w	Groups of 4 female CBA/CaOlaHsd mice	LLNA in accordance with OECD TG 429; positive and negative controls used	Not sensitizing; SI for 2.5, 5, and 10% test material were 1.25, 1.38, and 1.40, respectively; an EC_3 could not be calculated; controls yielded expected results	[2]

Table 6. Ocular irritation studies.

Ingredient	Concentration/Dose	Vehicle	Test Population	Procedure	Results	Reference
			IN VITRO			
Charcoal (batch with C-fix = 73.3%)	100%	None	6 Lohmann Selected Leghorn chicken eggs	HET-CAM method; membrane exposed to single application of ~50 mg for 5 min; negative and positive controls used	Not irritating; controls yielded expected results	[2]
Charcoal (batch with C-fix = 80.5%)	100%	None	6 Lohmann Selected Leghorn chicken eggs	HET-CAM method; membrane exposed to single application of ~50 mg for 5 min; negative and positive controls used	Not irritating; controls yielded expected results	[2]
Charcoal (batch with C-fix = 88.7%)	100%	None	6 Lohmann Selected Leghorn chicken eggs	HET-CAM method; membrane exposed to single application of ~50 mg for 5 min; negative and positive controls used	Not irritating; controls yielded expected results	[2]
			ANIMAL			
Charcoal (batch with C-fix = 80.5%)	100%	None	3 male New Zealand White rabbits	Ocular irritation study in accordance with OECD TG 405; observations made 1, 24, 48, and 72 h and 7 d after instillation	Not irritating according to EU criteria; slight to severe conjunctival irritant effects fully reversible within 1 wk, no irritant reaction observed in cornea and iris	[2]

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