Environmental Assessment

1. **Date**	May 17, 2017
2. **Name of Applicant/Petitioner**	Cabot Corporation
3. **Address**	Cabot Corporation 157 Concord Rd Billerica, MA 01821 All communications on this matter are to be sent to the technical contact for the Notifier: Tim Verslycke, PhD Gradient 20 University Road Cambridge, MA 02138 Telephone: 617-395-5594 E-mail: tverslycke@gradientcorp.com

4. Description of Proposed Action:

a. Proposed Action

The proposed action in this notification is to establish a clearance for the food contact substance (FCS) High Purity Furnace Black (HPFB), a form of carbon black, when used in the manufacture of food contact materials. The intended uses for HPFB are shown in Table 1 and include: use as a component of adhesives as described in 21 CFR 175.105(b)(5); use as a colorant in resinous and polymeric coatings as described in 21 CFR 175.300(b)(3)(xxvi); use as a colorant in paper and paperboard in contact with aqueous and fatty foods as described in 21 CFR 176.170(b)(2); use as a colorant in paper and paperboard in contact with dry food as described in 21 CFR 176.180(b)(1); and use as a colorant for polymers as described in 21 CFR 178.3297(e); except for use in contact with infant formula and human milk. The FCS will be used at the levels shown in Table 1 and will not exceed the minimum required to accomplish its intended technical effect. The FCS is not for use in contact with infant formula and human milk.

Carbon black is an engineered material, primarily composed of elemental carbon, obtained from the partial combustion or thermal decomposition of hydrocarbons under controlled conditions (definition developed by American Society for Testing and Materials (ASTM) and cited in ICBA, 2016, p. 7[1]). Carbon black can be prepared by several processes, and the resulting products are typically referred to by the process or source material, such as thermal black, channel black and furnace black. HPFB is a purified form of furnace black that is manufactured such that polycyclic aromatic hydrocarbon (PAH) impurities are present at substantially lower concentrations than in channel black as defined in 21 CFR 178.3297(e); specifically, total PAHs not to exceed 0.5 parts per million (ppm), and benzo[a]pyrene not to exceed 5.0 parts per billion (ppb). HPFB is chemically identical to the colorant, channel black, which has been used in food contact materials for many years. The two colorants differ only in their method of manufacture and, as a result of the production process and conditions, the level of organic impurities that remains in the final product. Therefore, HPFB provides an alternative colorant to channel black for food contact applications that contains lower levels of PAH impurities than typically present in channel black.

Types of food contact materials in which HPFB is expected to be used

The Notifier is requesting that HPFB be allowed in food contact applications in a manner and use consistent with those for which carbon black manufactured through the channel process (also called channel black) is approved (Table 1).

Table 1: Food Contact Applications for High Purity Furnace Black

CFR Title	CFR Listing	Currently Listed for this Application?	Current Weight Limit	Requested Weight Limit	Typical Loading Levels[a]
Substances for use only as components of adhesives	21 CFR 175.105(b)(5)	No	Not applicable	No specified upper limit, similar to channel black	Loading of 2.5% is typically sufficient
Substances for use as components of resinous and polymeric coatings	21 CFR 175.300(b)(3)(xxvi)	Yes	Used in accordance with limitations under 21 CFR 178.3297	No specified upper limit, similar to channel black	Loadings of 10% to greater than 50% (thin layers less than 1/8th inch).
Components of paper and paperboard in contact with aqueous and fatty foods	21 CFR 176.170(b)(2)	No	Not applicable	No specified upper limit, similar to channel black	Loading is typically around 35% and sometimes more
Components of paper and paperboard in contact with dry foods	21 CFR 176.180(b)(1)	Yes	Used in accordance with limitations under 21 CFR 178.3297	No specified upper limit similar, to channel black	Loading is typically around 35% and sometimes more

[1] International Carbon Black Association (ICBA). 2016. "Carbon Black User's Guide: Safety, Health & Environmental Information." 36p. Accessed at http://www.carbon-black.org/images/docs/2016-ICBA-Carbon-Black-User-Guide.pdf.

Colorants for polymers	21 CFR 178.3297(e)	Yes	Not to exceed 2.5% by weight of the polymer	No specified upper limit, similar to channel black	Loading of 2.5% is typically sufficient

[a] Loading levels are expressed as a percentage by weight of the FCS in the product application.

The food contact applications listed in Table 1 are currently approved for channel black with no specified maximum loading limits. Please note that channel black (listed in the regulation as carbon black – channel process, prepared by the impingement process from stripped natural gas) is approved for use as a colorant for polymers in 21 CFR 178.3297(e), and by reference may be used as components of the uncoated or coated food-contact surface of paper and paperboard, subject to the provisions of 21 CFR 176.180.

Use levels

The specific use levels will depend on the specific application, as shown in Table 1, and described below.

As a component and colorant for adhesives, a carbon black loading of 2.5% is typically sufficient. However, there may be situations that require higher loadings to prevent light transmission.

Resinous and polymeric coatings are generally thin layers that are less than 1/8th inch thick. For example, coatings and inks may be used in a film that may be 1/100th inches thick. For an article of that thickness it is common to use channel black loadings of 10% to greater than 50%. At lower loadings it is possible to see through the film, thus lower loadings are ineffective. Since HPFB will be used in a similar manner to channel black it will be necessary to use loadings of 10% to greater than 50% in coating and ink applications.

For paper and paperboard applications, the carbon black loading is typically around 35% and sometimes more to make the paper and paperboard black. These products are sometimes used as resinous and polymeric coatings (like above) but sometimes the FCS is directly integrated into the pulp during the manufacturing of black paper.

As a colorant for polymers, a carbon black loading of 2.5% is typically sufficient as most plastic parts are more than 1/8 inch thick. At this thickness, carbon black loadings of ≤ 2.5% by weight of the polymer results in a very black color and prevents light from transmitting. However, there may be situations where thinner plastic parts may require higher loadings to prevent light from transmitting.

b. Need for Action

Currently channel black is used as a colorant for components of food contact articles. Channel black has significantly higher PAH impurities compared to HPFB. HPFB is carbon black that is manufactured by the furnace process such that total PAH impurities do not exceed 0.5 ppm, and benzo[a]pyrene does not exceed 5.0 ppb. The proposed uses and use levels in food contact applications for HFPB are the same as for carbon black and are shown in Table 1. If approved, HPFB will replace channel black as a colorant in existing applications at loadings similar to those used today, thereby resulting in a lower potential for incorporation of PAH impurities in the final product.

c. Location of Use/Disposal

Finished food contact materials containing the FCS will be used widely across the US. As a result, use and disposal are expected to occur nationwide consistent with population density. Food contact materials manufactured using HPFB are expected to be disposed of as municipal solid waste (MSW). According to the US Environmental Protection Agency (US EPA, 2016[2]), 34.6% of MSW in 2014 was recycled, 12.8% was incinerated, and 52.6% was landfilled.

The use and disposal of HPFB is expected to be consistent with the use and disposal of many other food contact materials currently approved for use. As a result, the Notifier has not identified any extraordinary circumstances related to either the use or disposal of food contact articles prepared using the FCS. Further details regarding the use and disposal of HPFB for the sought applications are provided in Section 6.

5. <u>Identification of the Subject of the Proposed Action</u>

The FCS is High Purity Furnace Black (HPFB), which is carbon black manufactured using the furnace manufacturing process and designed to have very low PAH impurities (total PAH less than 0.5 ppm, and benzo(a)pyrene less than 0.005 ppm).

<u>Chemical Abstracts Service (CAS) Registration Number</u>: 1333-86-4. Note that acetylene black, channel black, furnace black, lamp black, and thermal black are all considered carbon black with the same chemical identity and the same CAS number.

<u>Molecular formula</u>: Elemental carbon, C

<u>Structural formula</u>: C

<u>Molecular weight</u>: 12.01 (elemental carbon)

<u>Physical description</u>: Black odorless powder (ECHA, 2017a[3])

<u>Melting point:</u> 3,550°C (ECHA, 2017b[4])

<u>Vapor pressure</u>: ca. 0 mmHg. The vapour pressure of carbon black is negligible (ECHA, 2017c[5]).

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[2] US EPA. 2016. "Advancing Sustainable Materials Management: 2014 Fact Sheet. Assessing Trends in Material Generation, Recycling, Composting, Combustion with Energy Recovery and Landfilling in the United States." 22p., November. Accessed at https://www.epa.gov/sites/production/files/2016-11/documents/2014_smmfactsheet_508.pdf.

[3] European Chemicals Agency (ECHA). 2017a. "Physical & Chemical Properties: Appearance/Physical State/Color." In *Reach Dossier for Carbon Black (CAS No. 1333-86-4)*. Accessed at https://iuclid6.echa.europa.eu/de/web/guest/registration-dossier/-/registered-dossier/16056/4/2.

[4] European Chemicals Agency (ECHA). 2017b. "Melting Point/Freezing Point: Exp WoE Melting point." In *Reach Dossier for Carbon Black (CAS No. 1333-86-4)*. Accessed at https://iuclid6.echa.europa.eu/de/web/guest/registration-dossier/-/registered-dossier/16056/4/3.

Morphology: Carbon black is composed of spheroidal primary particles that fuse together to form aggregates (typical size of 85-500 nanometers). Once produced, individual aggregates join together by van der Waals forces to form agglomerates (typical size of 1-100+ micrometers). Aggregates are robust structures, able to withstand shear forces; they are the smallest dispersible units. Agglomerates are difficult to measure accurately as they break apart when shear forces are applied. Typically, carbon black is shipped and placed on the market in the form of pellets (*i.e.*, compressed agglomerates) to facilitate the ease of handling and to reduce the creation of dust. The size of pellets generally is less than one millimeter (ICBA, 2016[6]).

Density: The measured density using the pycnometer method at 20°C is 1.97-1.98 g/cm³ (ECHA, 2017d[7]).

Specific gravity: 1.7-1.9 at 20°C (Cabot Corp., 2016[8]).

Partition coefficient: Not applicable since carbon black is an inorganic substance (does not contain carbon bound to hydrogen); is insoluble in water and all solvents; and cannot be measured analytically in water or in octanol (ECHA, 2017e[9]).

Solubility: Carbon black is inert, inorganic and contains no water-soluble groups (*e.g.*, alcohols, ethers, or acids) and is therefore insoluble in water (<0.1 mg/L). Carbon black is stable and cannot be measured analytically in water (ECHA, 2017f[10]).

Manufacturing process: Carbon blacks are manufactured by different processes, commonly referred to as channel black, furnace black, thermal black, lampblack and acetylene black processes. The furnace black process generates >95% of all carbon black produced in the world. It was developed in 1943 and rapidly displaced previous gas-based technologies because of its higher yields and the broader range of carbon blacks that could be produced. The last channel black plant in the USA was closed in 1976. Limited operations still exist in Europe. Carbon-black - channel process has been almost entirely replaced given the rapid introduction of the carbon black – furnace process grade alternatives (Wang *et al.*, 2003[11]).

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[5] European Chemicals Agency (ECHA). 2017c. "Vapour Pressure: Exp WoE Vapour pressure." In *Reach Dossier for Carbon Black (CAS No. 1333-86-4)*. Accessed at https://iuclid6.echa.europa.eu/de/web/guest/registration-dossier/-/registered-dossier/16056/4/7.

[6] Ibid.

[7] European Chemicals Agency (ECHA). 2017d. "Physical and Chemical properties: Density: 001 Key/Experimental result." In *Reach Dossier for Carbon Black (CAS No. 1333-86-4)*. Accessed at https://iuclid6.echa.europa.eu/de/web/guest/registration-dossier/-/registered-dossier/16056/4/5.

[8] Cabot Corp. 2016. "Safety data sheet for BLACK PEARLS 4350 Carbon Black." 17p., June 3. Accessed at http://www.cabotcorp.com/solutions/products-plus/specialty-carbon-blacks/for-food-contact.

[9] European Chemicals Agency (ECHA). 2017e. "Partition coefficient." In *Reach Dossier for Carbon Black (CAS No. 1333-86-4)*. Accessed at https://echa.europa.eu/registration-dossier/-/registered-dossier/16056/4/8.

[10] European Chemicals Agency (ECHA). 2017f. "Water Solubility: 001 Supporting/Experimental result." In *Reach Dossier for Carbon Black (CAS No. 1333-86-4)*. Accessed at https://iuclid6.echa.europa.eu/de/web/guest/registration-dossier/-/registered-dossier/16056/4/9.

[11] Wang, MJ; Reznek, SA; Mahmud, K; Kutsovksy, Y. 2003. "Carbon black." In *Kirk-Othmer Encyclopedia of Chemical Technology, Volume 4*. John Wiley & Sons, Inc. p761-803. Abstract listed in: http://onlinelibrary.wiley.com/doi/10.1002/0471238961.0301180204011414.a01.pub2/abstract

6. Introduction of Substances into the Environment

According to 21 CFR Part 25.40(a), an environmental assessment ordinarily should focus on relevant environmental issues relating to the use and disposal from use, rather than the manufacturing of FDA-regulated articles. Further, information available to the Notifier does not suggest that there are any extraordinary circumstances in this case indicative of any adverse environmental impact as a result of the manufacture of the FCS. Consequently, information on the manufacturing site and compliance with relevant emissions requirements is not provided here.

HPFB is expected to be incorporated into finished food contact materials, and remain in these materials throughout use/disposal by the consumer. Any waste material generated in the process of manufacturing food contact articles, *e.g.*, plant scraps, is expected to be disposed as part of the food article/packaging manufacturer's overall nonhazardous solid waste in accordance with established procedures. Any other potential environmental releases are expected to be handled in accordance with the food article/packaging manufacturer's waste disposal practices. As a result, no significant environmental releases of HPFB are expected for the applications listed in Table 1. There is a potential for environmental introduction of HPFB when added in the wet-end of the paper making process in paper and paperboard applications. Further detail regarding potential environmental introductions of HPFB as a result of paper and paperboard applications are provided at the end of this section.

HPFB is proposed as a substitute for channel black. As a result, no additional carbon black waste is expected resulting from post-consumer disposal of food contact articles and packaging material containing HPFB. Food contact materials manufactured using HPFB are expected to be disposed of either by recycling, conventional rubbish disposal (*i.e.*, sanitary landfill), or incineration. As described below, no significant environmental introductions are expected from disposal through these mechanisms.

HPFB consists of elemental carbon which is widely present in the environment. It is therefore not expected to have an impact on the recyclability of any food-contact materials. HPFB is insoluble in common solvents (Section 5), including aqueous and fatty foods. As a result, HPFB incorporated into the finished food contact material is expected to remain in these materials throughout use/disposal by the consumer. Studies have shown there is no potential for significant migration of carbon black embedded in plastics or rubber to contacted food (Bott, 2014[12]; Hamm, 2009[13]). The main migrants of concern associated with the use of carbon black in food-contact applications are the PAH impurities. Several studies have investigated the bioavailability of PAHs adsorbed on the surface of carbon black, reporting findings showing that PAHs and other organics are tightly adhered to carbon black particles (Borm *et al.*, 2005[14]; Buddingh *et al.*, 1981[15]). These studies have reported release of PAHs from carbon black only

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[12] Bott, J; Stormer, A; Franz, R. 2014. "Migration of nanoparticles from plastic packaging materials containing carbon black into foodstuffs." *Food Addit. Contam. Part A Chem. Anal. Control Expo. Risk Assess.* 31(10):1769-1782. doi: 10.1080/19440049.2014.952786. Accessed at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4205858/.

[13] Hamm, S; Frey, T; Weinand, R; Gilles, M; Nicole, P. 2009. "Investigations on the extraction and migration behavior of polycyclic aromatic hydrocarbons (PAHs) from cured rubber formulations containing carbon black as reinforcing agent." *Rubber Chem. Technol.* 82(2):214-228. doi: http://dx.doi.org/10.5254/1.3548246. Abstract listed in: https://www.researchgate.net/publication/271346025_Investigations_on_the_Extraction_and_Migration_behavior_of_Polycyclic_Aromatic_Hydrocarbons_PAHS_from_Cured_Rubber_Formulations_Containing_Carbon_Black_as_Reinforcing_Agent

[14] Borm, PJA; Cakmak, G; Jermann, E; Weishaupt, C; Kempers, P; Jan van Schooten, F; Oberdoster, G; Schins, RPF. 2005. "Formation of PAH-DNA adducts after *in vivo* and *vitro* exposure of rats and lung cells to different commercial carbon blacks."

during rigorous laboratory extractions with harsh organic solvents (*e.g.*, benzene and toluene), and not for extractions using solvents more representative of natural tissue fluids such as saline or surfactant-containing saline (in addition, please see confidential Attachment 1). Therefore, leaching of the FCS from the food contact articles when disposed of is not expected.

The disposal by the consumer of food contact articles made from this FCS *via* MSW landfill is not expected to result in environmental releases. US EPA regulations at 40 CFR Part 258 that were published in the Federal Register of October 9, 1991 (56 FR 50978), with revisions July 29, 1997, and June 18, 2003, require new and expanded landfills to have leachate collection systems and liners to prevent leachate from entering surface or groundwater. Although operators of existing landfills are not required to retrofit liner systems, they are required to monitor groundwater quality adjacent to landfills and to take corrective action as appropriate. However, given that HPFB is insoluble (Section 5), it is not expected to leach and become part of the groundwater matrix. HPFB is also not expected to volatilize given its low vapor pressure (Section 5), such that releases to air are also not expected.

As the FCS is elemental carbon, greenhouse gas (GHG) emissions of carbon monoxide and carbon dioxide are possible following combustion of MSW containing the final products. With respect to GHG emissions, the Council on Environmental Quality (CEQ) has provided a 25,000 metric tons (mT) carbon dioxide equivalent (CO_2-e) GHG/year threshold for GHG emissions; emissions above this threshold warrant quantitative disclosure (Goldfuss, 2016[16]). The total amount of CO_2-e GHG/year that is expected to be produced by the combustion of the FCS was calculated and then compared to the 25,000 mT CO_2-e GHG/year threshold set by CEQ (see confidential Attachment 2 – *Calculation of annual Green House Gas emissions*). The estimated amount of CO_2-e GHG/year produced from combustion of the FCS is significantly lower than the CEQ threshold of 25,000 mT of CO_2-e emissions on an annual basis. In accordance with the CEQ's guidance on GHG and climate change impacts, for annual emissions falling below 25,000 mT, a quantitative analysis of emissions is not warranted. A possible combustion product of some carbon blacks is sulfur oxides, although production of sulfur oxides is likely to be minimal for the FCS which is manufactured from a low-sulfur feedstock with less than 0.5 wt% sulfur. Sulfur oxides are considered “criteria” air pollutants regulated by the US EPA’s National Ambient Air Quality Standards (NAAQS) (40 CFR Part 50). NAAQS provide strict airborne limits that cannot be exceeded by incineration facilities. Additionally, the Acid Rain Program in Title IV of the 1990 Clean Air Act Amendments (40 CFR Parts 72 through 78) regulates emissions of sulfur dioxide (SO_2). Based on the proposed use and use level of the FCS, it can be concluded that the FCS will not significantly alter emissions from properly operating MSW combustion facilities, nor threaten violation of applicable Federal, State, or local emission laws and regulations (40 CFR part 60, and/or relevant state and local laws). Additionally, no significant quantities of the FCS or combustion products will be added to water systems,

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Toxicol. Appl. Pharmacol. 205:157-167. doi: 10.1016/j.taap.2004.10.020. Abstract listed in: http://www.sciencedirect.com/science/article/pii/S0041008X04004788.

[15] Buddingh, F; Bailey, MJ; Wells, B; Haesemeyer, J. 1981. "Physiological significance of benzo(a)pyrene adsorbed to carbon blacks: Elution studies, AHH determinations." *Am. Ind. Hyg. Assoc. J.* 42(7):503-509. Abstract listed in: https://www.ncbi.nlm.nih.gov/pubmed/6264776.

[16] Goldfuss, C. [Council on Environmental Quality]. 2016. Memorandum to Heads of Federal Departments and Agencies re: Final Guidance for Federal Departments and Agencies on Consideration of Greenhouse Gas Emissions and the Effects of Climate Change in National Environmental Policy Act Reviews. 34p., August 1. Accessed at https://toolkit.climate.gov/sites/default/files/nepa_final_ghg_guidance.pdf

including freshwater, estuarine, and marine ecosystems, upon proper incineration of food contact materials that contain the FCS.

For paper and paperboard applications, while the intent is for the FCS to be substantially incorporated into the paper, some excess FCS could be removed during the dewatering process and enter the white water. As a result, further details regarding the use of HPFB by paper manufacturers and potential introductions into the environment as a result of this specific application are provided below.

Use of HPFB in paper and paperboard applications

The Notifier does not manufacture the paper and paperboard to which the FCS will be applied as a colorant. Instead, the Notifier will sell the FCS to a color formulator who makes a liquid dispersion containing the FCS. The color formulator will then sell to various customers, including to paper manufacturers. The Notifier assumes that formulators and paper manufacturers comply with all applicable Federal, State, and local manufacturing and waste regulations. Consequently, the Notifier does not consider the proposed use of HPFB as a substitute colorant for the currently approved colorant channel black to pose any extraordinary circumstances. More specifically, the use of the FCS in paper and paperboard applications is not expected to result in unique emission scenarios, violations of environmental laws or requirements, or adverse impacts to listed species or critical habitats. However, since there is a potential for environmental introductions when the FCS is added to the wet-end of the paper making process, further details are provided regarding the use, potential environmental introductions, and potential environmental risks associated with the FCS in these applications.

The FCS is intended to be used in paper and paperboard similar to the manner in which channel black is currently used (Table 1). The FCS may be used as coatings or inks on paper and paperboard, or it may be directly integrated into the pulp at the wet-end of the paper machine during the manufacturing of black paper. Use of the FCS as a coating or ink after the paper has been formed and dried is not expected to result in any environmental releases of HPFB. When added during the paper making process, the FCS is expected to be incorporated into, and remain a component of, the finished paper and paperboard. Any of the FCS that is not incorporated in the paper would be incorporated into the wet-end process wastewater. The wet-end of the paper machine refers to any point in the paper machine at or prior to the dryer can. Conventionally, colorants are introduced into the pulp stream prior to or at the head box where the pulp slurry consists of approximately 99.5% water and approximately 0.5% pulp fiber (Bajpai, 2012[17]). After exiting the head box, the fibers are spread out on a continuous traveling wire mesh loop and as the wire mesh moves along the machine path, water drains through the mesh. As the wet web of fiber forms on the wire mesh, it is dewatered through various techniques (*e.g.*, vacuum boxes located under the wire mesh) and the water that is collected during dewatering is called "white water" (Bajpai, 2012[18]). The FCS is added at the wet end of a paper machine where the pore structure of the fiber mat is very open and the dewatering process is still occurring. While the intent is for the FCS to be substantially incorporated into the paper, some excess FCS could be removed during the dewatering process and enter

[17] Bajpai, P. 2012. "Brief description of the pulp and paper making process." In *Biotechnology for Pulp and Paper Processing*. Springer Science Business Media, LLC. p7-14. doi: 10.1007/978-1-4614-1409-4_2. Accessed at http://www.springer.com/cda/content/document/cda_downloaddocument/9781461414087-c1.pdf?SGWID=0-0-45-1262248-p174191470.
[18] Ibid.

the white water. Most white water is reused within several seconds to minutes while excess white water is passed to a save-all where solids are collected by filtration or flotations. While white water is recycled in pulp and paper mills to conserve energy and raw materials, some must be discarded. The discarded process water is either treated on-site or sent to a publicly-owned wastewater treatment works (POTW) (WADOE, 2008[19]). A small number of pulp mills, and a much larger proportion of papermaking establishments, discharge effluents to a POTW (WADOE, 2008[20]). The majority of pulp and integrated mills that operate their own wastewater treatment systems, generate sludge on-site. In summary, the FCS is expected to be incorporated into the finished product during the paper coloring process and no significant releases to the environment are expected. However, there is the potential that excess amounts of HPFB added during the wet-end of the paper machine end up in the non-recycled portion of the white water that would either be treated on-site or at a POTW. Further details regarding the potential for introduction of the FCS into the environment as a result of paper manufacturing *via* wastewater or sludge are provided below.

Potential environmental introductions following use of HPFB in paper and paperboard applications

As described above, HPFB is expected to be incorporated into the finished product and minimal releases *via* the wet end process wastewater are expected. Any excess amounts of HPFB that end up in the white water would be either treated on-site or sent to a POTW for treatment. As described in Section 5, HPFB is insoluble and it has no functional groups that can solubilize in water or organic solvents. As a result, the octanol-water partition coefficient (K_{ow}) and organic carbon partition coefficient (K_{oc}) of HPFB cannot be experimentally determined and a quantitative estimate of its partitioning behavior during wastewater treatment is therefore not possible (Environment Canada and Health Canada, 2013[21,22]). Consequently, a qualitative discussion of potential environmental introductions associated with the use of HPFB in paper and paperboard applications follows.

While HPFB is not expected to biodegrade, hydrolyze, or volatilize (*i.e.*, negligible vapor pressure) during wastewater treatment, it is expected to form larger sized agglomerates in aqueous media (OECD, 2006[23]; Schaudien et al. 2011[24]). Based on these physical-chemical properties, it is expected that any excess amounts of HPFB present in paper process wastewater will separate from the water phase,

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[19] Washington State Dept. of Ecology (WADOE). 2008. "Waste Stream Reduction and Re-Use in the Pulp and Paper Sector." Industrial Footprint Project, Report to Center for Sustainable Economy, Santa Fe, NM. 45p., August. Accessed at http://sustainable-economy.org/wp-content/uploads/Waste-Stream-Analysis-FINAL.pdf.
[20] Ibid.
[21] Environment Canada; Health Canada. 2013. "Screening Assessment for the Challenge: Carbon Black (CAS No. 1333-86-4)." 88p., June. Accessed at https://www.ec.gc.ca/ese-ees/default.asp?lang=En&n=2CF34283-1.
[22] An environmental fate analysis of HPFB based on the K_{oc} or K_{ow} is not possible since HPFB is essentially elemental carbon and therefore insoluble in water or organic solvents. The measurement of a K_{oc} for HPFB is technically unjustified because HPFB cannot be analytically distinguished from other forms of carbon.
[23] Organisation for Economic Co-operation and Development (OECD). 2006. "SIDS Initial Assessment Profile on Carbon Black (CAS No. 1333-86-4)." UNEP Publications. 4p. Accessed at http://webnet.oecd.org/hpv/ui/handler.axd?id=b2394717-5545-46c3-9194-ae15f987df25.
[24] Schaudien, D., J. Knebel, I. Mangelsdorf, J.-U. Voss, W. Koch and O. Creutzenberg. 2011. "Dispersion and Retention of Dusts Consisting of Ultrafine Primary Particles in Lungs." Project F 2133 – on behalf of the Federal Institute for Occupational Safety and Health. Dortmund, Germany. Accessed at https://www.researchgate.net/publication/265533372_Dispersion_and_Retention_of_Dusts_Consisting_of_Ultrafine_Primary_Particles_in_Lungs

settle into the wastewater sludge phase, and be removed as solid waste (see further discussion below regarding potential environmental introductions associated with sewage sludge incineration, landfilling, and land application). Although HPFB is insoluble and forms aggregates and agglomerates, it cannot be excluded that potentially a small fraction will remain suspended and contribute to the total suspended solid (TSS) load of the paper processing plant's wastewater. Because TSS can affect water quality and aquatic biota (*e.g.*, Bilotta and Brazier, 2008[25]), the amount of TSS released into receiving bodies of water is regulated. Any FCS that remains in wastewater as TSS will be subject to either on-site treatment or treatment at a POTW. On-site treatment facilities and POTWs are subject to wastewater discharge limits that restrict the amount of solids (such as the TSS) and other pollutants that can be safely released to the environment (see further discussion of those regulations in Section 7.b). For example, the US EPA established wastewater guidelines for paper processing facilities with on-site treatment facilities as point sources (US EPA, 2000[26]). The US EPA also established wastewater pre-treatment guidelines for paper processing facilities before disposal to a POTW, but TSS was not included in this early guidance (US EPA, 1984[27]). Therefore, on-site treatment facilities are expected to have pre-treatment programs that address TSS among other pollutants (US EPA, 2004[28]). Even if some HPFB were to be present as suspended solids in regulated releases to receiving waters, then it would not be expected to pose adverse effects to aquatic organisms given its very low toxicity to aquatic organisms (see Section 8). Further, carbon is a ubiquitous element in the aquatic environment such that any additional contributions associated with the use of HPFB in paper coloring would not change existing environmental concentrations of carbon.

As described above, HPFB is expected to be incorporated into the finished product and minimal releases *via* the wet end process wastewater are expected. Based on its physical-chemical properties (Section 5), any excess HPFB that remains in the process wastewater is expected to settle into sewage sludge either in the on-site treatment plant or in a POTW. According to a 2002 study by the American Forestry and Paper Association, WWTP sludge from paper processing facilities is typically landfilled (52%), land applied (15%), incinerated for energy production (22%), or used for other beneficial uses (12%) (WADOE, 2008[29]). According to the US EPA (1999[30]), sludge from a POTW is typically landfilled (17%), land applied (or used for other beneficial uses) (60%), or incinerated (22%).

There is the potential for HPFB to enter the terrestrial environment when sewage sludge from an on-site treatment plant or POTW or boiler ash from sewage sludge incineration is applied to land. The Department of Energy (DoE) and US EPA generally consider proper land application of paper sector

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[25] Bilotta, GS; Brazier, RE. 2008. "Understanding the influence of suspended solids on water quality and aquatic biota." *Water Res.* 42:2849-2861. doi: 10.1016/j.watres.2008.03.018. Abstract listed in: http://www.sciencedirect.com/science/article/pii/S0043135408001401

[26] US EPA. 2000. "Permit Guidance Document: Pulp, Paper and Paperboard Manufacturing Point Source Category (40 CFR §430)." Office of Water, EPA-821-B-00-003. 219p., May. https://www3.epa.gov/npdes/pubs/pretreatment_pulp.pdf.

[27] US EPA. 1984. "Guidance Manual for Pulp, Paper, and Paperboard and Builders' Paper and Board Mills Pretreatment Standards." Office of Water. 49p., September. Accessed at https://www3.epa.gov/npdes/pubs/owm0023.pdf.

[28] US EPA. 2004. "Local Limits Development Guidance." Office of Wastewater Management, EPA 833-R-04-002A. 134p., July. Accessed at https://www3.epa.gov/npdes/pubs/final_local_limits_guidance.pdf.

[29] Ibid.

[30] US EPA. 1999. "Biosolids Generation, Use, and Disposal in the United States." Office of Solid Waste and Emergency Response (OSWER), EPA530-R-99-009. 81p., September. Accessed at https://www.epa.gov/sites/production/files/2015-07/documents/biosolids_generation_use_disposal_in_u.s_1999.pdf.

sludge a beneficial use (WADOE, 2008[31]). Generally, a land application for each paper mill is covered under a general permit and in some cases each site must be individually permitted. Land application of paper mill sludges are primarily regulated at the state level and since mill residuals are not defined as hazardous wastes, they are not regulated under the Resource Conservation and Recovery Act (RCRA) (WADOE, 2008[32]). Many states use the guidelines for heavy metals and management practices defined in 40 CFR Part 503 standards for land application of municipal sewage sludge biosolids as a baseline for land application of paper mill residuals (US EPA, 1994[33]). Additionally, biosolids are managed by the US EPA through guidance such as the report "Biosolids Generation, Use, and Disposal in The United States" (US EPA, 1999[34]). As with any soil amendment, water quality standards for nutrients and heavy metals developed under the Clean Water Act must not be exceeded. When released to dry soil, HPFB is expected to become part of the soil matrix with some potential for transportation by runoff to nearby surface waters (Environment Canada and Health Canada, 2013[35]). If released to surface waters following runoff, HPFB is generally expected to settle into bottom sediments unless turbulent waters exist (Environment Canada and Health Canada, 2013[36]). The potential for runoff of land-applied sludge to nearby surface waters is further mitigated by specific provisions in some state standards which require information on site and soil characteristics, set-back distances from surface water and wells, depth to groundwater, slope, vegetative cover, and proximity to floodplains or wetlands (WADOE, 2008[37]). Existing aquatic toxicity data (Section 8) demonstrate that no aquatic effects are expected even if HPFB were to be introduced to surface waters following sludge land application and subsequent runoff. Further, existing terrestrial toxicity data (Section 8) indicate that HPFB is not toxic to terrestrial organisms, such that any releases to the terrestrial environment associated with the use of HPFB in the paper coloring process would not pose an adverse effect. Finally, carbon is a ubiquitous element in the terrestrial environment such that any additional contributions associated with the use of HPFB in paper coloring would not change existing environmental concentrations of carbon. In summary, while environmental introductions of HPFB *via* land application of sludge cannot be completely excluded, they are expected to be very small and are not expected to result in adverse environmental effects as discussed further in Section 8.

Finally, sludge that is produced on-site or at a POTW can be incinerated by on-site or MSW combustion facilities. As the FCS is elemental carbon, products of complete combustion include carbon monoxide and carbon dioxide. HPFB is either going to be incorporated into the product and become part of disposal-related GHG emissions (*e.g.*, from incineration of MSW containing disposed products) or it is going to be part of use-related GHG emissions (*i.e.*, from incineration of paper and paperboard application-related sewage sludge potentially containing HPFB). As described above, the total estimated amount of CO_2-e GHG/year produced from combustion of the FCS is significantly lower than the CEQ threshold of 25,000 mT of CO_2-e emissions on an annual basis. As such, a quantitative analysis of CO_2 emissions is not warranted.

[31] Ibid.
[32] Ibid.
[33] US EPA. 1994. "Land Application of Sewage Sludge: A Guide for Land Appliers on the Requirements of the Federal Standards for the Use or Disposal of Sewage Sludge, 40 CFR Part 503." Office of Enforcement and Compliance Assurance, EPA/831-B-93-002b. 105p., December. Accessed at https://www3.epa.gov/npdes/pubs/sludge.pdf.
[34] Ibid.
[35] Ibid.
[36] Ibid.
[37] Ibid.

7. Fate of Emitted Substances in the Environment

Physical-chemical properties of the FCS are provided in Section 5. This section describes the fate of the FCS in air, water, and soil for the potential environmental introduction pathways discussed in Section 6.

a. Air

No significant effect on the concentrations of and exposures to any substances in the atmosphere are anticipated due to the proposed use of the FCS. The vapor pressure of HPFB is negligible (Section 5) and it is therefore not expected to volatilize and enter the air compartment (Environment Canada and Health Canada, 2013[38]). Therefore, no significant quantities of HPFB will be released upon the use and landfill disposal of food contact articles manufactured with the FCS. Furthermore, based on the proposed use and use level of the FCS it can be concluded that the FCS will not significantly alter emissions from properly operating MSW combustion facilities during the incineration of sludge for energy generation or cause MSW combustors to threaten a violation of applicable Federal, State, or local emissions laws and regulations (40 CFR Part 60). The GHG analysis (discussed above) showed that the estimated amount of CO_2-e GHG/year produced from combustion of the FCS is significantly lower than the CEQ threshold of 25,000 mT of CO_2-e emissions on an annual basis.

b. Water

No significant effects on the concentrations of and exposures to any substances in freshwater, estuarine or marine ecosystems are anticipated due to the proposed use of the FCS in food contact articles. No significant quantities of HPFB will be added to these water systems upon the proper incineration of food packaging employing the FCS. Similarly, no significant quantities of HPFB will be added to these water systems upon its disposal in landfills due to existing EPA regulations for landfills (Section 6) and the anticipated very low levels of aqueous extraction of the FCS, as it is not soluble in water (Section 5).

As described in Section 6, there is the potential for environmental introductions associated with the use of HPFB in paper and paperboard applications. However, the majority of the FCS is expected to be incorporated into the final paper/paperboard product and any excess amounts present in white water will be processed through on-site or POTW facilities. Any HPFB in white water is expected to partition primarily into the sludge matrix given its water insolubility and aggregating behavior. Even though HPFB is expected to primarily partition into the sludge matrix, it is possible that small amounts of the FCS could remain suspended in the water phase and potentially be released in the wastewater effluent as suspended solids. Any HPFB potentially present in suspended solids and released to surface waters would be regulated as a part of the TSS criteria where the US EPA (2003[39]) states, "Surface waters shall be free from pollutants in amounts that cause objectionable conditions or impairment of designated uses (including aquatic life uses)." In general, if a pulp or paper mill utilizes on-site wastewater treatment

[38] Ibid.

[39] US EPA. 2003. "Developing Water Quality Criteria for Suspended and Bedded Sediments (SABS): Potential Approaches (Draft)." Office of Water, Office of Science and Technology. 58p., August.

facilities (*i.e.*, direct dischargers), they must comply with their NPDES permit pursuant to 40 CFR Section 402 where it is required that all receiving waters have ambient water quality standards that are established by the states or the US EPA to maintain and protect designated uses of the receiving water. Users of a POTW (*i.e.*, indirect dischargers) are prohibited from discharging pollutants that cause a violation of any requirement of that POTW's NPDES permit pursuant to 40 CFR Section 403.5(a)(1). Therefore, POTWs that receive wastewater from indirect dischargers subject to categorical pre-treatment standards must develop and enforce local limits to comply with the National Pre-treatment Standards. Based on the physical-chemical properties of HPFB (Section 5), the K_{ow} and K_{oc} which are relevant for environmental fate and distribution estimation cannot be analytically measured. As a result, it is not possible to quantitatively estimate potential concentrations of the FCS in sediment or surface water for paper and paperboard applications. However, if potential releases of the FCS were to occur to surface waters, then it is expected to eventually deposit into sediments because it contains no water-soluble groups and is denser than water (Section 5). As an inorganic substance, HPFB is not biodegradable. As substantially elemental carbon, it will not degrade through hydrolysis (OECD, 2006[40]). As an insoluble inert solid and given its potential to form aggregates and agglomerates (Section 5), HPFB is not expected to cross biological membranes and bioaccumulation is not expected to occur (Environment Canada and Health Canada, 2013[41]). Additionally, toxic effects in aquatic environments are not expected based on existing quality aquatic toxicity studies (see Section 8). In summary, while it is not possible to conduct a quantitative aquatic exposure assessment for the use of the FCS in paper and paperboard applications, a qualitative evaluation of the environmental behavior of the FCS is possible and indicates no environmental concerns.

c. Land

No significant effects on the concentrations of and exposures to any substances in terrestrial ecosystems are anticipated as a result of the proposed use of the FCS and its proper disposal. Because HPFB contains no water-soluble groups, no leaching is expected under normal environmental conditions when finished food-contact materials are disposed.

As described in Section 6, there is the potential for environmental introductions associated with the use of HPFB in paper and paperboard applications. Pulp and paper mill sewage sludge that potentially contains small amounts of the FCS (*i.e.*, amounts that were not incorporated into the final product) may be applied to land as a beneficial use (WADOE, 2008[42]) or disposed to a landfill (WADOE, 2008[43]). A quantitative environmental fate analysis for land-applied sludge potentially containing HPFB related to paper and paperboard uses is not possible given that the K_{oc} cannot be determined. However, a qualitative evaluation is possible. When released to dry soil, HPFB is expected to remain adhered to soil based on its insolubility, negligible vapor pressure, and expected persistence. Land application of paper mill sludges are primarily regulated at the state level and since mill residuals are not defined as hazardous wastes, they are not regulated under RCRA (WADOE, 2008[44]). However, as with any soil amendment, water quality standards for nutrients and heavy metals developed under the Clean Water Act must not be

[40] Ibid.
[41] Ibid.
[42] Ibid.
[43] Ibid.
[44] Ibid.

exceeded. Therefore, many states use the guidelines for heavy metals and management practices defined in 40 CFR Part 503 standards for land application of municipal sewage sludge biosolids as a baseline for land application of paper mill residuals (US EPA, 1994[45]). Additionally, biosolids are managed by the US EPA through guidance such as the report "Biosolids Generation, Use, and Disposal in The United States" (US EPA, 1999[46]). Toxic effects of HPFB in terrestrial environments are not expected based on a quality terrestrial toxicity study with the FCS (see Section 8). In summary, while it is not possible to conduct a quantitative terrestrial exposure assessment associated with the use of the FCS in paper and paperboard applications, a qualitative evaluation of the environmental behavior of the FCS is possible and indicates no environmental concern.

8. Environmental Effects of Released Substances

As described above, no significant increases are expected in the terrestrial, aquatic, and atmospheric compartments following use and disposal of the FCS. The use and disposal of the FCS are not expected to threaten a violation of applicable laws and regulations, such as the EPA's regulations in 40 CFR Parts 60 and 258.

As described in Section 6, environmental introductions associated with use of the FCS in paper and paperboard manufacturing are possible. Even though environmental exposure concentrations of the FCS for paper and paperboard applications could not be quantified, a qualitative evaluation demonstrates that significant increases in environmental exposures are not expected. Further, given that the FCS is not toxic to aquatic and terrestrial organisms and does not bioaccumulate (see data below), it can be concluded with significant certainty that no environmental concerns are expected for paper and paperboard applications of the FCS.

a. Terrestrial Toxicity

Earthworm tests have been conducted with filtered extractions of tire dust containing the FCS. These tests, on filtrate from 100 g of material, shaken for 24 hours in one liter of water, showed no toxicity to earthworms. This supports the expected low toxicity of the FCS to terrestrial organisms (ECHA, 2017g[47]; OECD, 2006[48]). Additionally, the FCS is an insoluble, inorganic, inert solid with an expected aggregate and agglomerate size between 85 nm and 100+ µm. Therefore, although the FCS may be ingested by terrestrial organisms, the FCS is considered too large to cross biological membranes and bioaccumulation is not expected to occur (Environment Canada and Health Canada, 2013[49]).

b. Aquatic Toxicity

The FCS is not toxic to aquatic organisms based on quality (OECD Guideline and GLP-

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[45] Ibid.
[46] Ibid.
[47] European Chemicals Agency (ECHA). 2017g. "Ecotoxicological information: Toxicity to other above-ground organisms." In *Reach Dossier for Carbon Black (CAS No. 1333-86-4)*. Accessed at https://iuclid6.echa.europa.eu/de/web/guest/registration-dossier/-/registered-dossier/16056/6/4/7.
[48] Ibid.
[49] Ibid.

compliant) experimental data for all three trophic levels (fish, aquatic invertebrates, and algae) with all $L(E)C_{50}$'s exceeding 1,000 mg/L (fish [ECHA, 2017h[50]], aquatic invertebrate [ECHA, 2017i[51]], and algal [ECHA, 2017j[52]] studies). Additionally, the FCS is an insoluble, inorganic, inert solid with an expected aggregate and agglomerate size between 85 nm and 100+ µm. Therefore, the FCS is not expected to cross biological membranes and bioaccumulation is not expected to occur (Environment Canada and Health Canada, 2013[53]).

9. Use of Resources and Energy

The production of HPFB involves the use of natural resources such as petroleum products. HPFB will mainly be used as a substitute for channel black which uses similar raw materials. Therefore, the use of this FCS will have no significant impact on the use of resources and energy.

10. Mitigation Measures

HPFB is chemically identical to the channel black it is intended to replace. The intended use of the FCS is not reasonably expected to create new environmental problems that would require mitigation measures of any kind. As discussed above, the manufacturing, use and disposal of food contact materials manufactured using the FCS are not expected to result in significant adverse environmental impacts.

11. Alternatives to the Proposed Action

No potential adverse effects are identified herein which would necessitate alternative actions to that proposed in this FCN. The alternative of not approving the action proposed herein would simply result in the continued use of channel black that the subject FCS would otherwise replace; such action would have no significant environmental impact. The FCS contains lower levels of PAH impurities than typically are present in other forms of carbon black, such as channel black. Although PAH impurities are tightly bound to the surface of carbon black and are unlikely to be released into the environment, it is still beneficial to have a substitute material with a lower PAH concentration.

12. List of Preparers

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[50] European Chemicals Agency (ECHA). 2017h. "Ecotoxicological information: Short-term toxicity to fish: 001 Key/Experiment result." In *Reach Dossier for Carbon Black (CAS No. 1333-86-4)*. Accessed at https://iuclid6.echa.europa.eu/de/web/guest/registration-dossier/-/registered-dossier/16056/6/2/2.
[51] European Chemicals Agency (ECHA). 2017i. "Ecotoxicological information: Short-term toxicity to aquatic invertebrates: 001 Key/Experiment result." In *Reach Dossier for Carbon Black (CAS No. 1333-86-4)*. Accessed at https://iuclid6.echa.europa.eu/de/web/guest/registration-dossier/-/registered-dossier/16056/6/2/4.
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[53] Ibid.

Dr. Verslycke is an environmental toxicologist with specialized expertise in ecological risk assessment. He is a researcher in the Biology Department at the Woods Hole Oceanographic Institution (WHOI, Woods Hole, MA) and a Principal at Gradient (Cambridge, MA), an environmental consulting company that specializes in the fate and transport of chemicals in the environment and risk assessment. Dr. Verslycke received a B.A. in bioscience engineering, an M.S. in environmental technology and engineering, and a Ph.D. in applied biological sciences from Ghent University (Ghent, Belgium) in a leading research group for ecological risk assessment. Thereafter, Dr. Verslycke was a postdoctoral scholar in a renowned marine environmental toxicology laboratory at WHOI, under WHOI Ocean Life Institute and Belgian American Educational Foundation scholarships and competitively-funded government grants. In 2007, Dr. Verslycke joined Gradient where he has a consulting practice that consists of ecological risk assessments of contaminated sites, environmental safety assessments of new and existing products, and product stewardship. Dr. Verslycke has served in an advisory capacity to a wide range of private, governmental, and non-profit organizations on issues related to environmental toxicology and ecological risk assessment. He has also been active in the Society of Environmental Toxicology and Chemistry (SETAC), the largest global professional organization in the field of environmental risk assessment, for many years and served as president of its North Atlantic Chapter in 2013-2014. He has served on the steering committees of SETAC's global Pharmaceutical Advisory (PAG) group and SETAC's global Endocrine Disruptor Testing and Risk Assessment (EDTRA) group with members from academia, government (*e.g.*, FDA, EPA), and industry. Dr. Verslycke has published articles on environmental toxicology and risk assessment in peer-reviewed journals, books, and meeting proceedings. He has also been a peer reviewer for multiple journals in the environmental sciences field. At Gradient, Dr. Verslycke has conducted many environmental assessments to satisfy National Environmental Policy Act (NEPA) requirements that were submitted and approved by FDA.

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Dr. Lunsman is an environmental toxicologist with specialized expertise in aquatic toxicology and ecological risk assessment. She is a Senior Environmental Toxicologist at Gradient (Seattle, WA), an environmental consulting company that specializes in the fate and transport of chemicals in the environment and risk assessment. Dr. Lunsman received a B. Sc. in Marine Biology from Texas A&M University (Galveston, TX) and a Ph.D. in Marine Sciences (focused on contaminant fate and transport research) from the University of California (Santa Barbara, CA) in the renowned Interdisciplinary Graduate Program in Marine Sciences. Dr. Lunsman has over 10 years of experience in aquatic toxicology, water quality, and environmental fate and pathways. Her expertise includes evaluating environmental risks of pharmaceuticals and other industrial chemicals and products, conducting environmental hazard assessments, green chemistry and sustainability, and regulatory ecotoxicity testing. Dr. Lunsman has evaluated many natural resource projects for NEPA compliance, including Federal threatened and endangered species, natural resource damage, impact, biological, and environmental assessments. Dr. Lunsman is an active member of SETAC, the Scientific Research Society, Sigma Xi and has published articles in peer-reviewed journals and presented at multiple scientific conferences on topics related to ecological risk assessment.

13. <u>Certification</u>

The undersigned official certifies that the information provided herein is true, accurate, and complete to the best of his knowledge.

Date: May 17, 2017

[redacted]

Tim Verslycke, Ph.D.
Principal

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15. Attachments

1. Confidential. Cabot-Carbon Black Food Contact Letter to FDA – final signed 2014-12-09.
2. Confidential. Calculation of Annual GHG Emissions.