ENVIRONMENTAL ASSESSMENT
TRADE SECRET/CONFIDENTIAL COMMERCIAL INFORMATION
FOR THE PRODUCT CURRENTLY IDENTIFIED AS COPENHAGEN SNUFF FINE CUT

Environmental Resources Management

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Memorandum

To: Altria Client Services LLC on behalf of U.S. Smokeless Tobacco Company LLC

From: Environmental Resources Management, Inc.

Date: January 24, 2018

Subject: Environmental Assessment: Modified Risk Tobacco Product Application for the Grandfathered Product *Copenhagen Snuff Fine Cut* (GF1200194)

This environmental assessment has been prepared in accordance with 21 CFR 25.40, the Food and Drug Administration's (FDA's or Agency's) regulations implementing the National Environmental Policy Act of 1969. Under NEPA, "all applications or petitions requesting Agency action require the submission of an environmental assessment or a claim of categorical exclusion."[1]

Environmental Resources Management, Inc. (ERM) respectfully submits the following environmental assessment with the *Modified Risk Tobacco Product Application (MRTPA)* for the grandfathered product currently identified as *Copenhagen Snuff Fine Cut* (GF1200194) pursuant to 21 CFR 25.20 because there is no applicable categorical exclusion for this type of application.

This environmental assessment was conducted in accordance with 21 CFR 25.40 and relevant aspects of FDA technical guidance documents including:

- *Environmental Considerations for Tobacco Product Applications Submitted to CTP, presented by Cristi Stark, M.S., Associate Director for Science Policy, Office of Science, CTP, FDA (August 2016);*
- *Guidance for Industry: Environmental Impact Assessments (EIA's) for Veterinary Medicinal Products (VMP's) – Phase I (March 2001);* and

[1] 21 CFR 25.15(a)

- *Guidance for Industry: Environmental Assessment of Drug and Biologics Applications (July 1998)*.

This environmental assessment was prepared at the direction of Altria Client Services LLC (ALCS) on behalf of U.S. Smokeless Tobacco Company LLC (USSTC), a wholly owned subsidiary of Altria Group Inc. The assessment addressed the grandfathered product, *Copenhagen Snuff Fine Cut (*GF1200194) ("the GF Product").[2] The potential atmospheric, aquatic, and terrestrial environmental impacts were considered using a conservative set of assumptions. The assessment identified no significant environmental risks associated with the proposed action of authorizing the marketing of the GF Product with the proposed modified risk claim. No additional environmental protection measures or alternative actions are necessary with respect to the proposed action. As such, a Finding of No Significant Impact (FONSI) by FDA is warranted for this environmental assessment of the GF Product.

This memorandum contains trade secret and confidential commercial information that USSTC considers to be proprietary and highly sensitive, and which is protected from disclosure under the Food, Drug and Cosmetic Act §§ 301(j) and 906(c) (21 U.S.C. §§ 331(j) and 387f(c)), the Trade Secrets Act (18 U.S.C. § 1905), the Freedom of Information Act (5 U.S.C. § 552), and FDA's implementing regulations, 21 CFR Part 20. If FDA receives a request for these records and tentatively determines that any portion of this submission is disclosable, USSTC requests that FDA provide notice and opportunity for USSTC to object to any disclosure in accordance with 21 CFR § 20.47 and 21 CFR § 20.61. USSTC reserves all of its legal rights to protect against public disclosure of its trade secret and confidential commercial information and to seek legal recourse against anyone who discloses such information without legal authorization.

1. DATE

January 24, 2018

2. NAME OF APPLICANT/SUBMITTER

Altria Client Services LLC on behalf of U.S. Smokeless Tobacco Company LLC

[2] FDA refers to tobacco products that were commercially marketed (other than exclusively in test markets) in the United States as of February 15, 2007, as grandfathered tobacco products.

3. ADDRESS

2325 Bells Road, Richmond, Virginia 23234

4. MANUFACTURER

U. S. Smokeless Tobacco Company LLC

5. DESCRIPTION OF PROPOSED ACTION

USSTC seeks a modified risk tobacco product order under Section 911(g) of the Federal Food, Drug and Cosmetic Act. USSTC is seeking authorization to market the GF Product as an MRTP with the proposed MRTP claim. In particular, this MRTPA is submitted for the purpose of obtaining a proposed modified risk claim order under Section 911(g)(1)(1) of the FD&C Act for the GF Product.

If approved for marketing, USSTC expects manufacture and sales of the modified risk GF Product to replace manufacture and sales of the currently marketed provisional product of the same name and/or the soon to be re-introduced GF Product marketed without a modified risk claim. For purposes of this environmental assessment, however, ERM has employed the most conservative approach by basing the environmental impact estimates on the projected first-year and fifth-year market volumes for the modified risk GF Product. In other words, we have not reduced the environmental impact estimates for the modified risk GF Product by taking into account any reduction in environmental impact resulting from the discontinuation of products replaced by the modified risk GF Product.

6. IDENTIFICATION OF THE PRODUCT THAT IS THE SUBJECT OF THE PROPOSED ACTION

6.1. Type of Tobacco Product

The GF Product is moist smokeless tobacco comprised of a tobacco blend and ingredients added to tobacco (various salts, flavors, and other ingredients).

6.2. Estimated Market Volumes

The following table presents the estimated first-year and fifth-year market volumes for the GF Product. These volume estimates form the basis for the environmental exposure estimates provided in this assessment.

Table 1 – Estimated First-Year and Fifth-Year Market Volumes for the GF Product

STN	Unit	GF Product	
		First-Year Projected Market Volume	Fifth-Year Projected Market Volume
GF1200194	Cans	(b) (4)	
	Metric Tons		

6.3. Product Composition

The composition of the tobacco, ingredients added to tobacco and packaging are described below.

6.3.1. Ingredients Added to Tobacco

The formulation of the ingredients added to tobacco is given in the following table. All values are reported in milligrams (mg) per gram (g) of product or mg/g. Note that 1 part per million (ppm) is equal to 0.001 mg/g.

Table 2 – Ingredients Added to Tobacco – Absolute Value

CAS	Substance	Absolute Value (mg/g)
(b) (4)		

Table 2 – Ingredients Added to Tobacco – Absolute Value

CAS	Substance	Absolute Value (mg/g)
[redacted]	[redacted]	(b) (4) [redacted]
(b) (4) [redacted]	(b) (4) [redacted]	(b) [redacted]
[redacted]	[redacted]	(b) (4) [redacted]

Table 2 – Ingredients Added to Tobacco – Absolute Value

CAS	Substance	Absolute Value (mg/g)
(b) (4)		(b) (4)
(b) (4)	Ethyl Alcohol	(b) (4)

Table 2 – Ingredients Added to Tobacco – Absolute Value

CAS	Substance	Absolute Value (mg/g)
		(b) (4)

Table 2 – Ingredients Added to Tobacco – Absolute Value

CAS	Substance	Absolute Value (mg/g)
		(b) (4)

Table 2 – Ingredients Added to Tobacco – Absolute Value

CAS	Substance	Absolute Value
(b) (4)		(b) (4)
(b) (4)	Sodium Carbonate	(b)
(b) (4)	Sodium Chloride	(b) (4)
(b) (4)		(b) (4)
(b) (4)	Water	(b)
(b) (4)		(b) (4)

6.3.2. Tobacco

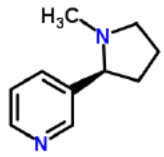
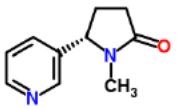
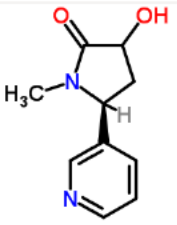
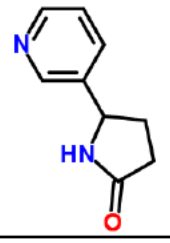
The total tobacco content and total nicotine content of the GF Product are reported in the following table.

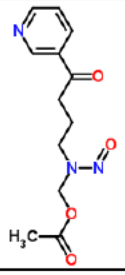
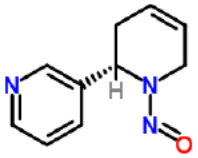
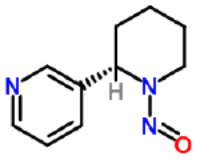
Table 3 - Tobacco and Nicotine in GF Product

Substance	% in GF Product Formulation	Absolute Value (mg/g)
Total Tobacco	(b) (4)	
Total Nicotine in Product		

Tobacco comprises (b) (4) of the GF Product, and is itself composed of a complex assemblage of individual constituents (Roberts, 1988). The vast majority of these constituents are typical phytochemical plant components, mostly cellulosics, carbohydrates, phenolics, and the like (Rosa & Alvarez-Parilla, 2010). Assessing the environmental impact of all of these constituents, most of which are non-specific to tobacco, would not be expected to change the overall conclusion of this assessment. Consensus reports indicate that the bioactive tobacco compounds in tobacco have been identified and are used to assess environmental health impact of tobacco *per se* (Lange, 2010), (IARC, 2007). These compounds are tobacco alkaloids including nicotine and related compounds and tobacco-specific nitrosamines, which are described in the following table.

Table 4 – Tobacco-Specific Nitrosamines, Nicotine and Related Compounds

Common Name	Chemical Descriptor	Structure
Nicotine	3-[(2S)-1-Methyl-2-pyrrolidinyl]pyridine CAS 54-11-5	
Cotinine	(5S)-1-Methyl-5-(3-pyridinyl)-2-pyrrolidinone CAS 486-56-6	
Trans-3′-hydroxycotinine	(5S)-3-Hydroxy-1-methyl-5-(3-pyridinyl)-2-pyrrolidinone CAS 34834-67-8	
Norcotinine	5-(3-Pyridinyl)-2-pyrrolidinone CAS 17114-40-8	

Common Name	Chemical Descriptor	Structure
N-nitrosonornicotine	3-[(2S)-1-Nitroso-2-pyrrolidinyl]pyridine CAS 16543-55-8	
4-methyl-N-nitrosamino-1-(3-pyridyl)-1-butanone	{Nitroso[4-oxo-4-(3-pyridinyl)butyl]amino}methyl acetate CAS 127686-49-1	
N-nitrosoanatabine	(2S)-1-Nitroso-1,2,3,6-tetrahydro-2,3'-bipyridine CAS 119738-26-0	
N-nitrosoanabasine	3-[(2S)-1-Nitroso-2-piperidinyl]pyridine CAS 1133-64-8	

For this environmental assessment, nicotine was used as a marker compound for tobacco.

6.3.3. *Packaging*

Packaging material for the GF Product comprises the following components, with weight represented on a per unit of product basis.

Table 5 – Type and Weight of Packaging Materials

Packaging Material	Composition
Fiberboard Can with Metal Lid	Lid: Tin plated steel (7.0 grams) Can Bottom: Fiberboard (9.5 grams)

Processing aids and coatings are used on the underside of product can lids.

Each of these materials (presented in Table 6) is approved for safe use as an indirect or direct food additive, including as a production aid or a coating in food-contact surfaces, and satisfies the regulatory requirements authorizing such uses. The specific materials used in the tobacco product packaging are listed in the table below, along with the regulatory citation of each chemical's approval for such use.

Table 6 – Tobacco Product Packaging Materials

		Regulation	
(b) (4)		21 CFR 175.300	Resinous and Polymeric Coatings (Food Contact Surfaces)
		21 CFR 172.880	Petrolatum (Direct Additive)
		21 CFR 178.3700	Petrolatum (Production Aids)
		21 CFR 178.3710	Petrolatum wax (Indirect Additive)
		21 CFR 172.886	Petroleum wax (Direct Additive)
		21 CFR 176.170	Components of paper and paperboard in contact with aqueous and fatty foods (Indirect Additive)
		21 CFR 176.180	Components of paper and paperboard in contact with dry food (Indirect Additive)

These materials are acceptable for use in food packaging or processing and are categorically exempt from the need for an environmental assessment pursuant to 21 CFR 25.32. We believe that an environmental assessment is also unnecessary for the use of these materials as processing aids or packaging coatings in tobacco products. To the submitter's knowledge, no extraordinary circumstances exist that require

submission of an environmental assessment for these materials. We report their status here for sake of completeness.

6.4. Location of Manufacture

The GF Product is manufactured at the USSTC facility located at 800 Harrison St., Nashville, TN, 37203. The modification of the product's label will not change any aspect of the location of the product's manufacture.

6.5. Location of Use

USSTC intends to market the GF Product to adult tobacco consumers throughout the United States. The modification of the product's label will not change any aspect of the location of the product's use.

6.6. Disposal Sites

The distribution of waste generated due to disposal of the GF Product and its packaging is expected to correspond to the pattern of product use. Disposed packaging materials will either enter the recycling stream or be disposed of in municipal solid waste (MSW) landfills or as litter. The modification of the product's label will not change any aspect of the location of the product's disposal. Additional information is provided in Section 7.1.3 below.

7. ENVIRONMENTAL ISSUES

7.1. Introduction of the GF Product into the Environment

Amending the label of the product is not expected to result in any new or additional adverse environmental impacts. The GF Product with proposed modified risk claim will contain the same ingredients and packaging materials as the grandfathered product. Therefore, its manufacture, transport, use and disposal are not expected to contribute to any significant new or additional environmental impacts.

7.1.1. As a Result of Manufacture

The GF Product is manufactured at the USSTC facility located at 800 Harrison St., Nashville, TN 37203. Manufacture of the GF Product will not result in an increase in overall permitted manufacturing capacity at the Nashville facility. If approved for marketing, USSTC expects manufacture and sales of the modified risk GF Product to replace manufacture and sales of the currently marketed provisional product of the

same name and/or the soon to be re-introduced GF Product marketed without a modified risk claim. Any change in total production volume at the facility is expected to be nominal and have little or no increased waste generated. The nature of the waste will not change and will not require new or expanded disposal capacity or resources, such as landfills or recycling centers.

Manufacturing the GF Product will not result in an expansion at the USSTC Nashville manufacturing facility. The manufacturing capacity at the facility is regulated within the facility's air permit. Based on production rates in 2016, the facility is operating at less than 55% of permitted capacity. The five year projection of smokeless tobacco product manufacturing at the facility, including the GF Product, is within existing capacity and will not require expansion.

The manufacture of the GF Product is not expected to result in emissions of new or additional compounds (pollutants) to the environment from the facility. USSTC anticipates the same or similar substances and types of emissions to be generated from manufacturing the GF Product as those associated with current smokeless tobacco production at the facility.

The methods used to control air emissions and wastewater emissions at the manufacturing facility are contained within the facility's regulatory permits (described in Section 7.4.3). The manufacture of the GF Product is not expected to result in changes in the type of air emissions or wastewater discharges from the manufacturing facility or require additional environmental controls. The facility is designed and permitted at smokeless tobacco product manufacturing capacity above the current and five year projections for smokeless tobacco manufacturing levels even when GF Product projections are included. No revised or new air or wastewater permits are required. Federal and State air quality and wastewater regulations, and the facility's air quality and wastewater permits, require the facility to evaluate the applicability of new or additional pollutants and could lead to additional control requirements if they exceed the regulatory threshold criteria.

No changes in solid waste generation are expected to result from the manufacturing of the GF Product. Waste generated as a result of manufacturing the GF Product will be disposed of in the same manner as any other smokeless tobacco products manufactured in the same facility, such as in landfills, recycled, transferred to publicly owned treatment works (POTWs), and/or released to the environment in accordance with environmental permits.

Based on the above, no significant environmental effects or impacts are anticipated as a result of manufacturing the GF Product. Therefore, the introduction to the

environment of released substances due to manufacturing the GF Product is negligible from an environmental perspective.

7.1.2. As a Result of Use

The aquatic and terrestrial environment are the primary compartments of concern for environmental releases of the GF Product as a result of use. The GF Product is used orally. Therefore, exposure to the atmosphere is not anticipated. Introduction of the GF Product to the environment as a result of use is further characterized in the following subsections.

7.1.2.1. Aquatic

7.1.2.1.1. Ingredients Added to Tobacco

The ingredients added to tobacco are expected to be released primarily to the aquatic environment via excretion as a result of product use. To quantify the anticipated amount of each chemical substance contained in the ingredients added to tobacco to the aquatic environment, ERM calculated the annual load (kilograms per year, or kg/yr) and the aquatic expected introduction concentration (EIC) (micrograms per liter, or µg/L). ERM applied the approach FDA established for human drugs and biologics to calculate the aquatic EIC as follows:

EIC-aquatic (ppb or µg/L) =A * B * C * D, where

A=Weight of Ingredient (kg/yr produced),

B=1/1.071x10^{11} L/day entering POTW

(Source: Clean Watersheds Needs Survey (NWNS) 2012 Data and Reports, Detailed Listing of Waste Water Treatment Plant Flows for the Nation accessible at https://ofmpub.epa.gov/apex/cwns2012/f?p=134:4::::RP::),

C=year/365,

D=10^{9} µg/kg

In calculating the aquatic EIC values, ERM maintained the following highly conservative assumptions that were established in FDA guidance:[3]

[3] Guidance for Industry: Environmental Assessment of Drug and Biologics Applications (July 1998)

- The kg/year produced is based on the highest quantity expected to be produced for direct use in any of the next five years;
- All product produced in a year is used and enters the POTW system [The ingredients are absorbed by the human body during use and 100% of the ingredients are then excreted to sanitary sewer and to treatment within the POTW];
- Product usage occurs throughout the United States in proportion to the population and amount of wastewater generated;
- No dilution occurs in receiving waters; and
- There is no metabolism.

The results of these calculations were compared to FDA's established concentration of concern (1 µg/L or ppb). As described in its 2001 technical guidance document, *Guidance for Industry: Environmental Impact Assessments (EIA's) for Veterinary Medicinal Products (VMP's) – Phase I*, FDA considers this value to be below the level shown to have adverse effects in aquatic ecotoxicity studies with human drugs. This was deemed appropriate for the current assessment as No Observed Effect Concentration (NOEC) values for each substance, where available, are greater than 1 µg/L or ppb.

A brief summary of publicly available fate and effects data for each ingredient of the GF Product is provided in the appendices for reference. For each ingredient estimated to meet or exceed 1 µg/L using the conservative assumptions listed above, a more detailed discussion of these data are provided in Sections 7.2 and 7.3 of this assessment.

Table 7 - Aquatic Annual Load and EIC for the Ingredients Added to Tobacco

Substance	Annual Load (kg/yr)[4]	Aquatic EIC (µg/L)[5]
	(b) (4)	

[4] (annual production forecast)x(relative amount in formulation)

[5] EIC-aquatic (ppb or µg/L)=A*B*C*D; where A=Weight of Ingredient(kg/yr produced), B=1/1.071x10^{11} L/day entering POTW (Source: Clean Watersheds Needs Survey (NWNS) 2012 Data and Reports, Detailed Listing of Waste Water Treatment Plant Flows for the Nation accessible at https://ofmpub.epa.gov/apex/cwns2012/f?p=134:4::::RP::), C=year/365, D=10^{9} µg/kg

Table 7 - Aquatic Annual Load and EIC for the Ingredients Added to Tobacco

Substance	Annual Load	Aquatic EIC
(b) (4)		
(b) (4)	(b) (4)	
(b) (4)		

Table 7 - Aquatic Annual Load and EIC for the Ingredients Added to Tobacco

Substance	Annual Load [4]	Aquatic EIC [5]
(b) (4)		

Table 7 - Aquatic Annual Load and EIC for the Ingredients Added to Tobacco

Substance	Annual Load (kg/yr)[4]	Aquatic EIC (µg/L)[5]
		(b) (4)
Ethyl Alcohol		(b) (4)
		(b) (4)

Table 7 - Aquatic Annual Load and EIC for the Ingredients Added to Tobacco

Substance	Annual Load (kg/yr)[4]	Aquatic EIC (µg/L)[5]
		(b) (4)

Table 7 - Aquatic Annual Load and EIC for the Ingredients Added to Tobacco

Substance	Annual Load (kg/yr)[4]	Aquatic EIC (µg/L)[5]
(b) (4)		
Sodium Carbonate		(b) (4)
		(b) (4)
Water	(b) (4)	
		(b) (4)

ERM noted that in every case except (b) (4), sodium chloride and water, the aquatic EIC is less than (b) (4) at the point of entry into the aquatic environment, which is below the relevant concentration of concern identified in FDA guidance.

The aquatic EIC for (b) (4), sodium chloride is (b) (4) and water is (b) (4) calculated using the highly conservative assumptions described above. In practice, the substrate will not be ingested or excreted, and release to the environment will primarily be the result of disposal. Nonetheless, the fate and effects of (b) (4) and sodium chloride are further described in Sections 7.2 and 7.3 of this assessment.

7.1.2.1.2. Tobacco

The GF Product is (b) (4) by weight tobacco. The environmental impact of tobacco is assessed as nicotine. The nicotine content of the GF Product is approximately (b) (4) ERM calculated the annual load and the aquatic EIC for both tobacco and nicotine. These values are presented in Table 8. The calculations are shown in the footnotes for the table.

Table 8 - Aquatic Annual Load and EIC for Tobacco and Nicotine

Substance	Annual Load (kg/yr)[6]	Aquatic EIC (µg/L)[7]
Tobacco	(b) (4)	
Nicotine		

As shown in Table 8, the EIC for nicotine is slightly over (b) (4) at the point of entry into the aquatic environment. If wastewater treatment removal and destruction rates for POTWs[8] were applied, the EIC calculated for nicotine would decrease to less than

[6] (annual production forecast)x(relative amount in formulation)

[7] EIC-aquatic (ppb or µg/L)=A*B*C*D; where A=Weight of Ingredient(kg/yr produced), B=1/1.071x10^{11} L/day entering POTW (Source: Clean Watersheds Needs Survey (NWNS) 2012 Data and Reports, Detailed Listing of Waste Water Treatment Plant Flows for the Nation accessible at https://ofmpub.epa.gov/apex/cwns2012/f?p=134:4:::::RP::), C=year/365, D=10^{9} µg/kg

[8] The rates are from "Table VI. Removal and Destruction Rates for POTWs" of EPA's "Toxic Chemical Release Inventory Reporting Forms and Instructions" (EPA 260-R-15-001); December 2015. Additional documentation for

(b) (4) at the point of entry into the aquatic environment. Since nicotine represents the most concentrated constituent that is expected to be of ecotoxicological relevance, the fate and effects data for nicotine are discussed in detail in Sections 7.2 and 7.3 of this assessment.

7.1.2.2. Terrestrial

7.1.2.2.1. Ingredients Added to Tobacco

Introduction of the GF Product to the terrestrial environment was calculated as surface density. The surface density for each component of the tobacco ingredient package is calculated using the weight of each component within the GF Product. (b) (4)

The daily terrestrial surface density values are presented in following table as the production tonnage distributed across the surface area of the United States per day (nanograms per square meter per day, or ng/m^2 per day). These values were based on the very conservative assumptions that the entire production volume was introduced to commerce and that the GF Product is released to the terrestrial environment in its complete and unused state. The calculation is shown in the footnote for the table.

Table 9 – Daily Terrestrial Surface Density Values for the Ingredients Added to Tobacco

Substance	Terrestrial Surface Density [2] [9]
(b) (4)	

the values presented in Table VI can be found in Technical Appendix B of the RSEI Model Documentation, available at: http://www2.epa.gov/toxics-release-inventory-tri-program/documentation-potw-removal-rates.

[9] Daily Surface Density (ng/m^2 per day) = A*B*C*D*E; where A = Weight of Ingredient (mg/yr produced), B = 1/9.158x10^6 km^2 surface area of the United States, C = year/365, D = 10^{-6} km^2/m^2, E = 10^6 ng/mg

Table 9 – Daily Terrestrial Surface Density Values for the Ingredients Added to Tobacco

Substance	Terrestrial Surface Density (ng/m^2 per day)[9]
[redacted]	(b) (4)

Table 9 – Daily Terrestrial Surface Density Values for the Ingredients Added to Tobacco

Substance	Terrestrial Surface Density (ng/m^2 per day)[9]
	(b) (4)

Table 9 – Daily Terrestrial Surface Density Values for the Ingredients Added to Tobacco

Substance	Terrestrial Surface Density (ng/m^2 per day)[9]
Ethyl Alcohol	(b) (4)

Table 9 – Daily Terrestrial Surface Density Values for the Ingredients Added to Tobacco

Substance	Terrestrial Surface Density (ng/m^2 per day)[9]
	(b) (4)

Table 9 – Daily Terrestrial Surface Density Values for the Ingredients Added to Tobacco

Substance	Terrestrial Surface Density (ng/m^2 per day)[9]
(b) (4)	
Sodium Carbonate	(b)
Sodium Chloride	(b) (4)
(b) (4)	
Water	(b)
(b) (4)	

With the exception of sodium chloride and water, the daily terrestrial surface density values presented as a production tonnage distributed across the surface area of the United States are below (b) (4) per day as determined using the calculations

shown in the footnote in the table above. Regarding sodium chloride, the level of exposure to the terrestrial environment (daily terrestrial surface density of (b) (4) (b) (4)) is significantly less than available toxicity data.

The mass of non-nicotine ingredients shown in Table 2 is not expected to cause localized effects if a single smokeless product was improperly disposed of to the terrestrial environment. The tobacco portion of the product is biodegradable. Adverse effects are highly unlikely because disposal should occur only on rare occasions and the non-nicotine ingredients are expected to exhibit a low order of toxicity. Considering in more realistic terms that a minimal quantity of the GF Product will be released through sputum and that a portion of the sputum will be collected and disposed of, actual exposure will be less than the daily surface density distributed across the United States.

7.1.2.2.2. Tobacco

The GF Product is (b) (4) by weight tobacco. The environmental impact of tobacco is assessed as nicotine. The nicotine content of the GF Product is approximately 1.26%. The daily terrestrial surface density are presented in following table as the production tonnage distributed across the surface area of the United States (ng/m2 per day). These values were based on the very conservative assumptions that the entire production volume was introduced to commerce and that the GF Product is released to the terrestrial environment in its complete and unused state. The calculation is shown in the footnote for the table.

Table 10 – Daily Terrestrial Surface Density for Tobacco and Nicotine

Substance	Terrestrial Surface Density (ng/m^2 per day)[10]
Tobacco	(b) (4)
Nicotine	

The daily terrestrial surface density value for nicotine presented as a production tonnage distributed across the surface area of the United States is below (b) (4) per day. Since nicotine represents the most concentrated constituent that is expected to be

[10] Daily Surface Density (ng/m^2 per day) = A*B*C*D*E; where A = Weight of Ingredient(mg/yr produced), B = $1/9.158 \times 10^6$ km^2 surface area of the United States, C = year/365, D = 10^{-6} km^2/m^2, E = 10^6 ng/mg

of ecotoxicological relevance, the fate and effects data for nicotine are discussed in detail in Sections 7.2 and 7.3 of this assessment.

7.1.3. As a Result of Disposal

The GF Product and associated packaging materials will either be recycled or be disposed of in MSW landfills or as litter. Following use, the GF Product will be disposed of in the same way as other commercially marketed smokeless tobacco products. The distribution of waste generated due to disposal of the GF Product and packaging is expected to correspond to the pattern of product use in the United States.

7.1.3.1. Disposal of Tobacco Product Following Use

According to the U.S. Environmental Protection Agency (USEPA) document, *Advancing Sustainable Materials Management: 2014 Fact Sheet Assessing Trends in Material Generation, Recycling, Composting, Combustion with Energy Recovery and Landfilling in the United States*, 258 million tons of MSW were generated across the United States in 2014. Of this, over 89 million tons (34.6%) were recycled and composted, more than 136 million tons (52.6%) were discarded in a landfill, and more than 33 million tons (12.8%) were combusted with energy recovery (USEPA, 2016a). Smokeless tobacco products are not expected to be recycled.

Assuming the entire maximum anticipated annual shipping quantity is disposed of via landfill, the GF Product is expected to generate an absolute maximum of (b) (4) tons of MSW per year. This represents up to (b) (4) of the total MSW in the country and up to (b) (4) of MSW that is disposed of in landfills in the country. Thus, the contribution of the GF Product to total MSW disposed annually in the United States is miniscule. Also, USSTC expects manufacture and sales of the modified risk GF Product to replace manufacture and sales of the currently marketed provisional product of the same name and/or the soon to be re-introduced GF Product marketed without a modified risk claim. Any change in total production volume at the facility is expected to be nominal and have little or no increased waste generated. Therefore, additional resources (e.g., new landfills, recycling centers, etc.) will not be required for disposal following use of the GF Product.

Proper disposal will be to landfill and not directly to the terrestrial environment. Disposal to MSW landfills will not result in adverse effects to the environment based on landfill design and regulatory requirements. Disposed waste streams within a landfill are prevented from entering the environment and ultimately landfill leachate is treated and/or sent to POTWs for effective treatment.

Disposal following use of the GF Product is not expected to result in new or additional compounds emitted to the environment. USSTC anticipates the same or similar substances and types of emissions as those associated with current smokeless tobacco products to be released into the environment as a result of disposal following use of the GF Product. The GF Product will be disposed of following use in the same way as other commercially marketed smokeless tobacco products. Disposed products will enter MSW stream and be disposed of in MSW landfills or as litter. No new or additional environmental effects, as defined within 40 CFR 1508.8, are anticipated.

For the purpose of the assessment, calculations were performed to establish a very conservative quantitative assessment. The aquatic and terrestrial environment are the primary compartments of concern for environmental releases of the GF Product as a result of disposal. The calculations provided in Section 7.1.2 conservatively address product that is inappropriately disposed of directly to the environment.

7.1.3.2. Disposal of Packaging Following Use

Packaging materials are expected to be disposed of as household waste or as litter. The GF Product's packaging is expected to be disposed of following use in the same way as packaging from other commercially marketed smokeless tobacco products. The distribution of waste generated due to disposal of packaging is expected to correspond to the same pattern of product use. Assuming all packaging is disposed of via landfill, packaging from the GF Product is expected to generate up to (b) (4) tons of MSW per year. This represents up to (b) (4) of the total MSW in the country and up to (b) (4) of MSW that is disposed of in landfills in the country. Thus, the contribution of the GF Product's packaging to total MSW disposed annually in the United States is miniscule. Therefore, disposal of the GF Product and the packaging following use of the GF Product is not expected to require additional resources (e.g., new landfills, recycling centers, etc.) for waste disposal.

Disposal of packaging following use of the GF Product is not expected to result in new or additional compounds emitted to the environment. The materials used in the packaging of the GF Product (b) (4) are common packaging materials used for consumer products in general. Proper disposal will be to landfill and not directly to the terrestrial environment. Disposal to MSW landfills will not result in adverse effects to the environment based on landfill design and regulatory requirements. Therefore, the same or similar compounds and types of emissions are anticipated from disposal of the packaging of the GF Product as those associated with disposal of the packaging of other smokeless tobacco product currently on the market. No new or additional environmental effects, as defined within 40 CFR 1508.8, are anticipated.

7.2. Fate of Product Released into the Environment

Nicotine represents the most concentrated constituent that is expected to be of ecotoxicological relevance. The fate of nicotine released into the environment is discussed here in detail. Additionally, sodium chloride and (b) (4) are addressed in this section because each's aquatic EIC is greater than (b) (4) at the point of entry into the aquatic environment.

7.2.1. Nicotine

Nicotine was used as a marker compound for tobacco that will enter the environment via excretion, spitting and subsequent leaching. Nicotine accounts for approximately 95% of the alkaloid content of tobacco (Lange, 2010) with the remainder being made up of the nitrosamines and nicotine-related compounds from Table 4. In animals, these alkaloids have been reported to be pharmacologically active, but less so than nicotine. Thus, we conservatively propose to use nicotine as a marker compound to represent the toxicity of the alkaloid substances in tobacco.

With the exception of nicotine, there are few data on the toxicity of these alkaloids to terrestrial or aquatic organisms. Quantitative Structure Activity Relationships (QSARs) have been used to describe some of the physical-chemical properties of these materials and to provide predicted aquatic toxicity values to support the use of nicotine as a marker compound. Acceptable QSARs are not available to predict toxicity to terrestrial organisms. All QSAR predictions were determined using the USEPA's EpiWeb 4.1.[11] Note that the fate and toxicity predictions for nicotine were based on pure nicotine. Nicotine in tobacco is in a complex matrix from which nicotine and other alkaloids are extracted. The actual availability and exposure to nicotine will be reduced by the matrix (i.e., the tobacco leaf).

7.2.1.1. Physical Chemical Properties

The physical-chemical properties of pure nicotine (CAS 54-11-5) and its metabolites are presented in the following table. Nicotine's physical-chemical properties can be used to assess the fate of nicotine introduced into the environment.

[11] The EPI (Estimation Programs Interface) Suite™ is a Windows®-based suite of physical/chemical property and environmental fate estimation programs developed by the USEPA's Office of Pollution Prevention Toxics and Syracuse Research Corporation (SRC). EPI Suite™ uses a single input to run the following estimation programs: KOWWIN™, AOPWIN™, HENRYWIN™, MPBPWIN™, BIOWIN™, BioHCwin, KOCWIN™, WSKOWWIN™, WATERNT™, BCFBAF™, HYDROWIN™, KOAWIN and AEROWIN™, and the fate models WVOLWIN™, STPWIN™ and LEV3EPI™. ECOSAR™, which estimates ecotoxicity, is also included in EPI Suite™ (USEPA, 2016b).

Nicotine introduced into water will stay mainly in water and will not readily partition to air based on its low Henry's Law Constant ($3x10^{-9}$ atmospheres – cubic meters per mole or atm-m^3/mole) and negative air/water partitioning coefficient (K_{aw} = -6.910). Nicotine in water should not bioaccumulate or bioconcentrate in aquatic organisms (measured log K_{ow} = 1.17) (Hansch, Hoekman, Leo, Zhang, & Li, 1995). (b) (4)

Nicotine introduced into the soil can volatilize to air based on the vapor pressure of 0.032 mm Hg (Boublik, 1984). However, the extent to which it actually volatilizes will depend on its sorption. The log K_{oc} predicted at neutral pH is 2.720 and indicates that nicotine in soil has moderate mobility. The mobility of nicotine, a weak acid (pK_a 8.5), is pH dependent and will increase at alkaline pH. Because nicotine is highly soluble (predicted solubility $1.000x10^6$ milligrams per liter, or mg/L) and has a negative K_{aw}, it will most likely partition to soil pore-water rather than air.

Table 11a – Predicted Physical-Chemical Properties of Tobacco-Specific Nitrosamines, Nicotine and Related Compounds

CAS	IUPAC Name	Water Solubility	Vapour Pressure	Henry's Law Constant	Log K_{ow}	log K_{oc}	Log K_{oa}
		mg/L	mm Hg	atm-m^3/mol			
54-11-5	3-[(2S)-1-Methyl-2-pyrrolidinyl]pyridine	1 000E+06	3 200E-02	3 000E-09	9 980E-01	2 720E+00	8 080E+00
486-56-6	(5S)-1-Methyl-5-(3-pyridinyl)-2-pyrrolidinone	9 990E+05	3 810E-04	3 330E-12	3 400E-01	2 110E+00	8 038E+00
34834-67-8	(5S)-3-Hydroxy-1-methyl-5-(3-pyridinyl)-2-pyrrolidinone	1 000E+06	2 160E-07	5 200E-13	-1 200E+00	1 010E+00	9 190E+00
171140-40-8	5-(3-Pyridinyl)-2-pyrrolidinone	1 000E+06	1 660E-05	1 520E-12	-3 000E-01	2 100E+00	9 900E+00
16543-55-8	3-[(2S)-1-Nitroso-2-pyrrolidinyl]pyridine	6 030E+05	5 120E-04	1 970E-10	3 210E-01	3 200E+00	8 480E+00
127686-49-1	{Nitroso[4-oxo-4-(3-pyridinyl)butyl]amino}methyl acetate	5 040E+03	5 130E-07	3 000E-14	6 860E-01	2 190E+00	1 260E+01
119738-26-0	(2S)-1-Nitroso-1,2,3,6-tetrahydro-2,3'-bipyridine	3 060E+05	6 040E-05	1 970E-10	5 970E-01	3 470E+00	8 690E+00
1133-64-8	3-[(2S)-1-Nitroso-2-piperidinyl]pyridine	1 960E+05	6 680E-05	8 580E-11	8 120E-01	3 470E+00	8 850E+00

Table 11b – Predicted Physical-Chemical Properties of Tobacco-Specific Nitrosamines, Nicotine and Related Compounds

CAS	IUPAC Name	Log K_{aw}	BCF	Photo-chemical half-life	Half-life in water	Half-life in soil
				hrs	days	days
54-11-5	3-[(2S)-1-Methyl-2-pyrrolidinyl]pyridine	-6.910E+00	4.400E-01	1.410E+00	3.750E+01	7.500E+01
486-56-6	(5S)-1-Methyl-5-(3-pyridinyl)-2-pyrrolidinone	-8.040E+00	5.000E-01	4.900E+00	3.750E+01	7.500E+01
34834-67-8	(5S)-3-Hydroxy-1-methyl-5-(3-pyridinyl)-2-pyrrolidinone	-1.067E+01	5.000E-01	4.300E+00	3.750E+01	7.500E+01
171140-40-8	5-(3-Pyridinyl)-2-pyrrolidinone	-1.027E+01	5.000E-01	7.990E+00	6.000E+01	1.200E+02
16543-55-8	3-[(2S)-1-Nitroso-2-pyrrolidinyl]pyridine	-8.160E+00	5.000E-01	5.400E+00	6.000E+01	1.200E+02
127686-49-1	{Nitroso[4-oxo-4-(3-pyridinyl)butyl]amino}methyl acetate	-1.191E+01	5.000E-01	4.200E+00	6.000E+01	1.200E+02
119738-26-0	(2S)-1-Nitroso-1,2,3,6-tetrahydro-2,3'-bipyridine	-8.090E+00	5.000E-01	1.430E+00	6.000E+01	1.200E+02
1133-64-8	3-[(2S)-1-Nitroso-2-piperidinyl]pyridine	-8.030E+00	5.000E-01	3.380E+00	6.000E+01	1.200E+02

7.2.1.2. Degradation

Nicotine lacks hydrolyzable groups and; therefore, will not undergo abiotic hydrolysis. However, nicotine has the potential to undergo direct photolysis.

Nicotine's electronic absorption spectrum shows an intense absorption band at 260-262 nanometers (nm) with some absorption above 290 nm (toward sunlight spectral region) (Sangster & Stuart, 1965). The predicted photochemical half-life for nicotine in air is 1.4 hours. Nicotine can also degrade in surface waters via indirect photolysis by naturally occurring photosensitizers such as dissolved organic matter and hydroxyl radicals. Thus, indirect photolysis can play an important role in the degradation of nicotine.

Biotransformation of nicotine in soils and water-sediment systems has been documented. In soils, nicotine is oxidized by the bacteria *Arthrobacter oxydans* (now known as *Arthrobacter nicotinovarans*). The relative amounts and conditions of biotransformation will vary with soil and bacterial populations. The nature of the transformations in soil is not as well defined as those in animals. It has been demonstrated *in vitro* that the first metabolite of nicotine is 6-hydroxynicotine, which further breaks down to 6-hydroxypseudonicotine (oxynicotine) and other compounds. Cotinine, which is a major oxidation product of nicotine in the liver, has not been reported to form in soils; however, microorganisms isolated from soils in tobacco fields are capable of degrading nicotine to cotinine in solution (Wang et al., 2012).

Nicotine and its metabolite, cotinine, have been reported to biotransform in sediments (Bradley, Barber, Kolpin, McMahon, & Chapelle, 2007). Under oxidizing conditions nicotine and cotinine degrade completely to CO_2 within 72 days. Under anoxic conditions the biotransformation of nicotine and cotinine is slower. EpiWeb 4.1 predicts half-lives of 37.5 days for nicotine and cotinine in water and 75 days in soil under aerobic conditions.

Data on the transformation products or metabolites of nicotine are very limited. In order to have a common frame of reference, we compared the predicted values for nicotine to the predicted values for the metabolites. Predicted physical-chemical properties of nicotine metabolites and transformation products compare to those of nicotine as follows. Predicted log K_{ow} values range from -1.200 to 0.998. Predicted log K_{oc} ranges from 1.010 to 3.470. Predicted water solubilities range from 5.040×10^3 mg/L to 1.000×10^6 mg/L with nicotine being among the more soluble substances. Predicted Henry's Law Constants range from 3.000×10^{-14} atm-m^3/mole to 3.000×10^{-9} atm-m^3/mole for nicotine and related compounds. Predicted photochemical half-lives range from 1.410 to 7.990 days for nicotine and related compounds. Predicted half-lives in water are all less than 60 days and half-lives in soil are predicted to be less than 120 days. Relative to its metabolites, nicotine is more water soluble and more volatile, and degrades somewhat more quickly. Its behavior was deemed similar

enough to that of its metabolites to serve as an appropriate surrogate in the environmental assessment.

7.2.2. Other Ingredients or Substances

Data on the physical-chemical properties of (b) (4) are very limited due to its naturally occurring nature. (b) (4) is not expected to exhibit harmful degradation or biotransformation products. (b) (4) is currently listed as an FDA GRAS (Generally Recognized as Safe) substance under 21 CFR 184.1408 (b) (4) derivatives. Also, (b) (4) is listed as an inert ingredient by USEPA under 40 CFR 180.950 (Tolerance exemptions for minimal risk active and inert ingredients) which allows exemption from tolerance requirements under the *Section 408* of the *Federal Food, Drug, and Cosmetic Act* (*FFDCA*), and is also exempt as an inert ingredient from Federal regulation under the Minimum Risk Exemption regulations in 40 CFR 152.25(f).

The physical-chemical properties of sodium chloride (b) (4) can be used to assess the fate of sodium chloride (NaCl) in the environment. The water solubility of sodium chloride is greater than 10,000 mg/L (approximately 320 g/L). Sodium chloride introduced into water will fully dissociate into its component ions. The high water solubility and low vapor pressure indicate that sodium chloride will be found predominantly in the aquatic environment. NaCl is an electrovalent substance. Electrovalent substances are made up of ions in the solid state. The oppositely charged ions are held together by strong electrostatic (coulombic) force of attraction. Due to these forces the ions cannot move. When these substances are dissolved in water, the ions free themselves from this binding. Thus the breakup of an electrovalent compound into free mobile ions when dissolved in water or when melted, is called electrolytic dissociation. In the liquid state the ions become free and mobile. But the oppositely charged ions always remain in close proximity of each other. NaCl(s) ---> Na+ (aq) + Cl- (aq). This is a 100% dissociation (ECHA, 2017). In water, sodium chloride will not adsorb to surfaces and will not accumulate in living tissues. The addition of significant amounts of NaCl into the freshwater aquatic environment could elevate the salinity of waterbody with potential effects to freshwater aquatic organisms. Note that NaCl present at greater than 30 parts per thousand is considered saline water.

The sodium ion is ubiquitously present in the environment and it has been measured extensively in aquatic ecosystems. Sodium and chloride concentrations in water are tightly linked. They both originate from natural weathering of rock, from atmospheric transport of oceanic inputs and from a wide variety of anthropogenic sources. The sodium concentration was reported for a total number of 75 rivers in North and South

America, Africa, Asia, Europe and Oceania, with a 10th percentile of 1.5 mg/l, mean of 28 mg/l and 90th percentile of 68 mg/l (UNEP, 1995).

7.3. Environmental Effects of Product Released into the Environment

Nicotine represents the most concentrated constituent that is expected to be of ecotoxicological relevance. The environmental effects of nicotine released into the environment are discussed here in detail. Additionally, sodium chloride and (b) (4) (b) (4) are addressed in this section because each's aquatic EIC is greater than (b) (4) at the point of entry into the aquatic environment.

7.3.1. Nicotine

Tobacco (*Nicotiana tabacum, Nicotiana rustica, Nicotiana* spp.)[12] is a member of the nightshade family (*Solanaceae*). This family also includes potatoes, tomatoes, eggplant and peppers. Members of the *Solanaceae* family contain alkaloids that can be desirable, toxic, or both. The predominant alkaloid in tobacco is nicotine. Other alkaloids and nicotine transformation products are present in lesser amounts. QSAR analysis and limited data also indicate that these compounds are of lesser toxicity than nicotine thus supporting the use of nicotine as a conservative marker compound for tobacco.

QSAR predictions in Table 12 were used here as a basis of comparison among the compounds and should be taken as qualitative rather than quantitatively definitive. Equations for different classes of compounds used to develop the ECOSAR model within OECD Toolbox V2.38 (OECD, 2012) are of differing reliabilities depending on the dataset used to develop the equation.

[12] The focus of this EA is on the *tabacum* and *rustica* species.

Table 12 - Acute Aquatic Toxicity of Tobacco-Specific Nitrosamines, Nicotine and Related Compounds

CAS	IUPAC Name	Algal 96-hr EC_{50}	Daphnia 48-hr - EC_{50}	Fish 96-hr LC_{50}
		mg/L	mg/L	mg/L
54-11-5	3-[(2S)-1-Methyl-2-pyrrolidinyl]pyridine	44.70	0.20	4.86
486-56-6	(5S)-1-Methyl-5-(3-pyridinyl)-2-pyrrolidinone	17.80	1.92E+03	8.11E+02
34834-67-8	(5S)-3-Hydroxy-1-methyl-5-(3-pyridinyl)-2-pyrrolidinone	176.00	5.35E+04	1.11E+04
171140-40-8	5-(3-Pyridinyl)-2-pyrrolidinone	22.20	2.75E+03	1.06E+03
16543-55-8	3-[(2S)-1-Nitroso-2-pyrrolidinyl]pyridine	131.00	0.22	8.66
127686-49-1	{Nitroso[4-oxo-4-(3-pyridinyl)butyl]amino}methyl acetate	42.50	38.00	372.00
119738-26-0	(2S)-1-Nitroso-1,2,3,6-tetrahydro-2,3'-bipyridine	93.30	0.23	7.57
1133-64-8	3-[(2S)-1-Nitroso-2-piperidinyl]pyridine	69.00	0.24	6.55

Predicted algal 96-hr EC_{50} values range from 17.8 mg/L to 176 mg/L. The predicted EC_{50} for nicotine (CAS 54-11-5) is 44.7 mg/L. While not predicted to be the most toxic compound, nicotine toxicity is within a factor of 2 of the most toxic compounds and likely not significantly different (i.e., within the confidence limits of the prediction). Measured 96-hr EC_{50} values for the toxicity of nicotine to the alga *Selenastrum capricornutum* were 72.9 mg/L for growth and 115 mg/L for biomass (Seckar, et al., 2008). The predicted EC_{50} values for nicotine were lower than the measured values but within a factor of 2.

The predicted 48-hr EC_{50} of nicotine to *Daphnia* is 0.2 mg/L. Predicted toxicity values for the nicotine metabolites range from 0.22 mg/L to 5,350 mg/L. The measured EC_{50} value for *Daphnia pulex* is 0.24 mg/L (Savine & Tanabe, 1989).

The predicted fish 96-hr LC_{50} for nicotine is 4.86 mg/L. The predicted LC_{50} values for metabolites of nicotine range from 6.55 to 11,000 mg/L. Measured LC_{50} values for nicotine toxicity to *Oncorhynchus mykiss* larvae are 4 mg/L (96 hrs), 5 mg/L for fry (60 days), and 6 mg/L for fry (21-31 days).

Terrestrial toxicity data for invertebrates were of limited availability. Because nicotine has a history of use as a pesticide, it is expected that terrestrial invertebrates will be very sensitive to nicotine. Rizvi et al. reported that the 24-hr LD_{50} of nicotine dust was 7.2 micrograms (µg)/nymph for *Dysdercus koenigii (Fabr.)* (Rizvi, Ahmed, & Naqvi, 2012). Additional toxicity data are included on dermal toxicity to the brown tree snake, oral toxicity to rats, and dermal toxicity to rabbits. Terrestrial toxicity to the brown tree snake (*Boiga irregularis*) is reported as 40 milligrams per kilogram (mg/kg) dermally, a dose that killed 100% of snakes (Brooks, Savarie, & Johnston, 1998). The oral LD_{50} dose for nicotine in rats is 50 mg/kg to 60 mg/kg (Klaasen, Amdur, & Doull, 1995). The dermal LD_{50} in rabbits is reported as 140 mg/kg (Lewis, 1996).

7.3.2. Other Ingredients or Substances

Data on the physical-chemical properties of (b) (4) are very limited due to its naturally occurring nature. (b) (4) is not expected to exhibit ecotoxicity. (b) (4) is currently listed as an FDA GRAS substance under 21 CFR 184.1408 (b) (4) derivatives. Also, (b) (4) is listed as an inert ingredient by EPA under 40 CFR 180.950 (Tolerance exemptions for minimal risk active and inert ingredients) which allows exemption from tolerance requirements under the ***Section 408*** of the ***FFDCA***, and is also exempt as an inert ingredient from Federal regulation under the Minimum Risk Exemption regulations in 40 CFR 152.25(f).

Sodium chloride is essentially non-toxic to aquatic organisms, including fish, invertebrates, and algae, at any environmentally relevant concentration. The Algal 96-hr EC_{50} value is 6,870 mg/L (Lemna minor) and the 48-hr EC_{50} to *Daphnia magna* is 874 mg/L. The Fish 96-hr LC_{50} for sodium chloride is 5,840 mg/L (Bluegill (Lepomis macrochirus)), 7,341 mg/L (Goldfish (Carassius auratus)), and the 96-hr LC_{50} to Fathead minnows (Pimephales promelas) is 7,650 mg/L (ECHA, 2017).

Availability of terrestrial toxicity data were limited, but similarly indicated very low toxicity. Test data for terrestrial plants indicate 7-day IC_{50} values greater than 500 mg/kg soil (ECHA, 2017) and 24-hour LD_{50} for silkworm larvae at 8,900 ppm (ECHA, 2017) and earthworm 10-week NOEC at 3,507 mg/kg soil wet weight (ECHA, 2017).

7.4. Use of Resources and Energy

The GF Product is anticipated to compete with other tobacco products currently on the market and any net increase in production volume will be nominal and have little or no increased energy or resources used. In 2013, there was approximately 128 million pounds of smokeless tobacco sold by manufacturers to wholesalers and retailers in the United States.[13] The annual market volume of the GF Product is expected to be up to (b) (4) pounds (lbs), which is a small fraction (b) (4)) of all smokeless tobacco products in the United States. Accordingly, the use of resources and energy due to the proposed action is negligible.

[13] https://www.cdc.gov/tobacco/data_statistics/fact_sheets/economics/econ_facts/

7.4.1. Energy Consumption / Greenhouse Gas Emissions

The manufacture of the GF Product is not expected to result in a significant net increase of energy use at the USSTC Nashville manufacturing facility. The facility cannot directly measure energy consumption for individual SKUs. However, USSTC expects manufacture and sales of the modified risk GF Product to replace manufacture and sales of the currently marketed provisional product of the same name and/or the soon to be re-introduced GF Product marketed without a modified risk claim. Therefore, net total production at the facility is not expected to increase due to manufacturing of the GF Product. And, because energy use is expected to directly correlate to changes in production volume, we likewise estimate that total energy use at the facility will not increase due to manufacturing the GF Product.

All fuel-burning equipment utilizes clean, natural gas and is covered under existing air permits. Also, the facility replaced their two coal-fired boilers in 2014. Additional information on energy, resources, and sustainability efforts are described in Section 7.4.4.

7.4.2. Compliance with ESA and CITES

No adverse effects are expected on a species or the critical habitat of a species identified under the Endangered Species Act (ESA) or the Convention on International Trade in Endangered Species of Wild Flora and Fauna (CITES) due to the manufacture or marketing of the GF Product. If approved for marketing, USSTC expects manufacture and sales of the modified risk GF Product to replace manufacture and sales of the currently marketed provisional product of the same name and/or the soon to be re-introduced GF Product marketed without a modified risk claim. The GF Product will be manufactured in the same manner as other smokeless tobacco products manufactured at the same facility. Also, there are no changes in solid waste generation expected to result from the manufacturing of the GF Product. In addition, the GF Product will be commercially distributed and used by consumers in the same manner as other currently marketed smokeless tobacco products.

USSTC does not anticipate that any endangered species or critical habitat will be affected from materials or ingredients used to manufacture the GF Product, or from production of the GF Product. USSTC's long-term supply contracts with tobacco growers and material suppliers, and the purchase order terms and conditions applicable to suppliers without long-term contracts, contain provisions that require compliance with all applicable laws and regulations.

USSTC does not anticipate that any critical habitat or endangered or threatened species will be affected due to the manufacture of the GF Product. The manufacturing facility is not within or in close proximity to a critical habitat of a threatened or endangered species. This is based on a review of critical habitat maps (https://databasin.org/datasets/d579d87eb54f4374a77ea53e7ef66449) created by the U.S. Fish and Wildlife Service (US FWS), which show no critical habitat within close proximity to the manufacturing facility. The nearest critical habitat is approximately nine miles from the facility, northwest of Nashville along the Cumberland River.

Regarding threatened or endangered species, the US FWS's list of species by county (https://www.fws.gov/endangered/) shows that the Nashville area (Davidson County) may have eleven endangered species (six types of Clams; one Crustacean – Nashville crayfish (*Orconectes shoupi*); two Flowering Plants (Short's bladderpod (*Physaria globosa*) and Leafy prairie-clover (*Dalea foliosa*)); two Mammals (Indiana bat (*Myotis sodalis*) and Gray bat (*Myotis grisescens*)). The area may have two threatened species (Flowering Plant – Price's potato-bean (*Apios priceana*); Mammal – Northern Long-Eared Bat (*Myotis septentrionalis*)). However, these threatened or endangered species are not known to be in the vicinity of the manufacturing facility.

None of the materials or ingredients used to manufacture the GF Product are listed by the US FWS (https://www.fws.gov/endangered/species/us-species.html) or the CITES (http://checklist.cites.org/) as endangered or threatened species. USSTC is not aware that any materials or ingredients to be used in the GF Product are manufactured using any of the endangered or threatened species listed by either the US FWS or the CITES.

As described in Section 7.1.3, there are no changes in solid waste generation expected to result from the manufacturing of the GF Product and the GF Product will be disposed of in the same way as other commercially marketed smokeless tobacco products. The distribution of waste generated due to disposal of the GF Product and packaging is expected to correspond to the pattern of product use in the United States.

Thus, USSTC is not aware of any extraordinary circumstances that would cause adverse environmental impact to an endangered or threatened species or a critical habitat for such species (per US FWS and the CITES) from the manufacture or production of the GF Product, the manufacturing process itself, or the materials and ingredients used to manufacture the GF Product.

7.4.3. Compliance with Federal, State, and Local Environmental Regulations

The USSTC Nashville manufacturing facility, where the GF Product will be manufactured, complies with the Clean Air Act (CAA), Clean Water Act (CWA) and Resource Conservation and Recovery Act (RCRA). USSTC is not aware of any potential violation of any federal, state, or local regulation. USSTC Nashville manufacturing facility's compliance with the CAA, CWA, the RCRA, and other environmental regulations can be assessed on the USEPA's Enforcement and Compliance History Online (ECHO) website.

USSTC maintains an effective Environmental Management System (EMS) that is designed and implemented to facilitate environmental compliance and sustainability. Key components of the EMS include: personnel, policy, directives, guidance and training, data management and internal assessments. The manufacture of the GF Product will not result in changes in compliance with relevant federal, state, and local environmental regulations. USSTC anticipates the same or similar substances and types of air emissions and wastewater discharges to be generated from manufacturing the GF Product as those associated with current smokeless tobacco production at the facility. The manufacture of the GF Product is not expected to require additional environmental controls. No revised or new air or wastewater permits are required for the manufacture of the GF Product at the facility. Federal and State air quality and wastewater regulations and the facility's air quality and wastewater permits require the facility to evaluate the applicability of new or additional pollutants and could lead to additional control requirements if they exceed the regulatory threshold criteria.

The methods used to control air emissions at the manufacturing facility are contained in the attached documents: U.S. Smokeless Tobacco Manufacturing, LP – Nashville, Tennessee – Synthetic Minor Air Pollutant Source Operating Permits (Permit Numbers 81-2 through 81-4, 81-6, 81-8 through 81-10) issued by the Metropolitan Government of Nashville and Davidson County, Public Health Department. These air permits were issued in accordance with the Nashville and Davidson County Metropolitan Code of Laws, specifically Chapter 10.56 (Air Pollution Control). Additionally, the USSTC Nashville manufacturing facility is required to comply with applicable USEPA and Tennessee Department of Environmental and Conservation (TDEC) regulations. Among other requirements and conditions, the permits place limits on air emissions and production capacities, and require submittal of compliance data to the local agency.

Regarding wastewater, the USSTC Nashville manufacturing facility has an Industrial User Discharge Permit (i.e., wastewater pretreatment permit; permit number CP-0286); from the local POTW facility which is the Department of Water and Sewerage

Services within the Metropolitan Government of Nashville and Davidson County. The permit requires compliance with effluent limitations and requires monitoring to ensure the wastewater is of a certain quality to be effectively treated at the POTW facility. In accordance with regulation and the permit, USSTC regularly submits Discharge Monitoring Reports to the County/POTW which detail its compliance with the applicable water quality standards. The POTW is permitted by the TDEC and regulated under the USEPA's National Pollutant Discharge Elimination System (NPDES) and its relevant effluent standards (40 CFR 400 – 699).

Regarding the RCRA, USSTC seeks to minimize the amount of waste generated. When feasible, wastes are recycled or composted or otherwise used beneficially instead of disposed. Wastes generated at USSTC's Nashville manufacturing facility are subject to and comply with certain federal, state and local regulations. The facility is registered for waste generation under EPA ID# TND982109289. The company's Safety and Environmental Management Systems Policy provides guidance to actively lead and integrate environmental matters into the business and to promote ongoing compliance with environmental requirements. Under this policy, the Waste Management Directive (the Directive) provides guidance on how to effectively and responsibly manage and dispose of Hazardous and Solid Wastes and ensure federal environmental regulatory compliance. The Directive and its requirements are required to be followed by USSTC facilities unless specifically preempted by a more strict state or local regulation. USSTC facility personnel also have access to internal guidance to support proper waste management and disposal or recycling activities.

7.4.4. Environmental Sustainability

The manufacture of the GF Product will not affect environmental sustainability at the manufacturing facility. USSTC has an ongoing initiative to improve environmental sustainability across all facilities. One piece of infrastructure that supports this initiative is the EMS. USSTC's commitment to environmental sustainability is demonstrated by reducing its environmental footprint by increasing efficiency and consolidating manufacturing operations. As a result of these efforts, USSTC expects its overall energy use to decrease over time. For more information on USSTC's environmental sustainability initiatives, refer to the company's website and the company's Corporate Responsibility Progress Report http://www.altria.com/Interactive/2016CRReport/index.html).

The manufacture of the GF Product will occur at USSTC's Nashville facility, and will not affect environmental sustainability. At the USSTC Nashville manufacturing facility, the established sustainable practices, such as material reuse and recycling will continue. For example, in 2016, the Nashville facility composted or recycled 50% of its

solid waste that otherwise would have been disposed to landfill. As described in Section 7.4.1 above, the manufacture of the GF Product is not expected result in a significant net increase in energy consumption at the USSTC Nashville manufacturing facility. Energy use is expected to directly correlate to the nominal change in production. The facility's commitment to greenhouse gas (GHG) emissions reduction is demonstrated by its use of clean, natural gas and replacement of its two coal-fired boilers in 2014 with natural gas boilers.

If approved for marketing, USSTC expects manufacture and sales of the modified risk GF Product to replace manufacture and sales of the currently marketed provisional product of the same name and/or the soon to be re-introduced GF Product marketed without a modified risk claim. Any change in total production volume at the facility is expected to be nominal and have little or no increased waste generated. Because energy use is expected to directly correlate to changes in production volume, it is estimated that total energy use at the facility will not increase due to manufacturing the GF Product.

The USSTC manufacturing facility does not produce its own energy (power), does not generate electricity, does not use renewable energy/fuels, and does not use alternative green energy resources. All fuel-burning equipment utilizes clean, natural gas and is covered under existing air permits. However, the power supplier to the manufacturing facility is Nashville Electric Service (NES), which purchases electric power from the Tennessee Valley Authority (TVA). One of TVA's environmental objectives is to stop the growth in the volume of emissions and reduce the rate of carbon emissions by 2020 while still providing reliable, affordable energy. TVA has been decommissioning some of its oldest, least-efficient coal-fired units and adding cleaner forms of power generation. These include more clean-burning natural gas units.

Approximately (b) of the raw material used to manufacture the GF Product is tobacco. USSTC utilizes a direct contracting program, Tobacco Leaders Program (TLP), to encourage consistent high-quality tobacco, innovation, efficiency and open communications with tobacco growers. Additionally, in 2012, USSTC endorsed the U.S. Tobacco Good Agricultural Practices (GAP) handbook that promotes agricultural practices that produce quality crops while protecting the environment and supporting farm laborer rights.

Altria's Supplier Code of Conduct addresses compliance with applicable laws, regulations, and standards, including environmental compliance. In addition, long-term supply contracts with tobacco growers and material suppliers, and the purchase order terms and conditions applicable to suppliers without long-term contracts,

contain provisions that require compliance with applicable laws and regulations. USSTC conduct supplier reviews and regularly monitor tobacco growers and suppliers through assessments to ensure they are accountable for their actions. For more information on supply chain management and responsibility, refer to the company's website and the company's Corporate Responsibility Progress Report http://www.altria.com/Interactive/2016CRReport/index.html).

8. MITIGATION MEASURES

ERM herewith provides the basis for a Finding of No Significant Impact for this environmental assessment of the GF Product due to *de minimis* exposure and no significant increase in environmental impact from the proposed action. As such, no additional environmental protection measures, mitigation measures or alternative actions are necessary to address environmental impacts due to the GF Product.

9. ALTERNATIVES TO THE PROPOSED ACTION

Alternative A (No-action alternative): The no-action alternative is to not allow the marketing of the GF Product in the United States as a modified risk tobacco product.

Alternative B (Proposed action): Issuing a Finding of No Significant Impact due to the proposed action of issuing an order authorizing the GF Product to be marketed in the United States as a modified risk tobacco product.

10. LIST OF PREPARERS

In accordance with 40 CFR 1502.17, this section includes a list of names and qualifications (including position/title, education, experience, and expertise) of individuals who were primarily responsible for preparing and reviewing this environmental assessment. No Agencies or persons besides subject matter experts within ERM and ALCS were consulted. However, feedback from FDA on prior submissions and examples of Environmental Assessments posted by FDA were considered in developing this assessment.

Daniel Goldstein, PE, CPEA, *Partner-in-Charge*, ERM, Inc.

Education: M.S. in Chemical Engineering; MBA

Years of Experience: > 25 years in environmental consulting

Qualifications: Environmental assessments and audits, environmental risk assessment, environmental compliance & assurance activities, air quality, and product stewardship and sustainability.

Kathleen Sellers, PE, *Technical Director*, ERM, Inc.

Education: B.S. in Chemistry; M.S. in Environmental Engineering

Years of Experience: > 25 years in environmental management and regulatory activities

Qualifications: Environmental assessments, environmental risk assessment, environmental compliance & assurance activities, life cycle assessment, engineering design of pollution control measures, and product stewardship and sustainability.

Quentin Cannatella, *Senior Project Manager*, ERM, Inc.

Education: B.S. in Mechanical Engineering

Years of Experience: 24 years in environmental management and regulatory activities

Qualifications: Environmental assessments and audits, environmental risk assessment, environmental compliance & assurance activities, air quality, Toxic Substances Control Act (TSCA) compliance, and product stewardship and sustainability.

Kristen Schulz, *Senior Project Manager*, ERM, Inc.

Education: B.S. in Environmental, Safety and Occupational Health Management; M.S. in Environmental and Industrial Hygiene

Years of Experience: 12 years in global product regulatory affairs

Qualifications: Environmental assessments, chemical control regulation, hazard communication, downstream product regulation, and product stewardship and sustainability.

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12. APPENDICES

As a final measure of substantiation for the minimal environmental risk associated with the use of the GF Product, ERM has included the following Appendices.

Data summaries provide a brief summation of the available physico-chemical properties, toxicology and ecotoxicology data for the product ingredients and are included in Confidential Appendix 1. Data contained in the attached summaries are from publicly available compilations from sources including the USEPA and the European Chemicals Agency (ECHA). Specific references are noted as appropriate.

Additional information regarding the regulatory status of product ingredients are provided in Confidential Appendix 2 to further substantiate FDA's acceptance of these substances from an environmental perspective.

CERTIFICATION

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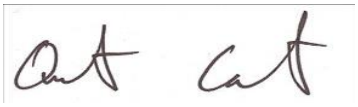
Partner-in-Charge
ERM, Inc.



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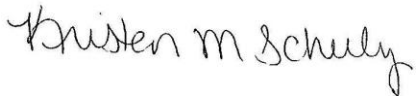

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