



**Environmental Assessment for the
ZYN Wintergreen 3 mg Proposed Modified Risk Tobacco Product**

Environmental Assessment for a Marketing Authorization for New Non-Combusted, Smoke-free, Spit-free and Tobacco leaf-free, Nicotine Pouch that contains nicotine derived from tobacco, and is produced by Swedish Match

Prepared by Swedish Match USA, Inc.

February 15, 2024

This environmental assessment has been prepared in accordance with 21 C.F.R. §25.40, the Food and Drug Administration (“FDA” or “Agency”)’s regulations implementing the National Environmental Policy Act of 1969 (“NEPA”), as part of a submission under Section 911 of the Food, Drug, and Cosmetic Act (“FD&C Act”). The Agency action under consideration is the modified risk tobacco product application (“MRTPA”) for the proposed ZYN modified risk tobacco product manufactured by Swedish Match.

SUMMARY

Swedish Match's proposed ZYN modified risk tobacco product ("MRTP") is a tobacco leaf-free nicotine pouch that provides a smoke-free and spit-free experience. The MRTP contains nicotine that is derived from tobacco leaves, as well as certain additional ingredients. ZYN, generally, is produced in two Swedish Match factories. The principal manufacturing facility is in the United States in Owensboro, Kentucky. A supplementary, manufacturing facility is in Kungälv, Sweden. Except for a few chemically identical single chemical substances, the sources of all components are the same regardless of manufacturing location. Thus, the finished products are the same, regardless of manufacturing location (i.e., have the same per weight composition, design features, and all other features). Except for a difference in manufacturing location, and the suppliers of two chemically identical additives, the finished products are otherwise identical.

This environmental assessment has been prepared in accordance with 21 C.F.R. §25.40, the Food and Drug Administration ("FDA" or "Agency")'s regulations implementing the National Environmental Policy Act of 1969 ("NEPA"), as part of a submission under Section 911 of the Food, Drug, and Cosmetic Act ("FD&C Act"). The Agency action under consideration is the MRTPA for the proposed MRTP manufactured by Swedish Match. We wish to commercially distribute the MRTP in interstate commerce in the U.S. As detailed below, there is no significant¹ environmental impact associated with FDA's potential decision to issue an order under section 911 of the FD&C Act in this instance. Additionally, a net positive benefit from the introduction of the MRTP into the U.S. market may exist in that manufacturing the MRTP may result in a decrease of highly wasteful combustible products, e.g., cigarettes.

¹ Swedish Match uses the term "significantly" as defined at 40 CFR 1508.27.

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7.1 ENVIRONMENTAL ASSESSMENT

7.1.1 Applicant and Manufacturer Information

Applicant/Submitter Name:	Gerard J. Roerty, Jr., Esq. Vice President, General Counsel & Secretary Swedish Match USA, Inc.
Applicant/Submitter Address:	Two James Center 1021 East Cary Street Suite 1600 Richmond, VA 23219
Primary Product Manufacturing Name and Address	Swedish Match North America LLC 1121 Industrial Drive Owensboro, KY 42301
Secondary Product Manufacturing Name and Address	Swedish Match North Europe Rollsbovagen 45 SE-441 17 Kungälv, Sweden

7.1.2 Product Information

7.1.2.1 Identification of the Product

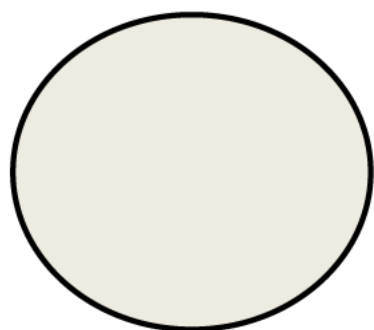
New Product Trade Name and Strength, Applicant Unique ID number:

New Product Trade Name and Strength	SM Unique ID no. Stock-Keeping Unit ("SKU"): ID#
ZYN Wintergreen 3 mg	(b) (4)

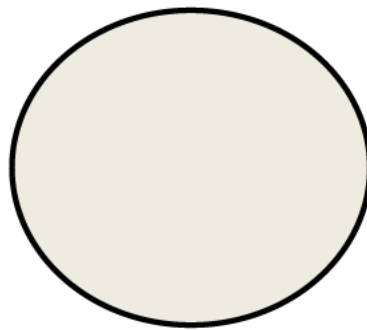
7.1.2.2 Description of the Product

The proposed modified risk tobacco product is categorized as an "other, tobacco product": nicotine pouch. Its sub-category is defined as "other": Oral Tobacco-Derived Nicotine (OTDN). The proposed MRTP is a portioned smoke-free tobacco product intended for oral use, with an appearance like that of portioned moist snuff and portioned snus products, that is intended for adult tobacco consumers. The proposed modified risk tobacco product's application has been submitted under the MRTPA pathway in compliance with section 911 of the Federal Food, Drug and Cosmetic Act, as amended by the Family Smoking Prevention and Tobacco Control Act.

The pouch measures 28 mm in length and 14 mm in width. It is a 0.40-gram tobacco leaf-free sealed pouch. The final granulate is portioned into pouches that have 3 mg of nicotine per pouch. The pouches are packaged in a cylindrical polypropylene can. The net can weight is 6 g. The can is filled with 15 pouches:



One (1) lid



One (1) base



Fifteen (15) pouches

The pouches are then packaged in a polypropylene primary container. The primary container is shrink wrapped into five can rolls (i.e., secondary container). The shrink-wrapped rolls are packed into a corrugated cardboard case (i.e., tertiary container) containing 18 rolls per case, for a total of 90 cans per case.

The primary packaging of the proposed MRTTP is a child-resistant container and consists of a 21 Code of Federal Regulations (CFR) 177.1520(c)-compliant polypropylene can (container) and lid. The container and the lid of the new “other tobacco product” product is composed of recyclable polypropylene resin with the resin identification code “5” contained within the Universal Recycling Symbol stamped into each respective component:



(Image not to scale)

The packaging material description, ingredients, dimensions, and regulatory authority are found in the Confidential Appendix to the Environmental Assessment (see [Table 3](#) in the Confidential Appendix to the Environmental Assessment).

In order to quantitatively assess the environmental impact of manufacturing, use, and disposal from use of the proposed MRTP, Swedish Match is providing forecasted year one (2024) and year five (2028) data of market volume projections for the proposed MRTP (see [Table 1](#) in the Confidential Appendix to the Environmental Assessment).

7.1.3 Description of Proposed Action

7.1.3.1 Purpose of Need for Action

The proposed action, requested by Swedish Match, is for FDA to issue a marketing order finding the proposed MRTP reduces harm or the risk of tobacco-related disease associated with commercially marketed tobacco products, under the provisions of section 911 of the Federal Food, Drug, and Cosmetic Act. We wish to commercially distribute the proposed MRTP in interstate commerce in the U.S. market.

7.1.3.2 Location of Use

The proposed MRTP will be manufactured at Swedish Match's facility in Owensboro, KY, with support from Swedish Match's facility in Kungälv, Sweden. The proposed MRTP will be sold to adult consumers at a variety of retail establishments and consumed primarily in homes and automobiles. The proposed MRTP will be widely distributed, and use of the product will correspond with national population density, as do tobacco products from other categories, including those of "other tobacco products" and smokeless tobacco (e.g., "moist snuff tobacco" or "snus").

7.1.3.3 Location of Disposal

Used tobacco products and empty packaging, including those associated with the proposed MRTP, are typically disposed of in community solid waste management systems, which may include landfills, incineration, and recycling. This disposal by the end user would be in the same manner as other products contained in similar recyclable packaging, including the recyclable packaging used in smokeless tobacco products manufactured in the same facility. According to the U.S. Environmental Protection Agency,² regarding municipal solid waste in the United States, about 52.3% of municipal solid waste was land disposed, 12.7% was combusted, and 35.0% was recovered (recycled and composted).

7.1.3.4 Alternative to the Proposed Action

An alternative to the proposed action would be if FDA does not issue a marketing order. The environmental impact of this action would not change the existing condition. The no-action

² See https://www.epa.gov/sites/default/files/2021-01/documents/2018_ff_fact_sheet_dec_2020_fnl_508.pdf

alternative would not change trends in nationwide use of combusted, filtered cigarettes. Thus, under the no-action alternative, no changes are expected in trends in the overall level of municipal solid waste generated from cigarette butts and cigarette packaging disposal in the United States. The environmental effects of cigarette butt litter, including the leaching of toxic substances into aquatic environments and soil would remain unchanged in the no-action alternative. These effects were summarized as follows in Novotny et al. (2015):³

Cigarette butts are the most commonly discarded piece of waste globally and are the most frequent item of litter picked up on beaches and water edges worldwide . . . The non-biodegradable cellulose acetate filter attached to most manufactured cigarettes is the main component of cigarette butt waste . . . Hazardous substances have been identified in cigarette butts – including arsenic, lead, nicotine and ethyl phenol. These substances are leached from discarded butts into aquatic environments and soil.

Littered cigarette butts also are a notable worldwide environmental concern. For example, it has been estimated that 65 percent of cigarettes disposed of in five types of non-residential public locations (recreational sites, bars/restaurants, retail stores, medical/hospital facilities, and city center) were littered (e.g., see Action Research, 2009).⁴ Under the no-action alternative, no changes are expected in the overall level of cigarette butt litter in the United States.

7.1.4 Environmental Issues

7.1.4.1 Introduction of Products into the Environment

The proposed modified risk product is not expected to raise any new or additional environmental concerns relative to other tobacco product categories currently sold on the U.S. market. The proposed MRTP, a portioned tobacco product, reasonably would not be introducing materials or ingredients that are new and novel relative to materials and ingredients currently sold in the U.S. market. The proposed MRTP is intended to offer alternatives to prevalent and wasteful tobacco product categories (e.g., combustible cigarettes). Swedish Match expects certain tobacco product users to cease using – or reduce the amount they use of – tobacco products from other categories, including combustible cigarettes, snus, moist snuff tobacco, or chewing tobacco. This action may result in a corresponding reduction of the materials associated with the production, manufacture,

³ Novotny et al. (2015): The environmental and health impacts of tobacco agriculture, cigarette manufacture and consumption. Bulletin of the World Health Organization 93 (12): 877-880.

⁴ Action Research (2009): Littering Behavior in America: Results of a National Study. Keep America beautiful. See www.kab.org/

transport, and disposal after use of these tobacco product categories. Continued declines in other statutory smokeless tobacco products produced by Swedish Match, as well as the historical national tobacco product use declines, should also mitigate any increases, resulting in a net positive for public health.

7.1.4.1.1 As a Result of Manufacture and Transport

The proposed modified risk product is manufactured at the Owensboro, KY, facility, with support from Swedish Match's facility in Kungälv, Sweden. Each respective address is listed in Section I of this Report. This facility has historically manufactured statutory smokeless tobacco products (e.g., chewing tobacco, moist snuff tobacco, plug tobacco). Production of the aforementioned products will not be affected by the manufacturing of the proposed MRTP at the Owensboro facility. The Owensboro facility will manufacture the proposed MRTP and continue to manufacture the already existing statutory tobacco products.

The Owensboro facility is located in a highly industrialized portion of Owensboro, KY, in the northwestern part of the city. Land use is decidedly industrial and urban around the facility. Beyond the city lie rural areas to the west, south, and east, and the Ohio River to the north. More rural areas exist beyond the river, into southern Indiana. Swedish Match's Kungälv facility is located in a highly industrialized portion of Sweden. Land use is decidedly industrial and urban around the facility. Environmental laws are regulated by EU and Swedish national laws. Sweden has one of the world's most ambitious programs to improve environmental conditions and there is a comprehensive set of national laws and regulations with which companies must comply.

The Owensboro and Kungälv manufacturing locations are in compliance with all environmental laws today, and there are no risks associated with the manufacture of ZYN to critical habitats, species, or plants. To Swedish Match's knowledge, no critical habitat is affected by the materials or ingredients used to manufacture the proposed MRTP, or from the production of the proposed MRTP. The plant-based materials or ingredients used in the proposed MRTP are purchased from agricultural commodities on the existing market and other materials or ingredients are synthetic, artificial, or inorganic. No rare or protected flora or fauna are used as materials or ingredients in the proposed MRTP. There are no anticipated adverse effects on any endangered species, or the critical habitat of the species identified under CITES ("Convention on International Trade on Endangered Species") and ESA ("Endangered Species Act") due to (i) the materials used to manufacture the product; (ii) the manufacturing process itself; (iii) the disposal of the product. Subsections B.1 – B.5 discuss these topics in more detail.

Compliance of environmental laws is audited by local government agencies. Swedish Match's production site is classified as a manufacturing establishment. The Owensboro production facility producing the proposed MRTP is certified according to ISO 9001: 2015 (Quality

Management System) by (b) (4) and ISO 14001: 2015 (Environmental Management System) by (b) (4) .

Manufacturing the proposed modified risk products resulted in an expansion of the Owensboro manufacturing facility. No expansion of the Kungälv manufacturing facility regarding the products for the U.S. market has occurred or is planned. The portion of the Owensboro manufacturing facility dedicated to producing the products is a combination of remodeled internal space and new external facilities. The minor expansion for the Owensboro facility includes the following:

- 19,200 square foot internal packaging area remodeled within the existing facility;
- 36,000 square foot new process expansion;
- 2,100 square foot new ethanol storage building.

The proposed modified risk tobacco product's manufacturing process will include appropriate pollution control measures such as dust control for powder materials and vapor control for liquid materials. Additional controls were not necessary for the Kungälv manufacturing facility.

The construction site on the Swedish Match Owensboro campus was not occupied by wildlife. The Owensboro facility is located in an area of significant industrial development and not within or near critical habitat for any endangered or threatened species. Regarding the Owensboro facility, a completed waste analysis identified several areas in which additional resources would be needed. New additional environmental controls were required and implemented in the Owensboro manufacturing facility. These controls were the result of the production of the products, generally, and to handle additional ethanol and nicotine waste, specifically.

Ethanol:

(b) (4)

Nicotine Waste:

(b) (4)

The volume and nature of the waste generated from manufacturing the proposed MRTTP will not require new or expanded disposal/treatment/recycle capacity or resources, such as waste treatment or recycle facilities. The manufacturing facility is registered as a Large Quantity Generator (LQG) of hazardous waste (EPA Generator ID: KYR000004788). Nicotine from the proposed MRTTP would be managed as an acute hazardous waste under the Resource Conservation and Recovery Act (RCRA). This hazardous waste will be transported by a licensed hazardous waste transporter and treated at a commercial Treatment, Storage, & Disposal (TSD) facility. Any nicotine will be considered hazardous. (b) (4)

(b) (4) A third-party contractor will be responsible for disposal of nicotine waste, (b) (4) Nicotine waste will be handled in a controlled method. (b) (4)

(b) (4)

⁵ In Kungälv, the nicotine waste is considered hazardous and is disposed of per local regulations. (b) (4)

(b) (4)

All waste streams would be accumulated locally then shipped to a certified incinerator for destruction. A third-party contractor would be responsible for disposal of nicotine waste and

(b) (4)

Nicotine waste would be handled in a controlled method, including the application of shipping labels, verification of containers for shipping, and completing the manifest and providing copies for later reporting.

No significant environmental impacts are anticipated as a result of manufacturing the proposed MRTP. The proposed MRTP is expected to generate a relatively small amount of hazardous waste per year, representing less than 0.01% of the total hazardous waste generated each year in the U.S. and less than 0.1% of the total hazardous waste treated by incineration or used (combusted) for energy recovery in the U.S. Thus, the contribution of the proposed MRTP to the total hazardous waste generated and treated by incineration (combustion) annually in the United States is miniscule.

Swedish Match intends for the proposed MRTP to compete with tobacco products currently on the market (e.g., cigarettes). Accordingly, following receipt of a marketing order, Swedish Match expects certain smokers and users of these tobacco product categories to transition to the proposed MRTP or substitute their products out for the proposed MRTP. Additionally, the manufacturing of the proposed MRTP would not impede the continued decline in forecasted sales volumes in other statutory smokeless products manufactured at the Owensboro facility. These declines are expected to offset the impact, if any, of the previous expansion of the facility, and the production of the proposed MRTP, resulting in no significant environmental impact.

Revised air emissions and water discharge permits were not required as a result of manufacturing of the proposed MRTP.

Air Quality Permit Revisions: Swedish Match requested revised air quality permitting as a result of manufacturing the ZYN product line, generally. Pollution controls were implemented at the time of process commissioning. Swedish Match received the revised Air Quality Permit from the state of Kentucky, on 2/25/2018 (permit # V-14-019 R1).

Wastewater Discharge Permit Revisions: Swedish Match has been working with the local Regional Water Resource Agency (Daviess Co, KY) and is in compliance with all applicable regulations. Manufacturing the ZYN product line, generally, resulted in an expansion of existing

waste/sanitary water discharge. Additionally, manufacturing the ZYN product line, generally, resulted in an increase in changes to water discharge flow rates. RWRA issued an additional water permit for building expansion. The facility added additional sinks, floor drains, and toilets to accommodate increased facility discharges to the sewer system. This additional effluent flow is in compliance with all applicable regulations. The proposed MRTP would not be expected to require additional water discharge changes or the revised permitting.

Storm Water Permit Revisions: No revisions were necessary as a result of the expansion to the facility. No revisions will be necessary as a result of manufacturing the proposed MRTP.

U.S. Environmental Protection Agency's Toxic Release Inventory (TRI): The Owensboro facility satisfies TRI reporting criteria. The facility processes U.S. Environmental Protection Agency's Toxic Release Inventory (TRI) listing chemicals in quantities above the reporting threshold. Manufacturing the ZYN product line, generally, triggered TRI reporting.

Executive Order 12898 requires federal agencies to identify and address, as appropriate, disproportionately high and adverse human health or environmental effects on minority populations and low-income populations. No disproportionate impacts to minority or low-income populations would occur due to the manufacture of the proposed MRTP.

Manufacturing of the proposed MRTP is not expected to result in new or increased compounds being emitted at the Owensboro facility. Manufacturing is also not expected to result in disproportionate multiple and cumulative exposures to environmental hazards for minority or low-income populations. EPA's Enforcement and Compliance History Online ("ECHO") database summarizes the demographic information regarding the community in a three-mile radius surrounding the Owensboro facility. Based on the 2010 US Census and American Community Service data, minorities make up 16% of the population and the facility is not located in proximity to Indian Country.⁶ White residents make up approximately 86% of the population near the facility.⁷ Accordingly, manufacture, disposal, and use of the proposed MRTP would not be expected to affect subsistence patterns of consumption of fish, wildlife, and vegetation for minority or low-income populations (e.g., Native American/Alaska Native tribes). Further, no disproportionate disruption of the community structure or patterns of living of low income or minority populations would be expected as a result of manufacturing the proposed MRTP.

⁶ <https://echo.epa.gov/detailed-facility-report?fid=110013765559>

⁷ Per the definition of "minority population" in Executive Order 12898, minority populations do not exceed 50% of the affected area and minority populations are not meaningfully greater than the minority population percentage in the general populace. Reasonably, manufacturing, use, and disposal of the new product would not be expected to disproportionately affect these Environmental Justice populations.

Manufacturing the proposed MRTTP should not result in new or increased compounds being emitted from the manufacturing of the proposed MRTTP at the Owensboro facility. Release of new chemicals (i.e., (b) (4)) into the environment due to manufacturing the proposed MRTTP is not anticipated due to the proposed action. Additives used in the manufacture of the proposed MRTTP include ones that have been historically used in the facility for the manufacture of tobacco products. Many of the ingredient materials of the proposed MRTTP are used in other tobacco product categories (e.g., moist snuff tobacco) and the proposed MRTTP contains nicotine derived from tobacco leaves. No increases in the quantity of certain compounds (e.g., nicotine waste, which would be disposed of in a controlled manner) are anticipated given ongoing declines in manufacture of other smokeless tobacco products produced in Swedish Match facilities. Users of the proposed MRTTP, which is intended as a spit-free smokeless tobacco product, would not be expected to expectorate the proposed MRTTP into the environment. Any urine and bowel excretions would be processed through local municipal waste systems. Reasonably, the ability of these municipal waste systems to process these historically common ingredients (e.g., commonly found in smokeless tobacco products and foodstuffs) would present a low level of ecotoxic concern.

Sales and Marketing information is used to quantitatively assess the environmental impact of manufacturing, use and disposal. The proposed MRTTP's forecasted market volume for the first and fifth year of marketing are supplied in the Confidential Appendix to the Environmental Assessment. (b) (4)

(b) (4)

Moreover, over the past few decades, the tobacco market as a whole, both pre-and-post-Covid-19 pandemic, has been contracting (rather than expanding) in the U.S. (b) (4)

(b) (4)

No additional resources for manufacturing waste disposal, such as onsite solid or hazardous waste accumulation capacity, new or expanded landfills, recycling centers, or other waste disposal or handling capacity would be needed. In the time period covered by this EA, waste (in metric tons) generated from the production of all existing statutory and deemed new products

manufactured at the Owensboro facility is not projected to significantly increase from 2024 - 2028.

Table 1: Forecasted Waste by the Owensboro Manufacturing Facility (2024 – 2028)

Year	2024	2025	2026	2027	2028
Waste (metric tons)	(b) (4)				

This forecast takes into account:

(b) (4)

The Owensboro facility does not produce its own energy and does not generate electricity.

(b) (4)

. The manufacturing of the proposed MRTP would not require additional resources for manufacturing waste disposal, such as onsite solid or hazardous waste accumulation capacity, new or expanded landfills, recycling centers, or other waste disposal or handling capacity.

Energy use for the time frame covered by this environmental assessment would not be expected to significantly increase due to production of the proposed MRTP. Projections for the statutory and deemed products made by the Owensboro facility are presented in the following table:

Table 2: Forecasted Energy Resources by the Owensboro Manufacturing Facility (2024 – 2028)

Type (MW-h)	2024	2025	2026	2027	2028
Gas	(b) (4)				

Electricity	(b) (4)
Total	

This forecast takes into account:

(b) (4)

None of the environmental effects of manufacturing or transport of the proposed MRTP are expected to result in environmental effects that would significantly⁸ affect the quality of the human environment.

7.1.4.1.2 As a Result of Use

The proposed MRTP will be used similarly to other portioned smokeless tobacco products (i.e., portioned snus). No environmental effects of disposal of used product and “spit” generated during product use are anticipated. Contents of the pouch are gradually extracted during use, which should not result in expectorant. The pouch will then be disposed of in trash receptacles. The use of the proposed MRTP would result in the direct introduction of little or no change in the complexity of the ingredients nor any of the other ingredients into the environment because these ingredients are consumed during use.

⁸ Swedish Match uses the term “significantly” as defined at 40 CFR 1508.27.

The proposed MRTP's characteristics are similar to other portioned smokeless tobacco products in the market. Thus, consumer perceptions of harm and addictiveness should not be affected. Further, there is a high likelihood that certain tobacco product users will cease using – or reduce the amount they use of – cigarettes, moist snuff, or chewing tobacco. This likelihood would result in a corresponding effect on the materials associated with the production, manufacture, transport, and disposal after use of these tobacco products.

7.1.4.1.3 As a Result of Disposal

The proposed MRTP and any associated waste will be disposed of by the end user in the same manner as similarly marketed portioned tobacco products or tobacco product categories (e.g., moist snuff, snus). The proposed MRTP's container is not intended for repeat use. Disposal by the ultimate consumer of plastic cans, used product, and any other waste material will be by conventional rubbish disposal and, therefore, primarily by sanitary landfill or incineration. There is a high likelihood that certain tobacco product users will cease using – or reduce the amount they use of – cigarettes, moist snuff, or chewing tobacco. This likelihood would result in a corresponding effect on the materials associated with the production, manufacture, transport, and disposal after use of this tobacco product. The proposed action may result in an increased product sale. However, this increase is expected to be offset by the reduction in the use of other more wasteful tobacco products (e.g., cigarettes) as adult consumers switch completely to the proposed MRTP or substitute their product with the proposed MRTP. Further, each individual ZYN SKU⁹ currently sold on the U.S. market represents (b) (4) of the 131.43 million pounds of smokeless tobacco sold in the U.S., per the 2016 FTC Smokeless Tobacco Report. The proposed MRTP would be expected to continue this trend: each proposed MRTP SKU would also represent (b) (4) of smokeless tobacco sold in the U.S. Accordingly, the proposed MRTP would not significantly¹⁰ alter the emissions from properly operating municipal solid waste combustors. As a result, those municipal solid waste incinerators will continue to operate in compliance with applicable laws and regulations such as 40 C.F.R. Part 60, as well as relevant state and local laws.

⁹ In this context, Swedish Match refers to the ZYN “flagship” SKUs.

¹⁰ Swedish Match uses the term “significantly” as defined at 40 CFR 1508.27.

7.1.4.2 Fate of Products Released into the Environment

The proposed MRTP is expected to enter the environment in extremely small, negligible,¹¹ quantities, if at all, as a result of the use and disposal of the product. (b) (4)

Swedish Match does not anticipate that the fate of any materials from this product would be any different from other smokeless tobacco products commercially available. (b) (4)

, no meaningful impacts are expected on air, water, and land resources or on the organisms that inhabit these media as a result of the proposed action. Consumers would dispose of the proposed MRTP's used pouch and packaging materials in appropriate waste receptacles, including recycling centers, waste cans, or landfills. Disposal of excreted materials occurs through the sewage discharge of human solid waste.

Swedish Match assessed any potential impact from disposal following use of the proposed MRTP through a review of the available peer-reviewed research (via a 2/15/2024 PubMed search and Google Scholar search; citations discussed in more detail below). To our knowledge, there is no peer-reviewed research specifically assessing the environmental impact of the disposal after use of "other tobacco products," like the proposed MRTP, or smokeless tobacco, generally. Further, the available research assessing the external environmental impact of tobacco products has focused on combustible tobacco products, while not addressing any potential impact from "other tobacco products," or smokeless tobacco products, generally (e.g., see Novotny and Zhao, 1999 and Novotny and Slaughter, 2014). The waste from these prominent tobacco product categories are "butts, packages, cellophane wrappers, and cartons" discarded either in waste disposal or in the natural environment itself (Novotny and Zhao, 1999: 75 – 76). None of the aforementioned authors extrapolated from these results and applied them to the context of "other tobacco products," or non-combusted products, like smokeless tobacco, generally. Accordingly, Swedish Match does not find any correlation between the post-consumer waste of the proposed MRTP with the existing tobacco products assessed by the available literature (Novotny and Slaughter, 2014: 208). The proposed MRTP's manufacture, transport, use and disposal should be viewed with a low level of concern, as it is not expected to contribute to any significant new or additional environmental impacts. Nor is it likely to impact the environment in the manner of other waste materials connected to the use and disposal of other, far more prevalent, tobacco product categories. The type of significant

¹¹ EPA defines negligible as <5000 tons of municipal solid waste (see Table 1) in Advancing Sustainable Materials Management: 2017 Fact Sheet found at https://www.epa.gov/sites/production/files/2019-11/documents/2017_facts_and_figures_fact_sheet_final.pdf, accessed July 29, 2020. The new product represents approximately less than 50% of EPA's threshold for negligible tons of solid waste.

environmental impact outlined in the available literature would not be expected to occur as a result of the introduction of the proposed MRTP. Nor is it likely to impact the environment in the manner of other waste materials connected to the use and disposal of other, far more prevalent, tobacco product categories. The type of significant environmental impact outlined in the available literature would not be expected to occur as a result of the introduction of the proposed MRTP.

Section A.1 - Aquatic Exposure: The aquatic exposure approach taken in this environmental assessment assumes that the constituents of the proposed MRTP are consumed by the adult consumer and released to the aquatic environment via human excretion as a result of product use. Nicotine passing through the body and excreted into home septic tanks, if any, would present minimal ecological hazards and is considered readily biodegradable. Reasonably, the ability of these municipal wastewater systems and home septic systems to process these historically common ingredients (e.g., commonly found in smokeless tobacco products and foodstuffs), and treat/degrade any chemical substances, would present a low level of ecotoxicological concern. Nicotine residue present in the used and disposed product container, if any, would also present minimal ecological hazards and is also considered readily biodegradable.

The introduction of the substances in the proposed MRTP to the aquatic environment is expected to present minimal ecological toxicity hazards and negligible contamination of the environment with toxic compounds. No significant impacts to the aquatic environment are expected from the use of the proposed MRTP. In fact, continued decline in historical national tobacco product use (and thus, continued in nicotine), as well as the potential for switching from cigarettes, should also mitigate any potential increases in the use of the proposed MRTP, resulting in a net positive for the environment and public health.

Section A.2 - Terrestrial Exposure: This subsection addresses the terrestrial assessment of ingredients consumed during use of the proposed MRTP or from improper use or littering. No significant impacts to the terrestrial environment are expected from the use of the proposed MRTP. When the pouch of the proposed MRTP has been consumed by the adult consumer, a small portion of the contents of the pouch may remain. Much of the contents of the pouch are consumed during use and will gradually be extracted from the pouch during consumption and should not result in expectorant.

The introduction of ingredients into the environment from littering of the proposed MRTP, if any, is expected to be negligible. The proposed MRTP's container is expected to be recycled or disposed of as household waste consistent with current trends in the U.S. for similar types of plastic, recyclable containers. Improper disposal or littering of the container is expected to be

minimal due to its repeated use before disposal (as compared to single-use cigarette butts or disposable ENDS products, as well as other single-use “convenience products” such as paper, napkins/tissue, beverage containers, bottle caps, fast food and candy packaging), resulting in a lower tendency or motivation to litter by the adult consumers. The use of the proposed MRTP would result in the direct introduction of little or no change in the ingredients to the terrestrial environment and the residual amount of ingredients, including nicotine, would have minimal impacts on terrestrial ecosystems. These ingredients are fillers, flavors, pH adjustors, and processing aids and sweeteners, which are historically common ingredients (e.g., commonly found in smokeless tobacco products and foodstuffs). The potential for biological, chemical, or physical stressors to affect ecosystems is of low level of concern for these ingredients given their extreme commonality for use in foodstuffs and their generally recognized as safe (“GRAS”) status in consumer goods. Nicotine exposure from the proposed MRTP is also not expected to be more significant than that of competing moist smokeless tobacco pouch products (e.g., moist snuff). The decline in historical national tobacco product use should also mitigate any increases in the use of the proposed MRTP, resulting in a net positive for the environment and public health.

Based on the above discussion, the no-action alternative is assumed to result in no change to the current exposure of aquatic and terrestrial environments to leachate from littered combustible cigarette butts and other categories of statutory tobacco products including smokeless tobacco products, and no change in exposure of aquatic and terrestrial environments to excreted substances (urinary biomarkers from treated municipal wastewater to surface waters). Overall, the proposed action is expected to result in similar impacts to the aquatic and terrestrial environment as with the no action alternative, which is expected to be minor-to-negligible impacts.

9.1.4.3 Environmental Effect of Released Products

As Swedish Match mentioned in prior sections, manufacturing the proposed MRTP is not expected to affect any endangered species or result in the adverse modification of the habitat of any such species. To Swedish Match’s knowledge, no critical habitat is adversely affected by the materials or ingredients used to manufacture the proposed MRTP or from the production of the proposed MRTP. The plant-based materials or ingredients used in the proposed MRTP are purchased from agricultural commodities on the existing market and other materials or ingredients are synthetic, artificial, or inorganic. No rare or protected flora or fauna are used as materials or ingredients in the proposed MRTP. Only extremely small quantities of the ingredients of the proposed MRTP, if any, are expected to be released into the environment through leaching, and this quantity is not expected to be any different than currently marketed tobacco products. Consequently, no adverse effects on organisms in the environment are

expected. We discuss the effects, if any, the use and disposal of the proposed MRTP would have on wildlife, critical habitat, endangered and threatened species, natural and cultural resources, environmental justice, and socioeconomic impact in the subsequent paragraphs.

B.1 - Wildlife: the expansion to the Owensboro facility was conducted on the existing Swedish Match campus. This campus was not occupied by wildlife. The proposed MRTP will be commercially distributed and used by adult consumers in the same manner as other smokeless tobacco products (e.g., “moist snuff tobacco” or “snus”). No endangered species or critical habitat will be affected from materials or ingredients used to manufacture the proposed MRTP. Also, Swedish Match is not aware that any materials or ingredients to be used in the proposed MRTP are manufactured using any of the endangered or threatened species listed by either the U.S. Fish and Wildlife Service’s (US FWS) Endangered Species Act (ESA) or the Convention on International Trade in Endangered Species of Wild Flora and Fauna (CITES).¹² The plant-based materials or ingredients used in the proposed MRTP are purchased from agricultural commodities on the existing market and other materials or ingredients are synthetic, artificial, or inorganic. No rare or protected flora or fauna are used as materials or ingredients in the proposed MRTP.

B.2 - Critical Habitat: a review was performed in July 2023 to determine the location of any critical habitats of threatened or endangered species in proximity to the Owensboro manufacturing facility. The Owensboro facility is not within, or in close proximity to, a critical habitat of a threatened or endangered species. This conclusion is based on a review of critical habitat maps¹³ created by the U.S. FWS, which show the closest critical habitat within the geographical region to be 40 miles northeast of the manufacturing facility. The U.S. FWS’s list of species by county¹⁴ shows that Daviess County¹⁵ may have two threatened species (Mammal – Northern Long-Eared Bat (*Myotis septentrionalis*) and Clam – Rabbitsfoot (*Quadrula cylindrical cylindrical*)) and ten endangered species (Mammals – Gray bat (*Myotis grisescens*) and Indiana bat (*Myotis sodalis*) and Clams – Fat pocketbook (*Potamilus capax*), Clubshell (*Pleurobema clava*), Ring pink (mussel) (*Obovaria retusa*), Fanshell (*Cyprogenia stegaria*), Pink mucket (pearlymussel) (*Lampsilis abrupta*), Rough pigtoe (*Pleurobema plenum*), Snuffbox mussel (*Epioblasma triquetra*), and Orangefoot pimpleback (pearlymussel) (*Plethobasus*

¹² The Endangered Species Act (ESA) and the Convention on International Trade in Endangered Species of Wild Flora and Fauna (CITES) are referenced within FDA regulations 21 CFR §25.21 Extraordinary Circumstances in regards to “extraordinary circumstances” that would “significantly” affect endangered/threatened species or critical habitats that would prevent a product from having a Categorical Exclusion.

¹³ U.S. FWS critical habitat maps (<https://databasin.org/maps/new/#datasets=d579d87eb54f4374a77ea53e7ef66449>).

¹⁴ Accessed and reviewed in July 2023.

¹⁵ U.S. FWS’s list of species by county <https://www.fws.gov/endangered/>

cooperianus)).¹⁶ An additional creature, the Least tern (*Sternula antillarum*), was recently delisted from the ESA in 2021 due to its successful population growth.

Swedish Match has no knowledge or expectation that these threatened and endangered species are known to be in the vicinity of the manufacturing facility. Critical habitat has not been designated for the Gray and Northern Long-Eared bats in Daviess County, KY. The only critical habitat in Kentucky for the Indiana bat consists of caves, outside of Daviess County. The recovery plans and species profiles provided by U.S. Fish and Wildlife Service do not identify critical habitats for the Least tern or the aforementioned clams in Daviess County. The clams listed above are classified as endangered, threatened, and “under review.” The clams are primarily found in the Tennessee River and Cumberland region, or the Mississippi River area, in areas outside of Daviess County, and their recovery is focused on those regions. No critical habitat for these clams was identified in Daviess County. The Least tern is primarily found in breeding habitats in the Mississippi and Rio Grande River basins (i.e., Montana to Texas and from eastern New Mexico and Colorado to Indiana and Louisiana) and, accordingly, the recovery plans center around stabilizing adult populations in the Missouri River, Lower Mississippi River, Arkansas River, Red River, and Rio Grande River systems. No critical habitat for the Least tern was identified in Daviess County. The Least tern’s successful population growth has prompted the U.S. Fish and Wildlife agency’s recent delisting of the bird from the ESA due to recovery.¹⁷ Based on the U.S. Fish & Wildlife Service’s recent status review of the aforementioned bat species, the primary threat to these species is White Nose Syndrome, a devastating fungal disease that causes mortality and has resulted in significant reductions in bat populations since its identification in 2006. Other main threats to these species are disturbances to their winter hibernacula (mines and caves) and summer habitat (forests). None of these threats would be anticipated to result from the manufacturing process of the proposed MRTTP. Swedish Match 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 of the proposed MRTTP, the manufacturing process itself, the materials and ingredients used to manufacture the proposed MRTTP, or disposal of the proposed MRTTP by adult consumers.

B.3 - Natural and Cultural Resources: a review was performed in July 2023 to determine the potential impact of a similar proposed action on natural and cultural resources within the vicinity of the manufacturing facility. The natural resources review included determining the

¹⁶ Accessed and reviewed in July 2023.

¹⁷ <https://www.fws.gov/news/ShowNews.cfm?ref=recovery-of-america%E2%80%99s-smallest-tern-prompts-proposal-to-delist-& ID=36484>

likely presence of wetlands, streams, wetland soils, floodplains, local zoning, and coastal zoning. The United States Fish and Wildlife Service's (USFWS) National Wetland Inventory (NWI) Wetlands Mapper application was used to confirm the proximity of the facility to mapped wetlands and streams. The United States Geological Survey's (USGS) National Map application was used to review mapped streams and water bodies on the National Hydrography Dataset (NHD) and their proximity to the manufacturing facility. The Natural Resources Conservation Service's (NRCS) Web Soil Survey application was used to determine the proximity of the facility to mapped hydric soils. Current zoning and land use around the facility was assessed using the local county or city GIS application and Google Earth. ArcGIS was used to identify and document whether the facility was located within a Coastal Zone, as defined by the individual states and territories under the Coastal Zone Management Act of 1972 (CZMA). Generally, the coastal zone includes all territorial U.S. waters and adjacent land areas. Each state designates the area of land and water resources that are included in their coastal zone. Finally, the Federal Emergency Management Agency's (FEMA) Flood Map Service Center was used to identify and document flood hazard data for the facility and adjacent lands. From the site-specific natural resources review of the manufacturing site, it is anticipated that the manufacturing site will have a negligible effect on the natural and physical environment. There are no wetlands identified on the site and intermittent stream(s) on or near the property are not expected to be impacted by the manufacturing operations. Also, there is no expectation the manufacturing site would or lead to changes in soil, land use, zoning, floodplains, streams, or wetlands. Thus, it is anticipated that the manufacturing of the proposed MRTP will not have a significant impact on the natural resources.

Swedish Match also reviewed for the presence of any cultural resources within a certain radius of the Owensboro manufacturing facility. The area around the facility was reviewed in July 2023 for any federally listed properties using the National Park Service - National Register of Historic Places (NRHP) dataset. The NRHP dataset and the state specific cultural databases contain listed cultural resource sites which have been determined to have national or state historical significance were also reviewed. There were no relevant listings on the NRHP, and, therefore, the proposed MRTP will have a low potential to affect previously unidentified significant cultural resources. Additionally, it is anticipated that the manufacturing facility location and manufacturing of the proposed MRTP will not lead to changes in soil, land use, or zoning. Since there is no expansion beyond the current facility boundaries, there will be no effects on floodplains, wetlands, or coastal zones and no zone changes or land conversion of prime farmland, unique farmland, or farmland of statewide importance to non-agricultural use would be expected. Therefore, no adverse impact is expected on either cultural or natural resources in the vicinity of the proposed MRTP's manufacturing location.

B.4 - Environmental Justice: the USEPA defines environmental justice (EJ) as “the fair treatment and meaningful involvement of all people regardless of race, color, national origin, or income with respect to development, implementation, and enforcement of environmental laws, regulations and policies.” The USEPA’s EJSCREEN tool was used in July 2023 to provide a high-level overview of the county where the manufacturing facility is located. The USEPA developed EJSCREEN to highlight places that may be candidates for further review, analysis, or outreach. It is important to understand that EJSCREEN is not a detailed risk analysis. Environmental Justice screening helps detect groups near or within the area of the facility considered potentially vulnerable or marginalized due to minority or low-income status. An evaluation of the Owensboro facility location was completed and provided in the below section. It provides the minority population percentages and family poverty rates for the county where the proposed MRTTP will be manufactured. Minority population and Low-Income indicators for the 0.72 square miles where the manufacturing facility is located are higher than both state and county averages. However, in contrast, the median income and the percent manufacturing workforce is in-line with the state and county averages. The relatively high minority and low-income population statistics may be impacted by the small size of the Block Group and residential population to the immediate south/ southeast/ southwest of the facility. The overall U.S. minority population and low-income population is 39% and 33%, respectively. The County’s reported minority population is below the state average and the low-income population percentage mirrors the state average. The pre-Covid-19 pandemic state and county unemployment statistics, as of December 2019, provided from Federal Reserve Economic Data, identify the unemployment rate as 3.9% and 3.6%, respectively. EJSCREEN also includes environmental indicators defined by the USEPA, which are discussed below. Using methods similar to those used for demographic and income data above, the potential for exposure/risk/proximity to certain facilities or pollution sources was compared. This report includes screens for ozone, particulate matter (PM2.5), traffic proximity and volume, and hazardous waste proximity. The Block Group is only 0.72 square miles, and it contains two Hazardous Waste TSD Facilities. Also, based on the USEPA’s RCRA Info database, the Owensboro area has 11 LQGs and 49 locations that are some type of handler of hazardous waste. Based on the information above, no significant environmental justice effects are anticipated to result from the manufacture of the proposed MRTTP. No changes in environmental justice effects are anticipated due to manufacturing the proposed MRTTP.

B.5 - Socioeconomic Impacts: regarding socioeconomic impacts, the data was collected using the ESRI Tapestry Segmentation tool which helps supplement census data with socioeconomic, demographic and consumer markets data aggregation. ESRI Tapestry has identified 67 distinctive segments, which provide a detailed description of U.S. neighborhoods and residential areas. According to the U.S. Census Bureau, the median income for U.S. households

was \$62,843, and the Kentucky median household income is \$50,589. And according to the U.S. Department of Labor, Bureau of Labor Statistics, the total percentage of laborers working in the manufacturing industry in the U.S. has hovered around the 8.0% mark in recent years (2009 – 2019). The median income of both the county and the zip code where the manufacturing facility is located is below the state and national averages. The Block Group where the facility is located has a median income similar to the state and county median income. These median incomes are significantly lower than the national average. In general, Kentucky is consistently below the national average in median income and a higher than national average poverty rate. The manufacturing facility area has a median income that is lower than the county average but comparable to the state average. The manufacturing workforce rate in the manufacturing facility area is 15.2%, which is above the state average of 9.9% and the national average which is 8%. Overall, these indicators in the area of the manufacturing facility are relatively similar to the county and state levels. Thus, no significant socioeconomic effects are anticipated to result from the manufacture of the proposed MRTP. Manufacture, disposal, and use of the proposed MRTP is not expected to affect subsistence patterns of consumption of fish, wildlife, and vegetation for minority or low-income populations (e.g., Indian tribes). No changes in socioeconomic effects are anticipated due to manufacturing the proposed MRTP.

7.1.4.4 Use of Resources and Energy

As is the case with other smokeless tobacco and moist snuff products and their ingredients, the production, use, and disposal of the proposed MRTP and their ingredients require the use of natural resources such as petroleum products and coal. However, the proposed MRTP will not differ from the currently marketed smokeless tobacco products in the market.

7.1.5 Mitigation Measures

Based on current information, Swedish Match has not identified any adverse environmental effects associated with the proposed action. Therefore, mitigation measures need not be discussed.

7.1.6 Alternatives to the Proposed Action

An alternative to the proposed action would be if a marketing order is not issued. The environmental impact of this action would not change the existing condition.

7.1.7 List of Preparers

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Title: Vice President, General Counsel & Secretary, Swedish Match

Education: J.D., Vanderbilt University Law School; B.B.A., University of Notre Dame
Experience: 26+ years with the company, charged with regulatory compliance
Expertise: Regulatory Affairs

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Title: (b) (6)

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Experience: 39 years in various product development and regulatory activities

Expertise: Scientific and Regulatory Affairs

7.1.8 References

Novotny and Slaughter (2014): Tobacco Product Waste: An Environmental Approach to Reduce Tobacco Consumption. Current Environment Health Report. 1:208-216.

Novotny and Zhao (1999): Tobacco Control. 8:75-80.

U.S. Environmental Protection Agency, Advancing Sustainable Materials Management: 2017 Fact Sheet. EPA-530-F-19-007, November 2019, Washington, D.C.

World Health Organization (2017): Tobacco and its environment impact: an overview. 1-72.

7.1.9 Agencies and Persons Continued

N/A

The undersigned official certifies that the information presented is true, accurate, and complete to the best of the knowledge of Swedish Match.

(b) (6)

Gerard J. Roerty, Jr.
Vice President, General Counsel & Secretary