

**Environmental Assessment for a Marketing Order for
a New Roll-Your-Own Non-Filtered Cigarette Tube
Manufactured by
Vandenberg Special Products, B.V.**

**Prepared by Center for Tobacco Products
U.S. Food and Drug Administration**

March 18, 2020

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1. Applicant and Manufacturer Information

Applicant Name:	Vandenberg Special Products, B.V.
Applicant Address:	P.O. Box 91083 3007 MB Rotterdam The Netherlands, NL
Manufacturer Name:	Vandenberg Special Products, B.V.
Address Where Product is Manufactured	JL Sumber Waras # 31-33 65216 Malang Indonesia

2. Product Information

New Product Name, Submission Tracking Number (STN), and Original Product Name

New Product Name	STN	Original Product Name
Cones Unbleached 1 1/4 6 Piece	EX0000892	Cones 6 Piece 83mm

Product Identification

Product Category	Roll-Your-Own
Product Subcategory	Non-Filtered Cigarette Tube
Product Quantity per Retail Unit	Six cones per blister pack
Product Package	The packaging materials consist of a clear plastic blister in a cardboard sleeve.

3. The Need for the Proposed Action

The proposed action, requested by the applicant, is for the Food and Drug Administration (FDA) to issue an exemption from substantial equivalence (SE) reporting for a marketing order under the provisions of section 905(j)(3) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for a roll-your-own (RYO) non-filtered cigarette tube. A tobacco product that is modified by adding or deleting a tobacco additive, or increasing or decreasing the quantity of an existing tobacco additive, may be considered for exemption from demonstrating substantial equivalence if: (1) the product is a modification of another tobacco product and the modification is minor, (2) the modifications are to a tobacco product that may be legally marketed under the FD&C Act, (3) an SE Report is not necessary to ensure that permitting the tobacco product to be marketed would be appropriate for the protection of public health, (4) the modified tobacco product is marketed by the same organization as the original product, and (5) an exemption is otherwise appropriate.

The applicant wishes to introduce the new tobacco product into interstate commerce for commercial distribution in the United States. The applicant must obtain a written notification that FDA has granted the product an exemption from demonstrating substantial equivalence under section 905(j)(3) before submitting an abbreviated report. Ninety days after FDA receipt of the abbreviated report, the applicant may introduce or deliver for introduction into interstate commerce for commercial distribution the new product for which the applicant has obtained an exemption from demonstrating substantial equivalence.

The new product is made by modifying the original product, a grandfathered product commercially marketed in the United States as of February 15, 2007. The new product differs from the original product in the removal of one ingredient (Confidential Appendix 1).

4. Alternative to the Proposed Action

The no-action alternative is FDA does not issue a marketing order for the new tobacco product in the United States.

5. Potential Environmental Impacts of the Proposed Action and the Alternative – Manufacturing the New Tobacco Product

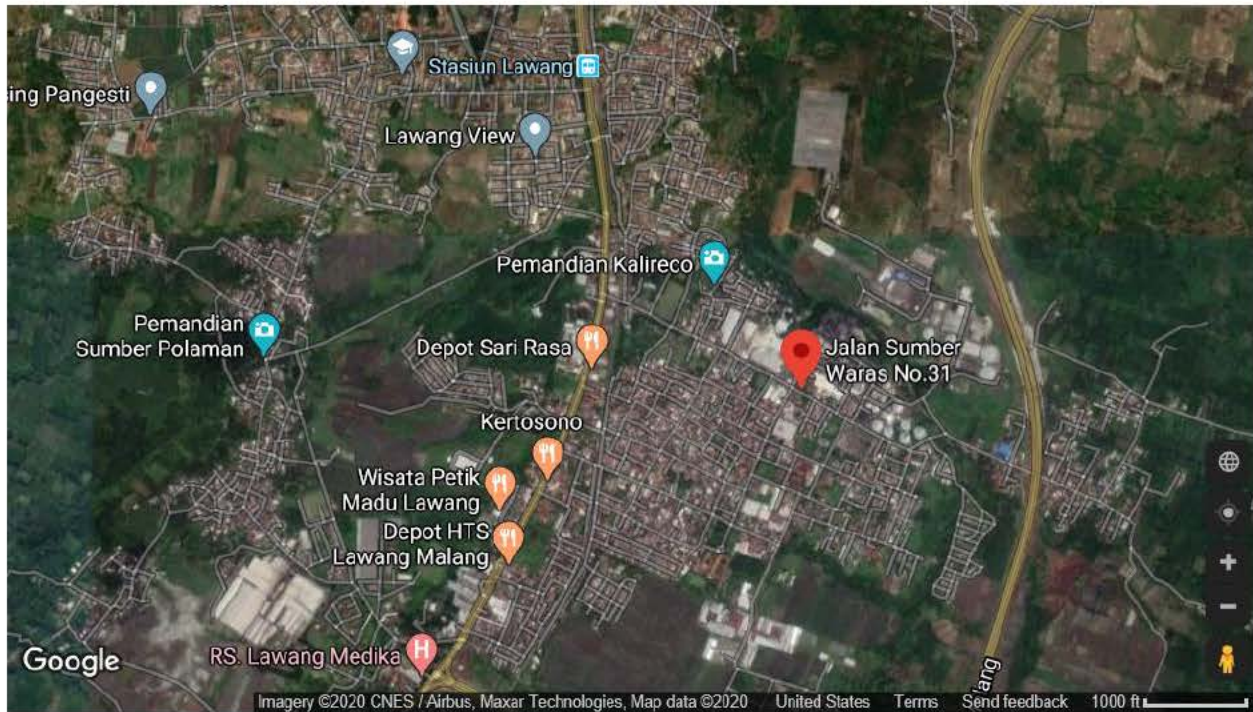
The Agency considered potential impacts on resources in the environment that may be affected by manufacturing the new product and found no significant impacts.

5.1 Affected Environment

The affected environment includes human and natural environments surrounding the manufacturing facility. The new product would be manufactured at the address listed in section 1 of this document (Figure 1).¹ The manufacturing facility is located in a mixed-use industrial, commercial, and residential area.

¹ Google. 2020. Map of JL Sumber Waras # 31-33, 65216 Malang, Indonesia. Retrieved from Google Maps: www.google.com/maps. March 6, 2020.

Figure 1. Location of the Manufacturer



5.2 Analysis of Potential Environmental Impacts

The Agency evaluated the proposed action for potential environmental impacts due to the new product manufacturing based on Agency-gathered information and the applicant’s submitted information, including projected market volumes for the new and original products (Confidential Appendix 2).

Environmental Resource	Analysis of Potential Impacts
Air quality	The applicant stated that manufacturing the new product is not expected to result in changes in air emissions or require any additional environmental controls or a revised or a new air emission permit.
Water resources	The Agency does not anticipate that manufacturing the new product would cause the discharge of any new chemicals into the water. The applicant stated that manufacturing the new product would not require any additional environmental controls for water discharges and, therefore, would not require a revised or new wastewater discharge permit.
Soil, land use, and zoning	The applicant stated that there would be no facility expansion due to manufacturing the new product. Therefore, there would be no zone change or land conversion of prime farmland, unique farmland, or farmland of statewide importance to non-agricultural use.
Biological resources	The applicant stated that no facility expansion is expected, and the manufacturing facility is not within or near a habitat, critical or not, of any endangered species listed under the Convention on International Trade in

	Endangered Species of Wild Flora and Fauna (CITES). Therefore, the Agency does not anticipate that manufacturing the new product would jeopardize the continued existence of any listed species or result in adverse effects on species or habitats addressed under CITES.
Socioeconomic conditions	No changes on socioeconomics are anticipated due to manufacturing the new product because no facility expansion is expected.
Solid waste and hazardous materials	The applicant stated that no additional capacity for disposal of manufacturing waste, or any additional environmental controls would be required. Additionally, proper disposal of any waste related to manufacturing the new product would be handled in compliance with applicable laws and regulations.
Floodplains, wetlands, and coastal cones	No facility expansion is expected due to manufacturing the new product and, therefore, no effects on floodplains, wetlands, or coastal zones are anticipated.
Regulatory compliance	The applicant stated that the manufacturing facility is in compliance with all applicable environmental regulations and CITES.

5.3 Cumulative Impacts

The Agency did not identify any actions that would lead to cumulative impacts when considered with manufacturing the new product under the proposed action.

5.4 Impacts of the No Action Alternative

The no-action alternative would not change the existing condition of manufacturing RYO non-filtered cigarette tubes at the listed facility, as other similar tobacco products would continue to be manufactured.

6. Potential Environmental Impacts of the Proposed Action and the Alternative – Use of the New Tobacco Product

The Agency considered potential impacts to resources in the environment that may be affected by use of the new product and found no significant impacts.

6.1. Affected Environment

The affected environment includes human and natural environments in the United States because the marketing order would allow for the new tobacco product to be sold to consumers in the United States. The new RYO tobacco product is intended to be filled with tobacco and smoked by users indoors or outside, as the law permits.

6.2. Analysis of Potential Environmental Impacts

The Agency evaluated the proposed action for potential environmental impacts from use of the new product based on the applicant’s submitted information.

Environmental Resource	Analysis of Potential Impacts
Air quality	The applicant stated that no new chemicals would be emitted from use of the new product because the ingredients in the new product are used in other similar tobacco products currently on the market. Therefore, the Agency does not anticipate that using the new product will lead to the release of new chemicals into the air, as compared to the original product or similar currently marketed RYO products.
Environmental justice	No new emissions are expected due to use of the new product. Therefore, there would be no new disproportionate impacts on the minority or low-income populations.

6.3. Cumulative Impacts

The Agency did not identify any actions that would lead to cumulative impacts when considered with the use of the new product under the proposed action.

6.4. Impacts of the No Action Alternative

The no-action alternative would not change the existing condition of use of RYO non-filtered cigarette tubes in the United States, as many other similar tobacco products would continue to be used.

7. Potential Environmental Impacts of the Proposed Action and the Alternative – Disposal of the New Tobacco Product

The Agency considered potential impacts to resources in the environment that may be affected by disposal of the new product and found no significant impacts.

7.1. Affected Environment

The affected environment includes human and natural environments in the United States because the marketing order would allow for the new tobacco product to be sold to consumers nationwide. Consumers would dispose of the used product and packaging via municipal solid waste (MSW) landfills, recycling centers, or as litter.

7.2. Analysis of Potential Environmental Impacts

The proposed action was evaluated for potential environmental impacts from disposal.

Environmental Resource	Analysis of Potential Impacts
Air quality	The Agency does not anticipate disposal of the product or the packaging material would lead to the release of new or increased chemicals into the air because introducing the new product into the U.S. market is not expected to increase the nationwide use and eventual disposal of RYO tobacco products.

Biological resources	Proper disposal of the used new product and packaging materials from the new product in the MSW stream would not affect biological resources. Improper disposal (littering) of used new product could lead to terrestrial wildlife having direct exposure to the used product and hazardous substances leaching to aquatic environments and soil. However, introducing the new product into the U.S. market is not expected to increase the nationwide use and disposal of RYO tobacco products, based on the projected market volumes reported by the applicant (Confidential Appendix 2). Therefore, littering levels are not expected to change from the current levels due to existing tobacco products.
Environmental justice	No significant environmental impacts associated with the disposal of the used new product and packaging were identified. Therefore, there would be no new disproportionate impacts on environmental justice populations.
Water resources	Proper handling of waste generated due to disposal of the new product and packaging would not affect water resources. Improper disposal could result in hazardous substances leaching to water systems. However, littering levels are not expected to change from the current levels due to existing products. Introducing the new product into the U.S. market is not expected to increase the nationwide use and disposal of RYO tobacco products, based on the projected market volumes reported by the applicant.
Regulatory compliance	The new product has no features that would lead to a different rate of littering for the used product compared to currently marketed RYO tobacco products. Despite state and local ordinances, it is assumed that noncompliance (littering) would occur at the same rate for the new product as for currently marketed RYO tobacco products. Therefore, these impacts are not considered significant.

7.3. Cumulative Impacts

The Agency did not identify any actions were identified that would lead to cumulative impacts when considered with the new product disposal under the proposed action.

7.4. Impacts of the No Action Alternative

The no-action alternative would not change the existing condition of disposal of RYO tobacco products and packaging in the United States, as many similar tobacco products would continue to be disposed of.

8. List of Preparers

The following individuals were primarily responsible for preparing and reviewing this environmental assessment:

Preparers:

Rudaina Alrefai-Kirkpatrick, Ph.D., Center for Tobacco Products
 Education: Ph.D. in Plant Molecular Biology and Virology
 Experience: Forty-two years in various scientific activities including eight years in NEPA practice
 Expertise: NEPA analysis, environmental risk assessment, evidence-based assessment of health technologies, NEPA Implementation

Susana Addo Ntim, Ph.D., Center for Tobacco Products

Education: Ph.D. in Environmental Science

Experience: Seven years in various scientific activities

Expertise: NEPA Analysis; fate, transport and ecotoxicology of new and emerging contaminants; applications and environmental implications of nanotechnology

Reviewer:

Gregory G. Gagliano, M.S., Center for Tobacco Products

Education: M.S. in Environmental Science

Experience: Thirty-seven years in environmental compliance and analysis

Expertise: Environmental toxicology, risk assessment, NEPA analysis, regulatory compliance

9. A Listing of Agencies and Persons Consulted

Not applicable.

Confidential Appendix 1. Modification in the New Product as Compared to the Original Product

STN	Component	Modification in the New Product as Compared to the Original Product
EX0000892	Non-Filtered Cigarette Tube	Removal of (b) (4)

Confidential Appendix 2. Current Year Market Volume for the Original Product and First- and Fifth-Year Market Volume Projections for the New and Original Products

The applicant intends to continue marketing the original product after receiving a marketing order for the new product. The applicant stated that the projected market volumes for the new product would account for less than one percent increase in the total production at the Vandenberg Special Products manufacturing facility.

STN	Market Volume					
	Unit	Current Year	First-Year Projection		Fifth-Year Projection	
		Original Product	New Product	Original Product	New Product	Original Product
EX0000892	Metric Tons	(b) (4)				