

**Programmatic Environmental Assessment for Marketing
Orders for New Pipe Tobacco
by Alliance One Specialty Products, LLC**

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

April 17, 2020

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1. Applicant and Manufacturer Information

Applicant Name:	Alliance One Specialty Products, LLC
Applicant Address:	2305 Baldree Road Wilson, NC 27893
Manufacturer Name:	Eastern Carolina Packaging, LLC
Product Manufacturing Location:	1900B Stantonsburg Road SE Wilson, NC 27893

2. Product information

New Product Submission Tracking Numbers (STN), Names, and Predicate Product Names

STN	New Product	Predicate Product
SE0015484	EC Pipe Blue (1 ounce)	Light Fine Cut
SE0015485	EC Pipe Blue (3 ounce)	
SE0015486	EC Pipe Blue (6 ounce)	
SE0015487	EC Pipe Blue (8 ounce)	
SE0015488	EC Pipe Blue (12 ounce)	
SE0015489	EC Pipe Red (1 ounce)	American Blend Regular Fine Cut
SE0015490	EC Pipe Red (3 ounce)	
SE0015491	EC Pipe Red (6 ounce)	
SE0015492	EC Pipe Red (8 ounce)	
SE0015493	EC Pipe Red (12 ounce)	
SE0015494	EC Pipe Menthol (1 Ounce)	American Blend Menthol Fine Cut
SE0015495	EC Pipe Menthol (3 Ounce)	
SE0015496	EC Pipe Menthol (6 Ounce)	
SE0015497	EC Pipe Menthol (8 Ounce)	
SE0015498	EC Pipe Menthol (12 Ounce)	

Product Identification

Product Category	Pipe Tobacco
Product Subcategory	Pipe Tobacco Filler
Product Quantity per Retail Unit	1 oz, 3 oz, 6 oz, 8 oz, and 12 oz loose tobacco per bag
Product Package	The filler is packaged in polyphenylene ether bags; 24, 36, or 144 bags are packed into cardboard cases depending on the weight of the bags.

3. The Need for the Proposed Actions

The proposed actions, requested by the applicant, are for the Food and Drug Administration (FDA) to issue marketing orders under the provisions of sections 910 and 905(j) of the Federal Food, Drug, and Cosmetic Act. The applicant wishes to introduce the new tobacco products into interstate commerce for commercial distribution in the United States and submitted to the Agency substantial equivalence (SE)

reports to obtain the marketing orders. The Agency shall issue the marketing orders if the new products are found substantially equivalent to the corresponding predicate products. The predicate products are grandfathered products (GF1907293, GF1907294, and GF1907295) commercially marketed in the United States as of February 15, 2007.

The new products differ from their corresponding predicate products in product quantity (Appendix 1).

4. Alternatives to the Proposed Actions

The no-action alternative is FDA does not issue marketing orders for the new tobacco products in the United States.

5. Potential Environmental Impacts of the Proposed Actions and Alternatives – Manufacturing the New Products

The Agency considered potential environmental impacts that may be caused by manufacturing the new products and found no significant impacts.

5.1 Affected Environment

The affected environment includes human and natural environments surrounding the facility. The new products are manufactured by Eastern Carolina Packaging, LLC in Wilson, NC (Figure 1). The manufacturing facility is located in a suburban light industrial tobacco processing area of Wilson, NC. The facility is bounded by State Route 1602 to the east and other tobacco processing facilities to the west.

Figure 1. Location of the Manufacturing Facility¹



Imagery ©2020 Maxar Technologies, USDA Farm Service Agency, Map data ©2020 500 ft

¹ Land use surrounding manufacturing facility via Google Map. <https://www.google.com/maps>. Accessed March 31, 2020.

5.2 Analysis of Potential Environmental Impacts

The Agency considered potential impacts to resources in the environment that could be affected by manufacturing the new products based on Agency-gathered information and the applicant's submitted information. Included in the information the Agency considered were the projected market volumes for the new and predicate products (Confidential Appendix 1).

Environmental Resource	Analysis of Potential Impacts
Air quality	The applicant stated that manufacturing the new products would not lead to changes in air emissions to the environment from the manufacturing facility and would not require a new or revised permit.
Water resources	The applicant stated that manufacturing the new products would not lead to changes in wastewater discharges from the manufacturing facility and would not require a new or revised wastewater discharge permit.
Soil, land use and zoning	The applicant stated that there would be no facility expansion due to manufacturing the new products. Therefore, no changes in land use or zoning would occur as a direct impact from the proposed actions.
Biological resources	The applicant stated that the manufacturing facility is not in close proximity to species and habitats addressed under the Endangered Species Act (ESA). No effects on listed species or their habitat and biological resources are anticipated because no facility expansion is expected.
Socioeconomic conditions	No impacts would be expected on employment, state or municipal revenue and taxes, or on police force and fire department resources because there would be no facility expansion anticipated.
Solid waste and hazardous materials	The applicant stated that no additional capacity for disposal of manufacturing waste and no additional environmental controls would be required. The product modifications do not include any changes to material composition. Therefore, the Agency does not anticipate that manufacturing the new products would lead to the presence of new chemicals in the manufacturing waste stream.
Floodplains, wetlands, and coastal zones	There would be no expected facility expansion due to manufacturing the new products. Therefore, no effects on floodplains, wetlands, or coastal zones are anticipated.
Regulatory compliance	The applicant stated that the manufacturing facility complies with all local, state and federal environmental laws, including the ESA and CITES.

5.3 Cumulative Impacts

No actions were identified that would lead to cumulative impacts when considered with manufacturing the new products under the proposed actions.

5.4 Impacts of the No-Action Alternative

The no-action alternative would not change the existing conditions of manufacturing pipe tobacco filler at the listed facility, as similar pipe tobacco products would continue to be manufactured.

6. Potential Environmental Impacts of the Proposed Actions and Alternatives – Use of the New Products

The Agency evaluated potential environmental impacts that may be caused by use of the new products and found no significant impacts.

6.1. Affected Environment

The affected environment includes, within the limits of the law, human and natural environments in the United States because the marketing orders would allow for the new tobacco products to be sold to consumers in the United States.

6.2. Analysis of Potential Environmental Impacts

The proposed actions were evaluated for potential environmental impacts from use of the new products based on Agency-gathered information and the applicant’s submitted SE Reports.

Environmental Resource	Analysis of Potential Impacts
Air quality	The Agency does not anticipate that using the new products would lead to the release of new chemicals into the air, as compared to the predicate products or other currently marketed pipe tobacco products.
Environmental justice	No new emissions are expected due to the use of the new products. Therefore, there would be no new disproportionate impacts on minority or low-income populations.

6.3. Cumulative Impacts

No actions were identified that would lead to cumulative impacts when considered with use of the new products under the proposed actions.

6.4. Impacts of the No-Action Alternative

The no-action alternative would not change the existing conditions of use of pipe tobacco products, as similar pipe tobacco products would continue to be used in the United States.

7. Potential Environmental Impacts of the Proposed Actions and Alternatives – Disposal of the New Products

The Agency evaluated potential environmental impacts that may be caused by disposal of the new products and found no significant impacts.

7.1. Affected Environment

The affected environment includes human and natural environments in the United States because the marketing orders would allow the new tobacco products to be sold to consumers nationwide who would dispose of the used products and packaging as municipal solid waste (MSW), recycled material, or litter.

7.2. Analysis of Potential Environmental Impacts

The Agency evaluated the proposed actions for potential environmental impacts from disposal of the new products based on information in the SE Reports, including market volume information for the new and predicate products (Confidential Appendix 1).

Environmental Resource	Analysis of Potential Impacts
Air quality	Introducing the new products into the U.S. market is not expected to increase the nationwide use of pipe tobacco products; therefore, disposal of the used products and packaging would not significantly affect air quality.
Biological resources	Proper disposal of the used new products and packaging materials in the MSW stream would not affect biological resources. Although the used products and packaging materials may be littered in undeveloped areas and wildlife habitat, littering levels are not expected to change from the current levels due to existing tobacco products. Introducing the new products into the U.S. market is not expected to increase the nationwide use of pipe tobacco products based on the projected market volumes reported by the applicant.
Water resources	Proper disposal of the used new products and packaging materials in the MSW stream would not affect water resources. Improper disposal (littering) of used new products could result in hazardous substances leaching to water systems. However, no net increase in littering is expected; introducing the new products into the U.S. market is not expected to increase the nationwide use and disposal of pipe tobacco products, because the new products would compete for the same market share with other currently marketed pipe tobacco products.
Environmental justice	No significant environmental impacts associated with the disposal of the used new products and packaging were identified, therefore no change in impacts to environmental justice populations are anticipated.
Solid waste and hazardous materials	The distribution of waste generated due to disposal of the new products and packaging is anticipated to correspond to the pattern of product use in the United States. However, introducing the new products into the U.S. market is not expected to increase the nationwide use and disposal. Therefore, no net increase in littering would be expected.
Regulatory compliance	The new products have no features that would lead to a different rate of littering for the used products and packaging compared to currently marketed pipe tobacco products. Despite state and local littering ordinances, it is assumed that noncompliance (littering) would occur at the same rate for the new products as for the currently marketed pipe tobacco products.

7.3. Cumulative Impacts

No actions were identified that would lead to cumulative impacts when considered with the new products disposal under the proposed actions.

7.4. Impacts of the No-Action Alternative

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

8. List of Preparers

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

Preparer:

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:

Hoshing W. Chang, Ph.D., Center for Tobacco Products

Education: M.S. in Environmental Science and Ph.D. in Biochemistry

Experience: Eleven years in FDA-related NEPA review

Expertise: NEPA analysis, environmental risk assessment, wastewater treatment

9. List of Agencies and Persons Consulted

Not applicable.

Appendix 1. Product Quantity: The New Products Compared to the Corresponding Predicate Products

STN	Product Quantity	
	Tobacco Filler per Bag (oz)	
	New Product	Predicate Product
SE0015484	1	16
SE0015489		
SE0015494		
SE0015485	3	
SE0015490		
SE0015495		
SE0015486	6	
SE0015491		
SE0015496		
SE0015487	8	
SE0015492		
SE0015497		
SE0015488	12	
SE0015493		
SE0015498		

Confidential Appendix 1. Market Volume Information for the New and Predicate Products

The applicant intends to continue marketing the predicate products after receiving marketing orders for the new products. The First- and fifth-year market volume projections for the new products were compared to the total 2018 pipe tobacco use in the United States.² If the current stable trend of pipe tobacco use³ in the United States persists, the projected use of the new products in the first and fifth year of marketing would account for (b) (4) respectively.

STN	Market Volume Projections (Pounds)							
	First Year		Fifth Year					
	New Product	Predicate Product	New Product	Predicate Product				
SE0015484	(b) (4)							
SE0015485								
SE0015486								
SE0015487								
SE0015488								
SE0015489								
SE0015490								
SE0015491								
SE0015492								
SE0015493								
SE0015494								
SE0015495								
SE0015496								
SE0015497								
SE0015498								
Total Market Volume								

² Total 2018 pipe tobacco use in the United States – 41,436,727 pounds.

$$\text{Projected Market Occupation of the New Product in the United States (\%)} = \frac{\text{Projected Market Volume of the New Product (pounds)}}{\text{Projected Use of Pipe Tobacco in United States (pounds)}} \times 100$$

³ Pipe tobacco use in the United States showed a stable trend from 1997 to 2008, increased from 2009 to 2012, and has since stabilized (2013 to date) <https://www.ttb.gov/tobacco/tobacco-statistics>. Accessed March 31, 2020.