

**Environmental Assessment for Midwest Tobacco Tube Inc.
dba Great Midwest Tube's "Cheap Tobacco Menthol 100mm
Size 200 Count" Prepared by Center for Tobacco Products,
U.S. Food and Drug Administration**

June 6, 2018

Table of Contents

| | | |
|------|--|---|
| 1. | Applicant and Manufacturer Information..... | 3 |
| 2. | Product information..... | 3 |
| | New and Predicate Products..... | 3 |
| 3. | The Need for the Proposed Action..... | 3 |
| 4. | Alternatives to the Proposed Action..... | 3 |
| 5. | Potential Environmental Impacts Considered of the Proposed Action and the Alternative-Manufacturing the New Product..... | 4 |
| 5.1 | Affected Environment..... | 4 |
| 5.2 | Analysis of Potential Environmental Impacts | 5 |
| 5.3 | Cumulative Impacts | 6 |
| 5.4 | Impacts from No Action Alternative | 6 |
| 6. | Potential Environmental Impact of the Proposed Action and the Alternative - Use of the New Product..... | 6 |
| 6.1. | Affected Environment..... | 6 |
| 6.2. | Analysis of Potential Environmental Impacts | 6 |
| 6.3. | Cumulative Impacts | 6 |
| 6.4. | Impacts from No Action Alternative | 7 |
| 7. | Potential Environmental Impact of the Proposed Action and the Alternative- Disposal of the New Product..... | 7 |
| 7.1. | Affected Environment..... | 7 |
| 7.2. | Analysis of Potential Environmental Impacts | 7 |
| 7.3. | Cumulative Impacts | 8 |
| 7.4. | Impacts from No Action Alternative | 8 |
| 8. | List of Preparers | 8 |
| 9. | List of Agencies and Persons Consulted..... | 8 |

1. Applicant and Manufacturer Information

Applicant Name: Midwest Tobacco Tube Inc. dba Great Midwest Tube
Applicant Address: 10825 Medallion Road,
Cincinnati, OH 45241
Manufacturer Name: Great Midwest Tube
Address Where the Product is Manufactured: 10825 Medallion Road,
Cincinnati, OH 45241

2. Product information

New and Predicate Products

| | |
|-------------------------------|--|
| New Product Name | Cheap Tobacco Menthol 100mm Size 200 Count |
| New Product STN | SE0014202 |
| Predicate Product Name | Hot Rod Menthol King Size 200 Count |

Product Identification

| | |
|-----------------------------|-------------------------|
| Product Type | Roll-Your-Own |
| Product Sub-Category | Filtered Cigarette Tube |
| Product Package | 200 tubes per box |

3. The Need for the Proposed Action

The proposed action, requested by the applicant, is for FDA to issue a marketing order finding the new tobacco product substantially equivalent to the predicate product under the provisions of sections 910 and 905(j) of the Food, Drug, and Cosmetic Act. The applicant wishes to introduce the new tobacco product into interstate commerce for commercial distribution in the United States.

The Agency shall issue a marketing order if, after considering the substantial equivalence (SE) report and its amendments submitted by the applicant, the new product is found substantially equivalent to the predicate product. The predicate product was previously found substantially equivalent and received a marketing order on May 19, 2016.

The product modifications compared to the predicate product are design changes, which includes some ingredient changes due to these changes (Confidential Appendix 1).

4. Alternatives 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.

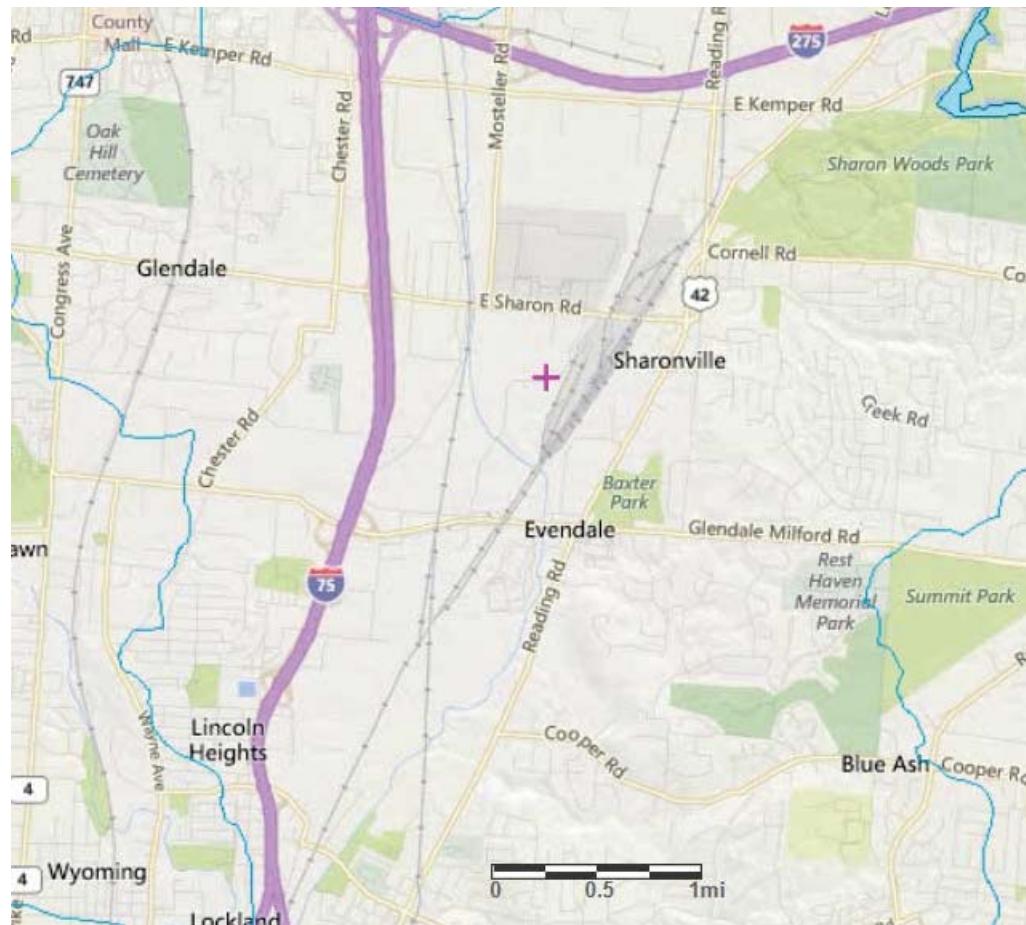
5. Potential Environmental Impacts Considered of the Proposed Action and the Alternative-Manufacturing the New Product

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

5.1 Affected Environment

The new and predicate products are manufactured at 10825 Medallion Road, Cincinnati, OH (Figure 1). The facility is in a mixed-use area, surrounded by industrial and commercial land as well as residential development to the east and west. Mill Creek is immediately west and Sharon Creek is immediately east of the facility.¹ The facility is in the Mill Creek watershed.

Figure 1. Location of the manufacturer (crosshairs) in relation to the Mill Creek watershed (blue outline).



¹ Map of 10825 Medallion Avenue, Cincinnati, OH. Retrieved from EPA's NEPA Assist: <https://nepassissttool.epa.gov/nepassisst/nepamap.aspx> (Retrieved May 3, 2018).

5.2 Analysis of Potential Environmental Impacts

The proposed action was evaluated for potential environmental impacts from manufacturing based on Agency-gathered information and the applicant's submitted information, including projected market volumes for the new and predicate products (Confidential Appendix 2).

| Environmental Resource | Analysis of Potential Impacts |
|--|--|
| Air quality | The applicant stated that the increase in manufacturing will not change air emissions. This is supported by the applicant's statement that the same materials used in manufacturing the new product are currently used in the facility and the new product manufacturing forecasts to add a fraction of one percent to the facility's total manufacturing (Confidential Appendix 2). |
| Water resources | The applicant stated that the manufacturing increase will not change the wastewater discharge. The applicant also stated that the manufacturing increase will not result in expanding the existing facility. Therefore, the Agency does not anticipate any impacts to water resources or water quality. |
| Land use and zoning | No facility construction or expansion will occur because of manufacturing the new product, thus no land conversion of prime farmland, unique farmland, or farmland of statewide importance to non-agricultural use is expected. Also, because no construction will occur, no change of zoning for land for a new or expanded facility will occur. |
| Biological resources | The applicant stated that the raw materials are from sustainable and renewable resources and protected by the Brazilian Forestry Sector Association and other world organizations. No facility expansion is expected, so no effect on listed species or their habitat will occur. No impacts on biological resources are anticipated. |
| Geological features and soils | No facility expansion is expected, so no effect on geological features or soils will occur. |
| Socioeconomic conditions | No facility expansion is anticipated. Therefore, no impacts are expected on employment; state or municipal revenue and taxes; or demand on community services, state and municipal resources, such as police force and fire department resources. |
| Solid waste and hazardous materials | The applicant stated that manufacturing the new product will result in no more than a negligible increase in municipal solid waste (MSW) generation. Compliance by the manufacturer with applicable laws, regulations, and local ordinances for solid waste and hazard materials management is assumed to indicate no significant impacts will occur. |
| Floodplains, wetlands, and coastal zones | No facility expansion will occur, so no effects to floodplains, wetlands, or coastal zones are anticipated. |
| Environmental justice | Because no significant environmental impacts were identified, there will be no disproportionate impacts to environmental justice populations near the manufacturing facility. |
| Regulatory compliance | The applicant stated that they are in compliance with all applicable federal, tribal and state environmental laws and regulations. |

5.3 Cumulative Impacts

No actions were identified that will lead to cumulative impacts due to the proposed action.

5.4 Impacts from No Action Alternative

The environmental impact of the no-action alternative will not change the existing condition of the manufacturing of RYO tobacco products, as many similar RYO tobacco products will continue to be marketed and therefore manufactured.

6. Potential Environmental Impact of the Proposed Action and the Alternative - Use of the New Product

The Agency considered potential environmental 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 is the entire United States because the marketing order will allow for the new tobacco product to be sold to consumers nationwide. The new product is a RYO product that is intended to be filled with tobacco and smoked. Users may smoke RYO cigarettes indoors or outside, as the law permits.

6.2. Analysis of Potential Environmental Impacts

The proposed action was evaluated for potential environmental impacts from use:

| Environmental Resource | Analysis of Potential Impacts |
|-------------------------------|---|
| Air quality | The applicant stated that no new compounds will be emitted from use of the new product. 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 use of the predicate product. |
| Environmental justice | The new product is expected to be used by the same consumers that use the predicate product. Therefore, no change in impacts to environmental justice populations are expected. |

6.3. Cumulative Impacts

No actions were identified that, when considered with the proposed action, would lead to cumulative impacts.

6.4. Impacts from No Action Alternative

The environmental impact of the no-action alternative will not change the existing condition of the use of RYO tobacco products, as many similar RYO tobacco products will continue to be marketed and therefore used.

7. Potential Environmental Impact of the Proposed Action and the Alternative- Disposal of the New Product

The Agency has considered potential environmental 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 is the entire United States because the marketing order will allow for the new tobacco product to be sold to consumers nationwide who will dispose of the used product and packaging. This disposal will be via 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 | Introducing the new product into the U.S. market is not expected to increase the nationwide use of RYO tobacco products, thus, disposal of the used product and packaging will not significantly affect air quality. |
| Biological resources | Proper disposal of used product and packaging in the municipal solid waste stream will not affect biological resources. Improper disposal could occur in undeveloped areas and wildlife habitat. However, because introducing the new product into the U.S. market is not expected to increase the nationwide use of RYO tobacco products, it is not expected that the amount of littering will change from the current amount due to existing products. Thus, this impact will not be significant. |
| Environmental justice | Because no significant environmental impacts were identified, there will be no disproportionate impacts to environmental justice populations from disposal of used product and packaging waste. |
| Water resources and water quality | Proper disposal of used product and packaging in the municipal solid waste stream will not affect water resources. Improper disposal could occur in or near surface water. However, because introducing the new product into the U.S. market is not expected to increase the nationwide use of RYO tobacco products, it is not expected that the amount of littering will change from the current amount due to existing products. Thus, this impact will not be significant. |
| Regulatory compliance | It is assumed that the portion of product and packaging waste that is disposed of by users, despite littering ordinances, will be no greater than the current tobacco product littering rates. |

7.3. Cumulative Impacts

No actions were identified that will lead to cumulative impacts due to the proposed action.

7.4. Impacts from No Action Alternative

The environmental impact of the no-action alternative will not change the existing condition of the disposal of RYO tobacco products, as many similar RYO tobacco products will continue to be marketed.

8. List of Preparers

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

Preparers:

Shannon K. Hanna, Ph.D., Center for Tobacco Products

Education: Ph.D. in Environmental Science and Management

Experience: Four years in environmental science, three years in toxicology

Expertise: Ecotoxicology of new substances and materials, bioaccumulation of chemicals including heavy metals, soil/sediment and water quality

Catherine W. McCollum, Ph.D., Center for Tobacco Products

Education: Ph.D. in Biochemistry and Cell Biology

Experience: 3 years in NEPA practice, 10 years in various scientific activities

Expertise: NEPA analysis, environmental impact analysis, ecotoxicity, developmental toxicology

Reviewer:

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

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

Experience: 9 years in FDA-related NEPA review

Expertise: NEPA analysis, environmental risk assessment, wastewater treatment

9. List of Agencies and Persons Consulted

Not applicable.

Confidential Appendix 1. Modifications between New and Predicate Products

The new product and the predicate product have different design features, which increase the amount of the ingredients in those design features. For example, more seam adhesive in the new product would increase the amount of ingredients in that adhesive. The tipping paper is both changed in design, longer in the new product, but also in ingredients, as a different tipping paper is used in the new product.

The SE Report provided the changes for the new product as listed in the following table:

| STN | Name | Component | Design Feature Changes | Ingredient Changes |
|-----------|--|------------------|--|---|
| SE0014202 | Cheap Tobacco Menthol 100mm Size 200 Count | Filter | 25 mm Filter Plug for new 20 mm Filter Plug for predicate | None |
| | | Tipping Paper | Longer tipping paper for new product | White tipping paper with two green bands for new product; Cork tipping paper with two gold bands for predicate product |
| | | Cigarette Paper | Longer cigarette paper for new product | None |
| | | Seam Adhesive | More seam adhesive for new product | None |
| | | Tipping Adhesive | Same as predicate | None |
| | | Packaging | Larger box for new product | None |

Confidential Appendix 2. Market Volume Projections of the New and Predicate Products

| STN | Name | Unit | First-Year Market Volume | | Fifth-Year Market Volume | |
|-----------|--|----------------------|--------------------------|-------------------|--------------------------|-------------------|
| | | | New Product | Predicate Product | New Product | Predicate Product |
| SE0014202 | Cheap Tobacco Menthol 100mm Size 200 Count | Tubes Metric Tons | (b) (4) | | | |

The applicant intends to continue marketing the predicate product after receiving a marketing order for the new product.