Programmatic Environmental Assessment for Tobacco Products in the category – other, subcategory – other, specifically, tobacco-derived and non-tobacco nicotine pouches, lozenges, discs, tablets, gums, nicotine infused products, and dissolvable tobacco products

Prepared by

United States Food and Drug Administration

March 10, 2026

Table of Contents

Table of Figures

Executive Summary

Tobacco use is one of the main causes of preventable death and disease every year in the United States. In addition to human health effects, tobacco products can have negative environmental effects. The negative environmental health effects range from fire risk to the potential for harmful chemicals entering and accumulating in the environment during manufacturing, use, and disposal. FDA evaluates the environmental effects of issuing marketing granted orders (MGO) for new tobacco products per rules described in 21 CFR part 25 for implementing the National Environmental Policy Act (NEPA). The environmental evaluation includes the effects of manufacturing, use, and disposal of new products.

The tobacco products subject to this programmatic environmental assessment (PEA) are characterized in premarket reviews as category "Other" and subcategory "Other" by FDA (herein "new products") and include tobacco-derived and non-tobacco nicotine pouches, lozenges, discs, tablets, gums, nicotine infused products, and dissolvable tobacco products. These tobacco products generally pose lower health risk than combusted tobacco products, although they can still deliver harmful chemicals to users. This category excludes smokeless tobacco products (dip, snuff, snus, and chewing tobacco).

The environmental effects of use and disposal of these new products are minimal because they do not result in airborne emissions during use, thus reducing or eliminating secondhand and thirdhand exposure to bystanders. Additionally, the waste from these products contains few harmful chemicals that can leach into, persist in the environment, and bioaccumulate. FDA evaluated the environmental effects that may result from authorizing products within this category on water resources, soil, and air quality. This evaluation includes potential changes in wastes due to manufacturing processes, use, and disposal of the used products and their packaging materials.

FDA considered potential effects on resources in the environment that could be affected by use of the new products. The new products are free of airborne emissions, and, therefore, will not affect air quality in the vicinity of use. Effects on non-users will be minimal given the lack of secondhand or thirdhand exposure to airborne emissions during use. For disposal-related effects, the Agency conducted an environmental risk assessment of select hazardous chemicals in the new products and found that they pose low to negligible environmental risks to aquatic organisms and water quality. Therefore, FDA does not anticipate significant impacts on the Publicly Owned Treatment Works (POTW) or to the natural environment from disposal of the new products.

Additional negative environmental effects may be associated with increased production, sales, and use of the new products as more products enter the developing market, but these effects will be similar to those of other consumer products and currently marketed tobacco products. Product specific environmental effects of new products will be evaluated when their premarket applications are submitted for FDA review. Additionally, site-specific environmental manufacturing impacts and any deviation from use and disposal-related effects considered in this evaluation will be addressed when the premarket applications are submitted to FDA for review.

1. Introduction

Under section 910 of the Federal Food, Drug, and Cosmetic (FD&C) Act, new tobacco products are subject to premarket review prior to receiving a marketing authorization order allowing introduction into interstate commerce in the United States. A Premarket Tobacco Product Application (PMTA) is required to provide sufficient scientific evidence to demonstrate that marketing of the new tobacco product is appropriate for the protection of the public health (APPH). Scientific evidence must address, among other things, any health risks and benefits of the new product to the United States population as a whole. This includes people who use the new product, as well as nonusers. As part of new tobacco product review, FDA evaluates the environmental effects of issuing MGOs per rules described in 21 CFR part 25 for implementing NEPA . The environmental evaluation includes effects of manufacturing, use, and disposal of new products.

Tobacco products contain toxicants that can persist in the environment and bioaccumulate. The manufacturing, use, and disposal of tobacco products degrade air and water quality, with potential negative effects on human health and the environment.

1.1. Scope of this Programmatic Environmental Assessment

The new products under PMTA review are characterized as category “Other” and subcategory “Other” by FDA and include tobacco-derived and non-tobacco nicotine pouches, lozenges, discs, tablets, gums, nicotine infused products, and dissolvable tobacco products. This category excludes smokeless tobacco products (dip, snuff, snus, and chewing tobacco). This PEA exclusively focused on tobacco products in the category “other” and subcategory “other” and did not include smokeless tobacco products.

The new products, particularly nicotine pouches, are generally recognized to be lower health risk because they contain low concentrations of harmful and potentially harmful constituents (HPHCs) (Back et al., 2023). However, they can still deliver harmful chemicals to users, including nicotine in high concentrations and HPHCs (Borowiecki et al., 2024; Food and Drug Administration, 2025b; Page et al., 2025; Travis et al., 2025).

The new products typically consist of a physical carrier, such as a pouch, lozenge, or toothpick, that contains nicotine, flavors, and in some products, a non-tobacco filler. Unlike traditional smokeless tobacco products (e.g., snuff or snus), the new products do not contain cut or ground tobacco leaf. Instead, they contain either tobacco-derived nicotine (i.e., nicotine extracted from tobacco leaf and crystalized into a white powder) or non-tobacco nicotine such as synthetic nicotine (i.e., nicotine synthesized from organic precursors). As such, some of the new products are marketed as “tobacco free” and “tobacco-leaf free” (Czaplicki et al., 2022; Robichaud et al., 2020). The new products are available in various flavors (e.g., mint, wintergreen, fruit, coffee) and vary in nicotine content (e.g., 1.4 – 16.3 mg/ pouch in the US, 1-47 mg / pouch in Germany) (Mallock et al., 2024; Page et al., 2025). Nicotine pouch products presently represent almost the entire market share of oral nicotine products within the ‘Other’ product category(Borowiecki et al., 2024; He et al., 2025). While relatively minor in the US market currently, the industry expects substantial growth in the category (e.g., lozenges, tablets, gummies, gums) that are not nicotine pouches (Borowiecki et al., 2024).

2. Purpose and Need of the Proposed Action

Purpose: Applicants intend to market new products within the category ”Other”, subcategory “Other”, in interstate commerce for commercial distribution in the United States. These products include tobacco-derived and non-tobacco nicotine pouches, lozenges, discs, tablets, gums, nicotine infused products, and dissolvable tobacco products, and exclude smokeless tobacco products. Upon receipt of a PMTA, FDA evaluates the submission, using criteria detailed in section 910 of the FD&C Act and 21 CFR Part 1114 to determine whether a MGO for the product would be APPH. Authorization to market new products is a federal action requiring environmental review of potential effects on human and environmental health in accordance with NEPA.

Need: Each year, 480,000 people die prematurely from a smoking-attributed diseases, making tobacco use the leading cause of preventable disease and death in the United States (U. S. Department of Health and Human Services, 2014) . Nearly all these adverse health effects are ultimately the result of addiction to the nicotine in combusted tobacco products, leading to repeated exposure to toxicants from those products. Oral nicotine products within the ‘Other’ product category may benefit public health by reducing the exposure to harmful chemicals for users who completely switch from combusted tobacco (Food and Drug Administration, 2025b) and traditional smokeless products, potentially reducing risks of adverse health outcomes. FDA’s responsibility to review a PMTA, make a determination as described above, and subsequently determine whether or not to issue a MGO for the new product is a statutory requirement under section 910 of the FD&C Act.

3. Proposed Action and Alternative

The proposed action is to issue MGOs under the provisions of section 910 of the FD&C Act following FDA’s determination that the new products would be APPH. The MGOs would authorize introduction or delivery for introduction of the new products into interstate commerce in the United States.

The no-action alternative is FDA does not issue MGOs for the new products.

4. Affected Environment

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

The environmental effects of this product category are evaluated based on sales volume in the United States as proxy for use, assuming use and disposal behaviors of the consumer will not change significantly with variations in market share among all tobacco products. Tracking precise sales of the new products across all retail outlets is challenging and slight variations exist among monitoring datasets due to different data collection methods. Data sources may or may not overlap, definitions can vary, and products with small market share may be difficult to track, resulting in differences in estimates. The data presented below estimate environmental effects and illustrate trends in the product category over time (Fig. 1 & 2). Sales data are only available for nicotine pouches, as these products dominate the market for the category. Pouch sales increased from less than one billion units in 2019 to close to 14 billion units in 2024 (Fig. 1) (Euromonitor International Ltd, 2025). The same trend is seen in the new market monitoring data (Fig. 2) (He et al., 2025). Adult current use of nicotine pouches was 0.4% in 2022 (Dai & Leventhal, 2024).

In 2024, nicotine pouches became the second most commonly used tobacco products among United States middle and high school students (Jamal et al., 2024). In 2024, 1.8% of youth currently used nicotine pouches compared to 1.1% of youth in 2022 (Food and Drug Administration, 2023; Jamal et al., 2024). Beyond pouch products, other tobacco products, including lozenges, discs, tablets, gums, and dissolvable tobacco products, were currently used by 1.2% of youth in 2024 (Jamal et al., 2024). Overall, the increase in sales tracks the increasing use prevalence. Broadly, sales volumes are related to, and indicators of, potential environmental effects from manufacturing, use, and disposal.

Figure 1. Euromonitor sales data for nicotine pouches sold per year in the United States.

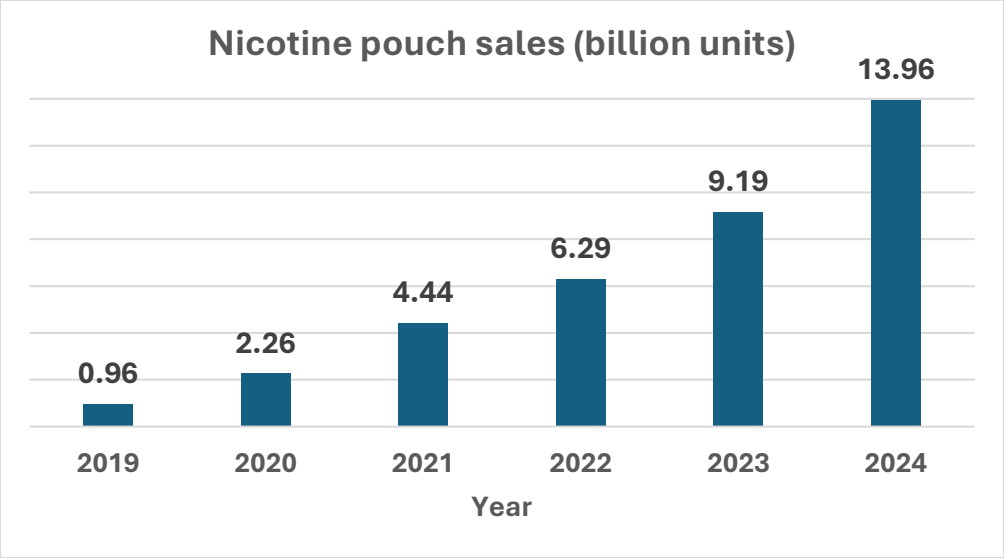
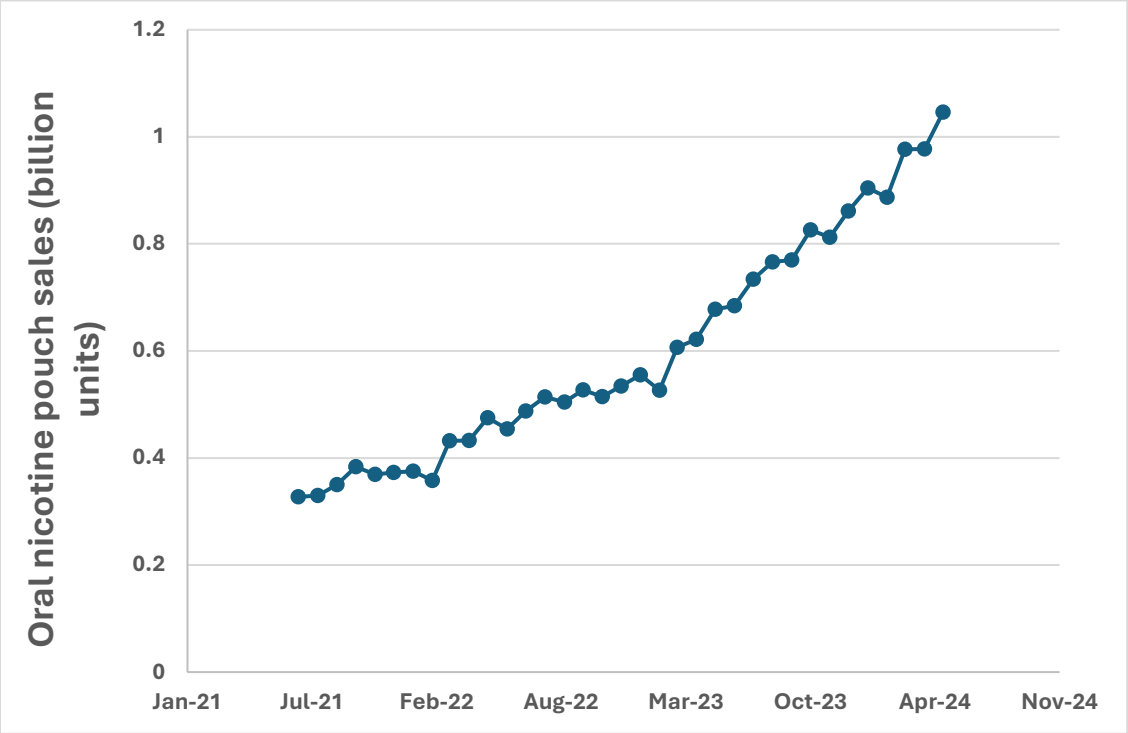


Figure 2. Nielsen sales data for nicotine pouches sold per month in the United States (data from He et al. 2025).



5. Potential Environmental Effects of the Proposed Action

5.1. Potential Environmental Effects of the Proposed Action – Manufacturing Oral Nicotine Products within the 'Other' Category

The significance of environmental effects (and thus the justification for a finding of no significant impact) is in part indicated by whether the action may violate federal, state, or local law or requirements imposed for the protection of the environment. Therefore, manufacturers are expected to comply with applicable local, state, or federal environmental regulations. The site-specific effects from manufacturing specific new products will be addressed during environmental review of the submitted new product applications.

5.1.1. Air Quality

Chemical extraction of nicotine from tobacco may result in increased use of organic solvents (ether and petroleum ether) and ammonium salts. Hence, tobacco manufacturers may need additional environmental controls, permits, and new waste management facilities to stay in compliance with existing environmental laws. Manufacturing tobacco products also generates emissions of pollutants to the air. The manufacture of new oral nicotine products is expected to increase with market authorizations for new products. Therefore, new emissions associated with the production of new oral nicotine products may occur. However, since the emissions will be managed by tobacco manufacturers, with compliance documented by regulators within the context of environmental permitting frameworks

(local, state and federal), FDA does not anticipate significant harm to the human environment.

5.1.2. Water Resources

Tobacco processing, nicotine extraction, and manufacturing of tobacco products is water intensive (World Health Organization, 2017; Zafeiridou, 2018). Expansion of manufacturing facilities and processes to accommodate increased sales will result in increased use of water and discharge. Manufacturing facilities are required to comply with local, state, and federal environmental regulations related to surface water.

5.1.3. Soil, Land Use, and Zoning

Many new products use tobacco-derived nicotine. Growing demand for the new products may lead to increased harvested tobacco acreage in the United States. However, since domestic harvested tobacco acreage has been decreasing in the United States; environmental effects from increased production will most likely occur outside of the United States. Regarding manufacturing impacts, the Agency does not anticipate that manufacturing the new products will lead to changes in soil, land use, or zoning. Any new construction associated with manufacturing the new products would likely result in localized, short-term construction related activities. Therefore, no zone changes or land conversion of prime farmland, unique farmland, or farmland of statewide importance to non-agricultural use would be anticipated.

5.1.4. Biological Resources

The Agency does not anticipate the actions would jeopardize the continued existence of any listed species or result in the destruction or adverse modification of the habitat of any such species identified under the Endangered Species Act (Oropesa, 2017). Expansion of tobacco product manufacturing facilities would be required to comply with local, state, and federal environmental regulations.

5.1.5. Solid Waste and Hazardous Materials

Nicotine is extracted from tobacco leaf using solvents (Kheawfu et al., 2021). The proposed actions will increase manufacturing, leading to more nicotine extraction and increased waste production. As part of manufacturing permitting and approval, establishments must comply with existing local, state, and federal environmental laws and regulations. Tobacco manufacturers may need additional environmental controls, permits, and new waste management facilities to stay in compliance with existing environmental laws. However, since the waste will be managed by the facilities, FDA does not anticipate harm to the human environment.

5.1.6. Floodplains Wetlands and Coastal Zones

The Agency does not anticipate that manufacturing the new products would lead to changes in floodplains, wetlands, and coastal zones. The Agency anticipates that construction to accommodate manufacturing the new products is associated with localized, short-term land alterations within an existing industrial footprint.

5.2. Potential Environmental Effects of the Proposed Action – Use of Oral Nicotine Products within the 'Other' Category

The Agency considered potential effects to resources in the environment that could be affected by use of the new products and found no significant impacts based on Agency-gathered information. Included

in the information the Agency considered were the projected market volumes for the new products (Fig. 1&2). The products are free of airborne emissions and therefore will not affect air quality in the vicinity of use. Effects on non-users will be minimal given the lack of secondhand or thirdhand exposure to airborne emissions during use. There is a potential risk of inadvertent exposure to nicotine from contact with the new products. This risk can be mitigated with childproof container closure systems and proper use of the new products.

5.3. Potential Environmental Effects of the Proposed Action – Disposal of Used Oral Nicotine Products within the 'Other' Category

The Agency evaluated potential environmental effects from disposal of the new products and found no significant impacts. Any disposal-related effects not addressed in this section will be evaluated during the environmental review for specific products seeking marketing authorization. Besides nicotine, the new products contain other constituents such as plastics, HPHCs or flavor ingredients that could contribute to the toxicological risks of these products. Overall, the new products are expected to have minimal toxicological risk for consumers due to the generally low levels of HPHCs present in these products (Back et al., 2023). However, since the new products are entirely formulated products, constituent variability exists among different individual products, and this variability is expected to differ between brands and sub-brands.

5.3.1. Air Quality

The Agency does not anticipate disposal of the new products, or their packaging materials would lead to the release of new or increased chemicals into the air. Currently, no studies are available that describe the air quality effects resulting from the disposal of used products. Many products in this category contain synthetic polymers and plastic materials, some of which are non-biodegradable or only slowly biodegradable. However, no changes in air quality from disposal of the packaging materials of new products are expected because (1) the paper, cardboard, and plastic components of the packages are likely to be recycled, at least partially, (2) these packaging materials are commonly used in the United States, and (3) the waste generated due to disposal of the packaging is a minuscule portion of the MSW based on current product sales.

5.3.2. Biological Resources

The proposed actions are not expected to change the continued existence of any endangered species or result in the destruction or adverse modification of their habitat, as prohibited under the United States Endangered Species Act. Proper disposal of the new products and packaging into MSW would not affect biological resources. If improper disposal as litter occurs, the products are not expected to result in significant concentrations of harmful constituents (e.g., nicotine) being emitted or released to the environment. Further, unlike combusted tobacco products, smoldering of used products is not a concern with disposal of the new products. Therefore, the risk of fires from smoldering tobacco products and associated effects on natural environments from littering are not a concern. The Agency does not anticipate that disposal of the new products or their packaging materials, would lead to significant impacts on biological resources.

5.3.3. Water Resources

Proper disposal of used products and packaging in the MSW stream will not affect water resources. However, improper disposal (littering) of these products could result in hazardous substances leaching into water systems. The material composition of the new products includes synthetic polymers and plastic materials, some of which are non-biodegradable or only slowly biodegradable. Despite these material properties, littering levels are not expected to increase beyond current levels associated with existing tobacco products.

5.3.4. 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 the products' use in the United States.

Users of the new products, which are designated as spit-free products, are not expected to expectorate consumed products into the environment. There is a potential risk of inadvertent exposure to nicotine from contact with the new products, as indicated by case reports of young children swallowing used pouches. This risk can be mitigated by proper disposal of the new products. Disposal of the new products could also pose a risk to aquatic organisms and ecosystems. The Agency conducted an environmental risk assessment of select hazardous chemicals in the new products by comparing ecotoxicity hazard thresholds to predicted exposure concentrations of six chemical ingredients (Appendix 1). Results indicate these hazardous chemicals pose low to negligible environmental risks to aquatic organisms due to the disposal of the new products (Table 3; Appendix 1). Therefore, the Agency does not anticipate significant impacts on POTW or the natural environment.

The Agency does not anticipate significant impacts from disposal of packaging materials and pouches because these materials are similar to other paper and plastic waste and will be handled accordingly. The Agency estimated waste generation by assuming 50g of packaging and pouch materials per the new products sales' unit, multiplied by 2024 market volume (13.96 billion units). Based on this calculation, packaging disposal waste represents a minuscule portion (less than 1%) of the overall MSW, consistent with FDA's experience evaluating tobacco product packaging waste. This percentage remains minimal even without accounting for recycling, although some portion will become litter (U.S. Environmental Protection Agency, 2018).

6. Potential Environmental Effects of the No-Action Alternative

For the purposes of the analysis in this programmatic environmental assessment, it is assumed that there will be no changes to the current market for the new products and no changes to current or future use of the new products. The environmental effects of the no-action alternative will not change the existing conditions of the new products manufacture, use, and disposal and their packaging, as many similar tobacco products will continue to be, manufactured used and disposed of in the United States.

7. List of Abbreviations and Acronyms

APPH- Appropriate for the Protection of the Public Health
CTP- Center for Tobacco Products

FD&C- Food Drug and Cosmetic
HPHCs-Harmful and Potentially Harmful Constituents
iSTREEM- In Stream Exposure Model
MGO- Marketing Granted Order
MSW- Municipal Solid Waste
NEPA- National Environmental Policy Act
PEC- Predicted Environmental Concentration
PMTA- Premarket Tobacco Product Application
PNEC- Predicted No-Effect Concentration
POTW- Publicly Owned Treatment Works

8. List of Preparers

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

Preparers:

Dilip Venugopal, Ph.D., Center for Tobacco Products
- Education: M.S. in Ecology and Ph.D. in Entomology
- Experience: Twenty-three years in regulatory science, environmental regulation, biodiversity conservation, and natural resource management
- Expertise: Toxicology and risk/benefit assessment, environmental impact analysis, ecological applications, socio-environmental synthesis, geo-statistics

Alex Lowe, Ph.D., Center for Tobacco Products
- Education: Ph.D. in Biology
- Experience: Twelve years in environmental science
- Expertise: Ecosystem science, human impacts, and water quality

Daniel Walker, M.S., Center for Tobacco Products
- Education: M.S. in Environmental Studies
- Experience: Sixteen years in environmental regulation, remediation, and conservation
- Expertise: NEPA analysis, water quality, environmental remediation, and Resource Conservation and Recovery Act investigator

Reviewers:

Sharon Edelson-Mammel, DrPH, MS, Center for Tobacco Products
- Education: DrPH in Environmental Health
- Experience: 24 years regulatory consumer safety of food and/or tobacco products
- Expertise: Microbial constituents in tobacco products, environmental science

Ronald L. Edwards Jr., MS, Center for Tobacco Products
- Education: MS in Biology
- Experience: Twenty-eight years in environmental regulation and six years in laboratory toxicology

Expertise: NEPA analysis, heavy metal analysis, water quality, environmental remediation, FDA, EPA, and USDA investigator

Rudaina Alrefai-Kirkpatrick, Ph.D., Center for Tobacco Products
Education: Ph.D. in Plant Molecular Biology and Virology
Experience: Forty-eight years in various scientific activities including fourteen 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: Thirteen years in various scientific activities
Expertise: NEPA analysis; fate, transport, and ecotoxicology of new and emerging contaminants; applications and environmental implications of nanotechnology

9. List of Agencies and Persons Consulted

None

10. References

Back, S., Masser, A. E., Rutqvist, L. E., & Lindholm, J. (2023). Harmful and potentially harmful constituents (HPHCs) in two novel nicotine pouch products in comparison with regular smokeless tobacco products and pharmaceutical nicotine replacement therapy products (NRTs). *BMC Chemistry*, *17*(1), 9. https://doi.org/10.1186/s13065-023-00918-1

Belanger, S., Barron, M., Craig, P., Dyer, S., Galay-Burgos, M., Hamer, M., Marshall, S., Posthuma, L., Raimondo, S., & Whitehouse, P. (2017). Future needs and recommendations in the development of species sensitivity distributions: Estimating toxicity thresholds for aquatic ecological communities and assessing impacts of chemical exposures. *Integrated Environmental Assessment and Management*, *13*(4), 664–674. https://doi.org/10.1002/ieam.1841

Belanger, S., Beasley, A., Brill, J. L., Krailler, J., Connors, K. A., Carr, G. J., Embry, M., Barron, M. G., Otter, R., & Kienzler, A. (2021). Comparisons of PNEC derivation logic flows under example regulatory schemes and implications for ecoTTC. *Regulatory Toxicology and Pharmacology*, *123*, 104933. https://doi.org/10.1016/j.yrtph.2021.104933

Belanger, S., & Carr, G. J. (2019). SSDs revisited: Part II—practical considerations in the development and use of application factors applied to species sensitivity distributions. *Environmental Toxicology and Chemistry*, *38*(7), 1526–1541. https://doi.org/10.1002/etc.4444

Borowiecki, M., Emery, S. L., & Kostygina, G. (2024). New recreational nicotine lozenges, tablets, gummies and gum proliferate on the US market. *Tobacco Control*, *33*(3), 414–416. https://doi.org/10.1136/tc-2022-057673

Codding, E., & Bartram, D. (2005). *Eastern Research Group (ERG). Memorandum to Effluent Guidelines Program Plan Docket, EPA-HQ-OW-2004-0032. "Publicly Owned Treatment Works (POTW) Percent Removals Used for the TRI Releases 2002 Database."* https://www.regulations.gov/docket/EPA-HQ-OW-2004-0032

Connors, K. A., Beasley, A., Barron, M. G., Belanger, S. E., Bonnell, M., Brill, J. L., Zwart, D. de, Kienzler, A., Krailler, J., Otter, R., Phillips, J. L., & Embry, M. R. (2019). Creation of a Curated Aquatic Toxicology Database: EnviroTox. *Environmental Toxicology and Chemistry*, *38*(5), 1062–1073. https://doi.org/10.1002/etc.4382

Czaplicki, L., Patel, M., Rahman, B., Yoon, S., Schillo, B., & Rose, S. W. (2022). Oral nicotine marketing claims in direct-mail advertising. *Tobacco Control*, *31*(5), 663–666. https://doi.org/10.1136/tobaccocontrol-2020-056446

Dai, H. D., & Leventhal, A. M. (2024). Prevalence of Nicotine Pouch Use Among US Adults. *JAMA*, *332*(9), 755–757. https://doi.org/10.1001/jama.2024.10686

Euromonitor International Ltd. (2025). *Market sizes: Nicotine Pouches. Tobacco 2025.* https://go.euromonitor.com/

European Union, European Commission. (2003). *Technical Guidance document on risk assessment in support of commission directive 93/67/EEC on Risk assessment for new notified substances, Commission Regulation (EC) No 1488/94 on risk assessment for existing substances, and directive 98/8/EC of the Euro- pean Parliament and of the Council Concerning the placing of biocidal products on the market* (No. (20418 EN)). European Commission. https://publications.jrc.ec.europa.eu/repository/bitstream/JRC23785/EUR%2020418%20EN-2.pdf

Food and Drug Administration. (2023, June 2). *Results from the Annual National Youth Tobacco Survey | FDA Center for Tobacco Products*. https://web.archive.org/web/20230602033930/https:/www.fda.gov/tobacco-products/youth-and-tobacco/results-annual-national-youth-tobacco-survey

Food and Drug Administration. (2025a, March 6). *Products, Ingredients & Components| FDA Center for Tobacco Products*. FDA; FDA. https://www.fda.gov/tobacco-products/products-guidance-regulations/products-ingredients-components

Food and Drug Administration. (2025b, July 17). *The Relative Risks of Tobacco Products*. FDA, Center for Tobacco Products; FDA. https://www.fda.gov/tobacco-products/health-effects-tobacco-use/relative-risks-tobacco-products

Food and Drug Administration. (2025c, September 29). *21 CFR § 25. Environmental Impact Considerations*. - https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-25

He, Y., Zhang, Z., Keller-Hamilton, B., Mays, D., Wagener, T. L., Berman, M. L., & Shang, C. (2025). Trends of oral nicotine pouch prices and sales by product characteristics in the USA, 2021–2024. *Tobacco Control*. https://doi.org/10.1136/tc-2024-059222

Health and Environmental Sciences Institute (HESI). (2025). *EnviroTox Database & Tools Version 2.0.0 User Guide. Https://envirotoxdatabase.org/index.php/documentation*. https://envirotoxdatabase.org/index.php/documentation

Jamal, A., Park-Lee, E., Birdsey, J., West, A., Cornelius, M., Cooper, M., Cowan, H., Wang, J., Sawdey, M. D., Cullen, K. A., & Navon, L. (2024). Tobacco product use among middle and high school students—National Youth Tobacco Survey, United States, 2024. *MMWR. Morbidity and Mortality Weekly Report*, *73*.

Kapo, K. E., DeLeo, P. C., Vamshi, R., Holmes, C. M., Ferrer, D., Dyer, S. D., Wang, X., & White-Hull, C. (2016). iSTREEM®: An approach for broad-scale in-stream exposure assessment of "down-the-drain" chemicals. *Integrated Environmental Assessment and Management*, *12*(4), 782–792. https://doi.org/10.1002/ieam.1793

Kheawfu, K., Kaewpinta, A., Chanmahasathien, W., Rachtanapun, P., & Jantrawut, P. (2021). Extraction of Nicotine from Tobacco Leaves and Development of Fast Dissolving Nicotine Extract Film. *Membranes*, *11*(6), 403. https://doi.org/10.3390/membranes11060403

Mallock, N., Schulz, T., Malke, S., Dreiack, N., Laux, P., & Luch, A. (2024). Levels of nicotine and tobacco-specific nitrosamines in oral nicotine pouches. *Tobacco Control*, *33*(2), 193–199. https://doi.org/10.1136/tc-2022-057280

Nabholz, J. V. (1991). Environmental hazard and risk assessment under the United States Toxic Substances Control Act. *Science of the Total Environment*, *109–110*, 649–665. https://doi.org/10.1016/0048-9697(91)90218-4

Oropesa, A. L. ; F., António Miguel; Palma, Patrícia. (2017). Toxic potential of the emerging contaminant nicotine to the aquatic ecosystem. *Environmental Science and Pollution Research International*, *24*(20), 16605–16616. https://doi.org/10.1007/s11356-017-9084-4

Page, M. K., Leigh, N. J., Block, A., C., Marrano, P. H., Travers, M. B., Adrover, J. E., Maley, G. E., Koenig, L. A., Salem, E. M., Heldwein, S. D., & Goniewicz, M. L. (2025). Comparison of Nicotine and Selected Flavoring Contents Between Tobacco-Free and Tobacco-Containing Oral Pouches. *Nicotine & Tobacco Research*, ntaf105. https://doi.org/10.1093/ntr/ntaf105

Robichaud, M. O., Seidenberg, A. B., & Byron, M. J. (2020). Tobacco companies introduce 'tobacco-free' nicotine pouches. *Tobacco Control*, *29*(e1), e145–e146. https://doi.org/10.1136/tobaccocontrol-2019-055321

Travis, N., Warner, K. E., Goniewicz, M. L., Oh, H., Ranganathan, R., Meza, R., Hartmann-Boyce, J., & Levy, D. T. (2025). The Potential Impact of Oral Nicotine Pouches on Public Health: A Scoping Review. *Nicotine & Tobacco Research*, *27*(4), 598–610. https://doi.org/10.1093/ntr/ntae131

U. S. Department of Health and Human Services. (2014). *The health consequences of smoking—50 years of progress: A report of the surgeon general* (U. S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, & Office on Smoking and Health, Trans.).

U.S. Environmental Protection Agency. (2018). *Advancing Sustainable Material Management: Facts and Figures*. https://www.epa.gov/sites/default/files/2021-01/documents/2018_ff_fact_sheet_dec_2020_fnl_508.pdf

U.S. Environmental Protection Agency. (2025). *Appendix VIII to Part 261, Hazardous Constituents. Title 40. Identification and Listing of Hazardous Waste*. https://www.ecfr.gov/current/title-40/part-261/appendix-Appendix%20VIII%20to%20Part%20261

World Health Organization. (2017). *Tobacco and its environmental impact: An overview* (p. 72). https://www.who.int/tobacco/publications/environmental-impact-overview/en/

Zafeiridou, M. H., Nicholas S; Voulvoulis, Nikolaos. (2018). Cigarette Smoking: An assessment of tobacco's global environmental footprint across its entire supply chain. *Environmental Science & Technology*, *52*(15), 8087–8094. https://doi.org/10.1021/acs.est.8b01533

Appendix 1. Screening environmental risk assessment of chemicals in oral nicotine products disposed 'down the drain'

The Agency conducted a screening environmental risk assessment of select chemicals in the new products to address the disposal-related effects. The assessment was conducted with the explicit assumption that the entire volume of the new products used enters the municipal wastewater stream through excretion and is released as effluents into surface waters, thereby potentially affecting aquatic organisms.

1. Chemical Selection for Risk Assessment

The Agency cross-referenced chemicals in the new products against the U.S. Environmental Protection Agency's (EPA) hazardous constituents list and selected only those enlisted as hazardous constituents by EPA (U.S. Environmental Protection Agency, 2025). EPA's hazardous constituents list pertains to regulating the disposal of chemicals per Resource Conservation and Recovery Act and Clean Water Act mandates and is relevant for evaluating disposal-related environmental effects of the new products. Six chemicals were selected based on their hazardous waste designation: nicotine – P075, phenol – U188, acetophenone – U004; nickel, chromium and N'-nitrosonornicotine. The P and U lists designate pure and commercial grade chemical formulations as hazardous waste when disposed, with the P list specifically identifying acute hazardous waste.

2. Environmental hazard characterization

The toxicity hazard of the selected new products' chemicals was characterized using Predicted No-Effect Concentration (PNEC) values. PNEC values determine chemical hazard thresholds in environmental risk assessments by incorporating dose-response data from multiple species for acute (short-term) or chronic (long-term) toxicities. When comprehensive ecotoxicity studies or data on the most sensitive species are unavailable, assessment factors are applied to toxicity values as a safety measure to protect sensitive species and ecosystem function (Belanger et al., 2017, 2021; Belanger & Carr, 2019). For the six selected chemicals (Table 1), the Agency estimated the PNEC values- the toxicity hazard threshold - based on available experimental bio-assay data on aquatic toxicity endpoints using the analysis module in the EnviroTox database and tools (Version 2.0.0) (Connors et al., 2019; Health and Environmental Sciences Institute (HESI), 2025). PNEC values for these chemicals were derived from 1117 rows of experimental bioassay data (999 acute and 118 chronic toxicity endpoints) representing 245 unique taxonomic entities (species/genus/taxa) and applying relevant Assessment Factors.

Table 1. The Predicted-No Effect Concentration (PNEC) of select chemicals in the new product for aquatic organisms.

Chemical name	Nicotine	Acetophenone	Phenol	Nickel	Chromium	N'-Nitrosonornicotine
CAS	54115	98862	108952	7440020	7440474	16543558
Acute Algae (mg/L)			132.919	0.132	0.351	51.392

Chemical name	Nicotine	Acetophenone	Phenol	Nickel	Chromium	N'-Nitrosonornicotine
Acute Invertebrate (mg/L)	15.807		97.685	5.857	11.789	0.219
Acute Fish (mg/L)	4.669	169.711	14.693	11.694	63.887	
Chronic Algae (mg/L)		100.000	14.884	5.08	0.015	
Chronic Invertebrate (mg/L)			7.377		0.159	
Chronic Fish (mg/L)	3.281		2.119		4	
Number of Acute Levels	2	1	3	3	3	2
Number of Chronic Levels	1	1	3	1	3	0
PNEC Group	PNEC8	PNEC7	PNEC10	PNEC8	PNEC10	PNEC5
Group Driving PNEC	C.FISH	A.FISH	C.FISH	C.ALGAE	C.ALGAE	A.INVERT
Application Factor	10	100	10	10	10	1000
Final PNEC (mg/L)	0.328	1.697	0.212	0.508	0.002	0.0002
Final PNEC (µg/L)	**328**	**1697**	**212**	**508**	**2**	**0.22**

3. Environmental Exposure Characterization

The Agency modeled the predicted environmental concentrations (PEC) of the six selected chemicals introduced into surface waters, assuming that the entire volume used enters the municipal wastewater stream excreted 'down the drain.' The exposure concentrations of the chemicals were predicted using the widely accepted "in-stream exposure model" (iSTREEM), which accounts for POTW removal rates, and in-river decay rates of the chemicals. iSTREEM is a screening-level exposure and risk assessment tool for chemicals that enter aquatic systems through wastewater treatment systems (Kapo et al., 2016). iSTREEM incorporates data from wastewater treatment plants, sewage discharge, chemical properties, river flow rates and decay. Thereby, the model generates spatially explicit predictions of chemical concentrations in approximately 228,000 river segments in the continental United States that receive municipal wastewater discharges from consumer product disposal (Kapo et al., 2016).

The PECs of the selected chemicals entering surface waters via disposal 'down the drain' was derived using a multi-step process. Annual sales data for nicotine pouch products from EuroMonitor International for 2024 (13.96 billion units; see Figure 1 in the report; Euromonitor International Ltd, 2025) were complied. This represents the highest sales volume in the past few years. Concentrations of specific chemicals in the new products were also compiled from available literature (e.g., Back et al., 2023; Mallock et al., 2024). The total discarded grams of each chemical per capita per day, as required for iSTREEM input, was calculated using the following steps –

Step 1: Calculate Total Chemical Quantity Disposed

$$Total\ Chemical\ Quantity\ (in\ grams)\ Q = MV * N * C * B$$

where,

MV = Total market volume for 2024 (13.9 billion units)

N = Number of pouches per unit (20)

C = Chemical concentration per pouch (assuming highest concentration) in mg

B = conversion factor mg to g (10^{-3})

Step 2: Calculate Total Grams Per Capita Per Day for Each Chemical

$$Total\ Disposed\ Grams\ Per\ Capita\ Per\ Day\ for\ each\ chemical = \ Q \div (P * D)$$

where,

Q = Total chemical quantity in grams from Step 1

P = Total U.S. Population in 2024 (340,110,98)

D = number of days in a year (365)

Information on the removal percentages for selected chemicals at the POTW facilities was compiled (Codding & Bartram, 2005). Also, information on the half-lives for biodegradation for these chemicals, obtained from EPA's Comptox dashboard (https://comptox.epa.gov/dashboard/), was used to derive the in-stream first order decay rate constants (see Table 7; European Union, European Commission, 2003). The PECs of these chemicals were modeled under a low-flow scenario (reflecting seasonal variation and low river flow conditions), a conservative approach, with the calculated g/c/day discarded down the drain, along with POTW removal percentages and in-stream decay values (Table 2).

Table 2. Loading factor calculations and data variables used as input values for predicting exposure of concentrations of the new product chemicals using iSTREEM.

Sales (units) volume 2024	13,960,000,000					
pouches / unit	20.0					
chemical	Nicotine	Phenol	Acetophenone	N-Nitrosonornicotine	Nickel	Chromium
concentration/ pouch (mg)	48	1	0.001	0.005	0.01	0.005
Total concentration (g)	13401600000.0	279200000.0	279200.0	1396000	2792000	1396000
2024 US population	340,110,988	340,110,988	340,110,988	340,110,988	340,110,988	340,110,988
loading factor (grams /capita /day)	0.107955	0.002249	0.000002	0.000011	0.000022	0.000011
Publicly Owned Treatment Works POTW % Removal	2	95	95	0	80	51
In-stream decay / day	0.047	0.047	0.047	0.047	0	0

4. Environmental Risk Characterization

The environmental risk from the selected chemicals was characterized by comparing the environmental toxicity thresholds (PNEC values) to the PEC values from iSTREEM for each chemical. In general, environmental risk is considered low, or negligible if the PEC is less than the PNEC. The environmental risk was characterized as the 90th percentile PEC value exceeding the PNEC value, consistent with regulatory environmental risk assessment guidance for the "worst-case" exposure assessment (Nabholz, 1991).

Results from the comparison of PEC with PNEC indicate that the selected chemicals pose low or negligible environmental risks to aquatic organisms from disposal of the new products (Table 3).

Table 3. Environmental risk of chemicals in the new products based on iSTREEM predicted environmental exposures in effluent-receiving rivers in the United States.

Chemical	Predicted Environmental Concentration (90th percentile PEC; µg/L)	Predicted No-Effect Concentration (PNEC; µg/L)	Environmental Risk (PEC: PNEC ratio)
Nicotine	120.92	328	0.36866
Phenol	0.13	212	0.00061
Acetophenone	0.00011	1697	0.00000
N-Nitrosonornicotine	0.01257	0.22	0.05714
Nickel	0.01405	508	0.00003
Chromium	0.00287	2	0.00144

5. Limitations

While the result of the environmental assessment indicates low to negligible risks, a few limitations related to the assumptions and methods used require consideration. The PEC values are highly dependent on the volume of the new products sales which dictates the overall concentrations of the chemicals entering the environment. Although the environmental risk assessment used the most recent sales data available, future increases in overall market may affect the concentrations of the chemicals entering the environment. Currently, only nicotine pouches sales data are available, and other tobacco products beyond pouch products may increase in sales as they gain market authorization. Therefore, although the Agency's assessment considered 'worst case' scenarios for modeling environmental exposure with high concentration of chemicals, similar future assessment may be warranted. Available baseline ecotoxicity data across taxa vary among the chemicals to estimate the PNECs. For example, more bioassay toxicity data may be available for some species/taxa than others, potentially influencing final PNEC values, although the use of application factors in EnviroTox partly addresses this limitation (Belanger et al., 2021; Belanger & Carr, 2019). Also, the instream decay constant used may not fully account for photodegradation, which affects chemical break-down in the environment. Further, the assessment also does not address the potential effects of plastics and microplastics from the pouch

materials. Finally, the risk assessment focuses on aquatic systems and does not address environmental risks to terrestrial biota, which may be affected in littering scenarios.

Any deviation from disposal-related effects not addressed in the environmental risk assessment will require further evaluation during the environmental review of individual product applications. This is particularly applicable when the new products contain hazardous chemicals not evaluated in this assessment.

List of chemical constituents in oral nicotine products and their EPA hazardous constituents code/listing status.

CASRN	PREFERRED_NAME	EPA Hazardous constituents code and listing
7785-26-4	(-)-alpha-Pinene	
6790-58-5	(-)-Ambroxide	
54-11-5	(-)-Nicotine	P075
10191-41-0	(+/-)-alpha-Tocopherol	
76-49-3	(+/-)-Bornyl acetate	
2216-51-5	(1R,2S,5R)-(-)-Menthol	
93-28-7	(2-Methoxy-4-prop-2-enylphenyl) acetate	
14073-97-3	(2S,5R)-2-Isopropyl-5-methylcyclohexan-1-one	
3681-71-8	(3Z)-3-Hexenyl acetate	
4180-23-8	(E)-Anethole	
25152-84-5	(E,E)-2,4-Decadienal	
23726-92-3	(Z)-1-(2,6,6-Trimethyl-1-cyclohexen-1-yl)-2-buten-1-one	
928-96-1	(Z)-3-Hexen-1-ol	
57-55-6	1,2-Propylene glycol	
470-82-6	1,8-Cineol	
51755-83-0	1-Hexanol, 3-mercapto-	
71159-90-5	2-(4-Methylcyclohex-3-en-1-yl)propane-2-thiol	
14667-55-1	2,3,5-Trimethylpyrazine	
15707-24-1	2,3-Diethylpyrazine	
23696-85-7	2,6,6-Trimethyl-1-crotonyl-1,3-cyclohexadiene	
576-26-1	2,6-Dimethylphenol	
4940-11-8	2-Ethyl-3-hydroxy-4-pyrone	
15707-23-0	2-Ethyl-3-methylpyrazine	
110-43-0	2-Heptanone	
93-51-6	2-Methoxy-4-methylphenol	
90-05-1	2-Methoxyphenol	
116-53-0	2-Methylbutanoic acid	
78-84-2	2-Methylpropanal	
79-31-2	2-Methylpropanoic acid	
60-12-8	2-Phenylethanol	
103-45-7	2-Phenylethyl acetate	
13494-06-9	3,4-Dimethyl-1,2-cyclopentanedione	
95-65-8	3,4-Dimethylphenol	
5392-40-5	3,7-Dimethyl-2,6-octadienal	
121-32-4	3-Ethoxy-4-hydroxybenzaldehyde	
765-70-8	3-Methyl-1,2-cyclopentanedione	
590-86-3	3-Methylbutanal	

CASRN	PREFERRED_NAME	EPA Hazardous constituents code and listing
123-92-2	3-Methylbutyl acetate	
104-54-1	3-Phenyl-2-propen-1-ol	
104-55-2	3-Phenylprop-2-enal	
14901-07-6	4-(2,6,6-Trimethyl-cyclohex-1-enyl)-but-3-en-2-one	
5471-51-2	4-(4-Hydroxyphenyl)butan-2-one	
64091-91-4	4-(N-Methyl-N-nitrosamino)-1-(3-pyridyl)-1-butanone	
2785-89-9	4-Ethyl-2-methoxyphenol	
123-07-9	4-Ethylphenol	
3658-77-3	4-Hydroxy-2,5-dimethyl-3(2H)furanone	
121-33-5	4-Hydroxy-3-methoxybenzaldehyde	
104-50-7	4-Hydroxyoctanoic acid lactone	
123-11-5	4-Methoxybenzaldehyde	
104-21-2	4-Methoxybenzyl acetate	
585-88-6	4-O-alpha-D-Glucopyranosyl-D-glucitol	
104-67-6	5-Heptyldihydro-2(3H)-furanone	
110-93-0	6-Methyl-5-hepten-2-one	
705-86-2	6-Pentyltetrahydro-2H-pyran-2-one	
55589-62-3	Acesulfame potassium	
64-19-7	Acetic acid	
513-86-0	Acetoin	
98-86-2	Acetophenone	U004
22047-25-2	Acetylpyrazine	
127-41-3	alpha-Ionone	
7779-50-2	Ambrettolide	
53956-04-0	Ammonium glycyrrhizate	
100-52-7	Benzaldehyde	
119-61-9	Benzophenone	
100-51-6	Benzyl alcohol	
23726-91-2	beta-Damascone	
8006-82-4	Black pepper oil	
107-92-6	Butanoic acid	
109-19-3	Butyl 3-methylbutanoate	
8028-89-5	Caramel	
497-19-8	Carbonic acid sodium salt (1:2)	
8007-80-5	Cassia oil	
9004-34-6	Cellulose	
8002-66-2	Chamomile oil	
7440-47-3	Chromium	Listed
8015-91-6	Cinnamon oil	

CASRN	PREFERRED_NAME	EPA Hazardous constituents code and listing
77-92-9	Citric acid	
68916-18-7	Coffee bean, roasted, ext.	
84650-00-0	Coffee extract	
68917-18-0	Cornmint oil	
80-71-7	Cyclotene	
2244-16-8	d-Carvone	
112-31-2	Decanal	
713-95-1	delta-Dodecalactone	
698-76-0	delta-Octanolactone	
105-53-3	Diethyl propanedioate	
75-18-3	Dimethyl sulfide	
99-49-0	dl-Carvone	
5989-27-5	D-Limonene	
89-78-1	dl-Menthol	
89-80-5	dl-Menthone	
89-48-5	dl-Menthyl acetate	
64-17-5	Ethanol	
7452-79-1	Ethyl 2-methylbutyrate	
141-78-6	Ethyl acetate	
105-54-4	Ethyl butyrate	
106-30-9	Ethyl heptanoate	
123-66-0	Ethyl hexanoate	
108-64-5	Ethyl isovalerate	
77-83-8	Ethyl methylphenylglycidate	
105-37-3	Ethyl propionate	
118-61-6	Ethyl salicylate	
706-14-9	gamma-Decanolactone	
105-21-5	gamma-Heptalactone	
104-61-0	gamma-Nonanolactone	
72968-42-4	GENTIAN ROOT, EXTRACT (GENTIANA LUTEA L.)	
106-24-1	Geraniol	
105-87-3	Geranyl acetate	
84696-15-1	Ginger extract	
8007-08-7	Ginger oil	
73398-61-5	Glycerides, mixed decanoyl and octanoyl	
56-81-5	Glycerol	
65381-09-1	Glyceryl caprylate caprate	
9000-01-5	Gum arabic	
66-25-1	Hexanal	

CASRN	PREFERRED_NAME	EPA Hazardous constituents code and listing
142-62-1	Hexanoic acid	
142-92-7	Hexyl acetate	
150-78-7	Hydroquinone dimethyl ether	
9004-64-2	Hydroxypropyl cellulose	
8013-17-0	Invert sugar	
64519-82-0	Isomalt	
123-51-3	Isopentyl alcohol	
499-75-2	Isopropyl-o-cresol	
68916-91-6	Licorice extract	
8008-26-2	Lime oil	
138-86-3	Limonene	
78-70-6	Linalool	
115-95-7	Linalyl acetate	
2623-23-6	L-Menthyl acetate	
118-71-8	Maltol	
1490-04-6	Menthol	
24851-98-7	Methyl (2-pentyl-3-oxocyclopentyl)acetate	
119-36-8	Methyl salicylate	
25086-15-1	Methylmethacrylate-methacrylic acid copolymer	
99-76-3	Methylparaben	
77341-67-4	Monomenthyl succinate	
16543-55-8	N’-Nitrosonornicotine	Listed
540-18-1	n-Amyl butyrate	
39711-79-0	N-Ethyl-2-(isopropyl)-5-methylcyclohexanecarboxamide	
7440-02-0	Nickel	Listed
6019-06-3	Nicotine ditartrate dihydrate	
37620-20-5	Nitrosoanabasine	
71267-22-6	N'-Nitrosoanatabine	
124-19-6	Nonanal	
4674-50-4	Nootkatone	
95-48-7	o-Cresol	
124-13-0	Octanal	
124-07-2	Octanoic acid	
638-25-5	Octanoic acid, pentyl ester	
8000-48-4	Oil of eucalyptus	
8001-88-5	Oils, birch-tar	
8015-77-8	Oils, bois de rose	
8000-66-6	Oils, cardamom	
8016-21-5	Oils, cognac	

CASRN	PREFERRED_NAME	EPA Hazardous constituents code and listing
8016-03-3	Oils, davana	
8006-75-5	Oils, dill	
68916-96-1	Oils, Ilex paraguayensis	
8023-95-8	Oils, immortelle	
9000-50-4	Oils, oakmoss-resinoid	
8008-57-9	Oils, Orange, sweet	
68514-75-0	Oils, Orange-juice	
68606-97-3	Oils, peppermint, terpene-free	
8006-87-9	Oils, sandalwood	
106-44-5	p-Cresol	
8006-90-4	Peppermint oil	
8014-17-3	Petitgrain oil	
108-95-2	Phenol	U188
103-82-2	Phenylacetic acid	
89-81-6	Piperitone	
120-57-0	Piperonal	
38462-22-5	p-Mentha-8-thiol-3-one	
9003-39-8	Polyvinylpyrrolidone	
590-00-1	Potassium 2,4-hexadienoate	
94-13-3	Propylparaben	
15932-80-6	Pulegone	
116-26-7	Safranal	
532-32-1	Sodium benzoate	
144-55-8	Sodium bicarbonate	
7647-14-5	Sodium chloride	
1310-73-2	Sodium hydroxide	
128-44-9	Sodium saccharin	
8008-79-5	Spearmint oil	
56038-13-2	Sucralose	
126-14-7	Sucrose octaacetate	
8029-43-4	Syrups, hydrolyzed starch	
68425-17-2	Syrups, hydrolyzed starch, hydrogenated	
8016-84-0	Tagetes minuta flower oil	
89-83-8	Thymol	
28069-72-9	trans-2,cis-6-Nonadien-1-ol	
102-76-1	Triacetin	
51115-67-4	Trimethyl isopropyl butanamide	
7732-18-5	Water	