

## Part IV – Environmental Impact of Food Contact Substance (21 CFR part 25)

### ***B. Environmental Assessment***

This environmental assessment has been prepared in accordance with 21 CFR 25.40(a).

- 1. Date:** 12 November 2019
- 2. Name of Notifier:** Nylon Corporation of America
- 3. Address:** 333 Sundial Avenue  
Manchester, NH 03103

#### **4. Description of Proposed Action:**

Intertek is pleased to submit this Environmental Assessment (EA) on behalf of Nylon Corporation of America as an attachment to a Food Contact Notification (FCN) for the Food Contact Substance (FCS), Fatty acids, C18-unsatd., dimers, hydrogenated, polymers with caprolactam and hexamethylenediamine. The FCS is a nylon polymer with the Chemical Abstracts Service Registry Number (CASRN) 475994-94-6 and is marketed under the trade name NYCOA 2012.

This FCN seeks approval for use in articles or as components of articles that contact all food types under temperature conditions E through G. Thus, the action requested in this FCN is to permit the subject Notifier's NYCOA 2012 polymer (CAS Reg. No.: 475994-94-6) for safe use in articles or as components of single-use food packaging that contact various types of food.

The notifier of this FCN commercializes NYCOA 2012 products that have an approximate molecular weight of 56,000 Daltons. According to the Notifier, the FCS will be used as a single layer within multilayer single-use food packaging for various types of food. See Section 5 for further details. Because the Notifier is not the end-product manufacturer, the percent content of the FCS in final products cannot be entirely predicted.

#### **5. Identification of substances that are the subject of the proposed action:**

The FCS that is the subject of this FCN is NYCOA 2012 (CASRN 475994-94-6). The chemical name of the FCS is Fatty acids, C18-unsatd., dimers, hydrogenated, polymers with caprolactam and hexamethylenediamine.

NYCOA 2012 is made by simple condensation/ring opening polymerization step using four monomers: fatty acids, C18-unsatd., dimers, hydrogenated (Diacid), hexamethylenediamine (HMD); caprolactam; and azelaic acid. Sodium hypophosphite is used as a catalyst and water is used as a solvent.

The general molecular formula for NYCOA 2012 is  $((C_{36}H_{68}O_4)-(C_6H_{16}N_2))_m-(C_6H_{11}NO)_n$  copolyamide and the approximate molecular weight of the NYCOA 2012 polymer is greater than 10,000 Daltons. Thus, the FCS is considered a high molecular weight polymer as per the EPA's High Molecular Weight Polymers in the New

Chemicals Program definition<sup>1</sup>. The structural (graphic) formula is presented below in Figure 1. The FCS is a thermoplastic copolyamide, and thus its appearance is of a white opaque or semi-opaque solid pellet.

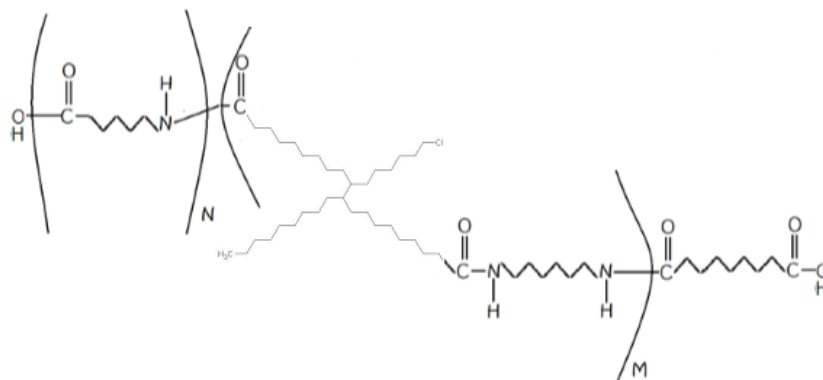


Figure 1: Structural (graphic) formula of NYCOA 2012

The Notifier does not intend to produce finished food-contact articles from the FCS. Rather, the FCS is produced by the Notifier as a component of varying finished polymeric materials that will be sold to manufacturers of finished food-contact articles. Nylon Corporation of America has both their headquarters and production plants located in New Hampshire. No environmental releases are expected from the production of the FCS. The NYCOA 2012 polymer is produced in the Manchester, NH facility. With a global distribution and client network, the FCS will be sold to manufacturers across the USA for inclusion in finished food-contact articles.

NYCOA 2012 is a single polymer layer in multilayer, single-use food packaging. The NYCOA 2012 polymer has desirable properties of copolyamides including yielding of extremely tough and resilient finished food-contact articles while maintaining flexibility and low moisture absorption.

## 6. Introduction of substances into the environment:

Given the known uses of NYCOA 2012 in various polymer materials and products, discussed in Section 5 above, we can expect the polymer to be used with typical polymer products in the food packaging industry, primarily in multilayer films. Therefore, in the context of food contact products, the introduction of the FCS into the environment is expected to be as a component of multilayer films at the end of life or disposal. This EA therefore, focuses on possible end-of-life pathways for the FCS as a component of multilayer films.

The FCS is manufactured in New Hampshire, USA by the Nylon Corporation of America and customers in the USA will use the FCS in the production of multilayer packaging and food contact articles. Disposal of the FCS in food contact articles is anticipated in various jurisdictions across the USA in patterns corresponding to population and disposal, recycling, and combustion rates described below.

<sup>1</sup> U.S. Environmental Protection Agency. High Molecular Weight Polymers in the New Chemicals Program. Available at <https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/high-molecular-weight-polymers-new>

The United States Environmental Protection Agency (US EPA) releases facts, figures and trends in municipal solid waste, recycling, composting, combustion and landfilling across the USA<sup>2</sup>. The most recent, *Advancing Sustainable Materials Management: 2015 Fact Sheet*, gives us perspective on the typical pathways for consumer polymer products disposal throughout the USA. Overall, of 262.4 million short tons of municipal solid waste generated in the United States in 2015, 25.8% was recycled, 8.9% was composted, 52.5% was landfilled and 12.8% was combusted with energy recovery<sup>3</sup>.

As discussed in Section 5 above, the FCS is a copolyamide primarily used as a single polymer layer in multilayer, single-use food packaging. Thus, the disposal rates for the FCS can be aligned with the subcategory “total plastics in containers and packaging” in the US EPA *Advancing Sustainable Materials Management: 2015 Tables and Figures report outlining* disposal and diversion trends<sup>4</sup>. Plastics in containers and packaging accounted for 14.68 million tons (5.6%) of total generated municipal solid waste in 2015. Of this amount, 2.46 million tons (16.8%) was combusted with energy recovery, 10.07 million tons (68.6%) was landfilled and 2.15 million tons (14.6%) was recycled<sup>5</sup>. For the purposes of the GHG emissions calculations presented in the confidential attachment, the more conservative overall disposal and diversion figures were used.

**Combustion:** The FCS consists of carbon, oxygen, nitrogen, and hydrogen as detailed in Section 5 above; elements that are normally found in municipal solid waste.

Complete combustion of nitrogen-containing hydrocarbons, such as the FCS, results in products including carbon dioxide (CO<sub>2</sub>), nitrous oxide (N<sub>2</sub>O), and water. The FCS is not expected to cause municipal solid waste combustors to threaten a violation of applicable emissions laws and regulations (i.e., 40 C.F.R Part 60 and/or relevant state and local laws).

Considering the worst-case scenario that the FCS is not recycled and only landfilled or combusted, it has been determined through calculations (see confidential attachment) and the use of the US EPA Greenhouse Gas Equivalencies Calculator<sup>6</sup>, that worst case of approximately 232 metric tons of equivalent carbon dioxide (eCO<sub>2</sub>) emissions would be produced as a result of combustion from incineration.

To evaluate the significance of the environmental impact of these GHG emissions, we refer to CEQ regulations under 40 CFR 1508.27, which defines 'significantly' as it relates to assessing the intensity of an environmental impact in NEPA documents. 40 CFR 1508.27(b)(10) states, that when evaluating intensity of an impact, one should consider "whether the action threatens a violation of Federal, State, or local law or requirements imposed for the protection of the environment." MSW combustion facilities are regulated by the EPA under 40 CFR 98, which “establishes mandatory GHG reporting requirements for owners and operators of certain facilities that directly emit GHG”. Part 2 of this regulation (40 CFR 98.2), describes the facilities that must report GHG emissions

<sup>2</sup> US EPA (2018) *Advancing Sustainable Materials Management: 2015 Fact Sheet*. Available at [<https://www.epa.gov/facts-and-figures-about-materials-waste-and-recycling/advancing-sustainable-materials-management>]

<sup>3</sup> Ibid. Figure 3 (Page 3). Management of MSW in the United States, 2015. 2015 data.

<sup>4</sup> US EPA (2018) *Advancing Sustainable Materials Management: 2015 Tables and Figures*. Available at [<https://www.epa.gov/facts-and-figures-about-materials-waste-and-recycling/advancing-sustainable-materials-management>]

<sup>5</sup> Ibid. Table 8 (page 9). percent of total generated = 14.68 million tons (mt) ÷ 262.4 mt x 100 = 5.6%; percent combusted = 2.46 mt ÷ 14.68 mt x 100 = 16.8%; percent landfilled = 10.07 mt ÷ 14.68 mt x 100 = 68.6%; percent recycled = 2.15 mt ÷ 14.68 mt x 100 = 14.6%

<sup>6</sup> US EPA (2016) Greenhouse Gas Equivalencies Calculator. Available at [<https://www.epa.gov/energy/greenhouse-gasequivalencies-calculator>]

and sets an annual 25,000 metric ton eCO<sub>2</sub>-emission threshold for required reporting. Based on the confidential market volume, the expected carbon dioxide equivalent emissions, as shown above, are below 25,000 metric tons on an annual basis. As the estimated GHG emissions are well below the threshold for mandatory reporting, no significant environmental impacts are anticipated to result from combustion of the FCS in MSW combustion facilities.

**Landfill:** No significant amounts, if any, of NYCOA 2012 polymers are expected to enter the environment as a result of landfill disposal of food contact packaging materials manufactured with materials containing the FCS, in light of the Environmental Protection Agency (EPA) regulations governing municipal solid waste landfills<sup>7</sup>. EPA's regulations require new municipal solid-waste landfill units and lateral expansions of existing units to have composite liners and leachate collection systems to prevent leachate from entering ground and surface water, and to have groundwater monitoring systems. Although owners and operators of existing active municipal solid waste landfills that were constructed before October 9, 1993, are not required to retrofit liners and leachate collection systems, they are required to monitor groundwater and to take corrective action as appropriate.

The FCS contains only minute levels of extractable materials, as confirmed by either worst-case calculation or extractable residue analysis.

Considering the foregoing discussion on combustion and landfill of the FCS, we respectfully submit that the use of the FCS would not create a significant environmental impact via its inclusion in market-ready products.

Additionally, 21 C.F.R § 25.40(a) indicates that an environmental assessment ordinarily should focus on relevant environmental issues relating to its use and disposal from use, rather than the production and manufacture of food contact articles. No environmental releases are expected with the use of the subject FCS to fabricate food-contact materials at manufacturer locations. In these applications, the FCS will be entirely incorporated into the finished food contact articles. Any waste materials generated in this process, *e.g.* scraps, are expected to be disposed of as part of the manufacturer's non-hazardous solid waste in accordance with established procedures.

## **7. Fate of Emitted Substances in the Environment**

**Air:** No significant effects on the concentrations of and exposures to any substances in the atmosphere are anticipated due to the proposed use of the NYCOA 2012 polymer. The polymer has a high molecular weight and does not volatilize. Therefore, no significant quantities of any substances will be released into the air upon use and disposal via landfill of food packaging materials manufactured with the NYCOA 2012 polymer. As detailed in Section 6, complete combustion of the FCS may result in products including carbon dioxide, nitrous oxide, and water.

**Water:** No significant effects on the concentrations of and exposures to any substances in freshwater, estuarine, or marine ecosystems are anticipated due to the proposed use of the FCS. No significant quantities of any substance will be added to ground or surface water systems through either the proper incineration of the FCS or through their disposal in landfills due to the very low levels of extractable residue of NYCOA 2012.

<sup>7</sup> U.S. Environmental Protection Agency. *Criteria for Municipal Solid Waste Landfills*. 40 C.F.R. part 258

As detailed in Section 6, EPA's regulations at 40 CFR 258 require new municipal solid-waste landfill units and lateral expansions of existing units to have composite liners and leachate collection systems to prevent leachate from entering ground and surface water, and to have groundwater monitoring systems. Although owners and operators of existing active municipal solid waste landfills that were constructed before October 9, 1993 are not required to retrofit liners and leachate collection systems, they are required to monitor groundwater and to take corrective action as appropriate.

**Land:** No significant effects on the concentrations of and exposures to any substances in terrestrial ecosystems are anticipated as a result of the proposed use of the NYCOA 2012. Any leaching that could potentially occur under normal environmental conditions which finished food packaging materials are disposed would be expected to be captured within landfill leachate containments and/or identified during regular monitoring efforts. Further, concentrations of monomers calculated to migrate from the packaging into food are very low so as to be considered negligible in the environment. Therefore, there is no expectation of any meaningful exposure of terrestrial organisms to the NYCOA 2012 polymer as a result of their proposed use in food contact articles in contact with fatty foods

## **8. Environmental Effects of Released Substances**

As discussed in the sections above, the only substances expected to be released to the environment from the use and disposal of food packaging materials containing NYCOA 2012 polymer consist of small quantities of combustion products. Extractable compounds are anticipated to be negligible given the nature of use of the polymer in finished products, and further, any disposed material would be expected to enter a landfill which have leachate capture systems as discussed in Sections 6 and 7 above. Therefore, no significant impacts on organisms in the environment are expected as a result of the use and disposal of finished food-contact articles containing the FCS. In addition, the use and disposal of the FCS is not expected to threaten a violation of applicable laws and regulations, *e.g.*, 40 CFR Part 60 (regulation of solid waste combustors) and Part 258 (regulation of landfills).

## **9. Use of Resources and Energy**

NYCOA 2012 is comprised of carbon, hydrogen, nitrogen and oxygen atoms and is derived from resources such as petroleum and water.

The effects of use and disposal of the FCS in food-contact articles was discussed in-depth in Section 6 of this environmental assessment. Thus, it is not anticipated that the production or fabrication of the FCS will have a significant environmental impact on resource use.

To achieve the desired characteristics of the final food-contact article, NYCOA 2012 is used as a single layer in multilayer, single-use food packaging products. NYCOA 2012 offers high thermal and chemical resistance properties similar to Nylon 6 polymer, while providing enhanced flexibility and toughness with low moisture absorption. Because the FCS is used in a manner that enhances the properties of food contact articles, we can expect that it may be selected in place of other thermoplastic polymer products that may have higher burdens on the environment. Thus, the replacement of currently used materials with the FCS is not expected to have significant environmental impact on the use of energy and resources. Manufacture of the FCS and its fabrication in food packaging articles will consume energy and resources in amounts comparable to the manufacture and

use of materials currently used.

## **10. Mitigation Measures**

As detailed in the sections above, no significant environmental impacts are anticipated. This is primarily due to the extremely low levels of leaching of potential migrants from the FCS, the insignificant impact on environmental concentrations of combustion products of the polymer, and the minor impacts on the recyclability of products made with the FCS. Thus, the FCS as proposed is not reasonably expected to result in any significant environmental impact that requires mitigation.

## **11. Alternatives to the Proposed Action**

As concentrations of monomers calculated to migrate from the packaging into food are very low so as to be considered negligible in the environment, the NYCOA 2012 polymer is not expected to migrate into food from food contact materials or into the environment through disposal pathways (i.e. land, water, air). Additionally, discussions on the environmental effects of combustion, landfilling, resources use and energy demonstrate that the FCS is not expected to have any significant environmental impacts that would necessitate alternative actions to those proposed in this notification. Thus, the use and disposal of the FCS as is outlined in this Environmental Assessment will have no significant impacts on the environment. Further, the alternative of not approving the action notified herein would result in the continued use of the materials that the subject FCS would otherwise replace. Such action would have no significant environmental impact.

## **12. List of preparers**

**Naeem Mady**, M.Sc.

VP of Regulatory Services, *Food Contact and Regulatory Services*, Intertek Health, Environmental, and Regulatory Services. With an educational background in Chemistry, Naeem has over 30 years of experience in chemical, health, and regulatory consulting.

**Sabrina Cescolini**, P.Eng, M.Sc., LEED AP, WELL AP

Program Manager - Sustainability, *Environmental, Safety and Sustainability Group*, Intertek Health, Environment and Regulatory Services. An Environmental Engineer with over 11 years of experience in environmental and sustainability consulting.

**Kirsten Hoedlmoser**, P.Eng., M.Eng., CHSC

Manager – Environmental and Safety, *Environmental, Safety and Sustainability Group*, Intertek Health, Environment and Regulatory Services. A Chemical Engineer with over 7 years of experience in chemical and environmental engineering and health and safety consulting.


## **13. Certification**

The undersigned officially certifies that the information presented is true, accurate, and complete to the best of

their knowledge.

April 15, 2020

Sincerely,



Naeem Mady  
VP, Regulatory Services  
Health, Environmental, & Regulatory Services  
Intertek

**14. References:**

Johnke B, Hoppaus R, Lee E, Irving B, Martinsen T, and Mareckova K. Emissions from Waste Incineration. *Good Practise Guidance and Uncertainty Management in National Greenhouse Gas Inventories*.

Polymer Properties Database (2015). *Heat Distortion Temperature*. Available at [<http://polymerdatabase.com/polymer%20physics/HeatDistortion.html>]

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**Appended:** Confidential Attachment: GHG Emissions