

Part IV - Environmental Impact of Food Contact Substance (21 CFR Part 25) Environmental Assessment

- 1) **Date:** April 23, 2015
- 2) **Name of Notifier:** Nestlé Nutrition U.S.
- 3) **Address:** Nestlé Nutrition U.S.
12 Vreeland Rd.
Florham Park, NJ 07932

All communication regarding this food contact notification (FCN) environmental assessment (EA) should be sent to the attention of the authorized representative:

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4) **Description of the proposed action:**

Requested action:

The action requested in this submission is the food contact notification (FCN) of the use of the food contact substance (FCS) polyvinylpyrrolidone-vinyl acetate copolymer (PVP-VA) (CAS RN 25086-89-9) as a pore forming agent in the production of a polymeric microporous poly(1,4-phenylenethersulfone) membrane, i.e. PESU membrane, that is used as a water filtering component of the Nestlé Gerber® BabyNes® Advanced Nutrition System (BabyNes ANS).

Need for action:

The manufacture of the PESU membrane involves no chemical reaction. The base polymer PESU is made by BASF (Ultrason E6020P), which has an effective FCN (FCN 726). The process uses several processing aids, including the FCS (PVP-VA) as a pore-forming

agent. This FCN is prepared to address the safety of the residual level of PVP-VA on the PESU membrane. Please see Confidential Attachment A for additional manufacturing details, which are claimed as confidential business information (CBI).

Condition of use:

The Babyne ANS dispensing machine utilizes single-serve capsules (or pods) containing powdered infant formulas or toddler beverages to be further diluted with water at ambient temperature to maximum temperature of 45 °C (machine operating temperature 40 ± 5°C). Inside the single-serve capsule the warmed water is filtered through the PESU membrane to remove microorganisms larger than 0.2 µm. The PESU membrane that contains residual levels of the FCS directly contacts the water being filtered but does not come into contact with the powdered infant formulas.

Location of use:

Within the Babyne ANS, the PESU membrane is incorporated into the single-serve capsules (or pods) that contain powdered infant formulas or toddler beverages. The PESU membrane and the capsules will be manufactured outside of United States. Once the infant formula or toddler beverage is made and delivered into the baby bottle, the capsule is disposed and the PESU membrane is also disposed along with the capsule. The capsule will be utilized in patterns corresponding to the national population density, including rural and urban residential neighborhoods, businesses, medical facilities, etc. and will be widely distributed across the country.

Location of Disposal:

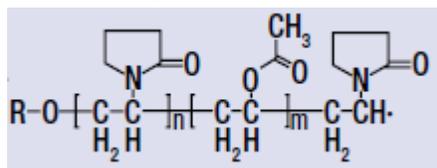
The PESU membrane, along with the Babyne ANS capsule, will be disposed of through municipal solid waste (MSW) systems nationwide throughout the United States. According to the U.S. Environmental Protection Agency (EPA)'s data regarding MSW in the United States, of the total 251 million tons of MSW generated in 2012, approximately 135 million tons (53.8%) generally was landfilled, 29.3 million tons (11.7%) was combusted, and 86.6 million tons (34.5%) was recovered for recycling (including composting) (U.S. EPA, 2014a).

Pursuant to the Council on Environmental Quality (CEQ) "Revised Draft Guidance for Greenhouse Gas Emissions and Climate Change Impacts," a quantitative analysis is required if greenhouse gas (GHG) emissions from the action are expected to exceed

25,000 metric tons CO₂ equivalent on an annual basis. Based on market volume information provided in Confidential Attachment D, the expected carbon dioxide emissions from combustion of discarded pods are below 25,000 metric tons on an annual basis; therefore, no quantitative analysis is required for this action.

5) Identification of the chemical substances that are the subject of the proposed action:

- CAS name and number: Polyvinylpyrrolidone-vinyl acetate copolymer (PVP-VA) (CAS RN 25086-89-9)
- Physical description: White powder
- Molecular formula:
(C₆-H₉-N-O.C₄-H₆-O₂)_x-
- Structural (graphic) formula:



Additional information related to the identification of the chemical substances that are the subject of the proposed action is claimed as CBI and is included in Confidential Attachment B.

6) Introduction of substances into the environment:

Introduction of substances into the environment as a result of manufacture:

The PESU membranes and Babyne ANS capsules will be manufactured outside of United States. Under 21 CFR 25.40(a), an environmental assessment ordinarily should focus on relevant environmental issues relating to the use and disposal from use, rather than the production, of FDA-regulated articles. Information has been provided by the manufacturer of the PESU filters related to the manufacture of the PESU membrane that demonstrates compliance with local and national regulations; there are no extraordinary circumstances in this case indicative of any adverse environmental impact as a result of its manufacture. Please see Confidential Attachment C for this information, which is claimed as CBI.

Introduction of substances into the environment as a result of use and disposal:

The maximum yearly market volume of the Babyne ANS capsule, in which the FCS is contained, based on total fifth year production estimates, would be disposed of

amongst MSW locations within the United States. This estimate is based on a projection of the number of capsules disposed of during the year. Two capsule sizes are available and, for both sizes, the PESU membrane weighs a fraction of the capsule weight. Details on the fifth year production estimates, projected number of capsules disposed of during the year, and disposal calculations are claimed as CBI and are included in Confidential Attachment D.

i. Landfills:

The proposed use of the capsule, including the FCS, and the market volume indicate that the capsule will make up a negligible portion of MSW in the United States that is disposed in landfill (U.S. EPA, 2014a). Additional information related to this determination is claimed as CBI and is included in Confidential Attachment D. Moreover, municipal solid waste landfills are regulated by the U.S. EPA (40 CFR Part 258) to restrict movement of waste into the environment, including location restrictions, composite liner requirements, leachate collection and removal systems, operating practices, groundwater monitoring requirements, and closure and post-closure care requirements (U.S. EPA, 2014b).

ii. Combustion:

The capsule, including the FCS, is composed of carbon, hydrogen, nitrogen, aluminum and oxygen, elements commonly found in municipal solid waste. The proposed use of the capsule and the market volume indicate that the use will make up a negligible portion of the total municipal solid waste combusted (U.S. EPA, 2014a). Additional information related to this determination is claimed as CBI and is included in Confidential Attachment D. Therefore the capsule, including the FCS, will not significantly alter the emissions from properly operating municipal solid waste combustors. Ultimately incineration of the capsule, including the FCS, will not result in a violation of applicable emissions laws and regulations for MSW combustors (40 CFR Part 60, as well as relevant state and local laws).

7) Fate of substances released into the environment:

Negligible amounts of the FCS are expected to be released into the environment as the result of use and disposal of the capsules. As discussed in Item 6, we do not expect any release to the environment as a result of the use and disposal of the FCS; therefore, we do not discuss fate or effects of the FCS in the environment.

8) Environmental effects of released substances:

Because negligible amounts of the FCS are expected to be released into the environment as the result of use and disposal of the capsules it is unlikely that the FCS will be a risk to aquatic or terrestrial organisms. As discussed in Item 6, we do not expect any release to the environment as a result of the use and disposal of the FCS; therefore, we do not discuss fate or effects of the FCS in the environment.

9) Use of resources and energy:

As described in Item 6, the Babynes ANS capsules and the PESU membranes, which contain residual amounts of the FCS, are manufactured outside of the United States. As is the case with other food contact materials, the production, use and disposal of the capsule and the FCS will involve the use of energy and natural resources such as petroleum products, coal, etc. The base PESU polymer membrane, the capsule body composed of polypropylene and the aluminum membrane are typical of similar filtration and single-use beverage capsules on the market; however, in the United States, the use and subsequent disposal of the FCS-containing capsules is not expected to result in a net increase in the energy and resources required to transport and/or dispose of wastes, as the disposal of the FCS-containing capsules is estimated to comprise a negligible component of MSW streams. In the United States, the annual disposal of FCS-containing capsules is expected to comprise a negligible component of total-generated MSW, as well as negligible components of landfilled and combusted MSW (U.S. EPA, 2014a). Additional information related to this determination is claimed as CBI and is included in Confidential Attachment D.

For the above stated reasons, the use of the FCS as described in this Notification will not have an adverse impact on energy and resources.

10) Mitigation measures:

We identify no adverse environmental risk, based upon our review of adequate and complete data information. Therefore no mitigation measures are required.

11) Alternatives to the proposed action:

No potential adverse environmental effects are identified herein which would necessitate alternative actions to that proposed in this request. Therefore, alternatives to the proposed action need not be considered.

12) List of Preparers:

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Ms. Sarraino has seven years of experience in chemical exposure assessment, environmental fate and ecological exposure modeling, and the research and review of environmental prevalence, biomonitoring, occupational exposure, chemical residue, and toxicity data.

13) Certification:

The undersigned official certifies that the information provided herein is true, accurate, and complete to the best of my knowledge.



Date: April 23, 2015

14) References:

Council on Environmental Quality (CEQ). Revised Draft Guidance on Consideration of Greenhouse Gas Emissions and the Effects of Climate Change. December 18, 2014. https://www.whitehouse.gov/sites/default/files/docs/nepa_revised_draft_ghg_guidance.pdf, accessed 4/23/2015.

U.S. Environmental Protection Agency (EPA). 2014a. Municipal Solid Waste Generation, Recycling, and Disposal in the United States: Facts and Figures for 2012. EPA-530-F-014-001, February 2014, Washington DC. Available at: http://www.epa.gov/waste/nonhaz/municipal/pubs/2012_msw_fs.pdf, accessed 2/26/2015

U.S. Environmental Protection Agency (EPA). 2014b. Wastes – Non-Hazardous Waste - Municipal Solid Landfills. Available at:
<http://www.epa.gov/waste/nonhaz/municipal/landfill.htm>. Last updated: January 10, 2014, accessed 2/26/2015

15) Attachments:

CONFIDENTIAL ATTACHMENT A: Manufacturing Details
(Separate enclosure)

CONFIDENTIAL ATTACHMENT B: Chemical Molecular Weight and Spectra
(Separate enclosure)

CONFIDENTIAL ATTACHMENT C: Environmental Aspects of Membrane Production
(Separate enclosure)

CONFIDENTIAL ATTACHMENT D: Market Volume and Associated Disposal Calculations
(Separate enclosure)