

Position on Impact of Pharmaceuticals and Personal Care Products in the Environment

Background

Pharmaceuticals and personal care products (PCPs) can enter the environment through several different pathways. The source of most active pharmaceutical ingredients (APIs) detected in aquatic ecosystems is normal patient and consumer use and excretion following the use of medicines that are taken to address medical conditions,¹ while PCP ingredients can enter the environment from washing off products from the body during cleansing activities.¹

As a leading global consumer health company, we recognize that human health and environmental health are inextricably linked. Our goal is to help people take care of themselves and their loved ones everyday while also protecting the planet. To do this, we take proactive steps to assess and address pharmaceuticals and personal care products in the environment as part of our ambition to create products that support the health and well-being of both people and our planet.

Our Approach

We are committed to the proactive risk assessment of our APIs and personal care ingredients that may enter aquatic and terrestrial ecosystems. We do this by:

- **Conducting environmental risk assessments (ERAs) on APIs and ingredients used in our products to understand any possible impacts in the environment**

ERAs can range from exposure assessments and screening for characteristics of persistence, bioaccumulation and toxicity (PBT) for low-volume products² to more extensive risk assessments that determine predicted no-effect concentrations (PNECs) based on environmental toxicology tests.

¹ Environmental Safety Aspects of Personal Care Products, <https://doi.org/10.1897/09-104.1>

² Products that result in a predicted surface water concentration of less than 0.01 µg/L

- **Advancing the science of assessing the environmental impacts of personal care products**

For our personal care products that are susceptible to entering the environment, there is no regulatory-mandated or established and standardized industry ERA methodology. Therefore, we developed and patented, a science-based method to assess the potential aquatic impacts of formulations under development. This method, referred to as Global Aquatic Ingredient Assessment Tool™ (GAIA), helps ensure that our products meet our product stewardship standards designed to minimize environmental impacts. Using GAIA, ingredients are scored on a 100-point scale using available data on inherent PBT and other environmental safety properties. A higher score indicates more favorable environmental safety characteristics. When published data are not available, we use modeled data and reduce GAIA scores to account for uncertainty. More information regarding our GAIA approach can be found at Kenvue.com. Our GAIA method to evaluating ingredients has also been published in a peer-reviewed journal.³

We are committed to controlling the concentrations of active pharmaceutical ingredients that may enter the environment from our manufacturing plants.

At our manufacturing plants handling active pharmaceutical ingredients, we monitor our wastewater using a variety of methods (e.g., analytical testing, mass balance calculations and whole effluent testing). We provide secondary wastewater treatment, at a minimum, for our manufacturing plants, and treatment may also include advanced technologies that target removal of APIs from wastewater

We are committed to collaborating with suppliers and educating patients and consumers to help mitigate concentrations of active pharmaceutical ingredients in the environment.

As outlined in our Responsibility Standards for Suppliers, suppliers to Kenvue are expected to operate in a sustainable and environmentally responsible manner, including continually working to reduce the environmental impacts of their operations and implementing programs to manage wastewater that ensure compliance and mitigate impacts to the environment. We verify supplier environmental performance through a comprehensive approach including: on-site audits conducted by Kenvue environmental professionals; supplier scans through EcoVadis, a sustainability ratings firm that evaluates companies' environmental and social responsibility; and through membership in the Pharmaceutical Supply Chain Initiative, which sets common standards for responsible supply chain practices.

We educate patients and consumers on how to locate disposal options and instruct them on proper disposal methods to limit environmental impact. We do this through several outreach efforts including participation in the MyOldMeds initiative in the United States and MEDSDISPOSAL in the EU. We are also a member of the Pharmaceutical Product

³ Reducing the environmental risks of formulated personal care products using an end-of-life scoring and ranking system for ingredients: Method and case studies, <https://doi.org/10.1016/j.jclepro.2018.01.140>

Stewardship Working Group, which is the largest extended producer responsibility (EPR) organization in the United States dedicated to the proper collection and disposal of unused and/or expired medicines as well as used sharps.

We believe in the power of partnerships to accelerate the advancement of science. We demonstrate this belief by proactively collaborating with other commercial partners.

We often partner with our peers in the pharmaceutical and personal care products industries to drive progress on these issues. For example, we are contributing to the European-based Inter Associations Initiative Pharmaceuticals in the Environment Task Force, which created the Eco-Pharmaco-Stewardship framework to address pharmaceuticals in the environment (PiE). This includes an approach to extended environmental risk assessments for pharmaceuticals. For more information on this effort, visit the Association of the European Self-Care Industry (AESGP) website⁴.

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⁴ <https://aesgp.eu/eco-pharmaco-stewardship>