March 30th, 2021

Response to Correspondence Regarding Beckman Coulter's NPnEO and OPnEO's Authorisation Application

Reference Number: 0186

Application Received: 16 February 2021

Inquiry From: Department for Environment, Food and Rural Affairs (DEFRA)

Date of Inquiry: 24 March 2021

Scope: Request for further information on Application for Authorisation ID0186

Substance(s): 4-(1,1,3,3-tetramethylbutyl) phenol, ethoxylated (4-tert-Octylphenol ethoxylates) (4-tert-OPnEO) and 4-Nonylphenol, branched and linear, ethoxylated (4-NPnEO)

Uses: 3, 4, and 5

Due Date: 01 April 2021

Dear Madam and/or Sir,

In response to the inquiry from DEFRA regarding the above reference number, Beckman Coulter wishes to provide the following information.

Questions from DEFRA

1) We would like an indication of how many customers are based in GB (England/Scotland/Wales), and what waste management practice looks like for these customers for their solid and liquid wastes containing 4-tert-OPnEO and 4-NPnEO.
This question is in relation to the paragraph from page 19 of ECHA's opinion for Use 3 on results of the second survey, to better qualify how downstream users handle the liquid and solid waste, along with Table 37 on page 84 of your submitted Chemical Safety Report (included below).

i.e. Of the [redacted]% of respondents for Use 3, how many were GB downstream users, and of that percentage, what percentage were and were not capturing liquid waste for treatment? The same questions would apply to Uses 4 and 5, and for solid waste. In case these data sets are not available for GB, are confidential, or the number of GB responders to the survey was so low that responses cannot be used to extrapolate to the whole of the GB market with any certainty, please can you provide us with an estimate of relative market size and any other information you may have on relevant waste management practices?

Table 37: Customer Survey Results – Percent of total respondents

Rate of response as a % of total respondents			
Use	% of Total Surveyed Respondents	Capturing Liquid Waste for Treatment	Not Capturing Effluent Waste
[redacted]			
Use	% of Total Respondents	Capturing Residual/Solid Waste for Treatment	Not Capturing Residual/Solid Waste
[redacted]			

BEC Response 1:

There are approximately over one hundred downstream users based in the United Kingdom. We received over [redacted]% of responses and all responded that the product's the liquid wastes and solid waste was collected for adequate treatment. Since ECHA did not have a concern for downstream users of Use 4 and Use 5, these customers were not included in scope of the survey.

Questions from DEFRA

2) On pages 22-24 of the CSR, tonnage of substances and numbers of 'sites' are stated as follows:
Use 3 OPnEO: (100-1,000) kg across ca. [redacted] sites
Use 3 NPnEO: (1,000-10,000) kg across ca. [redacted] sites
Use 4 OPnEO: (0.1-1) kg across ca. [redacted] sites
Use 4 NPnEO: (0.1-1) kg across ca. [redacted] sites
Use 5 OPnEO: (1-10) kg across ca. [redacted] sites

Are you able to clarify:

a) Whether, for example, the [redacted] sites for OPnEO in Use 3 are included within the [redacted] sites of NPnEO in Use 3, or whether there are ca. [redacted] sites in total for Use 3?
b) What these figures (tonnage and site numbers) might look like for GB sites only?

BEC Response:

2a). The total number of sites for Use 3 is [redacted] It is made up of [redacted] sites using reagents containing OPnEO and [redacted] sites using reagents containing NPnEO.

2b). Based on an initial GB customer analysis the Use 3 NPnEO annual tonnage is approximately [redacted] KG (based on 2020-2021 data). The other categories will therefore be significantly lower than this value, in line with the overall tonnage chart above.

The value for NPnEO will further decrease by approximately [redacted] % to [redacted] Kg after the first wave of reformulations in 2022

The value for OPnEO will further decrease by approximately [redacted] % to [redacted] Kg after the first wave of reformulations in 2025

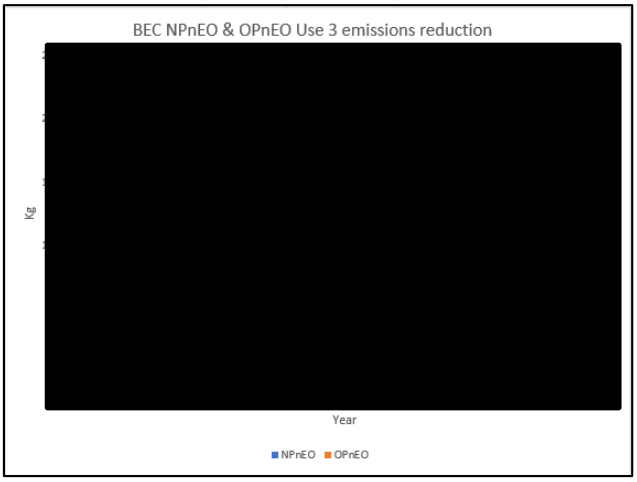
The number of GB users is over one hundred though a significant number of these show very low usage suggesting that they are not routine users of these products.

Questions from DEFRA

3) Quantified and/or qualitative impacts of ECHA's proposed conditions, specifically on GB downstream users.

BEC Response 3:

Beckman Coulter's proposed reformulation strategy is designed to maximize reduction of NPnEO and OPnEO, while minimizing the impact to the UK Healthcare system (downstream users). Product reformulations will take place in a series of waves; where products with the highest emissions concentrations will be reformulated first.



The data shown is specific to the GB downstream users

Based on the aggressive reformulation strategy provided in the application, ECHA did not impose additional conditions other than what is in place that would impact downstream users of Use3, Use4 and Use5 products.

ECHA's recommendation for downstream users are listed below:

A) Continue collecting all solid waste containing 4-ter-OPnEO and 4-NPnEO for adequate treatment.
B) Continue the collection of liquid wastes containing 4-ter-OPnEO and 4-NPnEO for adequate treatment at the sites where it is already implemented

4) Quantified and/or qualitative impacts in a non-use scenario on GB downstream users (e.g. forgone profits and job losses).

BEC Response 4:

Products for Use 3 are used for routine hospital diagnostic testing – restrictions to the supply of these products would require hospitals to source other commercially available products to complete their patient test panels – these alternative products may not be operate on Beckman Coulter instruments, and alternative instrumentation may need to be procured. Costs for small lab instruments range from £[redacted] to >£[redacted] with larger equipment ranging from £[redacted] to £[redacted] - lease options may be available. Implementation of new equipment is not a quick process – installation, training and validation of equipment to a state where patient samples can be processed would normally take several weeks to complete for smaller instruments.

Patient disorders identified through these diagnostic test kits include kidney failure, thyroid function, pancreatitis, skeletal disorders, fertility and cardiac health.

Products for Use 4 are used in medicine and vaccine research and development. These products are generally located in university or pharmaceutical research laboratories or in clinical trial environments. Equipment costs would be similar to above but are normally purchased directly by the customer. Impact on these downstream users would be harder to predict – clinical trial equipment is not normally changed mid-trial due to the introduction of uncertainty on the trial results, and the impact on pharmaceutical research might vary depending on the current phase of the process – early-stage development may be less impacted than late stage as the manufacturer is preparing the medicine or vaccine for evaluation for approval and the data is therefore critical to the success of the product.

Products for Use 5 are in the obsolescence category which have a short market life. These products will be removed from the market within [redacted] years and replaced by OPnEO and NPnEO free products.