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MAY 23 2024
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May 21, 2024

Mr. Michael Cox
Michigan Department of Environment, Great Lakes, and Energy
Air Quality Division
Kalamazoo District Office
7953 Adobe Road
Kalamazoo, MI 49009-5025

c. Jenine Camilleri, Enforcement Unit Supervisor

Re: Zoetis Violation Notice Response

Dear Mr. Cox:

Zoetis, Inc. (Zoetis), SRN B7149, submits this letter in response to the May 1, 2024 Violation Notice (VN) to document the corrective actions taken to address the exceedances of the 21-ton per 12-month rolling time period material limit for ethyl alcohol usage contained in Permit to Install (PTI) 30-05C, FGB248COMP, Special Condition II.2. The VN requested specific information be submitted with the response, which follows.

Dates the violations occurred

The 12-month rolling material usage limit of 21 tons of ethyl alcohol was exceeded from May 2020 through January 2023. Zoetis complied with the material usage limit from February 2023 through February 2024.

The 12-month rolling material usage limit was again exceeded starting in March 2024. Due to the nature of the 12-month rolling calculation, this exceedance will continue until the modified PTI 30-05D is issued, as described in the corrective actions section below. Refer to Attachment 1 for the PTI 30-05C Compliance Record updated to include the January 2019 through April 2024 timeframe.

Explanation of the causes and duration of the violations

The exceedance of the 12-month rolling ethyl alcohol material usage limit was discovered when Zoetis contracted Barr Engineering Co. (Barr) to complete a PTI 30-05C compliance review during 2023. Barr evaluated site records, re-evaluated and, in most cases, recalculated emission factors for the current product suite, and developed an updated recordkeeping methodology to evaluate compliance with the limits in PTI 30-05C, including the 12-month rolling ethyl alcohol material usage limit.

Historically, monthly recordkeeping of the isopropyl alcohol usage and ethyl alcohol usage were obtained from liquid transfer information within the Systems, Applications and Products in Data Processing (SAP) system at Zoetis' Kalamazoo facility. Prior to 2019, Zoloft was the primary product using ethyl alcohol as a raw material; the ethyl alcohol used for Zoloft production was stored in a dedicated bulk tank. Following

Zoetis, Inc.
2605 East Kilgore Rd.
Kalamazoo, MI 49001

The PTI 30-05C compliance review completed by Barr determined that Zoetis' processes have operated in compliance with both the isopropyl alcohol material limit of 3,440 tons per 12-month rolling period and the VOC emissions limit of 17.5 tons per 12-month rolling period throughout the timeline, even with the increased ethyl alcohol usage (Attachment 1). The additional ethyl alcohol usage did not impact compliance with the VOC emissions limit because the current products using ethyl alcohol are lower emitting than the prior products. Emission factors for the current product suite were re-evaluated and recalculated where appropriate.

Barr also evaluated the increased ethyl alcohol usage and maximum projected emission rate from the current products against the Michigan Toxic Air Contaminants (TAC) screening levels under Michigan Administrative Rule 227, which is the referenced regulatory basis for the ethyl alcohol material limit in condition II.2 of PTI 30-05C.

Rule 227 establishes the method for determining the maximum allowable emission rate of a TAC based on its health-based screening level. For ethyl alcohol (ethanol), the applicable initial threshold screening level (ITSL) is 19,000 $\mu\text{g}/\text{m}^3$ with a 1-hour averaging time. Per Rule 227, the allowable emission rate calculated from that ITSL is 19 pounds per hour (lb/hr). The maximum emission rate calculated by Emission Master during the Triamulox process is 4.19 lb/hr, although the process does not emit at that rate for a full hour. The average hourly emission rate for Triamulox and Antirobe combined is 2.11 lb/hr (i.e., if both processes are occurring simultaneously). Therefore, the maximum ethyl alcohol emission rate during Triamulox production is only 22.5% of the allowable emission rate of ethyl alcohol. Based on the Rule 227 analysis, the past and current production levels would not result in ambient impacts that exceed the ethyl alcohol screening level.

Please contact Joshua Coy of Zoetis at joshua.coy1@zoetis.com or (269) 220.8383, or Brian Greenwald of Barr at bgreenwald@barr.com or (616) 512.7012, to discuss this response or to schedule a meeting to discuss this matter in more detail.

Sincerely,



Ayron Stagra
Site Lead

Enclosed:

Attachment 1: PTI 30-05C Compliance Record – January 2019 through April 2024