6560-50-P

ENVIROMENTAL PROTECTION AGENCY

40 CFR Part 79

[EPA-HQ-OAR-2018-0131; FRL-9975-89-OAR]

Registration of Isobutanol as a Gasoline Additive: Opportunity for Public Comment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Request for information.

SUMMARY: The Environmental Protection Agency ("EPA" or "the Agency") is seeking public comment on any aspect of the use of isobutanol in gasoline. Butamax Advanced Biofuels, LLC ("Butamax"), a manufacturer of isobutanol, has submitted an application pursuant to the regulations titled "Registration of Fuels and Fuel Additives" for the registration of isobutanol as a gasoline additive at up to 16 volume percent. Butamax has submitted information that would likely satisfy the applicable registration requirements. The Clean Air Act requires the EPA to register a fuel or fuel additive once all the applicable registration requirements have been met by the manufacturer. Due to the potential for the widespread introduction of isobutanol into commerce, we are taking steps to make the public aware of the likelihood of this registration. We are seeking public comment regarding any issues we should take into consideration for this registration and any supplemental actions we should consider under the Clean Air Act to further protect public health and welfare.

DATES: Comments must be received on or before [INSERT DATE 30 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit your comments, identified by Docket ID No. EPA-HQ-OAR-2018-0131, to the Federal eRulemaking Portal: *https://www.regulations.gov*. Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or withdrawn. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will in general not consider comments or comment contents located outside of the primary submission (*i.e.* on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit https://www.epa.gov/dockets/commenting-epa-dockets.

FOR FURTHER INFORMATION CONTACT: James W. Caldwell, Environmental Engineer, Compliance Division, Office of Transportation and Air Quality, Mail Code 6405A, U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, NW., Washington, DC 20460; Telephone: (202) 343-9303; Fax: (202) 343-2802; Email address: *caldwell.jim@epa.gov*.

SUPPLEMENTARY INFORMATION:

The EPA is seeking public comment on any aspect of the use of isobutanol in gasoline. Butamax Advanced Biofuels, LLC ("Butamax"), a manufacturer of isobutanol, has submitted an application pursuant to the regulations at 40 CFR part 79, Registration of Fuels and Fuel Additives, for the registration of isobutanol, an alcohol, as a gasoline additive at up to 16 volume percent. Our review of the information Butamax has submitted leads us to believe that Butamax would likely satisfy the applicable registration requirements under 40 CFR part 79 (discussed in

more detail below). Section 211(b) of the Clean Air Act (Clean Air Act, CAA or the Act) requires the EPA to register a fuel or fuel additive once all the applicable registration requirements have been met by the manufacturer. While the EPA does not have any specific concerns, due to the potential for the widespread introduction of isobutanol into commerce, we are taking steps to make the public aware of the likelihood of this registration and are seeking public comment regarding any issues we should take into consideration for this registration and/or any potential supplemental actions we should consider under the Clean Air Act to further protect public health and welfare.

I. Statutory and Regulatory Background

Section 211(a) and (b) - Fuels and Fuel Additives Designation and Registration

Section 211(a) of the Act authorizes the Administrator to designate fuels and fuel additives (F/FAs) by regulations and, once designated, to register such F/FAs prior to introduction into commerce. To date, the Administrator has designated on-highway motor vehicle gasoline and gasoline additives and on-highway motor vehicle diesel and diesel additives for registration. The EPA codified the registration requirements under Sections 211(b) and 211(e) of the Act at 40 CFR part 79. Registration requirements at 40 CFR part 79 include emissions speciation testing and a literature search of the associated emissions (Tier 1 testing) and animal testing of exposure to emissions for purposes of determining health effects (Tier 2 testing). Manufacturers with less than $50 million in total annual sales are considered small businesses, as specified in the regulations at 40 CFR 79.58(d). In certain cases, a small business is exempt from some or all of these testing requirements. For any potential registrant with $50

million or more in total annual sales, Tier 1 and Tier 2 requirements must be met before registration.

In addition, §§79.11(i) and 79.21(h) respectively require that fuel and fuel additive manufacturers demonstrate that their fuels and fuel additives are substantially similar to those used in emissions certification or have a waiver as part of 40 CFR part 79 registration.

The Tier 1 registration regulations at 40 CFR 79.52 require a characterization of the emission products that are generated by evaporation and combustion of a gasoline with, if applicable, an oxygenated additive such as isobutanol. Combustion testing must be conducted with and without after-treatment of exhaust emissions. A literature search for information on the potential toxicological environmental, and other public welfare effects is required for emission products, except that it is not required for those emission products that are the same as the emission products for baseline gasoline (represented in testing by a gasoline with no oxygenates such as ethanol or isobutanol). This is because a test group organized by the American Petroleum Institute (API) has tested baseline gasoline and also conducted the literature search for its emission products. The results of this testing and literature search were reported in the 1997 API baseline gasoline Tier 1 literature review.

The regulations at 40 CFR 79.53 specify the requisite health effects testing for compliance with Tier 2 as well as provisions for a manufacturer that opts to rely on existing health effects test data to satisfy these testing requirements. Additionally, the flexibility to modify Tier 2 requirements and to require Alternative Tier 2 testing can be found at 40 CFR 79.58(c). In 1998, EPA opted to modify the standard Tier 2 testing requirements for gasoline and various oxygenated gasoline blends and issued Alternative Tier 2 testing requirements to the API "Section 211(b) Research Group." This was based on the EPA's determination that alternative

test procedures would yield more useful data than standard Tier 2 testing. The primary difference between the testing for baseline gasoline and various oxygenated gasoline blends, under the Alternative Tier 2 and standard Tier 2 testing requirements, was that the Alternative Tier 2 testing focused on identifying and evaluating potential adverse health effects of evaporative emissions. It did not include examination of combustion emissions. At the time, the EPA explained the rationale for focusing on evaporative emissions and why the combustion emission studies would likely not produce meaningful information as being due to methodological complications caused by carbon monoxide (i.e., the carbon monoxide component of the combustion exhaust emissions may be lethal or otherwise compromise the health of the test animals). The EPA required specific testing for baseline gasoline and various oxygenated gasoline blends and these health studies have now been largely completed and approved.

The regulations at 40 CFR 79.54 provide for additional testing under Tier 3 provisions if the Tier 1 and Alternative Tier 2 data or other data obtained by the Agency indicates that such testing is warranted. The EPA has yet to initiate a Tier 3 process for any fuel or fuel additive. If the EPA were to require Tier 3 testing, we would develop the testing protocol and requirements through a public process.

CAA Section 211(f) - Substantially Similar and Waivers

Section 211(f)(1) of the Act makes it unlawful for any manufacturer of any fuel or fuel additive to first introduce into commerce, or to increase the concentration in use of, any fuel or fuel additive for use by any person in motor vehicles manufactured after model year 1974 which is not substantially similar to any fuel or fuel additive utilized in the certification of any model year 1975, or subsequent model year, vehicle or engine under Section 206 of the Act. The EPA last issued an interpretive rule on the phrase ”substantially similar” at 73 FR 22281 (April 25,

2008). Generally speaking, this interpretive rule describes the types of unleaded gasoline that are considered ‘‘substantially similar’’ to the unleaded gasoline utilized in the EPA’s emissions certification program by placing limits on a gasoline’s chemical composition and its physical properties, including the amount of alcohols and ethers (oxygenates) that may be added to gasoline. Gasoline and diesel fuels that are found to be “substantially similar” to the EPA’s certification fuels may be registered and introduced into commerce. The current “substantially similar” interpretive rule for unleaded gasoline allows oxygen content up to 2.7 percent oxygen by weight for certain ethers and alcohols, which equates to approximately 12 volume percent isobutanol.[1] Gasoline-isobutanol blends containing up to 16 volume percent isobutanol would contain up to 3.7 percent oxygen by weight, which exceeds the allowable limit for oxygen content under the current “substantially similar” interpretive rule, and would require a waiver under section 211(f)(4) of the Act.

Section 211(f)(4) of the Act provides that upon application of any fuel or fuel additive manufacturer, the Administrator may waive the prohibitions of CAA section 211(f)(1) if the Administrator determines that the applicant has established that such fuel or fuel additive, or a specified concentration thereof, will not cause or contribute to a failure of any emission control device or system (over the useful life of the motor vehicle, motor vehicle engine, nonroad engine or nonroad vehicle in which such device or system is used) to achieve compliance by the vehicle or engine with the emission standards to which it has been certified pursuant to Sections 206 and 213(a) of the Act. In other words, the Administrator may grant a waiver for a prohibited fuel or fuel additive if the applicant can demonstrate that the new fuel or fuel additive will not cause or contribute to engines, vehicles or equipment failing to meet their emissions standards over their

[1] See 56 FR 5352 (February 11, 1991).

useful lives. The statute requires that the Administrator shall take final action to grant or deny the application, after public notice and comment, within 270 days of receipt of the application.

In addition, the regulations at §§79.11(i) and 79.21(h) require that fuel and fuel additive manufacturers must demonstrate that their fuels and fuel additives, respectively, are substantially similar or have a waiver as described in section 211(f) of the Act.

CAA Section 211(c) - Rulemaking to Regulate Fuels

Section 211(c)(1) of the Act allows the Administrator, by regulation, to "control or prohibit the manufacture, introduction into commerce, offering for sale, or sale of any fuel or fuel additive for use in a motor vehicle, motor vehicle engine, or nonroad engine or nonroad vehicle A) if, in the judgment of the Administrator, any fuel or fuel additive or any emission product of such fuel or fuel additive causes, or contributes, to air pollution or water pollution (including any degradation in the quality of groundwater) that may reasonably be anticipated to endanger the public health or welfare, or B) if emission products of such fuel or fuel additive will impair to a significant degree the performance of any emission control device or system which is in general use, or which the Administrator finds has been developed to a point where in a reasonable time it would be in general use were such regulation to be promulgated." Prior to doing so, the EPA must consider scientific and medical evidence as well as the costs of any control and setting regulations under Section 202 of the Act. The EPA must also publish a finding that a control or prohibition will not result in the use of other substitute fuels or fuel additives that will also endanger public health or welfare.

II. Registration of Isobutanol

Isobutanol Background

Isobutanol is a flammable colorless liquid that is used as a gasoline additive and as an industrial solvent. Isobutanol is composed of the chemical elements hydrogen, oxygen, and carbon and it can be made from petroleum or renewable biomass, such as corn, grasses, agricultural waste and other renewable sources. It can be used in internal combustion engines as an additive to gasoline and is registered under the 40 CFR part 79 as a gasoline additive for manufacturers that are exempt from the Tier 1 and Alternative Tier 2 testing. A blend level of 16 percent for a non-exempt manufacturer would require a new registration that would include meeting Tier 1 and Alternative Tier 2 health effects testing requirements and a waiver under CAA section 211(f)(4). Biobutanol is the common name for isobutanol made from renewable sources.

There has been an increased interest in the use of biobutanol as a direct result of the requirements for increased use of renewable fuel volumes, adopted in the Energy Information and Security Act of 2007. These provisions require an increase in the use of renewable fuels, with 36 billion gallons of renewable fuel to be used in the U.S. by 2022. Parties required to meet these standards are interested in cost effective and practical ways to satisfy the standards and meet the performance needs of the vehicles and engines. Biobutanol is one potentially attractive option because of its higher energy density, lower blending vapor pressure, and lower heat of vaporization in comparison to other alcohols such as ethanol.

Current Isobutanol Registrations

As previously discussed, regulations at 40 CFR 79.58(d) specify that a company with total annual sales of less than $50 million is a small business and is exempt in certain instances

from applicable testing requirements. The EPA has registered isobutanol as a fuel additive for companies that qualified under this provision.

Fuel and fuel additive manufacturers with total annual sales of $50 million or greater do not qualify as small businesses, are prohibited from registering the use of isobutanol produced by small businesses, and instead must comply with all applicable registration requirements, including health effects testing. Gasoline manufacturers typically have sales greater than $50 million per year and would need to register isobutanol as an additive to their gasoline if they wanted to use it. Therefore, a gasoline manufacturer cannot rely on the registration of a small additive manufacturer as a means of complying with the 40 CFR part 79 registration requirements. Additionally, because no gasoline manufacturer has completed the 40 CFR part 79 registration requirements, including required health effects testing for isobutanol, the agency has yet to grant a registration request of isobutanol as an additive to gasoline by a gasoline manufacturer. This has resulted in limiting isobutanol to blending at terminals by parties that are not gasoline manufacturers. See the definition of fuel manufacturer at 40 CFR 79.2(d). For this reason, among others, isobutanol has yet to be introduced into commerce in any significant volume.

Butamax – Isobutanol Registration

Butamax Advanced Biofuels, LLC (Butamax) has applied for registration of the use of up to 16 percent by volume isobutanol as a fuel additive in motor-vehicle gasoline.[2] As discussed above, fuels and fuel additives to motor-vehicle gasoline are required to be registered by the EPA under 40 CFR part 79 prior to introduction into commerce. As previously described, there are

[2] Ethanol is allowed in gasoline at up to 15 percent by volume for certain vehicles. Isobutanol at 16 percent by volume would not have a vehicle restriction.

two main requirements for the fuel or fuel additive manufacturer. First, the fuel or fuel additive must be substantially similar to fuel additives used in emissions certification, or, if not, have a waiver under CAA section 211(f)(4) (42 U.S.C. 7545(f)(4), 40 CFR 79.21(h)). A fuel containing a blend of gasoline and 16 percent isobutanol is not substantially similar to any EPA certification fuels so Butamax must operate via a waiver under CAA section 211(f)(4) prior to registration. The EPA allows manufacturers to use previously granted waivers if they can satisfy the waiver's terms and conditions. Of relevance here is the OCTAMIX waiver, which the EPA granted on February 8, 1988[3], and has since modified the waiver on October 28, 1988[4], June 7, 2012,[5] and June 14, 2012.[6] The waiver allows a variety of alcohols in gasoline, including isobutanol, at up to 3.7 percent oxygen by weight. For a gasoline with a typical density, this equates to a maximum of 16 percent isobutanol by volume when no other oxygenates are present. Butamax has stated that it intends to produce the isobutanol fuel additive for use in accordance with the OCTAMIX waiver. Butamax must show that it will comply with all seven conditions in the OCTAMIX waiver to be able to rely on that waiver to satisfy the registration requirement at 40 CFR 79.21(h). The Agency has evaluated Butamax's March 25, 2011 submission regarding Butamax™ Advanced Biofuels LLC and its application of the OCTAMIX Waiver for up to 16 volume percent isobutanol as a fuel additive if blended with gasoline and agrees with its evaluation that Butamax can meet all seven conditions specified in the OCTAMIX waiver.

Second, a manufacturer must conduct Tier 1 and either Tier 2 or Alternative Tier 2 health-effects testing, unless the manufacturer is exempt under the small-business provisions specified at 40 CFR 79.58(d). Butamax does not qualify as a small business and is not exempt

[3] See 53 FR 3636 (February 8, 1988).
[4] See 53 FR 43768 (October 28, 1988).
[5] See 77 FR 33733 (June 7, 2012).
[6] See 77 FR 35677 (June 14, 2012).

from these testing requirements. Additionally, the regulations at 40 CFR 79.53(b) allow a manufacturer to rely on existing health effects test data that would provide "reasonably comparable" information in lieu of conducting health effects testing "regarding the carcinogenicity, mutagenicity, neurotoxicity, teratogenicity, reproductive/fertility measures, and general toxicity effects of the emissions for a fuel or additive" for registration. The Agency's current review leads it to believe that Butamax will likely meet the requisite health effects testing requirements for isobutanol at 16 percent through its submittal of information on testing for the health effects end points identified under Alternative Tier 2 testing procedures for oxygenates.[7] Similarly, the Agency also believes that Butamax will likely meet the other requirements for registration on EPA Form 3520-13, Fuel Additive Manufacturer Notification.

III. Recent Studies Regarding Isobutanol Blended Gasolines

The OCTAMIX waiver evaluated a number of 1980s gasoline-fueled vehicles on the effects of gasoline-alcohol mixtures (applicable to isobutanol at up to 16 percent by volume) on those vehicles emissions controls. Since then, studies have been conducted to evaluate the potential effects of isobutanol on gasoline-fueled vehicles, engines, and fuel dispensing and storage equipment. Recent testing on the use of gasoline-isobutanol blended fuels illustrates that isobutanol-blended fuels generally do not significantly affect oxides of nitrogen (NOx), carbon monoxide (CO), or non-methane organic gas (NMOG) emissions. In a recent study, gasoline was splash blended with alcohols to produce four blends with a target value of 5.5 percent oxygen by

[7] Letter to Dr. Carol Henry, American Petroleum Institute, from Margo Oge, U.S. EPA, November 2, 1998.

weight including a gasoline-isobutanol blend of 21 volume percent isobutanol.[8] The study found that the gasoline-isobutanol blended fuel did not significantly affect NOx, CO, or NMOG emissions.

In a test of isobutanol exposure impacts on fueling infrastructure materials, the observed swell for elastomers for exposures to 16 percent and 24 percent gasoline blends were similar to but slightly less than the oxygen equivalent ethanol fuels of E10 and E17. Samples of metals commonly found in fuel storage and dispensing systems were immersed in 16 percent and 24 percent isobutanol blends at 60^{o}C for 28 days. In all cases, the annualized corrosion rates for isobutanol based on weight loss were negligible.[9]

Finally, in a 50-hour field emissions test of 175 horsepower and 215 horsepower boating engines, 16.1 volume percent isobutanol (blended to 93 octane) showed similar total HC+NOx emissions compared to a non-oxygenated certification gasoline.[10] In that same test, CO emissions were reduced using isobutanol vs. indolene which was expected as isobutanol is a partially oxidized fuel. The enleanment reported for 16.1 percent isobutanol was in line with what is typical of E10 relative to indolene. The study noted that no operability issues were observed while the marine engines were operated on the gasoline-isobutanol blended fuels.[11]

The Agency believes that based on the referenced studies on the potential effects of isobutanol on gasoline-fueled vehicles and engines and its engineering judgement, that modern

[8] Ratcliff, M. A.; Luecke, J.; Williams, A.; Christensen, E.; Yanowitz, J.; Reek, A.; and McCormick, R. L.; Impact of higher alcohols blended in gasoline on light-duty vehicle exhaust emissions. Environ. Sci. Technol., 2013, 47 (23), pp 13865–13872.

[9] Kass, M.; Theiss, T.; Janke, C.; Pawel, S.; et al; Compatibility study for plastic, elastomeric, and metallic fueling infrastructure materials exposed to aggressive formulations of isobutanol-blended gasoline. Oak Ridge National Laboratory, 2014.

[10] Until changed in the Tier 3 rulemaking (see 79 FR 23414, April 28, 2014), certification gasoline did not contain ethanol, or any other oxygenates. However, the Tier 3 rulemaking now requires federal motor vehicle gasoline certification fuel to contain 10 volume percent ethanol.

[11] Wasil, J. R.; McKnight, J.; Kolb, R.; Munz, D.; Adey, J.; and Goodwin, B.; In-use performance testing of butanol-extended fuel in recreational marine engines and vessels. SAE [Tech Pap.] 2012.

motor vehicles and engines should continue to meet emissions standards and suffer no issues with driveability or operability on gasoline-isobutanol blended fuels up to 16 volume percent. However, even though the information cited above concerning regulated emissions, retail fuel dispensing and storage equipment materials, and marine engines suggests that isobutanol blended into gasoline should not pose any significant issues, the narrowness of the size and scope of these studies does not address all potential effects isobutanol may have on gasoline-fueled vehicles and engines. Therefore, the Agency seeks comment on whether there is available information on other areas that should be addressed for gasoline-isobutanol blended fuels up to 16 volume percent. The Agency could use information gleaned from this public comment process to determine whether further controls might be necessary (potentially via rulemaking under section 211(c) of the Act) to help ensure the smooth introduction of isobutanol into the gasoline market or to help determine whether the Agency should impose certain conditions on the registration of isobutanol as a gasoline additive through 40 CFR part 79.

IV. Conclusion

The EPA will register isobutanol for Butamax in accordance with the regulations at 40 CFR part 79 once applicable requirements are met. Butamax has submitted the required information, including: 1) the speciation of exhaust and evaporative emissions for gasoline with 16 percent isobutanol (Tier 1 testing), 2) a literature search for health information on the Tier 1 emissions found for that blend that were not found in the Tier 1 testing of gasoline without any oxygenate, and 3) the results of the Alternative Tier 2 health-effects testing for that blend (animal exposure to evaporative emissions). Butamax has also submitted information to demonstrate that it can comply with the requirements of the OCTAMIX waiver, which allows the blending of

isobutanol into gasoline at up to 3.7 percent oxygen by weight, or 16 percent isobutanol by volume.

The EPA seeks comments and any information and data on the use of isobutanol in gasoline, including, but not limited to: 1) the need for additional health-effects testing under the Tier 3 provisions in the regulations, and 2) the need for additional regulatory controls for 16 percent isobutanol in gasoline, beyond those for gasoline at 40 CFR parts 79 and 80, under the authority of CAA section 211(c).

Dated: March 15, 2018.

Byron J. Bunker,

Director, Compliance Division,

Office of Transportation and Air Quality,

Office of Air and Radiation.

[FR Doc. 2018-06119 Filed: 3/28/2018 8:45 am; Publication Date: 3/29/2018]