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Office of Information and Regulatory Affairs
Office of Management and Budget
Executive Office of the President

E.O. 12866 Meeting
RIN: 2070-AK34
Title: Regulation of Persistent, Bioaccumulative, and Toxic Chemicals Under TSCA Section 6(h)

Comments on 2,4,6-tri-*tert*-butylphenol (2,4,6-TTBP)

Dear Office of Information and Regulatory Affairs,

As required by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, TSCA Section 6(h) requires the Environmental Protection Agency (EPA) to take expedited regulatory action to address risks from certain persistent, bioaccumulative, and toxic (PBT) chemicals on the basis of an exposure and use assessment.[1] One of the five substances identified for expedited regulatory action is 2,4,6-tri-tert-butylphenol (2,4,6-TTBP).

SI Group, a leading global developer and manufacturer of performance additives, process solutions, pharmaceuticals and chemical intermediates, is the sole manufacturer of 2,4,6-TTBP as identified from the 2016 Chemical Data Reporting (CDR) requirement.[2] Presumably we will therefore be a regulated entity by the Final Rule required under TSCA Section 6(h).[3]

Our company is dedicated to protecting the environment and respecting the communities in which we operate. SI Group believes that data-driven, scientifically sound methods for assessing chemicals is the foundation for effective chemical management. Throughout this regulatory process, we have tried to serve as a model for product stewardship by providing data and information necessary to support EPA in their evaluation.[4] In fact, we commend EPA for allowing ample opportunity for public participation and an open exchange of ideas required per Executive Order 13563.[5]

However, based on written materials EPA has produced and published to the Docket thus far, and without seeing the text of the Proposed Rule at this point in time, we are concerned that non-scientifically justified approaches and conclusions have been made and serve as the foundation to the rule.

[1] 15 U.S.C. § 2605(h)(1)(B)
[2] 40 C.F.R § 711; 15 U.S.C. § 2607(a)
[3] 15 U.S.C. § 2605(h)(3) - No later than 18 months after proposing a rule pursuant to paragraph (1), the Administrator shall promulgate a final rule under subsection (a).
[4] https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0734-0020
[5] E.O. 13563 § 2(b) of Jan 18, 2011

Executive Order 13563 explicitly states that our regulatory system "must be based on the best available science." [6] As described in further detail below, erroneous data and assumptions about the conditions of use are the basis for the *Exposure and Conditions of Use Assessment Peer Review Draft* document written by EPA. This is recognized by the Letter Peer Reviewers of the assessment; virtually all of whom identified the need for corrections. EPA has not acknowledged these issues nor published to the Docket a response to the concerns of SI Group or the Letter Peer Reviewers.

We are concerned that EPA has developed a Rule that is supposed to meet the statutory requirement to "reduce exposure to the substance to the extent practicable" while using erroneous data and making assumptions that do not accurately define the exposure potential under the conditions of use.[7]

Our specific comments are as follows.

1. **The *Exposure and Use Assessment of Five Persistent, Bioaccumulative and Toxic Chemicals - Peer Review Draft* published by EPA on 2,4,6-TTBP contains numerous errors that were never acknowledged or corrected in the public domain and does not represent the best available science**

In June 2018, EPA posted to the Docket the *Exposure and Use Assessment of Five Persistent, Bioaccumulative and Toxic Chemicals - Peer Review Draft* along with Charge Questions the Letter Peer Reviewers were supposed to address for each chemical as part of the peer review process. [8, 9, 10]

SI Group submitted comments where we specifically pointed out the following significant errors contained within the document that, to our knowledge, were never address nor resolved by EPA:[11]

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[6] E.O. 13563 § 1(a) of Jan 18, 2011

[7] 15 U.S.C. § 2605(h)(4)

[8] A letter review takes place when EPA seeks individual written peer review comments from independent experts, typically in the form of correspondence to EPA from the peer reviewer. The number of reviewers selected depends largely on the scientific and technical expertise required to address the issues presented in the peer review charge. Each reviewer evaluates the draft technical work product independently without consultation with other reviewers. No collaborative or consensus peer review report is developed. https://www.epa.gov/sites/production/files/2016-03/documents/epa_peer_review_handbook_4th_edition.pdf

[9] https://www.regulations.gov/document?D=EPA-HQ-OPPT-2018-0314-0005. This Exposure and Use Assessment document will be used by EPA in determining, under TSCA section 6(h)(1)(B), whether exposure to each identified PBT is likely, under the conditions of use.

[10] https://www.regulations.gov/document?D=EPA-HQ-OPPT-2018-0314-0008. Letter Peer Reviewers were instructed to provide a response for each charge question for each of the five chemicals for the peer review process.

[11] https://www.regulations.gov/document?D=EPA-HQ-OPPT-2018-0314-0018 Dated 20 July 2017

Section 7.1. – p. 128	An experimental value for water solubility (0.0629 mg/L) has been calculated and previously provided to EPA. This value should be utilized for all interpretations since 2,4,6-TTBP is negligibly soluble in water. EPA did not include this value and was inconsistent in the draft assessment since 2,4,6-TTBP was stated to be both highly water soluble (p. 132) and have low water solubility (p. 133).
Section 7.5. – p. 135	The utilization of butylated hydroxytoluene (BHT) as a surrogate for 2,4,6-TTBP in the environmental monitoring summary is not justified as the conditions of use for both substances are vastly different. 2,4,6-TTBP is predominately used as a chemical feedstock or in applications resulting in its destruction while people are intentionally exposed to BHT via foodstuffs, pharmaceuticals, and cosmetics – amongst other various uses, most of which are non-destructive.
Sections 7.5.1, 7.5.2, 7.5.3, 7.5.4, 7.5.5	The data in these sections are from countries outside the United States and it is not clear that the conditions of use of 2,4,6-TTBP in these countries are similar to those in the United States. These data should not be used to characterize potential exposures without additional supporting evidence.
Section 7.5.6. – p. 138	In Figure 7-8 (ref. USGS 2012) both 2,4,6-TTBP and BHT were not analytes reported in the reference cited by EPA, so it is unclear what data are being presented.
Section 7.6.1 – p. 140	In Figure 7-9 (ref. USGS 1991) 2,4,6-TTBP was not detected at the method detection limit (MDL) in fish tissue, but the data is not presented by EPA as such. The draft document should be corrected to clarify that all data were below the MDL for 2,4,6-TTBP.
Section 7.7 – p. 140	EPA should more accurately describe the data from the USGS monitoring database since 2,4,6-TTBP was consistently not detected in any of the 881 composite fish tissue samples collected from 500 lakes across the United States from 2000 – 2003.
Section 7.10	The vast majority of 2,4,6-TTBP manufactured is consumed as an intermediate in manufacturing other chemicals (94%) or through energy recovery being sold as a fuel (4%). The remaining 2% of the 2,4,6-TTBP manufactured is sold as a liquid antioxidant mixture (present at 9–13%) primarily for fuel – predominately military jet fuel. Additionally, 2,4,6-TTBP is manufactured in liquid form, and it is never isolated as a neat substance. 2,4,6-TTBP is not manufactured as a solid; therefore, dermal exposures and fugitive air emissions to dusts are not possible.

EPA is required to conduct an Exposure and Conditions of Use Assessment, and we are particularly concerned by EPA's proposed use of butylated hydroxytoluene (BHT) as a surrogate for 2,4,6-TTBP in the environmental monitoring summary. This attempt to develop an exposure read-across approach is not justified as the conditions of use for both substances are vastly different. 2,4,6-TTBP is predominately used as a chemical feedstock or in applications resulting in its destruction via combustion while people are intentionally exposed to BHT via foodstuffs, pharmaceuticals, and cosmetics – amongst other various uses, most of which are non-destructive. In fact, the Letter Peer Reviewers overwhelmingly agreed with our concern and provided comments such as "…I find it difficult to understand how BHT could it be used as a surrogate for 2,4,6-TTBP exposure…I would say the use of BHT exposure data in an exposure assessment of 2,4,6-TTBP are of essentially no value…", "inappropriate", and "unjustified". [12]

It is not clear the position EPA has taken with our concerns in the development of the Proposed Rule. As pointed out by one of the Letter Peer Reviewers, "…the comments raised by the SI Group do not appear to have been reflected in the 2,4,6-TTBP section, especially as pertains to water solubility and the use of BHT as a surrogate…Strongly recommend that EPA investigate further."[13]

2. **SI Group is a responsible chemical manufacturer of 2,4,6-TTBP and its conditions of use ultimately result in its destruction**

In the normal course of chemical processes involving the reaction of phenol with isobutylene to produce 2,6-di-*tert*-butylphenol (2,6-DTBP), 2,4,6-TTBP is formed as a coproduct in varying amounts depending on the conditions of the reaction and stoichiometry of the reactants.[14]

It is not possible to significantly suppress the formation of 2,4,6-TTBP without severely constraining the yield of the desired dialkylphenol products; a market sector core to the business of SI Group.

The production processes at SI Group that lead to the generation of 2,4,6-TTBP take place in closed systems under strictly controlled conditions aided by modern process controls thereby mitigating risks to our workers and the environment. In addition, workers in SI Group facilities involved in the production of di-alkylphenols are required to use personal protective equipment (PPE) consisting of: nitrile gloves, chemical resistant slicker suits, chemical resistant boots, respirators with face shields, and hardhats. We expect our workers to behave in an appropriate manner when operating process equipment.

While we report under the CDR rule the amount of 2,4,6-TTBP manufactured by SI Group, a value claimed as confidential business information (CBI), it is important to recognize that the conditions of use of this substance result in its destruction.[15, 16]

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[12] https://www.regulations.gov/document?D=EPA-HQ-OPPT-2018-0314-0029
[13] *Id.* Pg. 24
[14] Per 40 C.F.R. § 704.3 a coproduct by definition has commercial intent, separate from whatever commercial intent may concurrently exist to manufacture some other chemical substance or mixture
[15] *Id.*
[16] Section 14(a) of TSCA, 15 U.S.C. § 2613(a), applies Exemption 4 of the Freedom of Information Act (FOIA), 5 U.S.C. § 552(b)(4), as the basis for determining business information submitted under TSCA is entitled to confidential treatment. Exemption 4 protects from disclosure "trade secrets and commercial or financial information obtained from a person and privileged or confidential" (commonly referred to as "CBI").

The manufacturing operations at SI Group rely on the vast majority of the created 2,4,6-TTBP as a feedstock for other processes; resulting in approximately 94% of produced 2,4,6-TTBP being internally consumed and transformed into other chemical substances.

The remaining 2,4,6-TTBP is present as a coproduct in a fuel oil stream sold for energy value (4%) and in antioxidants marketed into fuel additive applications (2%); a key business sector for SI Group and discussed in further detail below.

3. **SI Group is a leading supplier of antioxidants that are key additives in the fuel value chain that meet multiple military and ASTM approvals for gasoline and aviation fuel stabilization.**

The fuel additives value chain starts with material and component suppliers that provide chemicals and catalysts to fuel additive manufacturers. Fuel additive manufacturers, like SI Group, develop these additives and supply them to two different markets – service providers and the aftermarket.

For antioxidants, the major portion goes to service providers who develop products for crude oil refiners.[17] After refining, petroleum products, like fuels, quickly begin to degrade due to oxidation rendering them unstable. The refiners use these additives to ensure smooth operations, improve storage stability, retard gum formation, increase refiner blending options, and supply better quality light and middle distillate products to the market.

For example, Figure 1 shows the supply chain for bringing automotive fuel to the market.[18] After refining, fuel that is ready for use is transported to terminals via multiple modes (e.g. pipeline, tanker, ship, etc.) for storage and staging. Once the refined fuel leaves the terminal, it is transported to its final point of sale. Fuel additives, like antioxidants, are added at multiple points in the supply chain.

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[17] While not discussed here, bio-based fuels also require the use of antioxidants to maintain stability and suitability.

[18] KRISTI MORIARTY, HIGH OCTANE FUEL: TERMINAL BACKGROUNDER, http://www.osti.gov/scitech.

Figure 1 - Automotive Fuel Supply Chain

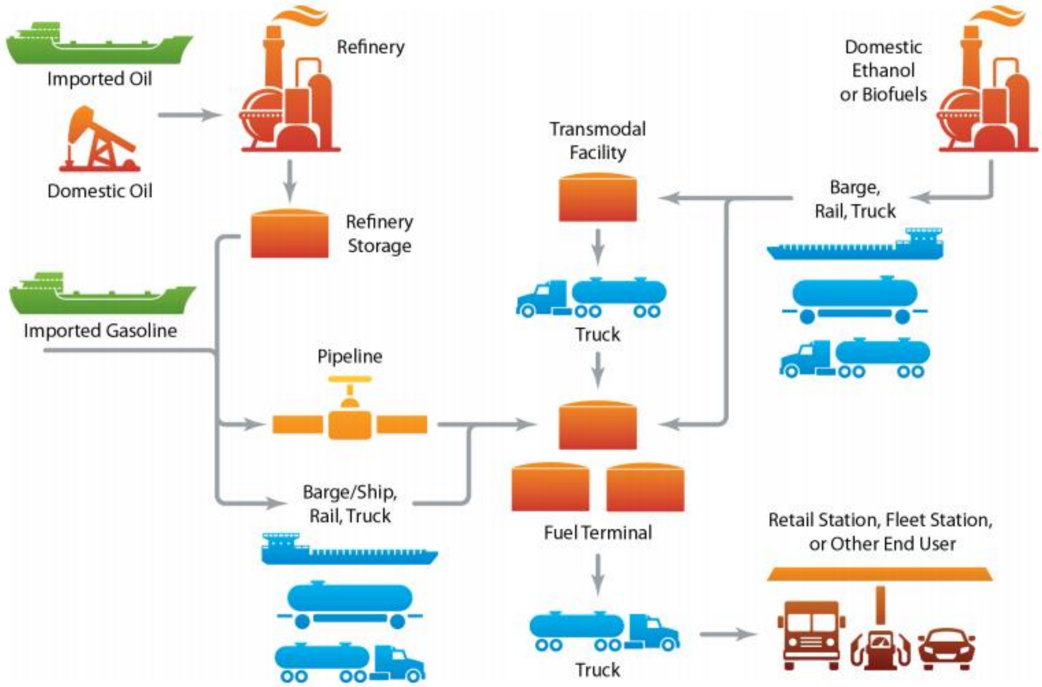

Table 1 shows that in 2017 the U.S. consumption of motor gasoline was approximately 400,000,000 T. [19] Additionally, jet fuel, kerosene, distillate fuel oil, residual fuel oil, and other refined products going into fuel applications also require antioxidants to maintain stability and suitability. [20]

[19] U.S. Energy Information Administration https://bit.ly/2A4jc8A

[20] In modern automotive and aviation fuels, a combination of several chemical additives are used so the fuel can meet desired performance specifications. While fuels are typically used quickly, they can be subjected to long-term storage (e.g. military fuels are stored for extended periods due to various operational and logistic needs). When not immediately used, untreated fuels will rapidly deteriorate via oxidation processes that take place resulting in insoluble varnish ("gum") as the end product. In the fuel systems, gums can be responsible for injection system fouling and are implicated in intake valve deposit formation.

Table 1 - 2017 US Consumption of Refined Petroleum Products

Type	Quantity (1000 MT)
Motor Gasoline	399,085
Jet Fuel	77,432
Kerosene	221
Distillate Fuel Oil	192,397
Residual Fuel Oil	18,726
Liquefied Petroleum Gases	39,060
Other Products [21]	136,254
Total Refined Petroleum Products	**863,175**

Not surprisingly, the demand for fuel antioxidants continues to increase. As assessed in a 2014 market research report, the North American antioxidant fuel additive market was expected to increase by +7.01 CAGR% between 2014-2019 to $148.1 million with an expected rise in demand by +3.66 CAGR% to 29.6 KT (Table 2).[22] SI Group's antioxidants are one solution to meeting this growing demand for stable and suitable fuels given the exceedingly limited number of options available.

Table 2 - Antioxidants Fuel Additives Market 2014-2019

Market size ($Million)	
2014	**2019**
105.6	148.1

Market quantity (KT)	
2014	**2019**
24.7	29.6

A much smaller portion of antioxidants is supplied to formulators who create products that are sold to consumers. This is known as the aftermarket segment.

The SI Group value proposition is that our antioxidants increase fuel stability that leads to reduced costs, better performance in use, and longer fuel life.

[21] The Other Products category includes asphalt, coke, aviation gasoline, lubricants, naphthas, paraffin wax, petrochemical feedstocks, unfinished oils, white spirits, and blending components. Antioxidants would be added to some of these products.

[22] MARKETSANDMARKETS, FUEL ADDITIVES MARKET BY APPLICATION - GLOBAL TRENDS & FORECAST TO 2019 (2014), https://www.marketsandmarkets.com/Market-Reports/fuel-additives-market-723.html.

In the US, to the best of our knowledge SI Group sales of fuel antioxidants that contain 2,4,6-TTBP as a co-product, an amount of only 2% of our total CDR production volume of 2,4,6-TTBP, is predominately to service providers (approximately 94% of sales) as opposed to the aftermarket (approximately 6% of sales).

SI Group intends to market in the United States only two products that contain 2,4,6-TTBP as a co-product in these two market segments; Isonox® 133 and Ethanox® 4733.

As compared to other antioxidants, Isonox® 133 and Ethanox® 4733 have desirable technical properties the market demands. For instance, their initial crystallization point is lower than alternative products, which means they do not require heating for material transfer and can be pumped directly into refinery operations. Therefore, compared to other products, SI Group antioxidants help customers save on operating costs and facilitate a safer worker environment.

Additionally, from customer anecdotes, we have been told that Isonox® 133 and Ethanox® 4733 have better performance and are preferred than compared to alternatives; such as 2,6-di-tert-butylphenol alone.

Regardless of the market sector the antioxidant goes into, they are destroyed during combustion.

4. **SI Group antioxidants meeting military specifications as aviation fuel antioxidants cannot be easily replaced due to the extensive time and cost associated with requalification.**

The total market for jet fuel in the United States is currently about 7,700,000 tons (Table 1). In fact, despite continued improvements in aircraft efficiency, the U.S. Energy Information Administration (EIA) projects domestic jet fuel demand will grow so that by 2040, consumption is projected to be 27% higher than 2014 levels.[23]

Both civilian and military jet fuel require antioxidants, like those produced and marketed by SI Group, to meet various stability and quality specifications.[24] SI Group antioxidants meet the following military specifications: [25]

- MIL-DTL-25524
- MIL-DTL-38219
- MIL-DTL-5624
- MIL-DTL-83133
- MIL- PRF-7024
- DEF STAN 91-91
- DEF STAN 91-90

[23] TONY RADICH, THE FLIGHT PATHS FOR BIOJET FUEL 18 (2015), https://www.eia.gov/workingpapers/pdf/flightpaths_biojetffuel.pdf.
[24] Jet fuels are derived from refined kerosene and blended to specification.
[25] MIL-DTL is the acronym for the United States Military Detail Specification. DEF-STAN is the acronym for Defence Standard, the United Kingdom equivalent of a US Military Standard.

- DEF STAN 91-87
- DEF STAN 91-86
- ASTM D 1655
- ASTM D 910

The antioxidants that SI Group produces that contain 2,4,6-TTBP as a co-product cannot be readily swapped out with alternatives due to the time and expense required to meet these qualifications. Bringing a new jet fuel blending component into use requires years of effort by the component supplier, engine manufacturers, airplane builders, and regulators at a significant cost.

For instance, the ASTM D4054-09 standard was developed to provide a framework for the qualification and approval of new fuels and new fuel additives for use in commercial and military aviation gas turbine engines.[26] As discussed by Yildirim and Abanteriba (2012), the qualification and approval of a new aviation turbine fuel or fuel additive is a lengthy 3-step process.[27]

Briefly described:

1. Testing Program
   [T]he purpose of the test program is to ensure that the candidate fuel or additive will have no negative impact on engine safety, durability, or performance. This is accomplished by investigating the impact of the candidate fuel or additive on fuel specification properties, fit-for-purpose properties, component rig tests, or engine tests.

2. OEM Internal Review
   [R]esults of the test program are reviewed by the respective OEM chief engineers and their discipline chiefs. When all the concerns and potential impacts on the engine and any related equipment/system have been explored and satisfactorily addressed the final product of the OEM internal review is a document or report that either rejects or approves the new fuel or additive. After the approval of the new fuel or additive, there may be a requirement for a Controlled Service Introduction (CSI). Under a CSI, engines in the field that are exposed to the new fuel or additive are monitored for an increased level of fair wear and tear. The CSI is directed at identifying possible long-term maintenance effects.

3. Specification Change Determination
   [A]pproval by the OEMs of a new fuel or additive may only affect OEM internal service bulletins and engine manuals and have no impact on the aviation fuel standard. If the OEM proposes changes to a given aviation fuel standard the proposed changes must

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[26] ASTM INTERNATIONAL, WEST CONSHOHOCKEN, PA, ASTM D4054-09, STANDARD PRACTICE FOR QUALIFICATION AND APPROVAL OF NEW AVIATION TURBINE FUELS AND FUEL ADDITIVES (2009), http://www.astm.org/cgi-bin/resolver.cgi?D4054.

[27] Yildirim, U., and S. Abanteriba. 2012. "Manufacture, Qualification and Approval of New Aviation Turbine Fuels and Additives." Procedia Engineering 49 (January): 310–15. https://doi.org/10.1016/j.proeng.2012.10.142.

> then be reviewed and balloted by ASTM D02.J0. Requested changes could include listing the additive or fuel as acceptable for use, changes to published limits, special restrictions, or additional precautions. The OEMs and the regulatory agencies regard the ASTM review and balloting process, and the subsequent scrutiny of industry experts, as an additional safeguard to ensure that issues relating to safety, durability, performance, and operation have been adequately addressed. **Although not a requirement, the OEMs typically wait for a successful ASTM ballot before changing their service bulletins and engine manuals to accommodate the new fuel or additive** [emphasis added].

As discussed in the standard:[28]

> [T]he OEMs will consider a new fuel or additive based on an established need or benefit attributed to its use. Upon OEM and regulatory authority approval, the fuel or fuel additive may be listed in fuel specifications such as Pratt & Whitney (P&W) Service Bulletin No. 2016; General Electric Aviation (GE) Specification No. D50TF2; and Rolls Royce (RR) engine manuals. Subsequent to OEM approval and industry (ASTM) review and ballot, the fuel or fuel additive may be listed in fuel specifications such as Specification D1655, Defence Standard 91-91, United States Air Force MIL-DTL-83133, and the United States Navy MIL-DTL-5624. This qualification and approval process has been coordinated with airworthiness and certification groups within each company, the Federal Aviation Administration (FAA), and the European Aviation Safety Agency (EASA).

While we have no reference to when the last jet fuel antioxidant was approved, we point to the DRAFT guide of the D4054 Clearinghouse established by the Federal Aviation Administration under its Center of Excellence for Alternative Jet Fuels and Environment (ASCENT) program suggesting that ASTM D4054-09 testing costs could be in the range of $3-$5M with the entire process taking 2 to 5 years.[29]

It has been recognized that bringing a new fuel additive to market is challenging and subject to many market forces because:

> [T]he product offered by the manufacturer, no matter how revolutionary and efficient it may be, may not be able to capture the market just because it lacked proper marketing or advertising in case of direct consumers or has not passed necessary testing criteria as in case of refiners. The product may also not sell despite its efficiency if it is very expensive. The customer, therefore, has a large number of options for buying the right product which meets the specifications, both technically and economically. [30]

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[28] ASTM INTERNATIONAL, WEST CONSHOHOCKEN, PA, *supra* note 23.
[29] https://s3.wp.wsu.edu/uploads/sites/192/2018/03/clearinhouse.pdf
[30] MARKETSANDMARKETS, *supra* note 19.

In closing, based on what is currently available within the public domain, it is not clear how EPA will simultaneously meet the statutory requirements of TSCA Section 6(h) and Executive Order 13563 when erroneous data and assumptions currently serve as the basis of the exposure and conditions of use assessment for 2,4,6-TTBP. The ultimate fate of 2,4,6-TTBP is its destruction either from use as a chemical feedstock under strictly controlled conditions (majority use pattern) or as a fuel antioxidant co-product that is combusted (minority use pattern).

Thank you for the opportunity to comment. For any questions about these comments, please feel free to contact us at kevin.kransler@siigroup.com and kari.mavian@siigroup.com.

Sincerely

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