

September 18, 2017

TSCA Confidential Business Information Center (7407M)
WJC East – Room 6428 Attn: TSCA CBI Substantiations
U.S. Environmental Protection Agency
1201 Constitution Avenue, NW
Washington, DC 20004-3302

Subject: Substantiation of Confidential Business Information for TS-KC07Y6.

██████████ asserts and substantiates this CBI information with the understanding that the Agency will maintain this information as confidential. If the Agency denies in part or in total this CBI claim, then it is our understanding that the EPA will notify ██████████ with respect to the reasons for denial in accordance with §14(g)(1)(B).

Pursuant to TSCA §14(c)(2), ██████████ understands that the following information shall not be subject to substantiation requirements.

- ██████████ considers information in the following sections as (A): Processes used in manufacture or processing of a chemical substance, mixture or article:
 - PMN Page 3, Section 3: Prenotice communication (PC);
 - PMN Page 3, Section 4: Previously submitted an exemption application for the chemical substance;
 - PMN Page 3, Section 5: Bona fide submission;
 - PMN Page 3, Section 6: Type of Notice;
 - PMN Page 5, Section B, (2)(b)(1): Monomer or other reactant specific chemical name, CAS Registry Number;
 - PMN Page 5, Section B, (2)(b)(3): Typical composition;
 - PMN Page 5, Section B, (2)(b)(4): Include in identity;
 - PMN Page 5, Section B, (2)(b)(6): Max residual;
 - PMN Page 8, Section A, (1): Operation Description;
 - PMN Page 8, Section A, (1)(d): Process Description;
 - PMN Page 8a: Operation description diagram;
 - PMN Page 9, Section A, (2): Occupation Exposure [Table Information (1) – (12)];
 - PMN Page 9a, Section A, (3): Environmental Release and Disposal [Table Information (1) – (6)];
 - PMN Page 10, Section B, 1(a): Process description;
 - PMN Page 10, Section B, 1(b): Process diagram;
 - PMN Page 10a, Section B, (2): Worker Exposure/Environmental Release [Table Information (1) – (15)];
 - PMN Page 12, List of Attachments: E-Fast Assessment, Manufacturing Process Description, Manufacturing Process Amendment – Per EPA Request October 19, 2016,

[REDACTED]

Manufacturing Diagram – November 10, 2016 Amendment, Customer Blending/formulation process.

- [REDACTED] considers information in the following sections as (B): Marketing and sales information:
 - PMN Page 3, Section 1, (a) – (c): Submitter identification;
 - PMN Page 3, Section 2: Technical contact;
 - PMN Page 6, Section B, (5): Trade identification
 - PMN Page 12, List of Attachments: US SDS

 - [REDACTED] considers information in the following sections as (C): Information identifying a supplier or customer:
 - PMN Page 10, Section B, 1(a): Number of sites;

 - [REDACTED] considers information in the following sections as (E): Specific information regarding the use, function, or application of a chemical substance or mixture in a process, mixture, or article:
 - PMN Page 7, Section C, (2): Use Information;

 - [REDACTED] considers information in the following sections as (F): Specific production or import volumes of the manufacture or processor:
 - PMN Page 7, Section C, (1): Production Volume (Max first 12-month production, Max 12-month production);
 - PMN Page 8, Section A, (1)(b) - (c): Type, Amount and Duration;
 - PMN Page 11, Optional Pollution Prevention Information;

 - [REDACTED] considers information in the following sections as (G): Specific identity of a chemical substance, including the chemical name, molecular formula, Chemical Abstracts Service number, and other information that would identify a specific chemical substance, if the specific identity was claimed as confidential at the time the information was submitted in a notice under section 5:
 - PMN Page 5, Section B, (2)(a): Methods of measurement or basis of estimates;
 - PMN Page 5, Section B, (2)(a)(i): Lowest number average molecular weight;
 - PMN Page 5, Section B, (2)(a)(ii): Max weight % below 500 molecular weight;
 - PMN Page 5, Section B, (2)(a)(iii): Max weight % below 1000 molecular weight;
 - PMN Page 5a, Section B, (2)(d): Chemical Abstracts (CA) name of polymer, CAS Registry Number;
 - PMN page 5a, Section B, (c): Method used to develop or obtain chemical identity;
 - PMN Page 5a, Section B, (2)(e): Chemical structure diagram of polymer;
 - PMN Page 6, Section B, (4): Synonyms;
 - PMN Page 12, List of Attachments: Representative chemical structure, CAS IES Report, Ecological Assessment, Sustainable Future Summary Assessment, ChemSTEER Assessment, and GPC Data Report
- [REDACTED] is also providing substantiation information for confidentiality of the appropriate information elements not covered by the above provisions.
- [REDACTED]



The following reports and/or documents have been submitted as attachments, along with sanitized copies of these reports. Information that is considered confidential in these reports include company names, substance identity (CAS RN and CAS Name), company name(s), and any individual names and signatures.

#	Attachment Name	Attachment Filename	Associated PMN Section Number
1	Available physical-chemical data	TS-KC07Y6_Phys-Chem Data.pdf	Physical and Chemical Properties Worksheet Continued (Chemical

Identified below are the appropriate information element(s) that we are substantiating.

1. For what period of time do you request that the information be maintained as confidential, e.g., until a certain date, until the occurrence of a specified event, or permanently? If the occurrence of a specific even will eliminate the need for confidentiality, please specify the event.

Response:

- [Redacted] requests that the information should be maintained as confidential indefinitely. This applies to all items listed above, and all attachments.

2. Information submitted to the EPA becomes stale over time. Why should the information you claim as confidential be protected for the time period specified in your answer to questions #1?

Response:

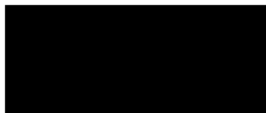
- Information identified in this document should remain confidential indefinitely. Disclosing information related to the substance such as identity (CAS RN and name), chemical structure, molecular weight, and any analytical data provided with the submission will not only be detrimental to [Redacted] competitive position. As the CAS-IES report reveals detailed process information and starting materials, this report is particularly sensitive. If any of the information above would become public knowledge, it will make the copying this product easier. This applies to all items listed above, and all attachments.

3. To the extent your business has disclosed any information to others (both internally and externally), what precautions has your business taken? Please identify the measures or internal controls your business has taken to protect the information claimed as confidential.

Response:

- [Redacted] has taken any number of measures to protect the confidentiality of its business information. The measures can be divided into four major areas: personnel access, site security, document security, and computer security.

- Personnel Access:





Access to confidential business information is restricted to individuals who specially require such information in order to adequately perform their job function and responsibilities.

Persons other than [REDACTED] employees are not given access to electronic systems storing confidential business information. Customers, competitors, and the public may be aware that a product is being manufactured or imported through promotional material, technical data sheets and Material Data Sheets. However, these documents would provide generic descriptions only, thus maintaining confidentiality, in many cases, of detailed formulations.

Such confidential business information is not made available to the public nor to customers unless they have signed a non-disclosure agreement.

- Document Security:

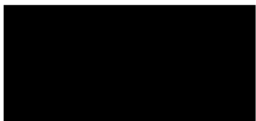
All [REDACTED] confidential business information it is marked "CONFIDENTIAL". The information is kept in locked filing cabinets. These filing cabinets are kept locked after office hours or whenever the responsible party is away from the area. Only the parties directly responsible for the confidential information are permitted to have keys. All confidential information is kept on site. Any confidential information which is to be discarded is first destroyed by on-site shredding or is discarded into a locked storage bin who contents is then shredded by a third part supplier.


[REDACTED] maintains information as confidential by employing such measures as (1) numbering and tracking all laboratory notebooks; (2) controlling information discussed with persons outside [REDACTED] by having a Supplier Contact Manager who controls and is present at all technical meeting with our suppliers; (3) controlling information discussed with persons outside [REDACTED] by management review of all information released to customer; (4) protecting information released in situations where there is technical collaboration between [REDACTED] and outside companies by means of secrecy agreements with long-term protection following termination of the relationship; and (5) informing employees of their obligation to hold such information a confidential if they should leave [REDACTED].

- Computer Security:

Access to all computer information is protected by password security at the system, sub-system, and file levels, with different passwords for each. Passwords are assigned to individual on a limited need-to-know basis, are changed as required and are administered by the Manager, Information Technology as Security Administrator. Access to computer hardware is restricted by use of key lock and secret code systems. In addition to these measures, [REDACTED] is using a mandatory "smart card" to log in the individual computers. [REDACTED] uses a robust firewall system to protect its network and information.

- Site Security:





goes to great lengths to protect proprietary information such as chemical structures of substances. These measures include internal distribution on a “need to know” basis, limited copies, secured computer networks, employee secrecy agreements, secure buildings, locked offices, locked file cabinets, and guards on duty after hours.

These practices generally apply to all sites, and to all items listed above, and all attachments.

4. Is the information contained in any publicly available material such as the Internet, publicly available databases, promotional publications, annual reports, or articles? If so specify which.

Response:

- To the best of our knowledge and after inquiry of those in the business who identify the need for confidentiality in this case, neither the identity of this substance nor intent to manufacture the product and sell it commercially have been disclosed publicly. This applies to all items listed above, and all attachments.

5. Is there any means by which a member of the public could obtain access to the information? Is the information of a kind that you would customarily not release to the public?

Response:

- This confidential information is not available to third parties, whether our competitors, our customers, our suppliers, or any other party, without our consent. No such information is shared outside of this company except within the scope of a secrecy agreement and for compelling business reasons. Disclosure to customers is only done via a signed confidentiality agreement. This applies to all items listed above, and all attachments.

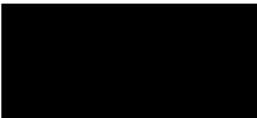
6. Has any governmental body made a determination as to the confidentiality of the information? If so, please attach a copy of the determination.

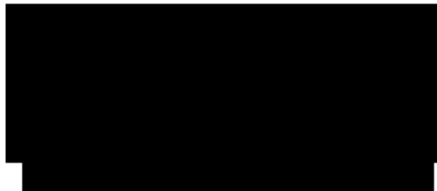
Response

- To the best of our knowledge, no other governmental body made a determination as to the confidentiality of the information. This applies to all items listed above, and all attachments.

7. Will disclosure of any information element claimed as CBI likely result in substantial harm to your business’s competitive position?

Response:

- Disclosing the information stated above would be harmful to our competitive position. It may provide a useful insight into the direction of our research activities. If this information is known to the competitors, they may replicate our product without investing into research and development, and offer it at a lower price.
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- Studies that are claimed confidential in this submission are [REDACTED] property. These will be submitted to other government agencies if the company decides to expand its markets to other countries. [REDACTED] would like to retain our competitive edge. If this information is made public, our competitors may use this information and enter new markets ahead of [REDACTED]. This would not be fair to [REDACTED], the inventor, innovator and developer of the substance and studies. This applies to all items listed above, and all attachments.

8. Do you assert that the information is submitted on a voluntary or a mandatory basis? Please explain the reason for your assertion. If you assert that the information is voluntarily submitted information, please explain whether the information is the kind that would customarily not be released to the public.

Response:

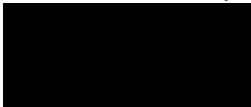
- Submission of any available data on the PMN chemical is mandatory during the notification process. This applies to all items listed above, and all attachments, none of which [REDACTED] is submitting voluntarily. However, [REDACTED] often submits surrogate data on analog substances to enable a better understanding of the health and safety effects of the PMN substance when that data is not available for the notified substance.

9. Whether you assert the information as voluntary or involuntary, please address why disclosure of the information would tend to lessen the availability to the EPA of similar information in the future.

Response:

- [REDACTED] will always submit the data mandated by the EPA for a notification of a chemical that it strongly desires. However, disclosure of confidential business information might make [REDACTED] less apt to pursue registration and investment in chemical infrastructure to synthesize more financially risky chemical substances. The EPA would lose out on obtaining data that can also be used in other areas of TSCA. [REDACTED] will also be inclined to submit less surrogate data if the CBI is revealed. If EPA routinely disclosed this kind of information in the face of [REDACTED] claims, [REDACTED] and the rest of the US chemical industry would become less inclined to want to share this kind of information with EPA in the future, as participants in the US chemical industry would not have any assurance of protecting the confidentiality of the significant investments in their new substance/formulation/technologies, and therefore would be unable to protect their investment through the use of trade secret protections. The efforts of some parties to establish or grow market share through the aggressive use of competitive intelligence already makes it difficult to identify, deter or delay the introduction of third party copy-cat products, often at reduced sales price, given the significantly lower investment such copy-cats have incurred to come to market. The disclosure of this sensitive information would also support the rise and commercial success of lower quality counterfeit products, sold under the guise of the trademarked product.

10. Does any of the information you are claiming as CBI contain (a) trade secret(s)?





Response:

- Very often the chemicals that we submit in section 5 notices has not been patented yet or in some cases will be held as trade secret. A series of PMNs of a class of compounds for a given use will have far fewer substances than the examples and claims of patents. Additionally, while a patent may have the favored compound in one of the examples, it never points to that compound or links a tradename with a compound that functions excellently. However, a patent takes longer to be issued than a PMN, so many times [REDACTED] has no choice than to claim CBI for a compound to protect its intellectual property. There are other times that it might be advantageous not to file a patent at all and maintain a new compound as a trade secret to confuse competitors.

11. Explain any other issue you deem relevant (including, if pertinent, reasons why you believe that the information you claim to be CBI is not emission data or effluent data).

Response:

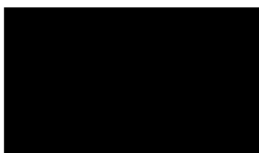
- No emission data was submitted in the notice, therefore substantiation is not required.


If you have any questions, please contact [REDACTED]

Sincerely,

[REDACTED]

[REDACTED]





Sanitized

Contains Confidential Business Information

September 18, 2017

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WJC East – Room 6428 Attn: TSCA CBI Substantiations
U.S. Environmental Protection Agency
1201 Constitution Avenue, NW
Washington, DC 20004-3302

Subject: TSCA CBI Substantiations:

I hereby certify to the best of my knowledge and belief that all information entered on this form is complete and accurate.

I further certify that, pursuant to 15 U.S.C § 2613 (c), for all claims for confidentiality made with this submission, all information submitted to substantiate such claims is true and correct, and that it is true and correct that

- (i) My company has taken reasonable measures to protect the confidentiality of the information;*
- (ii) I have determined that the information is not required to be disclosed or otherwise made available to the public under any other Federal law;*
- (iii) I have a reasonable basis to concluded that disclosure of the information is likely to cause substantial harm to the competitive position of my company; and*
- (iv) I have a reasonable basis to believe that the information is not readily discoverable through reverse engineering.*

Any knowing and willful misrepresentation is subject to criminal penalty pursuant to 18 U.S.C. § 1001.

