GENENCOR®
A Danisco Division

March 6, 2009

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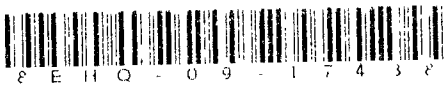
TSCA Confidential Business Information Center (7407M)
EPA East - Room 6428 Attn: Section 8(e)
U.S. Environmental Protection Agency
1201 Constitution Avenue, NW
Washington, DC 20004-3302



To: TSCA 8 (e) coordinator:

Danisco has recently obtained degradation and ecotoxicity data on the substance 4-hydroxy- 3,5 dimethoxy benzonitrile (syringonitrile), CAS # 72684-95-8. This substance has entered into US commerce solely as a component of a mixture with laccase enzyme as of February 23, 2009, as notified to EPA by NOC on March 3, 2009, PMN Case Number P-08-0002.

The attached information being submitted in accordance with TSCA section 8 (e) contains information from biodegradation and ecotoxicity studies performed by contract labs for Danisco on both the single substance and on the substance as part of the mixture notified to EPA in the NOC. Although the substance in isolation is not biodegradable and is regarded as potentially harmful to aquatic life, the substance is present in US commerce as part of a mixture with laccase enzyme and presents no environmental hazard in this format.

Part of the enclosed information is business confidential, as specified in section (b) and justified in section (a). Both a CBI version and a NCBI version are included in this submission.

If you have any questions, please contact me.

Sincerely,

Vincent J. Sewalt, PhD
Director of Regulatory Affairs
Genencor, a Danisco division

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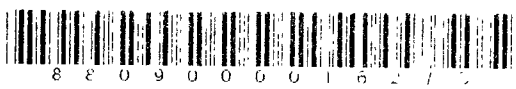

Encl.

Company Sanitized

MR 317666

(a) Confidential Business Claims

Danisco is claiming certain chemical substance information (product mixture with laccase enzyme) and laccase enzyme source information as confidential. Below are the answers to questions provided in 'Support Information for Confidentiality Claims,' on the TSCA Section 8 (e) website http://www.epa.gov/opptintr/tsca8e/pubs/confidentialbusinessinformation.htm.

Substantiation Questions

1. Is your company asserting this confidential business information (CBI) claim on its own behalf? If the answer is no, please provide company name, address and telephone number of entity asserting claim.

   Yes.

2. For what period do you assert your claim(s) of confidentiality? If the claim is to extend until a certain event or point in time, please indicate that event or time period. Explain why such information should remain confidential until such point.

   We request the product component concentration information and laccase enzyme source information be kept confidential for the indefinite future. Release of this information will give competitors knowledge about the product formula and cost structure. This information will give them unfair advantage on pricing and teach them Danisco's proprietary production process.

   As the mixture containing the chemical substance will be employed on an ongoing basis, no finite time deadline can be identified at which CBI status will lapse.

3. Has the information that you are claiming as confidential been disclosed to any other governmental agency, or to this Agency at any other time? Identify the Agency to which the information was disclosed and provide the date and circumstances of the same. Was the disclosure accompanied by a claim of confidentiality? If yes, attach a copy of said document reflecting the confidentiality agreement.

   No.

4. Briefly describe any physical or procedural restrictions within your company relating to the use and storage of the information you are claiming CBI.

   The confidential information that relates to product formulation and enzyme source is part of the company's internal operations documentation and is being claimed as confidential. Procedures are written and noted for "internal" use only. There is restricted access to the plant facility limiting information exchange with outside persons.

   All Danisco employees sign confidentiality agreements. They are informed that this type of information is confidential. Disclosure beyond employees only occurs (1) to companies that are contractually bound to preserve confidential status, and (2) to government agencies under appropriate, narrow circumstances.

5. If anyone outside your company has access to any of the information claimed CBI, are they restricted by confidentiality agreement(s). If so, explain the content of the agreement(s).

   At this time no one outside our company has access to the component concentration information of the mixture claimed as CBI. Any future access to the CBI information will be subject to standard non-disclosure agreements.

6. Does the information claimed as confidential appear or is it referred to in any of the following:

   a. Advertising or promotional material for the chemical substance or the resulting end product;

   No. Promotional materials for the ready-to-use laccase formulation do not even disclose the identity of the chemical substance used as mediator (syringonitrile), let alone the quantitative composition of the mixture or the enzyme source.

   b. Material safety data sheets or other similar materials (such as technical data sheets) for the substance or resulting end product (include copies of this information as it appears when accompanying the substance and/or product at the time of transfer or sale);

   The ingredient listing of the mixture comprising the OSHA hazardous chemical substances is disclosed in the MSDS. However, the quantitative composition (claimed as CBI) is not, and neither is the enzyme source.

   c. Professional or trade publications; or
   d. Any other media or publications available to the public or to your competitors.

   No, to the best of our ability confidential information is not disclosed in these public files.

7. Has EPA, another federal agency, or court made any confidentiality determination regarding information associated with this substance? If so, provide copies of such determinations.

   No.

8. Describe the substantial harmful effects that would result to your competitive position if the CBI information is made available to the public? In your answer, explain the causal relationship between disclosure and any resulting substantial harmful effects. Consider in your answer such constraints as capital and marketing cost, specialized technical expertise, or unusual processes and your competitors access to your customers. Address each piece of information claimed CBI separately.

   There are several types of confidential information:

   (1) concentration of components in mixture;

   (2) laccase source.

(1) Dissemination of quantitative mixture composition would allow a competitor to analyze Danisco's technical capabilities, production and cost structure and give them an unfair advantage in the market place. In addition, it would advance a competitor's process and product development capabilities in general, and potentially would also allow them to quickly develop a similar product.

(2) [redacted] laccase has high specificity for syringonitrile as a reaction mediator, as opposed to other laccases currently on the market. Dissemination of our laccase source would advance a competitor's process and product development capabilities in general, and potentially would also allow them to quickly develop a similar product.

9. Has the substance been patented in the U.S. or elsewhere? Is a patent for the substance currently pending?

No patents have been issued. The use of syringonitrile as mediator for laccase enzyme in textiles bleaching applications is patent pending, but the exact composition of the ready-to-use mixture is not disclosed. A separate patent application has been filed for the [redacted] laccase enzyme.

10. Is this substance/product commercially available and if so, for how long has it been available on the commercial market?
    a. If on the commercial market, are your competitors aware that the substance is commercially available in the U.S.?
    b. If not already commercially available, describe what stage of research and development (R&D) the substance is in, and estimate bow soon a market will be established.
    c. What is the substance used for and what type of product(s) does it appear in.

Yes, first import of the substance as part of the ready-to-use mixture containing the substance occurred on February 23, 2009. The NOC for syringonitrile was filed on March 3, 2009.

As the first import took place very recently and also because syringonitrile is not disclosed in promotional materials as the mediator for the ready-to-use laccase product, it is unlikely that our competitors are aware that the substance is in commerce in the U.S.

The substance, as component of a ready-to-use laccase enzyme product, is used for industrial textiles bleaching in commercial laundries, especially denim bleaching to create a faded look. Use of the product is describe in PMN TS-OJHPM6, except that the PMN states that the substance will be sold to Textile Chemical formulators for blending into a ready-to-use formulation, whereas since the filing of the PMN (and after its review was dropped by EPA), Danisco elected to develop and manufacture a ready-to-use blended product ex-U.S. for import into the U.S.

11. Describe whether a competitor could employ reverse engineering to identically recreate the substance?

Competitors have already entered the market and they have developed similar products. If fully disclosed, competitors would have no trouble 'reverse-engineering' our product, process, or parts of our process, and this would allow them a competitive advantage in the specific target market for this product. The new product is an enhanced version of an

existing product, and is based on a unique combination of a new laccase enzyme source and a laccase reaction mediator unique suited to this laccase source. Competitor introduction of a similar product would require specialized genetic technical expertise to identify and isolate the enzyme source and construct the production microorganism and development of a specialized process to produce the intended end product. Competitors clearly have the expertise to do this type of work. Dissemination of our confidential information could very well lead to disastrous effects for Danisco in our target market.

Disclosing actual quantitative information would accelerate a competitor's ability to reverse-engineer the ready-to-use product.

12. Do you assert that disclosure of this information you are claiming CBI would reveal:
    a. confidential processes used in manufacturing the substance;
    b. if a mixture, the actual portions of the substance in the mixture;
    c. information unrelated to the effects of the substance on human health or the environment?
    If your answer to any of the above questions is yes, explain how such information would be revealed.

    Disclosure of the CBI information would reveal

    a. the source of the laccase enzyme used in the mixture with the chemical substance, which is part of the confidential process used in manufacturing the mixture
    b. the approximate portions of the substances in the mixture.

13. Provide the Chemical Abstract Service Registry Number for the product, if known. Is your company applying for a CAS number now or in the near future? If you have applied for a CAS number, include a copy of the contract with CAS.
    The CAS Registry Number for syringonitrile is: 72684-95-8

14. Is the substance or any information claimed CBI the subject of FIFRA regulation or reporting? If so, explain.

    No.

(b) Study Data Summary

Syringonitrile, (3,5-dimethoxy-4-hydroxybenzonitrile) (CAS number 72684-95-8), here referred to as 'Mediator SNP' is used as mediator in conjunction with laccase enzyme originating from [redacted] for textile applications. A battery of toxicological tests was performed by various contract labs on behalf of Danisco to determine the ecotoxic potential and environmental impact of syringonitrile as a solitary substance and as part of a mixture with the enzyme laccase and appropriate buffer agents. Summaries for each study are reported below.

Summary of ecotoxicity studies on mediator SNP as a solitary product:

Algae *Selenastrum capricornutum* 96-hr growth inhibition test (OECD 201) – Mediator SNP was found to have an IC50 of 3.99 mg/L and a NOEC (no observed effect concentration) of <1 mg/L. Under GHS (global harmonization system) guidelines, this classifies SNP as Category Acute 1: "very toxic to aquatic life."

Daphnia magna 48-hr acute toxicity test (OECD 202) - Mediator SNP was found to have a NOEC of 25 mg/L and an EC50 of 37.73 mg/L. Under GHS guidelines, SNP is classified as Category Acute 3: "harmful to aquatic life."

28-day closed bottle biodegradation test (OECD 306) - Mediator SNP was found to achieve 2% biodegradation on day 28 in seawater (closed bottle test). This classifies SNP as "not readily biodegradable."

Based on the results of these ecotoxicity tests, Mediator SNP was determined to be very toxic to aquatic life and not biodegradable. However, mediator SNP is used in textile applications as a blend with laccase enzyme and environmental exposure to the Mediator SNP itself is practically non-existent. After use, the enzyme / mediator mixture is released into the environment through the sewage system and any impact to the environment would result from exposure to this mixture discharge and not to the mediator SNP alone. Taking that into consideration, two additional series of tests were conducted with the liquid mixture (representing water discharge) and a dry enzyme / mediator blend (commercial product).

Studies on dry powder mediator mixture (Mediator-Laccase Blend):

Another set of ecotoxicological studies was performed on the commercial powder blend product containing the Mediator SNP in conjunction with laccase enzyme and formulation ingredients. The biodegradation and ecotoxic potential of a dry mixture using the following blend ratios was determined:

Monosodium Phosphate
Adipic Acid
Mediator (Syringonitrile)
Laccase dry granule

[redacted]

Daphnia magna 48-hr acute toxicity to (OECD 202) - *Daphnia magna* was exposed to the blend at concentrations of 12.5, 25, 75 and 150 mg/l for 48 hours. The 48 hr EC50 was determined to be greater than 150 mg/l. The No Observed Effect Concentration (NOEC) = 150 mg/l. Under GHS guidelines, this classifies the powder blend as "not acutely toxic to Daphnia magna."

72-hr algal (*Desmodesmus subspicatus*) growth inhibition test (OECD 201) - *Desmodesmus subspicatus* was exposed to the blend at concentrations of 12.5, 25, 75 and 150 mg/l for 72 hours. The NOEC based on biomass integral was 12.5 mg/l and the ErC50 was determined to be 110 mg/l. Under GHS guidelines, this classifies the powder blend as "not acutely toxic to algae."

Biodegradation test (CO2 evolution/modified sturm test)(OECD 301B) - The objective of this study was to determine the biodegradability of the mixture by calculating the amount of CO2 released by inoculated medium. Under the conditions of this assay, the mixture attained 8% degradation after 1 day and 71% degradation after 9 days thereby satisfying the 10 day window validation criterion. After 28 days the mixture achieved 91% degradation, classifying the powder blend as "readily biodegradable."

Discussion

Ecotoxicological information was initially collected in order to assess the degree of hazard presented by a new substance purchased by Genencor, syringonitrile, for resale as enzyme mediator to be used with laccase enzyme in textile bleaching applications. Since the filing of the PMN for syringonitrile and after its review by EPA closed, Danisco elected to develop and manufacture a ready-to-use product blended ex-U.S. for import into the U.S. Since syringonitrile is in commerce in the US only as part of a mixture, environmental exposure in the US to the substance by itself in the US is negligible, and only the study results on the mediator / enzyme mixture are pertinent to Danisco's product. The use of this dry blended product does not constitute any environmental/ecological hazard.