Cover Letter

This is an Optional Cover Letter Test.

BIO2021P1

Form Approved. O.M.B. No. 2070-0012. Approval Expires 12/31/2022

EPA Biotech Form

Biotech Form Report Number		Mark (X) if anything is CBI [X]

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 protection for any confidential information made with this submission, all information submitted to substantiate such claims is true and correct, and that it is true and correct that the person submitting the claim has:

(i) taken reasonable measures to protect the confidentiality of the information;
(ii) determined that the information is not required to be disclosed or otherwise made available to the public under any other Federal law;
(iii) a reasonable basis to conclude that disclosure of the information is likely to cause substantial harm to the competitive position of the person; and
(iv) 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.

I. SUBMITTER IDENTIFICATION INFORMATION — CBI [X]

First Name	Brooke	Last Name	Plaisance
Position	Not Applicable	Company	CDX Test Org
Mailing Address (Number & Street)	123 Main St		
City	Virginia Beach	State	VA
Postal Code	23462		
e-mail	brooke.plaisance@cgifederal.com	Telephone (include area code)	3375231765

Ia. JOINT SUBMITTER -- If you are submitting this notice as part of a joint submission, mark (X) [ ] CBI [ ]

First Name		Last Name	
Position		Company	
Mailing Address (Number & Street)			
City		State	
Postal Code			
e-mail		Telephone (include area code)	

II. TECHNICAL CONTACT IDENTIFICATION INFORMATION — CBI [X]

First Name	Brooke	Last Name	Plaisance
Position		Company	CDX Test Org
Mailing Address (Number & Street)	123 Main St		
City	Virginia Beach	State	VA
Postal Code	23462		
e-mail	brooke.plaisance@cgifederal.com	Telephone (include area code)	3333333333

III. TYPE OF SUBMISSION (Check One)	
[X]	MCAN (Microbial Commercial Activity Notice)
[ ]	TERA (TSCA Experimental Release Application)
[ ]	Tier I Exemption
[ ]	Tier II Exemption
[ ]	Biotech TME (Test Market Exemption)

IIIa. TS Number
123456

IV. TEXT / COMMENTS	CBI [X]
Testing Submission	

V. FEES CERTIFICATION

If you are submitting a MCAN, Tier II Exemption, TERA, or Biotechnology TME, check the following Fees Certification statement that applies:

- [X] The Company named in Part I is a "small business concern" as defined under 40 CFR 700.43 and will remit the fee as specified in 40 CFR 700.45(c).
- [ ] The Company named in Part I will remit the fee as specified in 40 CFR 700.45(c).
- [ ] This joint submission includes at least one Company which is a "small business concern" and at least one Company which is not a "small business concern," as defined under 40 CFR 700.43. The fee will be remitted with the joint submission. Any remaining balance due for this joint submission is to be paid by the secondary submitter(s).
- [ ] The company named in Part I is submitting a sustainable futures TME. The company has graduated from EPA's Sustainable Futures program and is therefore exempt from fees for this sustainable futures TME.

I certify that to the best of my knowledge and belief:

The company named in this submission intends to manufacture, import, or process for a commercial purpose, other than in small quantities solely for research and development, the microorganism identified in this submission. All information provided in this submission is complete and truthful as of the date of submission. I am including with this submission all test data in my possession or control and a description of all other data known to or reasonably ascertainable by me as required by 40 CFR 725.160 or 725.260.

				Confidential
Signature and title of the Authorized Official (Original Signature Required)	ES/Brooke E Plaisance	Date	08/24/2021	X

LIST OF ATTACHMENTS

#	Attachment Name	Attachment Filename	Number of Pages	Associated Section Number	CBI
1	Attachment Description Test	cgi-logo.png	1		X

Mark (X) this box if the data continues on the next page. ☐

Part IV -- CBI Substantiation

This substantiation contains CBI: **Yes** [X] **No** [ ]

Pursuant to TSCA section 14(c)(3), you must substantiate any CBI claims for information elements other than specific chemical identity at the time this notice is submitted. EPA guidance for complying with TSCA section 14(c)(3) may be found at https://www.epa.gov/tsca-cbi/substantiating-cbi-claims-under-tsca-time-initial-submission. You may also substantiate a request to maintain an existing CBI claim for a specific chemical identity at the time this notice is submitted, but this is not required. Rather, you must substantiate the existing CBI claim for the specific chemical identity by the deadline established in a forthcoming Review Plan, to be promulgated at a later date in accordance with TSCA section 8(b)(4)(C).

If you do not assert a CBI claim at time of submission of this form, or otherwise fail to assert a proper CBI claim (i.e., by failing to substantiate your CBI claim or not providing a certification statement), the information shall be treated as not subject to a CBI claim, and may be made public without further notice. If a single substantiation response applies for all or a class of information claimed as CBI, you should indicate this in your substantiation response. If different substantiation responses are necessary to support CBI claims for different information types, you should provide separate substantiation responses for each information type, clearly identifying the information for which each substantiation applies in the free text boxes (e.g. Question A.1. or 2) or in the additional information box at the end of this form.

Information element(s) that you identified as CBI in previous parts:

[X] Name of Authorized Official/Mailing address (Part I)

[X] Technical Contact/Telephone Number (in U.S.) (Part I)

[X] Specific Confidential Chemical Identity (as listed on the TSCA Inventory)

A. APPLICABLE TO ANY CBI CLAIM (Submitter Identification Information)

(i) Will disclosure of the information claimed as confidential likely cause substantial harm to your business's competitive position? If you answered yes, describe the substantial harmful effects that would likely result to your competitive position if the information is disclosed, including but not limited to how a competitor could use such information, and the causal relationship between the disclosure and the harmful effects.	[ ] Yes [X] No
(ii) Has your business taken precautions to protect the confidentiality of the disclosed information? If yes, please explain and identify the specific measures, including but not limited to internal controls, that your business has taken to protect the information claimed as confidential. If the same or similar information was previously reported to EPA as non-confidential (such as in an earlier version of this submission), please explain the circumstances of that prior submission and reasons for believing the information is nonetheless still confidential.	[X] Yes [ ] No

test

(iii) (A) Is any of the information claimed as confidential required to be publicly disclosed under any other Federal law? If yes, please explain.	[X] Yes [ ] No

test

(B) Does any of the information claimed as confidential otherwise appear in any public documents, including (but not limited to) safety data sheets; advertising or promotional material; professional or trade publications; state, local, or Federal agency files; or any other media or publications available to the general public? If yes, please explain why the information should be treated as confidential.	[X] Yes [ ] No

test

(C) Does any of the information claimed as confidential appear in one or more patents or patent applications? If yes, provide the associated patent number or patent application number (or numbers) and explain why the information should be treated as confidential.	[X] Yes [ ] No

test

(iv) Is the claim of confidentiality intended to last less than 10 years (see TSCA section 14(e)(1)(B))? If yes, please indicate the number of years (between 1-10 years) or the specific date after which the claim is withdrawn.	[X] Yes [ ] No
test	
(v). Has EPA, another federal agency, or court made any confidentiality determination regarding information associated with this microorganism? If yes, please provide the circumstances associated with the prior determination, whether the information was found to be entitled to confidential treatment, the entity that made the decision, and the date of the determination.	[ ] Yes [X] No
test	
Additional comments:	

B. APPLICABLE ONLY TO A SPECIFIC CHEMICAL (Microorganism) IDENTITY CBI CLAIM

(i) Has the identity of the microorganism been kept confidential to the extent that competitors do not know it is being manufactured or imported into US commerce? If not, explain why the microorganism identity should still be afforded confidential status (e.g., the microorganism is publicly known only as being distributed in commerce for research and development purposes, but no other information about the current commercial distribution of the microorganism in the United States is publicly available).	[X] Yes [ ] No
test	
(ii) Does the microorganism leave the site of production or testing in a form which is accessible to the public or to competitors? If yes, please explain what measures have been taken to guard against the discovery of its identity. Further, what is the cost to a competitor, in time and money, to develop appropriate use conditions? What factors facilitate or impede product analysis?	[X] Yes [ ] No
test	
Additional comments:	

C. CERTIFICATION

I certify that all claims for confidentiality made or sought to be maintained with this submission are true and correct, and all information submitted herein to substantiate such claims is true and correct. I further certify 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 conclude 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.

Signature of authorized official		Date	