![SOLVAY logo]

December 23, 2019

<u>Via CDX</u>

Mr. Greg Schweer, Chief
New Chemicals Management Branch
Chemical Control Division
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460

       Re: [   ]
            <u>15-Day Notice Under 40 C.F.R. § 723.50(i)</u>

Dear Mr. Schweer:

This submission is intended to share certain data and information recently received by [   ] regarding the following two proprietary chemical substances that [   ] under Low Volume Exemptions ("LVEs"):

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- *]*

LVE Substance Background

The two referenced chemical substances ("LVE Substances") are not manufactured in the U.S. and are not sold in the U.S. as commercial chemical products. Rather, the LVE Substances are imported by [   ] for use in various industries including automotive, aerospace and electronics. The LVE Substances are manufactured [   ]. The LVE Substances are important to manufacturing operations [   ].

Additional Information

On December 2, 2019, [   ] employees received preliminary human biomonitoring-related information from [   ] pertaining to blood analyses performed on [   ] plant employees.[1] At the same time, [ ] employees obtained information concerning estimates of the half-lives of the respective LVE Substances in blood of those employees. The biomonitoring information indicates that the [   ] has analyzed worker blood samples for PFOA dating back to 2004 and, in 2011, the plant expanded the biomonitoring program to include the LVE Substances. Depending on their tenure and job responsibilities, some workers in the study have

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[1]   At a certain point the biomonitoring program was expanded to include employees at a [   ]. The results described in this letter refer to data from both the [   ] and that R&D facility.

the potential to be exposed to each of the substances addressed by the biomonitoring program.[2] The LVE Substances are both manufactured and used at the [   ]. This is unlike operations in the U.S. where the LVE Substances are only used, and only in TSCA-limited volumes. We understand that the [   ] has used this biomonitoring program to assesses the effectiveness of – and continuously improve – its industrial hygiene-related engineering controls, administrative controls and workplace personal protective equipment.

        In 2004 [   ] began collaborating with the [   ] for this biomonitoring program. Through this collaboration, blood samples were analyzed not only for PFOA and the additional substances, but also for various hematological/clinical chemistry blood parameters, *i.e.*, hematology (Ht, Hb, WBC, RBC, PLTS); liver (albumin, globulins, bilirubin, AST, ALT, ALP, GT); renal (blood urea nitrogen, creatinine, uric acid); pancreas function (amylase); lipid metabolism (cholesterol, triglycerides, Apo-A and Apo-B lipoproteins); hormonal function (TSH, FT3, FT4, testosterone, estradiol, PSA); glucose; and C Reactive Protein (CRP).[3] The [   ] plant also has been providing the [   ] with work history (*i.e.*, date of hire, departments/jobs, dates of changes) and demographic information (*i.e.*, gender, age, BMI, smoking, alcohol consumption and use of medications) on monitoring subjects.

        We understand that the [   ] has been using the blood analyses, the work history and demographic information to perform statistical analyses, on an ongoing basis, with reference to the following objectives: (1) identify trends in blood concentrations of the monitored perfluoro compounds produced at the [   ] facility; and (2) identify any statistical correlation between blood levels of each substance with the monitored blood parameters. As to the LVE Substances, the monitoring and statistical analyses – which are ongoing at this time – currently report or suggest the following:[4]

➢ All analyses for the period 2011-2019 confirm substantial decreasing levels of LVE Substances in the blood of [   ] plant workers. *See* attached data tables (Attachment 1).

➢ Positive statistical associations between the LVE Substances' level in the blood of [   ] plant workers and serum lipids, ALT, γGT, and apoliporotein B; however, when adjusted for PFOA, these associations were not apparent, which points to PFOA as a confounding factor.

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[2]   We understand that the blood analyses used in the program do not (and cannot) differentiate between the two LVE Substances. Accordingly, if both LVE Substances are present in a blood sample, the reported value in the information necessarily reflects a total of the two LVE Substances in the sample. In addition to PFOA and the LVE Substances, the biomonitoring program and results also include another analyte manufactured at the [   ] known as [   ] That product is not manufactured or distributed in the U.S. as a commercial chemical product.

[3]   Blood samples were analyzed for the LVE Substances and PFOA by the [   ]. The hematological parameters were analyzed for by the [   ].

[4]   The preliminary information on the biomonitoring program obtained remains in draft form and incomplete.

➢ Positive statistical associations between the LVE Substances' level in the blood and triglycerides albumin, albumin/globulin ratio, and FT3, and negative statistical associations for alpha-2-globulins, IgG, IgM, and estradiol.

➢ Potential positive statistical associations also were noted for TSH and PSA; however, the researchers reported that these associations were based on relatively few measurements and were therefore considered to be less reliable.

In addition, [   ] has informed us that they estimate the half-life of the LVE Substances in the blood of monitored workers to be approximately 2.5-3 years.

[   ] has informed us that the [   ] researchers have concluded that none of these results raise concerns from a clinico-toxicological point of view, and that the overall results are not indicative of any pathological effects. We understand that [   ] concludes from these preliminary results and analyses that the workplace industrial hygiene controls that it has used and improved during the relevant time frame are effectively serving their intended purpose to reduce potential workplace exposures to the monitored substances. Although the [   ] only *uses* the LVE Substances and, unlike the [   ], does not manufacture them, we understand that the workplace industrial hygiene controls used at the [   ] facility are comparable to those used at like operations at [   ].

We understand that EPA would wish to be timely informed of this additional information and data under TSCA. We assume that EPA's LVE program office would have the principal interest in receiving and understanding this new information. Therefore, we are sharing this new information now and within the LVE program's 15 working day time frame, even though we do not view it as qualifying under 40 C.F.R. § 723.50(i), given the apparent lack of any significant acute or chronic health or environmental effects.

We would be pleased to meet with the Agency to provide further details and answer any questions.

Sincerely,

[   ]

By: [   ]
Attachment

4846-0901-2143, v. 1

ATTACHMENT 1
LVEs L-99-284 and L-02-017

Data tables from the [   ] biomonitoring survey which report blood serum level trends of the LVE Substances L-99-284 and L-02-017 (all in mg/L= ug/mL) in workers at the identified plants (tables renumbered). We understand that the data was approximately log-normally distributed and therefore were $\log_e$ transformed to approach Gaussian distributions.

KEY:

[   ]: Refers to analytes representing a total concentration of both the [   ] substances (if both present). We understand that the blood serum analyses used in the biomonitoring program do not (and cannot) differentiate between these two LVE substances.

ITSM: Refers to the [   ] plant.

ITBL: Refers to the [   ].

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Table 1: [   ] **blood levels (all measurements), 2011-2019.**

Plant		2011	2012	2013	2014	2015	2016	2017	2018	2019	P-value for linear decreasing trend of mean log([ ]
ITSM	N	65	123	264	407	443	242	365	390	408	
	Min	0.007	0.014	0.008	0.003	0.003	0.003	0.003	0.003	0.003	
	Median	0.434	0.380	0.458	0.203	0.177	0.456	0.228	0.150	0.136	
	Mean	0.821	0.872	1.169	0.481	0.478	0.751	0.548	0.412	0.343	<0.001
	Max	4.690	9.540	14.386	4.632	8.485	5.485	6.563	6.842	3.822	
ITBL	N	0	0	63	114	134	46	57	59	77	
	Min			0.003	0.003	0.003	0.003	0.003	0.003	0.003	
	Median			0.083	0.037	0.020	0.110	0.076	0.044	0.028	
	Mean			0.259	0.138	0.089	0.217	0.152	0.102	0.072	<0.001
	Max			2.213	1.394	1.173	1.153	0.810	0.873	0.556	

Table 2: [   ] **blood levels in workers having measurements in each of the last 2 years.**

Plant		2018	2019	P-value for linear trend of mean log([ ])
ITSM	n	368	366	
	Min	0.003	0.003	
	Median	0.160	0.149	
	Mean	0.428	0.360	<0.001
	Max	6.842	3.822	
ITBL	n	56	58	
	Min	0.003	0.003	
	Median	0.043	0.037	
	Mean	0.103	0.080	0.004
	Max	0.873	0.556	

Table 3: [   ] **blood levels in workers having measurements in each of the last 3 years.**

Plant		2017	2018	2019	P-value for linear trend of mean log([ ])
ITSM	n	323	323	322	
	Min	0.003	0.003	0.003	
	Median	0.243	0.174	0.153	
	Mean	0.561	0.444	0.371	<0.001
	Max	6.563	6.842	3.822	
ITBL	n	50	50	51	
	Min	0.003	0.003	0.003	
	Median	0.078	0.061	0.053	
	Mean	0.150	0.115	0.091	<0.001
	Max	0.810	0.873	0.556	

Table 4: [   ] **blood levels in workers having measurements in each of the last 4 years.**

Plant		2016	2017	2018	2019	P-value for linear trend of mean log([ ])
ITSM	n	187	187	187	186	
	Min	0.003	0.003	0.003	0.003	
	Median	0.481	0.476	0.346	0.317	
	Mean	0.736	0.802	0.628	0.522	<0.001
	Max	4.515	6.563	6.842	3.550	
ITBL	n	41	41	41	42	
	Min	0.003	0.003	0.003	0.003	
	Median	0.108	0.096	0.070	0.056	
	Mean	0.205	0.175	0.134	0.105	<0.001
	Max	1.027	0.810	0.873	0.556	

Table 5: [   ] **blood levels in workers having measurements in each of the last 5 years.**

Plant		2015	2016	2017	2018	2019	P-value for linear trend of mean log[ ]
ITSM	N	175	174	174	174	173	
	Min	0.003	0.003	0.003	0.003	0.003	
	Median	0.556	0.503	0.504	0.370	0.336	
	Mean	0.804	0.774	0.843	0.663	0.549	<0.001
	Max	8.485	4.515	6.563	6.842	3.550	
ITBL	N	39	40	40	40	41	
	Min	0.003	0.003	0.003	0.003	0.003	
	Median	0.111	0.110	0.097	0.069	0.057	
	Mean	0.237	0.208	0.177	0.135	0.107	<0.001
	Max	1.173	1.027	0.810	0.873	0.556	

Table 6: [   ] blood levels in workers having measurements in each of the last 6 years.

Plant		2014	2015	2016	2017	2018	2019	P-value for linear trend of mean log([ ])
ITSM	N	162	162	162	162	162	161	
	Min	0.003	0.003	0.003	0.009	0.003	0.003	
	Median	0.613	0.542	0.499	0.488	0.352	0.321	
	Mean	0.832	0.789	0.748	0.812	0.641	0.530	<0.001
	Max	4.632	8.485	4.515	6.563	6.842	3.550	
ITBL	N	36	36	36	36	36	37	
	Min	0.009	0.016	0.012	0.003	0.003	0.003	
	Median	0.171	0.120	0.130	0.098	0.072	0.064	
	Mean	0.295	0.248	0.220	0.187	0.145	0.114	<0.001
	Max	1.394	1.173	1.027	0.810	0.873	0.556	

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