Exponent
1075 Worcester Street
Natick, MA 01760

telephone 508 652 8500
www.exponent.com
Offices in Asia, Europe, and North America

June 4, 2024

John Estrada
Co-Founder, CEO
RiseWell
13795 N Deer Canyon Dr.
Kamas, UT 84036

Subject: RiseWell Kids Toothpaste PFAS Testing Results
Exponent Project No. 2404286.000

Dear Mr. Estrada:

At your request, Exponent, Inc. (Exponent) directed testing of RiseWell Kids Toothpaste samples to assess if certain per- and polyfluoroalkyl substances (PFAS) were present in specific product lots. In this letter, we describe the scope of this testing, the test methods utilized, and the results.

Exponent is a large technical consulting firm with expertise across several disciplines, including analytical chemistry. Dr. Sarah Parker is a Senior Managing Scientist who holds two academic degrees, including a Ph.D. in Chemistry from Harvard University. Dr. Parker specializes in detecting, quantifying, and understanding the presence of chemicals and contaminants (including PFAS) in formulated products, such as cosmetics and over-the-counter (OTC) pharmaceutical products. Linda Cook is a Managing Scientist who holds two academic degrees and specializes in the assessing the reliability of PFAS analytical chemistry data in consumer products. Exponent's findings in this matter, described below, are based on the education, training, and experience of Dr. Parker and Ms. Cook, as well as samples and information provided by RiseWell.

Materials and Methods

A single retained tube of RiseWell Kids Toothpaste product from each of seven manufacturing lots was supplied by RiseWell for analysis, including lots 23061, 23216, 23304, 3E142A,[1] 3E254A, 3E347A, and 4E079A. Exponent understands that these lots represent manufacturing batches from each of the two facilities that manufacture the RiseWell Kids Toothpaste product.

This testing was performed by Eurofins Environment Testing at their Sacramento, CA facility (Eurofins Sacramento). Eurofins Sacramento analyzed these samples according to Method 537.1[2] with modification to prepare solid samples using solvent extraction and to extend the analyte list to 66 target analytes. This sample preparation step included extraction using shaking and ultrasonication in accordance with US EPA method SW846.[3] The analytical approach for PFAS detection is consistent with Method 537.1 and involves analysis of the sample extracts by liquid chromatography tandem mass spectrometry (LC-MS/MS). The modifications to Method 537.1 are necessary because current standardized methods available for the detection of PFAS are limited to specific sample types (e.g., water and soil samples), and there are currently no industry standard methods for the detection of PFAS in cosmetics or over-the-counter pharmaceutical products such as toothpaste. The 66 specific PFAS analyzed by Eurofins Sacramento for these samples are listed in Attachment A.

Analysis

None of the seven tested samples of RiseWell Kids Toothpaste contained detectable levels of any PFAS in the Eurofins Sacramento testing. Specifically, no perfluorooctanesulfonate (PFOS), perfluorooctanoic acid (PFOA), perfluorononanoic acid (PFNA), perfluoroundecanoic acid (PFUnDA), perfluorotridecanoic acid (PFTriDA), or any of the other 61 PFAS analyzed by this method were detected in the toothpaste samples. These test results are summarized in Table 1.

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1 Chain of custody documentation lists lot number ID as “4E142A”. Container label listed “3E142A”.

2 Method 537.1 Determination of selected per- and polyfluorinated alkyl substances in drinking water by solid phase extraction and liquid chromatography/tandem mass spectrometry (LC/MS/MS). EPA Document # EPA/600/R-20/006. Version 2.0, March 2020, United States EPA.

3 Test methods for evaluating solid waste: physical/chemical methods, SW-846, Third edition. 1986, United States EPA.

Table 1. PFAS Result Summary in RiseWell Kids Toothpaste Samples analyzed by Eurofins Sacramento

RiseWell Lot Number	Detection Result (66 PFAS)[4]
23061	None detected
23216	None detected
23304	None detected
3E142A[1]	None detected
3E254A	None detected
3E347A	None detected
4E079A	None detected

Eurofins Sacramento's reported method detection limits (MDLs)[5] for each of the 66 PFAS analytes in these tests were equal to or below a concentration of 0.7 ppb (ranging from 0.1 to 0.7 ppb). Therefore, the "non-detect" results from these tests indicate that the specific PFAS analytes measured in this analysis, if present at any level, must be below a concentration of at most 0.7 ppb in the seven product samples.[6]

Exponent's team reviewed the quality of the analytical data for these samples consistent with procedures detailed in EPA's document Data Review and Validation Guidelines for Perfluoroalkyl Substances (PFASs) Analyzed Using EPA Method 537 (EPA 910-R-18-001, November 2018)[7]. Based on our data quality review, we found these data to be acceptable as reported by the laboratory. Several high and low recoveries were noted for a few isotope dilution analytes (IDAs) however, these QA exceptions would not be expected to impact the quality or accuracy of the reported nondetect results.

[4] For the specific PFAS that are included in the Eurofins testing method, see Attachment A.

[5] The minimum concentration of the PFAS compound in a sample that can be accurately and consistently detected in a sample with 99% confidence that the measured response (concentration) is distinguishable from the measured method blank response.

[6] This analysis relies on Eurofins' analysis and interpretation of the test results, which have not been independently analyzed or verified by Exponent at this time.

[7] Data Review and Validation Guidelines for Perfluoroalkyl Substances (PFASs) Analyzed Using EPA Method 537 (EPA 910-R-18-001, November 2018) https://nepis.epa.gov/Exe/ZyPDF.cgi/P100VW12.PDF?Dockey=P100VW12.PDF

Evaluation of Complainant's Sample Data

Data Reporting

For the RiseWell product PFAS data generated at the Eurofins Environment Testing laboratory in Lancaster, PA on behalf of the complainants, we were provided with only a basis data report (Level 2). We were unable to review the quality of these PFAS data for the toothpaste and associated tubing samples due to the limited nature of the Level 2 data report.

EPA's Data Review and Validation Guidelines for PFASs "contains guidance to aid the data reviewer in determining the usability of analytical data generated for perfluoroalkyl substances (PFAS)."[8] While some of the critical data quality elements assessed using EPA's data validation procedures are provided in a standard Level 2 data package, to perform a complete validation of the PFAS data, a more comprehensive laboratory data package (Level 4) is required.

Some of the data quality elements outlined in EPA's Data Validation procedure that are not included in a Level 2 data package, but are included in a Level 4 data package, include:

- Liquid Chromatograph/Mass Spectrometer Instrument Performance Check – a test performed to ensure acceptable chromatography performance of the instrument before calibration begins.
- Initial Calibration – multiple standards at varying concentrations are analyzed on the instrument to develop a calibration range.
- Continuing Calibration Check (CCC) – a single standard analyzed throughout the analytical process to demonstrate that the instrument is still within the initial calibration.
- Target Analyte Identification – to verify analyte identification the data reviewer needs access to the quantitation reports, mass spectra, and chromatograms. The purpose of this validation step is "to minimize the number of erroneous analyte identifications."
- Target Analyte Quantitation – to verify analyte quantitation the data reviewer needs access to the sample preparation sheets, initial calibration, quantitation reports, and chromatograms. The purpose of the validation step is "to ensure the reported results and MRLs for the target analytes are accurate."

[8] Data Review and Validation Guidelines for Perfluoroalkyl Substances (PFASs) Analyzed Using EPA Method 537 (EPA 910-R-18-001, November 2018)

- System Performance – to verify system performance the data reviewer needs access to the chromatograms.

Without a Level 4 data package, these data quality elements cannot be assessed, and we (or anyone else) are unable to fully validate the data and determine if the reported results are true and accurate detections.

Exponent assessed these data for reasonableness based on our experience with this class of chemicals and our understanding of the challenges presented by chemical analysis of complex matrices, such as toothpaste.

Sample Handling

Inadvertent contamination of a product can occur prior to testing due to improper storage or handling at or after point of purchase. We were unable to assess the likelihood of contamination for this sample, because no information or documentation was provided regarding sample selection, shipment, or subsampling. In fact, the chain-of-custody information present in the Level 2 data set provided by complainants was redacted.

Sample Detections

Because certain PFAS were detected in the testing conducted at Eurofins Lancaster (complainant's testing with only Level 2 data available) but not detected in the testing conducted at Eurofins Sacramento (RiseWell's testing with Level 4 data available), we have analyzed the data carefully to understand whether it is likely or unlikely that the detected PFAS were truly present in the RiseWell toothpaste samples. Our analysis takes into consideration indicators of data quality that are available in Level 4 data from the Eurofins Sacramento testing but are not available in the Level 2 data from the Eurofins Lancaster testing. To the extent that Level 4 data become available for the Eurofins Lancaster testing, our analysis may be supplemented to account for these new data.

Because the MDLs associated with the Eurofins Lancaster testing (ranging from 0.2 to 1 ppb[9]) were similar to the MDL range of 0.1 to 0.7 ppb associated with the Eurofins Sacramento sample analyses, we expect that PFAS present in the sample at levels above 1 ppb would have been detected in both sets of testing.

The data report for the Eurofins Lancaster analysis contained four trace-level detections (below 1 ppb) and three higher concentration detections, as summarized in Table 2.

[9] Range excludes the reporting limit of 2 ppb reported for Perfluoropropionic acid since this compound was not reported for the RiseWell sponsored testing.

Table 2. Complainant's PFAS Result Summary from Eurofins Lancaster

Target Chemical	Carbon Number	Concentration (ppb)
Perfluorooctanoic acid	C8	0.82
Perfluorononanoic acid	**C9**	**74**
Perfluorodecanoic acid	C10	0.53
Perfluoroundecanoic acid	**C11**	**67**
Perfluorododecanoic acid	C12	0.64
Perfluorotridecanoic acid	**C13**	**45**
Perfluorotetradecanoic acid	C14	0.28

All seven detections in the Eurofins Lancaster testing were reported at concentrations above the associated MDLs for these compounds in the subsequent Eurofins Sacramento testing. As such, if these PFAS compounds were truly present in any of the seven RiseWell toothpaste samples analyzed at Eurofins Sacramento, the testing would have been expected to detect them. However, none of these compounds were detected by Eurofins Sacramento suggesting that the detections in the Eurofins Lancaster analyses may be false positives or may be attributable to contamination or another source that was not shared by all RiseWell toothpaste samples.

In addition to the discrepancies in results from the two laboratories, the likelihood of the Eurofins Lancaster results being accurate is decreased by the unusual profile of specific substances detected. There were three long-chain PFAS with odd-numbered perfluorinated chain lengths (C9, C11, and C13) reported in these results, without the presence of any homologues with even-numbered chain lengths of similar concentrations. Review of EPA's publicly available UCMR5[10] data for approximately 17,000 samples, reveals that detections of these compounds were reported at very low frequencies with only 48 (0.3%), 1 (0.01%) and 0 (0%) positive results reported for C9, C11, C13 PFAS, respectively. Likewise, our review of testing data for many other commercial products and environmental samples has similarly shown very low incidence of positive detections for these compounds.

[10] https://www.epa.gov/dwucmr/fifth-unregulated-contaminant-monitoring-rule

False Positive Detections

In our experience, we have observed false positive detections for PFAS compounds in results reported by testing laboratories for samples with complex matrices, like toothpaste. However, without Level 4 data packages, we are unable to determine if the positive detections reported by Eurofins Lancaster are true and accurate detections.

The ion chromatograms for the C9, C11, C13 PFAS compounds in the Eurofins Sacramento testing were evaluated to assess whether interferences would have been likely to cause positive detections in the analysis of the RiseWell toothpaste. For all three of the long-chain PFAS (C9, C11, and C13) that had previously been detected by Eurofins Lancaster, we observed interfering peaks within the ion chromatogram windows for these target PFAS analytes. Although Eurofins Sacramento correctly interpreted that these were interfering peaks, as the spectra did not have the characteristics expected of the targeted PFAS analytes, it is possible that these peaks may have been incorrectly interpreted as true detections in the analysis reported by Eurofins Lancaster.

Without chain-of-custody information, details regarding sample origin and handling, and a Level 4 data package, the quality of the complainant's sample results cannot be further assessed to determine whether the detections reported by Eurofins Lancaster are true and accurate detections, or whether they represent false positive detections.

Conclusions

Seven lots of RiseWell toothpaste were analyzed for the potential presence of 61 targeted PFAS by Eurofins Sacramento, however, none of these PFAS were detected at concentrations above the method detection limits. Our review of the underlying data supports this conclusion for the Eurofins Sacramento testing. We were unable to independently assess the quality of the Eurofins Lancaster results that had previously indicated the presence of seven PFAS in the analysis of one RiseWell toothpaste sample. However, our review of the Eurofins Sacramento data demonstrated the likelihood of the RiseWell toothpaste generating false positive detection results because of the presence of other substances in the RiseWell toothpaste that generate interfering signals in the data. To definitively determine whether the detections reported in the Eurofins Lancaster results were true and accurate, we would need to review indicators of data quality that are not available in the Level 2 data package provided to date.

Limitations

The findings described in this letter are made to a reasonable degree of scientific certainty and are based on the information currently available, as well as relevant education, training, and experience. The results of this analysis may not be suitable for use outside the scope described in this letter. Toothpaste product samples and information relied upon in the generation of this

report was provided by RiseWell. The specific data relied upon in the generation of this report includes the results of testing conducted and reported by Eurofins and has not been separately verified by Exponent.

If you have any questions or require additional information, please do not hesitate to contact Dr. Parker at (652) 856-8510 or sparker@exponent.com, or Ms. Linda Cook at (978) 760-9000 or lcook@exponent.com.

Sincerely,

Sarah Parker, Ph.D.
Senior Managing Scientist

Linda Cook
Managing Scientist

Enclosures (1)

cc:

Attachment A – List of PFAS Analytes

CAS No.	Analyte	Acronym
375-22-4	Perfluorobutanoic acid	PFBA
307-24-4	Perfluorohexanoic acid	PFHxA
375-85-9	Perfluoroheptanoic acid	PFHpA
335-67-1	Perfluorooctanoic acid	PFOA
375-95-1	Perfluorononanoic acid	PFNA
335-76-2	Perfluorodecanoic acid	PFDA
2058-94-8	Perfluoroundecanoic acid	PFUnA
307-55-1	Perfluorododecanoic acid	PFDoA
72629-94-8	Perfluorotridecanoic acid	PFTriA
376-06-7	Perfluorotetradecanoic acid	PFTeA
67905-19-5	Perfluoro-n-hexadecanoic acid	PFHxDA
16517-11-6	Perfluoro-n-octadecanoic acid	PFODA
375-73-5	Perfluorobutane sulfonic acid	PFBS
2706-91-4	Perfluoropentane sulfonic acid	PFPeS
355-46-4	Perfluorohexane sulfonic acid	PFHxS
375-92-8	Perfluoroheptane sulfonic acid	PFHpS
1763-23-1	Perfluorooctane sulfonic acid	PFOS
68259-12-1	Perfluorononane sulfonic acid	PFNS
335-77-3	Perfluorodecane sulfonic acid	PFDS
79780-39-5	Perfluorododecane sulfonic acid	PFDoDS
754-91-6	Perfluorooctane sulfonamide	PFOSA
2355-31-9	N-Methyl Perfluorooctanesulfonamidoacetic acid	NMeFOSAA
2991-50-6	N-Ethyl perfluorooctanesulfonamidoacetic acid	NEtFOSAA
757124-72-4	4:2 Fluorotelomer sulfonic acid	4:2 FTS
27619-97-2	6:2 Fluorotelomer sulfonic acid	6:2 FTS
39108-34-4	8:2 Fluorotelomer sulfonic acid	8:2 FTS
120226-60-0	10:2 Fluorotelomer sulfonic acid	10:2 FTS
4151-50-2	N-Ethylperfluorooctane sulfonamide	NEtFOSA

CAS No.	Analyte	Acronym
31506-32-8	N-Methylperfluorooctane sulfonamide	NMeFOSA
24448-09-7	N-Methylperfluorooctane sulfonamidoethanol	NMeFOSE
1691-99-2	N-Ethylperfluorooctane sulfonamidoethanol	NEtFOSE
13252-13-6	Hexafluoropropylene oxide dimer acid	HFPO-DA (Gen X)
756426-58-1	9-Chlorohexadecafluoro-3-oxanone-1-sulfonic acid	9Cl-PF3ONS
763051-92-9	11-Chloroeicosafluoro-3-oxaundecane-1-sulfonic acid	11Cl-PF3OUdS
919005-14-4	4,8-Dioxa-3H-perfluorononanoic acid	ADONA
356-02-5	3:3 Fluorotelomer carboxylic acid	3:3 FTCA
914637-49-3	2H,2H,3H,3H-Perfluorooctanoic acid	5:3 FTCA
812-70-4	3-(Perfluoroheptyl)propanoic acid	7:3 FTCA
53826-12-3	2-(Perfluorohexyl)ethanoic acid	6:2 FTCA
70887-88-6	3,4,4,5,5,6,6,7,7,8,8,8-Dodecafluoro-2-octenoic acid	6:2 FTUCA
27854-31-5	2-(Perfluorooctyl)ethanoic acid	8:2 FTCA
70887-84-2	2H-Perfluoro-2-decenoic acid	8:2 FTUCA
53826-13-4	2-(Perfluorodecyl)ethanoic acid	10:2 FTCA
70887-94-4	2H-Perfluoro-2-dodecenoic acid	10:2 FTUCA
133201-07-7	Perfluoroethylcyclohexane sulfonate	PFECHS
423-41-6	Perfluoropropanesulfonic acid	PFPrS
151772-58-6	Nonafluoro-3,6-dioxaheptanoic acid	NFDHA
863090-89-5	Perfluoro(4-methoxybutanoic) acid	PFMBA
377-73-1	Perfluoro-3-methoxypropanoic acid	PFMPA
113507-82-7	Perfluoro (2-ethoxyethane) sulfonic acid	PFEESA
674-13-5	Perfluoro-2-methoxyaceticacid	PFMOAA
801212-59-9	Perfluoro-4-isopropoxybutanoic acid	PFECA-G11
39492-90-5	Perfluoro-3,5,7,9-butaoxadecanoic acid	PFO4DA
39492-89-2	Perfluoro-3,5,7-trioxaoctanoic acid	PFO3OA
39492-88-1	Perfluoro-3,5-dioxahexanoic acid	PFO2HxA

[11] Discrepancy between listed CAS number and analyte abbreviation was noted in results; listed substance was PFPE-1, while CAS number corresponds to PFECA-G.

CAS No.	Analyte	Acronym
39492-91-6	Perfluoro-3,5,7,9,11-pentaoxadodecanoic acid	PFO5DA
13140-29-9	Perfluoro-2-(perfluoromethoxy)propanoic acid	PMPA
267239-61-2	Perfluoro-2-ethoxypropanoic acid	PEPA
93449-21-9	2,2,3,3-Tetrafluoro-3-methoxypropanoic acid	MTP
2416366-22-6	4-(2-Carboxy-1,1,2,2-tetrafluoroethoxy)-perfluoropentanoic acid	R-EVE
801209-99-4	1,1,2,2-Tetrafluoro-2-(1,2,2,2-tetrafluoroethoxy)ethanesulfonic acid	NVHOS
773804-62-9	2,2,3,3-Tetrafluoro-3-{[1,1,1,2,3,3-hexafluoro-3-(1,2,2,2-tetrafluoroethoxy)propan-2-yl]oxy}propanoic acid	Hydro-EVE Acid
2416366-18-0	Perfluoro-4-(2-sulfoethoxy)pentanoic acid	R-PSDA
2416366-19-1	Fluoro[perfluoro-2-(perfluoro-2-sulfoethoxy)propoxy]acetic acid	Hydrolyzed PSDA
2416366-21-5	1,1,2,2-Tetrafluoro-2-[(1,1,1,2,3,3,4,4-octafluorobutan-2-yl)oxy]ethane-1-sulfonic acid	R-PSDCA
749836-20-2	7H-Perfluoro-4-methyl-3,6-dioxaoctanesulfonic acid	Hydro-PS Acid