## AMA Analytical Services, Inc.

Focused on Results. CERTIFICATE OF ANALYSIS

Chain of Custody: 626190
Client: US Food \& Drug Adminitration
Address: Office of Cosmetics \& Colors
4300 River Road
College Park, MD 20740
Attention: John Gasper

Date Submitted: 4/12/2021 Date Analyzed: 5/14/2021-5/28/2021
Report Date: 7/23/2021
Date Sampled: Not Provided
erson Submitting: Martha Schwartz
Revised: 7/27/2021 (Revision \#1)
SUMMARY OF ANALYSIS
TEM LOD TEM LOQ

| AMA Sample ID | Client Sample ID | TEM LOD <br> Using ASTM D5756 <br> Mass Calculation | TEM LOQ <br> Using ASTM D5756 <br> Mass Calculation | \% Chrysotile by TEM <br> Using ASTM D5756 <br> Mass Calculation | \% Tremolite by TEM <br> Using ASTM D5756 <br> Mass Calculation | Tremolite by TEM <br> Using ASTM D5756 <br> Mass Calculation | Asbestos by PLM | \% Organics | \% Acid <br> Soluable | \% Other | Comments |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 626190-1A | 03242021-1 | 0.00000243\% | 0.00000973\% | ND | ND | < 0.00001\% | ND | 25.48\% | 3.43\% | 71.08\% |  |
| 626190-1B | 03242021-1 | 0.00000336\% | 0.00001346\% | ND | ND | < 0.00001\% | ND | 25.57\% | 5.03\% | 69.40\% |  |
| 626190-1C | 03242021-1 | 0.00000256\% | 0.00001023\% | ND | ND | < 0.00001\% | ND | 25.42\% | 3.79\% | 70.79\% |  |
| 626190-2A | 03242021-2 | 0.00000197\% | 0.00000788\% | ND | ND | < 0.00001\% | ND | 61.83\% | 7.88\% | 30.29\% |  |
| 626190-2B | 03242021-2 | 0.00000194\% | 0.00000777\% | ND | ND | < 0.00001\% | ND | 61.77\% | 8.08\% | 30.15\% |  |
| 626190-2C | 03242021-2 | 0.00000214\% | 0.00000857\% | ND | ND | < 0.00001\% | ND | 61.79\% | 7.98\% | 30.23\% |  |
| 626190-3A | 03242021-3 | 0.00000272\% | 0.00001089\% | ND | ND | < 0.00001\% | ND | 17.60\% | 3.43\% | 78.97\% |  |
| 626190-3B | 03242021-3 | 0.00000246\% | 0.00000984\% | ND | ND | < 0.00001\% | ND | 17.37\% | 3.54\% | 79.09\% |  |
| 626190-3C | 03242021-3 | 0.00000269\% | 0.00001077\% | ND | ND | < 0.00001\% | ND | 17.22\% | 6.64\% | 76.14\% |  |
| 626190-4A | 03242021-4 | 0.00000310\% | 0.00001239\% | ND | ND | < 0.00001\% | ND | 2.42\% | 1.16\% | 96.42\% |  |
| 626190-4B | 03242021-4 | 0.00000347\% | 0.00001388\% | ND | ND | < 0.00001\% | ND | 2.49\% | 4.14\% | 93.37\% |  |
| 626190-4C | 03242021-4 | 0.00000278\% | 0.00001112\% | ND | ND | < 0.00001\% | ND | 2.42\% | 3.72\% | 93.85\% |  |
| 626190-5A | 03242021-5 | 0.00000201\% | 0.00000802\% | ND | ND | < 0.00001\% | ND | 20.57\% | 10.56\% | 68.86\% |  |
| 626190-5B | 03242021-5 | 0.00000217\% | 0.00000866\% | ND | ND | < 0.00001\% | ND | 20.48\% | 9.83\% | 69.69\% |  |
| 626190-5C | 03242021-5 | 0.00000201\% | 0.00000804\% | ND | ND | < 0.00001\% | ND | 20.51\% | 10.70\% | 68.79\% |  |
| 626190-6A | 03242021-6 | 0.00000190\% | 0.00000762\% | ND | ND | < 0.00001\% | ND | 0.08\% | 6.61\% | 93.31\% |  |
| 626190-6B | 03242021-6 | 0.00000207\% | 0.00000828\% | ND | ND | < 0.00001\% | ND | 0.06\% | 6.03\% | 93.91\% |  |
| 626190-6C | 03242021-6 | 0.00000282\% | 0.00001127\% | ND | ND | < 0.00001\% | ND | 0.06\% | 8.02\% | 91.92\% |  |
| 626190-7A | 03242021-7 | 0.00000205\% | 0.00000821\% | ND | ND | < 0.00001\% | ND | 19.98\% | 8.81\% | 71.21\% |  |
| 626190-7B | 03242021-7 | 0.00000223\% | 0.00000894\% | ND | ND | < 0.00001\% | ND | 20.13\% | 8.18\% | 71.68\% |  |
| 626190-7C | 03242021-7 | 0.00000243\% | 0.00000973\% | ND | ND | < 0.00001\% | ND | 20.08\% | 7.88\% | 72.04\% |  |
| 626190-8A | 03242021-8 | 0.00000247\% | 0.00000988\% | ND | ND | < 0.00001\% | ND | 16.69\% | 14.07\% | 69.25\% |  |
| 626190-8B | 03242021-8 | 0.00000263\% | 0.00001051\% | ND | ND | < 0.00001\% | ND | 16.74\% | 11.65\% | 71.61\% |  |
| 626190-8C | 03242021-8 | 0.00000250\% | 0.00000998\% | ND | ND | < 0.00001\% | ND | 16.69\% | 11.64\% | 71.67\% |  |
| 626190-9A | 03242021-9 | 0.00000196\% | 0.00000784\% | ND | ND | < 0.00001\% | ND | 5.07\% | 8.11\% | 86.82\% |  |
| 626190-9B | 03242021-9 | 0.00000196\% | 0.00000782\% | ND | ND | < 0.00001\% | ND | 5.15\% | 9.22\% | 85.64\% |  |
| 626190-9C | 03242021-9 | 0.00000251\% | 0.00001004\% | ND | ND | < 0.00001\% | ND | 5.03\% | 5.87\% | 89.10\% |  |
| 626190-10A | 03242021-10 | 0.00000241\% | 0.00000962\% | ND | ND | < 0.00001\% | ND | 26.89\% | 5.97\% | 67.14\% |  |
| 626190-10B | 03242021-10 | 0.00000235\% | 0.00000941\% | ND | ND | < 0.00001\% | ND | 26.83\% | 5.59\% | 67.58\% |  |
| 626190-10C | 03242021-10 | 0.00000257\% | 0.00001029\% | ND | ND | < 0.00001\% | ND | 26.79\% | 5.08\% | 68.13\% |  |
| 626190-11A | 03242021-11 | 0.00000199\% | 0.00000795\% | ND | ND | < 0.00001\% | ND | 32.95\% | 5.87\% | 61.17\% |  |
| 626190-11B | 03242021-11 | 0.00000183\% | 0.00000733\% | ND | ND | < 0.00001\% | ND | 32.91\% | 6.95\% | 60.15\% |  |
| 626190-11C | 03242021-11 | 0.00000167\% | 0.00000669\% | ND | ND | < 0.00001\% | ND | 32.86\% | 6.87\% | 60.27\% |  |

LOD $=$ Limit of Detection
LOQ $=$ Limit of Quantification
ND $=$ Not Detected
PLM $=$ Polarized Light Microscopy
TEM = Transmission Electron Microscopy

## AMA Analytical Services, Inc.

Focused On Results. CERTIFICATE OF ANALYSIS

Chain of Custody: 626190
Client: US Food \& Drug Adminitration
Address: Office of Cosmetics \& Colors
4300 River Road
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Attention: John Gasper

## Date Submitted: 4/12/2021

 Date Analyzed: 5/14/2021-5/28/2021Report Date: 7/23/2021
Date Sampled: Not Provided
Person Submitting: Martha Schwartz
Revised: 7/27/2021 (Revision \#1)

TEM LOD

AMA Sample ID Client Sample ID \begin{tabular}{cc}

\& | Using ASTM D5756 |
| :---: |
| Mass Calculation |

 

Using ASTM D5756 <br>
Mass Calculation

$\quad$

Using <br>
Mas
\end{tabular}

SUMMARY OF ANALYSIS
Job Name: Assignment DFPG \#21-18
Job Location: Batch No. 03242021 (Batch \#3)
ob Number: CLIN 0001
PO Number: 75F40119P10689

## SUMMARY OF ANALY

| \% Chrysotile by TEM | \% Tremolite by TEM |  <br> Tremolite by TEM |
| :---: | :---: | :---: |
| Using ASTM D5756 | Using ASTM D5756 | Using ASTM D5756 |
| Mass Calculation | Mass Calculation | Mass Calculation |



Comments



All results are to be considered preliminary and subject to change unless signed by the Technical Director or Deputy
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Re: FDA Office of Cosmetics \& Colors
Case Narrative for COC 626190
626190-1A, 1B, 1C/03242021-1


Re: FDA Office of Cosmetics \& Colors
Case Narrative for COC 626190
626190-2A, 2B, 2C/03242021-2


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Re: FDA Office of Cosmetics \& Colors
Case Narrative for COC 626190
626190-3A, 3B, 3C/03242021-3


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Re: FDA Office of Cosmetics \& Colors
Case Narrative for COC 626190
626190-5A, 5B, 5C/03242021-5


Re: FDA Office of Cosmetics \& Colors
Case Narrative for COC 626190
626190-6A, 6B, 6C/03242021-6


626190-7A, 7B, 7C/03242021-7


Re: FDA Office of Cosmetics \& Colors
Case Narrative for COC 626190

## 626190-8A, 8B, 8C/03242021-8



## 626190-9A, 9B, 9C/03242021-9



Re: FDA Office of Cosmetics \& Colors
Case Narrative for COC 626190
626190-10A, 10B, 10C/03242021-10



AMA Analytical Services, Inc.

## Sample Preparation

Samples were gravimetrically reduced and filtered by (b)(6) on: May 10, 2021 through May 13, 2021 for samples 626190-1A through 626190-4C and NB21-312; on May 14, 2021 through May 18, 2021 for samples 626190-5A through 626190-8C, 626190-12DQC, 626190-13RQC and NB21-325; and on May 19, 2021 through May 20, 2021 for samples 626190-9A through 626190-11C and NB21-329. PLM slide preparations were made by (b) (6) on May 21, 2021. TEM grid preparations were made by:(b)(6) on May 13, 2021 for samples 626190-1A through 626190-4C and NB21-312; (b)(6) on May 19, 2021 for samples 626190-5A through 626190-8C, 626190-12DQC, 626190-13RQC and NB21-325; and (b)(6) on May 20, 2021 and for samples 626190-9A through 626190-11C and NB21-329.
Sample preparation consisted of the following steps:

1) Label and weigh two 8 mL glass vials for each sample in the set - one vial for the PLM preparation and one vial for the TEM preparation.
2) Weigh out 0.1 to 0.8 -grams of material and place in the corresponding 8 mL glass vial. Record weight.
3) Burn samples at $480^{\circ} \mathrm{C}$ for at least 12 -hours.
4) Record Post-Ash weight.
5) Treat ashed sample with reagent grade hydrochloric acid.
6) Filter acid reduced material with a pre-weighed disposable filtration apparatus onto a $47 \mathrm{~mm} 0.4 \mu \mathrm{~m}$ PolyCarbonate filter.
7) Place disposable filtration apparatus with filter into drying oven for 3 hours and then record Post-Acid Reduced weight.
8) Make four PLM slide preparations from the PLM residue for each sample in 1.550 dispersion oil. Make additional preparations in $1.605,1.625,1.680$ and 1.700 dispersion oil(s) as necessary for particle identification.
9) Weigh a portion of the material from the TEM residue and place it into the corresponding pre-weighed 100 mL jar.
10) Fill the 100 mL jar with deionized water
11) Sonicate the jar for $\sim 5$-minutes.
12) Filter 0.1 mL to 2 mL of the solution onto a $47 \mathrm{~mm} 0.22 \mu \mathrm{~m}$ MCE filter.
13) Dry the filter for ${ }^{\sim} 10$-minutes then collapse, carbon coat, and place on a 3 TEM grids.

TEM grid preparations were examined prior to analysis and were rejected if they met the following criteria:

1) Less than $50 \%$ of the carbon coating was intact
2) The grid was too dark due to incomplete dissolution of the filter
3) Heavy particulate loading in excess of $25 \%$
4) Light particulate loading below $10 \%$
5) Uneven distribution of particulate

## Problems Encountered During Preparation \& Resolutions:

No problems were encountered during sample preparation. All gravimetric data was consistent among each group of aliquots and all TEM grid preparations were deemed acceptable for analysis.

## PLM Analysis

Analysis was performed in accordance with NY ELAP 198.6 protocols. The analysis was conducted using an Olympus BH2 polarized light microscope (PLM) equipped with a dispersion staining objective. All four slide preparations for each aliquot were examined; each slide preparation consisted of two (2) coverslips for a total of eight (8) coverslips. 400point count was performed for those samples on which asbestos was observed. If no asbestos was detected on any of the slides, the percentage of fibrous components was determined by visual estimation. The results of this analysis are detailed below in the Discussion and Interpretation of Analytical Findings section for each individual sample.

## Point Counting

If asbestos was observed on the slide preparations, the amount of asbestos was quantified using point count techniques. Point counting is form of quantifying PLM samples. One of the oculars of each PLM microscope is etched with a crosshair. When point counting, whatever is under the crosshair is counted as one point of whatever the material is. Four (4) slide preparations with a total of eight (8) coverslips are prepared for each sample. The microscope mechanical
stage is used to randomly move the slide. After each movement, whatever is under the crosshair, provided the point is not empty, is counted. Fifty (50) non-empty points are counted on each of the eight (8) coverslips for a total of four hundred (400) points. The total asbestos points counted are divided by the total points counted to calculate the percentage.

Example:
11 points of asbestos were counted out of the 400 total points
Slide percentage $=(11 \mathrm{pts} / 400 \mathrm{pts}) * 100 \%$
Slide percentage $=2.75 \%$
This number is not the final asbestos percentage. To calculate the final percentage, this number must be corrected to account for the material lost during gravimetric reduction preparation. See the Calculations section below for additional details.

## TEM Analysis

Analysis was performed in accordance with modified NY ELAP Method 198.4 protocols. The analysis was performed using JEOL JEM-100CX II and JEOL JEM-100CX transmission electron microscopes (TEM) equipped with Thermo Fisher NSS System 7 Energy Dispersive X-Ray Analyzers (EDXA), at magnifications of 19,000x. All TEM scopes are equipped with a Selective Area Electron Diffraction (SAED) setting that allows the operator to view the diffraction pattern of any mineral substance. Twenty (20) grid openings over two (2) grids were examined for each aliquot.

Modifications to the NY ELAP 198.4 Method were:

1) The residue was not placed in alcohol and prepared using the quick drop method. To obtain a more uniform preparation, the residue was placed in a jar and filled with 100 mL of deionized water. The jar was sonicated, and a portion of the solution was filtered onto a $47 \mathrm{~mm} 0.22 \mu \mathrm{~m}$ MCE filter.
2) Any amphibole or chrysotile particle(s) observed were not quantified by visual estimation. The length and width of the observed particle(s) were measured, and the mass of each amphibole and chrysotile particle was calculated using the ASTM D5756 method.
3) All particles identified as amphibole were included with the counts/concentrations, regardless of size and aspect ratio.

The results of this analysis are detailed below in the Discussion and Interpretation of Analytical Findings section for each individual sample.

## Calculations

TEM ASTM D5756 Mass:
$\mathrm{M}=\pi / 4 \mathrm{~L}^{*} \mathrm{~W}^{2} * \mathrm{D}^{*} 10^{-12}$
Where: M: Mass
L: Length
W: Width
D: Density

## Asbestos Percent Calculation:

```
TEM
EFA(mm}\mp@subsup{}{}{2})*100\textrm{ml}*\textrm{MA}(\textrm{g})*RW(g
    VF(ml) * IW(g) * AA(mm ') * RJ(g)
(The calculated value is then multiplied by 100 to convert it to percent)
Where: EFA: Effective filter area
MA: Mass of asbestos
RW: Weight of residue
TEM
EFA \(\left(\mathrm{mm}^{2}\right)^{*} 100 \mathrm{ml} * \mathrm{MA}(\mathrm{g}) * \mathrm{RW}(\mathrm{g})\) \(\mathrm{VF}(\mathrm{ml}) * \mathrm{IW}(\mathrm{g}) * \mathrm{AA}\left(\mathrm{mm}^{2}\right)^{*} \mathrm{RJ}(\mathrm{g})\)
(The calculated value is then multiplied by 100 to convert \(i\) to percent)
```


## Gravimetric Reduction Percentages:

Organic: $\quad((W 1-W 2) * 100 / W 1$
Acid Soluble: $\quad((\mathrm{W} 2-\mathrm{W} 3) * 100 / \mathrm{W} 1$
Other* Percent: ((W3/W1) * 100) - Calculated Asbestos \%
*Other is defined as the non-asbestos, inorganic, acid insoluble portion of the sample
Where: W1: Weight of sample prior to ashing/acid wash
W2: Weight of sample after ashing
W3: Weight of sample after acid treatment

$$
\begin{aligned}
& \text { PLM } \\
& (\mathrm{ASB} * \mathrm{~W} 3) / \mathrm{W} 1
\end{aligned}
$$

Where: W1: Weight of sample prior to ashing/acid wash
W3: Weight of sample after acid treatment
ASB: Calculated Point Count Result

## VF: Volume filtered

IW: Initial weight of the sample
AA: Area analyzed
RJ: Weight of residue placed into the jar
Note: All reported concentrations were calculated using the gravimetric data from the TEM preparations.

## Limit of Detection and Quantification

We used the mass of a $0.5 \times 0.04$-micron tremolite fiber as the basis for our calculations. Limit of detection (LOD) was defined as 1 fiber and limit of quantification (LOQ) was defined as 4 fibers.

## Discussion and Interpretation of Analytical Findings:

626190-1A, 1B, 1C/Client Sample: 03242021-1

## PLM

All three aliquots of sample 03242021-1 were analyzed by (b)(6) on May 28, 2021. No asbestos or nonasbestos amphibole variants were observed during analysis. The results were calculated using the equations detailed in the Calculations section above.

| 626190-1A | No Asbestos Detected |
| :--- | :--- |
| 626190-1B | No Asbestos Detected |
| 626190-1C | No Asbestos Detected |

TEM
(b)(6)
inalyzed aliquot 1A May 14, 2021. Andreas Saldivar analyzed aliquots $1 B$ and $1 C$ on May 14, 2021. The primary particles observed were talc and mica; silica spheres and iron particles were also observed along with a few talc fibers/ribbons, silica particles, and particles containing magnesium, aluminum, and silicon. No asbestos or non-asbestos amphibole variants were observed during analysis. The results were calculated using the equations detailed in the Calculations section above.

| 626190-1A | No Asbestos Detected |
| :--- | :--- |
| 626190-1B | No Asbestos Detected |
| 626190-1C | No Asbestos Detected |

Below are pictures, diffraction patterns, and chemistry from some of the observed particles. The copper peaks in the chemistry spectra are from the TEM grid. The unidentified (and some identified) peaks in the chemistry spectra are zinc and carbon from the TEM specimen holder.

Re: FDA Office of Cosmetics \& Colors Case Narrative for COC 626190

## Sample 626190-1A, Talc Particle



Hexagonal Diffraction Pattern from the Talc Particle pictured above


626190 FDA 004. tif
626190-1a
Talc Particle Dif
10:05 5/14/2021
TEM Mode: Diffraction
Microscopist: (b)(6)
Camera: NANOSPRT5, Exposure: $800(\mathrm{~ms}) \times 5$ std. frames, Gain: 1, Bin: 1 Gamma: 1.00, No Sharpening, Normal Contrast
$100(1 / \mathrm{A})$
$\mathrm{HV}=100 \mathrm{kV}$
$\mathrm{HV}=100 \mathrm{kV}$
Cam Len: 0.2200 m
AMA Analytical Services, Inc

Re: FDA Office of Cosmetics \& Colors Case Narrative for COC 626190

Chemistry from the Talc Particle pictured above


Sample 626190-1A, Mica Particle


Re: FDA Office of Cosmetics \& Colors Case Narrative for COC 626190

Hexagonal Diffraction Pattern from the Mica Particle pictured above


Chemistry from Mica Particle pictured above


Re: FDA Office of Cosmetics \& Colors Case Narrative for COC 626190

626190-1A, Silica Sphere


626190 FDA_008.tif
626190-1a
Silica Sphere
Cal: $0.002144 \mu \mathrm{~m} /$ pix
10:19 5/14/2021
600 nm
$\mathrm{HV}=100 \mathrm{kV}$

TEM Mode: Ima
Microscopist:(b)(6)
Camera: NANOSPRT5, Exposure: $800(\mathrm{~ms}) \times 5$ std. frames, Gain: 1, Bin: 1 Gamma: 1.00, No Sharpening, Normal Contrast

Direct Mag: $4800 \times$
AMA Analytical Services, Inc

Chemistry from the Silica Sphere pictured above


Re: FDA Office of Cosmetics \& Colors Case Narrative for COC 626190

626190-1A, Iron Particles


626190-1a
Fe Particles
200 nm
Cal: $0.001029 \mu \mathrm{~m} / \mathrm{pix}$
10:29 5/14/2021
TEM Mode: Imaaina
Microscopist:
Camera: NANOSPRT5, Exposure: $800(\mathrm{~ms}) \times 5$ std. frames, Gain: 1, Bin: 1 Gamma: 1.00, No Sharpening, Normal Contrast

## Diffraction Pattern from the Iron Particles pictured above



Re: FDA Office of Cosmetics \& Colors Case Narrative for COC 626190

Chemistry from the Iron Particles pictured above


626190-1A, Talc Fiber


Re: FDA Office of Cosmetics \& Colors Case Narrative for COC 626190

Hexagonal Diffraction Pattern from the Talc Fiber pictured above


Chemistry from the Talc Fiber pictured above


Re: FDA Office of Cosmetics \& Colors Case Narrative for COC 626190

626190-1A, Silica Particles


Chemistry from the Silica Particles pictured above


Re: FDA Office of Cosmetics \& Colors
Case Narrative for COC 626190
626190-1A, Particle containing Magnesium, Aluminum, Silicon, Potassium, and Iron


Hexagonal Diffraction Pattern from the Particle containing Magnesium, Aluminum, Silicon, Potassium, and Iron pictured above


626190 FDA_002.tif
626190-1a
SiMgAIFeK Dif
10:01 5/14/2021
TEM Mode: Diffraction
Microscopist:(b) (6)
Camera: NANOSPRT5, Exposure: $800(\mathrm{~ms}) \times 5$ std. frames, Gain: 1, Bin: 1 Gamma: 1.00, No Sharpening, Normal Contrast
$100(1 / \mathrm{Al}$
$\mathrm{HV}=10 \mathrm{kV}$
Cam Len: $\mathbf{0 . 2 2 0 0} \mathrm{m}$
AMA Analytical Services, Inc

Chemistry from the Particle containing Magnesium, Aluminum, Silicon, Potassium, and Iron pictured above


626190-2A, 2B, 2C/Client Sample: 03242021-2
PLM
All three aliquots of sample 03242021-2 were analyzed by (b)(6) on May 28, 2021. No asbestos or nonasbestos amphibole variants were observed during analysis. The results were calculated using the equations detailed in the Calculations section above.

| 626190-2A | No Asbestos Detected |
| :--- | :--- |
| 626190-2B | No Asbestos Detected |
| 626190-2C | No Asbestos Detected |

TEM
(b)(6) analyzed aliquot 2A on May 14, 2021 and aliquot $2 B$ on May 17, 2021. (b)(6) analyzed aliquot 2C on May 19, 2021. The primary particle observed was talc; talc fibers/ribbons and iron particles were also observed along with a few calcium particles. No asbestos or non-asbestos amphibole variants were observed during analysis. The results were calculated using the equations detailed in the Calculations section above.

$$
\begin{array}{ll}
\text { 626190-2A } & \text { No Asbestos Detected } \\
\text { 626190-2B } & \text { No Asbestos Detected } \\
\text { 626190-2C } & \text { No Asbestos Detected }
\end{array}
$$

Below are pictures, diffraction patterns, and chemistry from some of the observed particles. The copper peaks in the chemistry spectra are from the TEM grid. The unidentified (and some identified) peaks in the chemistry spectra are zinc and carbon from the TEM specimen holder.

Re: FDA Office of Cosmetics \& Colors Case Narrative for COC 626190

626190-2A, Talc Particle


Hexagonal Diffraction Pattern from the Talc Particle pictured above


Re: FDA Office of Cosmetics \& Colors Case Narrative for COC 626190

Chemistry from the Talc Particle pictured above


626190-2A, Talc Fiber


Re: FDA Office of Cosmetics \& Colors Case Narrative for COC 626190

Hexagonal Diffraction Pattern from the Talc Fiber pictured above


Chemistry from the Talc Fiber pictured above


Re: FDA Office of Cosmetics \& Colors Case Narrative for COC 626190

626190-2A, Iron Particles


626190-2a
Fe Particles
Cal: 0.001774 m/pix
500 nm
Cal: $0.001774 \mu \mathrm{~m} /$ pix
HV $=100 \mathrm{kV}$
11:47 5/14/2021
Direct Mag: $5800 \times$
TEM Mode: Imanina
Microscopist: $(b)(6)$
Camera: NANOSPRT5, Exposure: $800(\mathrm{~ms}) \times 5$ std. frames, Gain: 1, Bin: 1 Gamma: 1.00, No Sharpening, Normal Contrast

## Diffraction Pattern from the Iron Particles pictured above



Re: FDA Office of Cosmetics \& Colors Case Narrative for COC 626190

Chemistry from the Iron Particles pictured above


626190-2B Calcium Particle


Re: FDA Office of Cosmetics \& Colors Case Narrative for COC 626190

Diffraction Pattern from the Calcium Particle pictured above


Chemistry from the Calcium Particle pictured above


626190-3A, 3B, 3C/Client Sample: 03242021-3
PLM
All three aliquots of sample 03242021-3 were analyzed $b_{1}(b)(6)$ n May 28, 2021. No asbestos or nonasbestos amphibole variants were observed during analysis. The results were calculated using the equations detailed in the Calculations section above.

| 626190-3A | No Asbestos Detected |
| :--- | :--- |
| 626190-3B | No Asbestos Detected |
| 626190-3C | No Asbestos Detected |

TEM
(b)(6) analyzed aliquot 3A on May 14, 2021 and aliquot 3B on May 17, 2021.(b)(6) analyzed aliquot 3C on May 19, 2021. The primary particles observed were talc and mica; several iron particles were also observed along with silica spheres and a few talc ribbons/fibers. No asbestos or non-asbestos amphibole variants were observed during analysis. The results were calculated using the equations detailed in the Calculations section above.

| 626190-3A | No Asbestos Detected |
| :--- | :--- |
| 626190-3B | No Asbestos Detected |
| 626190-3C | No Asbestos Detected |

Below are pictures, diffraction patterns, and chemistry from some of the observed particles. The copper peaks in the chemistry spectra are from the TEM grid. The unidentified (and some identified) peaks in the chemistry spectra are zinc and carbon from the TEM specimen holder.

626190-3A, Talc Particle


Re: FDA Office of Cosmetics \& Colors Case Narrative for COC 626190

Hexagonal Diffraction Pattern from the Talc Particle pictured above


Chemistry from the Talc Particle pictured above


Re: FDA Office of Cosmetics \& Colors Case Narrative for COC 626190

626190-3A, Mica Particle


626190 FDA_025.tif
626190-3a
Mica Particle
Mica Particle
Cal: $0.001774 \mu \mathrm{~m} /$ pix
Cal: $0.001774 \mu \mathrm{~m}$
13:23 5/14/2021
13:23 5/14/2021
TEM Mode: Imaging
TEM Mode: Imaging
Camera: NANOSPRT5, Exposure: $800(\mathrm{~ms}) \times 5$ std. frames, Gain: 1, Bin: 1 Gamma: 1.00, No Sharpening, Normal Contrast

Hexagonal Diffraction Pattern from the Mica Particle pictured above


Re: FDA Office of Cosmetics \& Colors Case Narrative for COC 626190

Chemistry from the Mica Particle pictured above
Full scale counts: 1044 626190-3a(2)


626190-3A, Iron Particles


Re: FDA Office of Cosmetics \& Colors Case Narrative for COC 626190

Diffraction Pattern from the Iron Particles pictured above


Chemistry from the Iron Particles pictured above


Re: FDA Office of Cosmetics \& Colors Case Narrative for COC 626190

626190-3A, Silica Sphere


Chemistry from the Silica Sphere pictured above


Re: FDA Office of Cosmetics \& Colors Case Narrative for COC 626190

626190-3A, Talc Ribbon


## Diffraction Pattern from the Talc Ribbon pictured above



Re: FDA Office of Cosmetics \& Colors Case Narrative for COC 626190

Chemistry from the Talc Ribbon pictured above
Full scale counts: $1068 \quad$ 626190-3a(3)


626190-3B, Talc Fiber


Re: FDA Office of Cosmetics \& Colors Case Narrative for COC 626190

Hexagonal Diffraction Pattern from the Talc Fiber pictured above


Chemistry from the Talc Fiber pictured above


## 626190-4A, 4B, 4C/Client Sample: 03242021-4

## PLM

All three aliquots of sample 03242021-4 were analyzed by (b)(6) on May 28, 2021. No asbestos or nonasbestos amphibole variants were observed during analysis. The results were calculated using the equations detailed in the Calculations section above.

| 626190-4A | No Asbestos Detected |
| :--- | :--- |
| 626190-4B | No Asbestos Detected |
| 626190-4C | No Asbestos Detected |

TEM
(b)(6) analyzed aliquot 4A on May 14, 2021. Andreas Saldivar analyzed aliquot 4B on May 19, 2021 and aliquot 4C on May 20, 2021. The primary particles observed were talc and mica; iron and particles containing magnesium, aluminum, and silicon were also observed along with a few talc fibers/ribbons. No asbestos or nonasbestos amphibole variants were observed during analysis. The results were calculated using the equations detailed in the Calculations section above.

| 626190-4A | No Asbestos Detected |
| :--- | :--- |
| $626190-4 B$ | No Asbestos Detected |
| $626190-4 \mathrm{C}$ | No Asbestos Detected |

Below are pictures, diffraction patterns, and chemistry from some of the observed particles. The copper peaks in the chemistry spectra are from the TEM grid. The unidentified (and some identified) peaks in the chemistry spectra are zinc and carbon from the TEM specimen holder.

626190-4A, Talc Particle


Re: FDA Office of Cosmetics \& Colors Case Narrative for COC 626190

Hexagonal Diffraction Pattern from the Talc Particle pictured above


Chemistry from the Talc Particle pictured above


Re: FDA Office of Cosmetics \& Colors Case Narrative for COC 626190

626190-4A, Mica Particle


TEM Mode: Imaging
Camera: NANOSPRI5, Exposure: $800(\mathrm{~ms}) \times 5$ std. frames, Gain: 1, Bin: 1 Gamma: 1.00, No Sharpening, Normal Contrast

Hexagonal Diffraction Pattern from the Mica Particle pictured above


Re: FDA Office of Cosmetics \& Colors
Case Narrative for COC 626190
Chemistry from the Mica Particle pictured above


626190-4A, Iron Particle


Re: FDA Office of Cosmetics \& Colors Case Narrative for COC 626190

Diffraction Pattern from the Iron Particle pictured above


Chemistry from the Iron Particle pictured above


Re: FDA Office of Cosmetics \& Colors
Case Narrative for COC 626190
626190-4A, Particle containing Magnesium, Aluminum, Silicon, and Iron
$2 \mu \mathrm{~m}$

$$
\begin{aligned}
& \text { al: } 0.010289 \mu \mathrm{~m} / \mathrm{p} \\
& 5: 245 / 14 / 2021
\end{aligned}
$$

$\mathrm{HV}=100 \mathrm{kV}$

$$
\begin{aligned}
& \text { 15:24 5/14/2021 } \\
& \text { TEM Mode: Iman }
\end{aligned}
$$

AMA Analytical Services, Inc

Microscopist: (b)(6)
Camera: NANOSPRT5, Exposure: $800(\mathrm{~ms}) \times 5$ std. frames, Gain: 1, Bin: 1 Gamma: 1.00, No Sharpening, Normal Contrast

Diffraction Pattern from the Particle containing Magnesium, Aluminum, Silicon, and Iron pictured above


Re: FDA Office of Cosmetics \& Colors Case Narrative for COC 626190

Chemistry from the Particle containing Magnesium, Aluminum, Silicon, and Iron pictured above


626190-4A, Talc Ribbon


Re: FDA Office of Cosmetics \& Colors Case Narrative for COC 626190

Diffraction Pattern from the Talc Ribbon pictured above


Chemistry from the Talc Ribbon pictured above


## 626190-5A, 5B, 5C/Client Sample: 03242021-5

## PLM

All three aliquots of sample 03242021-5 were analyzed by (b)(6) on May 28, 2021. No asbestos or nonasbestos amphibole variants were observed during analysis. The results were calculated using the equations detailed in the Calculations section above.

| 626190-5A | No Asbestos Detected |
| :--- | :--- |
| 626190-5B | No Asbestos Detected |
| 626190-5C | No Asbestos Detected |

TEM
(b)(6) analyzed aliquot 5A on May 19, 2021. Andreas Saldivar analyzed aliquots 5B and 5C on May 20, 2021. The primary particle observed was mica; several titanium and iron particles were also observed along with talc particles, titanium fibers, silica particles and silica spheres. No asbestos or non-asbestos amphibole variants were observed during analysis. The results were calculated using the equations detailed in the Calculations section above.

| 626190-5A | No Asbestos Detected |
| :--- | :--- |
| 626190-5B | No Asbestos Detected |
| 626190-5C | No Asbestos Detected |

Below are pictures, diffraction patterns, and chemistry from some of the observed particles. The copper peaks in the chemistry spectra are from the TEM grid. The unidentified (and some identified) peaks in the chemistry spectra are zinc and carbon from the TEM specimen holder.

626190-5A, Mica Particle


Re: FDA Office of Cosmetics \& Colors Case Narrative for COC 626190

Diffraction Pattern from the Mica Particle pictured above


Chemistry from the Mica Particle pictured above


Re: FDA Office of Cosmetics \& Colors Case Narrative for COC 626190

## 626190-5A, Titanium Particles



## Diffraction Pattern from the Titanium Particles pictured above



Re: FDA Office of Cosmetics \& Colors Case Narrative for COC 626190

Chemistry from the Titanium Particles pictured above


626190-5A, Particle(s) containing Iron, Magnesium, and Silicon


Re: FDA Office of Cosmetics \& Colors Case Narrative for COC 626190

Diffraction Pattern from the Particle(s) containing Iron, Magnesium, and Silicon pictured above


Chemistry from the Particle(s) containing Iron, Magnesium, and Silicon pictured above


Re: FDA Office of Cosmetics \& Colors Case Narrative for COC 626190

626190-5A, Talc Particle


Hexagonal Diffraction Pattern from the Talc Particle pictured above


Re: FDA Office of Cosmetics \& Colors Case Narrative for COC 626190

Chemistry from the Talc Particle pictured above
Full scale counts: 1129 626190-5a(13)


626190-5A, Titanium Fiber in Mica


Re: FDA Office of Cosmetics \& Colors Case Narrative for COC 626190

Diffraction Pattern from the Titanium Fiber in Mica pictured above


Chemistry from the Titanium Fiber in Mica pictured above


Re: FDA Office of Cosmetics \& Colors Case Narrative for COC 626190

626190-5A, Silica Particle


Microscopist (b) (6)
Camera: NANOSPRT5, Exposure: $800(\mathrm{~ms}) \times 5$ std. frames, Gain: 1, Bin: 1 Gamma: 1.00, No Sharpening, Normal Contrast

## Diffraction Pattern from the Silica Particle pictured above



Re: FDA Office of Cosmetics \& Colors Case Narrative for COC 626190

Chemistry from the Silica Particle pictured above


626190-5A, Silica Sphere


Chemistry from the Silica Sphere pictured above


## 626190-6A, 6B, 6C/Client Sample: 03242021-6

PLM
All three aliquots of sample 03242021-6 were analyzed by l(b)(6) on May 28, 2021. No asbestos or nonasbestos amphibole variants were observed during analysis. The results were calculated using the equations detailed in the Calculations section above.

| 626190-6A | No Asbestos Detected |
| :--- | :--- |
| 626190-6B | No Asbestos Detected |
| 626190-6C | No Asbestos Detected |

TEM
(b) $(6)$ analyzed aliquot 6A on May 19, 2021 and aliquot 6B on May 20, 2021. aliquot 6C on May 21, 2021. The primary particle observed was talc; talc fibers/ribbons were also observed along with a few particles containing magnesium, aluminum, and silicon and calcium particles. No asbestos or non-asbestos amphibole variants were observed during analysis. The results were calculated using the equations detailed in the Calculations section above.

| 626190-6A | No Asbestos Detected |
| :--- | :--- |
| 626190-6B | No Asbestos Detected |
| 626190-6C | No Asbestos Detected |

Below are pictures, diffraction patterns, and chemistry from some of the observed particles. The copper peaks in the chemistry spectra are from the TEM grid. The unidentified (and some identified) peaks in the chemistry spectra are zinc and carbon from the TEM specimen holder.

Re: FDA Office of Cosmetics \& Colors Case Narrative for COC 626190

626190-6A, Talc Particle


Hexagonal Diffraction Pattern from the Talc Particle pictured above


Re: FDA Office of Cosmetics \& Colors Case Narrative for COC 626190

Chemistry from the Talc Particle pictured above
Full scale counts: $1103 \quad$ 626190-6a(1)


626190-6A, Talc Fiber


Re: FDA Office of Cosmetics \& Colors Case Narrative for COC 626190

Hexagonal Diffraction Pattern from the Talc Fiber pictured above


Chemistry from the Talc Fiber pictured above


Re: FDA Office of Cosmetics \& Colors Case Narrative for COC 626190

626190-6A, Talc Ribbon


TEM Mode: Ima
TEM Mode: $\operatorname{Imacing}^{(b)}{ }^{\text {Microscopist: }}$ (6)
Camera: NANOSPRT5, Exposure: $800(\mathrm{~ms}) \times 5$ std. frames, Gain: 1, Bin: 1 Gamma: 1.00, No Sharpening, Normal Contrast

## Diffraction Pattern from the Talc Ribbon pictured above



Re: FDA Office of Cosmetics \& Colors Case Narrative for COC 626190

Chemistry from the Talc Ribbon pictured above


626190-6A, Fiber containing Magnesium, Aluminum, and Silicon


Re: FDA Office of Cosmetics \& Colors Case Narrative for COC 626190

Chemistry from the Fiber containing Magnesium, Aluminum, and Silicon pictured above


626190-6B, Calcium Particles


Re: FDA Office of Cosmetics \& Colors Case Narrative for COC 626190

Diffraction Pattern from the Calcium Particles pictured above


Chemistry from the Calcium Particles pictured above


## 626190-7A, 7B, 7C/Client Sample: 03242021-7

## PLM

All three aliquots of sample 03242021-7 were analyzed by (b)(6) m May 28, 2021. No asbestos or nonasbestos amphibole variants were observed during analysis. The results were calculated using the equations detailed in the Calculations section above.

| 626190-7A | No Asbestos Detected |
| :--- | :--- |
| 626190-7B | No Asbestos Detected |
| 626190-7C | No Asbestos Detected |

TEM
(b)(6) analyzed aliquot 7A on May 19, 2021. Andreas Saldivar analyzed aliquots 7B and 7C on May 25, 2021.

The primary particles observed were talc and mica; titanium and calcium particles were also observed along with a few talc fibers/ribbons and titanium fibers. No asbestos or non-asbestos amphibole variants were observed during analysis. The results were calculated using the equations detailed in the Calculations section above.

| 626190-7A | No Asbestos Detected |
| :--- | :--- |
| 626190-7B | No Asbestos Detected |
| 626190-7C | No Asbestos Detected |

Below are pictures, diffraction patterns, and chemistry from some of the observed particles. The copper peaks in the chemistry spectra are from the TEM grid. The unidentified (and some identified) peaks in the chemistry spectra are zinc and carbon from the TEM specimen holder.

626190-7A, Talc Particle


Re: FDA Office of Cosmetics \& Colors Case Narrative for COC 626190

Hexagonal Diffraction Pattern from the Talc Particle pictured above


Chemistry from the Talc Particle pictured above


## Re: FDA Office of Cosmetics \& Colors

 Case Narrative for COC 626190626190-7A, Mica Particle


## Diffraction Pattern from the Mica Particle pictured above



Re: FDA Office of Cosmetics \& Colors Case Narrative for COC 626190

Chemistry from the Mica Particle pictured above


626190-7A, Titanium Particle


Re: FDA Office of Cosmetics \& Colors Case Narrative for COC 626190

Chemistry from the Titanium Particle pictured above


626190-7A, Calcium Particle


Re: FDA Office of Cosmetics \& Colors Case Narrative for COC 626190

Diffraction Pattern from the Calcium Particle pictured above


Chemistry from the Calcium Particle pictured above


Re: FDA Office of Cosmetics \& Colors Case Narrative for COC 626190

626190-7A, Talc Fiber


Hexagonal Diffraction Pattern from the Talc Fiber pictured above


Re: FDA Office of Cosmetics \& Colors Case Narrative for COC 626190

Chemistry from the Talc Fiber pictured above


626190-7A, Titanium Fiber


Re: FDA Office of Cosmetics \& Colors Case Narrative for COC 626190

Diffraction Pattern from the Titanium Fiber pictured above


Chemistry from the Titanium Fiber pictured above


## 626190-8A, 8B, 8C/Client Sample: 03242021-8

PLM
All three aliquots of sample 03242021-8 were analyzed by (b)(6) on May 28, 2021. No asbestos or nonasbestos amphibole variants were observed during analysis. The results were calculated using the equations detailed in the Calculations section above.

| 626190-8A | No Asbestos Detected |
| :--- | :--- |
| 626190-8B | No Asbestos Detected |
| 626190-8C | No Asbestos Detected |

TEM
(b)(6) inalyzed aliquot 8 A on May 20, 2021. Andreas Saldivar analyzed aliquots 8 B and 8 C on May $26,2021$. The primary particles observed were talc and mica; titanium particles and iron particles/fibers were also observed along with a few silica spheres and barium sulfate particles. No asbestos or non-asbestos amphibole variants were observed during analysis. The results were calculated using the equations detailed in the Calculations section above.

| 626190-8A | No Asbestos Detected |
| :--- | :--- |
| 626190-8B | No Asbestos Detected |
| 626190-8C | No Asbestos Detected |

Below are pictures, diffraction patterns, and chemistry from some of the observed particles. The copper peaks in the chemistry spectra are from the TEM grid. The unidentified (and some identified) peaks in chemistry spectra are zinc and carbon from the TEM specimen holder.

626190-8A, Talc Particle


Re: FDA Office of Cosmetics \& Colors Case Narrative for COC 626190

Hexagonal Diffraction Pattern from the Talc Particle pictured above


Chemistry from the Talc Particle pictured above


Re: FDA Office of Cosmetics \& Colors
Case Narrative for COC 626190
626190-8A, Mica Particle with Iron Particles


Hexagonal Diffraction Pattern from the Mica Particle with Iron Particles pictured above


Re: FDA Office of Cosmetics \& Colors
Case Narrative for COC 626190
Chemistry from the Mica Particle with Iron Particles pictured above


626190-8A, Titanium Particles


Re: FDA Office of Cosmetics \& Colors Case Narrative for COC 626190

Diffraction Pattern from Titanium Particles pictured above


Chemistry from the Titanium Particles pictured above


Re: FDA Office of Cosmetics \& Colors Case Narrative for COC 626190

626190-8A, Iron Particles/Fibers


Diffraction Pattern from the Iron Particles/Fibers pictured above


Re: FDA Office of Cosmetics \& Colors
Case Narrative for COC 626190
Chemistry from the Iron Particles/Fibers pictured above


626190-8A, Silica Sphere


Re: FDA Office of Cosmetics \& Colors Case Narrative for COC 626190

Chemistry from the Silica Sphere pictured above


626190-8A, Barium Sulfate Particle


Re: FDA Office of Cosmetics \& Colors Case Narrative for COC 626190

Diffraction Pattern from the Barium Sulfate Particle pictured above


Chemistry from the Barium Sulfate pictured above


## 626190-9A, 9B, 9C/Client Sample: 03242021-9

## PLM

All three aliquots of sample 03242021-9 were analyzed by (b)(6) on May 28, 2021. No asbestos or nonasbestos amphibole variants were observed during analysis. The results were calculated using the equations detailed in the Calculations section above.

| 626190-9A | No Asbestos Detected |
| :--- | :--- |
| 626190-9B | No Asbestos Detected |
| 626190-9C | No Asbestos Detected |

TEM
(b)(6) analyzed aliquot 9A on May 21, 2021. Andreas Saldivar analyzed aliquots 9B and 9C on May 26, 2021. The primary particle observed was talc; silica particles were also observed along with a few calcium particles, talc fibers/ribbons and particles containing magnesium, aluminum, and silicon. No asbestos or non-asbestos amphibole variants were observed during analysis. The results were calculated using the equations detailed in the Calculations section above.

| 626190-9A | No Asbestos Detected |
| :--- | :--- |
| 626190-9B | No Asbestos Detected |
| 626190-9C | No Asbestos Detected |

Below are pictures, diffraction patterns, and chemistry from some of the observed particles. The copper peaks in the chemistry spectra are from the TEM grid. The unidentified (and some identified) peaks in chemistry spectra are zinc and carbon from the TEM specimen holder.

626190-9A, Talc Particle


Re: FDA Office of Cosmetics \& Colors Case Narrative for COC 626190

Hexagonal Diffraction Pattern from the Talc Particle pictured above


Chemistry from the Talc Particle pictured above


Re: FDA Office of Cosmetics \& Colors Case Narrative for COC 626190

626190-9A, Silica Particles


Chemistry from the Silica Particles pictured above


AMA Analytical Services, Inc.

Re: FDA Office of Cosmetics \& Colors Case Narrative for COC 626190

626190-9A, Calcium Particle


Diffraction Pattern from Calcium Particle pictured above


Re: FDA Office of Cosmetics \& Colors Case Narrative for COC 626190

Chemistry from the Calcium Particle pictured above


626190-9A, Talc Ribbon


Re: FDA Office of Cosmetics \& Colors Case Narrative for COC 626190

Diffraction Pattern from the Talc Ribbon pictured above


Chemistry from the Talc Ribbon pictured above


Re: FDA Office of Cosmetics \& Colors Case Narrative for COC 626190

626190-9A, Fiber containing Magnesium, Aluminum, and Silicon


Chemistry from the Fiber containing Magnesium, Aluminum, and Silicon pictured above


AMA Analytical Services, Inc.

## 626190-10A, 10B, 10C/Client Sample: 03242021-10

## PLM

All three aliquots of sample 03242021-10 were analyzed by $(\mathrm{b})(6)$ on May 28, 2021. No asbestos or non-asbestos amphibole variants were observed during analysis. The results were calculated using the equations detailed in the Calculations section above.

| 626190-10A | No Asbestos Detected |
| :--- | :--- |
| 626190-10B | No Asbestos Detected |
| 626190-10C | No Asbestos Detected |

TEM
(b)(6) analyzed aliquot 10A on May 21, 2021. Andreas Saldivar analyzed aliquots 10 B and 10 c on May 27, 2021. The primary particles observed were talc and mica; iron and titanium particles were also observed along with some talc fibers/ribbons. No asbestos or non-asbestos amphibole variants were observed during analysis. The results were calculated using the equations detailed in the Calculations section above.

| 626190-10A | No Asbestos Detected |
| :--- | :--- |
| 626190-10B | No Asbestos Detected |
| 626190-10C | No Asbestos Detected |

Below are pictures, diffraction patterns, and chemistry from some of the observed particles. The copper peaks in the chemistry spectra are from the TEM grid. The unidentified (and some identified) peaks in chemistry spectra are zinc and carbon, which are from the TEM specimen holder.

626190-10A, Talc Particle


Re: FDA Office of Cosmetics \& Colors Case Narrative for COC 626190

Hexagonal Diffraction Pattern from the Talc Particle pictured above


Chemistry from the Talc Particle pictured above


## Re: FDA Office of Cosmetics \& Colors

 Case Narrative for COC 626190626190-10A, Mica Particle


Hexagonal Diffraction Pattern from the Mica Particle pictured above


Re: FDA Office of Cosmetics \& Colors
Case Narrative for COC 626190
Chemistry from the Mica Particle pictured above
Full scale counts: $878 \quad$ 626190-10a(2)


626190-10A, Iron Particles


Re: FDA Office of Cosmetics \& Colors Case Narrative for COC 626190

Diffraction Pattern from Iron Particles pictured above


Chemistry from the Iron Particles pictured above


## Re: FDA Office of Cosmetics \& Colors

Case Narrative for COC 626190
626190-10A, Titanium Particles


Microscopist:(b)(6)
Camera: NANOSPRT5, Exposure: $800(\mathrm{~ms}) \times 5$ std. frames, Gain: 1, Bin: 1 Gamma: 1.00, No Sharpening, Normal Contrast

## Diffraction Pattern from the Titanium Particles pictured above



Re: FDA Office of Cosmetics \& Colors Case Narrative for COC 626190

Chemistry from the Titanium Particles pictured above


626190-10A, Mica Particle with Titanium


Re: FDA Office of Cosmetics \& Colors Case Narrative for COC 626190

Hexagonal Diffraction Pattern from the Mica Particle with Titanium pictured above


Chemistry from the Mica Particle with Titanium pictured above


Re: FDA Office of Cosmetics \& Colors Case Narrative for COC 626190

626190-10A, Talc Ribbon


Chemistry from the Talc Ribbon pictured above


## 626190-11A, 11B, 11C/Client Sample: 03242021-11

## PLM

All three aliquots of sample 03242021-11 were analyzed by (b)(6) on May 28, 2021. No asbestos or non-asbestos amphibole variants were observed during analysis. The results were calculated using the equations detailed in the Calculations section above.

| 626190-11A | No Asbestos Detected |
| :--- | :--- |
| 626190-11B | No Asbestos Detected |
| 626190-11C | No Asbestos Detected |

TEM
(b)(6) analyzed aliquot 11A on May 21, 2021. Andreas Saldivar analyzed aliquots 11B and 11C on May 27, 2021. The primary particle observed was talc; titanium particles were also observed along with a few talc fibers/ribbons. No asbestos or non-asbestos amphibole variants were observed during analysis. The results were calculated using the equations detailed in the Calculations section above.

| 626190-11A | No Asbestos Detected |
| :--- | :--- |
| 626190-11B | No Asbestos Detected |
| 626190-11C | No Asbestos Detected |

Below are pictures, diffraction patterns, and chemistry from some of the observed particles. The copper peaks in the chemistry spectra are from the TEM grid. The unidentified (and some identified) peaks in chemistry spectra are zinc and carbon, which are from the TEM specimen holder.

626190-11A, Talc Particle


Re: FDA Office of Cosmetics \& Colors Case Narrative for COC 626190

Hexagonal Diffraction Pattern from the Talc Particle pictured above


Talc Particle Dif
15:52 5/21/2021
TEM Mode: Diffraction
$100(1 / \mathrm{Al}$
$\mathrm{HV}=100 \mathrm{kV}$
Cam Len: 0.2200 m
Microscopist: (b)(6)
Camera: NANOSPRT5, Exposure: $800(\mathrm{~ms}) \times 5$ std, frames, Gain: 1 , Bin: 1 Gamma: 1.00 , No Sharpening, Normal Contrast

Chemistry from the Talc Particle pictured above


Re: FDA Office of Cosmetics \& Colors Case Narrative for COC 626190

626190-11A, Titanium Particles


Microscopist: (b) (6)
Camera: NANOSPRT5, Exposure: $800(\mathrm{~ms}) \times 5$ std. frames, Gain: 1, Bin: 1 Gamma: 1.00, No Sharpening, Normal Contrast

## Diffraction Pattern from the Titanium Particles pictured above



Re: FDA Office of Cosmetics \& Colors
Case Narrative for COC 626190
Chemistry from the Titanium Particles pictured above
Full scale counts: 1020 626190-11a(2)


626190-11A, Talc Fiber


Re: FDA Office of Cosmetics \& Colors Case Narrative for COC 626190

Hexagonal Diffraction Pattern from Talc Fiber pictured above


Chemistry from the Talc Fiber pictured above


Re: FDA Office of Cosmetics \& Colors Case Narrative for COC 626190

626190-11A, Talc Ribbon


TEM Mode: Imaging
Microscopist: (b)(6)
Camera: NANOSPRT5, Exposure: $800(\mathrm{~ms}) \times 5$ std. frames, Gain: 1, Bin: 1 Gamma: 1.00, No Sharpening, Normal Contrast

## Diffraction Pattern from Talc Ribbon pictured above



Chemistry from the Talc Ribbon pictured above
Full scale counts: 1016 626190-11a(3)


## QC Discussion:

Microscope alignment and calibration for both the PLM and TEM scopes, and EDXA unit calibration were performed on each day of analysis as specified by method requirements and standard laboratory operating procedures. The analytical balance used for gravimetric reduction is verified weekly at three (3) tare levels using three NIST-traceable weights -$10.0-\mathrm{g}, 0.1-\mathrm{g}, 0.5-\mathrm{g}$ - and on each day of operation using the $0.1-\mathrm{g}$ and $0.5-\mathrm{g}$ weights tared with an $8-\mathrm{mL}$ glass vial. The muffle furnace is verified monthly at a temperature of $480^{\circ} \mathrm{C}$. All equipment was functioning within normal operating parameters

Matrix blank samples were prepared at rate of $10 \%$ or greater alongside the client samples with each series of samples that were put into the muffle furnace together. The matrix blank samples were prepared using Sigma-Aldrich Talc Powder 18654 (Cas No. 14807-96-6; EC No. 238-877-9, Lot 82330). Analysis of the matrix blank samples was only required if asbestos, or the non-asbestos versions of the regulated minerals, was found on the associated client samples unless otherwise noted. Matrix blank sample numbers NB21-312/313, NB21-324/325 and NB21-329/330 were not analyzed since no asbestos was observed on the associated client samples.

A talc reference control sample was randomly selected from our library of TEM grid preparations made from SigmaAldrich Talc Powder, <10 micron (Product No. 643604-500G; Batch No. 10830AJ) spiked with various levels of Chrysotile ranging from $0.4 \%-10 \%$. One (1) reference control sample, sample number 626190-RB1, was analyzed with this set. It was analyzed by $(\mathrm{b})(6)$ on July 21,2021 and found to be within acceptable limits.

Filtration blank samples were prepared alongside the client samples with each use of the filtration apparatus. Analysis of these samples was only required on those blanks associated with a client sample on which asbestos, or the nonasbestos versions of the regulated minerals, was found unless otherwise noted. Filtration blank sample numbers DI-Blank-01 through DI-Blank-11 were not analyzed since no asbestos was observed on the associated client samples.

TEM grid preparation (EB) blank samples were prepared with each batch of carbon coated filters. AMA policy is to analyze these blank samples whenever asbestos, or the non-asbestos versions of the regulated minerals, is detected on an associated client sample or when the laboratory blank identification number ends in a " 0 " or " 5 ." Since no asbestos was observed on any of the client samples, only EB Blank IDs 56710, 56730 and 56740 were analyzed.(b)(6) analyzed these samples on July 21, 2021. No asbestos was detected on the TEM grid preparation blank samples.

Our laboratory information management system (LIMS) randomly selected sample 626190-6A/03242021-6 for additional duplicate QC analysis. Independent preparations were made for the PLM and TEM portions of analysis. The duplicate QC analysis was performed by (b)(6) on May 28, 2021 for PLM and by (b)(6) on June 2,2021 for TEM. The QC results were consistent with the original findings.

Our laboratory information management system (LIMS) randomly selected sample 626190-7A/03242021-7 for additional replicate QC analysis. Independent preparations were made for the PLM and TEM portions of analysis. The replicate QC analysis was performed by(b)(6) on May 28, 2021 for PLM and by Andreas Saldivar on June 2, 2021 for TEM. The QC results were consistent with the original findings.

## Attachments:

The following items are attached to this case narrative for your reference:

1) Sample Log-In Sheet
2) Analytical Balance Verification Log
3) Daily PLM Scope Verification Log
4) Refractive Index Oil Verification Log
5) Daily TEM Scope Verification Log(s)
6) QC Results Summary for 626190
7) NB (Matrix) Blank Preparation Log
8) $R B$ (Reference) Sample Bench Sheet(s)
9) EB (TEM Grid) Blank Preparation Log
10) EB (TEM Grid) Blank Bench Sheet(s)
11) Duplicate \& Replicate QC Charts for (b)(6) for samples analyzed between $1 / 1 / 2021$ \& $5 / 28 / 2021$
12) Duplicate \& Replicate QC Charts for (b)(6) for samples analyzed between $1 / 1 / 2021$ \& $5 / 28 / 2021$
13) Duplicate \& Replicate QC Charts for (b)(6) for samples analyzed between $1 / 1 / 2021$ \& $5 / 28 / 2021$
14) Duplicate \& Replicate QC Charts for Andreas Saldivar for samples analyzed between $1 / 1 / 2019$ \& 5/28/2021
15) Raw Data Sheets
a. PLM Gravimetric Reduction Bench Sheet
b. TEM Gravimetric/Filtration Bench Sheet
c. PLM Analysis
d. TEM Analysis
e. Duplicate QC Analysis
f. Replicate QC Analysis

I certify that all information contained in this report pertaining to laboratory events, procedures, and protocols is true to the best of my knowledge and accurately describes the handling of this project by AMA Analytical Services, Inc., and its personnel.


Andreas Saldivar 7/23/2021

President

