

UNITED STATES  
ENVIRONMENTAL PROTECTION AGENCY

BEFORE THE ADMINISTRATOR

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IN THE MATTER OF: )	
)	
Elementis Chromium Inc., )	Docket No. TSCA-HQ-2010-50
f/k/a Elementis Chromium, LP )	
)	
Respondent. )	COMPLAINANT'S REBUTTAL
)	PREHEARING EXCHANGE
)	
)	
_____ )	

Pursuant to Rule 22.19(a) of the Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties, Issuance of Compliance or Corrective Action Orders, and the Revocation/Termination or Suspension of Permits (Consolidated Rules of Practice), 40 C.F.R. § 22.19(a), and the Prehearing Order (Order) of Presiding Officer Susan L. Biro, dated April 28, 2011, Complainant, the United States Environmental Protection Agency (EPA or the Agency), respectfully submits Complainant's Rebuttal Prehearing Exchange.

I. WITNESSES COMPLAINANT INTENDS TO CALL AT HEARING  
(SUPPLEMENTAL BRIEF NARRATIVE SUMMARY OF EXPECTED  
TESTIMONY)

Complainant provided a complete list of its proposed fact and expert witnesses in Complainant's Prehearing

Exchange. Complainant does not wish to add to its list of proposed witnesses in its Rebuttal Prehearing Exchange. However, Complainant reserves the right to have its fact and expert witnesses named in the Initial Prehearing Exchange testify in rebuttal to any matter raised by Respondent that is not addressed in Respondent's Prehearing Exchange.

Additionally, Complainant wishes to supplement the brief narrative summary of expected testimony for one of its previously identified fact witnesses. This supplemental summary is responsive to Respondent's Prehearing Exchange.

Complainant notes that some of the testimony described below may be rendered unnecessary by stipulations or by rulings on dispositive motions. It is Complainant's intent to promote judicial efficiency by resolving factual issues through stipulations or dispositive motions where possible.

Complainant's Fact Witness - Supplemental Narrative

Amanda Edens, Department of Labor, Occupational Safety and Health Administration (OSHA). In addition to the matters described in the brief narrative summary of Ms. Edens' expected testimony as part of Complainant's Initial Prehearing Exchange, Ms. Edens will testify about OSHA's findings concerning the information in the Modern Four

Plant Report<sup>1</sup> (CX 1), as discussed in the preamble to the Final Rule promulgating a new Permissible Exposure Limit for hexavalent chromium (PEL rulemaking). See CX 76. Ms. Edens will testify that Respondent's allegation that OSHA expressly found that the Modern Four Plant Report "provided no new useful information on risk of injury from hexavalent chromium" is not supported by the facts. See Resp't Prehearing Exchange at 13; CX 76. Ms. Edens will testify how Elementis and the Chrome Coalition described the quality and relevance of the Gibb et al. (2000a) study in testimony and comments before OSHA during the PEL rulemaking. Ms. Edens will testify about the role the Gibb study played in the OSHA's promulgation of a revised Permissible Exposure Limit for hexavalent chromium.

#### Respondent's Witnesses

Respondent has indicated that it intends to call three witnesses to testify at the hearing in this matter. (Resp't Prehearing Exchange at 1-5). Complainant reserves the right to cross-examine all witnesses offered by Respondent. If any of the following witnesses listed in Respondent's Prehearing Exchange are not called by Respondent to testify at a hearing on the above captioned

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<sup>1</sup> As noted in previous filings, "Modern Four Plant Report" or "Modern Report" refers to the study at issue in this case entitled: "Collaborative Cohort Mortality Study of Four Chromate Production Facilities, 1958-1998," Final Report, September 27, 2002.

matter, Complainant expressly reserves the right to call any or all of the following witnesses to testify at such a hearing:

A. Dr. Joel Barnhart, Vice President - Technical for Elementis Chromium Inc.;

B. Dr. Kenneth A. Mundt, Principal, ENVIRON International Corporation, formerly of Applied Epidemiology; and

C. Dr. Herman J. Gibb, President, Tetra Tech Sciences.

II. EXHIBITS COMPLAINANT INTENDS TO INTRODUCE INTO EVIDENCE AT HEARING

In addition to Complainant's Exhibits 1-90 submitted as part of Complainant's Initial Prehearing Exchange, Complainant intends to introduce at hearing the following additional exhibits numbered and listed below:

<b>COMPLAINANT'S PROPOSED EXHIBIT LIST (REBUTTAL)</b> <b>(Numbering resumes from Complainant's Initial Prehearing Exchange, CX 1-90)</b>		
<b>Complainant's Exhibit No.</b>	<b>Document</b>	<b>Number of Pages</b>
	<b>1965</b>	
91.	A.B. Hill, <i>The Environment and Disease: Association or Causation?</i> , PROCEEDINGS OF THE ROYAL SOCIETY OF MEDICINE 58:295-300 (1965)	6
	<b>2000</b>	
92.	Letter from Kenneth A. Mundt, Applied Epidemiology, Inc., to Marianne C. Kaschak, Industrial Health Foundation, Inc., dated June 1, 2000, transmitting progress report	4
	<b>2001</b>	
93.	Memorandum from Marianne C. Kaschak, Industrial Health Foundation, Inc. to IHF Chromium Chemicals Health and Environmental Committee dated July 3, 2001, entitled "Cohort	5

	Mortality Study of Four Chromate Production Facilities – Interim Report,” with attached copy of Interim Report prepared by Applied Epidemiology, Inc. (July 1, 2001)	
94.	Applied Epidemiology, Inc., <i>Cohort Mortality Study of Four Chromate Production Facilities – Interim Report</i> , dated October 25, 2001	2
	<b>2004</b>	
95.	J. Barnhart, Comments of Elementis Chromium LP dated December 31, 2004 regarding Proposed Rule for Occupational Exposure to Hexavalent Chromium, Docket H054A EX. 45-1	10
	<b>2005</b>	
96.	J. Barnhart, Hearing Testimony dated January 3, 2004 [sic] submitted on behalf of Chrome Coalition regarding Proposed Rule on Occupational Exposure to Hexavalent Chromium, Docket H054A EX. 45-1	10
97.	U.S. Department of Labor, Occupational Safety and Health Administration, Transcript of February 1, 2005 Informal Public Hearing for the Proposed Rule On Hexavalent Chromium, Docket H054A EX. 45-1	195
	<b>2011</b>	
98.	Average Hexavalent Chromium Concentrations in Air: Gibb and Modern Four Plant Report Studies	1
99.	Lung Cancer Mortality Risk in Relation to Cumulative Chromium Exposure Using External Referent Groups (Standardized Mortality Ratios (SMRs)): Gibb and Modern Four Plant Report Studies	2
100.	Lung Cancer Mortality Risk in Relation to Cumulative Chromium Exposure Using Internal Referent Groups: Gibb and Modern Four Plant Report Studies	2

III. STATEMENTS IN RESPONSE to RESPONDENT’S PREHEARING EXCHANGE

The following is responsive to the Presiding Officer’s Prehearing Order directing Complainant to submit as part of its Rebuttal Prehearing Exchange a statement and/or documents in response to Respondent’s Prehearing Exchange submittals as to provisions 3(A) through 3(D) in the Prehearing Order. (Order at 3).

Provision 3(A) of the Prehearing Order directs Respondent to submit "[a] narrative statement, and a copy of any documents in support, explaining in detail the legal and/or factual basis for the assertions in Paragraphs 7, 13 and 49 of the Answer." Complainant's rebuttal to Respondent's statements in its Prehearing Exchange with respect to Paragraphs 7, 13 and 49 of the Answer is as follows:

Paragraph 7: Paragraph 7 of the Complaint alleges, "Respondent has a domestic chromium manufacturing facility known as Castle Hayne (Castle Hayne Facility), located at 5408 Holly Shelter Road in North Carolina. Respondent was the owner and operator of the Castle Hayne Facility at all times relevant to this Complaint." (Compl., ¶ 7). Respondent's Answer denied the allegation in Paragraph 7 stating: "Denied. Elementis acquired the Castle Hayne Facility in December, 2002." (Answer, ¶ 7). Respondent reiterated this position in its Prehearing Exchange: "As the relevant times to the Complaint appear to include times before December, 2002, Respondent denied this allegation." (Resp't Prehearing Exchange at 8).

As discussed in Complainant's Initial Prehearing Exchange, Respondent acquired and continued to own the Castle Hayne Facility during the period of continuing

violation. (Complainant's Initial Prehearing Exchange at 34-35). More importantly, for purposes of EPA's prima facie case, Complainant need only prove that Respondent is one of the following: a manufacturer, a processor, or a distributor in commerce of a chemical substance or mixture. Id. at 35. As previously discussed, there is no dispute that Elementis is a manufacturer, processor and distributor in commerce of a chemical substance or mixture. Id. (citing Resp't Mem. in Opposition to Complainant's Mot. for Accelerated Decision on Liability at 4, 11).

Paragraph 13: Paragraph 13 of the Complaint alleges, "Respondent manufactures chromium chemicals using the metallic element chromium." (Compl., ¶ 13). Respondent's Answer denies this allegation. (Answer, ¶ 13). Similarly, Respondent, in its Prehearing Exchange, states that Elementis does not manufacture chromium chemicals from metallic chromium. (Resp't Prehearing Exchange at 9). Complainant, in its Initial Prehearing Exchange, previously clarified that it is more accurate to state that chromium chemicals are manufactured using sodium dichromate or other chromate compounds derived from sodium dichromate. (Complainant's Initial Prehearing Exchange at 36). As discussed previously, for purposes of EPA's prima facie case, Complainant need only prove that Respondent is

a manufacturer, processor, or distributor in commerce of a chemical substance or mixture. Id. at 36-37. Respondent has stated "there is no dispute that Elementis is a manufacturer, processor and distributor in commerce of hexavalent chromium-containing chemicals." (Resp't Mem. in Opposition to Complainant's Mot. for Accelerated Decision on Liability at 11).

Paragraph 49: Paragraph 49 of the Complaint alleges, "Respondent did not immediately inform the Administrator of the Final Four Plant Report as information which reasonably supports the conclusion that hexavalent chromium exposure presents a substantial risk of injury to the health of certain workers in modern chromium production facilities utilizing low-lime or no-lime kiln manufacturing processes, as required by TSCA § 8(e)." (Compl., ¶ 49). Respondent's Answer denies this allegation stating: "By way of further response, Complainant had adequate knowledge of the information contained in the referenced report." (Answer, ¶ 49).

In its Prehearing Exchange, Respondent advances two arguments to support its answer to the allegation in Paragraph 49 of the Complaint. (Resp't Prehearing Exchange at 9-10). First, Respondent argues that Complainant has been adequately informed for more than 25 years that

hexavalent chromium exposure has been associated with elevated lung cancer mortality risk. Id. at 9.

Respondent's first argument misses the point entirely. The question is not whether hexavalent chromium exposure is associated with increased lung cancer mortality risk. That question has long been settled. (CX 1 at 26, 27-28).

Rather, the question the Modern Four Plant Report sought to answer is whether and to what extent lung cancer mortality risk from hexavalent chromium exposure remains under modern plant conditions. (CX 1 at 27 ("The primary goal of this study was to evaluate the possible cancer mortality risks associated with hexavalent chromium exposure in the post-change environment....")). The Modern Four Plant Report adds to the scientific knowledge base by demonstrating that it is reasonable to conclude that an increased risk of lung cancer remains under modern plant conditions. As such, the Administrator was not adequately informed of the information contained in the Modern Four Plant Report.

Second, Respondent argues that the "only" information contained in the Modern Four Plant Report which reasonably supports the conclusion that hexavalent chromium presents a substantial risk of injury to health is the finding of elevated lung cancer mortality risk related to the "high cumulative exposure group." (Resp't Prehearing Exchange at

9-10). Respondent further argues that this finding merely corroborates information previously known to the Administrator. Respondent wrongly asserts that the information in the Modern Four Plant Report which reasonably supports the conclusion that hexavalent chromium presents substantial risk of injury to health is limited to the "high cumulative exposure group." Id. The study summarized in the Modern Four Plant Report found elevated lung cancer mortality risk among members of both the high and intermediate exposure groups in the combined study cohort. See, e.g., CX 1 at 17, 98, 99. In particular, the Modern Four Plant Report contains information which reasonably supports the conclusion that hexavalent chromium presents substantial risk of injury to health related to the intermediate group. Id. at 82-83. Specifically, Table 18 in the Modern Four Plant Report shows that workers in the intermediate exposure group are twice as likely to die from lung cancer compared to members of the low exposure group. Id. at 122. This substantial increased risk was neither well-known nor well-established, and in fact runs counter to findings of earlier studies that examined risk in chromium production plants utilizing the low- or no-lime manufacturing processes. Thus, Respondent's second argument is contradicted by the Modern Four Plant Report.

Provision 3(B): Provision 3(B) of the Prehearing Order directs Respondent to submit "[a] narrative statement, and copy of any documents in support, explaining in detail the legal and/or factual basis for the Respondent's first, second, third and fifth affirmative defenses." (Order at 3). Complainant's rebuttal to Respondent's affirmative defenses includes, but is not limited, to the following:

First Affirmative Defense: "Complainant was adequately informed of the information described in the September 27, 2002 Collaborative Cohort Mortality Study of Four Chromate Production Facilities, 1958-1998 [Modern Four Plant Report] at the time of Elementis's alleged receipt thereof." (Resp't Prehearing Exchange at 10-11). Respondent's first affirmative defense rests on the mistaken assumption that the Modern Four Plant Report's finding of elevated lung cancer risk for the highest exposure level" is the "only" information on substantial risk of injury from hexavalent chromium contained in the Modern Four Plant Report, and that EPA was aware of such information through the EPA-funded 2000 Gibb et al. study (Gibb study) and "numerous" other studies. Id. at 10. Given how Respondent has framed its affirmative defenses, Respondent's first and third affirmative defenses are

essentially the same because both concern the association between increased risk of lung cancer and "high levels" of exposure.<sup>2</sup> Cf. id. at 10 ("highest exposure level") and 11 ("high levels of exposure").

In raising its first affirmative defense, Respondent asks the Presiding Officer to accept that EPA was adequately informed of information in the Modern Four Plant Report even though some of the information in the Modern Four Plant Report did not previously exist. According to the Modern Four Plant Report itself, while numerous epidemiology studies have examined lung cancer mortality risk from hexavalent chromium exposure, the vast majority of these studies predate the industry's change-over from high-lime to modern, low- or no-lime manufacturing processes. (CX 1 at 27-32). This change-over renders these numerous studies "obsolete" and "unrepresentative of new exposure conditions" associated with modern plant

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<sup>2</sup> Respondent has failed to produce substantial and probative evidence regarding its affirmative defenses. For example, in describing the factual and legal bases for its first, third, and fifth affirmative defenses, Respondent uses vague and undefined terms to describe the scope of what was known regarding the association between hexavalent chromium exposure levels and lung cancer mortality risk. Respondent refers to "highest exposure level" (first affirmative defense), "high levels of exposure to hexavalent chromium" (third affirmative defense), and "high cumulative respiratory exposure" (fifth affirmative defense). (Resp't Prehearing Exchange at 10, 11, 12). Elsewhere, in its Paragraph 49 submittal, Respondent refers to "elevated exposure levels" and "high cumulative exposures." Id. at 9-10.

conditions. (CX 2 at 10 [Modern Report Draft Protocol]; CX 3 at 15 [Modern Report Revised Protocol]; CX 1 at 26-27). The Modern Four Plant Report also states that only a few epidemiologic studies had evaluated the lung cancer mortality risk from hexavalent chromium exposure under modern plant conditions at the time of the Modern Four Plant Report study. (CX 1 at 86). In addition, the Modern Four Plant Report states, as of the late 1990s, that these limited post-process change studies reported negative results but were not conclusive. Id. at 15, 29, 32. In contrast to these limited studies, the Modern Four Plant Report reported positive results by finding elevated lung cancer mortality risk among high and intermediate exposure group workers under modern plant conditions. (CX 1 at 17, 98, 99).

Moreover, according to the Modern Four Plant Report, the scientific understanding of lung cancer mortality risk from hexavalent chromium exposure under modern plant conditions was continuing to evolve at the time of the Modern Four Plant Report study. Id. at 15, 32, 97-98. The Modern Four Plant Report recognizes that the extent to which lung cancer mortality risk to workers from hexavalent chromium remains under modern plant conditions had yet to be established. See C's Ex. 1 at 29, 32. Thus, it was not

possible for EPA to have been adequately informed of information that, as the Modern Four Plant Report itself acknowledges, did not exist regarding the extent of risk to workers from hexavalent chromium exposure under modern plant conditions.<sup>3</sup>

Second Affirmative Defense: "Elementis had actual knowledge that Complainant was adequately informed of the information described in the September 27, 2002 Collaborative Cohort Mortality Study of Four Chromate Production Facilities, 1958-1998 [Modern Four Plant Report] at the time of Elementis's alleged receipt thereof." (Resp't Prehearing Exchange at 11). Respondent's second affirmative defense is contingent upon its first affirmative defense. In other words, Elementis's alleged actual knowledge is predicated on Complainant having been adequately informed of the information in the Modern Four Plant Report because such information was available in prior studies, including the Gibb study. However, as discussed above under Respondent's first affirmative

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<sup>3</sup> There are numerous characteristics of the Modern Four Plant Report that distinguish it from prior studies. See Complainant's Mem. in Support of Complainant's Mot. for Accelerated Decision on Liability; Complainant's Reply to Resp't Mem. in Opposition to Complainant's Mot. for Accelerated Decision on Liability. For example, the Gibb study did not evaluate lung cancer mortality risk to workers who had worked exclusively in new facilities (CX 1 at 30), whereas the Modern Four Plant Report specifically assessed risk only for those who had worked exclusively in plants utilizing low or no-lime manufacturing processes (CX 1 at 43). Id.

defense, the Modern Four Plant Report contains information that was not previously available. Therefore, Respondent could not have had actual knowledge that EPA had been adequately informed of the information contained in the Modern Four Plant Report as required by TSCA section 8(e).

Third Affirmative Defense: "At the time of Elementis's alleged receipt of the September 27, 2002 Collaborative Cohort Mortality Study of Four Chromate Production Facilities, 1958-1998 [Modern Four Plant Report], Complainant was aware of information indicating an increased risk of cancer among certain workers with high levels of exposure in chromium processing plants." (Resp't Prehearing Exchange at 11-12). Respondent's argument in support of its third affirmative defense repeats the argument for its first affirmative defense. That is, Respondent argues that EPA was in possession of "numerous" studies that had established an association between hexavalent chromium exposure and elevated lung cancer mortality risk among workers with "high levels of exposure." (Resp't Prehearing Exchange at 11).

Respondent specifically relies upon the Gibb study to support its contention. Id. Respondent's reliance is misplaced. Respondent wrongly asserts that the information contained in the Modern Four Plant Report is identical to

the information previously known to EPA through the Gibb study. EPA was certainly aware of the EPA-funded Gibb study which is widely regarded as one of the most methodologically strong and comprehensive epidemiologic studies of hexavalent chromium exposure conducted to date. However, the Modern Four Plant Report and the Gibb study have important differences in terms of what was assessed and the actual findings. These two studies evaluated different populations at different plants with different exposure scenarios under varying manufacturing process conditions, and each study contains distinct information about increased risk of lung cancer mortality from hexavalent chromium exposure. It is also important to note that, as discussed above with respect to Paragraph 49, the Modern Four Plant Report study found elevated lung cancer mortality risk among members of both the high and intermediate exposure groups in the combined study cohort. See, e.g., CX 1 at 17, 98, 99. In particular, the Modern Four Plant Report contains information which reasonably supports the conclusion that hexavalent chromium presents substantial risk of injury to health related to the intermediate exposure group. Id. at 82-83.

Fifth Affirmative Defense: "Complainant's own guidance and interpretation of law stated that the Toxic

Substances Control Act did not require information contained in the September 27, 2002 Collaborative Cohort Mortality Study of Four Chromate Production Facilities, 1958-1998 [Modern Four Plant Report].” In its Prehearing Exchange, Respondent argues in support of its fifth affirmative defense that the Modern Four Plant Report need not have been reported under TSCA section 8(e) pursuant to EPA guidance because information “need not be reported under section 8(e) if it...[c]orroborates (i.e., substantially duplicates or confirms) in terms of, for example, route of exposure, dose species, strain, sex, time to onset of effect, nature and severity of effect, a well-recognized/well-known established serious adverse effect for the chemical(s) under consideration.” (Resp’t Prehearing Exchange (citing RX 10 and 11)). In a repeat of the argument for its first and third affirmative defenses, Respondent essentially contends that the Modern Four Plant Report “corroborates” a well-recognized and well-established effect of hexavalent chromium, that is, the association between “high cumulative respiratory exposure” to hexavalent chromium and elevated lung cancer mortality risk. Id. at 12. For the reasons discussed herein, the Modern Four Plant Report does not substantially duplicate or confirm “well-recognized/well-established” information.

See also Mem. in Support of Complainant's Mot. for Accelerated Decision on Liability at 29-30. Consequently, Respondent's argument is without merit.

Provision 3(C): Provision 3(C) of the Prehearing Order directs Respondent to submit a copy of any and all documents it intends to rely upon in support of the position it is unable to pay the proposed penalty. Respondent did not take the position that Elementis is unable to pay the proposed penalty. See Resp't Prehearing Exchange.

Provision 3(D): Provision 3(D) of the Prehearing Order directs Respondent to submit a copy of any and all documents it intends to rely upon in support of a position that the proposed penalty should be reduced or eliminated. In its Prehearing Exchange, Respondent states that the Agency's proposed civil penalty should be reduced or eliminated because the penalty is without merit and is grossly excessive.<sup>4</sup> (Resp't Prehearing Exchange at 13-14). Respondent has not provided any credible arguments or documentary evidence to support its position. See id. Respondent has not clearly stated how Complainant has

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<sup>4</sup> In light of the fact that Respondent has not raised an ability to pay issue regarding the proposed civil penalty amount in its Prehearing Exchange in response to Paragraph 3(C) of the Presiding Officer's Prehearing Order (Order at 3), it is Complainant's understanding that a penalty adjustment based on ability to pay factors is not at issue in this matter.

failed to properly apply the statutory factors that must be considered when assessing a civil penalty. See id. The evidence will show that Respondent waited for six-and-a-half years to submit the Modern Four Plant Report to EPA until it was compelled to do so in response to subpoenas issued pursuant to EPA's TSCA information gathering authorities. As such, Respondent has failed to provide any evidence that Complainant can rely upon to justify a downward adjustment to the Agency's proposed penalty of \$2,338,000.

Complainant will prove at hearing that Respondent violated the mandatory reporting requirement in TSCA section 8(e) when it failed to immediately submit the Modern Four Plant Report to the Administrator. As explained in Complainant's Initial Prehearing Exchange, Complainant's proposed penalty of \$2,338,000 is reasonable given the nature and gravity of this violation, consistent with both the statutory factors that must be considered when assessing a civil penalty (TSCA section 16(a)(2)(B), 15 U.S.C. § 2615(a)(2)(B)), and the Agency's guidance on calculating proposed penalties (Guidelines for Assessment of Civil Penalties Under Section 16 of the Toxic Substances Control Act; PCB Penalty Policy, 45 Fed. Reg. 59,770 (Sept 10, 1980) (Guidelines); Enforcement Response Policy for

Reporting and Recordkeeping Rules and Requirements for TSCA Sections 8, 12 and 13, (March 31, 1999) (TSCA ERP)).

IV. COMPLAINANT'S REBUTTAL TO RESPONDENT'S PREHEARING EXCHANGE SUBMITTALS

In addition to responding to the information provided by Respondent in response to Provisions 3(A) through 3(D) of the Prehearing Order, Complainant wishes to provide the Presiding Officer with rebuttal to Respondent's Prehearing Exchange submittals regarding its affirmative defenses, particularly in light of the parties' filings related to Complainant's Motion for Accelerated Decision on Liability. As summarized below, based on the record, EPA has proven all four elements of the prima facie case<sup>5</sup> and Respondent has not provided any evidence to establish an affirmative defense to liability. As to the four elements of EPA's prima facie case:

Element #1: "Elementis does not contest that it is a manufacturer of chromium chemical products, including some that contain hexavalent chromium." (Resp't Mem. in Opposition to Complainant's Mot. for Accelerated Decision

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<sup>5</sup> The four elements of the prima facie case are: (1) Elementis is a person who manufactures, processes, or distributes in commerce a chemical substance or mixture; (2) Elementis obtained the Modern Report; (3) the Modern Report reasonably supports a conclusion that hexavalent chromium exposure presents a substantial risk of injury to health; and (4) Elementis failed to immediately inform the Administrator of the Modern Report. 15 U.S.C. § 2607(e).

on Liability at 2). Consequently, there is no dispute regarding element #1.

Element #2: "Elementis does not contest ... that it received the [Modern] Report on October 8, 2002." Id. at 2. Consequently, there is no dispute regarding element #2.

Element #3: "The [Modern] Report concludes that exposure to high levels of hexavalent chromium leads to an increased risk of lung cancer. This conclusion identifying an elevated risk of lung cancer in the highest cumulative exposure group is the only Substantial Risk Information in the [Modern] Report." Id. at 12. Similarly, Respondent states in its Prehearing Exchange, "The only substantial risk information in the [Modern Report] was that an elevated risk of lung cancer existed in workers who had high cumulative exposures to hexavalent chromium...." (Resp't Prehearing Exchange at 9-10). Respondent, on a consistent basis in its filings, has conceded that the Modern Four Plant Report contains information which reasonably supports the conclusion that hexavalent chromium exposure presents a substantial risk of injury to health. As such, the Modern Four Plant Report contains information that meets the statutory reporting threshold. Consequently, element #3 is satisfied.

Element #4: "Further, Elementis concedes that it did not submit the [Modern] Report to EPA until November 17, 2008 in response to a subpoena from EPA to one of Elementis' employees." (Resp't Mem. in Opposition to Complainant's Mot. for Accelerated Decision on Liability at 2). Consequently, there is no dispute regarding element #4.

EPA has proven all four elements of the prima facie case. While Respondent has raised multiple affirmative defenses, with the exception of the statute of limitations defense (fourth affirmative defense) Respondent's defenses are all variations on the TSCA section 8(e) statutory defense: "unless such person has actual knowledge that the Administrator has been adequately informed of such information." 28 U.S.C. § 2607(e). As such, the case ultimately rests on Respondent's statutory affirmative defense. In its Prehearing Exchange, Respondent has failed to produce substantial and probative evidence on a disputed factual issue entitling Elementis to an evidentiary hearing on its statutory affirmative defense.

In raising its affirmative defenses, Respondent states that EPA possessed "numerous studies" containing identical substantial risk information to the Modern Four Plant Report. Notably, other than the Gibb study (RX 17),

Respondent does not identify any of the studies it relies upon by name to support its assertion. Additionally, except for the Gibb study, the studies that Respondent has proposed as exhibits generally date from the 1940s and 1950s (RX 18-21), well before the change-over from the high-lime to the modern low- or no-lime manufacturing processes. Even studies from the 1970s and 1990s (RX 22, 30-31) that Respondent has proposed as exhibits were limited to updating mortality rates for workers previously employed in plants that operated before the change-over. The one remaining study Respondent has proposed as an exhibit (RX 24) concerned a plant that did not utilize the modern low- or no-lime processes. CX 1 at 93 (Describing Baltimore as "high-lime chromate production facility").

EPA is not aware of any studies that contain the same information about substantial risk under modern plant conditions as the Modern Four Plant Report. In relying upon the Gibb study, Respondent would have the Presiding Officer conclude that the existence of a single study, namely, the Gibb study which evaluated lung cancer mortality risk under different exposure scenarios than were studied in the Modern Four Plant Report, operates to relieve Respondent's reporting obligation under TSCA section 8(e). In fact, the Modern Four Plant Report's

authors characterize the Baltimore plant studied by Gibb et al. (2000) as a "high lime" chromate production plant. CX 1 at 93. The evidence will show that these two studies, on their face, provide the Agency with different information about the increased risk of lung cancer mortality to workers exposed to hexavalent chromium. Consequently, the Administrator's knowledge about the information in the Gibb study cannot be equated with knowledge about the information in the Modern Four Plant Report.

In closing, Complainant renews its Motion for Accelerated Decision on Liability.

Respectfully submitted,



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