

GP Inc., and Elementis Chromium GP Inc. then changed its name to Elementis Chromium, Inc.

4. Elementis Chromium Inc. is a manufacturer of chemical substances, including chromic acid, chromic oxide, and sodium dichromate.
5. Elementis Chromium Inc. and its predecessors have been manufacturing chromium chemicals for more than 35 years.
6. Elementis Chromium Inc. is a distributor in commerce of chemical substances, including chromic acid, chromic oxide, and sodium dichromate.
7. Chromic acid and sodium dichromate are hexavalent chromium compounds.
8. There is a well-recognized association between occupational exposure to hexavalent chromium and lung cancer mortality risk.
9. In the 1950s and 60s, the chromate industry implemented manufacturing process changes and industrial hygiene controls to reduce the amount of dust containing hexavalent chromium compounds to which workers were exposed, with the goal of reducing their risk of developing lung cancer from hexavalent chromium exposure.
10. In 1984, EPA classified hexavalent chromium as a human carcinogen, which is supported by many epidemiological studies linking hexavalent chromium exposure to lung cancer.
11. In or about 1998, the Industrial Health Foundation (IHF) Chromium Chemicals Health and Environmental Committee initiated an epidemiological study a decade after EPA classified hexavalent chromium as a human carcinogen in 1984 to investigate whether lower exposure levels after the process changes and industrial hygiene controls implemented by the chromate industry in the 1950s and 60s had successfully reduced workers' risk of developing lung cancer from hexavalent chromium exposure.
12. Although the carcinogenicity of hexavalent chromium was well-recognized at the time of the Final Four Plant Report, the carcinogenic effects of hexavalent chromium under long-term, low-intensity exposure conditions were not well-established when the report became available in September, 2002.
13. Only two exposure data sets for quantifying the carcinogenic potency of hexavalent chromium for dose-response assessment existed at the time the Final Four Plant Report became available in September, 2002: Mancuso (1975, 1997) and Gibb *et al.* (2000).
14. A third exposure data set for quantifying the carcinogenic potency of hexavalent chromium for dose-response assessment did not exist until 2003, after the Final Four Plant Report became available in September, 2002: Luippold (2003).
15. Each of these three exposure data sets has limitations that affect the interpretation of the

results, including, for example: (1) method and timing of exposure measurements; (2) small study cohort size; (3) lack of or incomplete smoking data; and (4) inclusion of short-term workers in the study cohort.

16. The EPA-funded Gibb et al. study has a cohort of approximately 2,300 workers at a chromate production plant in Baltimore, Maryland.
17. Fifty percent of the Gibb et al. study cohort had worked less than five months, and an even higher percentage had worked less than one year.
18. The Final Four Plant Report has a combined cohort of approximately 1,518 employees from two German and two United States chromium chemicals manufacturing plants.
19. The Final Four Plant Report cohort does not include short-term workers; all of the employees in the cohort had worked at least one year.
20. The exclusion of short-term workers from the Final Four Plant Report cohort eliminated a key limitation in the Gibb et al. study.
21. The average duration of work exposure to hexavalent chromium in the Gibb et al. study was 3.1 years.
22. The average duration of work exposure in the Final Four Plant Report was 8 to 12 years.
23. Both the Final Four Plant Report and the Gibb et al. study found elevated risk of lung cancer mortality with increasing exposure to hexavalent chromium; however, the studies' respective findings of elevated lung cancer mortality risk are based on different exposure conditions.
24. The Final Four Plant Report's finding is based on long-term, low-intensity exposure conditions.
25. The Gibb et al. study's finding is based on short-term, high-intensity exposure conditions.
26. The long-term, low-intensity exposure conditions examined in the Final Four Plant Report are of prime interest to the Agency for human health risk assessment.
27. On or about October 8, 2002, Kenneth A. Mundt, Ph.D., of Applied Epidemiology Inc., emailed a copy of the Final Four Plant Report, dated September 27, 2002, to the Industrial Health Foundation (IHF).
28. On or about October 8, 2002, Joel Barnhart, Ph.D., of Elementis Chromium, obtained a copy of the Final Four Plant Report by email from Marianne Kaschak of the IHF.
29. From 1988 until present, Joel Barnhart has served as Vice-President-Technical for Elementis Chromium, Inc.

30. On or about October 8, 2002, Respondent obtained the Final Four Plant Report.
31. Elementis did not submit the Final Four Plant Report to EPA until November 17, 2008, in response to an EPA subpoena.
32. The Final Four Plant Report was prepared at a total cost in excess of \$500,000.
33. Complainant uses the Guidelines for the Assessment of Civil Penalties Under Section 16 of the Toxic Substances Control Act; PCB Penalty Policy, dated September 10, 1980 (“Guidelines”), and the Enforcement Response Policy for Reporting and Recordkeeping Rules and Requirements for TSCA Section 8, 12, and 13, dated March 31, 1999 (“TSCA ERP”), as guidance when assessing penalties for violations of TSCA section 8(e).
34. The Guidelines and the TSCA ERP ensure that enforcement actions are “assessed in a fair, uniform, and consistent manner; that the penalties are appropriate for the violation committed; that economic incentives for violating TSCA are eliminated; and that persons will be deterred from committing TSCA violations.”
35. Complainant used the Guidelines and the TSCA ERP to calculate the proposed penalty of \$2,338,000 to be assessed against Elementis.

II. PROPOSED CONCLUSIONS OF LAW

1. Respondent is a “person who manufactures, processes, or distributes in commerce a chemical substance or mixture,” and, as such, is subject to the requirements of TSCA section 8(e).
2. Respondent “obtain[ed] information which reasonably supports the conclusion” that a chemical substance “presents a substantial risk of injury to health” because the Final Four Plant Report found elevated lung cancer mortality risk from exposure to hexavalent chromium.
3. Respondent failed to “immediately inform the Administrator” of the information in the Final Four Plant Report “which reasonably supports the conclusion that such substance or mixture presents a substantial risk of injury to health.”
4. The information contained in the Final Four Plant Report, “which reasonably supports the conclusion that such substance or mixture presents a substantial risk of injury to health,” constitutes new information about the risk of lung cancer mortality from hexavalent chromium exposure under long-term, low-intensity exposure conditions; and Respondent did not have “actual knowledge that the Administrator ha[d] been adequately informed” of the new information in the Final Four Plant Report at the time Respondent obtained the report in 2002.

III. PROPOSED ORDER

Complainant's proposed penalty of \$2,338,000 for Respondent Elementis's continuing violation of TSCA section 8(e), 28 U.S.C. § 15 U.S.C. 2607(e), is fair and equitable based upon the seriousness and egregiousness of the violation.

Respectfully submitted,

03.16.2012
Date

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