Chloroplatinate Toxicity: Use and Misunderstanding of Merget

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Abstract: Platinum is a rare but vital chemical in modern life, used in almost all automotive catalytic converters to limit pollution, and to catalyze a multitude of energy-efficient industrial processes from petroleum refining to creation of pharmaceuticals and agricultural fertilizer consitituents. But its refining and manufacturing carry a significant occupational health concern: chloroplatinate sensitization. While platinum itself is considered to be non-toxic, the unavoidable creation of chloroplatinates within the platinum industry leads to worker exposure, to respiratory irritation and, if prolonged, to asthma and severe respiratory distress. Occupational exposure is therefore subject to strict management controls and exposure regulation. Government agencies in Europe and the United States are now asserting, however, that the regulation of chloroplatinate sensitization in the workplace, and beyond, should be far more strict, and are proposing new exposure limits for chloroplatinates that are orders of magnitude below current limits. Consequences to the platinum industry, and thus to the downstream uses of platinum, are significant; a platinum industry worker would reach the proposed new eight-hour limit after only one minute of exposure at the current occupational exposure limit (OEL). The platinum industry would be crippled. These agencies claim to rely upon an early 1990's study of workplace exposure in a German catalytic converter manufacturing facility[2], and assert that this study supports their calculation of an extremely low exposure limit to protect against sensitization to chloroplatinates. They are wrong; the study does not and cannot support the calculation of a new exposure threshold. Indeed, the principal author of the study said so in the conclusion of the report of his study, in another contemporary published report, and in a recent personal communication. Furthermore, analysis of the exposure data from this study confirms that it provides no support for a quantified dose-response relationship or threshold exposure limit for chloroplatinate sensitization.

1. Introduction

Platinum is the primary active constituent of automotive catalytic converters, arguably the most important environmental control advancement over the past three decades. Within chemical manufacturing and petroleum refining, it is an essential and energy-saving catalyst. Products as diverse as pharmaceuticals and nitrate fertilizer, the backbone of United States agriculture, rely upon platinum catalysis in the chain of their production. But production of platinum itself, and of platinum catalysts, necessarily involves the creation of chloroplatinates, because platinum does not dissolve outside of chlorine-based chemistry. Chloroplatinates

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[2] Reported in Merget, R; Kulzer, R; Dierkes-Globisch, A; et al. (2000) Exposure-effect relationship of platinum salt allergy in a catalyst production plant: conclusions from a 5-year prospective cohort study. J Allergy Clin Immunol 105:364– 370, cited hereafter as Merget et al. (2000). The study is cited as the Merget study.

can be potent respiratory sensitizers, and worker sensitization is a long-known and significant health problem in the platinum industry. Some workers who are exposed to inhalation of chlorinated platinum salts, most specifically chloroplatinic acid (CPA)[3], develop symptoms of skin rash and/or respiratory irritation, *e.g.*, runny nose and eyes, sneezing, shortness of breath, which can progress to moderate or severe asthma and respiratory distress with prolonged, repeated exposure. Even in modern, well-controlled working environments, out of about 4000 workers exposed worldwide to CPA, about one percent are sensitized annually[4], leading to their permanent removal from even short, small exposure, and thus often removal from employment within the platinum industry[5].

Most countries with platinum industry activity impose one of the lowest limits for workplace chemical exposure: an eight-hour time-weighted average (TWA) exposure limit of 2 ug/m^3 for water-soluble species of platinum. Even so, it is clear to the platinum industry, to regulatory agencies, and to the World Health Organization[6], that this workplace exposure limit alone is not completely protective; sensitization can occur despite consistent compliance with this limit. The exact exposure circumstances that cause sensitization, however, are not yet known; direct contact and dermal exposure to CPA, and/or "short sharp exposures above this limit could also have been responsible for the sensitization observed."[7] Statistically significant data that not only encompass but identify those short sharp exposures, as well as prolonged steady exposures, and that track those exposures to subsequent symptoms of sensitization,[8] have not been available within the very limited and widespread potential cohorts of exposed workers. A science-based threshold of exposure that causes sensitization has not yet been found. Industry has therefore responded to the concern, as the WHO and independent researchers have recommended, with improved control measures such as substitution of non-sensitizing platinum species in applications where that is possible, enclosed and robotic processing, optimal ventilation, etc., together with close medical surveillance.

Some government agencies in Europe and the United States now claim, however, to have found statistically significant data in Merget et al. (2000)[9], the report of a study performed from 1989-1994 in an automotive catalyst manufacturing plant in Germany, and thus a scientific basis for new and drastically lower exposure limits. The Dutch Expert Committee for

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[3] Hexachloroplatinic acid, H2PtCl6, CASRN 16941-12-1, EINECS 241-010-7. Platinum dissolves only in aqua regia ($HCl:HNO_3$ 3:1) or hydrochloric acid/chlorine, in both cases yielding hexachloroplatinic acid. It is thus a product of the platinum refining industry and of manufacturing in which platinum is dissolved, such as the creation of automotive catalyst washcoats.

[4] Industry survey results, acknowledged to be estimates. This represents a dramatic improvement from times when worker protection was less prevalent, and sensitization rates among chloroplatinate-exposed workers were very high. Exposure controls and medical surveillance have significantly improved worker circumstances, but chloroplatinate exposure is nevertheless a matter of concern.

[5] Once sensitized, the concentration that elicits an adverse response is lower, and complete removal from a platinum industry setting where CPA is used may be necessary. Removal of a worker from exposure following observation of symptoms has been medically effective.

[6] World Health Organization 1991 International Programme on Chemical Safety, Geneva, Switzerland. Environmental Health Criteria No. 125, hereinafter cited as WHO 1991

[7] WHO 1991

[8] Symptoms of sensitization do not appear immediately, and a subsequent chloroplatinate exposure that elicits a response may occur much later, making it more difficult to find the circumstances of the original sensitization.

[9] Merget, R; Kulzer, R; Dierkes-Globisch, A; et al. (2000) Exposure-effect relationship of platinum salt allergy in a catalyst production plant: conclusions from a 5-year prospective cohort study. J Allergy Clin Immunol 105:364– 370, hereafter cited as Merget et al.(2000)

Occupational Standards (DECOS) of the Health Council of the Netherlands has asserted that "the Merget study indicates that there is a threshold for the sensitising effects of chloroplatinates" and that "Merget and co-workers showed in a five-year prospective cohort study a clear dose-response relationship between airborne soluble platinum concentrations, platinum concentrations in sera of exposed workers, and newly occurring sensitisations."[10] Based upon its reading of Merget et al. (2000), DECOS has proposed an occupational exposure limit for chlorinated platinum salts of 5 ng/m^3 eight hour TWA. This is four hundred times below the current OEL, and a platinum industry worker would reach this proposed daily limit in just over one minute at the current OEL. The European Union Scientific Committee on Occupational Exposure Limits (SCOEL) is reviewing the DECOS proposal, and is considering endorsing it for application throughout the EU. In the United States, the US EPA has proposed a lifetime limit for exposure of the general public to halogenated platinum salts of 1 pg/m^3[11], two million times below the current OEL. Like DECOS, EPA has relied exclusively upon Merget et al. (2000) for its numerical calculation of this proposed limit.

Both DECOS and EPA have misread and/or misunderstood the study reported in Merget et al. (2000), as well as the actual data developed by Dr. Merget in the course of that study. The medical observation conducted and reported by Dr. Merget was prospective and rigorous, with repeated examination of 275 exposed workers over five years. But the measurement of actual exposures of those 275 workers was neither prospective nor large; it was collected only in the third and fourth years of the study, was sparse, and was often not representative of actual exposures. DECOS and EPA nevertheless use that data to calculate a dose-response relationship and a safe exposure threshold.

Dr. Merget certainly understood the limitations of his study's data. His report does not discuss the actual numerical exposure data, restricting its presentation to one figure containing box-and-whisker plots to show relative gradations among exposure cohorts. This is a cautious and understandable step by its author; the unreported actual data does not support a causal connection of any observed sensitization to any measured exposure. Nor does it claim to do so. As Dr. Merget said in the report of this study, "a valid cut-off value for occupational hygiene cannot be defined by this study." Dr. Merget repeated this admonition in still another published report: "Available information does not permit the definition of an exposure limit for Pt salts."[12] And in a recent communication to the platinum industry, Dr. Merget said again that "no valid threshold of airborne platinum can be derived from the available data."[13]

EPA and DECOS have nevertheless proposed a safe threshold dose, claimed to have been derived from the data of the Merget study. This paper presents and critically examines the raw data underlying Merget et al. (2000) in relation to the assertions of DECOS and EPA that

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[10] Health Council of the Netherlands. Platinum and platinum compounds. Healthbased recommended occupational exposure limit. The Hague: Health Council of the Netherlands, 2008; publication no. 2008/12OSH, p62, hereafter cited as DECOS 2008. The document is a co-production of DECOS and the Nordic Expert Group (NEG)

[11] EPA/635/R-08/018 Toxicological Review of Halogenated Platinum Salts and Platinum Compounds. While the document points out that it is an External Review Draft and "does not represent and should not be construed to represent any Agency determination or policy," it is the published expression of EPA thinking on an issue of significant importance. It is cited hereafter as EPA Draft 2009.

[12] Occupational Platinum Salt Allergy. Diagnosis, Prognosis, Prevention and Therapy, Anthropogenic Platinum-Group Element Emissions, Zereini, Alt Eds., Springer 2000, p.261

[13] September 2009 letter

it supports such a quantified dose-response relationship between exposure to chloroplatinates and sensitization.

2. Description of the Merget Study

Beginning in December 1989, Dr. Merget recruited workers in a Degussa automotive catalytic converter manufacturing facility in Rheinfelden, Germany, to form a large cohort for a human epidemiological study of platinum sensitization. Dr. Merget believed that catalyst production operations, in contrast to platinum refining, would provide a more controlled setting in which platinum sensitization could be carefully studied.[14] He recruited 166 persons then employed at the facility, and another 142 who were newly employed during the course of the study. Of 306 workers thus recruited, 275 workers participated with both an initial medical examination and at least one followup examination[15], and were considered to be part of the statistical analysis.

To better understand the general relationship between exposure and sensitization, these 275 workers were then categorized into four study cohorts according to their anticipated exposures to soluble platinum, in descending order, with the following descriptions taken verbatim from Dr. Merget's report:

> High Exposure: Subjects working directly in production lines were included in the high exposure category. This was a rather uniform group because operators worked in all production lines and in all parts of the lines. The high-exposure category also contained craftsmen engaged in maintenance or demolition of production lines.
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> Persistently Low Exposure: The category with persistently low exposure consisted of people working within the catalyst department but not in the production lines (ie. white collar employees or workers of the wash coat preparation, quality control, analytic laboratory, or warehouse staff).
>
> Intermittently Low Exposure: Subjects who entered the catalyst building intermittently, among them 19 subjects originally recruited as control subjects (eg. craftsmen who never worked in the production lines or security staff), were assigned to the intermittent low-exposure category. This category was obviously exposed to a considerably lower degree than the persistently low-exposure subjects.
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> No Exposure: Subjects who never entered the catalyst building were assigned to the no-exposure category.[16]

By the end of the study, of the 275 workers so categorized, 13 were found to have been sensitized, nine during the third year of the follow-up, and one in each of years 1, 2, 4, and 5

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[14] "Because of more uniform production processes and intensified protective measures, lower Pt salt exposures and a lower incidence of Pt salt allergy may be expected in catalyst production plants." Merget et al. (2000) p364

[15] Subjects were examined in intervals of 6 months during the first year and afterward in yearly intervals, averaging five per subject. Merget et al. (2000) p367

[16] There was apparently no area where there was literally no exposure. As Dr. Merget reported, there was exposure to soluble platinum in control "no-exposure" areas outside the catalyst building in the range of 30 to 90 pg/m^3.

after their initial survey.[17] All 13 sensitized workers were in the High Exposure cohort, working in the catalyst production lines. There was no sensitization among workers in either of the two Low Exposure cohorts or in the No Exposure cohort.[18]

Exposures of workers to chloroplatinates ranged from well above the OEL to well below, tracking the four categories described above, but the levels of exposure that caused the 13 sensitizations among the High Exposure cohort were not determined. Dr. Merget reported that the high variability of his exposure data precluded determination of a threshold for sensitization: "a valid cut-off value for occupational hygiene cannot be defined by this study."[19] Nevertheless, the occurrence of sensitization in the High Exposure cohort led to his conclusion that platinum salts "are relevant allergens in catalyst production plants," less so than in platinum refining, but still relevant, notwithstanding indications of "the effectiveness of primary prevention measures" to reduce rates of sensitization. And Dr. Merget observed that TWA concentrations below 10 ng/m^3 in the Low Exposure and No Exposure cohorts, outside of catalyst production and where no sensitization had been observed, were safe.

3. DECOS and EPA Assertions Regarding the Merget Study

Notwithstanding its lead author's conclusion that a dose-response relationship and sensitization threshold could not be defined, DECOS and EPA have asserted that the Merget study presents a specific quantified exposure threshold. Neither agency did any independent epidemiological research, relying instead upon extensive literature search and review, but each saw the data and findings of Merget et al. (2000) as evidence of a specific, quantified dose-response relationship. DECOS said that the Merget study "provides reliable and valid data with respect to a threshold."[20] "In a 5-year prospective cohort study, Merget and co-workers showed a dose-response relationship between airborne soluble platinum-compound concentrations, platinum concentrations in sera of exposed workers, and newly occurring sensitisations"[21] and "The committee is of the opinion that the Merget study indicates that there is a threshold for the sensitising effects of chloroplatinates."[22] Citing the Merget study, DECOS said that "Sensitisation was shown to develop already at occupational exposure to airborne soluble platinum-salt levels of approximately 50-100 ng/m^3."[23] In its recommendation, DECOS said "In the Merget study, sensitisation occurred in workers exposed to median levels of ca. 180 ng/m^3."[24] EPA similarly said: "The exposure data from Merget et al. (2000) for the high-exposure group identify an occupational exposure concentration associated with sensitization, as 13/115 workers in the high-exposure group developed Pt-specific allergic sensitization as determined by positive SPT during the 5-year study."[25] EPA asserted this concentration to be 59.2 ng/m^3.[26]

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[17] Merget et al. p367

[18] Dr. Merget found sensitization in one worker who had originally been categorized in a Low Exposure cohort, but subsequently found that this person had direct contact with platinum salt sources, performing catalyst impregnation by hand, and thus had been misclassified. This worker was therefore not included in the study's statistical data or analysis.

[19] Merget et al. p370

[20] DECOS 2000 p90

[21] DECOS 2008 p21

[22] DECOS 2008 p24

[23] DECOS 2008 p80

[24] DECOS 2008 p90

[25] EPA Draft 2009 p126

[26] EPA Draft 2009 p145

Dr. Merget is correct, and DECOS and EPA are wrong; there was no quantified occupational exposure concentration associated with sensitization in the Merget study. The study did, of course, observe sensitization among 13 of 115 workers in the High Exposure cohort, and thus it certainly suggests that sensitization is caused by chloroplatinates at some concentration to which the High Exposure cohort was exposed, but not by exposure to a concentration to which the Low Exposure and No Exposure cohorts were exposed. But those suggestions say nothing about quantification of a dose-response relationship, or of the threshold of sensitization. Sound, statistically significant data is required for such determinations, and that data is not present in the Merget study.

First, the exposure data was primarily retrospective. Over the five years of the study, beginning in December 1989, 13 sensitizations were observed, with 11 having taken place within 3 years of initial subject survey.[27] But the Merget study's data collection of workplace soluble platinum concentrations did not begin until 1992, the third year. In that year, 32 fixed area samples were taken at selected points of the manufacturing facility: 16 in High Exposure areas, 8 in Low Exposure areas[28] and 8 in No Exposure areas. In 1993, the fourth year of the Merget study, an additional 24 fixed area samples were taken, 12 in High Exposure areas, 8 in Low Exposure areas (all different than 1992), and 4 in No Exposure areas (all different than 1992). Most significantly, the Merget study did not take personal samples of worker exposure until 1993, the fourth year of the study. Even then, personal samples were taken from only five workers, all in the High Exposure cohort, with eighteen personal samples taken in all.[29] In all, this chloroplatinate exposure data must be considered to be retrospective of the great majority of observed sensitization.

Second, much of the data was not representative of actual exposures, because it was collected by fixed area samplers. EPA has acknowledged that such samples "may have underestimated exposure."[30] Indeed it must do so, because there are extreme differences between personal sampling among High Exposure workers and fixed area sampling in the same High Exposure areas, all from the same round of sampling activities in 1993. Fixed area samples (12) showed concentrations of soluble platinum with a high of only 102 ng/m^3, barely 5% of the OEL. But personal samples (18) showed consistent exposures that were much higher. Every worker who was sampled was exposed over the course of at least two full working shifts during a single week at TWA concentrations that were higher than the maximum area concentration. The highest full shift TWA concentration of soluble platinum was 3697 ng/m^3, or thirty-six times higher than the highest area sample concentration. Looking with somewhat greater focus, in the High Exposure area of Production Line 4, there were 6 fixed area samples taken at three locations along that line in 1993, and 8 personal

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[27] Merget et al. (2000) p367

[28] The data does not indicate whether these samples were taken in Persistent Low Exposure or in Intermittent Low Exposure areas.

[29] Dr. Merget reported that 22 personal samples were taken, and this number has been repeated by DECOS and EPA. His raw data, however, shows only 18 samples specifically identified by 5 worker numbers. Degussa management has confirmed that there were 18 personal samples taken from 5 identified workers. Several additional sampling results were marked in Dr. Merget's compilation of raw data with "?", and Dr. Merget is believed to have misidentified these additional sample results as personal samples. Dr. Merget has said in personal communication that he was unable to obtain consent from more than 5 workers to participate in personal sampling.

[30] EPA Draft 2009 p66

samples taken from two workers assigned to that line, with the following results (ng/m^3 soluble platinum TWA):

Line 4 Area Samples (1993)	Line 4 Personal Samples (1993)
102	3697
87	2459
32	359
15	359
12	338
7	226
	203
	156
Max: 102	Max: 3697
Mean: 43	Mean: 975

Even the lowest full-shift personal sample TWA concentration at Line 4 was 50% higher than the highest fixed area sample concentration. The mean personal exposure concentration was more than twenty times higher than the mean area sample. It is thus very clear that actual exposures of workers in the High Exposure cohort to soluble platinum were far higher than fixed area sampling would suggest. This is, of course, not surprising; it is a recognized systemic bias of fixed area sampling: "Area measurements are collected at fixed positions and therefore, usually do not accurately reflect the exposure of individuals"[31] and it is the reason why the U.S. Occupational Safety and Health Administration requires personal sampling to demonstrate compliance with workplace concentration limits, as "essential for acquiring documented and valid exposure data."[32] Therefore the 28 fixed area samples in the High Exposure area must be rejected as unrepresentative of actual exposures in the High Exposure cohort.

EPA nevertheless determined that the fixed area sampling data were sufficient. In the High Exposure cohort where sensitization occurred, EPA rejected all personal sampling data[33] and asserted that an arithmetic mean of the 28 fixed area concentrations - 52.9 ng/m^3 - was representative of worker exposures in the cohort, and thus of causation of sensitization, and represents a lowest-observed-adverse-effect level (LOAEL): "exposure in this group represents a LOAEL."[34] That is, EPA asserts that chloroplatinate sensitization was observed in the course of the Merget study to have been caused at a concentration of 52.9 ng/m^3. No such observation is evident in the report of the study.

Third, even the valid, representative data are sparse. The only possibly valid measurements of worker exposures to soluble platinum in the High Exposure cohort, the only cohort in which sensitization occurred, are the 18 full-shift TWA personal sampling measurements taken in

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[31] Ignacio, et al., A Strategy for Assessing and Managing Occupational Exposures, American Industrial Hygiene Association, p.88.

[32] OSHA Technical Manual: Personal Sampling for Air Contaminants

[33] EPA Draft 2009 p144

[34] "[T]he arithmetic mean across both years (52.9, 3.37, and 0.048 ng soluble Pt/m^3 for the high-, low-, and no-exposure groups, respectively) was selected as the most appropriate metric for these exposure measurements." EPA Draft 2009 p144

1993, the fourth year of the study. While each sample encompassed a full work shift in High Exposure areas, only 5 workers were sampled, each two or four times. Even before looking at the detail, it is questionable that exposure sampling of 5 out of 115 workers in the High Exposure cohort, conducted only in the fourth year of a five year study, could provide a statistically sound basis for determination of a dose-response relationship and threshold of sensitization.

Fourth, even if the numbers of subjects and samples are deemed to be statistically sufficient, the exposure data do not support the conclusions of DECOS and EPA. The exposure sampling results are as follows:

Worker[35]	Exposure (TWA ng/m^3 soluble Pt)	
3	3697	
6	2885	
3	2459	OEL: 2000
6	490	
8	359	
3	359	
3	338	
8	226	
8	203	
9	184	
9	170	
6	158	
8	156	
5	138	
5	122	
9	59	
6	46	
9	43	

There is no indication in Merget et al. (2000) that any of the five sampled workers was subsequently observed to have been sensitized. Therefore none of these exposure data points can be taken as directly associated with observed sensitization of the sampled worker. The full set of data points may, at best, be representative of the chloroplatinate exposures of all workers in the High Exposure cohort over the five year study.

The exposure data points are obviously, as Merget described them, highly variable and range far above and below the OEL over full shift TWA measurements. EPA simply rejects the data, calling it erroneous[36] without explanation, and holds to its finding of observed sensitization at a mean area measurement of 59.2 ng/m^3. DECOS uses the High Exposure cohort personal sampling data, but only a part of it. DECOS simply dismisses the full range and variability[37], avoiding the three very high exposure concentrations and the mean of 1074 ng/m^3 by using a

[35] The five worker identification numbers were included with Dr. Merget's data, and were confirmed with Degussa data, but have been abbreviated here.

[36] “Epidemiologists often call this variability in exposure "measurement error" or "exposure misclassification error." EPA Draft 2009, Appendix B, pB-4

[37] DECOS: “Peak levels may have played a role, but its significance cannot be assessed.” DECOS 2008 p90

median personal exposure of 177 ng/m^3 [38], as if that were representative and indicative of a sensitization-causing dose.[39] DECOS repeatedly cited this median as indicative of actual concentrations in workplace air[40], said that sensitization had been "shown to develop" at even lower concentrations[41], and concluded from this that "Obviously, exposures below the occupational threshold limit value (generally 2000 ng Pt/m^3) may still result in sensitization."[42]

In fact, that DECOS conclusion is certainly not obvious from the Merget study. To conclude that sensitization within the High Exposure cohort was observed by the Merget study to have been caused by a dose of 177 ng/m^3, when the data shows that the workers in that cohort had been exposed to doses that were twenty to thirty times higher, turns analysis of dose-response data on its head. Within the High Exposure cohort, the frequency of measured, full-shift exposure above the OEL was much higher (17% (3/18 samples) – or even 40% (2/5 workers sampled) – than the frequency of sensitization (11% (13/115)). Therefore, if the Merget exposure data is to be used as a scientific foundation, all sensitization observed during the five year Merget study can be explained by measured personal exposures well above the OEL.

Then, having mistakenly found sensitization at chloroplatinate concentrations of only 177 and 59.2 ng/m^3, DECOS and EPA looked in Merget et al. (2000) for a concentration that did not cause sensitization. Standard data analysis would have taken them back to the same cohort in which sensitization was observed, i.e., to the list of data points from the High Exposure cohort personal sampling, set forth above. But EPA had already expressly rejected this data in its entirety, and DECOS had already rejected all of its high exposure data points by declaring a median concentration to be a data point of sensitization. DECOS and EPA turned instead to the Low Exposure cohorts, and to the fixed area samples taken in five locations to measure chloroplatinate exposures of 112 workers in those two cohorts. No personal samples were taken within these cohorts. The Merget study data show fixed area concentrations of soluble platinum in 16 Low Exposure area samples no higher than 8.6 ng/m^3, and Dr. Merget concluded, because there had been no sensitization among these two cohorts over five years, that concentrations below 10 ng/m^3 were safe. DECOS simply took the 10 ng/m^3 concentration "as a starting point" and recommended 5 ng/m^3 as a health-based occupational exposure limit.[43] EPA took the arithmetic mean of the 16 fixed area samples for the Low Exposure cohorts – 3.37 ng/m^3 – as a no-observed-adverse-effect level (NOAEL), a concentration at which workplace sensitization would not occur.[44]

The use by DECOS and EPA of the Low Exposure cohorts to find a safe concentration for chloroplatinate exposure is another serious flaw. It is quite clear that these cohorts were

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[38] The actual median of personal sampling exposures is 194 ng/m^3. Because both DECOS and EPA accepted the misunderstanding of Dr. Merget that there were several additional personal samples, he and they cited 177 ng/m^3 as the median exposure. The difference is obviously small and not significant.

[39] EPA cited this median concentration as suggestive that its LOAEL based upon area samples "may have underestimated exposure." EPA Draft 2009 p66

[40] DECOS 2008 p63, p80, p90: "In the Merget study, sensitisation occurred in workers exposed to median levels of ca. 180 ng/m^3"

[41] "Sensitisation was shown to develop already at occupational exposure to airborne soluble platinum-salt levels of approximately 50-100 ng/m^3" DECOS 2008 p80

[42] DECOS 2008 p63, p80.

[43] DECOS 2008 p90

[44] EPA Draft 2009 p147. EPA then applied a series of uncertainty factors and downward adjustments to reach a proposed reference concentration – a safe limit for lifetime general public exposure – of 1 pg/m^3 .

composed of different workers, working in non-production areas, who were not engaged in direct contact with point sources of CPA[45] – in stark comparison to the High Exposure cohort where sensitization occurred. These Low Exposure cohorts were essentially subjects of different studies, being conducted in parallel. In the absence of any sensitization among 112 Low Exposure cohort workers, their exposure data provide no information regarding a dose-response relationship or a threshold of sensitization within those cohorts.

The ultralow concentrations proposed by DECOS and EPA are, of course, safe, just as Dr. Merget said. But agency proposals of zero would be equally safe, and equally ill-founded. By switching between the High Exposure cohort, where exposures were very different in kind and were very high, to find causation, and the Low Exposure cohorts to find safety, DECOS and EPA have impermissibly mixed datasets. They have avoided the very high chloroplatinate concentrations that were the likely cause of sensitization, and simultaneously avoided the very wide range of exposure concentrations that are quite likely to be safe. The necessary question is not, as DECOS and EPA appear to have assumed, what is the lowest possible safe exposure concentration, but what is the highest safe concentration. There is, of course, a need to be cautious and protective in setting that highest safe concentration, with safety factors, but that need for caution does not replace the need for data. It needs to be determined whether 100 ng/m^3 would be safe, or 500, or indeed whether the current OEL of 2 ug/m^3 would be safe if it were consistent and "short sharp exposures above this limit"[46] were eliminated, i.e., a ceiling limit rather than a full-shift TWA. The determination of a dose-response relationship, and of a causative threshold dose, requires a range of data that include, for a single cohort, multiple points of sensitization and points of non-sensitization. Merget et al. (2000) does not present such a range, especially not within the same exposure cohort. The assertions of DECOS and EPA that it does, and that it provides evidence of a dose-response relationship defined by a LOAEL and NOAEL, are simply not correct.

4. Conclusions

Historically, occupational exposure to chloroplatinates has been a cause of worker sensitization and illness, sometimes severe, at high rates[47], and although rates of sensitization are now lower, the issue must continue to be addressed with a range of controls and studies. Dr. Merget performed a thorough and rigorous study of this issue in the context of autocatalyst manufacturing, in a controlled environment with enclosed robotic processing, and nevertheless found that sensitization occurred. But his study was not designed to find a key factor of exactly what chloroplatinate concentration or what circumstances of exposure caused that sensitization. And no other study within the very small and widespread platinum industry has done so. It does not advance the cause of worker health when occupational exposure levels are set without an epidemiological study foundation, particularly at proposed levels that will be highly disruptive, if not destructive, of an industry that is vital to environmental protection, chemical production, agriculture, energy conservation and more. DECOS' proposed OEL of 5 ng/m^3 and EPA's proposed safe exposure level for the general public of 1 pg/m^3 are not grounded in Merget et al. (2000). That study does not support the agencies' claims, nor do its data, and DECOS and EPA are simply wrong.

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[45] Dr. Merget intended and ensured that this non-contact was so. See footnote 14 above.
[46] WHO 1991
[47] See DECOS 2008, p58

That is not to say that the current OEL of 2 ug/m^3 eight hour TWA is protective of exposed workers, because it is not, at least not as an eight-hour limit. Platinum industry workers continue to be exposed and sensitized. But how the OEL fails is not known to industry, or to DECOS, or to EPA, and so how it is to be fixed is similarly not known. And so the OEL should stay where it is, until a science-based study shows otherwise. That study can only be performed by the platinum industry, with a cohort large enough to be statistically significant, and prospective both in medical examination and in comprehensive measurement of worker exposure. That measurement must also consider the wide range of types and concentrations of exposures that are hidden with any eight hour TWA limit. And while that study is underway, the platinum industry must maintain chloroplatinate exposures as low as reasonably achievable, well below the current OEL.