REDEFINING METAL SAFETY STANDARDS: THE PROMISE OF ANCHORCERT PRO.

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1. INTRODUCTION

DespKeeping abreast of evolving legislation is paramount in today's dynamic regulatory landscape. As a Technical Director and Chief Assayer of a consumer protection laboratory, I've found that each morning brings its own set of regulatory complexities from various corners of the world. While these legislative updates often bring more opportunities for the lab, the complexities they introduce can be challenging for jewellery suppliers, particularly smaller enterprises with tight budget constraints. Consequently, the prohibitive costs associated with ensuring compliance can dissuade many from undergoing necessary testing, potentially compromising product safety.

After years in product testing, I've become keenly aware of how different analyses are interconnected. All it requires is a lateral perspective to unify them into a singular, cohesive methodology. While this vision required substantial resources – time, samples, funding, and operational freedom – a golden opportunity eventually arose in collaboration with a leading UK High Street Retailer, determined to ensure their jewellery products were free from causing skin allergies to wearers.

In the rapidly evolving landscape of consumer goods, particularly jewellery and metallic accessories, the incidence of allergic contact dermatitis (ACD) presents a significant challenge to both manufacturers and consumers. The manifestation of metal allergies can range from mild irritation to severe reactions, markedly diminishing the quality of life for affected individuals. A distressing illustration of this is depicted in Figure 1, where a lady is shown experiencing a skin allergy on her wrist, a common contact point for metallic items like watches, bangles and bracelets. This visual representation starkly highlights the discomfort and constraints imposed by metal allergies, underscoring the urgent need for solutions that guarantee safety and comfort. The high street retailer, our mission partner, never wanted his customer to face such an issue experienced by the lady in Figure 1.

Figure 1: A photograph illustrating the adverse effects of metal allergies.

The shared mission was clear: thoroughly examining how different metals react in products such as jewellery, watches, eyewear, and other metallic items to determine which metals are kind on the skin. We aimed to identify the safest levels of metal release and the optimal combination of metals that would not trigger allergies. Our primary goal was to significantly enhance product safety, reducing the likelihood of skin reactions during typical use.

This collaborative effort led to the development of the AnchorCert Pro (AP) methodology at the AnchorCert Analytical Laboratory, part of the Birmingham Assay Office. Following its implementation, the retailer introduced jewellery lines tailored for sensitive skin, using knowledge from this methodology. These lines, sold globally, provided valuable feedback and insights, helping us refine our testing approaches.

Our aspirations went beyond mere commercial interest. Fundamentally, we aimed to significantly lower the risk of metal-induced skin allergies, ensuring the highest level of consumer protection. This would be realised if AnchorCert Pro-compliant products could verifiably minimise allergic reactions, even in individuals previously sensitised to metals, effectively preventing both the induction and elicitation phases in the majority.
The method's success became clear in 2020 when data on allergies from the retailer's products that followed AnchorCert Pro showed

it met its goals. In 2021-22, we partnered with another world-renowned high street retailer to conduct a similar exercise with a significantly large number of AnchorCert Pro Compliant jewellery and watches. The results once again confirmed the effectiveness of the AnchorCert methodology in achieving its goals i.e., offering 'complete freedom from metal allergy' as summarised by the caption of figure 1, 'AnchorCert Protect… For complete freedom from metal allergy.' Due to confidentiality agreements, we cannot disclose the specific data, but UKAS auditors have verified it during the accreditation process and subsequent audits. This methodology not only tackles immediate concerns regarding metal allergens but also establishes a new standard in hypoallergenic compliance, marking the dawn of a new era in consumer safety and satisfaction across the jewellery sector and beyond.

AnchorCert Pro is more than just a business project; it's a journey of change. As we collected more test data over time, we began to see clear patterns that linked different pieces of information into a complete story. The methodology not only aligns with notable legislations – including the EU's nickel regulation, the Lead/Cadmium Regulation, the EU RoHS Directive for watches, and the General Product Safety Regulation 2005 concerning metal allergies – but it also sets a benchmark for hypoallergenic assurance and safety against lead and cadmium poisoning through both acute and chronic exposure. The logical sequence of the AnchorCert Methodology is outlined below for enhanced comprehension.

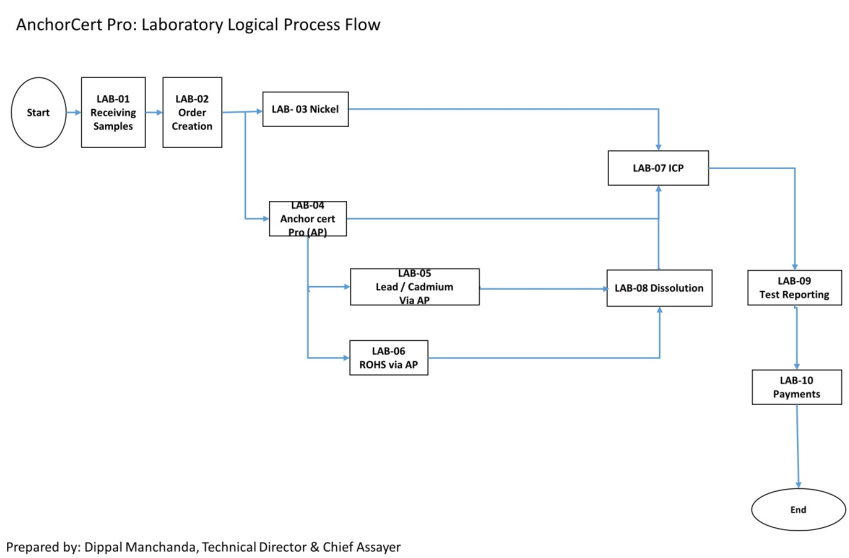

Figure 2: AnchorCert Pro – Process Flow Chart.

AnchorCert Pro stands out for its broad potential and unique benefits, offering both cost-effectiveness and quick results. As it gains worldwide recognition, it aims to set new benchmarks in metal safety, aligning with our paper's vision: "Redefining Metal Safety Standards: The Promise of AnchorCert Pro."

The subsequent sections of this paper will delve into the technical underpinnings of the AnchorCert Pro methodology, explaining how it offers a comprehensive solution to the challenge of metal induced ACD.

2. Beyond Nickel: Unmasking the Spectrum of Skin-Reactive Metals

To set new metal safety standards, we focused on identifying metals in jewellery, watches, and similar items that could cause allergic reactions. To meet our goal, we used patch-testing data as a key investigative tool. This method, primarily for diagnosing allergic contact dermatitis (ACD) and identifying specific allergens, helped us determine which metals cause allergic reactions in people with sensitive skin.

We conducted a thorough review of the literature, including both published and unpublished positive patch testing data, and also considered research articles on contact allergies penned by renowned medical experts. Noteworthy among the referenced databases was the European Surveillance System of Contact Allergies (ESSCA).

Patch testing is a simple process for identifying allergies. Small amounts of potential allergens substances are placed on respective adhesive patches, which are then stuck to the skin. After two days, expert dermatologists check for any skin reactions under the patches to find out which substances might be causing allergies. We thoroughly searched databases like PubMed, Science Direct, Willy, and Google Scholar, using many search terms from "dermatitis" to "EU/US patch test database" and including specific metal names into these searches to enhance precision.

Our detailed review uncovered a standout finding: The Mayo Clinic's patch test data (1), as shown in Table 1 below, covering the years 2000 to 2009, was exceptionally comprehensive. It involved 42 different metal tests, a scope not seen in any other study and even surpassing ESSCA's efforts.

Table 1: Reaction Rates of Allergic Patch Tests with Metal Allergens, Ranked According to Frequency of reaction.

Test Substance	Mayo Clinic Metal Series, 2000-2009		
	Patient Tested	Reaction (%)	Relevance of Allergic Reaction (%)
		Allergic	R
Gold Sodium thiosulphate 2%	90	23.3	23.8
Nickel sulfate hexahydrate 2.5%	1,060	22.5	45.0
Potassium dicyanoaurate 0.1% aq	1,098	20.2	37.4
Manganese chloride 2%	94	20.2	15.8
Gold sodium thiosulphate 0.5%	1,105	18.4	40.4
Palladium chloride 2%	1,059	13.3	36.2
Cobalt chloride 1%	1,060	13.1	46.0
Cobalt (II) sulfate 2.5%	39	12.8	60.0
Potassium dichromate 0.5%	945	11.3	36.4

Ticonium (as is)	102	10.8	18.2
Gold sodium thiosulfate 0.25%	375	10.1	42.1
Potassium dichromate 0.25%	620	8.5	45.3
Mercury 0.5%	1,105	8.1	42.7
Cobalt sulfate 1%	965	7.7	52.7
Gold chloride 0.5% alc	966	6.9	53.7
Ammoniated mercury 1%	392	5.9	69.6
Beryllium sulfate tetrahydrate 1% aq	965	5.6	31.5
Mercury ammonium chloride 1%	1,104	5.6	53.2
Mercuric chloride 0.1%	1,104	5.6	50.0
Chromium chloride 5%	997	4.2	40.5
Silver nitrate 1% aq	1,103	3.6	27.5
Zinc chloride 2% aq	963	3.4	33.3
Manganese chloride 2% aq	1,056	2.7	20.7
Chromium (III) chloride 1%	37	2.7	100.0
Amalgam (non-gamma-2) 5%	94	2.1	50.0
Copper sulfate 1%	268	1.9	20.0
Rhodium 1%	567	1.6	55.6

Amalgam 5%	1,096	1.6	44.4
Copper sulfate 2%	839	1.3	36.4
Ferrous chloride 2%	94	1.1	0.0
Molybdenum 5%	90	1.1	0.0
Titanium alloy disc	904	0.9	25.0
Cadmium chloride 1% aq	1,057	0.7	0.0
Molybdenum chloride 1%	963	0.6	16.7
Ammonium tetrachloroplatinate 0.25% aq	1,057	0.6	0.0
Tin 50%	1,058	0.3	0.0
Ferric chloride 1% aq	964	0.1	0.0
Zinc 2.5%	1,059	0.1	0.0
Aluminium powder 100%	1,059	0.0	0.0
Titanium dioxide 1%	119	0.0	0.0
Vitallium (as is)	100	0.0	0.0
Titanium 10%	94	0.0	0.0
aq=aqueous; alc= in alcohol; R = allergic, relevant; All allergens were in petrolatum unless otherwise specified.			

During research, we participated in key dermatology conferences, such as the European Society of Contact Dermatitis (ESCD) events in Manchester (2016) and Amsterdam (2022). These interactions with skin experts and metal researchers greatly influenced our study's direction and outcomes.

After reviewing a wide range of sources, including research papers, books, patch test data and regulations, and data from ESSCA and the Mayo Clinic, we pinpointed **sixteen metals (Ni, Cr, Co, Au, Hg, Be, Pd, Pt, Mn, Al, Cu, Fe, Mo, Sn, Ti, and Zn**) that could potentially cause skin allergies, provided the condition is favourable.

After identifying the allergenic metals, we conducted random tests on approximately 8,500 pieces of jewellery and watches, sourced from various customers and our mission partner. The aim was to measure the release rates of these allergy-inducing metals when in contact with sweat, quantified in micrograms per square centimetre per week ($\mu g/cm^2/week$). This analysis allowed us to assess the potential risk these metals pose in terms of causing skin reactions.

Table 1 above provides a simplified summary of the Mayo Clinic's patch test results from 2000 to 2009, illustrating how often people reacted to various metal allergens. This table is part of a broader analysis conducted during our preliminary research. During this period, the highest allergy reaction rate recorded by the Mayo Clinic was 23.3% to Gold Sodium Thiosulfate 2%, observed in 90 tested individuals. Similarly, Nickel Sulphate Hexahydrate 2.5% and Potassium Dicyanoaurate 0.1% aqueous solutions triggered skin allergy reactions in 22.5% and 20.2% of the 1,060 and 1,098 patients tested, respectively. For clarity, the table selectively highlights reactions that are definitively associated with allergies, excluding those in more ambiguous categories.

The occurrence of skin allergies from gold was unexpectedly surprising for us as well. The ionization of elemental gold is crucial for triggering a contact allergy and causing allergic contact dermatitis (ACD). It is understandable that when gold exists in a solution as a soluble or complex ion, it might lead to contact dermatitis. However, considering the electrochemical stability of gold, it remains unclear how metallic gold or gold alloys used in jewellery and similar items could react with body sweat quickly enough to provoke an allergic reaction in individuals sensitized to gold. The challenge of defining gold's role in contact allergies became evident, especially since the literature's data on gold's release in sweat is inconclusive. Our separate study on skin allergies from gold concluded that under certain conditions, gold items, whether plated or un-plated, can interact with body fluids like sweat to release soluble gold ions, which could trigger allergic contact dermatitis in those sensitized to gold. Further details on skin allergies from gold are available in our paper "Can Gold Cause Allergy?" by Dippal & Niall, presented at the Santa Fe Jewelry Symposium in Albuquerque, NM.

3. Characterising the Potency of Allergen Metals

Identifying an allergen metal is only the first step; understanding its relative ability to cause allergic reactions, often termed potency, is crucial for assessing product compliance in tests. Allergic contact dermatitis (ACD) involves two stages: initial sensitisation, when the skin first reacts to an allergen, leading to a sensitised condition, and elicitation, when dermatitis symptoms appear. While a higher dose is usually needed for sensitisation, the threshold for eliciting reactions in sensitive individuals varies less. Despite this, there's often no direct correlation between an allergen's sensitisation strength and its elicitation reaction threshold for several allergens. Using the nickel regulation as an example, we see that a dose triggering ACD in a few sensitised individuals (5%) can protect most people (95%) from developing ACD, thereby reducing overall allergy rates. To safeguard the wider population from allergy and sensitisation, the elicitation threshold dose can serve as a benchmark for evaluating product safety.

Determining metal-specific elicitation thresholds is typically based on clinical data, notably patch tests on individuals already sensitised to the allergen metal. These tests usually cover a skin area of 0.5 cmˆ2 and involve 10 to 30 sensitised participants to establish a dose-response relationship. This relationship is represented by a curve plotting the patch test dose (µg/cmˆ2) against the percentage of positive reactions, defining the Minimum Elicitation Threshold (MET) doses for reactions in 5%, 10%, 50%, or 90% of subjects. For instance, the MET5% value indicates the concentration that triggers a reaction in 5% of subjects, implying protection against allergic symptoms for 95% of sensitised individuals.

Figure 3 illustrates the logistic dose-response curve, as published in 'Contact Dermatitis - 2012 - Thyssen - The Critical Review of Methodologies and Approaches to Assess the Inherent Skin (2).' It showcases the correlation between patch test doses and allergic reactions in sensitive individuals. Derived from sixteen studies across fifteen publications, this curve highlights the concentrations required to provoke a reaction in 10% of allergic individuals for each allergen, complete with 95% confidence intervals, as detailed in Table 2. The median ED10% value stands at 0.835 µg/cm^2, spanning a range of 0.025 to 20.1 µg/cm^2.

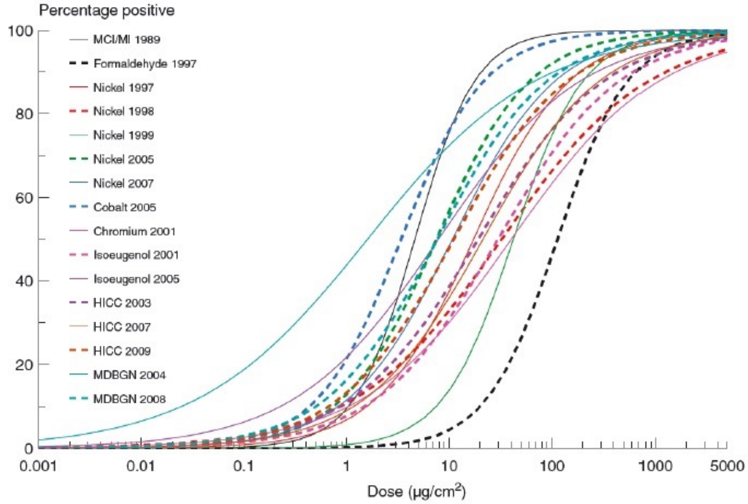

Figure. 3. Logistic dose-response curve for 16 patch test elicitation dose-response studies with methylchloroisothiazolinone/methylisothiazolinone (MCI/MI), formaldehyde, nickel, cobalt, chromium, isoeugenol, hydroxyisohexyl 3-cyclohexene carboxaldehyde (HICC), and methyldibromo glutaronitrile (MDBGN).

Table 2: ED10 patch test values from each of the 16 selected studies, with 95% confidence intervals.

Study	No_of_patients	ED10_ug_cm²	CI_lower	CI_upper
MCI/MI	12	1.05	0.17	2.27
Formaldehyde	20	20.1	4.09	43.9
Nickel 1997	24	1.58	0.32	4.04
Nickel 1998	19	0.8	0.078	2.59
Nickel 1999	26	7.49	2.42	14.5
Nickel 2005	13	0.74	0.066	2.38
Nickel 2007	20	0.82	0.13	2.37
Cobalt 2005	11	0.44	0.033	1.3
Chromium	17	1.04	0.0033	5.55
Isoeugenol 2001	24	1.48	0.22	4.74
Isoeugenol 2005	13	0.23	0.0073	1.32
HICC 2003	18	0.85	0.062	3.26
HICC 2007	14	1.17	0.043	5.05
HICC 2009	17	0.66	0.052	2.35
MDBGN 2004	19	0.025	0.00021	0.19
MDBGN 2008	18	0.5	0.052	1.69

The statistical analysis of the ED10 values (Effective Dose for 10% of the population) and the spans of the 95% Confidence Intervals

(CIs) for each of above studies yielded the following results:
ED10 Values (µg/cm²)
- Mean: 2.44
- Median: 0.84
- Minimum: 0.03
- Maximum: 20.10

Confidence interval (CI) Span
- Mean: 5.61
- Median: 2.41
- Minimum: 0.19
- Maximum: 39.81

These statistics reveal that the average ED10 value across all studies is 2.44 µg/cm², with a median value of 0.84 µg/cm², indicating variability in the sensitivity across different studies and allergens. The confidence interval (CI) spans, which reflect the uncertainty or variability in the ED10 estimates, also show significant variation, with a mean span of 5.61 and a median span of 2.41, suggesting differences in the precision of the ED10 estimates across studies. The wide range in both ED10 values and CI spans highlights the diverse responses to different allergens and the varying levels of certainty in these responses across studies.

There are three obvious outliers—Nickel 1999, MDBGN 2004, and Formaldehyde. After excluding them from the above analysis, the statistical examination of the remaining data yielded the following results:
ED10 Values (µg/cm²) without Outliers
- Mean: 0.87
- Median: 0.82
- Minimum: 0.23
- Maximum: 1.58

Confidence interval (CI) Span without Outliers
- Mean: 2.90
- Median: 2.31
- Minimum: 1.27
- Maximum: 5.55

The exclusion of these outliers led to a more uniform data set, which is evident in the decreased mean and maximum values for both the ED10 values and their CI spans. This refinement suggests a more uniform allergenic response across the analysed substances and denotes enhanced precision in the ED10 estimations, unaffected by the previously identified outliers.

The analysis of the dose-response curve indicated a potential for a standardised threshold for exposure to various allergens, leading to discussions about setting a general regulatory limit in the absence of specific metal data. However, a more detailed examination of test data from 8,500 samples at the AnchorCert Laboratory, covering all sixteen potential allergens within the AnchorCert methodology, suggested that more stringent limits might be required for strong allergens, while less reactive ones could have higher thresholds. The research also highlighted the importance of considering the 'Synergistic Effects' of allergens, 'Cross-reactivity and Concomitant Sensitisation,' along with REACH Annex I section 1.1.2 and ECHA Guidance R.8. These guidelines advocate for a qualitative approach when clear sensitisation thresholds are not well-defined.

In situations where established clinical thresholds for metal allergens are absent, we employed a statistical approach during the trial phase, using a robust dataset of approximately 8,500 test samples. This method constructs a probability distribution curve to illustrate the frequency of allergen levels within our sample set, identifying outliers as data points in the curve's tails. To precisely determine these extremes—and thereby ascertain the MET5% value, which represents the threshold below which 95% of sample values fall—both a significant volume of data and advanced statistical software for sophisticated distribution analysis are crucial, though they are currently beyond the scope of this paper. Given the database's expanding nature, we rigorously monitor the MET5% (Minimum Elicitation Threshold 5%) value for each metal allergen derived from our initial dataset. We continuously assess variability and maintain the flexibility to recalibrate the threshold to enhance precision. This approach explains why a negligible percentage of individuals experienced skin allergies from using AnchorCert Pro Compliant products in the second customer trial experiment conducted in 2021-22. Furthermore, the data from this statistical method were also used to validate the accuracy of the Minimum Elicitation Threshold (MET) value determined by clinical studies, with both methods complementing each other within an acceptable level of uncertainty.

4. Minimum Elicitation Threshold (MET) Dose - Nickel

The EU (REACH) nickel regulation, as stipulated in entry 27, Annex XVII (REACH), is grounded on the elicitation threshold (ED5%). Table 3 below presents results from logistic regression analysis of nickel dose-response studies (3), indicating the estimated doses of nickel that would elicit an allergic reaction in a certain percentage of a sensitised population.

Table 3: Results of logistic regression analysis performed on the data from each of the chosen occluded nickel dose-response studies.

Study Number	Doses (μg/cm²)		Agreement		Estimated Doses (μg/cm²)								
	Min.	Max.	χ^2	P Value	ED1%	ED5%	ED10%	ED25%	ED50%	ED75%	ED90%	ED95%	ED99%
12	0.067	335	0.2	0.91	0.15	0.43	0.7	1.4	2.8	5.7	11.5	18.5	53
17	0.0063	558	0.31	0.96	0.028	0.124	0.24	0.64	1.72	4.6	12.2	24	104
19	0.17	335	24.3	0.0068	0.054	0.36	0.85	3	10.8	38	135	320	2148
20	3.9	495	8.57	0.2	0.38	1.37	2.5	5.8	13.5	32	74	132	476
21	0.087	335	13.3	0.1	0.29	1.6	3.5	10.8	34	106	330	715	3956
22	0.23	254	3.18	0.67	0.05	0.3	0.67	2.2	7.2	24	77	173	1030
15	0.087	838	6.74	0.24	0.175	0.172	0.48	2.2	10.1	46	210	590	5783
16	0.087	828	4.76	0.31	0.165	0.9	1.94	6	18.5	57	177	382	2083
Average	0.0063	838	114	<0.0001	0.067	0.44	1.04	3.6	12.8	45	158	370	2440

The estimated doses that predict an allergic reaction to nickel in 1, 5, 10, 25, 50, 75, 90, and 99% of a sensitised population are shown. Furthermore, the analysis based on the data from all the studies, resulting in a weighted estimated average value, is shown. Small P values of the χ^2-statistic indicate lack of agreement between the observed response frequencies and estimated logistic curves.

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The key conclusions from Table 3 are:

a) The range of minimum and maximum doses across studies varies significantly, from as low as 0.0063 µg/cm² to as high as 838 µg/cm².

b) The x^2 statistic and P values suggest that for most studies, there is a reasonable agreement (The null hypothesis is accepted) between observed response frequencies and the estimated logistic curves, except for Study 19, which has a low P value (0.0068), indicating a lack of fit.

c) The estimated elicitation doses (ED) increase with the percentage of the sensitised population. For example, the dose needed to elicit an allergic reaction in 1% of the population (ED1%) is much lower across the studies compared to the dose needed for 99% of the population (ED99%).

d) The average estimated doses are provided, showing a trend that, as expected, higher doses are required to elicit responses in a larger percentage of the population. The average ED1% is 0.067 µg/cm², and the average ED99% is 2440 µg/cm².

e) There is variability between the studies in terms of estimated elicitation doses for the same percentage of the population, which could be due to differences in study design, population, and other factors.

f) The outcomes of this analysis revealed that 5% of a sensitised population is reactive to a dose of 0.44 µg Ni/cm² and 10% to 1.04 µg Ni/cm²—computed based on a 2-day exposure timeframe. The EU legislation (Entry 27, Annex XVII, REACH) adjusted this value to 0.5 µg/cm²/week for items anticipated for extended and direct skin contact.

Overall, the data suggests that as the concentration of nickel increases, so does the proportion of the sensitised population that would react, and this reaction can vary based on individual sensitivities and study conditions. The average values provide a general benchmark for elicitation doses across the sensitised population. Furthermore, a targeted study (4) conducted by LGC, UK, entitled 'Risks of Sensitisation of Humans to Nickel by Piercing Post-Assemblies' (2003), demonstrated that the sensitisation thresholds for items inserted into pierced parts of the body are lower compared to the elicitation thresholds for items intended for direct and prolonged contact with the skin. LGC proposed a limit of 0.2 µg/cm²/week for test items inserted into pierced parts of the body.

5. Classifying Metal Allergens by Hazard Level

The analysis of test data of 8,500 test samples analysed at the AnchorCert Laboratory for all potential allergens within the scope of the AnchorCert methodology revealed that stricter limits might be necessary for more allergens with higher hazard potential, whereas milder ones could allow for higher limits.

The mechanism to categorise allergen metals based on their hazard potential involves understanding how these metals can cause allergic contact dermatitis (ACD). This process typically includes diagnosing ACD through patch tests and considering the clinical implications of metal exposures from everyday items. The review of data from the Molecular Diversity Preservation International (MDPI) in Basel, Switzerland, provided valuable insights into metal allergy mechanisms, which are crucial for categorising metals based on their allergenic potential. Using this approach, we sorted allergen metals into categories based on their hazard potential, as shown in Table 4, and established their sensitisation thresholds, as detailed in Table 5 below.

Table 4: Hazard Potential Classification of Elements Based on Allergic Contact Dermatitis Risk

Hazard Potential	Elements	Notes
High	Nickel (Ni), Chromium (Cr), Cobalt (Co), Gold (Au), Mercury (Hg)	Mercury is listed due to extreme toxicity despite being a less-known skin sensitiser.
Medium	Beryllium (Be), Palladium (Pd)	-
Low	Manganese (Mn), Molybdenum (Mo), Titanium (Ti)	Variability in nickel release from steel alloys with high Mn content.
Extremely Low	Aluminium (Al), Copper (Cu), Iron (Fe), Tin (Sn), Zinc (Zn), Platinum (Pt)	Rare cases of allergic contact dermatitis.

Table 5: Sensitization Thresholds for Allergenic Metals by Hazard Category

Hazard Category	Induction Threshold
High to Medium Hazard	≤ 500 µg/cm²
Low Hazard	> 500 µg/cm²

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The likelihood of these elements causing skin allergies primarily depends on how well they dissolve in sweat and their ability to form biologically active metal ions. These ions can bond with proteins, forming stable metal-protein complexes that can injure the skin at the contact site, leading to conditions like allergic dermatitis and eczema. This classification shows that Nickel, Chromium (VI), Cobalt, Gold, and Mercury are highly hazardous. Mercury is unique because, despite its rare presence in everyday items like jewellery, its high toxicity necessitated its high-risk classification. Our internal tests even detected mercury that could be released from religious figures embedded in rings, covered by glass or plastic. While most allergic reactions to mercury are linked to cosmetics, tattoos, and dental work, its broad harmful impacts align with the EU's goal for a Mercury-free environment.

Beryllium and Palladium are considered medium risk, while Manganese, Molybdenum, and Titanium are considered low risk. Aluminium, Copper, Platinum, and Iron fall into the "Extremely Low Hazard Potential" category. However, no metal can be guaranteed to be completely "allergically safe," as even those with the lowest risk might still cause allergic reactions in sporadic cases.

6. Synergistic Effects of Allergens

In immunology and allergology, "synergistic effects" refer to how different allergens, including metals, can combine to enhance the body's allergic response significantly. For example, someone already sensitised might not react to a low-risk metal alone, but the reaction could be much stronger in the presence of a high-risk metal like nickel. This highlights the importance of understanding multiple allergen sensitivities, including low-risk ones. A parallel "synergistic effects" phenomenon occurs with heavy metals and pesticides within living systems. Research (5) shows that exposure to combinations of heavy metals and pesticides can cause more severe effects in living organisms than exposure to each one separately.

7. Cross-reactivity and Concomitant Sensitisation

Metal allergies, especially to those metals considered very low risk, are uncommon and usually occur under specific conditions in people who are especially prone to them. Research reveals numerous cases of allergies to various metals in individuals, including low-risk ones, raising questions about whether these allergies are due to cross-reactivity, where an allergy to one metal causes a reaction to another, or due to concomitant sensitisation (simultaneous allergies) to multiple metals. Studies (6 to 8) show that reactions to multiple allergens are often more severe than to single ones, as one high-risk allergen can lower the threshold for another low-risk allergen, especially in sensitive individuals. Thus, low-risk metals may not usually provoke allergies alone due to higher exposure thresholds. However, these thresholds of low-risk allergens can drop significantly in the presence of more reactive high-risk metals, making low-risk metals trigger immune responses even at levels lower than usual. This complicates the assumption that any metal is entirely allergen-safe, as under specific conditions, any metal could cause an allergic reaction.

8. Do 'AnchorCert Pro compliance' and 'Hypoallergenic' mean the same thing?

As said above, no metals can be considered "allergy-safe" in the true sense. Hypoallergenic, when used in context to the skin, means "below normal" or "slightly" allergenic to the skin, but this is no guarantee that the product is safe for the skin.

Searches for a legal or universally accepted definition of 'hypoallergenic' were inconclusive, revealing industry discrepancies. Consultations with industry trade bodies revealed variations in the term's interpretation and use. 'Hypoallergenic' broadly means:

a) the allergenic potential of the product has been identified and minimised.
b) the product in question is less allergenic than similar products available for sale; and
c) that these claims are supported by testing or formulation.

Products marked compliant with AnchorCert Pro meet these criteria, allowing them to be labelled as 'hypoallergenic' concerning metal allergies only.

Terms like 'nickel-free', 'nickel safe' or 'non-toxic' must comply with regulations. The manufacturer, supplier and retailer are responsible for ensuring claims are substantiated and accurate.

9. The Distinctiveness of the AnchorCert Pro Methodology

The AnchorCert Pro methodology not only adheres to the latest version of the EN 1811 standards for nickel release but also extends its scope to define the release patterns of 16 potential skin sensitisers. This broadened perspective underscores our commitment to comprehensive safety and regulatory compliance. Customer trial data collected thus far suggests that products verified through this methodology are highly unlikely to induce skin allergies, providing reassurance even to individuals already sensitised to metal allergens.

Subsequent research has expanded the scope of AnchorCert Pro's compliance, moving beyond solely ensuring safety against skin allergies. This encompassing methodology now aligns with other key EU regulations and includes compliance with EU RoHS criteria (excluding Phthalates and organotin) specifically for watches, along with addressing the risks of lead (Pb) and cadmium (Cd) poisoning through both acute and chronic exposure. Currently, the methodology ensures adherence to four key pieces of EU legislation relevant to jewellery articles and watches, accredited by the United Kingdom Accreditation Services (UKAS):

a) Nickel Regulation (Annex XVII, Section 27, REACH)
b) Lead/Cadmium Regulation (Annex XVII, Sections 63 & 23, REACH)
c) RoHS Directive (specifically applicable to watches)
d) General Product Safety Regulation with respect to metal allergies.

Moreover, products that meet AnchorCert Pro standards may be labelled 'hypoallergenic' in the context of metal allergies.

While this methodology lays the foundation for compliance with the EU Lead/Cadmium Regulation (Annex XVII, Sections 63 & 23, REACH) and the EU RoHS Directive (pertaining to watches), this paper intentionally focuses on allergenic metals to maintain conciseness.

In the upcoming "Part II" of this series, scheduled for publication next year, we'll delve into the AnchorCert Pro method and focus on how this method assists in meeting the standards set by the EU Lead and Cadmium regulations and the RoHS Directive, which limits hazardous substances in electronic products including watches. Our discussion will clarify the process and benefits of using AnchorCert Pro to navigate these complex regulations, ensuring both product safety and environmental protection.

10. Enhancing EU Market Surveillance

The REACH4Textiles project, supported by the European Commission, was designed to bolster market surveillance of textile products within the EU. Its primary goal was to prevent non-compliant products, especially those with potentially hazardous chemicals, from entering the single market. A significant discovery from the project's extensive product testing indicated that about 16% of the evaluated items did not meet the established safety standards. Many of these non-compliant products, found to contain dangerous substances such as Chromium VI and nickel, were traced back to imports from China. This finding underscores the complexities of regulating imports and highlights the necessity for a comprehensive, cost-effective methodology to ensure consumer safety and compliance with EU chemical regulations.

In alignment with the objectives of REACH4Textiles, the AnchorCert Pro methodology presents itself as a crucial instrument, providing a broad testing framework that extends beyond textiles to include both metallic and non-metallic substances, as well as inorganic non-metallic materials like glass and ceramic. The presence of toxic metals such as Chromium VI and Nickel in many tested items highlights the relevance of AnchorCert Pro's extensive testing capabilities. The methodology's ability to assess a wide array of materials (metal, non-metals & inorganic non-metals) for potential allergens and toxic substances makes it a vital tool in pursuing consumer safety.

11. Redefining Metal Safety Standards

The purpose of the AnchorCert Pro test methodology is multifaceted:

I. To prevent sensitisation to sixteen potentially known metal allergens among individuals.
II. To minimise the risk of allergic reactions from prolonged and direct contact with items that release high levels of these sixteen known metal allergens.
III. To ensure products comply with Entry 27 of Annex XVII (REACH), which restricts the use of nickel in all post assemblies inserted into pierced parts of the human body and articles intended for direct and prolonged contact.
IV. To adhere to sections 23 and 63 of Annex XVII (REACH) concerning Cadmium & Lead in jewellery, watches, and consumer products, ensuring all components are tested and meet the criteria to be marked as compliant with EU (REACH) Lead & Cadmium regulations.
V. To ensure compliance with the EU RoHS directive (excluding phthalates and organotin), specifically for watches.
VI. To affirm that products meet the General Product Safety Directive 2005 and upcoming General Product Safety Regulation 2024 from a metal allergy perspective.
VII. To declare that products compliant with AnchorCert Pro can be considered hypoallergenic concerning metal allergies and labelled accordingly.

The testing framework extends beyond metals to include both metallic and non-metallic substances, as well as inorganic materials such as glass and ceramics. All components in a product are tested, thereby offering comprehensive protection.

The AnchorCert Pro test methodology has been validated to ensure that its ‘compliance report’ effectively mitigates the risk associated with sixteen potential metal allergens and their derivatives, as listed in the CLP Regulation (Classification, Labelling and Packaging), Annex VI, Table 3.1. This validation ensures that if these substances are present or formed during the product’s end use, they pose a minimal risk of skin sensitisation.

12. Ongoing research

AnchorCert Pro’s methodology stands out due to its broad scope and dedication to continuous research, which aims to integrate further regulations and standards. These include the U.S. Consumer Product Safety Improvement Act (CPSIA) regulations for lead, California’s metal-containing jewellery laws covering lead & cadmium, and heavy metal standards that draw on the concept of safe harbour limits. This forward-thinking approach ensures that AnchorCert Pro remains at the forefront of safety and compliance testing, continually evolving to meet the complex and changing needs of the global market.

13. Making a claim.......

Pursuant to the Trade Descriptions Act of 1968, which was subsequently superseded by the Unfair Commercial Practices Directive 2005/29/EC (“UCPD”), the methodology employed by AnchorCert Pro complies with legal standards designed to prevent false or misleading trade descriptions.

The AnchorCert Pro methodology is based on extensive research, with the aim of protecting the majority, though not all, of sensitized individuals. Additionally, it is designed to significantly reduce the risk of non-sensitized individuals developing allergies to metal allergens.

A very small fraction of the population exhibits hypersensitivity to certain metals, demonstrating a hyper-reactive dermal response to metals that are generally considered low risk. This hypersensitivity can lead to varying degrees of irritation, which are usually well tolerated by non-hypersensitive skin. It’s noteworthy that the characteristics of individuals who report hypersensitivity to these low-risk metal allergens often differ from those who experience allergic reactions to common, everyday metals. Hypersensitive individuals may react to extremely low concentrations of these metals upon skin contact, making it crucial to prevent such reactions on an individual basis.

Although the AnchorCert Pro approach is anticipated to protect a large portion of individuals in the aforementioned category, we refrain from making absolute claims due to the variability in individual responses.

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