



REACH legislation has shown that Cr III presents no health threat to the vast majority of people and that its correct and responsible use in tanneries is perfectly safe. Chromium-tanned leather from reliable sources presents no danger to the average consumer. ALL CREDITS: WTP

Chrome VI limits called into question

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AFIRM, a group of brands in the apparel, footwear and sporting goods industries, has said it is hard to see how any tightening of the allowable limits of chrome VI in leather can be approved. Further, the group believes the validity of the current limit is open to question.

In 2018, the European Chemicals Agency (ECHA) launched a consultation process on the inclusion or amendment of regulation for skin sensitising chemicals under the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) regulations. Included in the consultation was a proposal that the limit from Chromium VI (Cr(VI)) in leather articles, should be reduced to 1 mg/kg. The consultation has been considered by two ECHA committees, the Committee for Risk Assessment (RAC) and Committee for Socio-economic Analysis (SEAC) and their opinions published for comment by stakeholders.

Many respondents, including leather manufacturers, chemical companies and trade associations, correctly noted that the limit of detection for existing analytical techniques for Cr(VI) is 3mg/kg and, in the absence of a more sensitive

procedure, the new proposed limit was unenforceable. However, included in the responses was the more startling suggestion that the current limit did not need to be reduced, because it was already unnecessarily stringent.

The AFIRM Group, a forum of leading brands in the apparel, footwear and sporting goods industries working to harmonise product chemical requirements, stated in its response to the consultation that the existing REACH restriction on Cr(VI) in leather articles "is already stricter and more conservative than what is verifiable in the scientific literature". It said AFIRM considered that the proposal to further reduce the REACH restriction on Cr(VI) in leather from 3mg/kg to 1mg/kg was "not scientifically justified and in direct conflict with ECHA's Opinion dated 19 March 2012". On that date, ECHA published a background document to



Exposure Assessment Calculations for Leather Footwear Containing Low, Intermediate, or High Concentrations of Cr (VI)

Descriptor	Value			Unit	Justification
Concentration (C _{bulk})	3	10	25	mg/kg	Leather Cr (VI) Concentration
Density of leather (ρ)	1500	1500	1500	kg/m ³	-
Thickness of product layer on skin (T)	0.001	0.001	0.001	cm	ECHA (2016)
Conversion factor (CF)	0.001	0.001	0.001	(μg/mg) × (m ³ /cm ³)	1,000 / 1,000,000
Migration rate (MR)	0.3	0.3	0.3	-	ECHA (2012), Korn et al. (2003)
Exposure = C _{bulk} × ρ × T × CF × MR					
Exposure	0.0014	0.0045	0.011	μg/cm ²	-

give further reference material to add the information the two committees mentioned above had already submitted about Cr(VI) in leather.

AFIRM's conclusion was supported by a report it had commissioned, which reviewed the data used by ECHA to establish the limit for Cr (VI) in leather. During its first consideration of Cr(VI) in leather, ECHA determined that 0.02 μg Cr (VI)/cm² was an appropriate "lowest-observed-adverse-effect-level" (LOAEL) for elicitation of acute-contact dermatitis (ACD) in Cr (VI)-sensitised individuals. They also concluded that this limit was below the level of exposures associated with the 3 mg/kg detection limit of the analytical method for leather. As such, a limit for Cr (VI) in leather articles was set at 3mg/kg.

However, using exposure assumptions taken directly from ECHA documents, AFIRM found that dermal Cr(VI) exposures associated with 3 to 25 mg/kg of Cr(VI) in leather shoes were less than the ECHA LOAEL of 0.02 μg CrVI/cm². This meant it was possible to have Cr (VI) concentrations in

leather that are higher than 3mg/kg without exceeding the LOAEL. They also concluded that the basis for the LOAEL was unsupported. A concentration of Cr (VI) equal to 3mg/kg for a leather article in contact with skin would result in an exposure of 0.00135 μg/cm², which is 15 times lower than the chosen threshold.

Furthermore, AFIRM found that studies by ECHA were based on assumptions that were inconsistent with its own assessment guidelines. ECHA calculated that a 1cm² piece of leather that was 1 mm thick and contained 10mg/kg Cr (VI) would exceed the LOAEL of 0.02 μg/cm² by a factor of 20. On this basis, any leather article containing 0.5 mg/kg Cr (VI) would exceed the LOAEL and it would be impossible for any chromium-tanned leather to comply with REACH.

However, this risk assessment assumed that the full thickness of the leather (1mm) would come into contact with the skin. This is inconsistent with ECHA's own guidance on Information Requirements and Chemical Safety Assessments, which notes that a thickness layer of 0.01 mm is generally used for articles. To exceed the LOAEL using this assumption, a leather article would need to contain 44mg/kg of Cr (VI). AFIRM concluded that the amount of Cr (VI) that can migrate to the skin from a piece of leather in contact with the skin "was highly over-estimated in the ECHA risk assessment". Therefore, ECHA's conclusions that leather concentrations of 3mg/kg (or even lower) may pose a substantial risk of ACD are "without merit".

AFIRM concluded that the proposal to further reduce the REACH restriction on Cr (VI) in leather was not scientifically justified and in direct conflict with ECHA's opinion dated March 19 2012. This is only one opinion, but it is a very well researched and referenced opinion and this should be more than enough to give pause to any change in the current REACH restriction in Cr (VI) in leather articles.

The consultation is now closed, and the decision will be made by ECHA. If the issues around measuring Cr (VI) in leather and the arguments made by AFIRM on the validity of the current limit are given proper consideration, it is hard to see how any tightening of that limit could be approved. Furthermore, this analysis gives the industry a basis to address the concerns of our customers, on the risks arising from Cr (VI) in leather, which appear to have been significantly overstated. ☺



In 2019, ECHA proposed to reduce the concentration limit of Cr (VI) in leather articles from 3 to 1 mg/kg (ECHA 2019). The concentration limit was derived using an elicitation threshold dose of 0.02 μg/cm², a migration factor of 0.30, along with an exposure scenario of two shoe changes occurring over 24 hours.