

Denmark prepared a restriction report on chromium VI in leather articles¹

SUMMARY

Denmark has submitted a report proposing a restriction on the placing on the market of articles of leather coming into direct and prolonged or repetitive contact with the skin if the leather contains chromium VI in concentrations above a certain limit.

Chromium VI is not intentionally used in the preparation of leather from skins and hides and in the manufacturing of articles of leather, but may be formed during the processing. The presence of chromium VI in tanned leather and articles of tanned leather can be avoided, under properly controlled conditions.

Chromium VI is known amongst other effects to cause severe allergic contact dermatitis in humans and to be able to elicit dermatitis at very low concentrations. The dossier demonstrates that extractable chromium VI from shoes and other articles of leather represents a risk for the development of contact allergy to chromium for the consumers and workers.

Surveys of chromium VI in articles of leather in some of the Members States have demonstrated that more than 30% of the tested articles of leather contained chromium VI in concentrations above 3 mg/kg (which is the proposed concentration limit).

ECHA today starts the public consultation on the restriction report, which will end on 16 September 2012. However, ECHA encourages interested parties to give their comments by 1 June 2012.

SUGGESTED RESTRICTION

Denmark has submitted a report (a so called Annex XV report) proposing to restrict chromium VI in leather articles. In the report, Denmark proposed that *articles of leather, coming into direct and prolonged or repetitive contact with the skin, shall not be placed on the market if the leather contains chromium VI in concentrations equal to or higher than 3 mg/kg.*

The report contains a non-exhaustive exemplary list of articles that may be in prolonged contact with skin. These are given in Annex 1.

CHROMIUM VI IN LEATHER ARTICLES

Chromium VI compounds are assumed not to be used for tanning anywhere in the world today.

¹ The information note has been prepared based on the Annex XV report prepared by Denmark.

PUBLIC CONSULTATION

The main chromium compound used for tanning of leather is chromium III hydroxide sulphate, $\text{Cr}(\text{OH})\text{SO}_4$ (CAS No 12336-95-7; EC No 235-595-8). The substance is not included in Annex VI of the CLP Regulation (CLP-Regulation (EC) No 1272/2008) (harmonised classification) but its classification has been notified by several companies to the C&L inventory (<http://echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database>).

Chromium III hydroxide sulphate is made by the reduction of sodium dichromate in the presence of sulphuric acid. By varying the sulphuric acid to chromium VI ratio, chromium III sulphates of differing basicity are produced. The basicity of a chrome tanning agent depends on the proportion of hydroxyl groups (OH groups) in the molecule. The optimum basicity is obtained by addition of alkalis such as sodium bicarbonate or sodium ash.

According to Industry, measures for preventing the formation of chromium VI in leather are implemented in tanneries across the European Union. Furthermore, many importers of leather and articles of leather require that the leather does not contain chromium VI in measureable concentrations. The survey data, however, clearly demonstrates that the risk management measures implemented by some EU manufacturers and importers are not sufficient to protect the consumers against exposure to chromium VI in leather. Surveys in Germany and Denmark have demonstrated that more than 30% of the tested articles of leather contained chromium VI in concentrations above 3 mg/kg. The surveys in general do not report on the origin of the tested articles but it is known that many of the leather articles on the EU market are imported.

REASONS FOR ACTION

Chromium VI is known to cause severe allergic contact dermatitis in humans and to be able to elicit dermatitis at very low concentrations. The risk assessment performed as part of this dossier demonstrates that chromium VI from shoes and other articles of leather represents a risk for the development of contact allergy to chromium for consumers.

Articles of leather, when in direct and prolonged contact with the skin can result in skin sensitisation with symptoms such as contact dermatitis. In principle, everybody across the EU is at risk of exposure to chromium VI in leather.

It is estimated, on the basis of the available data, that 0.2-0.7% of the population in the EU are allergic to chromium VI corresponding to approximately one to three million people. Chromium VI in leather has been demonstrated to be one of the causative exposures for development of contact dermatitis in humans. Based on survey data from Denmark, it has been estimated that during the last 10 years about 45% of the new chromium allergy cases were due to exposure to leather.

In spite of the implemented measures (in some EU Members States or voluntary by the industry), many consumers develop a chromium allergy due to exposure to chromium VI in leather each year.

The proposed restriction covers articles of leather that are extensively traded among and used in all EU Member States. According to the Danish proposal, an EU wide action is needed also to ensure that legislation is harmonised in the Member States so that market conditions are equal to all manufacturers and importers in the EU.

CONSEQUENCES OF THE ACTION

The restriction is estimated to cover about 90% of the cases where leather articles placed on the EU market contain chromium VI in concentrations above 3 mg/kg. The remainder of the articles have short-time contact with the body. As those leather articles are, to a large extent, manufactured or imported by the same companies manufacturing or importing the articles covered by the restriction, it is most likely that same measures for preventing chromium VI would be applied in both cases.

It is estimated that the effectiveness of the restriction in preventing new cases of chromium allergy caused by leather would be about 80%. This would mean a reduction of some 4 000 allergy cases per year in the EU.

COMMENTS PREFERABLY BY 1ST JUNE

The opinion forming process of the ECHA Committees for Risk Assessment (RAC) and Socio-economic Analysis (SEAC) starts with a public consultation on 16 March 2012. Interested parties can comment on the proposal and the restriction report using the ECHA website. Although the public consultation concludes on 16 September 2012, the rapporteurs of RAC and SEAC would appreciate receiving comments by 1 June 2012 to assist them in the detailed discussion of the restriction proposal in June 2012.

The final opinions of both Committees are scheduled to be available by 16 March 2013. ECHA will send these two opinions to the European Commission, which will take the decision whether to include new restrictions in Annex XVII of the REACH Regulation.

Annex 1:

EXAMPLES OF LEATHER ARTICLES FOR WHICH PART OF THE SURFACE MAY BE IN PROLONGED CONTACT WITH THE SKIN UNDER NORMAL USE CONDITIONS (quotation from the Danish restriction dossier)

Product group	Application
Footwear	Leather shoes, sandals and boots. When used without stocking the skin is in prolonged contact with both the leather i.e. sole and the uppers.
Gloves	Many leather gloves (apart from protective gloves) have inner lining which reduces the direct exposure to the leather. Some types of thin soft leather such as suede and gloves used for riding, driving, cycling, etc. are not equipped with a lining. All types of gloves usually leave a small part of the leather in contact with the wrist. Leather is widely used in protective gloves for personal protection which often do not have inner lining. Gloves have been more common as causative exposure in male patients than in female, which may be due to the males' more common use of protective gloves. Today regulated at < 3 mg/kg Cr VI).
Underwear	The leather is probably in direct contact with the skin although some products may have lining.
Watch straps and other wrist straps/bands/braces	Commonly used for watches but also for braces and bracelets. The straps or braces are in direct contact with the skin. Some wrist straps e.g. used as bandages have a lining.
Neck straps	Commonly used as small straps used for necklaces. The strap is in direct contact with the skin.
Covers for car steering wheels	Prolonged contact with the hands.
Jackets and coats	Jackets and coats usually have inner lining, but the leather will be in direct contact with the skin around the wrist and the neck.
Trousers	Most leather trousers have inner lining, but trousers often do not have lining below the knee. A small part of the skin below the knee may be in prolonged contact with the leather.
Hats	Leather hats may have inner lining, but usually a part of the leather is in contact with the head.
Auto seats	The contact between the auto seats and the skin highly depends on the clothing of the user. During summer where many users of the cars wear shorts or short dresses, the legs are in prolonged contact with the leather.
Other furniture	The contact between the other furniture and the skin highly depends on the clothing of the user. During summer where many people wear shorts or short dresses, the legs are in prolonged contact with the leather.
Bags	For most types of bags contact between the handle and the skin of the hand when the bag is carried or opened/handled. Small handbags may be in prolonged contact with the hand. Shoulder bags may be in prolonged contact with the shoulder if the user wears a dress with bare shoulders.
Toys	E.g. leather dolls and animals. Prolonged contact with hand when playing with the toy.
Riding gear	In contact with the hand when handled. Prolonged contact with the reins when riding.
Dog leashes	Prolonged contact between the leash and the hand when the dog is taken out.