

Veterinär- und Lebensmittelüberwachungsamt

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Leaflet for Importers / Suppliers of Toys, Textiles, Jewellery and Leather Goods 有關進口玩具,紡織品,珠寶和皮革製品一般信息

Preface

The above mentioned product groups are, according to German law, captured by the following laws:

a) According to § 2 of the German Food and Feed Code (LFGB) they are classified under the generic term "Commodities" ("Bedarfsgegenstände"). In § 30 it is stipulated that it is forbidden to produce or market commodities in such a manner that they might bear health risks due to their composition of substances, especially by toxicological effective substances or contamination while used in a proper and foreseeable way.

In the context of the Commodities' Ordinance, there are further regulations with regards to the composition and marking of commodities.

- b) Also according to the Equipment and Operations Safety (GPSG) such commodities may only be placed on the market if they are designed in such a manner that they do not harm the safety and health of users or others when used as intended or foreseeable misused. In order to substantiate these safety requirements, nationally and internationally accredited standards can be consulted.
- c) With regards to toys, please also note (with transitional rule) the rules of DIRECTIVE 2009/48/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 June 2009 on the safety of toys. 前言

上述產品為德國法律所規管:

- a) 根據德國食品及日用品法(LFGB)§2條例,它們統稱為"日用品"。條例§ 30禁止製造、販售或處理含有危害人體健康物質的食品容器、或與人體皮膚、黏液接觸的日用品,特別是在適當的和可預見方式下使用的有毒物質或受污染物質。日用品更是受到其多條例和標籤所監管的。
- b)根據"技術設備和消費產品法"(GPSG),日用品在正常或可預見不正確使用下, 用者或第三方的安全和健康不會受到損害,產品才可以在市場上出售.為了實施安全 要求,國家和國際認可的標準可能被採用。
- c)2009年6月18日起玩具安全(過渡措施)是受到歐盟指令2009/48/EC所規管。

1. Safety of Children's Clothing

In the past, children have repeatedly been injured – some even died – because the cords and strings of their anoraks and jackets got caught in doors and devices. In

spring 2005, DIN EN 14682 "Safety of Children' s Clothing – Cords and Drawstrings on Children' s Clothing" was issued, which applies generally for children up to 14 years of age. According to this standard, for instance cords and strings in the area of hoods and necks are banned for clothes for children up to 7 years of age. The standard also defines precisely safety requirements for children' s clothing for older children, e.g. when are cords acceptable and which length should they have.

1. 兒童服裝安全

過去,不斷有孩子因風衣及夾克的繩所纏而致命或受傷的事件發生。 在 2005 年春天, 有關兒童服裝安全-繩及細帶的標準 DIN EN 14682 成立,標準適用於所有給 14歲以下兒童穿著的服裝,根據條例,如7歲以下兒童穿著服裝的帽及衣領是禁止配置有繩及細帶的。此標準亦為專為年齡較大兒童穿著的衣服,設置有關繩及細帶長度具體安全標準。

2. Dyes

2.1 Azo Dyes

All products made of textiles and leather are banned that might be in direct contact with skin for a longer time and which contain azo dyes, if they release one or more certain carcinogenic chemical compounds (amines) through dispartment in detectable amounts. The use of azo dyes is regarded as proven if the release is more than 30 mg in one kg of a finished good or a dyed part of it.

These are items such as:

□Clothing, bed linen, towels, hair pieces, wigs, hats, diapers and other toiletries, sleeping bags

Shoes, gloves, watch band, handbags, purses and wallets, brief cases, chair covers, neck pouches

Toys made of textiles and leather and toys with textile or leather clothing

2. 染料

2.1 偶氮染料

禁止長時間直接接觸到皮膚及可能含有及釋放可檢測數量違禁致癌化合物偶氮染料的紡織品和皮革產品。在一千克成品著色部分,偶氮染料的含量不得超過 30 毫克。

標準應用於以下產品:

服裝、床上用品、毛巾、假髮用品、假髮、帽子、尿布等衛生用品、睡袋、鞋、手套、手錶帶、手袋、錢包和錢夾、公文包、椅子套、手提包、皮革玩具和玩具、其中包括紡織品和皮革服裝

Potential causes for contaminations 污染潛在原因

- Mix-up of dyes in dyeing factory / tannery 錯誤使用染料來染色/制革
- Mix-up with products which have not been produced fort he German / European market
- 錯配不是為德國/歐洲市場生產的產品
- Contamination due to change of dyes 更改染料引致污染
- Technical contamination of the dyes or shading with banned dyes 不純熟染整技術或使用違禁染料造成的污染
- Use of banned azo dyes in appliqués, pocket linings, borders, cords, etc. 使用 被禁的偶氮染料於口袋內層,裝飾,邊框,細帶等

Critical Components 關鍵部份

Very colourful, fashionable items, which are produced in small quantities per colour: e.g. bandanas, neck scarves, ties, jewellery, wristbands, neck pouches 小批生產色彩 繽紛款式新穎的產品,如絲巾、圍巾、領帶、首飾、手鐲、頸袋

Brief cases, chair covers 公文包、椅子套

Leather and furs, especially black and red colours 皮革和皮草,特別是紅色和黑色的 Intensive colours 強烈顏色

2.2. Allergenic Disperse Dyes

In the meantime, many indications of dermatologists as well as clinical trials have proven that certain disperse dyes do have a sensitive (sensibilisierend) effect.

Disperse dyes are lipophilic substances whose dying principle is that they can be dissolved in chemical fibres. Due to technological reasons, only small molecules come into consideration. In the process, organic solvents (carrier) are additionally used. If the dyeing is not done according to state of the technology (e.g. overdyeing, wrong textile substrate or insufficient removal of the carrier), this might result into a higher exposition of dyes and carriers while wearing those textiles. As these substances can be well resorbed through the skin, health risks might occur.

2.2 致敏分散染料.

許多研究結果顯示通過皮膚科臨床試驗清楚顯示某些分散染料是會帶來致敏的影響。 分散染料是油性的物質,其染色的原則是,它們可溶於化學纖維。

基於技術原因, 只有小的份子才會被採用, 在過程中, 有機溶劑也會加入.

如果著色不按照預先技術執行,如不正確或不完整著色會移除了紡織品的總材質,會可能導致穿上這樣染色織物更高風險。

由於這些物質會通過皮膚而被吸收,會帶來對健康構成的風險。

That is why, for instance, the work group Textiles of The Federal Institute for Risk Assessment (BfR) is calling for an abandonment of the following eight dyes in textiles worn closely or directly on the skin:

有見及此,德國聯邦風險評估研究所(BfR)紡織品研討會中呼籲放棄於貼身穿著的紡織品使用以下 8 種染料:

Disperse Dye	CAS-No.
Disperse Blue 1	569-61-9
Disperse Yellow 3	2832-40-8
Disperse Blue 35	56524-77-7 und 56524-76-7
Disperse Orange 3	2581-69-3
Disperse Blue 106	12223-01-7
Disperse Orange 37/76	13301-61-6
Disperse Blue 124	61951-51-7
Disperse Red 1	2872-52-8

Critical Components 關鍵部份

通過利用分散染料染滌綸織物和聚酰胺紡織品於以下產品中,問題經常出現:

內衣,襯衣,襯裡

絲襪,褲襪,襪子

Due to the use of disperse dyes for dyeing textiles made of polyester and polyamide, for the following items problems often arise:

Tights, socks, leggings

Underwear, blouses, linings

As these products normally contain polyamide fibres which do not allow a good colour fastness in conjunction with disperse dyes.

因為這些產品通常含有聚酰胺纖維,聯同分散染料使用時,產生較差的色牢度。

Rules with regards to Allergenic Disperse Dyes 過敏分散染料守則

The use of disperse dyes are considered to be proven if a defined test method detects more than 5 mg/l (extract).

以明確測試程序檢出含量超過 500 毫克/升(吸取)的分散染料時,它便被定為檢出。

3. Flame Retardant

For commodities which are not only in short time contact with the human body, such as clothes, bed linen, masks, wigs, hairpieces, artificial eyelashes, armbands, glasses frames; as well as soft toys and dolls, the following flame retardants may not be used:

Tri-(2,3-dibrompropyl)-phosphate (TRIS), Tris-(aziridinyl)-phosphine oxide (TEPA), polybrominated biphenyls (PBB)

3.阻燃劑

不是短時間與人體接觸的商品,如衣服、毛巾、口罩、假髮、假髮配件、人造睫毛、 手鍊、眼鏡架、以及玩具和洋娃娃,不得使用以下阻燃劑:

三(2.3-二溴丙基)磷酸、三(氮丙啶)氧化膦、多溴聯苯(PBB)

4. Formaldehyde in Textiles

Textiles with a formaldehyde content of more than 1500 mg/kg have to be marked with the following sentence: " Contains formaldehyde. It is recommended to wash the clothes prior to the first use in order to improve skin kindness." (" Enthält Formaldehyd. Es wird empfohlen das Kleidungsstück zur besseren Hautverträglichkeit vor dem ersten Tragen zu waschen.")

4. 紡織品內含甲醛

紡織品內含甲醛濃度超過 1500 毫克/千克要貼上" 含有甲醛" 標句,為了服裝與皮膚有更佳的兼容性,建議在第一次穿著服裝時應先作清洗。"

Causes for contaminations

Preserving agent, e.g. for colorants, glues and other auxiliary materials

Reaction component in resins, e.g. for nonwoven fabrics or finishing of, for example, cotton and wooden or paper fibre materials

Auxiliary material during tanning

受污染的原因

防腐劑,如著色劑、粘合劑和其他輔助工具

在樹脂中的反應元件,如非織造布纖維或加工材料,如棉花、木材/紙張纖維材料制革輔助工具

Critical Components 關鍵配件

Baby apparel with coloured carbon prints, especially in conjunction with binders that use formaldehyde as a preserving agent or binder

Specially equipped textiles, "non-iron", "crease-resistant", e.g. shirts for men Fibre materials in stabilising components, e.g. interlining materials, insoles 有彩色塗料印花的嬰兒衣服,尤其是以甲醛作為防腐劑結合粘合劑特別功能紡織品,"免燙","防皺"如男士襯衫固定作用的纖維材料,如網底、鞋底

5. Pentachlorophenol (PCP)

5. 五氯苯酚(PCP)

According to the Ban of Chemicals Regulations, there is a ban on marketing products with a PCP content of more than 5 mg/kg. This ban applies for all products which are merchandised.

化學品管制條例 Chemikalienverbotsverordnung 禁止市場銷售產品含有五氯酚濃度大於 5 毫克/千克,這項禁令適用於所有產品中。

Causes for contaminations 受污染的成因

Use for storage and transport preservation against mould

Contamination of considerable leather charges due to single, highly contaminated wet blues

Preservation / transport preservation of pre-products (e.g. cotton)

Pigment pastes (especially for silk), wood, paper et al.

儲存模具和運輸用的防腐劑

皮革會透過高污染藍濕(鉻革濕程序中)受嚴重污染

保護/保存和運輸的初級產品(如棉花)

色漿(尤其是用於絲綢)、木材、紙張等

Critical Components

Leather fibres in shoes, e.g. front and rear caps

Simple leather, e.g. for work gloves, wrist bands, accessories

Printed silk scarves and blouses made of synthetic fibre

Latex coating in balls

關鍵配件

鞋的皮革纖維,例如前後腳跟

簡單皮革,如 勞保手套、首飾、色帶、配件

印花絲綢和合成纖維襯衫

有乳膠塗料的球

6. Dimethylfurane (DMF) in Leather and Textiles

DMF is a Biocide that is used for shoes and upholstered furniture in the form of small bags together with desiccants or also for leather via impregnation for the protection against. According to the European Commission's ruling 2009/251/EC, products containing DMF bear a serious risk for consumers' safety and health. Products do not comply with the requirements of § 4 GPSG, if

it is stated that they contain DMF, or he product (or parts of the product) show(s) a DMF concentration of more than 0.1 mg/kg.

皮革和紡織品的富馬酸二甲酯(DMF)

富馬酸二甲酯是一種殺菌劑 , 用於傢俱及鞋子 , 以乾燥劑小袋形式出現,或用於皮革的浸漬以防止黴菌生長。 根據歐盟委員會決定 2009/251/EC, 含 DMF 的產品是嚴重 威脅消費者安全和健康的。 根據 GPSG§ 4 規定產品不得含有富馬酸二甲酯或在產品或其材料含濃度高於 0.1 毫克/千克的富馬酸二甲酯

7. Chromium (VI) Compounds

Residues of hexavalent chromium compounds can be produced from faulty tanning or conditioning (glue, coating) in leather tanned with chromium, but have also been detected in textiles. As hexavalent chromium compounds are classified as carcinogenic (EU C2), they are banned from manufacturing clothing and shoes. The BfR recommends restricting allergenic chromium (VI) compounds in leather goods to 3 mg/kg.

六價鉻化合物

已有證明顯示有紡織品因鞣革及制革時的不當(粘合劑、塗料)引致六價鉻化合物丙 殘留,六價鉻化合物歸類為致癌物質(第二類),在服裝和鞋類製造中它們是不可使 用的。德國 Bfr 建議限制在皮革製品中使用引起過敏的六價鉻化合物限制為 3 毫克/公 斤。

Causes for contaminations

Contamination of tanning materials

Double-bath tanning method (Zweibad Gerbverfahren) during incomplete reduction from chromium (VI) to chromium (III)

Oxidation of Chromium (III) in chromium tanned leather via aerial oxygen in the presence of heavy alkaline components, e.g. latex glue, equipments et al.

受污染原因

染鞣劑受污染

在兩浴曬黑法中,鉻三轉變至六價鉻時受污染

在鉻革過程中強鹼性組件會在大氣中出現鉻 Ⅲ 氧化,如乳膠粘合劑、設備等

Critical Components

Critical with regards to Chromium (VI) and its compounds are all chromium tanned leathers and leather fibre materials, especially:

Natural coloured, bright lining leather in shoes and clothes

Leather for traditional costumes, which consists of bigger amounts of fats and fish oils

Leather bands, leather gloves

關鍵部份

由於六價鉻(VI)及其化合物被證明為所有鉻鞣革和皮革纖維關鍵的材料,尤其是自然色、光皮革襯裡的鞋子和衣服 含大量脂肪和含魚油的皮革服裝 皮帶、皮手套

8. TBT and other tin organic compounds

The most important tin organic compounds in connection with textiles and leather goods are:

8.TBT和其他有機錫化合物

這是在紡織品和皮革產品有關連的主要有機錫化合物:

MBT (Monobutyl tin compounds) (丁醚	MOT (Monooctal tin compounds)
錫)	
DBT (Dibutyl tin compounds)	DOT (Dioctal tin compounds)
TBT (Tributyl tin compounds) (三丁基	TCyT (Tricyclohexyl tin compounds)
錫)	
TeBT (Tetrabutyl tin compounds)	TPhT (Triphenyl tin compounds)

Within this group, tributyl tin compounds TBT are very important due to their extensive technical usage (anti fouling paint for vessels) and their documented high efficiency even in the range of traces.

For higher concentrations, the following applies: TBT is classified as toxic, can be absorbed through the skin and can harm – depending on the concentration – the nervous

For higher concentrations on DBT and other tin organic compounds, similar reasons apply as for TBT.

At this point, four potential sources have been identified:

- Antimicrobial finish, in order to inhibit the bacterial decomposition of sweat and the aligned displeasing smell of sweat.
- PU (Polyurethane) and TPU (thermoplastic polyurethane) are often produced with the use of organo tin catalysts, which are often MBT and/or DBT. It is widely known that DBT and MBT could be contaminated with TBT.

- It is possible to use other catalysts which contain other tin organic compounds (e.g. DOT), but no TBT. The safest way is to fully abstain from tin organic compounds.
- In addition, parting agents could contain catalysts such as DBT and MBT, too.
- Polysiloxanes are often used as grasp giving (griffgebende) plasticizers, e.g. for woven polyester. Polysiloxanes could be stabilised with small amounts of tin organic compounds.
- PVC, used as binders for prints, is sometime stabilised with DOT and also other tin organic compounds. This is necessary in order to ensure that the PVC is not decomposed at a temperature of up to 180°C, that can be achieved during the transmission of printing foils.

在此組中,三丁基錫廣泛應用於(船舶防污塗料)和其他重要用途。高濃度的三丁基錫化合物被列為有毒性的及可經皮膚吸收,吸收過量時會破壞神經系統。高濃度 DBT 和其他有機錫如 TBT 出現的情況相若。

- 以防止汗水和產生出臭味的東西細菌分解的抗微生物處理
- 有機錫催化劑常被使用製成聚氨酯(聚氨酯)和 TPU(熱塑性聚氨酯)。據了 解 DBT 和 MBT 可能受 TBT 的污染。
- ◆ 如可能,應使用其他催化劑,如有機錫化合物(如 DOT),但不是 TBT。最安全的方法是放棄使用有機錫
- 此外,分離劑是內含 MBT 及/或 DBT 的。
- ◆ 聚矽氧烷通常被用抓住增塑劑,例如:滌綸梭織。少量有機錫化合物可使聚矽氧烷穩 定
- 聚氯乙烯用作為印畫粘結劑,會以 DOT 和其他有機錫化合物作固定.這是必然的過程 以來確保聚氯乙烯在高度高達 180℃時分解,特別是在轉印膜時。
- 脫模劑也可以包含催化劑,如 DBT 和 MBT。

Critical Components

Materials treated with biocides, e.g. inserted soles, cycling tights, PES-blankets Textiles coated with PVC and Polyurethanes (rainwear, mud pants for kids)

PVC materials

All plastic materials in shoes, soles and appliqés

Appliqés made of plastics attached to textiles, artificial leather and coated textile components on shoes

關鍵配件

殺菌劑處理過的材料,如鞋墊,緊身短褲, PES 的羽絨被

聚氯乙烯和聚氨酯塗層紡織品(雨具,孩童短褲)

PVC 材料

應用於塑料鞋的鞋底材料

綜合應用於紡織品,皮革和鞋類紡織塗層組成部分

Limits for tin organic compounds

For most materials, a value of 0.025 – 0.1 mg/kg TBT can be met. Consumer magazines more and more include the TBT content in products in their comparative tests. Positive results lead to a devaluation of the respective product.

Therefore, it is recommended to strictly avoid TBT contaminations in articles, especially as there is no technical must for a TBT contamination in materials.

對有機錫化合物限制

使用 TBT 於 0.025 - 0.1 毫克/千克於材料中是允許的。

在消費類雜誌中, 越來越多比較產品 TBT 含量的測試, 正面的測試結果會貶值的產品價值. 因此 , 應盡量避免產品受 TBT 污染 , 特別是大部份材料中的 TBT 都不是技術上所需要的。

9. Cadmium and Cadmium Compounds:

Due to the Ban of Chemicals Regulations (ChemVerbotsV) there is a ban of using cadmium and cadmium compounds as colourants or stabiliser in certain synthetic fibres and plastics:

Commodities or commodity parts which are dyed with cadmium and cadmium compounds that have been produced with

鎘和鎘化合物

由於化學品管制條例(ChemVerbotsV)禁止在合成纖維和塑料中使用著色劑或穩定劑使用鎘和鎘化合物的彩色產品或其組成部分,分別為

- 1. Polyvinyl chloride (PVC), 聚氯乙烯 (PVC)
- 2. Polyurethane (PUR), 聚氨酯 (PU)
- Polyethylene with low densitiy except for Polyethylene of lower densitiy used for " master batches" ,

顏料製劑(母粒)過程中採用的低密度 聚乙烯例外

- 4. Acetyl cellulose (CA),), 醋酸纖維素 (CA)的
- 5. Cellulose acetate butyrate (CAB), 醋酸丁酸纖維素(CAB)的,
- 6. Epoxy resins, 環氧樹脂
- 7. Melamine formaldehyde resin (MF), 三聚氰胺甲醛樹脂 (MF)

- 8. Urea formaldehyde (UF), 甲醛尿素 (UF),
- 9. unsaturated polyesters (UP), 不飽和 聚酯
- 10. Polyethylene terephthalate (PET), 聚對苯二甲酸乙二醇酯 (PET)
- 11. Polybutylene terephthalate (PBT),), 聚對苯二甲酸乙二醇酯 (PBT)
- 12. Polystyrene crystal clear/Standard, 聚苯乙烯透明/通用,
- 13. Acrylnitrilemethylmethaneacrylate (AMMA),
- 14. Polymerised Polyethylene (VPE), , 交聯聚乙烯 (XLPE
- 15. Polystyrene, impact resistant (SB), or 高衝擊聚苯乙烯
- 16. Polypropylene (PP) 聚丙烯 (PP

may not been marketed if their Cadmium rate exceeds 0.01% of the plastic's mass content.

For commodities such as, for instance, packaging material, clothing and accessories, artificial leather and diverse plastics, there is a limit for Cadmium of 100 mg/kg (0.01 %) throughout Europe.

對於常用產品如包裝、服裝和飾品、皮革及各種塑料,歐盟限制鎘為 100 毫克/千克 (0.01%)。 如總塑料制品中鎘的比例超過 0.01%便不得投放歐盟市場。

Causes for contaminations

Stabiliser for PVC materials, which are – amongst others – used for: Impregnated, coated, painted and/or laminated textiles, appliqués, shoes (soles and heels), hems of bags

Pigments for plastics, to a lesser extent for paints and varnishes

受污染的原因

使用於 PVC 材料的穩定劑

浸漬、塗層、塗層和/或層壓織物、貼花、鞋(鞋底和鞋跟),下擺的口袋 用于塑料的颜料,較少用於涂料,油漆

Critical Components 關鍵配件

Impregnation/coating of textiles, e.g. rainwear, mud pants, belts, labels, tags, applications on textiles and shoes, accessories (including gloves)

Stabilising components, interlinings and closures of bags, backpacks, travelling bags and other similar products

Closures, hems, bottom of bags

Transparent package, sheet protectors, packaging material

紡織品浸漬/塗層,如雨衣、優閑褲子、皮帶、標籤、拖車、應用在紡織品、 鞋類、配件(包括手套)

穩定組件,包的底部及內部、背包、旅行包及類似物品

包的口、折邊、腳

透明包裝、小口袋、包裝材料

10. Nickel in Metal Parts

Nickel containing commodities with direct and longer skin contact and which release more than $0.5~\mu$ g/cm²/Woche of Nickel, are prohibited. Exemplified are: Jewellery, dress fasteners, clips, rivets, zippers and metal markings.

Exempted are products which surfaces are covered with a nickel free protection layer that ensures the limit compliance of nickel release of < 0.5μ g/cm²/week for min. 2 years while the product is in normal use.

Piercings and studs: sticks in any form that are inserted in pierced ears or other body parts may not exceed a release of Nickel of more than 0,2 µg Nickel/cm²/week.

10. 於配件中的鎳金屬

直接及長時間與皮膚接觸的用品,禁止釋放超過 0.2 微克/平方厘米/星期的鎳金屬,例子如珠寶、鉚釘鈕、帶扣、鉚釘、拉鍊及金屬標誌。表面塗有鎳作保護及能確保在至少 2 年在正常使用下鎳釋放為 0.5 微克/平方厘米/星期的則可豁免。

耳環及配飾:含釋放超過 0.5 微克/平方厘米/週的鎳及直接和長期與皮膚接觸的產品是禁止的。

11. Phthalates (Plasticizers) in Toys and Childcare Articles

Toys and childcare articles are – according to the European Directive 2005/84/EC defined as follows:

Toys: Articles that are determined to be used for play by children up to 14 years of age.

Childcare article: " any product intended to facilitate sleep, relaxation, hygiene, the feeding of children or sucking on the part of children."

11. 在玩具和兒童護理用品 (鄰苯二甲酸鹽)增塑劑

根據歐盟指令 2005/84/EC 玩具和嬰兒用品的定義如下:

玩具:給年齡為 14 以下兒童使用的物品。

嬰兒產品:是指任何產品 其目的是促進兒童睡眠、放鬆、衛生、進食和哺乳的。

Products that are covered by this Directive, are for instance children's sleeping bags, play rugs for babies, baby carriers, buggy covers and changing mats.

此指令所包括的產品範圍為: 兒童睡袋、嬰兒玩耍地毯、兒童車及尿墊

Phthalates are technically used as plasticizers especially for PVC in large scales. 鄰苯二甲酸鹽通常用作 PVC 中的增塑劑。

Di(2-ethylhexyl)phthalate	Dibutyl phthalate (DBP)	Benzyl	butyl	phthalate
(DEHP)CAS-No. 117-81-7	CAS-No. 84-74-2	(BBP)		
EINECS-No. 204-211-0	EINECS-No. 201-557-4	CAS-No. 85-68-7		
		EINECS-No. 201-622-7		

may not be used as substances or as parts of components in concentrations of more than 0.1 weight-% of the plasticizer containing material, in toys and childcare articles. 不得在玩具和兒童護理用品中使用物質或製劑成分的濃度高於在 0.1%的鄰苯二甲酸鹽

	Di-"isononyl"phthalate		Di-"isodecyl"phthalate		Di-n-octyl	phthalate
	(DINP)		(DIDP)		(DNOP)	
CAS-No. 28553-12-0 and		CAS-No. 26761-40-0 and		CAS-No. 117-84-0		
	68515-48-0		68515-49-1		EINECS-No. 20	04-214-7
	EINECS-No. 2	249-079-5	EINECS-No.	247-977-1		

and 271-090-9	and	
	271-091-4	

DINP, DIDP und DNOP are judged less critically and are allowed in all articles that are not intended to be placed in the mouth by children.

DINP、DIDP 和 DNOP 被認為構成較少危險,故此容量於在不能放置在兒童的嘴內的產品中使用

For toys and childcare articles which are intended to be placed in the mouth by children the limit is 0.1 weight % of the plasticizer containing material also for DINP, DIDP, DNOP.

Toys and childcare articles which contain these phthalates in a concentration that exceeds the limit are prohibited from being marketed.

This rule applies to the sum of the three mentioned phthalates. In total, the respective three phthalates may not exceed the limit of 0.1%.

可放進孩子嘴裡的玩具及兒童護理用品,DINP, DIDP 及 DNOP 限制為 0.1%W/w。三種個鄰苯二甲酸鹽的總和也不得超過該限額的 0.1%。該規則包括 3 種指定鄰苯二甲酸鹽的總和。

Critical Components

The following products often lead to problems:

Varnishes and glues on painted wooden toys

Varnishes on products made of plastic

Small parts and attaching parts

Non-permanent tattoos

Low contents of phthalates can often be detected after a long time in form of carryovers after a conversion of production, especially if phthalate containing products have been manufactured on the machinery before.

A particular case is PVC gloves (e.g. disposable gloves). To some extent the skin absorbs such a high amount of phthalates that the Federal Ministry of Food, Agriculture and Consumer Products advise against the use of phthalates.

關鍵部份

以下產品及零部是經常出現問題的,例如:

木製玩具塗料和塗漆膠粘劑

塗層塑膠物品

小零件和附件

非永久紋身

經過長時間的生產轉化程序, 尤其是當機器是製作了包括鄰苯二甲酸鹽的產品, 少量鄰 苯二甲酸鹽會出現

消費者保護部、糧食和農業是不鼓勵使用鄰苯二甲酸鹽,一個特別的例子是 PVC 手套(如一次性手套),因通過皮膚接觸會吸收大量鄰苯二甲酸鹽

12. Nitrosamines

Nitrosamines are carcinogenic which occur through vulcanisation of natural rubber.

Therefore, all products are banned which lead to the fact that it is possible to detect N-Nitrosamines or in N-Nitrosamine convertible substances in a saliva solution in an amount of more than 0.01 mg of the total released N-Nitrosamines/kg or 0.1 mg of all N-nitrosable substances/kg (elastomer or rubber parts of the material sample) within the commodity with the help of a special extraction method.

Pacifiers and teats made of elastomer or rubber

Toys made of natural or artificial rubber which is intended or foreseeable to be put in the mouth for children up to 36 months

Balloons made of natural or artificial rubber: 0.05 mg/kg balloon or 1.0 mg/kg balloon

12. 亞硝胺

亞硝胺是致癌物質, 它是形成硫化橡膠時出現的物質。

因此以特殊方法檢測,禁止使用超過液體排放為 0.01 毫克的 N-Nitrosamine/kg 或 0.1 毫克的 N -亞硝胺/公斤(橡膠或橡膠件樣本)於產品上。

由橡膠或橡膠 製成的奶瓶奶咀

由天然或合成橡膠造給有意或給 36 個月大以下兒童放在嘴裡的玩具

由天然或合成橡膠製造的氣球:每公斤 0.05 毫克或每公斤 1.0 毫克的氣球

13. PAH – Polycyclic aromatic Hydrocarbons and Benzene in Rubber and Plastic Products

Finding of high PAH amounts in products of daily use and commodities have recently led to media recommending product recalls of these products.

PAH in products either results from creosotes that have been added to rubber or plastic as plasticizers or from contaminated soots which are used as black pigment. It makes economically sense to use additives for the production of rubber as this reduces the costs for natural rubber. The use of high amounts of additives (normally calcium sulphate) makes rubber very hard. The material can be softened if mineral oils are added.

However, if creosotes instead of clean mineral oils are used as plasticizers, then those often contain high amounts of PAH.

13. 橡膠和塑料製品中的多環芳烴及苯

近年來含大量多環芳烴在日常產品和商品不斷被發現 ,在媒體壓力下,這些產品更被要求從市場中回收。

多環芳烴是從焦油衍生的產品,作為橡膠或塑料增塑劑,或從受污染的媒用作黑色顏 料。

在製造橡膠,使用填料是有相當經濟效用 , 因為這種材料可被拉伸 從而降低天然橡膠的成本。當使用高含量的添加劑(通常是硫酸鈣) , 加入礦物油後橡膠是會變得很堅硬及柔軟。

可是使用碳酸代替清潔礦物油作為增塑劑,往往這些材料卻含有高水平的多環芳烴。

Evaluation

Actually, a health hazard due to its carcinogenic effect in case of a high PAH contamination and intensive skin contact cannot be ruled out.

Besides the best-known component benz[a]pyrene, there are numerous other PAH components (e.g. benz[a]anthracene, chrysene, benzo[b]fluoranthene, benzo[k]fluoranthene and dibenz[a,h] anthracene) classified as Category 2 with regards to their carcinogenicity (see Table 14).

There is reasonable suspicion that the exposure of a human to PAH may cause cancer.

As migration tests show, highly contaminated materials can release PAH to the skin. This transition is intensified by aliphatic cosmetics, moisturisers or the like. PAH can be absorbed by the skin; therefore, it is expected that parts of the PAH that have been crossed over to the skin will also penetrate the skin barrier. Hence, a health risk (such as cancer) via direct skin contact cannot be ruled out, depending on the concentration and form of contact.

At the moment, there are no legal limits with regards to the use of PAH and creosotes within products. According to the requirements of § 4(2) GPSG a product can only be placed on the market if it is manufactured in such a manner that it does not harm the safety and health of consumers when it is used as intended or with foreseeable misuse.

In view of the multi-purpose use of soft plastics and rubber materials in different products and the absence of precise limits, the following benchmarks for PAH have been harmonised.

The following table contains the limits for PAH in materials of commodities that have to be met, according to the expected contact time with the skin. This is in compliance with the recommendation of the expert discussion in Berlin on August 2, 2005 and the following definition by the Committee on Technical Equipment and Consumer Goods (AtAV):

評估

事實上,高含量多環芳烴暴露及與皮膚接觸是可致癌及危害健康。

除了已知的 Benz[a]pyren 為多環芳烴的組成部分外, (PAHs 的其他組成部份也包括其他被列為致癌(第 2 類)物質(見表 14)分類。

有合理懷疑人體暴露於 PAHs 是可能導致癌症。.

實驗結果表明物料中多環芳烴移徙會對皮膚造成很大的負荷。

這種移徙通常是由含油脂的化妝品、保濕劑等造成

但多環芳烴加強,它會穿過皮膚的屏障而進入。

根據不同類型的濃度和通過皮膚直接接觸的方式,所引起對健康如癌症等是不能排除 的。

直至目前沒有法律限制於產品中使用多環芳烴和焦油。按照 GPSG § 4 (2) 規定產品 為有意或在可預見濫用下對用者或第三方安全和健康不受到危害的。產品是可以投放 市場。基於軟塑料和橡膠材料是多功能性的產品,檢測多環芳烴的缺乏限制的情況已 作出了調整。下表顯示產品內含多環芳烴材料為消費者與預期的皮膚接觸的限制標 進

於 2005 年 8 月 2 日有專家在柏林建議進行討論, 其後技術工作設備和消費產品委員會 (AtAV)作出以下建議:

	Category 1第一類	Category 2 第二類	Category 3第三類
Limits for 限制	Materials with contact with foodstuffs or materials which are intended to be put into the mouth and toys for children < 36 months 用於與食物接觸的材料,以及給供36個月以下幼兒使用及與皮膚接觸	Materials with foresee- able skin contact for longer than 30 seconds (long-term skin con- tact) and toys which are not covered by Category 1 材料不包括在第1類之 內,可預見與皮膚接觸 超過30秒(長期與皮膚 接觸)	Materials with foresee- able skin contact for up to 30 seconds (short- term skin contact) or without skin contact 材料在可預見與皮膚接 觸不超過30秒(短暫地 與皮膚接觸)
Limits for Benzo[a]pyrene mg/kg	not detectable 不可檢出 (<0.2)*	<u><</u> 1	<u><</u> 20
Sum of 16 PAH (EPA美國環保處) mg/kg	not detectable 不可檢出 (<0.2)*	≤ 10	≤ 200

* If the limits of Category 1 are exceeded, but still within the limits of Category 2, the proof of suitability fort he contact with foodstuffs or oral mucosa can be given via an additional specific migration test of PAH components according to DIN EN 1186ff. and §64 LFGB 80.30-1. The results of the migration have to be evaluated according to food law requirements.

Similar reasons have caused a ban of discretionary / free available benzene (frei verfügbares Benzol) in toys with an amount of more than 5 mg/kg per weight of the toy or the benzene containing parts of the toy.

基於類似原因亦限制了在玩具及其配件中使用 Benzene 的限制為不超過每公斤 5 毫克。

14. Nonylphenolethoxylates (NPEO) and Octylphenolethoxylates (OPEO)

The group of alkylphenolethoxylates (APEO) are different long-chain substances that are mainly used as detergents (tensides). The ecological relevance of each substance differs due to the length of the chain. At this point, especially nonyl and octyl compounds are suspected to accumulate in the environment and to cause damages. According to the existing EU Directive (2003/53/EC of June 18, 2003) it is banned to place preparations and substances that contain nonylphenole or Nonylphenoleethoxylate on the market.

This Directive of the European Chemical's Act does not apply for finished products such as textiles, clothes and other non-food items. The use of these substances outside of the EU and the import f such goods into the territory of this Directive is permissible.

Therefore, it is problematic for trading companies that NPEO and OPEO are still used in the manufacturing process of textiles and leather goods around the world. This is criticised by press as well as non-governmental organisations ("Öko-Test" = German magazine on product testing, Greenpeace et al.). The use of those substances can only be controlled restrictedly. We consider a use of NPEO and OPEO as detected if textiles and leather goods contain more than 50 mg/kg.

Some terms of deliveries of retailers push for the following limits:

14. 壬基酚聚氧乙烯醚(氧乙烯)和辛基酚(Opeo)

烷基酚聚氧乙烯(APEO)類物資,他們是屬於不同類型的長鏈化合物,常被用來作洗滌和清潔劑(表面活性劑)之用。 各化合物鏈長之不同會與生態息息相關。目前壬基酚和 Octylverbindungen 懷疑會在環境中積累造成損害。根據現行歐盟指令(2003/53/EC 2003 年 6 月 18 日)禁止銷售含有壬基酚聚氧乙烯醚和壬基酚預備物質。

這歐洲化學品條例立法 ,不適用於製成品如紡織品、服裝和其他非食品物品。故此,

一些公司仍然於世界其他地方於製造過程中使用 NPEO 及 OPEO,都受到媒體及非政 府組織(Öko-Test,綠色和平組織等等)都作出批評。 並指出使用這些物質是應該有 限制。他們認為 在紡織和皮革製品使用氧乙烯和 Opeo 時,物質只可殘留超過 50 毫 克 /千克。在一些買家要求中 目前實施下列限制:

國家	物質	自願限制
德國	Alkylphenols (AP) > Nonylphenols (NP) > Octylphenols (OP)	30 mg/kg
	Alkylphenoleethoxylates (APEO) > Nonylphenoleethoxylates (NPEO) > Octylphenoleethoxylates (OPEO)	250 – 500 mg/kg

15. Perfluor octane sulphonates (PFOS)

PFOS are substances that are very difficult to degrade, that accumulate and that are – according to a survey of the OECD conducted in 2002 – toxic for mammals. The risk evaluation of the EU has proven that there is a need for a reduction of health risks and environmental hazards due to PFOS.

Rules for Perfluor octane sulphonates (PFOS)

According to the Ordinance on Hazardous Substances, Annex IV No. 32 Perfluoroctansulphonates (PFOS; Perfluoroctansulphoneacid, -metallic salts, -halogenides, - amides and other derivatives including polymers) and preparations with a mass content of 0.005 % PFOS or more are banned since June 27, 2008.

15. (全氟辛烷磺酸)

根據經合組織研究,全氟辛烷磺酸的物質在環境中難以積累,2002 年它更被認為是對哺乳動物有毒害的。 歐盟風險評估表明 ,是有需要減少全氟辛烷磺酸引起的對健康和環境的風險。

有關全氟辛烷磺酸的安排

根據有害物質規例附件四第 32 條,全氟辛烷磺酸鹽(全氟辛烷磺酸; Perfluoroctansulfonsäure,金屬鹽類,鹵化物,酰胺和其他衍生物包括聚合物)由 2008 年 6 月起全氟辛烷磺酸含量於準備物質中不得超過 0005%。

16. Labelling Rules

Textiles:

According to the Textile Labelling Act, only information on the textile fibres have to be given and not on the auxiliary materials which have been used as well. However, the Commodities' Ordinance stipulates the following:

Product	Labelling	Place on or at which the label has to be affixed
Textiles with a mass content of more than 0.15% of free formaldehyde, which will be in skin contact if used as intended and which are provided with a finish	mended to wash the clothes prior to the	Label which is placed on the
Cleaning and caring products which are used domestically, with a mass content of more than 0.1% formaldehyde		Commodity or Packaging or Label which is placed on the commodity or its packaging

16. 標籤

紡織品

根據紡織品標籤法規定,紡織品要標明紡織纖維的資訊 ,輔料則可豁免。 商品監管規定內容如下:

產品	標籤	標記位置
紡織品含超過百分之 0.15 的游離甲醛,	" 含有甲醛" 建議首次穿著前要清洗以	於該材料或物品或其
而其用途及設備是與皮膚接觸的	加強紡織品與皮膚的兼容性。	包裝上貼上標籤
於家居使用的清潔和護理產品,含超過百	" 含有甲醛。"	於材料或物品或包裝
分之 0.1 的甲醛		上標籤

Footwear:

(Extract of § 10a of the Commodities' Ordinance)

The manufacturer or his authorized agent established in the Community shall be responsible for supplying the label and for the accuracy of the information contained therein. If neither the manufacturer nor his authorized agent is established in the Community, this obligation shall fall on the person responsible for first placing the footwear on the Community market. The retailer shall remain responsible for ensuring that the footwear sold by him bears the appropriate labelling prescribed by this Directive.

Labelling shall involve affixing the required information to at least one article of footwear in each pair. The labelling must be visible, securely attached and accessible. Additional textual information, affixed, should the need arise, to the labelling may accompany the information.

The labelling of footwear shall provide information on the material (= material which constitutes at least 80% of the surface area of the upper, and the lining and the sock, of the footwear, and at least 80% of the volume of the outer sole. If no one material accounts for at least 80%, information should be given on the two main materials used in the composition of the footwear. In the case of the upper, classification shall be determined with no account being taken of accessories or reinforcements such as ankle patches, edging, ornamentation, buckles, tabs, eyelet stays or similar attachments.)

by using pictograms or written information according to the following table:

鞋類(摘自商品條例§ 10A)

鞋類產品製造商或其歐盟授權代表,或者,如果沒有製造商或其歐盟代表,負責會落在將鞋類 產品投放在歐盟市場上首次出售的一方, 而零售商要提供以下資料。 標籤資料應要明顯、持久 和清晰可見顯示於至少一隻鞋上。

鞋類標籤要表明鞋類及其部份有關材料用途:

(=表面物料至少由 80%的物料構成鞋的上層、內層和外底。 如鞋組成部分少於任何材料的 80%,要在兩種主要材料中選擇大份量的作確定。 在界定鞋面材料時,分類不應欲輔助配件 如踝丁、邊、裝飾、扣、帶、環或類似設備作計算。)

按照下表來確定圖象或書面聲明:

		Pictogram 圖標	Written indications 書面資料
a)	Upper 鞋面 鞋的外部, 與鞋底接觸的 This is the outer face of the structural element which is attached to the outersole	\\	Upper 鞋面材料
	Lining and sock 襯裡和鞋內襯底 These are the lining of the upper and the insole, constituting the inside of the footwear article 構成鞋類內部的上襯裡和鞋內襯底		Lining and sock 裡和 鞋內襯底
	Outer sole 大底 This is the bottom part of the footwear article, which is subjected to abrasive wear and attached to the upper 鞋類下部,會外露及磨損和連接到頂部的	\sim	Outer sole 大底

a) Leather 皮革

A general term for hide or skin with its original fibrous structure more or less intact, tanned to be rot-proof. The hair or wool may or may not have been removed. Leather is also made from a hide or skin which has been split into layers or segmented either before or after tanning.

However, if the tanned hide or skin is disintegrated mechanically and/or chemically into fibrous particles, small pieces or powders and then, with or without the combination of a binding agent, is made into sheets or other forms, such sheets or forms are not leather. If the leather has a surface coating, however applied, or a glued-on finish, such surface layers must not be thicker than 0.15mm.Thus, all leathers are covered without prejudice to other legal obligations, e.g. the Washington Convention.

Should the term "full grain leather" be used in the optional additional textual information referred to in § 10a para. 1, it will apply to a leather bearing the original grain surface as exposed by removal of the epidermis and with none of the surface removed by buffing, snuffing or splitting.

皮革是一般經鞣制,原纖維結構基本上仍保存完好及已曬黑的皮革。 其毛及毛髮可以保留或刪除的。皮革也是由一個已分裂或曬黑之前 或之後的皮層。



Leather

皮革

	但如果皮層是被機械或化學分解而成為纖維顆粒、小片或粉,在有或沒有粘結劑使用下形成網或其他形狀,這就不是皮革。在皮革表面使用的塗塑料或保護層不得大於 0.15 毫米。有皮革都為法例如華盛頓條約所規管。		
	根據§10A第1條,有關"全粒面革"會用於選擇性的附加信息,適用		
	於丟失皮革及經拋光,吸或分裂後仍保留原有顆粒表面的皮革。		
	Coated Leather 塗層皮革 Leather where the surface coating applied to the leather does not exceed one third of the total thickness of the product but is in excess of 0.15 mm 是指產品佔其中表面塗層或膠合層不超過皮革三分之一,厚度不大於 0.15 毫米		Coated Leather 塗層皮革
b)	Natural textile materials and synthetic or non-woven textile materials Textiles shall mean all products covered by the Textile Labelling Act.		Textiles
	天然和合成紡織品 紡織品標籤法規定紡織產品的範圍	7-7-7-7-	紡織品
	70] 74, 101 1示 34, 石 75, 仁 70 74 74	-1-1-1-1	
c)	All other materials 其他材料	\Diamond	Other materials 其他材料

German Code on Equipment and Product Safety (GPSG) 技術設備和消費產品法(GPSG)

- § 5 Particular Responsibilities when Placing Consumer Goods on the Market
- (1) The manufacturer, his authorized agent and the person responsible for first placing the footwear on the market have to within the limits of their business operations –
- § 5 投放消費品於市場的特別責任
- 1)消費產品製造商、其授權代理人及負責將鞋類產品投放市場,在商業營運的限制下
- 1. when placing the product on the market產品投放市場
- a) ensure that the user receives all necessary information in order to judge and protect himself against any hazards coming from the consumer good during the normal and reasonably foreseeable service life and which are unknowable without any respective indication

確保消費者要在正常或合理可預見的使用產品時獲得必要的信息 ,以評估和保護自己不受消費產品危害。

b) label the name of the manufacturer or – if he is not established in the Community – the name of the authorized agent or the retailer as well as the addresses on the consumer good or its packaging. Furthermore, he has to label the consumer good in that manner that it can clearly be identified. The information can be left out if this is justifiable, especially if the user is already informed about the indications or if placing the information is extraordinarily expensive,

製造商,或不在歐盟居住的製造商的名稱 , 代理人或進口商和它們的地址, 要在消費產品或其包裝以標記方式於消費產品標識,信息遺漏若用者已知是可以接受的,尤其是因將信息標示會涉及龐大的開支。

c) choose to take appropriate action including, if necessary to avoid risks, withdrawal from the market, adequate and effective warnings and recalls from consumers in alignment with the product's characteristics

採取有效措施通過產品回收和有效的預警措施,防止消費者面對風險。

2. take samples of the consumer goods placed on the market, depending on the potential risk that these goods bear. In addition, they have to consider complaints and keep – if necessary – a complaints book. On top, they have to inform retailers about further actions that have to be taken with regards to the consumer good.

根據市場銷售的產品所構成的危害程度,消費者有必要可以進行檢查、調查投訴 , 並酌情進行申訴,通知經銷商處理問題消費產品的措施。

(2) The manufacturer, his authorized agent and the person responsible for first placing the footwear on the market have to immediately notify the competent authorities according to Annex I of the Directive 2001/95/EC of European Parliament and Council of December 3, 2001 on general product safety (ABI. EG No. L 11 p. 4), where producers and distributers know or ought to know, on the basis of the information in their possession and as professionals, that a product that they have placed on the market poses risks to the consumer that are incompatible with the general safety requirement; they shall give details in particular, of action taken to prevent risk from the consumer. A notification according to paragraph 1 shall not lead to a criminal prosecution of the notifyer or to open a procedure according to the law of administrative offences.

根據歐盟指令 2001/95/EC, 2001 年 12 月決定有關一般產品安全(ABI. EG Nr. L 11 S. 4)的指令,製造商、其代理人及進口商如果知道或有表面信息提供給他們或他們有明確證據表明, 消費類產品在市場引起了健康和安全風險,他們必須都要向當局通知避免對消費者引起的風險. 根據通知條款 1, 不得對通報者進行起訴的程序 或根據行政命令去對通報者作出起訴。