







REACH COMPLIANCE


- SVHC & RSL


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WHEN YOU NEED TO BE SURE **SGS**



AGENDA





Reason for REACH Regulation

REACH Regulation – Authorization , Notification

Restricted Substance List

SGS solutions to face ahead challenges

Case Sharing - Compliance Requirements

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Reason for REACH Regulation

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What is REACH?

- **REACH** - Registration, Evaluation Authorization and Restriction of Chemicals
- **Regulation (EC) No 1907/2006**
- Entered into force in June 2007, main provisions started from June 2008
- A legislative tool to achieve sound chemical management - monitor chemicals on the market over 1 tonne per year
- Create ONE single system to manage all chemicals within the Community
- Cover chemicals, mixture of chemicals and finished products

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WHY REACH ?

- EFFECT OF CHEMICAL PROCESSING ON ENVIRONMENT
 - TOXIC TO HUMAN
 - TOXIC TO AQUATIC LIVES
 - NON-BIODEGRADABLE AND BIOACCUMULATIVE
- So many regulations in Europe after 1996
- Confusions on selection of proper regulation for a product



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Other Main Objectives of REACH

- To ensure a high level of protection of health & the environment



- Put articles under regulation

- | | |
|---|--|
| <input checked="" type="checkbox"/> Furniture | <input checked="" type="checkbox"/> Automotive |
| <input checked="" type="checkbox"/> Toys | <input checked="" type="checkbox"/> Cosmetics |
| <input checked="" type="checkbox"/> Apparels | <input checked="" type="checkbox"/> Personal Care Products |
| <input checked="" type="checkbox"/> Footwear | <input checked="" type="checkbox"/> Electronic Components |
| <input checked="" type="checkbox"/> Textiles | <input checked="" type="checkbox"/> Electrical Appliances |



- Encourage data sharing & reduce animal testing



- Safeguarding innovation & competitiveness





Drivers For RESTRICTION of Substances

- NON-GOVERNMENTAL ORGANISATIONS (NGOs)
- PUBLIC PRESSURE

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DEFINITION

Substance



Substances are generally chemical elements & its compounds. Examples are

Pigment



Solvent



Preparation

Preparations are defined as mixture of substances. Examples are

Shoe Cream



Adhesive



Articles

Article has the property that its shape determines its function to a greater degree than its chemical composition. Examples are

shoes



Apparel



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PRODUCTS NOT COVERED BY REACH

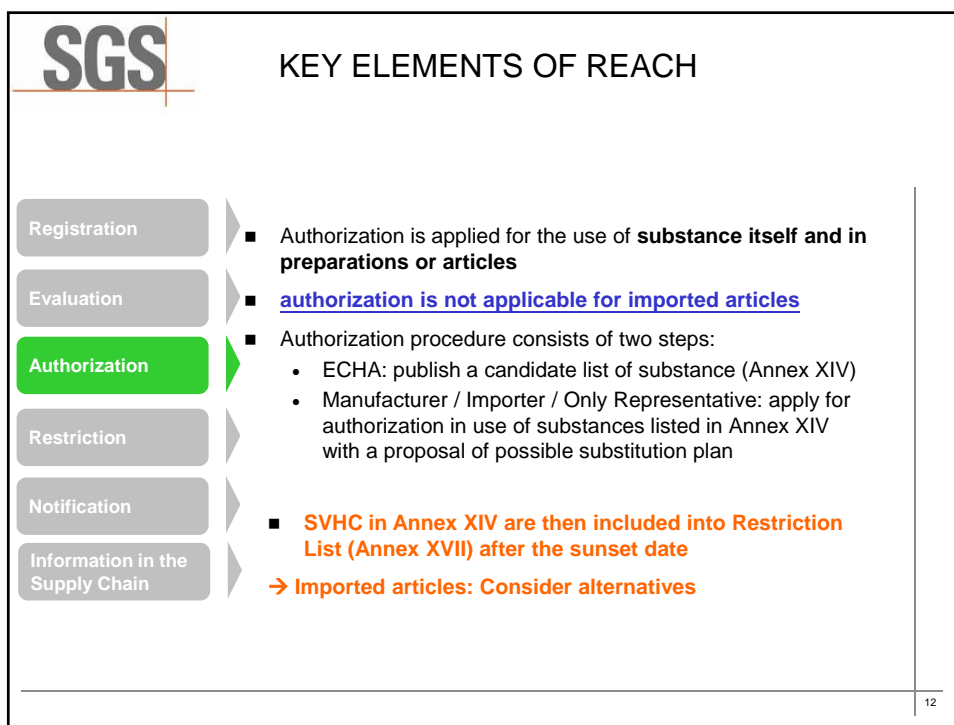
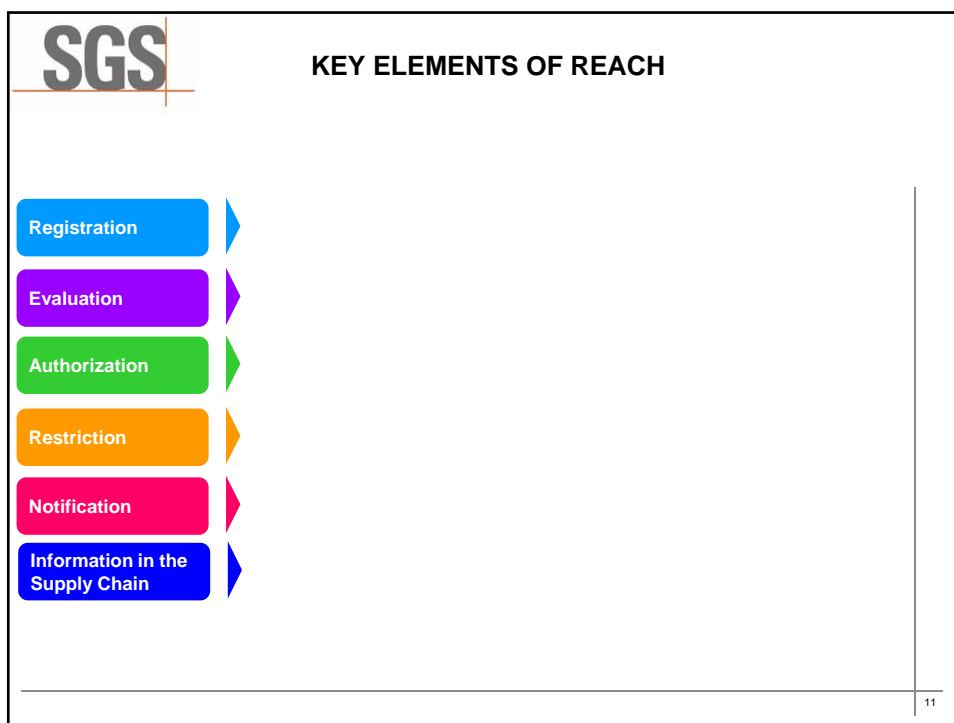
- Medicines and Medicinal products
- Explosives
- Radioactive materials
- R & D chemicals
- Food products

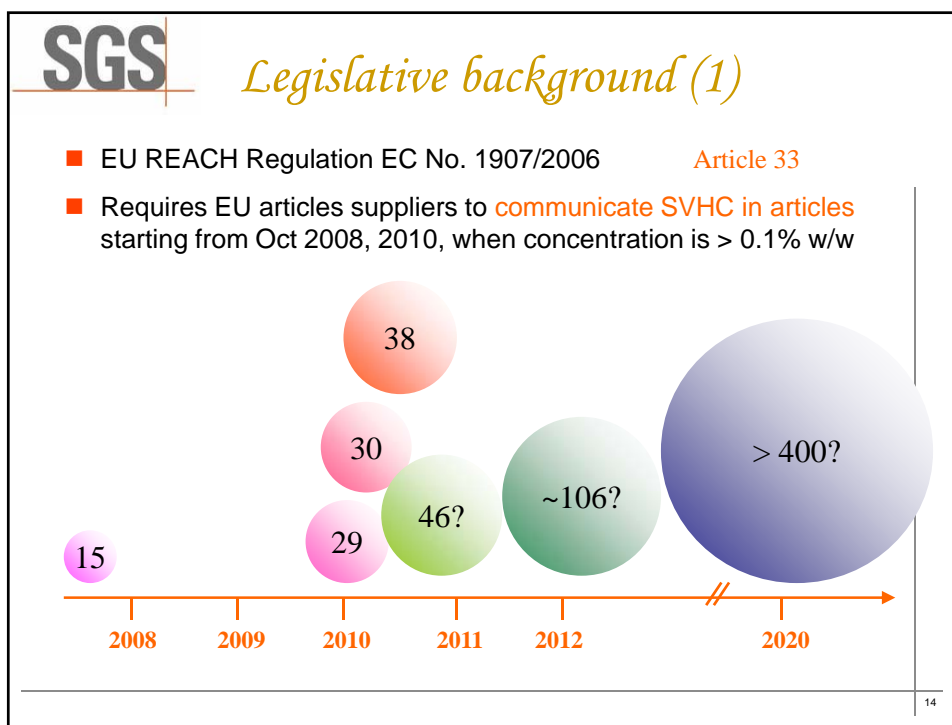
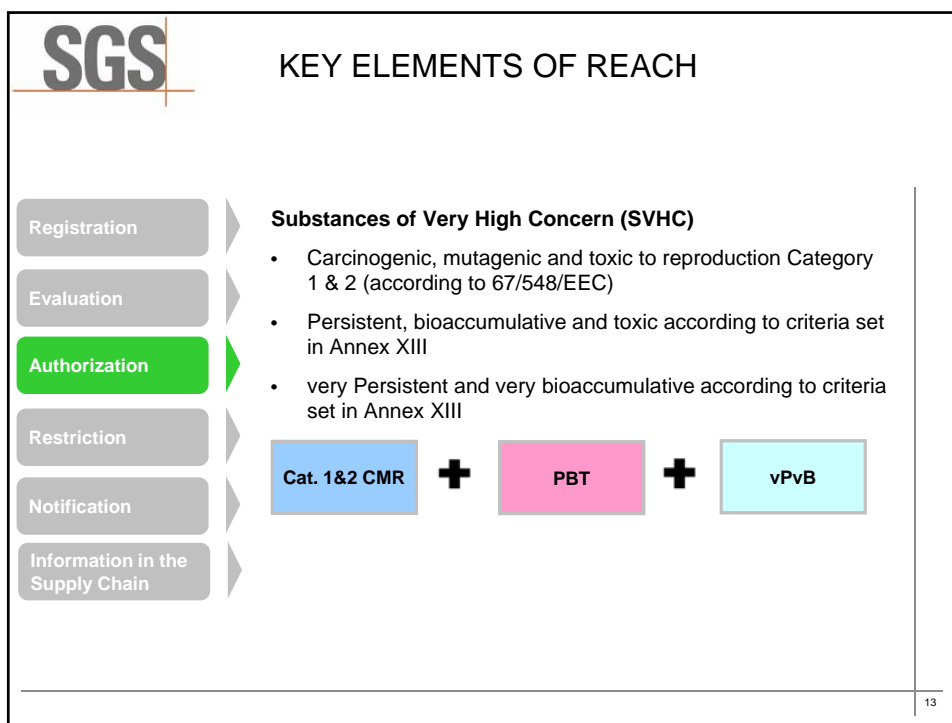
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REACH Regulation – Authorization , Notification

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<div>SGS</div> <div>KEY ELEMENTS OF REACH</div>			
ECHA published the Proposal of Substances in Annex XIV on 14 Jan 2009 and the list was confirmed on 1 June 2009 .			
Registration	Substances	CAS No.	Application
	Cobalt dichloride	7646-79-9	Drying agents in silica gel
Evaluation	Sodium dichromate	7789-12-0	wood preservatives, oxidizing agents
	Diarsenic pentaoxide	1303-28-2	Fungicides, insecticides
	Diarsenic trioxide	1327-53-3	Herbicides, insecticides
Authorization	Lead hydrogen arsenate	7784-40-9	Insecticides
	Triethyl arsenate	15606-95-8	Wood preservatives
Restriction	DBP	84-74-2	Plasticizers
	DEHP	117-81-7	PVC Plasticizers
	BBP	85-68-7	Plasticizer
Notification	Anthracene	120-12-7	Wood preservatives
	Bis(tributyltin) oxide	56-35-9	Wood preservatives
Information in the Supply Chain	musk xylene	81-15-2	Fragrance, cosmetic products
	HBCDD	25637-99-4	Flame retardants
	SCCP	85535-84-8	Flame retardants
	4,4'-DDM	101-77-9	Azo colorants

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<div>SGS</div> <div>15 SVHC included in Dec 2009</div>			
No.	Chemical name	EC No.	Possible occurrence
1-5	Anthracene oil and related compounds	292-602-7; 295-278-5; 295-275-9; 292-604-8; 292-603-2	- Wooden products - Paints - Rubbery products - Plastic products
6	Diisobutyl phthalate (DIBP)	201-553-2	- Plastic products - Printing inks
7	2,4-Dinitrotoluene	204-450-0	- Shoe sole - Lingerie - Mattress
8	Coal tar pitch, high temperature	266-028-2	- Active carbon fibres - Paints and coatings
9	Tris(2-chloroethyl)phosphate	204-118-5	- Upholstered furniture - Textile coatings
10	Aluminosilicate (RCF)	Index no. 650-017-00-8	- Fire protection for buildings and industrial process - Products with insulating functions
11	Zirconia Aluminosilicate (RCF)		
12	Lead sulfochromate yellow (C.I. Pigment Yellow 34)	215-693-7	- Paints, varnishes & coatings - Printing inks
13	Lead chromate molybdate sulfate red (C.I. Pigment Red 104)	235-759-9	- Textile printing, - Leather products
14	Lead chromate	231-846-0	- Art materials & products
15	Acrylamide	201-173-7	- Coatings & paints - Textile processing

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Next 8 included SVHC – June 2010

Substance	CAS No.	Applications
Trichloroethylene	79-01-6	- Cleaning and degreasing agent for metal parts Solvent carrier for textile desizing, sourcing and leather preparation Used in wool scouring process Solvent in adhesives
Boric acid	10043-35-3 and 11113-50-1	Biocides and preservatives Manufacturing of rubber Flame retardants Paints Auxiliaries used in leather tanning
Disodium tetraborate, anhydrous	215-540-4 (1330-43-4, 12179-04-3 and 1303-96-4)	- Uses as adhesives Flame retardants Biocides Auxiliaries used in leather tanning
Tetraboron disodium heptaoxide, hydrate	12267-73-1	
Sodium chromate	7775-11-3	Manufacture of other chromium compounds Leather tanning Mordant for dyes
Potassium chromate	7789-00-6	Treatment and coating of metals Manufacture of textiles Tanning and dressing of leather Manufacture of pigments/inks
Ammonium dichromate	7789-09-5	- Metal-complex dyes - Drier for paint coating - Electroplating
Potassium dichromate	7778-50-9	- Metal-complex dyes - Drier for paint coating - Electroplating


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Another 8 newly included SVHC's – Sep 2010

Substances	CAS No.	Application
Cobalt (di)acetate	71-48-7	➤ Used as metal-complex dyes ➤ Drier for paint coating ➤ Used in electroplating ➤ Used as metal-complex dyes
Cobalt (II) carbonate	513-79-1	
Cobalt dinitrate	10141-05-6	
Cobalt (II) sulphate	10124-43-3	
2-Ethoxyethanol	110-80-5	➤ Solvent for printing inks, adhesives, varnishes, lacquers, nitrocellulose, acetate fiber, spirit soluble dye and resin
2-Methoxyethanol	109-86-4	➤ Solvent for printing inks, adhesives, varnishes, lacquers, nitrocellulose, acetate fiber, spirit soluble dye and resin ➤ Solvent for dyeing leather
Chromium trioxide	109-86-4	➤ Used as fixing agent in waterborne wood preservative ➤ Used for metal finishing ➤ Existing as by-products of tanning on leather
Acid generated from chromium trioxide and their oligomers:		
Chromic acid	7738-94-5	
Dichromic acid	13530-68-2	
Oligomers of chromic acid and dichromic acid		

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Authorization

Responsibility of
EU manufacturers /
EU importers / EU downstream
users of substances

Objective of this title is to ensure SVHC is under control and progressively replaced by suitable alternative substance or technologies

SVHC included in Annex XIV can not be used, unless


- The use of substance is authorized
- Has been exempted
- Not reaching the sunset date

Eligible applicants

- EU manufacturers
- EU importers
- EU downstream users

Authorization related to substance, Substance in preparation and the incorporation of substance in article
→ Not applicable to imported articles

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Communication in supply chain

Responsibility of
EU manufacturers /
EU importers / EU suppliers
of articles

Article 33

Duty to communicate information on substances in articles

→ SVHC concentration in articles > 0.1% w/w

- Mandatory provide to recipient of article (industrial, professional users and distributors)
- Provide information to consumer upon request within 45 days

Information requires for communication:

- Name of SVHC (minimum)
- Safe use information



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SVHC for Article 33 (important remarks)

- ☆ **Packaging** is always consider as **separate article**. SVHC in packaging material has to communicate
- ☆ The substance concentration threshold of **0.1% (w/w)** applies to the **article as supplied**. It does not relate to the homogeneous materials or parts of an article, but to the article as such



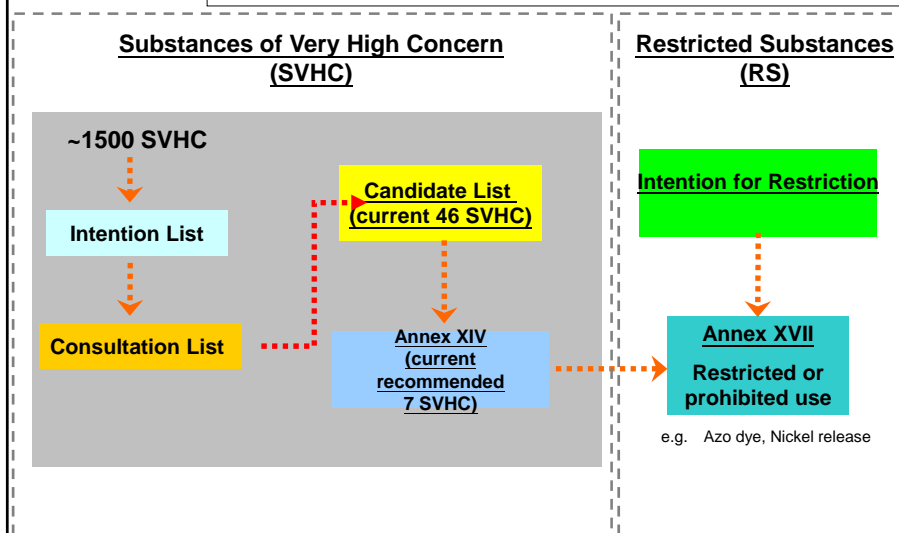
6 Member States do not agreed with this interpretation, there is still an on going discussion regarding this issue

- ☆ The obligation also applies to articles which were produced or imported before the substance was included in the candidate list and are supplied after the inclusion. Thus, the **date of supply** of the article is the relevant date here

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Establishment Process to Candidate List



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Restricted Substance List

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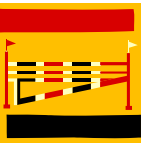
REACH - Restriction

Current EU regulations on restricted substance (76/769/EEC) was repealed by REACH on 1 June 2009

More stringent requirement of the restricted substances has been enforced i.e 'may' changed to 'shall'

Article 67(1)

- A **substance** on its own, in a **preparation** or in an **article**, for which Annex XVII contains a restriction **shall not be manufactured, placed on the market or used** unless it complies with the conditions of that restriction.
- Current Annexure XVII - 58 categories



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More stringent requirements Article 67(3)

Until 2013, Member states can maintain its existing and more stringent requirements regarding restrictions.

General restrictions under Annex XVII

Designation of the substance, of the groups of substances or of the preparation	Conditions of restriction
42. Alkanes, C ₁₀ -C ₁₃ , chloro (short-chain chlorinated paraffins) (SCCPs) EINECS No 287-476-5	Shall not be placed on the market for use as substances or as constituents of other substances or preparations in concentrations higher than 1 % — in metalworking, — for fat liquoring of leather.



More stringent national restrictions (Netherlands)

Designation of the substance, of the group of substances or of the mixture in Annex XVII of REACH	More stringent national provisions	Authorised by the Commission
42. Alkanes, C ₁₀ -C ₁₃ , chloro (short-chain chlorinated paraffins) (SCCPs) EC No 287-476-5 CAS No 85535-84-8	Restriction on the use of short-chain chlorinated paraffins: — as flame retardants in rubber, plastic or textiles; — as plasticisers in paints, coatings or sealants (?).	Commission Decision 2007/395/EC (*)

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Important restrictions in Annexure XVII

- VOC – Benzene, Toluene, chloroform, 1,1,2-Trichloroethane, 1,1,2,2-Tetrachloroethane, 1,1,1,2-Tetrachloroethane, Pentachloroethane, 1,1-Dichloroethene, Hexachloroethane, Trichlorobenzene, Cyclohexane
- Lead and its compounds
- Mercury and its compounds
- Arsenic and its compounds
- Pentachlorophenol
- Cadmium
- Nickel content
- Alkanes, C₁₀-C₁₃, chloro (short-chain chlorinated paraffins) (SCCPs)
- Azocolourants and Azodyes
- Nonylphenol & Nonylphenol ethoxylates
- Chromium VI compounds
- Phthalates
- PFOS
- Organotin compounds

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Specific RSL related to Leather products

- New restriction on the use of **Dimethylfumarate** (2009/251/EC):
- **Dimethylfumarate** (CAS No. 624-49-7) is a substance which has been found harmful, irritating and sensitizing on contact with the skin, and its use as a biocide is banned from all consumer products
- Source - used as fungicide to prevent mould growth during transportation or storage of leather products. Pure DMFu is packed into small sachets (similar to silica gel/anti humidity packs) and evaporates when it gets warm (above 50°C approx.). The DMFu vapour is then active, killing off mould and fungus that may grow at these warm temperatures. The sachets are usually found in footwear boxes or attached to leather furniture and are mainly used on leather products. The DMFu will either be found in these sachets or impregnated into the product after vaporisation. It has a strong smell which is often the first indicator that this substance is on a product.
- Alternative - safer anti-fungal agents are available

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Specific RSL related to Leather products

- Description of AP/APEO - A group of compounds which have one or more alkyl chains bound to a phenol which has a central aromatic (benzene) ring and a hydroxyl group. There are many groups of alkyl phenol (**AP**) and alkyl phenol ethoxylate (**APEO**) derivatives but the following ones are causing concern;
- AP derivatives; APEO derivatives;
- **NP** ~ nonyl phenol **NPEO** ~ nonyl phenol ethoxylate
- **OP** ~ octyl phenol **OPEO** ~ octyl phenol ethoxylate
- **Source** ~ used as **wetting and emulsifying agents and detergents** on all fibre types (non-ionic surfactants for degreasing, scouring and bleaching fibres and leather). Especially used in the de-gumming on linen which is hard to wet out.
- Alternatives Many other wetting agents available

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Specific RSL related to Leather products

- Description of Phenols - A group of chemicals derived from polychlorinated compounds and used as fungicides and preservatives;
- PCP and TeCP are the most widely found phenols. OPP is found less frequently.
- **PCP** ~ pentachlorophenol (CAS no 87-86-5)
- **TCP** ~ trichlorophenol (CAS no 88-06-2)
- **TeCP** ~ tetrachlorophenol (CAS no 25167-83-3)
- **OPP** ~ ortho-phenylphenol (CAS 90-43-7)
- **Source** ~ preservative used in sizing on woven goods and leather. Often found in cheaper leather shoe linings
- **Alternative** - Many non harmful preservatives are available

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Specific RSL related to Leather products

- **Volatile Organic Compounds (VOCs)** [aka Volatile Organic Solvents VOSs] are any organic compounds with a low boiling point VOCs tend to have strong peculiar smells.
Some of the many Volatile Organic Solvents in common use are: aldehydes, benzene, formaldehyde, hexane, hydrocarbons, isocyanates, ketones, methane, methylbenzene, methylene chloride, naphthalenes, tetrachloroethylene (dry cleaning solvent), toluene, trichlorobenzene, trichloroethylene (spot cleaners), xylene
VOCs are emitted as gasses from solvents used in a vast array of products:
- **Source** - **PU Foam** ~ toluene **Footwear** ~ adhesives and glues used in manufacture **Detergents and Cleaning Products**
- **Alternative** Use water-based alternatives whenever possible. Toluene-free adhesive applications . When it is not possible to use water based alternatives, there must be adequate extraction of fumes, good ventilation . Since VOC are volatile it should be fully evaporated from leather products in a controlled area before they are packed.

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SGS solutions to face ahead challenges

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SGS REACH SERVICES

<http://www.reach.sgs.com>




Seminars & workshops

- Tailor-made upon client request
- Introductory/Intermediate/Advance

e-learning programs

- Launched in April 2009
- tailor-made for Key accounts upon request
- 3 Different phases
 - Practical consideration under REACH
 - Possible SVHC and RS in different products

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SGS REACH SERVICES

Home > REACH Digest Online

reachdigestguest (logout)

REACH DIGEST ONLINE



REACH Digest Online provides with you

▶ General Consideration
▶ SVHC Management
▶ REACH in Practice
▶ REACH Digest Gadgets

REACH Digest 3


- Online tool to help you in understanding your obligations under REACH

<http://www.reach.sgs.com>

New Features:

- Product classification
- Possible SVHC and RS in different products
- And more...

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SGS REACH SERVICES

■ **Registration**

– data preparation for **technical dossier** and/or **chemical safety report (Complex Inventory)**:

- Filling data gap (toxicological, ecotoxicological data, exposure scenario)
- Accuracy check (physical, chemical data)
- Testing proposal (animal testing, application of QSAR)
- SIEF Participation (Third party representative, valuable information)

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Safety Data Sheets

- Mainly for **substance & preparations**

e.g. eye protection, handling safety

- Transport information (air, water & land)

e.g. international transport regulations




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Safety Data Sheets in REACH Format

1. Identification of substance	2. Hazard identification
3. Composition / information on ingredients	4. first-aid measures
5. fire-fighting measures	6. Accidental release measures
7. Handling & storage	8. Personal protection
9. Physical & chemical property	10. Stability & reactivity
11. Toxicological information	12. Ecological information
13. Disposal considerations	14. Transport information
15. Regulatory information	16. Other information



[illegible]

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AND

**Council for Leather Exports**
चर्म निर्यात परिषद
(Sponsored by Ministry of Commerce & Industry, Govt of India)

- We have signed MOU for CLE members exclusively as their official agency for information , advisory and guidance service for REACH and RSL testing

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Case Sharing - Compliance Requirements

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SGS**CASE STUDY 1**

Leather Supplier D
Chennai



Packaging
Supplier E
China



Leather Bag manufacturer F
Kolkata



EU Importer G

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SGS**CASE STUDY 1**

Leather Bag
Articles

SVHC:

Triethyl Arsenate – 0.05%

Bag weight – 50 g

1,000,000 pieces

Information in the Supply Chain?

Notification?



Packaging
Material
Articles

SVHC:

Triethyl Arsenate – 0.3%

Packing weight – 10 g

1,000,000 pieces

Information in the Supply Chain?

Notification?

Total Triethyl Arsenate tonnage:

0.3% x 10g x 1,000,000

= 3 ton /year



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SGS**CASE STUDY 1**~~Information in the Supply Chain~~~~Notification~~

Information in the Supply Chain

SVHC info & safe use

Notification

SVHC conc. & tonnage

Leather Bag Exporter -Kolkata

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SGS**CASE STUDY 1**Leather Supplier D
ChennaiPackaging material
Supplier E
ChinaLeather Bag manufacturer F
Kolkata

SVHC Info

EU Importer G



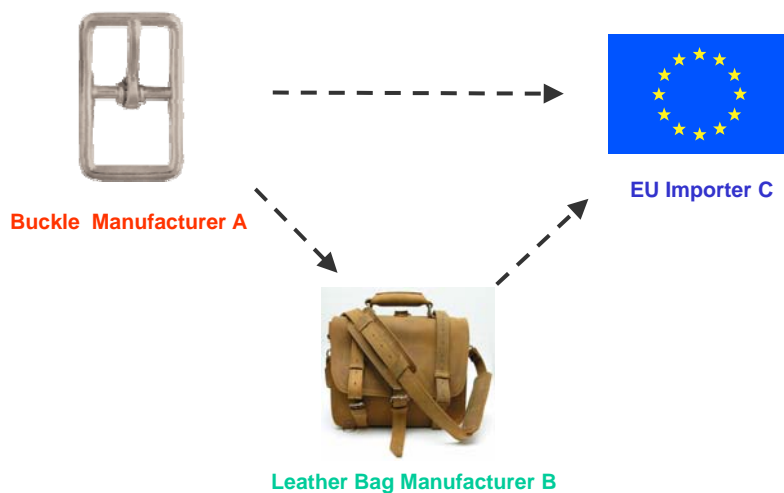
Notification

ECHA

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CASE STUDY 2



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CASE STUDY 2

<p>1 Buckle</p> 	<p>2 Leather Bag</p> 
<ul style="list-style-type: none"> • Buckle (5 g) contain SVHC X at 0.5% (w/w) 	<ul style="list-style-type: none"> • Buckle (5 g) contain SVHC X at 0.5% (w/w) as part of Leather Bag (total 200 g) <p>SVHC % = $(0.5\% \times 5) / 200$ = 0.01%</p>

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CASE STUDY 2



Buckle Manufacturer A **Leather Bag Manufacturer B** **EU Importer C**

SVHC > 0.1%

✓ **Information
in the supply
chain**



No obligation
since SVHC
<0.1%



Buckle: SVHC > 0.1%

✓ **Information in
the supply chain**

Buckle: SVHC > 0.1%

& >1t/a

✓ **Notification**

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**Product recall for DMF
in articles**




2009 - 24	24 0834/09	Spain	Category: Clothing, textiles and fashion items. Product: Children's shoes Brand: Tolites Type/number of model: Ref. 62077 Description: Children's leather shoes with Velcro fastener, packaged in a cardboard box. Country of origin: China	Chemical The product poses a chemical risk due to the presence of dimethylfumarate (DMF) in the footwear and in the sachet included in the packaging. Dimethylfumarate is a substance which has to be considered harmful, irritating and sensitising on contact with the skin, and its use as a biocide is not authorised. One incident has been reported.	Withdrawal from the market ordered by the authorities.	
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2009 - 22	13 0747/09	Finland	Category: Furniture Product: Recliner chair Brand: Buffalo / Rento Type/number of model: Unknown Description: Recliner chairs for single use, different colours, both fabric and leather chairs. Country of origin: China	Chemical The product poses a chemical risk because of the presence of dimethylfumarate (DMF), substance used as an anti-mould agent. Dimethylfumarate is a substance which is considered harmful, irritating and sensitising on contact with the skin, and its use as a biocide is not authorised.	Voluntary withdrawal from the market.	
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		Product recall for lead in Jewellery		2009 - 13	20 0476/09	Denmark	Category: Jewellery Product: Jewellery Brand: KARYANY Type/number of model: - 334: necklace - 340: necklace - 346: bracelet - 352: necklace - 350: bracelet - 337: necklace Description: - 334: Black textile necklace with silver coloured metal pendant, embossed, approx. 3.5 cm in diameter, - 340: Necklace with 8 circular pendants of embossed metal, - 346: Large metal bracelet with three shiny charms, between 2 and 3 cm in diameter, - 352: Long thin necklace, with crystal like light red, green and light blue pendants. Three droplet shaped pendants,	Chemical The products pose a chemical risk because the items release lead.	Sales ban and withdrawal from the market ordered by the authorities.		
				2009 - 13	10 0476/09	Denmark	Category: Jewellery Product: Earrings Brand: Monsoon Accessories Type/number of model: 381 721 08 00 Description: Silver coloured metal earrings, approximately 5 cm in diameter. Country of origin: Unknown 	Chemical The product poses a chemical risk because it releases lead.	Sales ban and withdrawal from the market ordered by the authorities.		

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Thank you

WHEN YOU NEED TO BE SURE

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