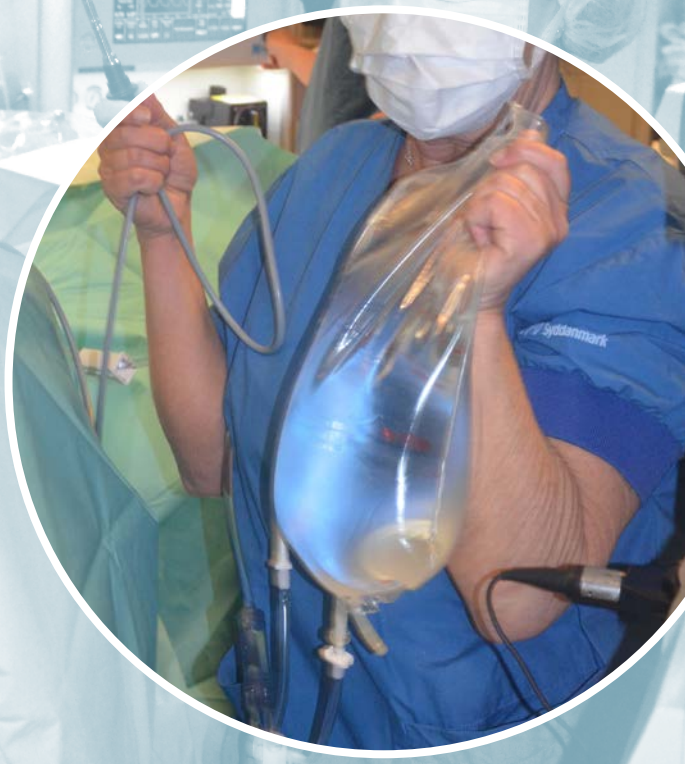
Alternatives to Classified Phthalates in PVC Medical Devices

27 MARCH 2014 · COPENHAGEN, DENMARK



Danish Ministry of the Environment
Environmental Protection Agency

PVC Med ALLIANCE

Sundhedsstyrelsen
Danish Health and Medicines Authority

Dear Conference Participant

On behalf of the Danish Environmental Protection Agency, The Danish Health and Medicines Authority and the PVC Information Council Denmark/PVC Med Alliance we are delighted to welcome you to Copenhagen, Denmark, at 27 March for the international conference on:

Alternatives to Classified Phthalates in PVC Medical Devices

House of Industry,
Town Hall Square,
H. C. Andersens Boulevard 18
Copenhagen
Denmark

The conference will focus on available alternative plasticisers to DEHP in medical devices in terms of human health evaluation and environmental impact of these. At the conference the Danish Environmental and Health authorities will for the first time present the conclusions in a report just published, where ten different existing alternative plasticisers have been evaluated. In addition to the presentation of the study all relevant aspects related to the latest development within the use of plasticised PVC in medical devices will be covered.

Yours sincerely,

Henrik Søren Larsen
Head of Division, Danish Environmental Protection Agency

Henrik G. Jensen
Head of Division, Danish Health and Medicines Authorities

Ole Grøndahl Hansen
General Manager, PVC Information Council Denmark/PVCMed Alliance Project Manager

Danish Ministry of the Environment
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Program

9.00 – 9.15	Registration with coffee/tea and rolls
9.15 – 9.30	*Welcome by Henrik Søren Larsen,* *Head of Division, Danish Environmental Protection Agency*

Session 1: Regulatory status of medical devices and classified phthalates - Danish and international aspects

9.30 – 9.45	**The point of view from the Danish Health and Medicines Authorities** *Henrik G. Jensen, Head of Division, Danish Health and Medicines Authorities* It is important to take initiatives to ensure a continued reduction of the use of classified phthalates in medical devices where possible. At the same time this substitution must not imply a violation of patient safety. In this presentation some of the concerns related to substitution will be covered.
9.45 – 10.05	**Conclusions from the new report "Alternatives to classified phthalates in medical devices"** *Shima Dobel, Chemist, The Danish Environmental Protection Agency* With the objective to guide the industry on how to choose alternatives to classified phthalates, the Danish EPA together with the Danish Health and Medicines authorities have published a new report. In the report ten commercial available alternatives have been examined for human and environmental effects. In this presentation the results of the report will be published for the first time.
10.05 – 10.20	**PVCMed Alliance activities** *Ole Grøndahl Hansen, General Manager,PVC Information Council Denmark, Project Manager PVCMed Alliance* PVC is the single most used polymer in medical devices. In this presentation a short history of the role of PVC in healthcare will be outlined, and the expectations for the future will be evaluated. In addition different activities carried out by the PVCMed Alliance - the European industry chain platform for PVC in healthcare – will be explained.
10.20 – 10.40	**The point of view from an NGO** *Christian Ege, Head of Secretariat, The Danish Ecological Council* In April 2014 European healthcare professionals and NGO's sent a joint letter to member state ministers to demand support for phasing out hazardous chemicals in medical devices. Among the signers is Christian Ege from the Danish Ecological Council. In his presentation he will explain the reason for the joint action.

10.40 – 10.55	Break with coffee/tea
10.55 – 11.30	Panel discussion
11.30 – 11.45	**The political setting in EU – the future ban of classified phthalates in medical devices** *Christel Schaldemose, MEP, Socialdemocrats* Ms Schaldemose's political presentation will focus on consumer protection related to the use of classified phthalates in medical devices. The expected outcome of the tripartite meetings between the European Parliament, the Council and the Commission which sequel the ban on classified phthalates decided by the European Parliament in 2013 will also be covered in this presentation.
11.45 – 12.00	**REACH regulation and medical devices** *Bent Horn Andersen, Deputy Head of Division, Chemicals, Danish Environmental Protection Agency* Medical devices are NOT relevant within the REACH regulation framework, because the devices are covered by the Medical Device Directive. Or is it really so? This presentation will give an overview on how the sunset date for DEHP, staged by REACH, will influence the manufacture and marketing of medical devices containing classified phthalates.
12.00 – 13.00	Lunch

Session 2: Substitution of phthalates with alternatives – challenges and regulatory requirements from notified bodies, case story

13.00 – 13.20	**Regulatory requirements related to substitution - a word from a notified body** *Carsten Worm Jensen, Certification Manager in Presafe Denmark A/S* When a medical device manufacturer decides to substitute a plasticizer, some approvals from a notified body are necessary. In this presentation aspects related to regulatory requirements – including costs – will be covered.
13.20 – 13.40	**"The classified phthalates should be phased out of medical devices"** *Peter Huntley, General Manager, Danish Medical Device Industry Association - Medicoindustrien* In 2013 the Danish Medical Devices Industry announced that the industry fully endorses the Danish Minister of Health's wish to phase out the use of classified phthalates in medical devices. In the presentation the reason for this announcement will be explained.
13.40 – 14.00	**View of the European Medical Device Industry – EUCOMED** *Thecla Sterk, EUCOMED* EUCOMED represents the medical technology industry in Europe. The impact on patients is paramount when considering the usage of substances in medical devices. Industry fully supports the phasing out of hazardous substances, including classified phthalates such as DEHP, as long as there is no negative impact for patients. This can only be determined by taking into account the risk-benefit of the product's medical safety needs and the availability and suitability of alternatives. For some medical applications such as urine bags there is no issue if phthalates are replaced by other materials, but this is not the case with blood bags. The presentation will examine some of the efforts made and challenges faced by the medical device industry when substituting phthalates such as DEHP.
14.00 – 14.20	**Case story – how we substituted classified phthalates in a laryngeal mask** *Annette Bitz, Clinical Research and Senior Biosafety Specialist / at AMBU* After the phthalate labeling requirements for medical devices came into force a few years ago, medical device companies have experienced an increase in demand for DEHP free devices. In this presentation a medical device manufacturer informs about the different challenges they had to surmount, before the company was able to provide the market with a phthalate-free laryngeal mask.
14.20 – 15.00	Panel discussion
15.00 - 15.30	Break with coffee/tea

Session 3: PVC and sustainability

15.30 – 15.50	**The VinylPlus program** *Dr. Brigitte Dero, ECVM and VinylPlus General Manager* VinylPlus is the renewed ten-year Voluntary Commitment to sustainable development of the European PVC industry. Launched in 2011, the program has been developed in an open process of stakeholder dialogue with industry, NGOs, regulators, public representatives and users. In this presentation the idea behind the VinylPlus initiative will be explained and the preliminary results of the program will be outlined.
15.50 – 16.10	**Recycling of PVC medical waste in Australia** *Sophi MacMillan, Chief Executive Vinyl Council Australia* Recycling of medical plastic waste is high on the sustainability agenda of European hospitals. In Australia there is already a successful project, where PVC medical plastic waste is being collected and recycled. In the presentation the different aspects of this PVC medical plastic waste management system will be explained.
16.10 – 16.20	Questions
16.20 – 16.30	*Closing remarks by Henrik Søren Larsen, Head of Division, Danish Environmental Protection Agency and Henrik G. Jensen, Head of Division, Danish Health and Medicines Authorities*
16.30	Networking and a glass of wine

List of speakers

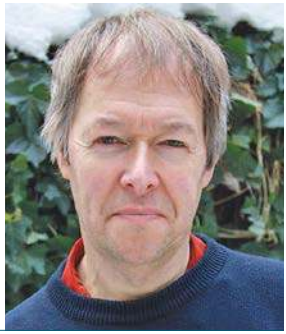
Bent Horn Andersen,
Danish Environmental Protection Agency
Bent Horn Andersen, Deputy Head of Division, MSc. Pharm, is 56 years old and has worked as an administrator within chemicals regulation in his entire career. First with Health and Safety regulation and later in Danish environmental Protection Agency as head of the group working with both REACH restriction and authorization, and with the Danish Phthalate regulation and Strategy.

Brigitte Dero
Dr. Brigitte Dero obtained her PhD in Molecular Biology in 1988 by working on a special programme of the World Health Organisation on parasitic diseases. She then focused on metals by specialising in toxicology at the Atomic Energy Commissariat in France and in ecotoxicology in The Netherlands. After nine years of experience representing the metals industry, in 1999 she joined Cefic, where she became Director of the Plastic Additives Platform and ESPA's secretary general. Currently, D. Dero is General Manager at ECVM and General Manager at VinylPlus.

Anette Bitz
Ms. Annette Bitz is working as a Clinical Research and Senior Biosafety Specialist at Ambu and is in charge of the company phthalate policy. She has 20 years of experience within the Medical Device Industry mainly in the areas of R&D, Environment, clinical and Biosafety. She is currently the Chairman of the Danish Biosafety Expert Group at MedicoIndustrien and is the Chairman of the Danish Standard Committee working on the ISO 10993 standard of Biocompatibility of medical devices.

Shima Dobel,
Danish Environmental Protection Agency
Shima Dobel, Head of Section, Chemical Division. She has worked in the Danish EPA since 2001. Shima has worked within the area of risk assessment and risk management of phthalates including combined exposure for phthalates. Shima has also worked with assessment of chemicals in consumer products as well as the chemical part of the toys safety area and childcare articles.

Christian Ege
Christian Ege, director, The Danish Ecological Council (DEC). DEC is an NGO, member of European Environmental Bureau (EEB). DEC is dealing with chemicals policy, energy conservation, transport and agriculture – at a national as well as at a European level.



Ole Grøndahl Hansen
Ole Grøndahl Hansen is Master of Arts in literature from Copenhagen University. Since 1995 General Manager of PVC Information Council DK – a knowledge centre for the widespread plastic material PVC financed by the industry. Ole Grøndahl Hansen is project manager of PVCMed – an alliance of international companies which seeks dialogue with stakeholders about the use of PVC in healthcare. He is a member of VinylPlus Communication Committee, the advisory board of European Medical Device Technology and board member of the Danish PVC recycling association WUPPI.

Peter Huntley
Peter Huntley is M.sc. Mech. Eng. , Ph.D. Materials Science, B.com Finance & Strategy General Manager in Danish Medical Device Industry since 20012 Previously general manager in Danish Packaging Industry for 10 years (2000-2012) Dept. Manager in Confederation af Danish Industries for 10 years. (1990 – 2000) Construction Engineer in windpower and offshore industry for 5 years (1985 – 1990).

Henrik G. Jensen
Henrik G. Jensen from The Danish Health and Medicines Authority (DHMA) is head of the division of Pharmacovigilance and Medical Devises. Henrik G. Jensen has for years worked with the administration and risk management of chemical hazards in a variety of contexts – including medical devices.

Sophi MacMillan
M.Env.Sci Chief Executive Officer, Vinyl Council of Australia. Sophi has worked with the PVC sector's industry association, the Vinyl Council of Australia, since its establishment in June 1998. She has been its Chief Executive since 2002. The purpose of the Vinyl Council is to advance a sustainable PVC industry in Australia. She has been instrumental in the establishment and management of the Australian PVC industry's Product Stewardship Program. Sophi qualified as an environmental scientist 20 years ago.

Christel Schaldemose
Christel Schaldemose is a Danish Member of the European Parliament. She took up office in 2006 and since then she has been a part of the Group of the Progressive Alliance of Socialists & Democrats (S&D). She is head of the Danish Delegation of Socialdemokraterne. She is a full member of The Committee of Internal Market and Consumer Protection and a substitute member of both The Committee on the Environment, Public Health and Food Safety and The Committee on Agriculture and Rural Development.

Laura Shields
Laura runs The Media Coach in Brussels. After graduating from Cambridge University in 2000, she worked for CNN and CNBC and BBC Radio 4's World at One and PM programmes, specialising in business and finance. Laura is now working as a journalist, panel moderator and media trainer in Brussels. Her clients include consumer goods and pharmaceutical companies, the UN, the European Commission, MEPs, trade associations and NGOs. As a moderator she has chaired panel discussions on topics including communicating scientific risk, technological innovation and trade.

Thecla Sterk, Eucomed

Thecla joined Eucomed in March 2003 and in 2005 became the Regulatory & Technical Affairs Assistant providing support to various regulatory working groups such as the Post Market Surveillance task force and the Human Tissue Products working group. Today, Thecla is Manager Regulations & Industrial Policy and takes the lead on topics such as notified bodies, blood safety and substances. Eucomed represents the medical technology industry in Europe.

Carsten Worm Jensen

- Certification manager, Presafe Denmark
- B.Sc. Electro Engineering
- 10 years industry experience with medical devices
- > 13 years audit and assessment experience (NB work)
- > 20 year experience with medical device requirements and regulations

List of participants

Alexander Kneifel	RAUMEDIC AG	Germany
Anders Jensen	Burson Marsteller	Denmark
Andrea Zanichelli	Resilia - Kem One Innovative Vinyls	Italy
Anette Bitz	AMBU	Denmark
Anna Svensson	Danish Technological Institute, Center for Plastics Technology	Denmark
Anna Nylander	Swedish chemicals agency	Sweden
Annette E. Monrad	Cook Medical	Denmark
Barbara Musi	Baxter-Gambro	Sweden
Benoit Monaco	MEDIPPEX - SIPPEX	France
Bent Horn Andersen	Miljøstyrelsen	Denmark
Bo Lorentsen	Coloplast A/S	Denmark
Brian Svend Nielsen	DHI Environment and Toxicology	Denmark
Brigitte Dero	VinylPlus	Belgium
Camilla Bjerre	Danske Bioanalytikere	Denmark
Carsten Worm Jensen	Presafe Denmark DK	Denmark
Christel Schaldemose	MEP	Denmark
Christian Ege	Ecological Council	Denmark
Christine Skak	Novo Nordisk	Denmark
Claus Jørgensen	Forbrugerrådet Tænk	Denmark
Daniel Jaworski	Primo Profile Sp. z o.o.	Poland
Declan McLaughlin	Colorite Europe Ltd.	United Kingdom

Diego Garcia Touza	VARTECO QUIMICA PUNTANA SA	Argentina
Dorthe Nørgaard Andersen	DHI Environment and Toxicology	Denmark
Elisabeth Paludan	Miljøstyrelsen	Denmark
Erik Gravenfors	The Swedish Chemicals Agency	Sweden
Ermanno Guasco	Sis-Ter, Fresenius Medical Care	Italy
Gabriele Bagnoli	TPV COMPOUND SRL	Italy
Heidi Laanstra	Region Hovedstaden	Denmark
Heinz G. Schratt	PlasticsEurope Austria	Austria
Helle Maigaard Erhardsen	Ingeniøren	Denmark
Helle Westphal	DHI Environment and Toxicology	Denmark
Henrik G. Jensen	Health and Medicines Authorities	Denmark
Henrik Søren Larsen	Miljøstyrelsen	Denmark
Inge Bondgaard	Teknological Institute	Denmark
Jan Kyster Madsen	DANISH TECHNOLOGICAL INSTITUTE	Denmark
Jeanne Bergman Bennick	CIMPAX	Denmark
Jens Priess	Thevinyl AB	Sweden
Jes Frederiksen	Burson Marsteller	Denmark
Jesper Simonsen	LiNA Medical ApS	Denmark
Jill Chen	Oxea Chemicals	Germany
Karen Marie Andersen	ConvaTec	Denmark
Kim Michael Christiansen	PlasticsEurope	Belgium
Kirstine Hindsberger	Ministry of Health	Denmark
Laura Schields	The Media Coach	Denmark
Lauriane Giet	Burson-Marsteller Bruxelles	Belgium
Leszek Kubica	Primo Profile Sp. z o.o.	Poland
Lodewijk Berkenbosch	RENOLIT Nederland BV	Netherlands
Madhu Kopparam	PlasticsEurope	Belgium
Mads Seirup	Region Nordjylland	Denmark
Martin James Stimpson	Eastman	United Kingdom
Martina Preysz	PVC Information Council Denmark	Denmark
Mayssa Badr	Burson-Marsteller Bruxelles	Belgium
Mette Iversen	Miljøstyrelsen	Denmark
Nanna Arrøe	Region Hovedstaden	Denmark
Natalie	Fotograf	Denmark
Nazarena Mazzaro	AMBU	Denmark
Nikolaj Hermann	Burson-Marsteller Bruxelles	Belgium
Ole Lisberg	Herlev, Convatec	Denmark
Ole Grøndahl Hansen	PVC Information Council DK	Denmark
Patrick Balteau	Baxter R&D	Belgium
Patrick Busch-Madsen	CIMPAX	Denmark
Patrizia Raffaelli	POLYNT SPA	Italy
Per-Håkan Nilsson	INEOS ChlorVinyls	Sweden
Peter Huntley	Medicoindustrien	Denmark
Peter Buch-Skals	Coloplast	Denmark
Peter Michael Larsen	Polymer Medical Device Components	Denmark
Petra Lindholm	Covidien	Sweden
Rainer Dr. Otter	BASF SE	Germany
Rie Kaspersen	Region Hovedstaden	Denmark
Scott Boito	Eastman Chemical Company	United States
Shima Dobel	Danish EPA	Denmark
Sophi Macmillian	Vinyl Council of Australia	Australia
Søren Freil	Danish EPA, Soil & Waste	Denmark
Thecla Sterk	EUCOMED	Denmark
Therese Høy Thomsen	Region Syddanmark	Denmark
Torsten Winther	Convatec	United Kingdom
Zdenek Hruska	Solvay	Belgium

For more information on this conference please contact either
Shima Dobel, Danish Environmental Protection Agency: sdo@mst.dk or
Ole Grøndahl Hansen, PVCMed Alliance/PVC Information Council DK: ogh@pvc.dk

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