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Evaluation of Plasticisers for PVC for Medical Devices

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Foreword

It is experienced that it is extremely complicated to find alternative materials to polyvinylchloride in general and in medical device applications particularly. In Denmark medical devices are pointed out as a field of high priority requiring a particular effort to substitute phthalates as plasticising agents. Medical devices are a field of high priority, because the phthalates are able to migrate from the plastic, and unwanted biological and environmental properties are suspected.

A number of national and international industrial development programmes on plasticisers alternative to phthalates – particularly di(2-ethylhexyl)-phthalate – have been and are being conducted.

In 1998 a Danish/British/Italian Brite-EuRam research project on development, evaluation and validation of plasticisers for use in flexible PVC medical device applications was proposed but rejected. However, the Danish Environmental Protection Agency decided to support the first two tasks of this original project. This work is presented in this report.

The objective of this project is to select and evaluate non-phthalate plasticisers for PVC for medical devices.

The project partners are Maersk Medical A/S, Totax Plastic A/S and Danish Technological Institute, Centre for Plastics Technology.

Subsuppliers are Hydro Polymers Limited, Laporte Performance Chemicals UK Ltd. and University of Strathclyde, Bioengineering Unit.

From the beginning of the work the working group consisted of Maersk Medical A/S, Totax Plastic A/S, Danish Technological Institute, Papyro-Tex A/S (a subsidiary of Maersk Medical A/S) and Hydro Polymers Limited. The working group was in current contact with Laporte Performance Chemicals, who later on was included in the project group particularly during the collection of information on commercially available plasticisers and the selection of substances to be included in the test program. Furthermore, the PVC Information Council Denmark (PVC Informationsrådet) has been represented at most of the working group meetings.

The below-mentioned experts have worked in the project:

Karen Marie Andersen, Papyro-Tex A/S
Paul Clutterbuck, Laporte Performance Chemicals UK Ltd.
Per O. Gravesen, Maersk Medical A/S
Ole Grøndahl Hansen, PVC Informationsrådet
Peer Grøndahl Hansen jr., Totax Plastics A/S
Ross Law, Hydro Polymers Limited
Merete Wuur, Danish Technological Institute, Medical Device Technology later substituted by
Kjeld Karbæk, Danish Technological Institute, Plastics Technology

A reference group has been formed with the above mentioned persons and those mentioned below as members:

Lea Frimann Hansen, Danish Environmental Protection Agency, chairman
Shima Dobel, Danish Environmental Protection Agency
Vagn Handlos, The State University Hospital, Association of County Councils in Denmark
Ib Johansen, Danish Polymer Centre, later substituted by
Kristoffer Almdal, Danish Polymer Centre
Jason Leadbitter, Hydro Polymers
Pernille Thomsen, The Danish Plastics Federation, later substituted by
Lars Blom, The Danish Plastics Federation

Summary and conclusions

On the basis of a feasibility study of the plasticiser substances and groups of substances that are commercially available on the market today, nine substances were selected for further investigations. PVC compounds plasticised with these selected substances were prepared and tested for a number of properties that were considered as primary selection criteria for medical applications. Compounding was easy with all the investigated plasticising substances and it was easy to prepare specimens and test samples by injection moulding with all the prepared compounds. An attempt was made to rank the selected and investigated substances in comparison with a reference DEHP plasticised PVC compound. Some have a slightly lower strength value, some have a slightly lower strain at break value, and some have a higher cold flexibility temperature. None of the substances was rejected as potential alternatives to DEHP. However, much more data are needed before DEHP can be seriously substituted in medical devices.

Sammenfatning og konklusioner

På basis af studier af de blødgørende stoffer og stofgrupper, der er kommercielt tilgængelige i dag, er der udvalgt og undersøgt ni stoffer. Der blev fremstillet PVC-kompounder med hvert af disse stoffer som blødgøringsmiddel. Disse kompounder er blevet prøvet for en række udvalgte egenskaber, som anses for at være primære udvælgelseskriterier for anvendelse i medicinsk udstyr. Alle kompounderne var lette at fremstille, og det var uden særlige problemer at forarbejde alle kompounderne ved sprøjtestøbning. Det er blevet forsøgt at rangere de undersøgte blødgørende stoffer i sammenligning med en DEHP-blødgjort PVC-kompound. Nogle har lidt mindre styrke, nogle lidt mindre brudtøjning (relativ brudforlængelse), og nogle har en højere *cold flexibility*-temperatur. Ingen af stofferne er blevet forkastet som potentielle alternativer til DEHP. Imidlertid kræves der mange flere data, før man kan erstatte DEHP i medicinsk udstyr.

1 Objective

The objective of this project is to select and evaluate plasticisers for PVC for medical devices using DEHP as a benchmark. The selection has been carried out on the basis of commercially available plasticisers that are presumed to be suitable for use as primary plasticisers with PVC materials used for medical devices. The substances have been selected and evaluated as regards the requirements defined for medical films and tubings.

No new plasticisers have been developed. However, considerations have also been given to other substances (e.g. polymeric substances) on the market, which might be suitable as plasticisers for PVC for medical applications.

On the basis of the results of testing conducted in the project an attempt has been made to rank the investigated plasticisers and PVC compounds according to their probability for success for use in medical device applications.

It is the intention of the project partners in a subsequent project for further investigations to be able to continue with the manufacture and testing of specific medical devices (e.g. catheters and drainage bags) made from the most promising compounds.

2 Background

It is experienced that it is extremely complicated to find alternative materials to PVC in medical device applications; reference to - among others - "Muligheder for substitution af PVC i udvalgte hospitalsartikler", Arbejdsrapport fra Miljøstyrelsen nr. 17/1991 *("Possibilities for substitution of PVC in selected hospital articles", Working report from the Danish Environmental Protection Agency No. 17/1991).* Furthermore, according to the Danish EPA's "Handlingsplan for at reducere anvendelsen af phthalater i blød plast" *(Action Plan for reducing and phasing out phthalates in soft plastics, Ministry of Environment and Energy, June 1999),* medical devices have been selected as a field of high priority requiring a particular effort to substitute phthalates as plasticising agents. According to the action plan, medical devices are a field of high priority, because of their migration from the plastic and subsequent exposure and possible adverse effects to patients.

The world market for plastics for the production of medical devices accounts for DKK 35 – 40 billions (ref. 1). Hereof PVC for disposable articles accounts for approximately one third. Every year approximately 150.000 tons of PVC is produced world wide for the medical market (ref. 2) corresponding to 1 – 2 % of the total market for PVC.

In Denmark the turnover of medical devices in plastics accounts for approximately DKK 7 billions (ref. 3). Approximately 97 % hereof are being exported (ref. 3). The largest quantity is disposable articles mainly different sorts of catheters, suctions, drains and urine and colostomy bags.

These many types of relatively low-cost disposable articles have formed a basis for and made it possible to introduce many of the new treatments that are being used today. Generally, in each case of hospitalisation the patient will come into contact with some of these disposable articles. Due to the rich possibilities of variation, which can be achieved in e.g. properties like flexibility, strength, barrier properties and transparency, plasticised PVC has been proven to be particularly suitable for these applications. These properties are to a high extent conditional on the addition of plasticisers to the PVC resins. In these types of medical devices the addition of plasticisers typically varies from approximately 5 % by weight up to approximately 45 %; mainly 30 – 45 %. Totally dominating as plasticiser is di(2-ethylhexyl) phthalate (DEHP), with which one has more than 47 years of experience in medical devices (ref. 4). Furthermore, in the European Pharmacopoeia DEHP is the only plasticiser which is listed for use in those kind of products (ref. 8a, 8b and 9). As the European Pharmacopoeia is put on the same footing as the Directive for Medical Devices (ref. 10), which was put into force in July 1998 the manufactures of medical devices are left with a serious dilemma. This is because no other plasticiser is listed in the European Pharmacopoeia and using another plasticiser would mean that the device manufacturer would have to declare that such a device does not conform to the compositional requirements of this Pharmacopoeia. Therefore, a development study and an investigation regarding plasticisers are highly needed. Any positive result is highly expected to form a basis for a decision in "Group 16 of the Council of Europe" to point out other plasticisers for consideration and inclusion in future amendments of the Pharmacopoeia.

During recent years the environmental aspect by the use of phthalates has been studied in many relations (e.g. ref. 5, 11, 12 and 13). The Swedish government has proposed the European Commission to initiate a risk assessment of DEHP.

However, other aspects will be important regarding the use of phthalates in medical devices. It is known that the plasticisers migrate to the surface of the plasticised PVC article, where it could cause a relative risk regarding the biocompatibility (ref. 6, 7, 14 and 15). Moreover, during recent years the potential for reprotoxic effects of DEHP has been observed in animal studies and whilst there is no knowledge in humans the fact that it has been observed in animals remains a significant concern (ref. 42).

Complicating the issue is that phthalates with different alkyl chain length behave differently in biological situations (like the case with different primary alcohols).

3 Procedure

This project has been conducted into two main phases.

3.1 Feasibility study

In phase one of the project, a market survey has been carried out for the relevant plasticisers based on the requirements, the wishes and the expectations outlined by the project participants. Relevant substances has been selected and evaluated in comparison with a selected DEHP plasticised PVC material as a reference compound. The resulting PVC compounds had also been briefly evaluated in comparison with a relevant non-PVC based plastic material. The development in PVC plasticisers during the project period has simultaneously and continuously been observed.

As an alternative non-PVC material an ethylene-vinyl acetate copolymer has been chosen.

3.2 Industrial research

In phase two of the project, PVC compounds with a limited number of the selected plasticisers have been prepared and tested for relevant properties. Each of these compounds has been prepared as granulates, from which appropriate test specimens have been made by injection moulding. From the compounds also film samples for testing have been made by roll milling.

3.3 Publication and information

The feasibility study of this project has been presented and discussed at a seminar held at Aarhus University Hospital (Skejby Sygehus) in Århus, Denmark in June 2001. The title of the seminar was “PVC free in Århus County”; the title of the presentation was “Alternative plasticisers (- an international project)”.

Additionally, the project has been presented at the 16th International Conference Medical Plastics 2002 held in Copenhagen late August 2002.

Furthermore it will be presented in the Danish magazine Plast Panorama Scandinavia.

4 Activities during the project

During the work, twelve working group meetings and two reference group meetings have been held. Furthermore, a meeting has been held with a representative from Reilly Chemicals, a company producing plasticisers for PVC. Three members of the working group have visited University of Strathclyde to present and discuss the project with Professor James Courtney, Bioengineering Unit. Finally, a number of meetings have been held with the Danish partners.

Further, the group has used the expertise of Laporte Performance Chemicals UK Ltd in the selection of non-DEHP plasticisers.

Hydro Polymers Limited have prepared the PVC compounds. Laporte Performance Chemicals UK Ltd have supplied one plasticiser. Danish Technological Institute, Plastics Technology have injection moulded tensile test specimens and square samples for testing of other properties. Papyro-Tex A/S have prepared film samples by roll milling and determined tensile properties on the film samples. Danish Technological Institute, Plastics Technology have determined tensile properties, indentation hardness, density and cold flexibility temperature on injection mouldings. Danish Technological Institute, Packaging and Transport have determined light transmission on film samples.

5 The feasibility study

The results generated during the feasibility study are presented in three parts.

1. A description of the relevant criteria for selection of plasticisers for PVC for medical applications
2. A plasticiser performance matrix (Appendix 1) listing the relevant data and information regarding each of a number of substances or groups of substances, which are considered as being potential PVC plasticisers
3. A list of the substances (Table 2), which have been selected for further investigations by compounding and characterisation

5.1 Plasticiser selection criteria

The relevance of the applied selection criteria for plasticisers for PVC for medical devices is described below. The list refers to the criteria mentioned in the plasticiser performance matrix, which is described in clause 6.2 and enclosed as appendix 1.

5.1.1 Availability

A plasticiser needs to be commercially available in large quantities (ton lots) to satisfy current demand for plasticised PVC for medical applications.

5.1.2 Compatibility towards PVC resins

The compatibility could be expressed as: To what extent is a substance capable of forming a stable compound with the polymer? The compatibility is often measured as the solution temperature, i.e. the temperature at which a mixture of plasticiser and suspension PVC apparently changes to a single-phase state.

A plasticiser needs to be compatible with PVC resins. If a substance is incompatible it will exude to the surface of an article and can be more easily extracted; i.e. an incompatible plasticiser will not plasticise PVC properly.

Furthermore, a plasticiser should be tolerant to the stabilisers and other additives in the compound to avoid exudation in the process or/and a sticky surface of the final article. The volatility of the plasticiser should be low - at least not higher than that of DEHP.

5.1.3 Plasticising efficiency

The plasticising efficiency of a plasticiser determines the level of plasticiser in a compound that is needed to achieve the required degree of modification of the compound. In this work the hardness of PVC compound has been chosen as the reference parameter. The more efficient the less plasticiser will be required. The efficiency is an important property when determining overall cost.

5.1.4 Processability

5.1.4.1 Compounding

A PVC material is made up from a blend of ingredients: PVC resin (the polymer that makes the material a plastic), plasticiser(s), stabilisers and lubricants. The ingredients are blended together in a high-speed mixer or a ribbon blender. During this process the plasticiser is absorbed into the PVC resin particles. This blend can then be processed directly into an article by extrusion, by injection moulding and by calendering. It can also go through an intermediate step of compounding. This is where the blend is fed into an extruder and by means of heat and pressure it becomes molten. The molten mass is extruded (pressed through a spaghetti die) and the solidified strands are cut into small pellets called granulate. The pellets are cooled from approx. 150°C to ambient temperature. The pellets can then be used to form articles by extrusion, by injection moulding and by calendering.

5.1.4.2 Component manufacture

Injection moulding
A plasticiser should be sufficiently stable to withstand the heat and the deformation associated with the injection moulding process. No sweating should occur. A low vapour pressure is also desirable.

Extrusion
A plasticiser should be sufficiently stable to withstand the heat and the deformation associated with the extrusion process. No sweating should occur. A low vapour pressure is also desirable.

Calendering
A plasticiser should be sufficiently stable to withstand the heat and the deformation associated with the calendering process.

5.1.4.3 Fabrication operations

Welding and bonding
A plasticiser should not harm the assembly process. No sweating should occur.

Machinability and printability
A plasticiser should not harm the machining or the printing processes. No sweating should occur.

5.1.4.4 Post fabrication operations

Radiation sterilisation
A plasticiser should be sufficiently stable towards the energy disposition associated with the radiation sterilisation process. No sweating should occur.

Ethylene oxide (EO) sterilisation
A plasticiser should be sufficiently stable towards the heat, humidity and chemicals associated with the ethylene oxide sterilisation process. No sweating should occur.

Steam sterilisation

A plasticiser should be sufficiently stable towards the heat and humidity associated with the steam sterilisation process. No sweating should occur. A low vapour pressure is also desirable, so the plasticiser does not distil away.

5.1.5 Cost

This breaks down into two sections and related to the overall cost/performance/efficiency of the system.

Plasticiser cost combined with plasticising efficiency needs to be as low as possible to keep materials cost low and to remain competitive.

Processing cost needs to be considered. The plasticiser has major influence on processing cost (see Processability)

5.1.6 Regulatory status

5.1.6.1 Toxicity

Toxicity is the effect of the plasticiser on life forms and plant material. Plasticiser needs to have low toxicity - food contact approval being one means of determining current toxicity status.

5.1.6.2 Handling

Plasticiser should be safe to handle and not cause any adverse effect upon industry employees. Material will be handled in large quantities i.e. > 1 tonne. In addition products manufactured from the compound will be widely handled by medical staff and come into skin contact with the patients and it is imperative that there is no allergic reaction to such products as observed by some latex products etc.

5.1.6.3 Health and safety

Medical devices made from this material should have no adverse effect on the users and the material should meet USP class VI (USP = United States Pharmacopoeia). Material should also not interact with substances (e.g. drugs) that it will come into contact with. Drug efficiency should not be impaired. These aspects has primarily been described for DEHP.

5.1.7 Environmental status

5.1.7.1 Emissions

Emissions during plasticiser manufacture
The production process should not have any detrimental effect upon the environment. Waste products and emissions need to be considered.

Emissions during processing
Material should not have any adverse effects on the environment during processing. Emissions and residues should be taken into account.

Emissions in use
Material should not have any adverse effect on the environment during use

5.1.7.2 Disposal issues

Due to the risk of spreading of infections all medical devices should be disposed of via incineration. Therefore plasticiser should be suitable for incineration without adverse effects i.e. emissions or residues.

5.1.7.3 Sustainable development

Plasticiser selection should consider whether the material can demonstrate sustainability, i.e. materials made from natural products being more sustainable than materials made from non renewable resources.

5.1.8 Physical properties of plasticiser

5.1.8.1 Aesthetic properties

Colour
Colour is considered important in that it conveys "purity of product" to the user. Plasticisers should give colourless compounds and articles. A lot of PVC additives either produce materials that are semi-opaque or yellow in appearance. They are by the medical industry and the hospital staffs perceived to be imperfect or contaminated.

Clarity
Plasticiser needs to give a clear/transparent material. This allows for the end user to see the contents of any article or device made from the material.

5.1.8.2 Odour

Material made with plasticiser should not have any odour, as odour indicates emission.

5.1.9 Physical properties of compounds

5.1.9.1 Mechanical properties

Tensile strength
The material needs to have sufficient strength to ensure that the article remains durable and intact throughout its entire service life. Any likely abuse of material needs to be considered. Properties need to be maintained throughout the service life of the product.

Cold flexibility
The material needs to retain its flexibility at low temperatures, as products are likely to be used or stored in low temperature environments. This property needs to be maintained throughout the service life of the product such as blood storage.

Elastic recovery
The rate or degree at which a material returns to its original shape after being deflected - the elastic recovery - is important at many applications and especially in flexible PVC tubing for use in peristaltic pumping applications.

5.1.10 Public perception

The public perception is the way the general public reacts to a description of a material or a product. (E.g. a substance called di-hydrogen oxide would probably be considered bad, but described as water it would be considered harmless).

5.2 Plasticiser performance matrix

A performance matrix for plasticisers for PVC for medical applications has been prepared based on the best knowledge collected by the project partners (see appendix 1). Data and comments in the matrix are primarily based on the experience of the partners and on the general literature (e.g. ref. 19 and 34).

In the performance matrix the term "Unknown" means unknown to the project workers for the moment. Many aspects have not been investigated and therefore data are not existing. Some aspects have been considered as being less important and therefore no effort has been made to search for data.

An asterisk (*) refers to knowledge transferred from DEHP or DEHP plasticised PVC.

Phthalates being assessed in the risk assessment program in the EU are marked with [EU)].

The plasticising efficiencies indicated are based on information from Hydro Polymers.

The abbreviations used in the matrix are explained in table 1:

Table 1

Abbreviations used in the plasticiser performance matrix

ASE	Alkylsulphonate of phenol
ATBC	Acetyltributyl citrate
ATHC	Acetyltrihexyl citrate
BTHC	Butyryltrihexyl citrate
DACM	Distilled acetylated monoglyceride based on hydrogenated coconut oil
DEHA	Di(2-ethylhexyl) adipate (Dioctyl adipate)
DEHP	Di(2-ethylhexyl) phthalate (Dioctyl phthalate)
DEHS	Di(2-ethylhexyl) sebacate (Dioctyl sebacate)
DEHZ	Di(2-ethylhexyl) azelate (Dioctyl azelate)
DIDP	Diisodecyl phthalate
DINP	Diisononyl phthalate
EAC	Ethylene-acrylate-carbon monoxide
ELO	Epoxidised linseed oil
EP	European Pharmacopoeia
ESO	Epoxidised soya bean oil
ETO	Ethylene oxide
EVAC	Ethylene-vinyl acetate plastic
PVC	Poly (vinyl chloride)
TEHTM	Triethylhexyl trimellitate (Trioctylmellitate)
USP	United States Pharmacopoeia

5.3 Substances selected for further investigation

The substances listed below are considered as having the highest potential for success as a plasticiser for PVC for medical applications and therefore they have been selected for further investigations. PVC compounds based on these substances have been prepared and substantial properties have been determined by testing and compared with the properties of a reference PVC compound plasticised with DEHP, so DEHP is also in the list:

Table 2

Plasticiser substances selected for further investigations

Chemical name	Abbreviations used in the performance matrix
Di(2-ethylhexyl) phthalate	DEHP
Diisononyl phthalate	DINP
Di(2-ethylhexyl) adipate	DEHA
Di(2-ethylhexyl) sebacate	DEHS
Triethylhexyl trimellitate	TEHTM
A benzoate	-
A polymeric adipate	-
Acetyltributyl citrate	ATBC
Ethylene-acrylate-carbon monoxide terpolymer	EAC Terpolymer

As an alternative non-PVC plastic material, ethylene-vinyl acetate copolymer (EVAC) has been chosen.

The arguments for selecting or rejecting each of the substances are as follows

DEHP: *Yes!*
DEHP is necessarily selected as a reference plasticiser. DEHP is available in one grade that is pure enough to be medical.

DINP: *Yes!*
During the work it became obvious to include diisononyl phthalate and diisodecyl phthalate, as they in the EU studies appear to be coming out reasonably favourable regarding their risk assessments.

Anyway, it is too narrow to consider phthalates as a uniform group of substances; phthalates should be considered as individual substances.

DINP is used in food contact and in toys, and we consider it as a potential substitute for DEHP for medical devices. Among phthalates DINP is probably the best alternative to DEHP.

Commercial DINP is always a mixture of isomers, the composition of which varies from producer to producer. Depending on the way of synthesis DINP exist as two different products with two CAS numbers. Therefore the product to be investigated has been specified in detail by selecting a specific product.

DIDP: *No!*
One alternative phthalate is sufficient.

Other phthalates: *No!*
One alternative phthalate is sufficient.

DEHA: *Yes!*
DEHA is already being used for medical applications. Some ecotoxicity problems have been considered. DEHA is available in one grade that is pure enough to be medical. It is being used by at least one company.

Other monomeric adipates: *No!*
One monomeric adipate is sufficient.

Polymeric adipates: *Yes!*
A polymeric adipate is considered as the sole potentially relevant polymer to substitute DEHP as a primary plasticiser in PVC. Polymeric adipates are mixtures of polymers of different chain length, the composition of which varies from producer to producer. Therefore a specific grade to be investigated has been chosen and the product has been specified in detail.

TEHTM: *Yes!*
TEHTM is available in medical grades and is already used in e.g. bags and infusion sets.

ATBC: *Yes!*
ATBC is currently being used in some special medical applications.

ATHC: *No!*
No information of the existence of ATHC in medical grades or medical applications of ATHC has been found; one citrate is sufficient.

BTHC: *No!*
Occupational and health problems have been reported from the State University Hospital in Denmark, where BTHC plasticised PVC blood bags are being handled at the blood bank. According to the producer this is an isolated exceptional case which can be avoided with different handling and storage procedures. The company has received no similar complaints from other European countries (Netherlands, Norway, Sweden, Finland and Iceland) where BHTC are in use; one citrate is sufficient.

Benzoates: *Yes!*
Only little information is available but they seem promising. A choice between a number of products available from at least two suppliers has been made.

Sulphonates: *No!*
Sulphonates are rejected mainly because of the emission of SO_2 (sulphur dioxide) during incineration as waste.

Phosphates: *No!*
Phosphates have poor technical properties, and they are forbidden according to the Nordic Pharmacopoeia (Ph. Nord. 63).

Soya Bean Oil (epoxidised): *No!*
Soya bean oils have limited compatibility and the processability is poor. However, soya bean oils are readily used as secondary plasticisers and as stabilisers.

DEHS: *Yes!*
Di(2-ethylhexyl) sebacate has extensive FDA approval and is frequently used in the cosmetic industry. It is commercially available from many sources.

Note: It is manufactured from sebacic acid, which is a by-product from cracking of castor oil. Thus is it produced from natural products.

DEHZ: *No!*
Di(2-ethylhexyl) azelate is commercially available from only a very few manufactures. The main raw material, azelaic acid, is only available from one source. The performance characteristics of DEHZ and DEHS are similar. Most compounders prefer to use DEHS.

Naphthenates: *No!*
Naphthenates are not commercial available in ton lots.

Polyhydric alcohol esters: *No!*
They are not commercially available in ton lots, not tested and probably the existing grades are not suitable for medical applications.

Aliphatic glycol esters. *No!*
They are not commercially available in ton lots, not tested and probably the existing grades are not suitable for medical applications.

Ethylene-acrylate-carbon monoxide terpolymer (Elvaloy®): *Yes!*
According to the producer these products can be used as a plasticiser on there own. Though only one producer is known it was considered worthwhile to include a suitable product for further investigation.

Nitrile rubber: *No!*
Generation of hazardous fumes when incinerated.

Polyurethane: *No!*
Polyurethanes are used as solid plasticisers in conjunction with a primary plasticiser. They are not suitable as primary plasticisers. Generation of hazardous fumes when incinerated.

EVAC: *No!*
EVAC is used as a solid plasticiser in conjunction with a primary plasticiser. It is not suitable as a primary plasticiser.

Metallocene catalysed polyolefines: *No!*
They are not readily available. The latest published development has not shown any reliable potential. They have limited compatibility with PVC, as polyolefines and PVC are generic very different from each other.

DACM: *No!*
DACM is commercially available only in small quantities. No medical application is known. High price!

Esters of palm oil, castor oil, corn oil and rapeseed oil: *No!*
Limited availability – unsuitable as primary plasticisers – no potential as substitutes for DEHP. An exception is castor oil, in that sebacates are based on castor oil.

6 Experimental

6.1 Preparation of compounds, films and test specimens

6.1.1 Preparation of PVC compounds plasticised with the selected substances

Approx. 25 kg of test compounds based on each of the selected substances as a plasticiser were prepared and pelletised at Hydro Polymers with the compositions shown in Table 3 below.

As a reference compound a standard DEHP plasticised PVC compound with a Shore A hardness of 80 was chosen, and the Shore A hardness of the test compounds should be as near as possible to 80 for comparison reasons.

Table 3

Formulation of the prepared PVC compounds (parts by weight)

Compound No.	036	037	038	039	040	041	042	043	106
Plasticiser type / Ingredients [1)]	DEHP	DINP	DEHA	DEHS	TEHTM	Benzoate	Polyadipate	ATBC	EAC Terpoly-mer
PVC resin	100	100	100	100	100	100	100	100	100
Epoxidised soya bean oil	4	4	4	4	4	4	4	4	4
A calcium-zinc stabiliser	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5
DEHP	48	-	-	-	-	-	-	-	-
DINP	-	52	-	-	-	-	-	-	-
DEHA	-	-	45	-	-	-	-	-	-
DEHS	-	-	-	51		-	-	-	-
TEHTM	-	-	-	-	59	-	-	-	-
A benzoate	-	-	-	-	-	52	-	-	-
A polyadipate	-	-	-	-	-	-	59	-	-
ATBC	-	-	-	-	-	-	-	53	-
EAC Terpolymer	-	-	-	-	-	-	-	-	40

[1)] Sources of the ingredients are listed in appendix 3

6.1.2 Preparation by injection moulding of specimens for material characterisation

From the prepared PVC compounds dumbbell shaped tensile test specimens of type 1A according to ISO 527-2:1993 and square test specimens 4 mm thick and 50 mm in side length were made by injection moulding at the Danish Technological Institute.

The detailed injection moulding reports are enclosed as appendix 2.

Table 4 shows the injection moulding parameters used.

TABLE 4

PARAMETERS USED FOR THE INJECTION MOULDING OF DUMBBELL SHAPED TENSILE TEST SPECIMENS AND SQUARE SPECIMENS – ZONE, NOZZLE AND MOULD TEMPERATURES [°C]

Compound No.	036	037	038	039	040	041	042	043	106	EVAC
Plasticiser type	DEHP	DINP	DEHA	DEHS	TEHTM	Benzoate	Polyadipate	ATBC	EAC Terpoly-mer	-
Zone 4	170	170	182	180	170	170	177	170	170	170
Zone 3	185	185	195	195	185	185	191	185	185	185
Zone 2	185	185	195	195	185	185	191	185	185	185
Zone 1	190	190	199	199	190	190	195	190	190	190
Nozzle	190	190	199	199	190	190	195	190	190	190
Mould	35	35	35	35	35	35	35	35	35	35

6.1.3 Preparation by roll milling of film samples for testing

From the prepared compounds 185 – 400 m thick film samples were made by direct roll milling at Papyro-Tex.

The temperature of the front roll was 166°C; the temperature of the back roll was 160°C. Prior to testing the film samples were conditioned at room temperature for four days.

6.2 CHARACTERISATION OF THE PREPARED COMPOUNDS AND OF THE ALTERNATIVE NON-PVC MATERIAL

The test program was conducted at Danish Technological Institute, Centre for Plastics Technology except from the tensile test of film samples, which was performed at the laboratory at Papyro-Tex. The laboratory at Danish Technological Institute, Centre for Plastics Technology is accredited according to DS/EN ISO/IEC 17025 to perform a long range of tests on plastics and similar materials.

6.2.1 Tensile properties determined on injection moulded specimens

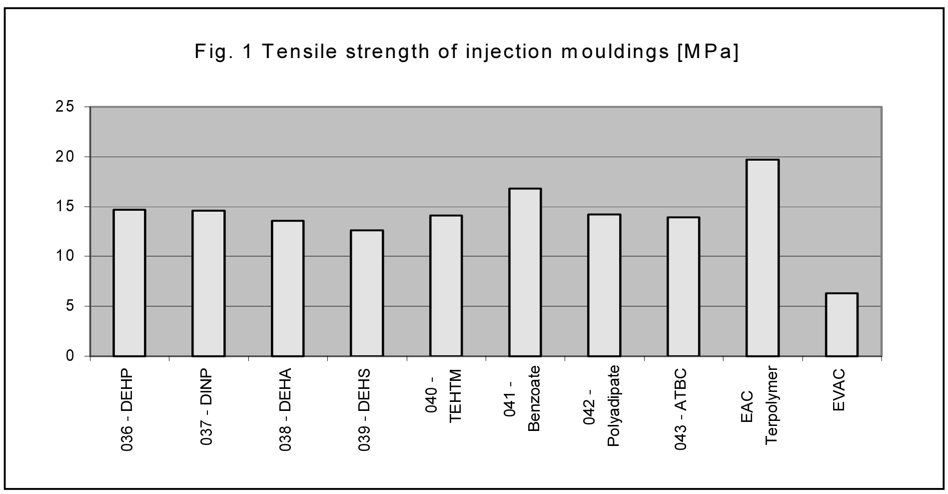
Test method: ISO 527-2, specimen type 1A. Crosshead speed 100 mm/min. The detailed test reports are enclosed in appendix 4.

TABLE 5

TENSILE STRENGTH AND TENSILE STRAIN AT BREAK OF INJECTION MOULDED SPECIMENS FROM PVC TEST COMPOUNDS AND FROM A SELECTED GRADE OF EVAC (SOURCE INFORMATION ENCLOSED IN APPENDIX 3)

Compound No.	Plasticiser type	Specimen width [mm]	Specimen thickness [mm]	Tensile strength [MPa]		Tensile strain at break [%]	
				Mean value	Statistical standard deviation	Mean value	Statistical standard deviation
036	DEHP	9.97	3.97	14.7	0.193	234	9.31
037	DINP	10.00	3.99	14.6	0.319	238	6.59
038	DEHA	9.99	4.00	13.6	0.197	279	9.86
039	DEHS	10.00	3.00	12.6	0.234	255	16.19
040	TEHTM	10.02	4.00	14.1	0.149	196	7.65
041	Benzoate	9.99	3.97	16.8	0.216	207	3.22
042	Polyadipate	9.98	3.97	14.2	0.190	211	9.75
043	ATBC	9.99	3.98	13.9	0.262	227	9.98
106	EAC Terpolymer	10.00	3.96	19.7	0.166	102	2.38
Alternative plastic	EVAC	10.00	3.97	6.29	0.153	> 934 *)	-

*) No break at this strain



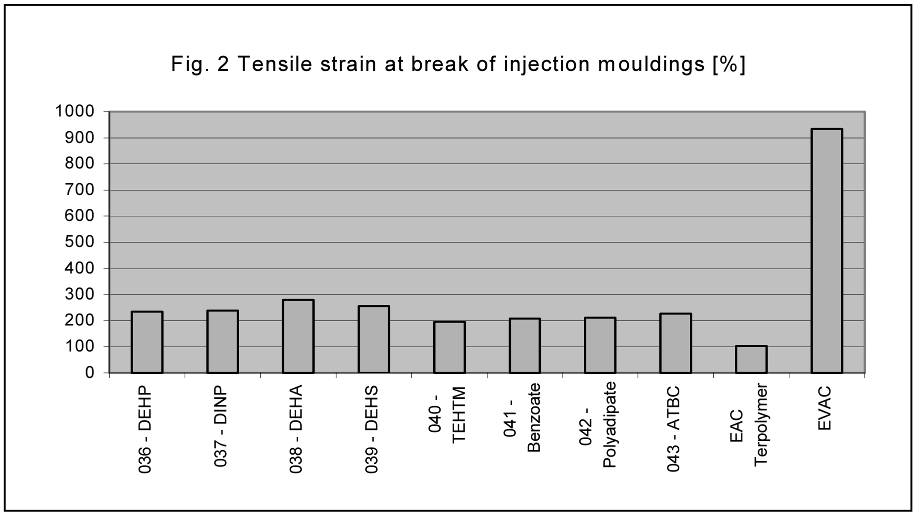


Fig. 2 Tensile strain at break of injection mouldings [%]
1000
900
800
700
600
500
400
300
200
100
0
036 - DEHP
037 - DINP
038 - DEHA
039 - DEHS
040 - TEHTM
041 - Benzoate
042 - Polyadipate
043 - ATBC
EAC Terpolymer
EVAC

6.2.2 Density of the prepared compounds

The density of the prepared PVC compounds and of the alternative plastic material was determined on square injection moulded specimens.

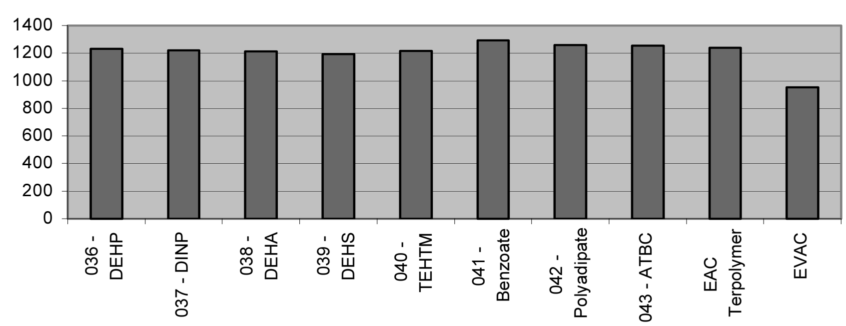
Test method: ISO 2781 method A, ver. 1.

Table 6

Density determined on square injection moulded specimens

Compound No.	Plasticiser type	Density [kg/m³]
036	DEHP	1232
037	DINP	1219
038	DEHA	1212
039	DEHS	1193
040	TEHTM	1216
041	Benzoate	1292
042	Polyadipate	1259
043	ATBC	1256
106	EAC Terpolymer	1240
Alternative plastic	EVAC	951

Fig. 3 Density [kg/m³]



6.2.3 Indentation hardness determined on square injection moulded specimens

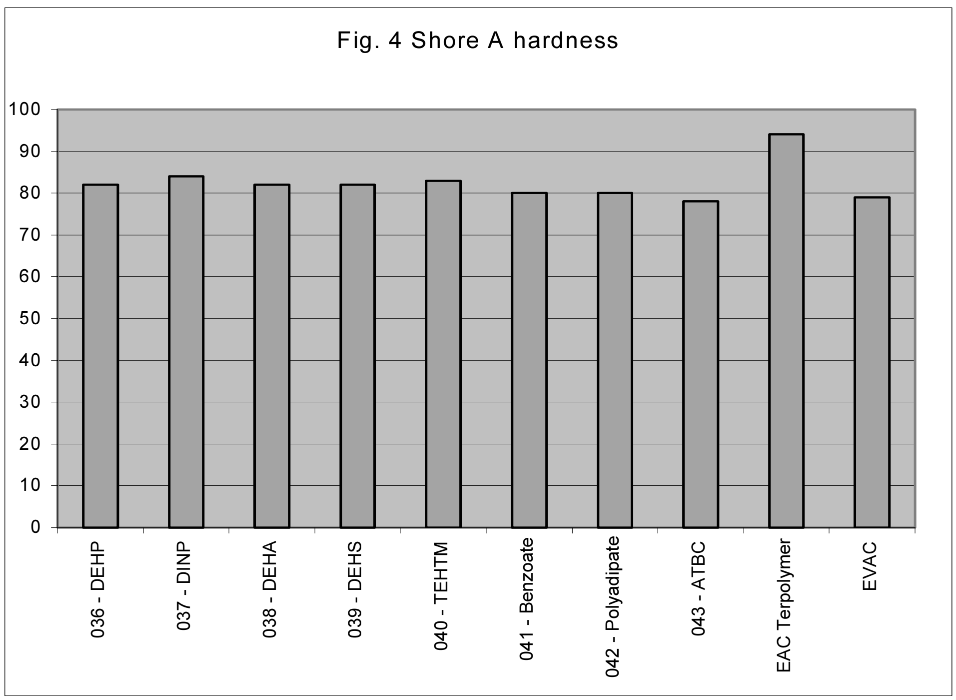
Test method: DS/EN ISO 868:1998 read after 15 seconds.

TABLE 7

SHORE A HARDNESS DETERMINED ON SQUARE INJECTION MOULDED SPECIMENS

Compound No.	Plasticiser type	Shore A
036	DEHP	82
037	DINP	84
038	DEHA	82
039	DEHS	82
040	TEHTM	83
041	Benzoate	80
042	Polyadipate	80
043	ATBC	78
106	EAC Terpolymer	94*)
Alternative plastic	EVAC	79

*) This value is beyond the interval valid for Shore A



6.2.4 Cold flexibility

The cold flexibility temperature was derived from the torsional moduli at varying temperatures determined on plane-parallel specimens cut out from injection moulded tensile test specimens.

Test method: ISO 458/1-1985.

The cold flexibility temperature is defined as the temperature, at which the torsional stiffness, determined by apparent torsional modulus testing, is 310 N/mm at an angular deflection value of 200 degrees.

The resulted graphs are enclosed in appendix 5.

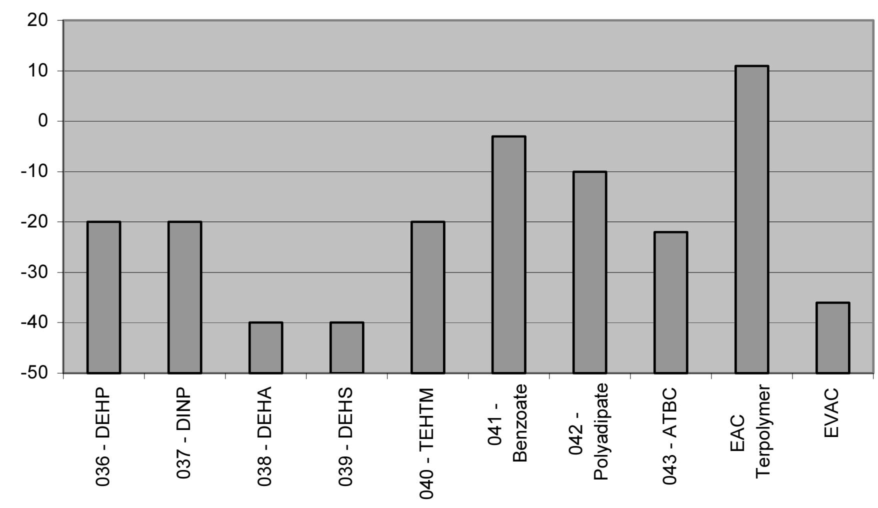
TABLE 8

COLD FLEXIBILITY TEMPERATURE OF PVC TEST COMPOUNDS AND OF A SELECTED GRADE OF EVAC DETERMINED BY TESTING ACCORDING TO ISO 458/1-1986 [°C]. ALSO EXPECTED VALUES FOR SOME COMPOUNDS ARE SHOWN.

Compound No.	Plasticiser or plastic material	Determined by testing	Approximate expected values *)	Approx. values expected by the project partners based on their experience
036	DEHP	- 20	- 19	- 22
½037	DINP	- 20	- 19	- 26
038	DEHA	< - 40	- 46	- 50
039	DEHS	< - 40	- 55	- 60
040	TEHTM	- 20	- 24	- 24
041	Benzoate	- 3	?	?
042	Polyadipate	- 10	- 13	- 13
043	ATBC	- 22	- 23	- 22
106	EAC Terpolymer	+ 11	?	?
Alternative plastic	EVAC	- 36	?	?

*) These expected values are derived from ref. 19 and interpolated to the actual hardness values

Fig. 5 Cold flexibility temperature [degrees C]



6.2.5 Tensile properties determined on roll milled film specimens

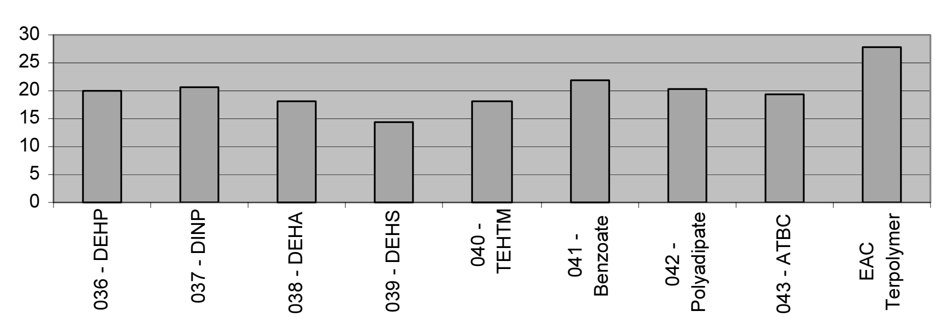
Test methods: ISO 527-3, specimen type 2. Width 10 mm, length 150 mm and clamp distance 100 mm. Crosshead speed 200 mm/min.

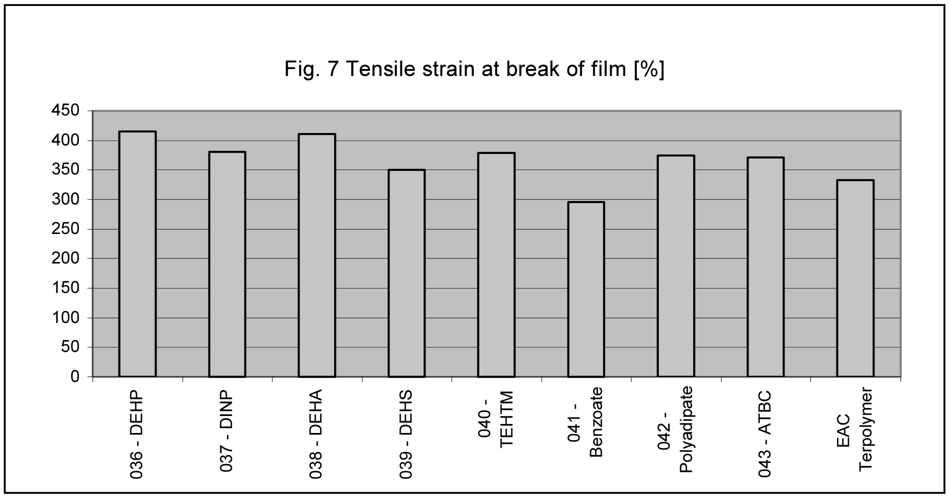
Prior to testing the film samples were conditioned at room temperature for four days. The mean values were derived from five single values. These tests were performed at Papyro-Tex. The detailed test reports are enclosed in appendix 6.

TABLE 9
TENSILE STRENGTH AND TENSILE STRAIN AT BREAK OF FILM SAMPLES FROM PVC TEST COMPOUNDS. NOTE: THE EVAC MATERIAL WAS NOT AVAILABLE IN THE FORM OF FILM.

Compound No.	Plasticiser type	Specimen thickness [m]	Tensile strength [MPa]		Tensile strain at break [%]	
			Mean value	Statistical standard deviation	Mean value	Statistical standard deviation
036	DEHP	250	20.08	0.36	415	7
037	DINP	210	20.56	0.26	381	7
038	DEHA	220	17.97	0.49	411	12
039	DEHS	220	14.42	0.32	350	8
040	TEHTM	220	18.18	0.45	379	5
041	Benzoate	185	21.90	0.90	296	19
042	Polyadipate	220	20.18	0.79	375	18
043	ATBC	220	19.37	0.39	371	26
106	EAC Terpolymer	400	27.70	1.05	333	20

Fig. 6 Tensile strength of film [MPa]





6.2.6 Light transmission determined on roll milled film specimens

Test method: USP XXIV <661> with the exception for the washing and drying of the film samples and with a wider range for the light transmission measurements (290 nm to 800 nm).

Instrument model: Perkin Elmer LAMBDA 18; data interval: 1.0000 nm; scan speed: 240.00 nm/min; slit width: 2.0000 nm; smooth bandwidth: 0.00 nm.

The single light transmission graphs are enclosed in appendix 7.

Table 10

Maximum light transmission at 450 and 800 nm of film samples from PVC test compounds [%].
Note: The EVAC material was not available in the form of film.

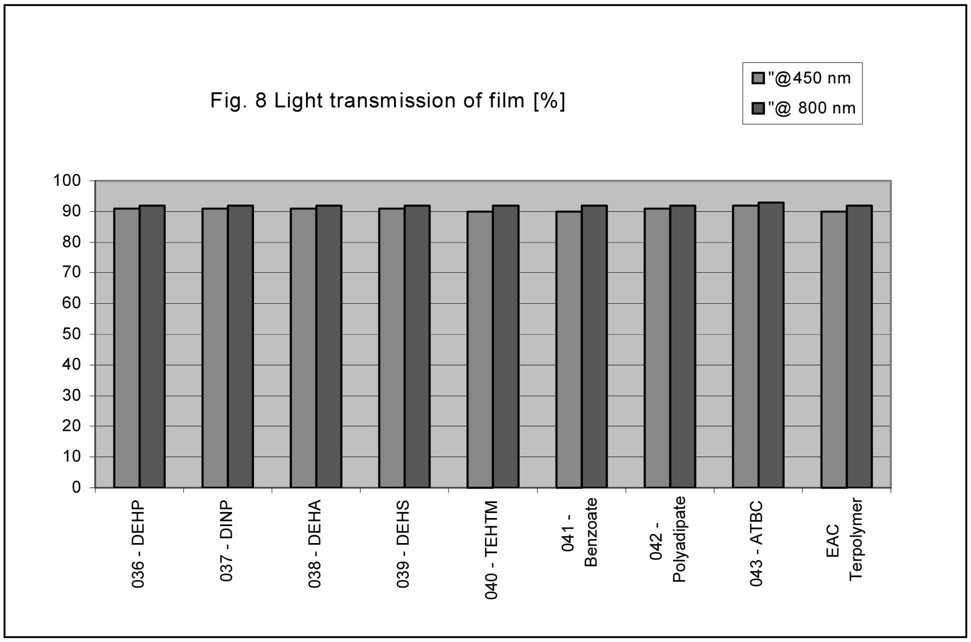
Compound No.	Plasticiser type		@ 450 nm [3]		@ 800 nm [4]	
			Sample No. 1	Sample No. 2	Sample No. 1	Sample No. 2
036	DEHP		91	91	92.0	92.1
037	DINP		91	91	92.1	92.1
038	DEHA		91	91	92.2	92.3
039	DEHS		91	91	92.3	92.4
040	TEHTM		90	90	91.8	91.7
041	Benzoate		90	90	91.6	91.6
042	Polyadipate		91	91	92.2	92.2
043	ATBC		92	92	92.6	92.5
106	EAC Terpolymer	[1]	91	91	92.1	92.3
		[2]	89	88	91.4	91.3

[1] Shiny side towards the light source

[2] Opposite side towards the light source

[3] Read from the graphs

[4] Calculated electronically by apparatus



6.3 Total assessment

Table 12 shows an attempt to make a total assessment

TABLE 12

TOTAL ASSESSMENT

Compound No./Material		036 DEHP	037 DINP	038 DEHA	039 DEHS	040 TEHTM	041 Benzoate	042 Polyadipate	043 ATBC	106 EAC Ter-polymer	EVAC
Availability		+	+	+	+	+	+	+	+	?	+
Compatibility		+	+	+	+	+	+	+	+	+	n.a.
Plasticising efficiency index [1]	Expected	+	+	+	+	+	+	?	-	-	n.a.
	Experienced [2]	+	+	+	+	+	+	+	+	+	n.a.
Processability	Compounding										
	Injection moulding	No specific difficulties experienced									
	Calendering	No experience gained from this project									
Cost	Plasticiser cost index [3]	100	100	120	500-700	400-500	200	350-700	300	500-600	n.a.
	Processing cost index [3]	100	100	120	120-140	120-140	?	150-200	150	?	?
Physical properties of plasticiser		+	+	+	+	+	+	+	+	+	n.a.
Physical properties of compound	Tensile strength of injection mouldings	+	+	+	(+)	+	+	+	+	134	÷
	Tensile strain at break of injection mouldings	+	+	+	+	(÷)	(÷)	+	+	÷	+
	Tensile strength of roll milled film	+	+	+	(÷)	+	+	+	+	+	n.a.
	Tensile strain at break of roll milled film	+	+	+	(÷)	+	÷	+	+	(÷)	n.a.
	Density	+	+	+	+	+	+	+	+	+	+
	Cold flex. temp. [°C]	+	+	+	+	+	(÷)	?	+	÷	+
	Light transmission [%]	+	+	+	+	+	+	+	+	+	n.a.

1) The efficiency index indicates weight parts of plasticiser necessary to gain approximately the same Shore A hardness as with 100 parts DEHP.
2) Calculated from the parts added at the preparation of the test compounds.
3) Expected values relative to DEHP.

7 Discussion

7.1 Uniformity of the compounds

All the compounds are apparently uniform, as there is no sign of phase separation.

7.2 Visual assessment of the prepared mouldings and films

The injection mouldings prepared from the compounds plasticised with DEHP, DINP, DEHA, DEHS, TEHTM and ATBC look all alike, i.e. transparent, very slightly yellow and with a smooth and shiny surface. The benzoate and polyadipate plasticised mouldings are slightly more yellow. However, with all the compounds the yellowness is only visible by the naked eye through the approx. 4 mm thick mouldings, not through any of the film samples.

The injection mouldings from the compound plasticised with EAC terpolymer have an uneven dull surface with indications of material flow directions. Because of the dull surface character it is difficult to compare the yellowness to that of the other compounds. Immediately the yellowness looks more like that of the benzoate and the polyadipate plasticised compounds. However, this yellowness is not visible in the film thickness.

The EVAC mouldings are colourless. The surface is almost as shiny as that of the first mentioned six compounds. However, indications of material flow directions are slightly visible near the injection inlet point.

Apart from the fact that all of the prepared film samples look fairly homogeneous, it makes no sense to visually assess the roll milled film samples, as they have been prepared by a method that is not representative for the industrial manufacture of PVC films in large quantities.

7.3 Evaluation of the test results

7.3.1 Hardness

For comparison reasons the PVC test compounds were prepared with the attempt to obtain the same hardness as near as possible to Shore A 80.

The hardness of the reference DEHP plasticised compound has been determined to be 82. That of the alternative compounds differs between 78 and 84, except the EAC terpolymer plasticised compound, which has a Shore A hardness of 94 (a value that is beyond the interval valid for Shore A). The hardness of the chosen alternative plastic material, EVAC, is 79.

The hardness values found for the test compounds plasticised with DEHP, DEHA, DEHS, TEHTM and polyadipate are within two units from the values that could be expected according to the literature (ref. 19).

Transformation from Shore A values to British Standard Softness Numbers can be found in the literature e.g. ref. 19 and 20.

It seems likely that any wanted specified interesting hardness of PVC compounds plasticised with the selected alternative plasticisers - with the exception of the EAC terpolymer - is possible. Obviously it is possible to purchase an EVAC with a Shore A hardness of approximately the reference value of 80.

7.3.2 Density

The density of the tested compounds varies from that of the DEHP plasticised compound with from -39 kg/m³ to +60 kg/m³ (from -3 % to +5 %) for the PVC compounds. The density of the EVAC is 951 kg/m³, which is to be expected as this material is based on olefins.

7.3.3 Mechanical properties

7.3.3.1 Tensile strength

The tensile strength of injection moulded samples of the PVC compounds vary from 12.6 MPa to 19.7 MPa. The strength of the DEHP plasticised compound is 14.7 MPa. The highest value (19.7 MPa) was found at the compound plasticised with the EAC terpolymer. Among the monomer plasticised compounds the highest value is 16.8 MPa.

With a tensile strength value of 6.3 MPa the strength of EVAC is less than half that of the reference PVC compound. For some medical applications, the EVAC probably results in uninterestingly weak compounds.

Due to different crosshead speeds during testing it is expected that the tensile strength values determined on the film samples are significantly higher than the values determined on the injection moulded specimens. The test results show 14 – 40 % higher tensile strength values determined on the film samples (at crosshead speed 200 mm/min) than on the injection moulded specimens (at crosshead speed 100 mm/min).

The results determined on film specimens for DEHP, DEHA and TEHTM do not contradict with the expected values found in the literature (ref. 19).

The tensile strength of the EAC terpolymer plasticised PVC compound is 34 - 38 % higher than that of the reference compound; however, the samples of this compound is significantly thicker.

Determined on the 4 mm thick specimens at 100 mm/min crosshead speed the highest tensile strength value among the PVC compounds is approx. 34 % higher than that of the reference compound; the lowest one is approx. 14 % lower than that of the reference compound. Determined on the film samples at 200 mm/min crosshead speed the highest value is approx. 38 % higher and the lowest value approx. 28 % lower than that of the reference compound.

7.3.3.2 Tensile strain at break

The tensile strain at break of injection moulded samples of the PVC compounds vary from 102 % to 279 %. The strain at break of the DEHP plasticised compound is 234 %. The highest value (279 %) was found at the compound plasticised with the DEHA and the lowest value (102 %) at the EAC terpolymer plasticised compound.

With a tensile strain at break of more than 934 % the strain of EVAC is more than four times that of the reference PVC compound.

Due to different crosshead speeds during testing it is expected that the tensile strain values determined on the roll milled films (at crosshead speed 200 mm/min) are significantly higher than the values determined on the injection moulded specimens (at crosshead speed 100 mm/min). This is confirmed by the test results.

The tensile strain at break values determined on film specimens for DEHP, DEHA and TEHTM do not contradict significantly with the expected values found in the literature (ref. 19), actually they are some 19 % higher.

The tensile strain at break of the EAC terpolymer plasticised PVC compound determined at 200 mm/min crosshead speed is 20 % lower than that of the reference compound; determined at 100 mm/min it is 56 % lower.

The actual values found are 333 % and 102 % respectively; the former is more than three times the latter. For the other compounds the high-speed results are 37 - 93 % higher than the low-speed values. Apparently the EAC terpolymer plasticised compound is significantly more sensitive to strain speed than the other ones.

7.3.3.3 Cold flexibility temperature

The determined cold flexibility temperature values are very close to the expected values. However, for the EVAC and the PVC compounds plasticised with benzoate and EAC terpolymer no information on expected values was available.

The cold flexibility temperature are approx. -20°C for PVC compounds plasticised with DEHP, DINP, TEHTM and ATBC. For DEHA and DEHS plasticised compounds the value are significantly below -40°C. For the benzoate plasticised compound it is approx. -3°C, and for the compound plasticised with polyadipate it is -10°C. In comparison with DEHP, the benzoate and the polyadipate seem critical as substitutes for DEHP.

The cold flexibility temperature of the compound plasticised with EAC terpolymer is as high as 11°C! This high value probably disqualifies the EAC terpolymer as a substitute for DEHP for PVC for medical devices.

The value for EVAC is approx. -36°C.

7.3.4 Light transmission

Light transmission values of 90 to 92 % in the visible wavelength range 450 nm to 800 nm does not disqualify any of the tested PVC compounds nor the EVAC.

7.4 Cost

The current cost relations of the used plasticiser products are shown in table 11.

Table 11

Plasticiser cost

Plasticiser substance	Current price (£ per ton)	Price index (relative to the price of DEHP)		Current price index taking the experienced plasticising efficiency according to the formulations (see Table 3) into account
		Current	Expected	
DEHP	550	100	-	100
DINP	580	105	100	114
DEHA	1500	273	120	256
DEHS	2500	455	500 - 700	483
TEHTM	1500	273	400 - 500	335
Benzoate	1000	182	200	197
Polyadipate	2700	491	350 - 700	603
ATBC	3300	600	300	663
EVA Terpolymer	2700	491	500 - 600	409

7.5 Comments to each of the tested plasticising substances

DINP
DINP is not available in medical grades. Concern on the available purity has been
expressed. The current price is as expected. Two CAS numbers exist.

DEHA
The current price of the used DEHA is more than twice the expected. According to a Danish EPA project, DEHA is considered more aqua-toxic than DEHP (ref. 31 and 32).

DEHS
The current price of the used DEHS is in the low end of the expected price interval.

TEHTM: Trimellitates are reported to migrate to the blood faster than DEHP (ref. 33), which, however, contradicts with the experience of the project partners. The price of the used TEHTM is significantly lower than expected.

Benzoate: According to correspondence with Velsicol Chemicals, which produces benzoates, they are reluctant to consider Benzoflex 9-88 as a suitable plasticiser for PVC for medical products. One obvious drawback is the poor resistance to extraction by water, which is an important consideration for PVC medical products. The price of the used benzoate is slightly lower than expected

Polyadipate
Polyadipates have successfully been used as plasticisers for medical grade PVC since around 1980. The price of the used polyadipate product is as expected.

ATBC
The price of the used ATBC is twice the expected.

EAC Terpolymer
The price of the used Elvaloy product is as expected.

7.6 Films versus tubings

In this project all the specimens were prepared only by injection moulding and the film samples only by roll milling, so this gives no basis for judging the ability of the prepared compounds to be processed by extrusion and calendering. So far no arguments were found to distinguish between compounds for tubings and compounds for films.

7.7 Preliminary ranking of the investigated substances and compounds

Based on the performed tests in this project DINP, DEHA and ATBC appear to give compounds with similar properties as DEHP.

A proper raking of the other plasticising substances is not possible to make as the drawbacks found concern different properties. The application in question of the final product will determine the required materials properties.

The investigated polyadipate shows a drawback in that the cold flexibility temperature of the compound is some 10°C higher than that of the DEHP plasticised compound.

TEHTM shows a decrease in the tensile strain at break and can only be used if this is acceptable for the application in question.

DEHS gives compounds with a decreased tensile strength, and the tensile strain at break is also lower at least in film thickness. Depending on the specific application DEHS might be an interesting substitute for DEHP.

It would be relevant to verify this apparent similarity in a succeeding investigation as a new round of compounding and characterisation, before one can select appropriate alternatives for the next tasks, e.g. the biological assessment etc.

7.8 General remarks

In the project period a new plasticiser has been reported. BASF has introduced di-isononyl-cyclohexane-1,2 dicarboxylate under the trade name Hexamoll® DINCH. They claim it to be suitable in PVC applications that are particularly sensitive from the toxicological point of view. Information on the product can be found on their homepage on Internet (ref. 35).

The possibilities for replacing plasticised PVC with other plastic materials are multiple and many attempts have been made during recent years. However, each single application has to be investigated on its own. This might very well include a total materials selection process. An example on a newly reported replacement material for certain medical applications is Dow Chemical's work with a metallocene catalysed polyolefin film called Corvelle (ref. 36).

8 Conclusion

The investigations conducted in this project confirm that an extensive effort is needed before one can decide to substitute di(2-ethylhexyl) phthalate (DEHP) with any other plasticiser. It is a well-known fact that DEHP is by far the most investigated PVC plasticiser substance. In the plasticiser performance matrix created in this project DEHP is the only substance, of which no information is lacking. No matter which alternative to DEHP one might want to use, a substantial new know-ledge must be generated.

Based on this project, i.e. within the limitations of the investigated properties, it seems likely, that diisononyl phthalate (DINP), di(2-ethylhexyl) adipate (DEHA) and acetyltributyl citrate (ATBC) can give PVC compounds with properties that are comparable to those of DEHP plasticised PVC.

The only drawback (apart from the cost) with the investigated polyadipate seems to be the poorer cold flexibility of the compound. The cold flexibility temperature is some 10°C higher than that of the DEHP plasticised compound. The values found are -10°C for the polyadipate and -20°C for DEHP. Even though the compatibility towards PVC has been reported to be limited, no drawback was found in this investigation that can be explained by this.

Triethylhexyl trimellitate (TEHTM) also looks interesting, if a decrease in the tensile strain at break can be accepted for the application in question.

Di(2-ethylhexyl) sebacate (DEHS) gives compounds with a substantially lower tensile strength, and the tensile strain at break is also lower at least in film thickness, but depending on the specific application it might also be an interesting replacement for DEHP.

The investigated benzoate (dipropylene glycol dibenzoate) results in a compound with a cold flexibility that is worse than with the polyadipate; the cold flexibility temperature value found is -3°C. Furthermore, the tensile strain at break is substantially decreased – nearly 30 % tested at a crosshead speed of 200 mm/min.

The most important disadvantage (apart from the cost) of the investigated ethylene-acrylate-carbon monoxide terpolymer (EAC terpolymer) is the very poor cold flexibility of the compound. The cold flexibility temperature was found to be as high as +11°C. The tensile strength of PVC compounds plasticised with this substance is some 35 % higher than that of compounds plasticised with DEHP. The tensile strain at break, however, is reduced to 44 % determined at a crosshead speed of 100 mm/min and to 80 % determined at 200 mm/min. Presumably, the potential for use for medical applications is limited due to these limited properties.

To replace plasticised PVC with another plastics material is highly depending on the actual final product and its application. In this project an ethylene-vinyl acetate copolymer has been considered. It is worth to note that EVAC is known to emit acetic acid during processing like extrusion or injection moulding.

The final evaluation can only be made after assessment of biological properties and further investigation of medical articles like tubings, catheters and bags made of the relevant compounds. However, this is not included in this project but is expected to be made in a subsequent project.

9 Proposal for further work

According to the original proposal for this project (ref. 41), which is shown in the project flow diagram on the next page, the manufacturing of medical tubes and bags and further physical and chemical characterisation of those articles should succeed this project. The need for more data and experience has not decreased during recent years.

The Swedish National Board of Health and Welfare have expressed their concern for the risk of the patients safety associated with (uncritical - authors remark) replacement of phthalates in PVC medical devices (ref. 37).

The Public Health Notification by FDA's Department of health & human services by July 12, 2002 recommends as follows (ref. 38), which is based on the FDA CDRH assessment of DEHP from September 2001 (ref. 39 and 40):

"Most important, you should not avoid the procedures cited above (a number of procedures that have been identified as posing the highest risk of exposure to DEHP in the patient treatment – authors remark) simply because of the possibility of health risks associated with DEHP exposure. The risk of not doing a needed procedure is far greater than the risk associated with exposure to DEHP.

For some of the above procedures, PVC devices that do not contain DEHP can be substituted, or devices made of other materials (such as ethylene vinyl acetate (EVAC), silicone, polyethylene or polyurethane) can be used, if available. If PVC devices containing DEHP must be used, you may be able to minimise exposure to DEHP by, for example, using the freshest possible blood products stored at the lowest possible temperature, or by using heparin-coated ECMO circuits.

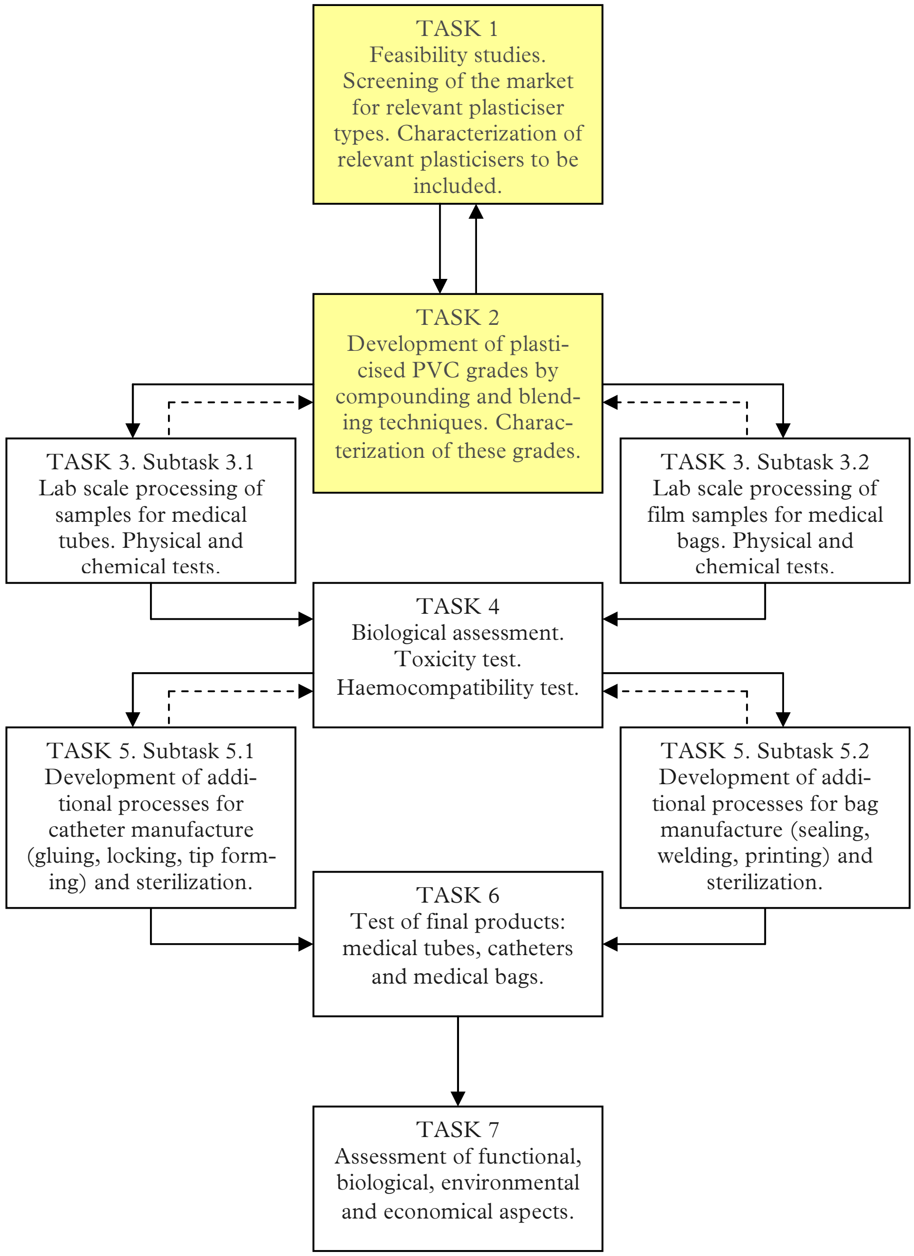
We recommend considering such alternatives when these high-risk procedures are to be performed on male neonates, pregnant women who are carrying male fetuses and peripubertal males…

For other patient groups, who are presumably at lower risk, the decision to use DEHP alternatives must take into account the medical advantages and drawbacks of the substitute materials and their availability."

A wide agreement appears on the necessary cautiousness to be shown in this question.

It is still the recommendation and the intention of the project group to proceed with the investigation of DEHP alternatives according to the original proposal mentioned above.

Overall project flow diagram



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Appendix 1 Plasticiser performance matrix

Performance matrix for plasticisers for PVC for medical applications

21 June 2002

Plasticiser selection criteria				Liquid substances: DEHP[(1)]	DINP[(1)]	DIDP[(1)]	Other phthalates	Adipates: DEHA	Adipates: Other monomeric	Adipates: Polymeric	Trimellitate TEHTM
Commercial availability				Readily available	Readily available but some differences in iso C9 alcohol distribution. Some medical compound usage.	Readily available. Some medical compound usage.	Readily available. Mainly used for specialised applications. No known use in medical compounds.	Readily available. Some medical compound usage.	Available but fewer suppliers than DEHA. No known use in medical compounds.	Available in "medical" grade but limited number of suppliers.	Available in "medical" grade but only four or five suppliers worldwide.
Compatibility with PVC resins				Good	Good	Good	Good	Fair	Fair	Limited	Good
Plasticising efficiency index				100	105	110	90 - 125	95 - 100	92 - 102	120 - 150	117
Processability	Compounding			Reference	Similar to DEHP but possibly more "fish-eyes"	Similar to DEHP but possibly more "fish-eyes"	Similar to DEHP. However <C8 will process easier & >C8 will be more difficult	Slightly more difficult than DEHP	Slightly more difficult than DEHP	Difficult	Slightly more difficult than DEHP.
	Component manufacture	Injection moulding		Reference	Similar to DEHP	Similar to DEHP	Generally similar to DEHP	As DEHP	As DEHP	More difficult than DEHP	Similar to DEHP
		Extrusion		Reference	Slightly more difficult than DEHP	Slightly more difficult than DEHP	Generally similar to DEHP	As DEHP	As DEHP	More difficult than DEHP	Similar to DEHP
		Calendering		Reference	Higher processing temperatures required (> 2 deg. C)	Higher processing temperatures required (> 2 deg. C)	Generally similar to DEHP	As DEHP	As DEHP	More difficult than DEHP	Similar to DEHP*
	Fabrication operations	Solvent welding		Reference	Similar to DEHP	Similar to DEHP	Generally similar to DEHP	As DEHP	As DEHP	Unknown	As DEHP *
		High frequency welding (HF)		Reference	Similar to DEHP	Similar to DEHP	More difficult as efficiency index increases *	As DEHP	As DEHP	As DEHP	As DEHP *
		Adhesive jointing		Reference	As DEHP *	As DEHP *	As DEHP *	As DEHP	As DEHP	Unknown	As DEHP *
		Machinability		Reference	As DEHP *	As DEHP *	As DEHP *	As DEHP	As DEHP	As DEHP	As DEHP *
		Printability		Reference	As DEHP *	As DEHP *	As DEHP *	As DEHP	As DEHP	As DEHP	As DEHP *
	Post fabrication operations	Sterilisation	Radiation sterilisation	Reference	As DEHP	As DEHP *	Unknown	As DEHP	As DEHP	Unknown	As DEHP *
			Ethylene oxide sterilisation	Reference	As DEHP	As DEHP *	Unknown	As DEHP	As DEHP	As DEHP	As DEHP *
			Steam sterilisation	Reference	Slightly more tolerant than DEHP *	Slightly more tolerant than DEHP *	Probably similar to DEHP	Solubility may be an issue	Solubility may be an issue	Unknown	As DEHP *
Cost	Materials cost index			100	100	110	120 - 200	275	120 -140	350 -700	275 - 300
	Processing cost index			100	100 *	110 *	120 - 200	120	140	150 - 200	120 -140
Regulatory status	Food contact approval	Toxicology		Approved for food contact with limitations and for medical applications	FDA, Beverage hoses Germany (BgVV/BGA)	Unknown	Unknown	Restricted food contact approvals exist	Restricted food contact approvals exist	Some food contact approvals dependant on level. At least two suppliers.	Used for blood bags and infusion sets.
	Handling, health and safety	Physical/ chemical	EP monograph	Listed	Not listed	Not listed	Not listed	Not listed	Not listed	Not listed	Not listed
			Drug compatibility	Possible problem with liquid soluble drugs, insulin	Unknown	Unknown	Unknown	Unknown; migration and solubility may be problem	Unknown	Unknown	Unknown
		Biological	Cytotoxicity	OK	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	OK
			Heamolysis	OK	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	OK
			Systemic tox.	OK	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	OK
		(USP Class VI)	Intracutaneous	OK	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	OK
			Implantation	OK	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	OK
Environmental status	Environmental classification	67/548/EEC Annex I + 26 amendment (2000/32/EF)		Not classified	Not classified	Not classified	Some are classified	Not classified	Not classified	Not classified	Not classified
	Emissions	- during manufacturing		Reference	Expected to be similar to DEHP*	Expected to be similar to DEHP	Expected to be similar to DEHP	Higher volatility than DEHP (5 x)	Higher volatility than DEHP (5 x)	Significantly lower volatility	Significantly lower volatility (1:5)
		- in use		Reference	Slightly less than DEHP	Slightly less than DEHP	Unknown	Higher volatility than DEHP (5 x)	Higher volatility than DEHP (5 x)	Significantly lower volatility	Significantly lower volatility (1:5)
	Incineration of final product according to EU directive			No issues	No issues	No issues	No issues	No issues expected	No issues expected	No issues expected	Unknown
	Sustainable development			Oil based	Oil based	Oil based	Oil based	Oil based	Oil based	Oil based	Oil based
Physical properties of plasticiser	Aesthetic properties	Colour		Colourless	Colourless	Colourless	Colourless	Colourless	Colourless	Pale yellow	Colourless
		Clarity		Excellent	Excellent	Excellent	Excellent	Excellent	Excellent	Good	Excellent
	Odour			Slight odour	Slight odour	Slight odour	Slight odour	Slight odour	Slight odour	Slight odour	Slight odour
Physical properties of compounds	Mechanical properties (reference Shore A 80)	Tensile properties		Adequate	Adequate	Adequate	Adequate	Adequate	Adequate	Adequate	Adequate
		Cold flexibility		Good	Slightly better than DEHP	Slightly better than DEHP	Linear phthalates better than equivalent branched	Good	Good	Slightly worse than DEHP	Slightly worse than DEHP
		Elastic recovery		Slow but acceptable	Slow but acceptable	Slow but acceptable	Slow but acceptable	Slow but acceptable	Slow but acceptable	Slow	Slow
Public perception				Politically incorrect	Perceived as more favourable than DEHP	Perceived as more favourable than DEHP.	Unknown	None	None	None	None

Plasticiser selection criteria				Citrates: Acetyltributyl-citrate (ATBC)	Citrates: Acetyltrihexyl-citrate (ATHC)	Citrates: Butyryltrihexyl-citrate (BTHC)	Benzoates	Alkylsulpho-nate of phenol (ASE)	Phosphates (organic)	Epoxies (ESO, ELO)	Sebacates DEHS	Azelates DEHZ	Naphthenates
Commercial availability				Available but limited number of suppliers. Some medical compound usage.	Available but limited number of suppliers. No data on medical applications.	Available but limited number of suppliers. Possible skin sensitisation issues.	Readily available but limited number of suppliers. No known use in medical compounds.	Single source. General purpose PVC compounds. No known use in medical compounds.	Readily available. Several different types. No known or expected use in medical compounds.	Readily available. Widespread use in medical compounds.	Readily available from many suppliers. No known use in medical compounds. Extensive use in food contact and cosmetic applications.	Available but only a limited number of suppliers. Azelaic acid is virtually a single source raw material.	No supplier found
Compatibility with PVC resins				Probably satisfactory but more data required.	Probably satisfactory but more data required.	Probably satisfactory but more data required.	Good	Good	Generally fair although a few types only have limited compatibility.	Limited compatibility. Used as secondary plasticisers and stabilisers.	Fair. Normally used as a secondary plasticiser.	Fair. Normally used as a secondary plasticiser.	Unknown
Plasticising efficiency index				Approx. 100	Approx. 100	Approx. 100	95 - 100	Approx. 100	110 - 150	110	110	110	Unknown
Processability	Compounding			Similar to DEHP but may discolour quicker	As ATBC	Unknown	Slightly easier than DEHP	Similar to DEHP	Difficult	More difficult than DEHP	As DEHP	As DEHP	Unknown
	Component manufacture	Injection moulding		As DEHP	As DEHP*	Unknown	Supplier's literature indicate no problems	As DEHP	Unknown	Not used on its own (used at 4 - 12 phr)	As DEHP	As DEHP	Unknown
		Extrusion		As DEHP	As DEHP*	Unknown	Supplier's literature indicate no problems	As DEHP	More difficult than DEHP	Not used on its own (used at 4 - 12 phr)	As DEHP	As DEHP	Unknown
		Calendering		Supplier's literature indicate no problems	Supplier's literature indicate no problems	Supplier's literature indicate no problems	Supplier's literature indicate no problems	As DEHP	As DEHP	Not used on its own (used at 4 - 12 phr)	As DEHP	As DEHP	Unknown
	Fabrication operations	Solvent welding		Unknown	Unknown	Unknown	Unknown	Unknown	Satisfactory	Not used on its own (used at 4 - 12 phr)	Unknown	Unknown	Unknown
		High frequency welding (HF)		Unknown	Unknown	Unknown	Unknown	As DEHP (Supplier claim it to be better)	Satisfactory	Not used on its own (used at 4 - 12 phr)	Unknown	Unknown	Unknown
		Adhesive jointing		Unknown	Unkown	Unknown	Unknown	Unknown	Unknown	Not used on its own (used at 4 - 12 phr)	Unknown	Unknown	Unknown
		Machinability		Satisfactory	Unknown	Unknown	Unknown	As DEHP	As DEHP *	Not used on its own (used at 4 - 12 phr)	Unknown	Unknown	Unknown
		Printability		Satisfactory	Unknown	Unknown	Used for printed flooring	As DEHP	Satisfactory *	Not used on its own (used at 4 - 12 phr)	Unknown	Unknown	Unknown
	Post fabrication operations	Sterilisation	Radiation sterilisation	As DEHP	As DEHP	As DEHP	Unknown	Unknown	Unknown	Considered as a benefit	Similar to DEHP	As DEHP	Unknown
			Ethylene oxide sterilisation	As DEHP *	As DEHP *	As DEHP *	Unknown	Unknown	Unknown	Satisfactory at 4 - 12 phr	Similar to DEHP	As DEHP	Unknown
			Steam sterilisation	Some hydrolysis expected *	Some hydrolysis expected *	Some hydrolysis expected *	Unknown	Unknown	Unknown	Satisfactory at 4 - 12 phr	Similar to DEHP	As DEHP	Unknown
Cost	Materials cost index			600	500	1000	200	100 - 120	250 - 400	120 - 150	450 - 700	500 - 700	Unknown
	Processing cost index			150	150	Unknown	Unknown	As DEHP	150	120	120 - 140	Unknown	Unknown
Regulatory status	Food contact approval	Toxicology		Accepted by FDA for food wrap applications. Listed in the EEC Directive 90/128.	No data from supplier	FDA approved for blood bags	FDA approved for food packaging	BgVV approved	A grade is FDA approved for food packaging	Listed in the USP and the EP	Physiologically satisfactory Extensive FDA approvals	Some FDA approvals	Unknown
	Handling, health and safety	Physical/ chemical	EP monograph	Not listed	Not listed	Not listed	Not listed	Not listed	Not listed		Not listed	Not listed	Not listed
			Drug compatibility	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown		As DEHP	As DEHP	Unknown
		Biological	Cytotoxicity	Unknown	Unknown	Unknown	A number of toxicity tests have been performed showing	Unknown	Unknown		As DEHP	As DEHP	Unknown
			Heamolysis	Unknown	Unknown	Unknown		Unknown	Unknown		As DEHP	As DEHP	Unknown
			Systemic tox.	Unknown	Unknown	Unknown		Unknown	Unknown		As DEHP	As DEHP	Unknown
		(USP Class VI)	Intracutaneous	Unknown	Unknown	Unknown		Unknown	Unknown		As DEHP	As DEHP	Unknown
			Implantation	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown		As DEHP	As DEHP	Unknown
Environmental status	Environmental classification	67/548/EEC Annex I + 26 amendment (2000/32/EF)		Not classified	Not classified	Not classified	Di-ethylene glycol dibenzoate and dipropylene glycol dibenzoate are not classified	o-Toluenesulphon-amide is not classified	Di-2-ethylhexyl phosphate and tri-2-ethylhexyl phosphate are not classified	ESO is not classified	Not classified	Not classified	Not classified
	Emissions	- during manufacturing		Ventilation required	Good ventilation required	Good ventilation required	Supplier claims low volatility	Similar to DEHP	Unknown	Non hazardous	Similar to DEHP	Similar to DEHP	Unknown
		- in use		As DEHP *	Unknown	Good ventilation required	Supplier claims low volatility	Similar to DEHP	Unknown	Non hazardous	Similar to DEHP	Much as DEHP	Unknown
	Incineration of final product according to EU directive			Possible acidic fumes *	Possible acidic fumes *	Possible acidic fumes *	No issues *	Potential issues with SO2 emissions & residues	Possible toxic emissions during incineration	Non hazardous	Similar to DEHP	Similar to DEHP	Unknown
	Sustainable development			Partially oil based	Partially oil based	Partially oil based	Oil based	Oil based	Coal tar or oil based	Natural product based	Partly natural (Castor oil)	Partly natural based	Unknown
Physical properties of plasticiser	Aesthetic properties	Colour		Colourless	Colourless	Colourless	Colourless	Colourless	Colourless	Light yellow	Colourless	Colourless	Unknown
		Clarity		Good	Good	Good	Good	Good	Good	Good	Good	Colourless	Unknown
	Odour			Slight odour	Slight odour	Odour present	Mild odour	Odourless???	Odourless???	Mild odour	Odourless	Odourless	Unknown
Physical properties of compounds	Mechanical properties (reference Shore A 80)	Tensile properties		Adequate	Adequate	Adequate	Adequate	Adequate	Adequate	Depends on primary plasticiser	Good	OK (10 % less than DEHP)	Unknown
		Cold flexibility		As DEHP	Slightly better than DEHP	Better than DEHP	Slightly worse than DEHP	Slightly worse than DEHP	Most are poor	Slightly worse than DEHP	Excellent	Very good	Unknown
		Elastic recovery		As DEHP *	As DEHP *	Unknown	Unknown	As DEHP	Poor	Depends on primary plasticiser	Excellent	Unknown	Unknown
Public perception				Good	None	Occupational safety and health problems reported	None	None	None	Slightly poor	None	None	None

Plasticiser selection criteria				Liquid substances: Polyhydric alcohol esters	Aliphatic glycol esters	EAC Terpolymer	Solid substances: Nitrile rubber	Polyurethane	Ethylen-vinylacetat copolymer EVAC	Metallocene catalysed polyolefines	Destilled acetylated monoglyceride DACM	Substances derived from natural products: Esters from palm oil	Esters from castor oil	Esters from corn oil	Esters from rapeseed oil
Commercial availability				Available but only a limited number of suppliers. No known use in medical compounds.	Available but only a limited number of suppliers. Used for antistatic PVC compounds. No known use in medical compounds.	Single source. Solid plasticiser normally used in conjuntion with a liquid primary plasticiser.	Several sources. Solid plasticiser normally used in conjunction with a liquid primary plasticiser.	Several sources. Solid plasticiser normally used in conjunction with a liquid primary plasticiser.	Several sources. Solid plasticiser normally used in conjunction with a liquid primary plasticiser.	Not readily available. Poor compatibility with PVC.	Commercially available but only in small quantities. No known use in medical compounds.	No known usage as PVC plasticiser	Unknown	Unknown	No known usage as PVC plasticiser
Compatibility with PVC resins				Unknown	Fair. Normally used as a secondary plasticiser.	Unknown but probably fair	Fair	Fair	Unknown. More data required.	Poor	Unknown	Unknown	Unknown	Unknown	Unknown
Plasticising efficiency index				Unknown	90	Poor efficiency	Poor efficiency	Poor efficiency	Poor efficiency	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown
Processability	Compounding			Unknown	Highly volatile	Difficult to process	Difficult to process	Difficult to process	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown
	Component manufacture	Injection moulding		Unknown	Volatile	Unknown	Very difficult to injection mould	Difficult to injection mould	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown
		Extrusion		Unknown	Volatile	Unknown	More difficult than DEHP	More difficult than DEHP	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown
		Calendering		Unknown	Volatile	A blend with DEHP was difficult to process. Compound was satisfactory.	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown
	Fabrication operations	Solvent welding		Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown
		High frequency welding (HF)		Unknown	Unknown	As DEHP *	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown
		Adhesive jointing		Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown
		Machinability		Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown
		Printability		Unknown	Used for printed flooring	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown
	Post fabrication operations	Sterilisation	Radiation sterilisation	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown
			Ethylene oxide sterilisation	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown
			Steam sterilisation	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown
Cost	Materials cost index			500	400 - 500	500 - 600	400	500 - 600	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown
	Processing cost index			Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown
Regulatory status	Food contact approval	Toxicology		Unknown	Unknown	Unknown	Food contact grades available	Food contact grades available. Meets BgVV requirements.	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown
	Handling, health and safety	Physical/ chemical	EP monograph	Not listed	Not listed	Not listed	Not listed	Not listed	Not listed	Unknown	Not listed	Unknown	Unknown	Unknown	Unknown
			Drug compatibility	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown
		Biological	Cytotoxicity	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown
			Heamolysis	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown
			Systemic tox.	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown
		(USP Class VI)	Intracutaneous	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown
			Implantation	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown
Environmental status	Environmental classification	67/548/EEC Annex I + 26 amendment (2000/32/EF)		Not classified	Unknown	Unknown	Not classified	Not classified	Not classified	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown
	Emissions	- during manufacturing		Unknown	Highly volatile	Hazardous fumes	Hazardous fumes (HCN risk)	Hazardous fumes (HCN risk and other nasties)	Acetic acid emitted *	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown
		- in use		Unknown	Highly volatile	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown
	Incineration of final product according to EU directive			Unknown	Unknown	Hazardous fumes	Hazardous fumes (HCN risk)	Hazardous fumes (HCN risk and other nasties)	Acid fumes produced during incineration	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown
	Sustainable development			Unknown	Unknown	Oil based	Partly oil based	Oil based	Oil based	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown
Physical properties of plasticiser	Aesthetic properties	Colour		Unknown	Unknown	White granules	Yellow powder	White powder	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown
		Clarity		Unknown	Unknown	Clear in compound	Semi opaque	Fair	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown
	Odour			Unknown	Unknown	Smell of acetic acid	Typical NBR odour	Odourless *	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown
Physical properties of compounds	Mechanical properties (reference Shore A 80)	Tensile properties		Unknown	As DEHP	Unknown	Good	Poor	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown
		Cold flexibility		Poor	Good low temperature properties	Unknown	Poor	Good	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown
		Elastic recovery		Unknown	Unknown	Unknown	Good	Good	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown
Public perception				None	None	None	None	None	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown

Data refers to Shore A 80 compounds

(1) Phthalates being assessed by EU

"Unknown" means unknown to the working group at the moment

* Knowledge assumed from DEHP

Appendix 2 Injection moulding reports (in Danish only)

Teknologisk Institut/Plastteknologi **Gregersensvej, 2630 Taastrup** **Tlf: 72 20 31 10, Fax: 72 20 31 11**		**Sprøjtestøberapport nr. 2**	
Teknologisk Institut sags nr.	131-02005	Dato:	20010507
Sagsbehandler:	Børge Sørensen	Filnavn:	kk-pvc-01
Firma:	KK/Teknologisk Institut	Tegning nr.:	
Emne:	Plade 4 mm	Ordre nr.:	
Maskine		Dyseboring	mm ø 2,5
Fabrikat:	Arburg	Dysetype:	Åben
Type:	C270-80-300	Snekkediameter:	mm 20
Formværktøj			
Opspændingsplade:	mm	Emneantal:	1
Indbygningshøjde:	mm 239	Projiceret areal, cm^2:	
Indløbstype:	Stang	Udstøderarrangement:	Stifter
Indløbsbøsning radius:	mm	Hjælpeudstyr:	Tempereringsanlæg
Centreringsring:	mm 125		
Åbnevej:	mm		
Emne			
Vægt af emne:	g	Godstykkelse, max.:	mm
Vægt af indløb:	g	Godstykkelse, min.:	mm
Støbevægt:	g	Flydevej i emne:	mm
Skudvægt:	g	Indløbspunkt, dimension:	mm
Materiale			
Kemisk betegnelse:	PVC og EVAC	Leverandør:	
Handelsnavn:	DP-01-	Farve:	
Type nr.:	36/37/40/41/43/106 + EVAC		
Tryk		**Kraft**	
Indstillet sprøjtetryk:		Lukkekraft:	kN 300
Hydraulik/omsat:	bar 1800	Dysetilhold:	
Eftertryk:		Tryk/kraft:	bar/kN
Hydraulik/omsat:	bar 500		
Modtryk:			
Hydraulik/omsat:	bar 25		
Snekkeindstilling			
Dosering:	ccm 20	Materialepude:	ccm
Omskift eftertryk, vejafh.:	ccm 11,5	Snekkeomdrejning:	m/min 17
Omskift eftertryk, tid:	sek	Sprøjteaggregat:	Fast
Omskift eftertryk, tryk:	bar		Retur *
Tid og hastighed			
Indsprøjtningshastighed:	ccm/sek 55	Restkøletid:	sek 10
Indsprøjtningstid:	sek	Pausetid:	sek
Eftertrykstid:	sek 20	Doserforhaling:	sek
Samlet sprøjtetid:	sek	Cyklustid:	sek
Temperatur			
Dysevarme:	°C 190	Fast formpart, indstillet:	°C 35
Zone 1:	°C 190	Fast formpart, overflade:	°C
Zone 2:	°C 185	Bevægelig formpart, indstillet:	°C 35
Zone 3:	°C 185	Bevægelig formpart, overflade:	°C
Zone 4:	°C 170	Fortørring [fortørring] timer:	°C
Traverstemperatur:	°C	Olietemperatur:	°C 40
Smeltetemperatur:	°C	Centrale køleanlæg:	°C 8
Varmekanal:	°C		
Bemærkning		Program:	
		Halvautomatisk	Helautomatisk *

Teknologisk Institut/Plastteknologi **Gregersensvej, 2630 Taastrup** **Tlf: 72 20 31 10, Fax: 72 20 31 11**		**Sprøjtestøberapport nr. 2**	
Teknologisk Institut sags nr.	131-02005	Dato:	20010507
Sagsbehandler:	Børge Sørensen	Filnavn:	kk-pvc-02
Firma:	KK/Teknologisk Institut	Tegning nr.:	
Emne:	Plade 4 mm	Ordre nr.:	
Maskine		Dyseboring	mm ø 2,5
Fabrikat:	Arburg	Dysetype:	Åben
Type:	C270-80-300	Snekkediameter:	mm 20
Formværktøj			
Opspændingsplade:	mm	Emneantal:	1
Indbygningshøjde:	mm 239	Projiceret areal, cm^2:	
Indløbstype:	Stang	Udstøderarrangement:	Stifter
Indløbsbøsning radius:	mm	Hjælpeudstyr:	Tempereringsanlæg
Centreringsring:	mm 125		
Åbnevej:	mm		
Emne			
Vægt af emne:	g	Godstykkelse, max.:	mm
Vægt af indløb:	g	Godstykkelse, min.:	mm
Støbevægt:	g	Flydevej i emne:	mm
Skudvægt:	g	Indløbspunkt, dimension:	mm
Materiale			
Kemisk betegnelse:	PVC	Leverandør:	
Handelsnavn:	DP-01-38	Farve:	
Type nr.:			
Tryk		**Kraft**	
Indstillet sprøjtetryk:		Lukkekraft:	kN 300
Hydraulik/omsat:	bar 1800	Dysetilhold:	
Eftertryk:		Tryk/kraft:	bar/kN
Hydraulik/omsat:	bar 500		
Modtryk:			
Hydraulik/omsat:	bar 25		
Snekkeindstilling			
Dosering:	ccm 20	Materialepude:	ccm
Omskift eftertryk, vejafh.:	ccm 12	Snekkeomdrejning:	m/min 17
Omskift eftertryk, tid:	sek	Sprøjteaggregat:	Fast
Omskift eftertryk, tryk:	bar		Retur *
Tid og hastighed			
Indsprøjtningshastighed:	ccm/sek 55	Restkøletid:	sek 10
Indsprøjtningstid:	sek	Pausetid:	sek
Eftertrykstid:	sek 20	Doserforhaling:	sek
Samlet sprøjtetid:	sek	Cyklustid:	sek
Temperatur			
Dysevarme:	°C 199	Fast formpart, indstillet:	°C 35
Zone 1:	°C 199	Fast formpart, overflade:	°C
Zone 2:	°C 195	Bevægelig formpart, indstillet:	°C 35
Zone 3:	°C 195	Bevægelig formpart, overflade:	°C
Zone 4:	°C 182	Fortørring [fortørring] timer:	°C
Traverstemperatur:	°C	Olietemperatur:	°C 40
Smeltetemperatur:	°C	Centrale køleanlæg:	°C 8
Varmekanal:	°C		
Bemærkning		Program:	
		Halvautomatisk	Helautomatisk *

Teknologisk Institut/Plastteknologi **Gregersensvej, 2630 Taastrup** **Tlf: 72 20 31 10, Fax: 72 20 31 11**		**Sprøjtestøberapport nr. 2**	
Teknologisk Institut sags nr. Sagsbehandler:	131-02005 Børge Sørensen	Dato: Filnavn:	20010509 kk-pvc-03
Firma: Emne:	KK/Teknologisk Institut Plade 4 mm	Tegning nr.: Ordre nr.:	
Maskine Fabrikat: Type:	 Arburg C270-80-300	Dyseboring Dysetype: Snekkediameter:	mm ø 2,5 Åben mm 20
Formværktøj Opspændingsplade: Indbygningshøjde: Indløbstype: Indløbsbøsning radius: Centreringsring: Åbnevej:	 mm mm 239 Stang mm mm 125 mm	 Emneantal: Projiceret areal, cm^2: Udstøderarrangement: Hjælpeudstyr:	 1 Stifter Tempereringsanlæg
Emne Vægt af emne: Vægt af indløb: Støbevægt: Skudvægt:	 g g g g	 Godstykkelse, max.: Godstykkelse, min.: Flydevej i emne: Indløbspunkt, dimension:	 mm mm mm mm
Materiale Kemisk betegnelse: Handelsnavn: Type nr.:	 PVC DP-01-42	 Leverandør: Farve:	
Tryk Indstillet sprøjtetryk: Hydraulik/omsat: Eftertryk: Hydraulik/omsat: Modtryk: Hydraulik/omsat:	 bar 1800 bar 500 bar 25	**Kraft** Lukkekraft: Dysetilhold: Tryk/kraft:	 kN 300 bar/kN
Snekkeindstilling Dosering: Omskift eftertryk, vejafh.: Omskift eftertryk, tid: Omskift eftertryk, tryk:	 ccm 20 ccm 12 sek bar	 Materialepude: Snekkeomdrejning: Sprøjteaggregat:	 ccm m/min 17 Fast Retur *
Tid og hastighed Indsprøjtningshastighed: Indsprøjtningstid: Eftertrykstid: Samlet sprøjtetid:	 ccm/sek 55 sek sek 20 sek	 Restkøletid: Pausetid: Doserforhaling: Cyklustid:	 sek 10 sek sek sek
Temperatur Dysevarme: Zone 1: Zone 2: Zone 3: Zone 4: Traverstemperatur: Smeltetemperatur: Varmekanal:	 °C 195 °C 195 °C 191 °C 191 °C 177 °C °C °C	 Fast formpart, indstillet: Fast formpart, overflade: Bevægelig formpart, indstillet: Bevægelig formpart, overflade: Fortørring [fortørring] timer: Olietemperatur: Centrale køleanlæg:	 °C 35 °C °C 35 °C °C °C 40 °C 8
Bemærkning		Program: Halvautomatisk	 Helautomatisk *

Teknologisk Institut/Plastteknologi **Gregersensvej, 2630 Taastrup** **Tlf: 72 20 31 10, Fax: 72 20 31 11**		**Sprøjtestøberapport nr. 2**	
Teknologisk Institut sags nr. Sagsbehandler:	131-02005 Børge Sørensen	Dato: Filnavn:	20010509 kk-pvc-04
Firma: Emne:	KK/Teknologisk Institut Plade 4 mm	Tegning nr.: Ordre nr.:	
Maskine Fabrikat: Type:	 Arburg C270-80-300	Dyseboring Dysetype: Snekkediameter:	mm ø 2,5 Åben mm 20
Formværktøj Opspændingsplade: Indbygningshøjde: Indløbstype: Indløbsbøsning radius: Centreringsring: Åbnevej:	 mm mm 239 Stang mm mm 125 mm	 Emneantal: Projiceret areal, cm^2: Udstøderarrangement: Hjælpeudstyr:	 1 Stifter Tempereringsanlæg
Emne Vægt af emne: Vægt af indløb: Støbevægt: Skudvægt:	 g g g g	 Godstykkelse, max.: Godstykkelse, min.: Flydevej i emne: Indløbspunkt, dimension:	 mm mm mm mm
Materiale Kemisk betegnelse: Handelsnavn: Type nr.:	 PVC DP-01-39	 Leverandør: Farve:	
Tryk Indstillet sprøjtetryk: Hydraulik/omsat: Eftertryk: Hydraulik/omsat: Modtryk: Hydraulik/omsat:	 bar 1800 bar 500 bar 25	**Kraft** Lukkekraft: Dysetilhold: Tryk/kraft:	 kN 300 bar/kN
Snekkeindstilling Dosering: Omskift eftertryk, vejafh.: Omskift eftertryk, tid: Omskift eftertryk, tryk:	 ccm 20 ccm 12 sek bar	 Materialepude: Snekkeomdrejning: Sprøjteaggregat:	 ccm m/min 17 Fast Retur *
Tid og hastighed Indsprøjtningshastighed: Indsprøjtningstid: Eftertrykstid: Samlet sprøjtetid:	 ccm/sek 55 sek sek 20 sek	 Restkøletid: Pausetid: Doserforhaling: Cyklustid:	 sek 10 sek sek sek
Temperatur Dysevarme: Zone 1: Zone 2: Zone 3: Zone 4: Traverstemperatur: Smeltetemperatur: Varmekanal:	 °C 199 °C 199 °C 195 °C 195 °C 180 °C °C °C	 Fast formpart, indstillet: Fast formpart, overflade: Bevægelig formpart, indstillet: Bevægelig formpart, overflade: Fortørring [fortørring] timer: Olietemperatur: Centrale køleanlæg:	 °C 35 °C °C 35 °C °C °C 40 °C 8
Bemærkning		Program: Halvautomatisk	 Helautomatisk *

Appendix 3 Sources of the ingredients in the prepared PVC compounds and of the alternative thermoplastic material, EVAC

Sources of the ingredients and of EVAC			
Substance			
Abbreviation	Chemical nature	CAS No.	Supplier or producer
PVC	Polyvinylchloride		Norsk Hydro
DEHP	Di(2-ethylhexyl) phthalate	117-81-7	BP Chemicals Ltd.
ESBO	Epoxydised soya bean oil		Crompton Vinyl Additives GmbH
Stabiliser	A calcium-zink compound		Crompton Vinyl Additives GmbH
DINP	Diisononyl phthalate	68515-48-0	ExxonMobil Chemical
DEHA	Di(2-ethylhexyl) adipate	103-23-1	BASF plc
DEHS	Di(2-ethylhexyl) sebacate	122-62-3	Laporte Performance Chemicals
TEHTM	Tri(2-ethylhexyl) trimellitate	3319-31-1	Lonza Intermediates and Adeditives
Benzoate	Dipropylene glycol dibenzoate (> 5 % monoester)	27138-31-4 (125457-59-2)	Velsicol Chemical Corporation
Polyadipate	A polyester based on adipic acid/neopentyl glycol/1,4 butane diol modified with a mono alcohol in the range C6 – C12	-	Kemira Polymers
ATBC	Acetyltributyl citrate	77-90-7	Pfizer Chemicals
EVA Terpolymer	Ethylene terpolymer with n-butyl acrylate, fillers, additives, n-butylacrylate	141-32-2	Du Pont (U.K.) Limited
EVAC	Ethylene-vinyl acetate plastic		Du Pont Industrial Polymers

Appendix 4 Test reports from the tensile test of injection moulded specimens

Danish Technological Institute

Plastics Technology

Tensile test - ISO 527-2:1993

Specimen type 1A

Test type:	Tensile
Operator name:	FGU
Sample Identification:	T1054-1
Interface Type:	5500

Instron Corporation

Series IX Automated Materials Testing System 8.02.00

Test Date: 7. June 2001

Sample Rate (pts/secs):	10.0000	
Crosshead Speed:	100.0000	mm/min
2nd Crosshead Speed:	0.0000	mm/min
Full Scale Load Range:	5.000	kN

Humidity (%): 50

Temperature: 23 C

Project Plasticisers for PVC for medical devices

Compound No. 036 - DEHP

Sample comments:

	Width (mm)	Thickness (mm)	Gauge Length (mm)	Grip Distance (mm)	Load at Max.Load (N)	Stress at Max.Load (MPa)	% Strain at Max.Load (%)	Load at Auto. Break (N)	Stress at Auto. Break (MPa)
1 1	9.970	3.980	50.000	110.000	590.651	14.885	247.555	590.651	14.885
2 2	9.980	3.940	50.000	110.000	567.967	14.444	222.417	567.967	14.444
3 3	9.960	3.990	50.000	110.000	587.179	14.775	232.064	587.179	14.775
4 4	9.970	3.970	50.000	110.000	588.082	14.858	232.000	588.082	14.858
5 5	9.990	4.000	50.000	110.000	582.011	14.565	238.773	582.011	14.565
Mean	9.974	3.976	50.000	110.000	583.178	14.705	234.562	583.178	14.705
S.D.	0.011	0.023	0.000	0.000	9.064	0.193	9.312	9.064	0.193
C.V.	0.114	0.579	0.000	0.000	1.554	1.309	3.970	1.554	1.309
Median	9.970	3.980	50.000	110.000	587.179	14.775	232.064	587.179	14.775
Mean +2.00 SD	9.997	4.022	50.000	110.000	601.306	15.091	253.186	601.306	15.091
Mean -2.00 SD	9.951	3.930	50.000	110.000	565.050	14.320	215.938	565.050	14.320
Minimum	9.960	3.940	50.000	110.000	567.967	14.444	222.417	567.967	14.444
Maximum	9.990	4.000	50.000	110.000	590.651	14.885	247.555	590.651	14.885

	% Strain at Auto. Break (%)	Modulus (ManYoung) (MPa)	% Strain @ Pro-set 7 MPa (%)	Load/Width at Max.Load (N/mm)	Load/Width at Max.Load (N/50mm)	Displcment at Max.Load (mm)	Load/Width at Auto. Break (N/50 mm)
1 1	247.555	15.114	59.952	59.243	2962.141	123.778	2962.141
2 2	222.417	14.838	57.166	56.911	2845.527	111.208	2845.527
3 3	232.064	15.109	58.503	58.954	2947.685	116.032	2947.685
4 4	232.000	16.785	53.876	58.985	2949.258	116.000	2949.258
5 5	238.773	17.233	56.412	58.259	2912.970	119.387	2912.970
Mean	234.562	15.816	57.182	58.470	2923.516	117.281	2923.516
S.D.	9.312	1.106	2.288	0.945	47.255	4.656	47.255
C.V.	3.970	6.995	4.002	1.616	1.616	3.970	1.616
Median	232.064	15.114	57.166	58.954	2947.685	116.032	2947.685
Mean +2.00 SD	253.186	18.029	61.758	60.361	3018.027	126.593	3018.027
Mean -2.00 SD	215.938	13.603	52.605	56.580	2829.006	107.969	2829.006
Minimum	222.417	14.838	53.876	56.911	2845.527	111.208	2845.527
Maximum	247.555	17.233	59.952	59.243	2962.141	123.778	2962.141

Danish Technological Institute

Plastics Technology

Tensile test - ISO 527-2:1993

Specimen type 1A

Test type:	Tensile
Operator name:	FOU
Sample Identification:	T1154-2
Interface Type:	5500

Instron Corporation

Series IX Automated Materials Testing System 8.02.00

Test Date: 7. June 2001

Sample Rate (pts/secs):	10.0000	
Crosshead Speed:	100.0000	mm/min
2nd Crosshead Speed:	0.0000	mm/min
Full Scale Load Range:	5.000	kN

Humidity (%): 50

Temperature: 23 C

Project Plasticisers for PVC for medical devices

Compound No. 037 - DINP

Sample comments:

	Width (mm)	Thickness (mm)	Gauge Length (mm)	Grip Distance (mm)	Load at Max.Load (N)	Stress at Max.Load (MPa)	% Strain at Max.Load (%)	Load at Auto. Break (N)	Stress at Auto. Break (MPa)
1 1	10.040	3.990	50.000	110.000	578.331	14.437	232.371	578.331	14.437
2 2	10.010	4.000	50.000	110.000	609.436	15.221	246.701	609.436	15.221
3 3	9.980	3.990	50.000	110.000	581.241	14.597	238.069	581.241	14.597
4 4	10.000	3.990	50.000	110.000	577.056	14.463	232.116	577.056	14.463
5 5	10.000	4.010	50.000	110.000	586.579	14.628	243.834	586.579	14.628
Mean	10.006	3.996	50.000	110.000	586.529	14.669	238.618	586.529	14.669
S.D.	0.022	0.009	0.000	0.000	13.320	0.319	6.598	13.320	0.319
C.V.	0.219	0.224	0.000	0.000	2.271	2.177	2.765	2.271	2.177
Median	10.000	3.990	50.000	110.000	581.241	14.597	238.069	581.241	14.597
Mean +2.00 SD	10.050	4.014	50.000	110.000	613.168	15.308	251.815	613.168	15.308
Mean -2.00 SD	9.962	3.978	50.000	110.000	559.889	14.030	225.422	559.889	14.030
Minimum	9.980	3.990	50.000	110.000	577.056	14.437	232.116	577.056	14.437
Maximum	10.040	4.010	50.000	110.000	609.436	15.221	246.701	609.436	15.221

	% Strain at Auto. Break (%)	Modulus (Man Young) (MPa)	% Strain @ Pre-set 7 MPa (%)	Load/Width at Max.Load (N/mm)	Load/Width at Max.Load (N/50mm)	Displacement at Max.Load (mm)	Load/Width at Auto. Break (N/50 mm)
1 1	232.371	17.209	54.589	57.603	2880.134	116.186	2880.134
2 2	246.701	17.118	55.289	60.883	3044.137	123.351	3044.137
3 3	238.069	17.720	56.304	58.241	2912.029	119.035	2912.029
4 4	232.116	18.053	53.782	57.706	2885.281	116.058	2885.281
5 5	243.834	16.549	56.295	58.658	2932.897	121.917	2932.897
Mean	238.618	17.330	55.252	58.618	2930.896	119.309	2930.896
S.D.	6.598	0.580	1.095	1.336	66.785	3.299	66.785
C.V.	2.765	3.345	1.982	2.279	2.279	2.765	2.279
Median	238.069	17.209	55.289	58.241	2912.029	119.035	2912.029
Mean +2.00 SD	251.815	18.489	57.442	61.289	3064.466	125.908	3064.466
Mean -2.00 SD	225.422	16.170	53.062	55.947	2797.325	112.711	2797.325
Minimum	232.116	16.549	53.782	57.603	2880.134	116.058	2880.134
Maximum	246.701	18.053	56.304	60.883	3044.137	123.351	3044.137

Danish Technological Institute

Plastics Technology

Tensile test - ISO 527-2:1993

Specimen type 1A

Test type:	Tensile
Operator name:	FOU
Sample Identification:	T1154-3
Interface Type:	5500

Instron Corporation

Series IX Automated Materials Testing System 8.02.00

Test Date: 7. June 2001

Sample Rate (pts/secs):	10.0000	
Crosshead Speed:	100.0000	mm/min
2nd Crosshead Speed:	0.0000	mm/min
Full Scale Load Range:	5.000	kN

Humidity (%): 50

Temperature: 23 C

Project Plasticisers for PVC for medical devices

Compound No. 038 - DEHA

Sample comments:

	Width (mm)	Thickness (mm)	Gauge Length (mm)	Grip Distance (mm)	Load at Max.Load (N)	Stress at Max.Load (MPa)	% Strain at Max.Load (%)	Load at Auto. Break (N)	Stress at Auto. Break (MPa)
1 1	9.980	4.000	50.000	110.000	548.235	13.733	265.759	548.235	13.733
2 2	9.990	4.000	50.000	110.000	535.167	13.393	273.218	535.167	13.393
3 3	10.000	4.000	50.000	110.000	554.869	13.872	286.412	554.869	13.872
4 4	10.020	3.990	50.000	110.000	550.268	13.764	289.198	550.268	13.764
5 5	9.980	4.010	50.000	110.000	540.583	13.508	283.869	540.583	13.508
Mean	9.994	4.000	50.000	110.000	545.824	13.654	279.691	545.824	13.654
S.D.	0.017	0.007	0.000	0.000	7.881	0.197	9.862	7.881	0.197
C.V.	0.167	0.177	0.000	0.000	1.444	1.444	3.526	1.444	1.444
Median	9.990	4.000	50.000	110.000	548.235	13.733	283.869	548.235	13.733
Mean +2.00 SD	10.027	4.014	50.000	110.000	561.586	14.048	299.414	561.586	14.048
Mean -2.00 SD	9.961	3.986	50.000	110.000	530.063	13.260	259.968	530.063	13.260
Minimum	9.980	3.990	50.000	110.000	535.167	13.393	265.759	535.167	13.393
Maximum	10.020	4.010	50.000	110.000	554.869	13.872	289.198	554.869	13.872

	% Strain at Auto. Break (%)	Modulus (Man Young) (MPa)	% Strain @ Pre-set 7 MPa (%)	Load/Width at Max.Load (N/mm)	Load/Width at Max.Load (N/50mm)	Displacment at Max.Load (mm)	Load/Width at Auto. Break (N/50 mm)
1 1	265.759	15.323	78.533	54.933	2746.666	132.879	2746.666
2 2	273.218	14.835	78.993	53.570	2678.513	136.609	2678.513
3 3	286.412	13.398	70.536	55.487	2774.347	143.206	2774.347
4 4	289.198	14.855	79.466	54.917	2745.847	144.599	2745.847
5 5	283.869	14.001	67.595	54.167	2708.334	141.934	2708.334
Mean	279.691	14.482	75.025	54.615	2730.742	139.846	2730.742
S.D.	9.862	0.771	5.548	0.749	37.461	4.931	37.461
C.V.	3.526	5.322	7.395	1.372	1.372	3.526	1.372
Median	283.869	14.835	78.533	54.917	2745.847	141.934	2745.847
Mean +2.00 SD	299.414	16.024	86.121	56.113	2805.663	149.707	2805.663
Mean -2.00 SD	259.968	12.941	63.928	53.116	2655.820	129.984	2655.820
Minimum	265.759	13.398	67.595	53.570	2678.513	132.879	2678.513
Maximum	289.198	15.323	79.466	55.487	2774.347	144.599	2774.347

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Tensile test - ISO 527-2:1993
Specimen type 1A

Test type:	Tensile	Instron Corporation	
Operator name:	FGU	Series IX Automated Materials Testing System	8.02.00
Sample Identification:	T1154-4	Test Date: 7. June 2001	
Interface Type:	5500		

Sample Rate (pts/secs):	10.0000		Humidity (%): 50
Crosshead Speed:	100.0000	mm/min	Temperature: 23 C
2nd Crosshead Speed:	0.0000	mm/min	
Full Scale Load Range:	5.000	kN	

Project Plasticisers for PVC for medical devices

Compound No. 039 - DEHS

Sample comments:

	Width (mm)	Thickness (mm)	Gauge Length (mm)	Grip Distance (mm)	Load at Max.Load (N)	Stress at Max.Load (MPa)	% Strain at Max.Load (%)	Load at Auto. Break (N)	Stress at Auto. Break (MPa)
1 1	10.040	3.990	50.000	110.000	508.777	12.701	263.035	508.777	12.701
2 2	10.000	4.000	50.000	110.000	510.668	12.767	270.957	510.668	12.767
3 3	10.030	4.010	50.000	110.000	513.462	12.766	267.357	510.111	12.683
4 4	9.970	3.960	50.000	110.000	482.372	12.218	233.205	482.372	12.218
5 5	9.960	4.010	50.000	110.000	507.742	12.713	244.739	507.742	12.713
Mean	10.000	3.994	50.000	110.000	504.604	12.633	255.859	503.934	12.616
S.D.	0.035	0.021	0.000	0.000	12.617	0.234	16.190	12.107	0.225
C.V.	0.354	0.519	0.000	0.000	2.500	1.852	6.328	2.403	1.782
Median	10.000	4.000	50.000	110.000	508.777	12.713	263.035	508.777	12.701
Mean +2.00 SD	10.071	4.035	50.000	110.000	529.838	13.101	288.239	528.149	13.066
Mean -2.00 SD	9.929	3.953	50.000	110.000	479.371	12.165	223.478	479.719	12.166
Minimum	9.960	3.960	50.000	110.000	482.372	12.218	233.205	482.372	12.218
Maximum	10.040	4.030	50.000	110.000	513.462	12.767	270.957	510.668	12.767

	% Strain at Auto. Break (%)	Modulus (Man Young) (MPa)	% Strain @ Pre-set 7 MPa (%)	Load/Width at Max.Load (N/mm)	Load/Width at Max.Load (N/50mm)	Displacement at Max.Load (mm)	Load/Width at Auto. Break (N/50 mm)
1 1	263.035	14.711	69.372	50.675	2533.752	131.518	2533.752
2 2	270.957	16.660	66.230	51.067	2553.338	135.479	2553.338
3 3	271.391	14.896	81.947	51.193	2559.632	133.678	2542.926
4 4	233.205	18.683	71.484	48.382	2419.119	116.603	2419.119
5 5	244.739	17.308	80.289	50.978	2548.907	122.369	2548.907
Mean	256.665	16.452	73.864	50.459	2522.950	127.929	2519.608
S.D.	16.987	1.674	6.905	1.176	58.822	8.095	56.652
C.V.	6.619	10.174	9.349	2.331	2.331	6.328	2.248
Median	263.035	16.660	71.484	50.978	2548.907	131.518	2542.926
Mean +2.00 SD	290.640	19.799	87.675	52.812	2640.594	144.120	2632.913
Mean -2.00 SD	222.691	13.104	60.054	48.106	2405.305	111.739	2406.304
Minimum	233.205	14.711	66.230	48.382	2419.119	116.603	2419.119
Maximum	271.391	18.683	81.947	51.193	2559.632	135.479	2553.338

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Tensile test - ISO 527-2:1993
Specimen type 1A

Test type:	Tensile	Instron Corporation	
Operator name:	FGU	Series IX Automated Materials Testing System	8.02.00
Sample Identification:	T1154-5	Test Date: 8. June 2001	
Interface Type:	5500		

Sample Rate (pts/secs):	10.0000		Humidity (%): 50
Crosshead Speed:	100.0000	mm/min	Temperature: 23 C
2nd Crosshead Speed:	0.0000	mm/min	
Full Scale Load Range:	5.000	kN	

Project Plasticisers for PVC for medical devices

Compound No. 040 - TEHTM

Sample comments:

	Width (mm)	Thickness (mm)	Gauge Length (mm)	Grip Distance (mm)	Load at Max.Load (N)	Stress at Max.Load (MPa)	% Strain at Max.Load (%)	Load at Auto. Break (N)	Stress at Auto. Break (MPa)
1 1	10.010	3.990	50.000	110.000	570.318	14.279	206.749	570.318	14.279
2 2	10.000	3.990	50.000	110.000	569.635	14.277	200.589	569.635	14.277
3 3	10.010	4.010	50.000	110.000	558.600	13.916	186.695	558.600	13.916
4 4	10.070	3.990	50.000	110.000	568.902	14.159	192.538	568.902	14.159
5 5	10.030	4.020	50.000	110.000	572.857	14.208	197.477	572.857	14.208
Mean	10.024	4.000	50.000	110.000	568.062	14.168	196.810	568.062	14.168
S.D.	0.028	0.014	0.000	0.000	5.495	0.149	7.650	5.495	0.149
C.V.	0.279	0.354	0.000	0.000	0.967	1.054	3.887	0.967	1.054
Median	10.010	3.990	50.000	110.000	569.635	14.208	197.477	569.635	14.208
Mean +2.00 SD	10.080	4.028	50.000	110.000	579.053	14.466	212.110	579.053	14.466
Mean -2.00 SD	9.968	3.972	50.000	110.000	557.072	13.869	181.510	557.072	13.869
Minimum	10.000	3.990	50.000	110.000	558.600	13.916	186.695	558.600	13.916
Maximum	10.070	4.020	50.000	110.000	572.857	14.279	206.749	572.857	14.279

	% Strain at Auto. Break (%)	Modulus (ManYoung) (MPa)	% Strain @ Pre-set 7 MPa (%)	Load/Width at Max.Load (N/mm)	Load/Width at Max.Load (N/50mm)	Displacement at Max.Load (mm)	Load/Width at Auto. Break (N/50 mm)
1 1	206.749	20.209	48.450	56.975	2848.743	103.375	2848.743
2 2	200.589	20.859	46.853	56.964	2848.176	100.295	2848.176
3 3	186.695	20.951	48.003	55.804	2790.208	93.347	2790.208
4 4	192.538	20.397	47.855	56.495	2824.738	96.269	2824.738
5 5	197.477	19.128	47.315	57.114	2855.715	98.738	2855.715
Mean	196.810	20.309	47.695	56.670	2833.516	98.405	2833.516
S.D.	7.650	0.729	0.621	0.538	26.890	3.825	26.890
C.V.	3.887	3.591	1.302	0.949	0.949	3.887	0.949
Median	197.477	20.397	47.855	56.964	2848.176	98.738	2848.176
Mean +2.00 SD	212.110	21.767	48.937	57.746	2887.295	106.055	2887.295
Mean -2.00 SD	181.510	18.850	46.453	55.595	2779.736	90.755	2779.736
Minimum	186.695	19.128	46.853	55.804	2790.208	93.347	2790.208
Maximum	206.749	20.951	48.450	57.114	2855.715	103.375	2855.715

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Tensile test - ISO 527-2:1993

Specimen type 1A

Test type:	Tensile
Operator name:	FGU
Sample Identification:	T1154-6
Interface Type:	5500

Instron Corporation

Series IX Automated Materials Testing System 8.02.00

Test Date: 8. June 2001

Sample Rate (pts/secs):	10.0000	
Crosshead Speed:	100.0000	mm/min
2nd Crosshead Speed:	0.0000	mm/min
Full Scale Load Range:	5.000	kN

Humidity (%): 50

Temperature: 23 C

Project Plasticisers for PVC for medical devices

Compound No. 041 - Benzoate

Sample comments:

	Width (mm)	Thickness (mm)	Gauge Length (mm)	Grip Distance (mm)	Load at Max.Load (N)	Stress at Max.Load (MPa)	% Strain at Max.Load (%)	Load at Auto. Break (N)	Stress at Auto. Break (MPa)
1 1	10.010	4.000	50.000	110.000	677.590	16.923	210.282	677.590	16.923
2 2	9.970	3.980	50.000	110.000	673.064	16.962	205.818	673.064	16.962
3 3	10.020	3.960	50.000	110.000	657.558	16.572	203.110	657.558	16.572
4 4	9.980	3.970	50.000	110.000	663.211	16.739	207.785	663.211	16.739
5 5	10.000	3.960	50.000	110.000	678.508	17.134	210.920	678.508	17.134
Mean	9.996	3.974	50.000	110.000	669.986	16.866	207.583	669.986	16.866
S.D.	0.021	0.017	0.000	0.000	9.223	0.216	3.224	9.223	0.216
C.V.	0.207	0.427	0.000	0.000	1.377	1.282	1.553	1.377	1.282
Median	10.000	3.970	50.000	110.000	673.064	16.923	207.785	673.064	16.923
Mean +2.00 SD	10.037	4.007	50.000	110.000	688.433	17.298	214.032	688.433	17.298
Mean -2.00 SD	9.955	3.941	50.000	110.000	651.540	16.434	201.135	651.540	16.434
Minimum	9.970	3.960	50.000	110.000	657.558	16.572	203.110	657.558	16.572
Maximum	10.020	4.000	50.000	110.000	678.508	17.134	210.920	678.508	17.134

	% Strain at Auto. Break (%)	Modulus (Man Young) (MPa)	% Strain @ Pre-set 7 MPa (%)	Load/Width at Max.Load (N/mm)	Load/Width at Max.Load (N/50mm)	Displacment at Max.Load (mm)	Load/Width at Auto. Break (N/50 mm)
1 1	210.282	15.010	53.778	67.691	3384.564	105.141	3384.564
2 2	205.818	14.566	54.745	67.509	3375.449	102.909	3375.449
3 3	203.110	14.707	54.519	65.625	3281.229	101.555	3281.229
4 4	207.785	15.020	54.437	66.454	3322.698	103.893	3322.698
5 5	210.920	14.598	56.156	67.851	3392.541	105.460	3392.541
Mean	207.583	14.780	54.727	67.026	3351.296	103.792	3351.296
S.D.	3.224	0.221	0.876	0.955	47.745	1.612	47.745
C.V.	1.553	1.492	1.601	1.425	1.425	1.553	1.425
Median	207.785	14.707	54.519	67.509	3375.449	103.893	3375.449
Mean +2.00 SD	214.032	15.221	56.479	68.936	3446.787	107.016	3446.787
Mean -2.00 SD	201.135	14.339	52.975	65.116	3255.806	100.567	3255.806
Minimum	203.110	14.566	53.778	65.625	3281.229	101.555	3281.229
Maximum	210.920	15.020	56.156	67.851	3392.541	105.460	3392.541

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Tensile test - ISO 527-2:1993

Specimen type 1A

Test type:	Tensile	Instron Corporation	
Operator name:	FGU	Series IX Automated Materials Testing System	8.02.00
Sample Identification:	T1154-7	Test Date: 8. June 2001	
Interface Type:	5500		

Sample Rate (pts/secs):	10.0000		Humidity (%): 50
Crosshead Speed:	100.0000	mm/min	Temperature: 23 C
2nd Crosshead Speed:	0.0000	mm/min	
Full Scale Load Range:	5.000	kN	

Project Plasticisers for PVC for medical devices

Compound No. 042 - Polyadipate

Sample comments:

	Width (mm)	Thickness (mm)	Gauge Length (mm)	Grip Distance (mm)	Load at Max.Load (N)	Stress at Max.Load (MPa)	% Strain at Max.Load (%)	Load at Auto. Break (N)	Stress at Auto. Break (MPa)
1 1	9.950	3.980	50.000	110.000	572.039	14.445	212.180	572.039	14.445
2 2	10.000	4.000	50.000	110.000	563.996	14.100	213.108	563.996	14.100
3 3	10.010	3.970	50.000	110.000	571.831	14.389	216.328	571.831	14.389
4 4	9.980	3.950	50.000	110.000	552.831	14.024	195.878	552.831	14.024
5 5	10.000	3.970	50.000	110.000	570.465	14.369	222.055	570.465	14.369
Mean	9.988	3.974	50.000	110.000	566.233	14.266	211.910	566.233	14.266
S.D.	0.024	0.018	0.000	0.000	8.179	0.190	9.759	8.179	0.190
C.V.	0.239	0.457	0.000	0.000	1.444	1.331	4.605	1.444	1.331
Median	10.000	3.970	50.000	110.000	570.465	14.369	213.108	570.465	14.369
Mean +2.00 SD	10.036	4.010	50.000	110.000	582.591	14.645	231.428	582.591	14.645
Mean -2.00 SD	9.940	3.938	50.000	110.000	549.875	13.886	192.392	549.875	13.886
Minimum	9.950	3.950	50.000	110.000	552.831	14.024	195.878	552.831	14.024
Maximum	10.010	4.000	50.000	110.000	572.039	14.445	222.055	572.039	14.445

	% Strain at Auto. Break (%)	Modulus (MarYoung) (MPa)	% Strain @ Pre-set 7 MPa (%)	Load/Width at Max.Load (N/mm)	Load/Width at Max.Load (N/50mm)	Displacement at Max.Load (mm)	Load/Width at Auto. Break (N/50 mm)
1 1	212.180	16.138	50.510	57.491	2874.568	106.090	2874.568
2 2	213.108	15.951	52.258	56.400	2819.982	106.554	2819.982
3 3	216.328	16.068	51.863	57.126	2856.301	108.164	2856.301
4 4	195.878	16.132	52.105	55.394	2769.694	97.939	2769.694
5 5	222.055	15.990	53.283	57.047	2852.326	111.027	2852.326
Mean	211.910	16.056	52.004	56.691	2834.574	105.955	2834.574
S.D.	9.759	0.084	0.995	0.825	41.258	4.880	41.258
C.V.	4.605	0.520	1.914	1.456	1.456	4.605	1.456
Median	213.108	16.068	52.105	57.047	2852.326	106.554	2852.326
Mean +2.00 SD	231.428	16.223	53.994	58.342	2917.091	115.714	2917.091
Mean -2.00 SD	192.392	15.889	50.013	55.041	2752.057	96.196	2752.057
Minimum	195.878	15.951	50.510	55.394	2769.694	97.939	2769.694
Maximum	222.055	16.138	53.283	57.491	2874.568	111.027	2874.568

Danish Technological Institute

Plastics Technology

Tensile test - ISO 527-2:1993

Specimen type 1A

Test type: Tensile

Operator name: FGU

Sample Identification: T1154-8

Interface Type: 5500

Instron Corporation

Series IX Automated Materials Testing System 8.02.00

Test Date: 8. June 2001

Sample Rate (pts/secs): 10.0000

Crosshead Speed: 100.0000 mm/min

2nd Crosshead Speed: 0.0000 mm/min

Full Scale Load Range: 5.000 kN

Humidity (%): 50

Temperature: 23 C

Project Plasticisers for PVC for medical devices

Compound No. 043 - ATBC

Sample comments:

	Width (mm)	Thickness (mm)	Gauge Length (mm)	Grip Distance (mm)	Load at Max.Load (N)	Stress at Max.Load (MPa)	% Strain at Max.Load (%)	Load at Auto. Break (N)	Stress at Auto. Break (MPa)
1 1	9.970	3.970	50.000	110.000	536.681	13.559	213.823	536.681	13.559
2 2	10.030	3.990	50.000	110.000	551.940	13.792	225.728	551.940	13.792
3 3	9.990	3.970	50.000	110.000	554.920	13.992	225.578	554.920	13.992
4 4	10.000	4.000	50.000	110.000	570.800	14.270	241.787	570.800	14.270
5 5	9.980	4.010	50.000	110.000	557.219	13.924	228.738	557.219	13.924
Mean	9.994	3.988	50.000	110.000	554.312	13.907	227.131	554.312	13.907
S.D.	0.023	0.018	0.000	0.000	12.218	0.262	9.986	12.218	0.262
C.V.	0.230	0.449	0.000	0.000	2.204	1.880	4.397	2.204	1.880
Median	9.990	3.990	50.000	110.000	554.920	13.924	225.728	554.920	13.924
Mean +2.00 SD	10.040	4.024	50.000	110.000	578.749	14.430	247.103	578.749	14.430
Mean -2.00 SD	9.948	3.952	50.000	110.000	529.875	13.384	207.159	529.875	13.384
Minimum	9.970	3.970	50.000	110.000	536.681	13.559	213.823	536.681	13.559
Maximum	10.030	4.010	50.000	110.000	570.800	14.270	241.787	570.800	14.270

	% Strain at Auto. Break (%)	Modulus (Man Young) (MPa)	% Strain @ Pre-set 7 MPa (%)	Load/Width at Max.Load (N/mm)	Load/Width at Max.Load (N/50mm)	Displacment at Max.Load (mm)	Load/Width at Auto. Break (N/50 mm)
1 1	213.823	13.762	66.866	53.830	2691.481	106.911	2691.481
2 2	225.728	13.796	68.246	55.029	2751.445	112.864	2751.445
3 3	225.578	13.002	68.376	55.548	2777.376	112.789	2777.376
4 4	241.787	12.812	70.044	57.080	2854.003	120.894	2854.003
5 5	228.738	13.670	56.126	55.834	2791.679	114.369	2791.679
Mean	227.131	13.408	65.932	55.464	2773.197	113.565	2773.197
S.D.	9.986	0.465	5.596	1.185	59.244	4.993	59.244
C.V.	4.397	3.464	8.487	2.136	2.136	4.397	2.136
Median	225.728	13.670	68.246	55.548	2777.376	112.864	2777.376
Mean +2.00 SD	247.103	14.337	77.124	57.834	2891.684	123.551	2891.684
Mean -2.00 SD	207.159	12.479	54.740	53.094	2654.709	103.579	2654.709
Minimum	213.823	12.812	56.126	53.830	2691.481	106.911	2691.481
Maximum	241.787	13.796	70.044	57.080	2854.003	120.894	2854.003

Danish Technological Institute

Plastics Technology

Tensile test - ISO 527-2:1993
Specimen type 1A

Test type: Tensile
Operator name: FGU
Sample Identification: T1154-9
Interface Type: 5500

Instron Corporation
Series IX Automated Materials Testing System 8.02.00
Test Date: 8. June 2001

Sample Rate (pts/secs): 10.0000
Crosshead Speed: 100.0000 mm/min
2nd Crosshead Speed: 0.0000 mm/min

Full Scale Load Range: 5.000 kN

Humidity (%): 50
Temperature: 23 C

Project Plasticisers for PVC for medical devices

Compound No. 106 - EAC Terpolymer

Sample comments:

	Width (mm)	Thickness (mm)	Gauge Length (mm)	Grip Distance (mm)	Load at Max.Load (N)	Stress at Max.Load (MPa)	% Strain at Max.Load (%)	Load at Auto. Break (N)	Stress at Auto. Break (MPa)
1 1	10.020	3.980	50.000	110.000	777.950	19.507	101.481	768.772	19.277
2 2	10.030	3.950	50.000	110.000	789.704	19.933	103.769	731.474	18.463
3 3	10.000	3.960	50.000	110.000	785.568	19.838	104.741	785.568	19.838
4 4	9.990	3.950	50.000	110.000	782.424	19.828	98.643	770.418	19.524
5 5	10.000	3.960	50.000	110.000	779.401	19.682	103.113	775.086	19.573
Mean	10.008	3.960	50.000	110.000	783.009	19.758	102.349	766.264	19.335
S.D.	0.016	0.012	0.000	0.000	4.752	0.166	2.388	20.521	0.526
C.V.	0.164	0.309	0.000	0.000	0.607	0.841	2.333	2.678	2.723
Median	10.000	3.960	50.000	110.000	782.424	19.828	103.113	770.418	19.524
Mean +2.00 SD	10.041	3.984	50.000	110.000	792.513	20.090	107.125	807.303	20.388
Mean -2.00 SD	9.975	3.936	50.000	110.000	773.505	19.425	97.574	725.223	18.282
Minimum	9.990	3.950	50.000	110.000	777.950	19.507	98.643	731.474	18.463
Maximum	10.030	3.980	50.000	110.000	789.704	19.933	104.741	785.568	19.838

	% Strain at Auto. Break (%)	Modulus (Man Young) (MPa)	% Strain @ Pre-set 7 MPa (%)	Load/Width at Max.Load (N/mm)	Load/Width at Max.Load (N/50mm)	Displacement at Max.Load (mm)	Load/Width at Auto. Break (N/50 mm)
1 1	107.650	414.575	2.001	77.640	3881.985	50.740	3836.190
2 2	119.974	800.413	1.718	78.734	3936.709	51.884	3646.430
3 3	104.741	453.580	1.565	78.557	3927.840	52.370	3927.840
4 4	104.125	309.505	1.898	78.321	3916.034	49.322	3855.948
5 5	106.302	991.552	1.523	77.940	3897.005	51.557	3875.428
Mean	108.558	593.925	1.741	78.238	3911.915	51.175	3828.367
S.D.	6.528	288.748	0.207	0.448	22.380	1.194	107.276
C.V.	6.014	48.617	11.886	0.572	0.572	2.333	2.802
Median	106.302	453.580	1.718	78.321	3916.034	51.557	3855.948
Mean +2.00 SD	121.615	1171.422	2.155	79.133	3956.675	53.562	4042.919
Mean -2.00 SD	95.502	16.428	1.327	77.343	3867.155	48.787	3613.815
Minimum	104.125	309.505	1.523	77.640	3881.985	49.322	3646.430
Maximum	119.974	991.552	2.001	78.734	3936.709	52.370	3927.840

Danish Technological Institute
Plastics Technology

Tensile test - ISO 527-2:1993
Specimen type 1A

Test type: Tensile
Operator name: FOU
Sample Identification: T1154-10
Interface Type: 5500

Instron Corporation
Series IX Automated Materials Testing System 8.02.00
Test Date: 8. June 2001

Sample Rate (pts/secs): 10.0000
Crosshead Speed: 100.0000 mm/min
2nd Crosshead Speed: 0.0000 mm/min

Full Scale Load Range: 5.000 kN

Humidity (%): 50
Temperature: 23 C

Project Plasticisers for PVC for medical devices

Sample comments:

	Width (mm)	Thickness (mm)	Gauge Length (mm)	Grip Distance (mm)	Load at Max.Load (N)	Stress at Max.Load (MPa)	% Strain at Max.Load (%)	Load at Auto. Break (N)	Stress at Auto. Break (MPa)
Excluded	9.990	4.000	50.000	110.000	205.890	5.152	680.452	205.890	5.152
2 2	10.090	3.990	50.000	110.000	255.290	6.341	937.561	255.290	6.341
3 3	9.970	3.980	50.000	110.000	257.686	6.494	937.766	257.686	6.494
4 4	9.990	3.990	50.000	110.000	244.158	6.125	924.728	244.158	6.125
5 5	10.030	3.970	50.000	110.000	244.996	6.153	900.484	244.996	6.153
6 6	9.950	3.960	50.000	110.000	250.065	6.346	969.527	250.065	6.346
Mean	10.006	3.978	50.000	110.000	250.439	6.292	934.013	250.439	6.292
S.D.	0.055	0.013	0.000	0.000	6.026	0.153	24.991	6.026	0.153
C.V.	0.555	0.328	0.000	0.000	2.406	2.428	2.676	2.406	2.428
Median	9.990	3.980	50.000	110.000	250.065	6.341	937.561	250.065	6.341
Mean +2.00 SD	10.117	4.004	50.000	110.000	262.492	6.597	983.996	262.492	6.597
Mean -2.00 SD	9.895	3.952	50.000	110.000	238.386	5.986	884.030	238.386	5.986
Minimum	9.950	3.960	50.000	110.000	244.158	6.125	900.484	244.158	6.125
Maximum	10.090	3.990	50.000	110.000	257.686	6.494	969.527	257.686	6.494

	% Strain at Auto. Break (%)	Modulus (MaxYoung) (MPa)	% Strain @ Pre-set 7 MPa (%)	Load/Width at Max.Load (N/mm)	Load/Width at Max.Load (N/50mm)	Displacement at Max.Load (mm)	Load/Width at Auto. Break (N/50 mm)
Excluded	680.452	8.348		20.610	1030.478	340.226	1030.478
2 2	937.561	7.439		25.301	1265.062	468.780	1265.062
3 3	937.766	10.517		25.846	1292.307	468.883	1292.307
4 4	924.728	6.395		24.440	1222.010	462.364	1222.010
5 5	900.484	6.854		24.426	1221.315	450.242	1221.315
6 6	969.527	9.553		25.132	1256.606	484.763	1256.606
Mean	934.013	8.151		25.029	1251.460	467.007	1251.460
S.D.	24.991	1.791		0.605	30.233	12.496	30.233
C.V.	2.676	21.975		2.416	2.416	2.676	2.416
Median	937.561	7.439		25.132	1256.606	468.780	1256.606
Mean +2.00 SD	983.996	11.734		26.238	1311.925	491.998	1311.925
Mean -2.00 SD	884.030	4.569		23.820	1190.995	442.015	1190.995
Minimum	900.484	6.395		24.426	1221.315	450.242	1221.315
Maximum	969.527	10.517		25.846	1292.307	484.763	1292.307

Appendix 5 Test reports from the determination of torsional modulus versus temperature

Danish Technological Institute
Plastics Technology

Determination of torsional modulus vs. temperature acc. to ISO 458/1-1985

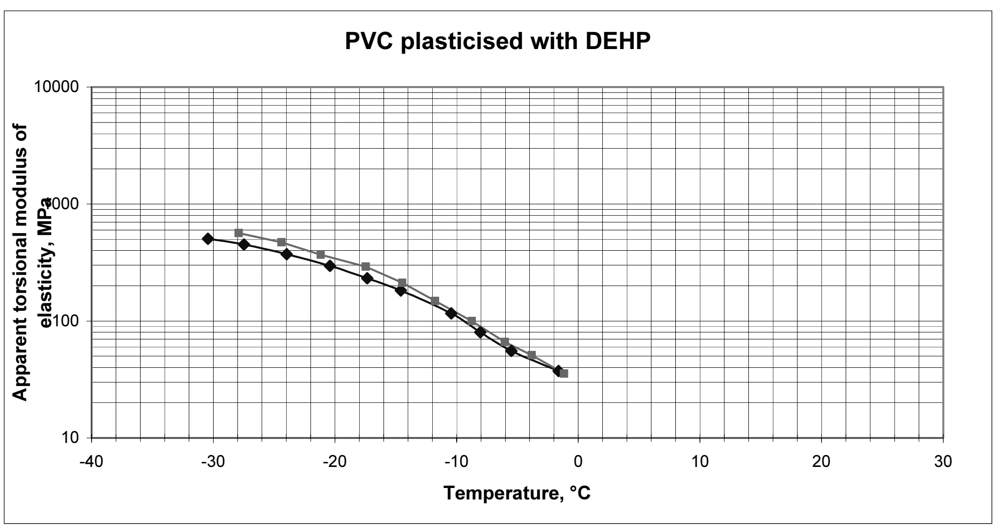
Version:	1	File name:	torsionPVC36
Date:	27 June 2001		
Operator:	fgu		
Lab. No.:	T1154		
Project No.:	13102005/33		

Compound No.: PVC: 036 - DEHP

Diameter of wheel (D1) [mm]	160	160
Length of the string [mm]	0,3	0,3
Average (R)	80,15	80,15
Load (W) total [g]	384	384
Load (W) [N]	3,76704	3,76704
Aplied torque (M) [Nm]	301,92826	301,92826
Span distance (L) [mm]	40	40
Width of specimen (b) [mm]	6,29	6,36
Thickness of specimen (d) [mm]	3,99	3,98
Factor (b/d)	1,58	1,60
Table value, μ	3,23	3,26

Reading No.	Deflection angle [θ] degrees [º]	Temperature [°C]	Torsion (T) [MPa]
1	17	-30,44	504,79
2	19	-27,48	451,66
3	23	-23,96	373,11
4	29	-20,41	295,91
5	37	-17,34	231,93
6	47	-14,59	182,58
7	74	-10,45	115,97
8	107	-8,06	80,20
9	155	-5,51	55,36
10	230	-1,62	37,31

Reading No.	Deflection angle [θ] degrees [º]	Temperature [°C]	Torsion (T) [MPa]
1	15	-27,90	564,83
2	18	-24,40	470,69
3	23	-21,17	368,37
4	29	-17,47	292,15
5	40	-14,47	211,81
6	57	-11,78	148,64
7	85	-8,75	99,68
8	128	-6,04	66,19
9	166	-3,82	51,04
10	238	-1,18	35,60



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Plastics Technology

Determination of torsional modulus vs. temperature acc. to ISO 458/1-1985

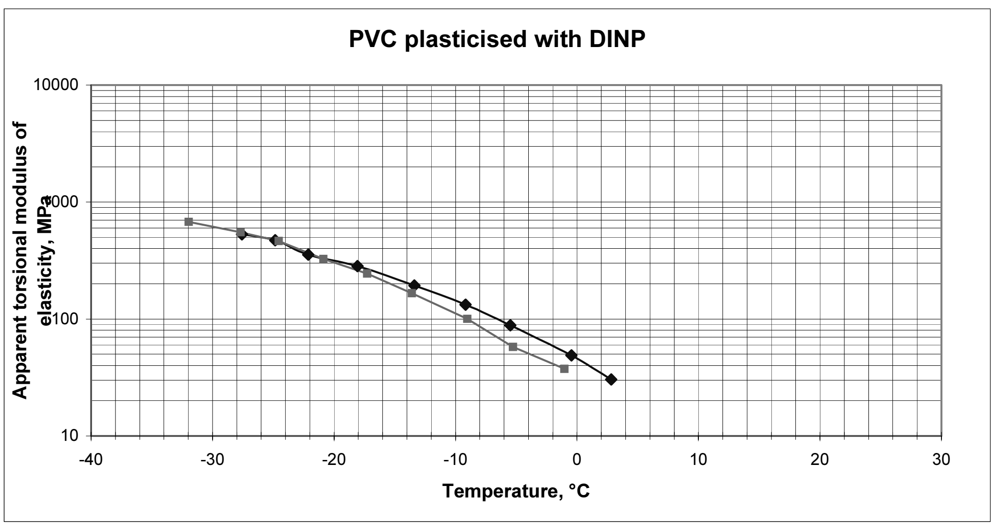
Version:	1	File name:	torsionPVC37
Date:	26 June 2001		
Operator:	fgu		
Lab. No.:	T1154		
Project No.:	13102005/33		

Compound No.: PVC: 037 - DINP

Diameter of wheel (D1) [mm]	160	160
Length of the string [mm]	0,3	0,3
Average (R)	80,15	80,15
Load (W) total [g]	200	384
Load (W) [N]	1,962	3,76704
Aplied torque (M) [Nm]	157,2543	301,92826
Span distance (L) [mm]	40	40
Width of specimen (b) [mm]	6,44	6,18
Thickness of specimen (d) [mm]	4,01	3,99
Factor (b/d)	1,61	1,55
Table value, μ	3,27	3,2

Reading No.	Deflection angle [θ] degrees [º]	Temperature [°C]	Torsion (T) [MPa]
1	8	-27,59	530,98
2	9	-24,85	471,98
3	12	-22,12	353,98
4	15	-18,07	283,19
5	22	-13,39	193,08
6	32	-9,17	132,74
7	48	-5,50	88,50
8	87	-0,45	48,83
9	140	2,82	30,34

Reading No.	Deflection angle [θ] degrees [º]	Temperature [°C]	Torsion (T) [MPa]
1	13	-31,97	678,16
2	16	-27,69	551,01
3	19	-24,55	464,00
4	27	-20,87	326,52
5	36	-17,27	244,89
6	53	-13,60	166,34
7	88	-9,03	100,18
8	153	-5,27	57,62
9	235	-1,03	37,52



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Determination of torsional modulus vs. temperature acc. to ISO 458/1-1985

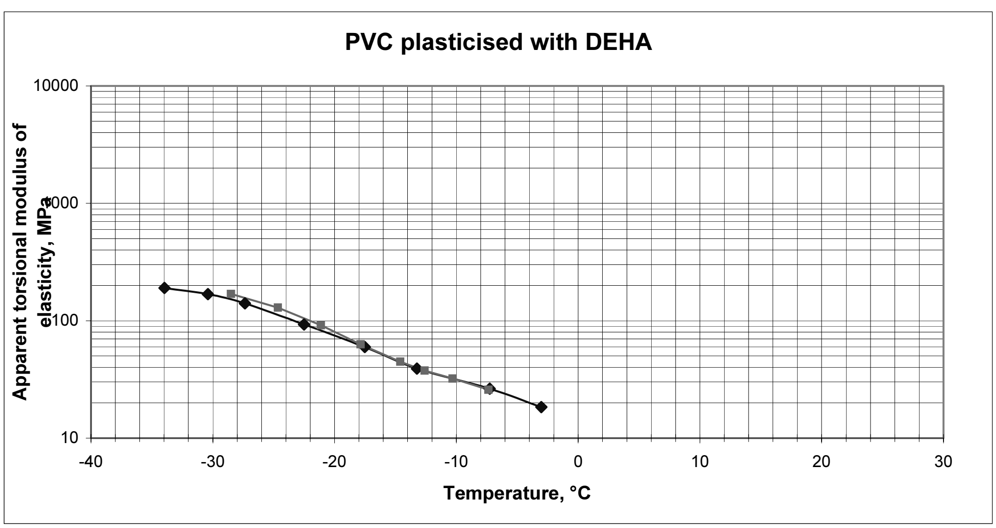
Version:	1	File name:	torsionPVC38
Date:	27 June 2001		
Operator:	fgu		
Lab. No.:	T1154		
Project No.:	13102005/33		

Compound No.: PVC: 038 - DEHA

Diameter of wheel (D1) [mm]	160	160
Length of the string [mm]	0,3	0,3
Average (R)	80,15	80,15
Load (W) total [g]	200	200
Load (W) [N]	1,962	1,962
Aplied torque (M) [Nm]	157,2543	157,2543
Span distance (L) [mm]	40	40
Width of specimen (b) [mm]	6,35	6,38
Thickness of specimen (d) [mm]	4	3,98
Factor (b/d)	1,59	1,60
Table value, µ	3,25	3,26

Reading No.	Deflection angle [θ] degrees [º]	Temperature [°C]	Torsion (T) [MPa]
1	23	-33,97	189,87
2	26	-30,39	167,97
3	31	-27,37	140,87
4	47	-22,51	92,92
5	73	-17,52	59,82
6	112	-13,23	38,99
7	166	-7,26	26,31
8	238	-3,02	18,35

Reading No.	Deflection angle [θ] degrees [º]	Temperature [°C]	Torsion (T) [MPa]
1	26	-28,51	169,19
2	34	-24,66	129,38
3	48	-21,13	91,64
4	70	-17,86	62,84
5	98	-14,60	44,89
6	117	-12,61	37,60
7	137	-10,31	32,11
8	170	-7,37	25,88



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Plastics Technology

Determination of torsional modulus vs. temperature acc. to ISO 458/1-1985

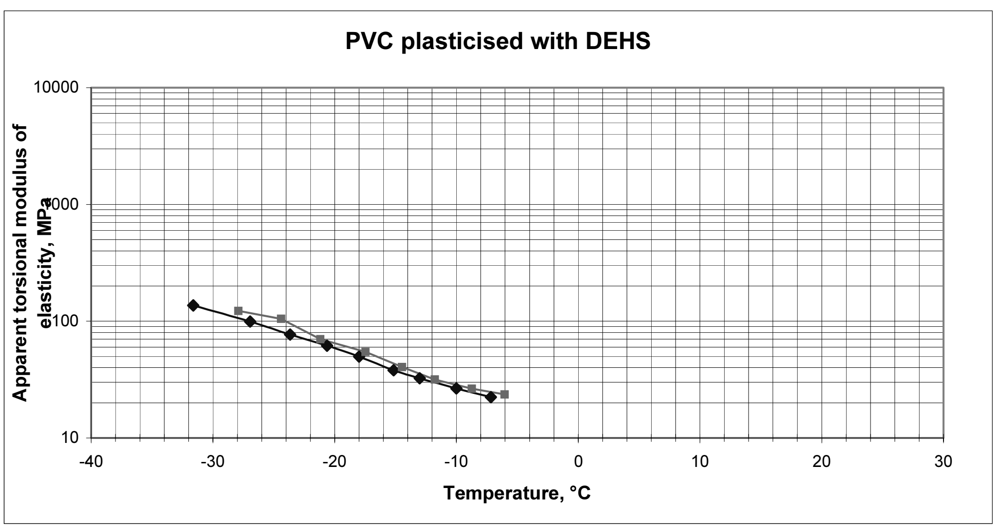
Version:	1	File name:	torsionPVC39
Date:	27 June 2001		
Operator:	fgu		
Lab. No.:	T1154		
Project No.:	13102005/33		

Compound No.: PVC: 039 - DEHS

Diameter of wheel (D1) [mm]	160	160
Length of the string [mm]	0,3	0,3
Average (R)	80,15	80,15
Load (W) total [g]	200	200
Load (W) [N]	1,962	1,962
Aplied torque (M) [Nm]	157,2543	157,2543
Span distance (L) [mm]	40	40
Width of specimen (b) [mm]	6,34	6,34
Thickness of specimen (d) [mm]	4	3,99
Factor (b/d)	1,59	1,59
Table value, µ	3,25	3,25

Reading No.	Deflection angle [θ] degrees [º]	Temperature [°C]	Torsion (T) [MPa]
1	32	-31,61	136,69
2	44	-26,94	99,41
3	57	-23,66	76,74
4	71	-20,63	61,61
5	88	-18,00	49,70
6	115	-15,17	38,03
7	135	-13,03	32,40
8	165	-10,00	26,51
9	196	-7,18	22,32

Reading No.	Deflection angle [θ] degrees [º]	Temperature [°C]	Torsion (T) [MPa]
1	36	-27,90	122,42
2	42	-24,40	104,93
3	63	-21,17	69,95
4	81	-17,47	54,41
5	109	-14,47	40,43
6	139	-11,78	31,70
7	167	-8,75	26,39
8	187	-6,04	23,57



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Plastics Technology

Determination of torsional modulus vs. temperature acc. to ISO 458/1-1985

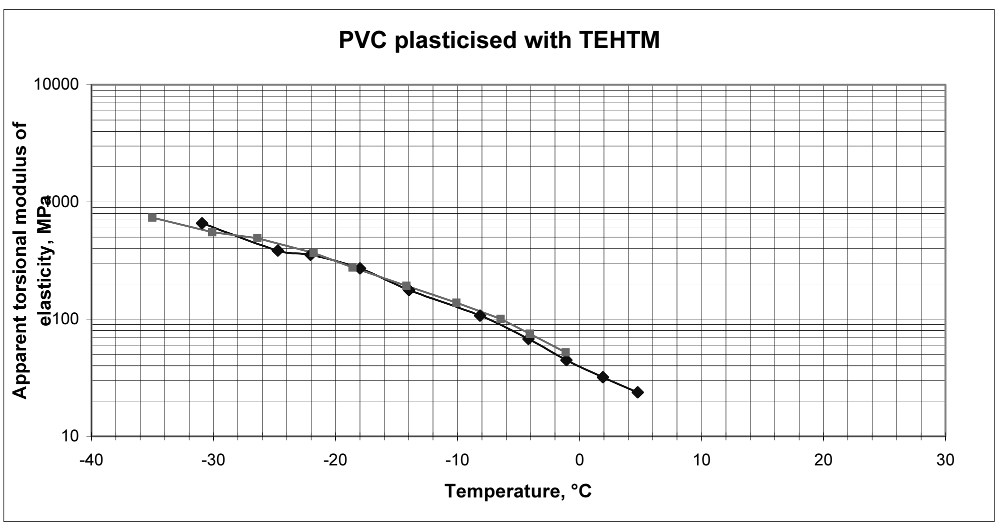
Version:	1	File name:	torsionPVC40
Date:	27 June 2001		
Operator:	fgu		
Lab. No.:	T1154		
Project No.:	13102005/33		

Compound No.: PVC: 040 - TEHTM

Diameter of wheel (D1) [mm]	160	160
Length of the string [mm]	0,3	0,3
Average (R)	80,15	80,15
Load (W) total [g]	200	200
Load (W) [N]	1,962	1,962
Aplied torque (M) [Nm]	157,2543	157,2543
Span distance (L) [mm]	40	40
Width of specimen (b) [mm]	6,15	6,35
Thickness of specimen (d) [mm]	4	3,98
Factor (b/d)	1,54	1,60
Table value, µ	3,18	3,26

Reading No.	Deflection angle [θ] degrees [º]	Temperature [°C]	Torsion (T) [MPa]
1	7	-30,94	658,34
2	12	-24,72	384,03
3	13	-22,04	354,49
4	17	-18,00	271,08
5	26	-13,97	177,25
6	43	-8,15	107,17
7	68	-4,19	67,77
8	103	-1,08	44,74
9	144	1,93	32,00
10	194	4,78	23,75

Reading No.	Deflection angle [θ] degrees [º]	Temperature [°C]	Torsion (T) [MPa]
1	6	-35,02	736,61
2	8	-30,10	552,46
3	9	-26,39	491,08
4	12	-21,79	368,31
5	16	-18,60	276,23
6	23	-14,19	192,16
7	32	-10,08	138,12
8	44	-6,46	100,45
9	59	-4,06	74,91
10	85	-1,13	52,00
11	122	1,59	36,23
12	160	4,69	27,62



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Plastics Technology

Determination of torsional modulus vs. temperature acc. to ISO 458/1-1985

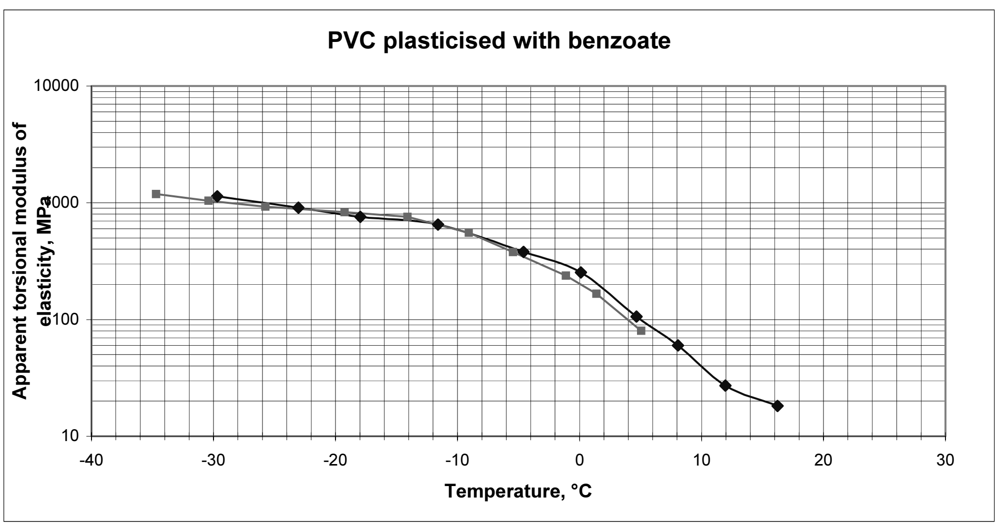
Version: 1 File name: torsionPVC41
Date: 27 June 2001
Operator: fgu
Lab. No.: T1154
Project No.: 13102005/33

Compound No.: PVC: 041 - Benzoate

Diameter of wheel (D1) [mm]	160	160
Length of the string [mm]	0,3	0,3
Average (R)	80,15	80,15
Load (W) total [g]	200	384
Load (W) [N]	1,962	3,76704
Aplied torque (M) [Nm]	157,2543	301,92826
Span distance (L) [mm]	40	40
Width of specimen (b) [mm]	6,19	6,38
Thickness of specimen (d) [mm]	4	4
Factor (b/d)	1,55	1,60
Table value, µ	3,2	3,26

Reading No.	Deflection angle [θ] degrees [º]	Temperature [°C]	Torsion (T) [MPa]
1	4	-29,70	1137,50
2	5	-23,04	910,00
3	6	-17,96	758,33
4	7	-11,60	650,00
5	12	-4,59	379,17
6	18	0,11	252,78
7	43	4,68	105,81
8	76	8,08	59,87
9	168	11,96	27,08
10	250	16,23	18,20

Reading No.	Deflection angle [θ] degrees [º]	Temperature [°C]	Torsion (T) [MPa]
1	7	-34,71	1188,55
2	8	-30,42	1039,98
3	9	-25,74	924,43
4	10	-19,25	831,98
5	11	-14,11	756,35
6	15	-9,08	554,66
7	22	-5,44	378,17
8	35	-1,12	237,71
9	50	1,39	166,40
10	104	5,05	80,00
11	228	9,08	36,49



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Plastics Technology

Determination of torsional modulus vs. temperature acc. to ISO 458/1-1985

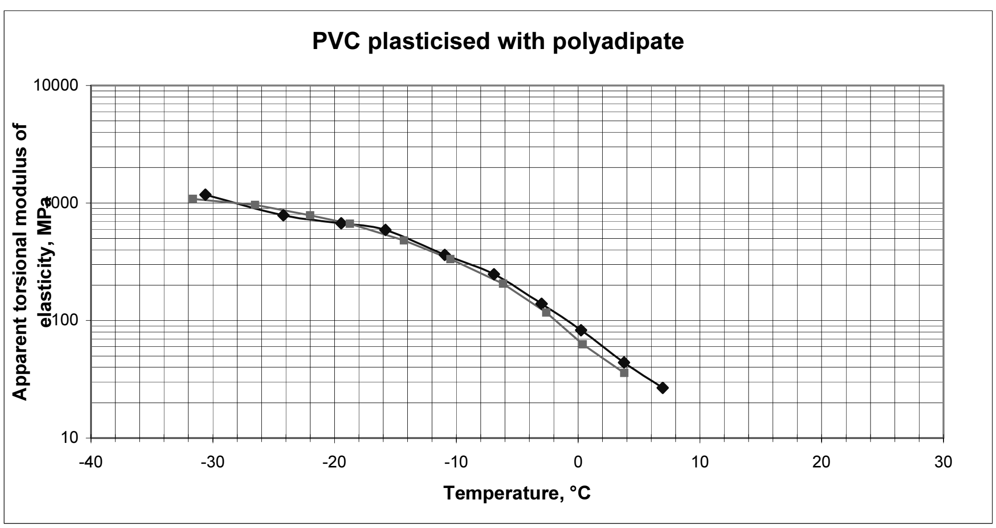
Version:	1	File name: torsionPVC42
Date:	27 June 2001	
Operator:	fgu	
Lab. No.:	T1154	
Project No.:	13102005/33	

Compound No.: PVC: 042 - Polyadipate

Diameter of wheel (D1) [mm]	160	160
Length of the string [mm]	0,3	0,3
Average (R)	80,15	80,15
Load (W) total [g]	200	384
Load (W) [N]	1,962	3,76704
Aplied torque (M) [Nm]	157,2543	301,92826
Span distance (L) [mm]	40	40
Width of specimen (b) [mm]	6,06	6,25
Thickness of specimen (d) [mm]	3,99	3,99
Factor (b/d)	1,52	1,57
Table value, µ	3,18	3,22

Reading No.	Deflection angle [θ] degrees [º]	Temperature [°C]	Torsion (T) [MPa]
1	4	-30,61	1178,02
2	6	-24,21	785,35
3	7	-19,46	673,16
4	8	-15,83	589,01
5	13	-10,96	362,47
6	19	-6,91	248,00
7	34	-3,01	138,59
8	57	0,23	82,67
9	107	3,77	44,04
10	176	6,94	26,77

Reading No.	Deflection angle [θ] degrees [º]	Temperature [°C]	Torsion (T) [MPa]
1	8	-31,62	1082,90
2	9	-26,53	962,58
3	11	-22,01	787,56
4	13	-18,74	666,40
5	18	-14,30	481,29
6	26	-10,49	333,20
7	42	-6,16	206,27
8	74	-2,61	117,07
9	138	0,38	62,78
10	242	3,78	35,80



Danish Technological Institute
Plastics Technology

Determination of torsional modulus vs. temperature acc. to ISO 458/1-1985

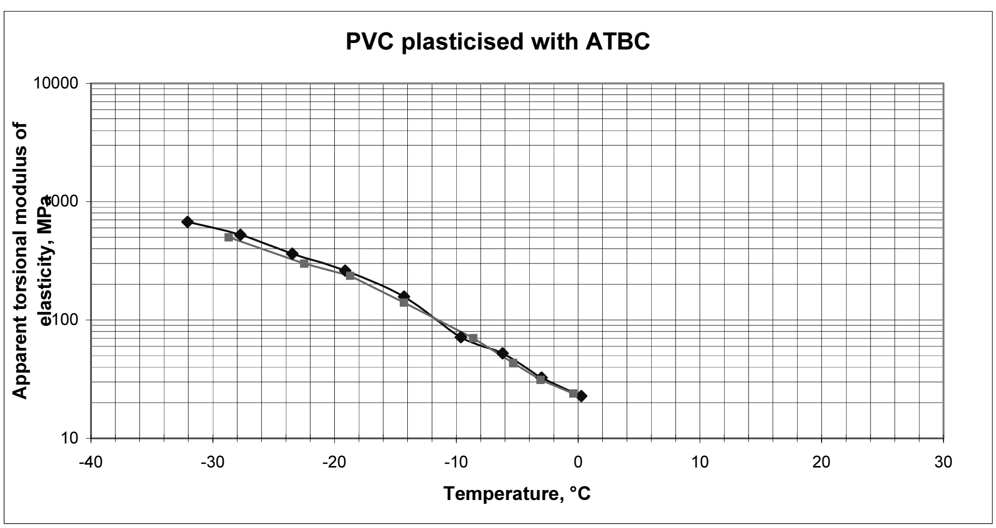
Version: 1 File name: torsionPVC43
Date: 27 June 2001
Operator: fgu
Lab. No.: T1154
Project No.: 13102005/33

Compound No.: PVC: 043 - ATBC

Diameter of wheel (D1) [mm]	160	160
Length of the string [mm]	0,3	0,3
Average (R)	80,15	80,15
Load (W) total [g]	200	200
Load (W) [N]	1,962	1,962
Aplied torque (M) [Nm]	157,2543	157,2543
Span distance (L) [mm]	40	40
Width of specimen (b) [mm]	6,06	6,28
Thickness of specimen (d) [mm]	3,99	3,99
Factor (b/d)	1,52	1,57
Table value, μ	3,18	3,22

Reading No.	Deflection angle [θ] degrees [º]	Temperature [°C]	Torsion (T) [MPa]
1	7	-32,08	673,16
2	9	-27,72	523,57
3	13	-23,46	362,47
4	18	-19,12	261,78
5	30	-14,29	157,07
6	66	-9,62	71,40
7	90	-6,21	52,36
8	145	-3,01	32,50
9	207	0,25	22,76

Reading No.	Deflection angle [θ] degrees [º]	Temperature [°C]	Torsion (T) [MPa]
1	9	-28,69	498,95
2	15	-22,50	299,37
3	19	-18,72	236,34
4	32	-14,30	140,33
5	64	-8,60	70,16
6	104	-5,33	43,18
7	144	-3,08	31,18
8	188	-0,40	23,89



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Determination of torsional modulus vs. temperature acc. to ISO 458/1-1985

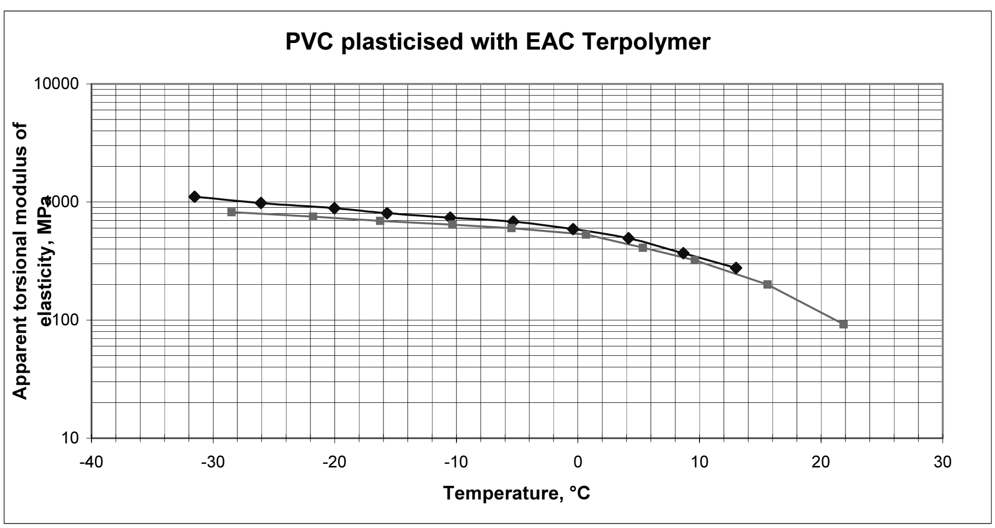
Version:	1	File name:	torsionPVC106
Date:	29 June 2001		
Operator:	fgu		
Lab. No.:	T1154		
Project No.:	13102005/33		

Compound No.: PVC: 106 - EAC Terpolymer

Diameter of wheel (D1) [mm]	160	160
Length of the string [mm]	0,3	0,3
Average (R)	80,15	80,15
Load (W) total [g]	384	384
Load (W) [N]	3,76704	3,76704
Aplied torque (M) [Nm]	301,92826	301,92826
Span distance (L) [mm]	40	40
Width of specimen (b) [mm]	6,24	6,14
Thickness of specimen (d) [mm]	3,96	3,97
Factor (b/d)	1,58	1,55
Table value, μ	3,23	3,2

Reading No.	Deflection angle [θ] degrees [º]	Temperature [°C]	Torsion (T) [MPa]
1	8	-31,52	1106,04
2	9	-26,06	983,15
3	10	-20,03	884,83
4	11	-15,70	804,39
5	12	-10,50	737,36
6	13	-5,32	680,64
7	15	-0,39	589,89
8	18	4,17	491,57
9	24	8,67	368,68
10	32	13,00	276,51
11	54	17,92	163,86
12	86	21,51	102,89
13	176	25,72	50,27

Reading No.	Deflection angle [θ] degrees [º]	Temperature [°C]	Torsion (T) [MPa]
1	11	-28,47	818,94
2	12	-21,77	750,69
3	13	-16,27	692,95
4	14	-10,32	643,45
5	15	-5,45	600,55
6	17	0,66	529,90
7	22	5,35	409,47
8	28	9,62	321,73
9	45	15,60	200,18
10	98	21,86	91,92
11	145	26,28	62,13



Danish Technological Institute
Plastics Technology

Determination of torsional modulus vs. temperature acc. to ISO 458/1-1985

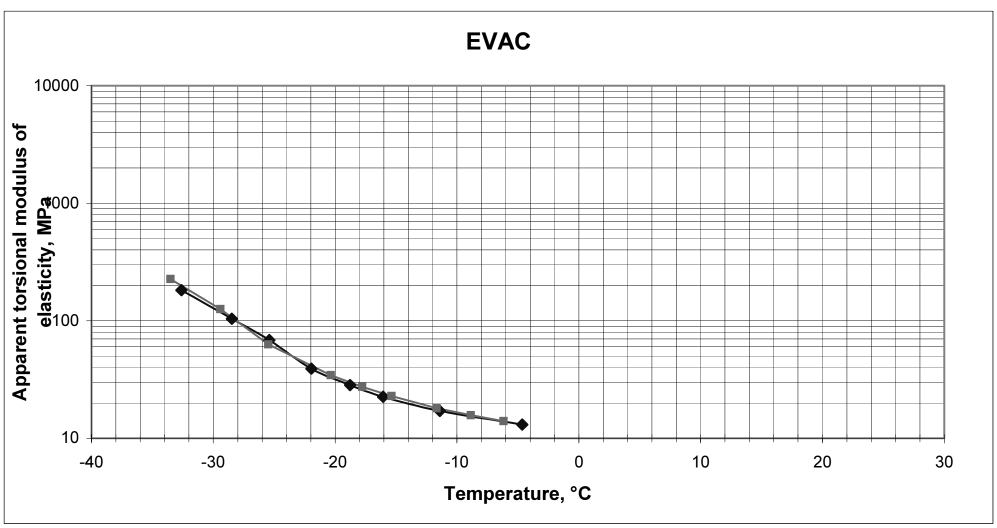
Version:	1	File name:	torsionEVAC
Date:	29 June 2001		
Operator:	fgu		
Lab. No.:	T1154		
Project No.:	13102005/33		

Compound No.: EVAC

Diameter of wheel (D1) [mm]	160	160
Length of the string [mm]	0,3	0,3
Average (R)	80,15	80,15
Load (W) total [g]	100	100
Load (W) [N]	0,981	0,981
Aplied torque (M) [Nm]	78,62715	78,62715
Span distance (L) [mm]	40	40
Width of specimen (b) [mm]	6,37	6,3
Thickness of specimen (d) [mm]	3,99	3,96
Factor (b/d)	1,60	1,59
Table value, μ	3,26	3,25

Reading No.	Deflection angle [θ] degrees [º]	Temperature [°C]	Torsion (T) [MPa]
1	12	-32,61	182,20
2	21	-28,47	104,11
3	32	-25,41	68,32
4	56	-21,95	39,04
5	77	-18,78	28,39
6	97	-16,07	22,54
7	128	-11,42	17,08
8	167	-4,65	13,09

Reading No.	Deflection angle [θ] degrees [º]	Temperature [°C]	Torsion (T) [MPa]
1	10	-33,51	226,83
2	18	-29,42	126,01
3	36	-25,49	63,01
4	66	-20,37	34,37
5	83	-17,78	27,33
6	99	-15,37	22,91
7	126	-11,68	18,00
8	144	-8,87	15,75
9	162	-6,18	14,00



Appendix 6 Test reports from the tensile test of roll milled films (in Danish only)

TRÆKPRØVNING

LOGBOG FOR TRÆKPRØVEAPPARAT / KUNDE						
ORDRENR.	DP 01036 Clear 97 DOP					
KVALITET / FARVE						
TYKKELSE	250 μm					
NARV						
ANALYSERESULTATER	1	2	3	4	5	GNM.
TRÆKSTYRKE MPa -LÆNGDERETNING	20,48	19,65	20,43	19,97	19,88	20,08
- TVÆRRETNING						
BRUDFORLÆNGELSE % - LÆNGDERETNING	426	414	408	412	415	415
- TVÆRRETNING						
VIDERE-RIVESTYRKE N/mm - LÆNGDERETNING						
- TVÆRRETNING						
10 - 50 % FORLÆNGELSE - LÆNGDERETNING						
- TVÆRRETNING						

I TILFÆLDE AF, AT DER IKKE KØRES EFTER DE FASTSATTE NORMER, SKAL DETTE ANFØRES UNDER BEMÆRKNINGER. ANALYSEBETINGELSERNE BESKRIVES.

TRÆKSTYRKE ISO 527-1 og ISO 527-3
BRUDFORLÆNGELSE ISO 527-1 og ISO 527-3
VIDERE-RIVESTYRKE DIN 53363
10 / 50 % FORLÆNGELSE BS 3924 : 1978

BEMÆRKNINGER: ____________________

DATO 14/5-01

UDFØRT AF JO

Reference:

DS/EN ISO 9001:2000 i 2216

TRÆKPRØVNING

LOGBOG FOR TRÆKPRØVEAPPARAT / KUNDE						
ORDRENR.	DP 01037 Clear 97 DINP					
KVALITET / FARVE						
TYKKELSE	210 µm					
NARV						
ANALYSERESULTATER	1	2	3	4	5	GNM.
TRÆKSTYRKE MPa -LÆNGDERETNING	20,22	20,66	20,37	20,69	20,87	20,56
- TVÆRRETNING						
BRUDFORLÆNGELSE % - LÆNGDERETNING	387	381	384	385	369	381
- TVÆRRETNING						
VIDERE-RIVESTYRKE N/mm - LÆNGDERETNING						
- TVÆRRETNING						
10 - 50 % FORLÆNGELSE - LÆNGDERETNING						
- TVÆRRETNING						

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BEMÆRKNINGER:______________________________

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DATO___14/5-01

UDFØRT AF____JO______

Reference:

DS/EN ISO 9001:2000 i 2216

TRÆKPRØVNING

LOGBOG FOR TRÆKPRØVEAPPARAT / KUNDE						
ORDRENR.	DP 01038 Clear 97 DOA					
KVALITET / FARVE						
TYKKELSE	220 µm					
NARV						
ANALYSERESULTATER	1	2	3	4	5	GNM.
TRÆKSTYRKE MPa -LÆNGDERETNING	17,75	18,23	18,40	17,22	18,26	17,97
- TVÆRRETNING						
BRUDFORLÆNGELSE % - LÆNGDERETNING	401	406	415	402	431	411
- TVÆRRETNING						
VIDERE-RIVESTYRKE N/mm - LÆNGDERETNING						
- TVÆRRETNING						
10 - 50 % FORLÆNGELSE - LÆNGDERETNING						
- TVÆRRETNING						

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VIDERE-RIVESTYRKE DIN 53363
10 / 50 % FORLÆNGELSE BS 3924 : 1978

BEMÆRKNINGER: ______________________________

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DATO ___14/5-01

UDFØRT AF ____JO______

Reference:

DS/EN ISO 9001:2000 i 2216

TRÆKPRØVNING

LOGBOG FOR TRÆKPRØVEAPPARAT / KUNDE						
ORDRENR.	DP 01039 Clear 97 DOS					
KVALITET / FARVE						
TYKKELSE	220 µm					
NARV						
ANALYSERESULTATER	1	2	3	4	5	GNM.
TRÆKSTYRKE MPa -LÆNGDERETNING	14,97	14,23	14,33	14,38	14,17	14,41
- TVÆRRETNING						
BRUDFORLÆNGELSE % - LÆNGDERETNING	362	348	345	341	355	350
- TVÆRRETNING						
VIDERE-RIVESTYRKE N/mm - LÆNGDERETNING						
- TVÆRRETNING						
10 - 50 % FORLÆNGELSE - LÆNGDERETNING						
- TVÆRRETNING						

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BRUDFORLÆNGELSE ISO 527-1 og ISO 527-3
VIDERE-RIVESTYRKE DIN 53363
10 / 50 % FORLÆNGELSE BS 3924 : 1978

BEMÆRKNINGER:____

DATO 14/5-01

UDFØRT AF JO

Reference:

DS/EN ISO 9001:2000 i 2216

TRÆKPRØVNING

LOGBOG FOR TRÆKPRØVEAPPARAT / KUNDE						
ORDRENR.	DP 01040 Clear 97 TOTM					
KVALITET / FARVE						
TYKKELSE	220 µm					
NARV						
ANALYSERESULTATER	1	2	3	4	5	GNM.
TRÆKSTYRKE MPa -LÆNGDERETNING	18,54	18,41	18,00	18,49	17,48	18,18
- TVÆRRETNING						
BRUDFORLÆNGELSE % - LÆNGDERETNING	382	381	372	385	375	379
- TVÆRRETNING						
VIDERE-RIVESTYRKE N/mm - LÆNGDERETNING						
- TVÆRRETNING						
10 - 50 % FORLÆNGELSE - LÆNGDERETNING						
- TVÆRRETNING						

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VIDERE-RIVESTYRKE DIN 53363
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BEMÆRKNINGER:____

DATO 14/5-01

UDFØRT AF JO

Reference:

DS/EN ISO 9001:2000 i 2216

TRÆKPRØVNING

LOGBOG FOR TRÆKPRØVEAPPARAT / KUNDE						
ORDRENR.	DP 01041 Clear 97 Benzoflex 9-88					
KVALITET / FARVE						
TYKKELSE	185 µm					
NARV						
ANALYSERESULTATER	1	2	3	4	5	GNM.
TRÆKSTYRKE MPa -LÆNGDERETNING	21,75	21,81	22,88	22,53	20,55	21,90
- TVÆRRETNING						
BRUDFORLÆNGELSE % - LÆNGDERETNING	292	299	324	296	272	296
- TVÆRRETNING						
VIDERE-RIVESTYRKE N/mm - LÆNGDERETNING						
- TVÆRRETNING						
10 - 50 % FORLÆNGELSE - LÆNGDERETNING						
- TVÆRRETNING						

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VIDERE-RIVESTYRKE DIN 53363
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DATO___14/5-01

UDFØRT AF____JO______

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DS/EN ISO 9001:2000 i 2216

TRÆKPRØVNING

LOGBOG FOR TRÆKPRØVEAPPARAT / KUNDE						
ORDRENR.	DP 01042 Clear 97 Diolpate					
KVALITET / FARVE						
TYKKELSE	220 µm					
NARV						
ANALYSERESULTATER	1	2	3	4	5	GNM.
TRÆKSTYRKE MPa -LÆNGDERETNING	20,10	20,36	21,26	20,17	19,03	20,18
- TVÆRRETNING						
BRUDFORLÆNGELSE % - LÆNGDERETNING	370	368	407	369	360	374
- TVÆRRETNING						
VIDERE-RIVESTYRKE N/mm - LÆNGDERETNING						
- TVÆRRETNING						
10 - 50 % FORLÆNGELSE - LÆNGDERETNING						
- TVÆRRETNING						

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VIDERE-RIVESTYRKE DIN 53363
10 / 50 % FORLÆNGELSE BS 3924 : 1978

BEMÆRKNINGER: ______________________________

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DATO 14/5-01

UDFØRT AF JO

Reference:

DS/EN ISO 9001:2000 i 2216

TRÆKPRØVNING

LOGBOG FOR TRÆKPRØVEAPPARAT / KUNDE						
ORDRENR.	DP 01043 Clear 97 Citroflex					
KVALITET / FARVE						
TYKKELSE	220 µm					
NARV						
ANALYSERESULTATER	1	2	3	4	5	GNM.
TRÆKSTYRKE MPa -LÆNGDERETNING	18,72	19,45	19,33	19,64	19,70	19,36
- TVÆRRETNING						
BRUDFORLÆNGELSE % - LÆNGDERETNING	336	384	355	378	403	371
- TVÆRRETNING						
VIDERE-RIVESTYRKE N/mm - LÆNGDERETNING						
- TVÆRRETNING						
10 - 50 % FORLÆNGELSE - LÆNGDERETNING						
- TVÆRRETNING						

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Reference:

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TRÆKPRØVNING

LOGBOG FOR TRÆKPRØVEAPPARAT / KUNDE						
ORDRENR.	DP 01106 Clear 97 Elvaloy					
KVALITET / FARVE						
TYKKELSE	400 µm					
NARV						
ANALYSERESULTATER	1	2	3	4	5	GNM.
TRÆKSTYRKE MPa -LÆNGDERETNING	27,67	28,22	27,70	28,88	26,04	27,70
- TVÆRRETNING						
BRUDFORLÆNGELSE % - LÆNGDERETNING	329	331	356	347	304	333
- TVÆRRETNING						
VIDERE-RIVESTYRKE N/mm - LÆNGDERETNING						
- TVÆRRETNING						
10 - 50 % FORLÆNGELSE - LÆNGDERETNING						
- TVÆRRETNING						

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BEMÆRKNINGER: ____________________

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DATO ___14/5-01

UDFØRT AF____JO______

Reference:

DS/EN ISO 9001:2000 i 2216

Appendix 7 Light transmission graphs

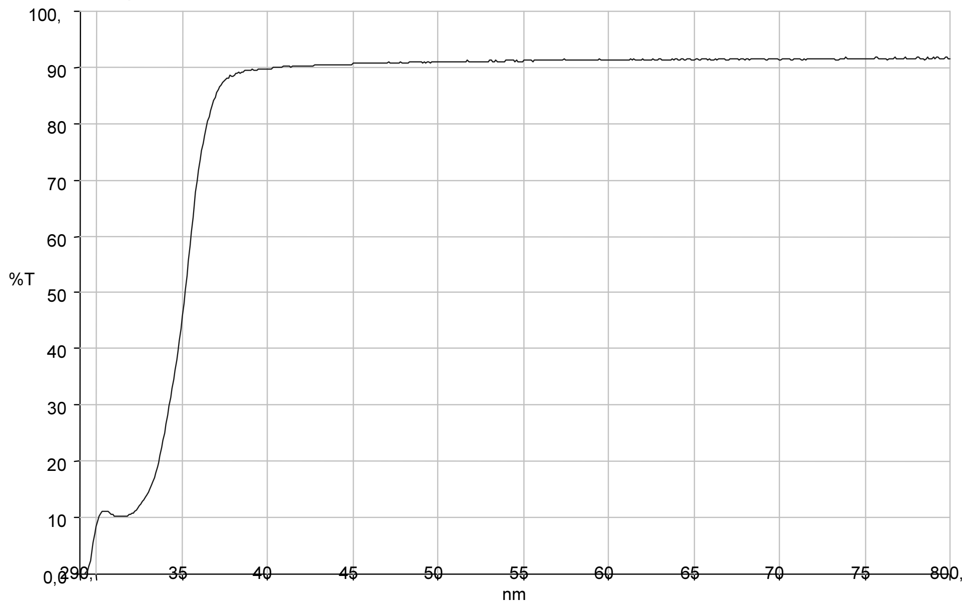
Light transmission of plasticised PVC film

DEHP (DP01-036)

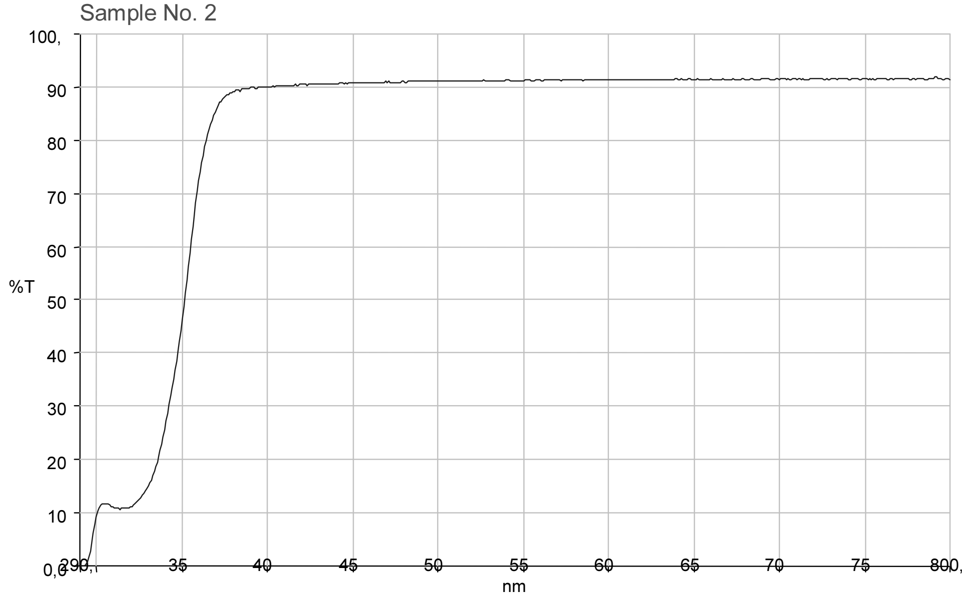
3601207750

Sample No. 1

16.05.2001



Sample No. 2

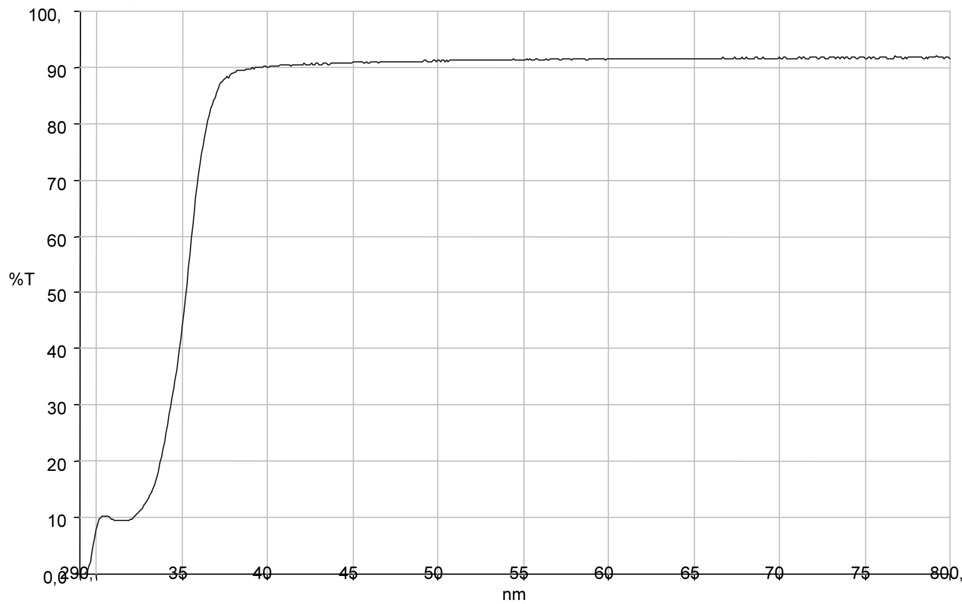


Light transmission of plasticised PVC film

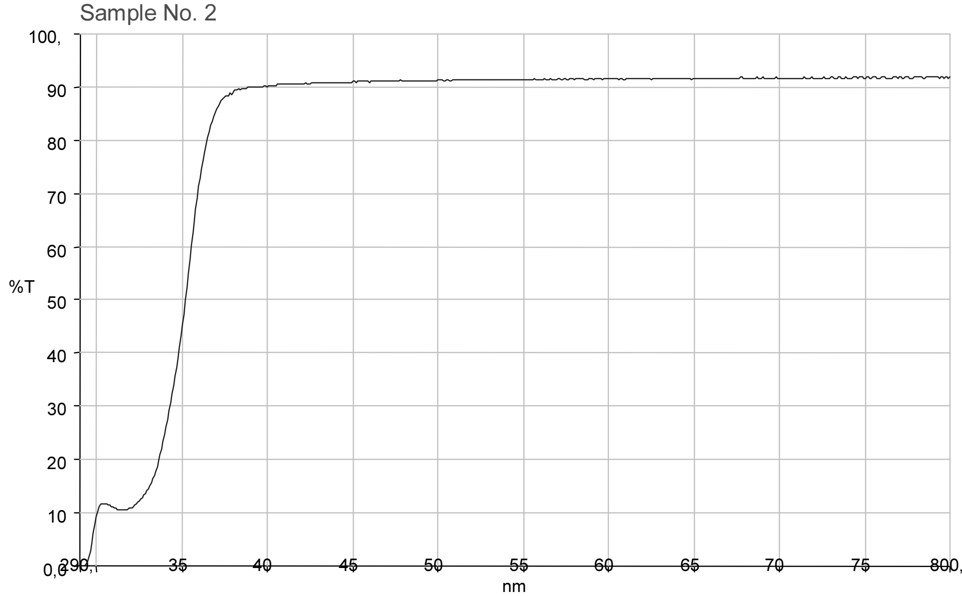
DINP (DP01-037)

3601207750
16.05.2001

Sample No. 1



Sample No. 2

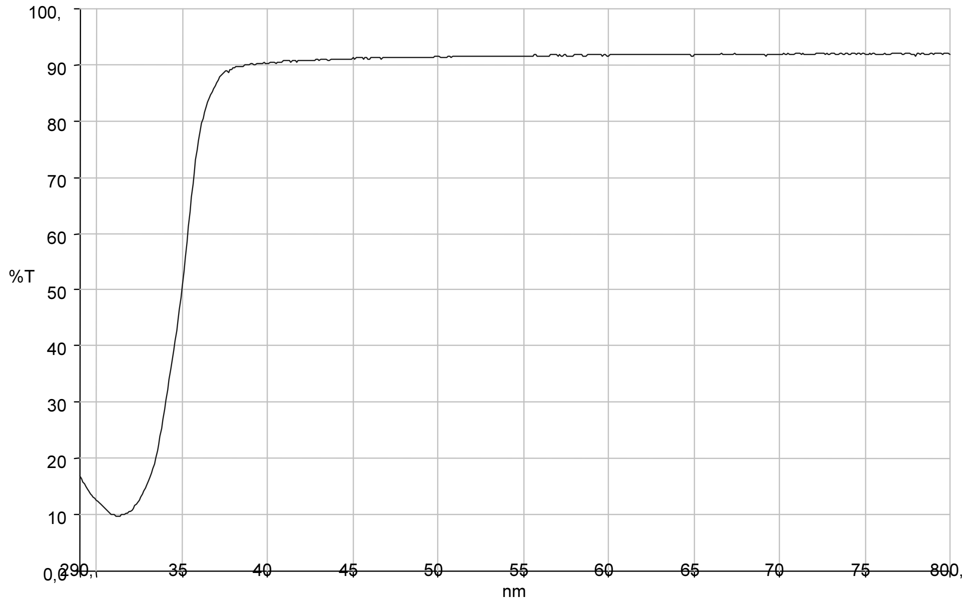


Light transmission of plasticised PVC film

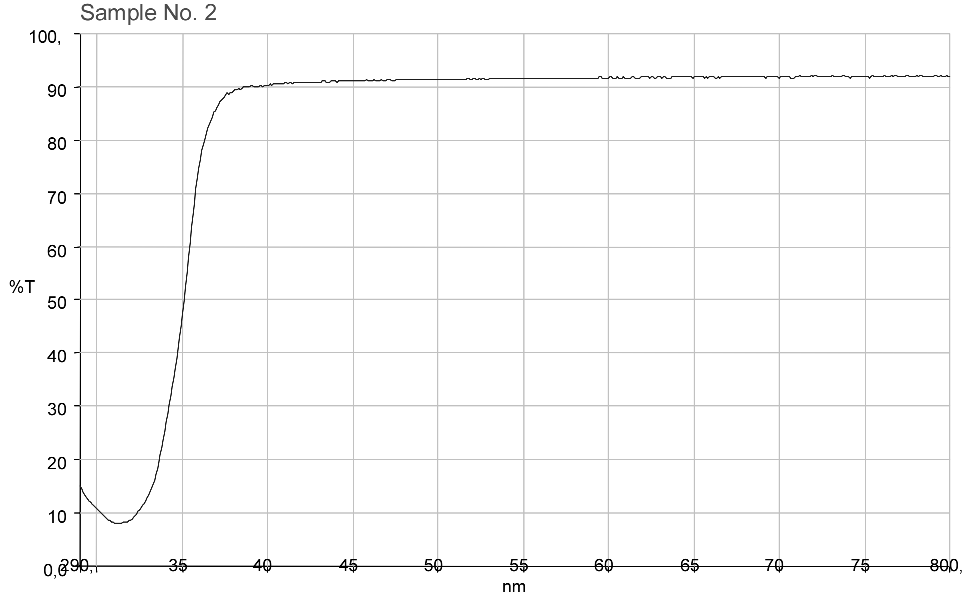
DEHA (DP01-038)

3601207750
16.05.2001

Sample No. 1



Sample No. 2

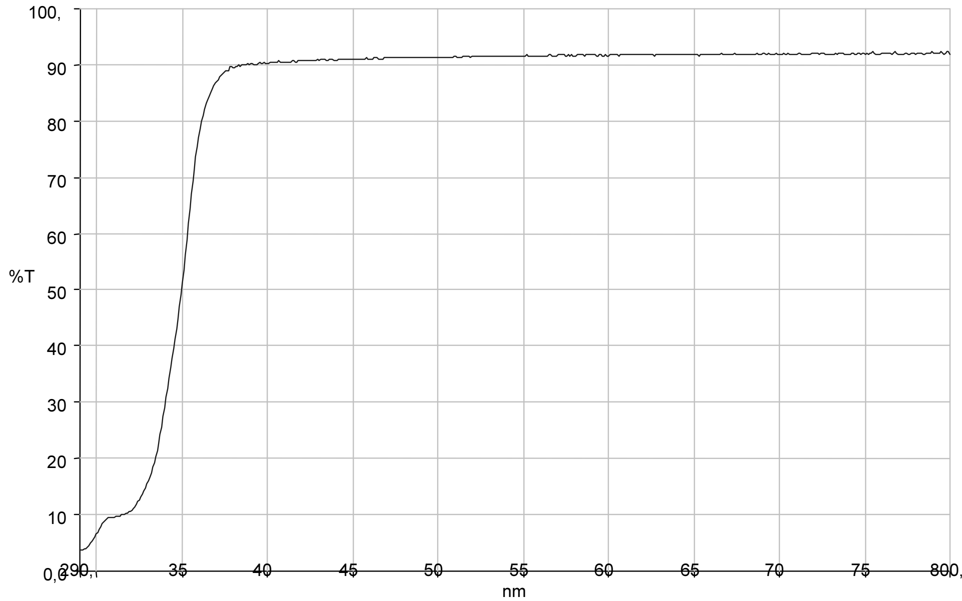


Light transmission of plasticised PVC film

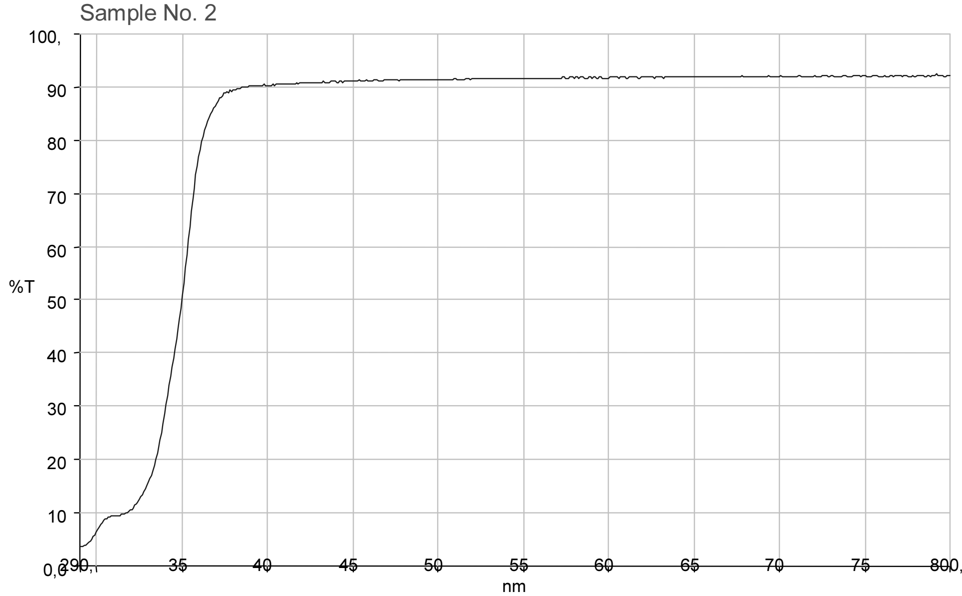
DEHS (DP01-039)

3601207750
16.05.2001

Sample No. 1



Sample No. 2

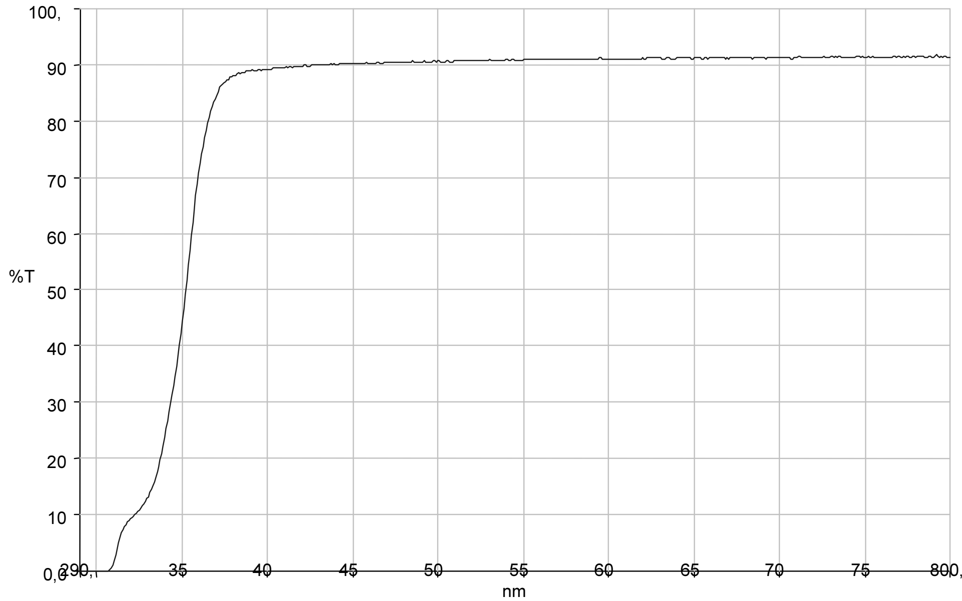


Light transmission of plasticised PVC film

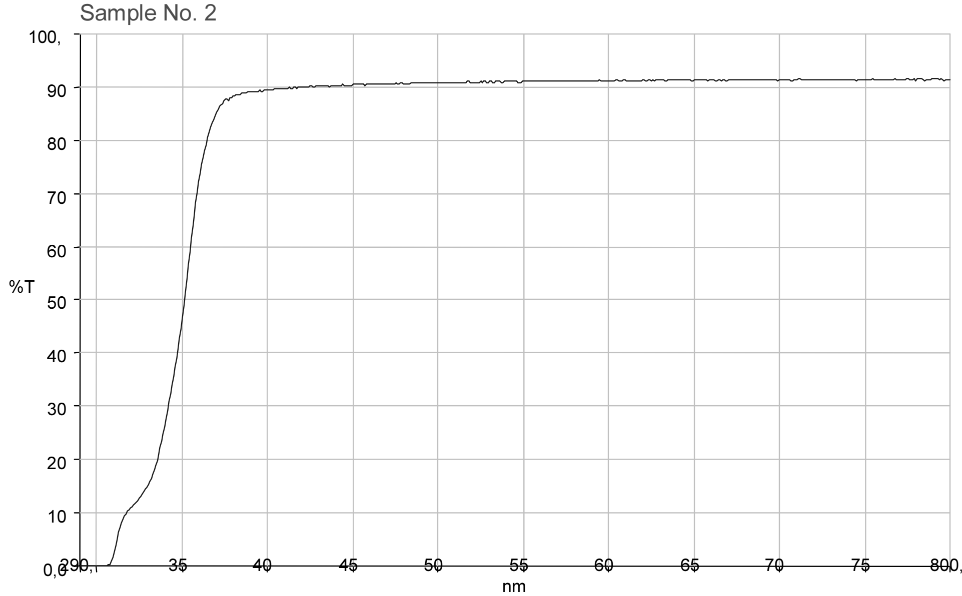
TEHTM (DP01-040)

3601207750
16.05.2001

Sample No. 1



Sample No. 2

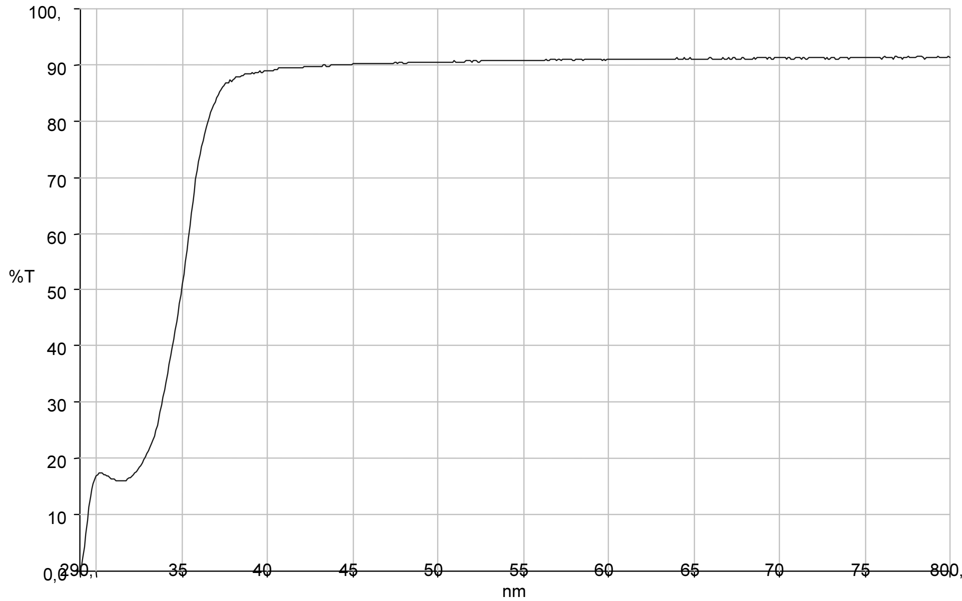


Light transmission of plasticised PVC film

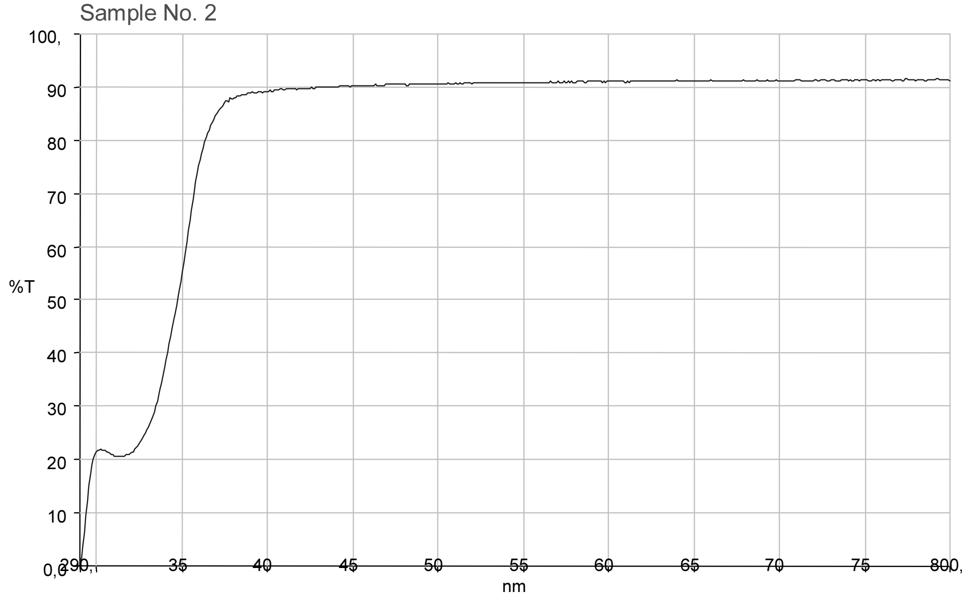
Di(propylene glycol) dibenzoate (DP01-041)

3601207750
16.05.2001

Sample No. 1



Sample No. 2

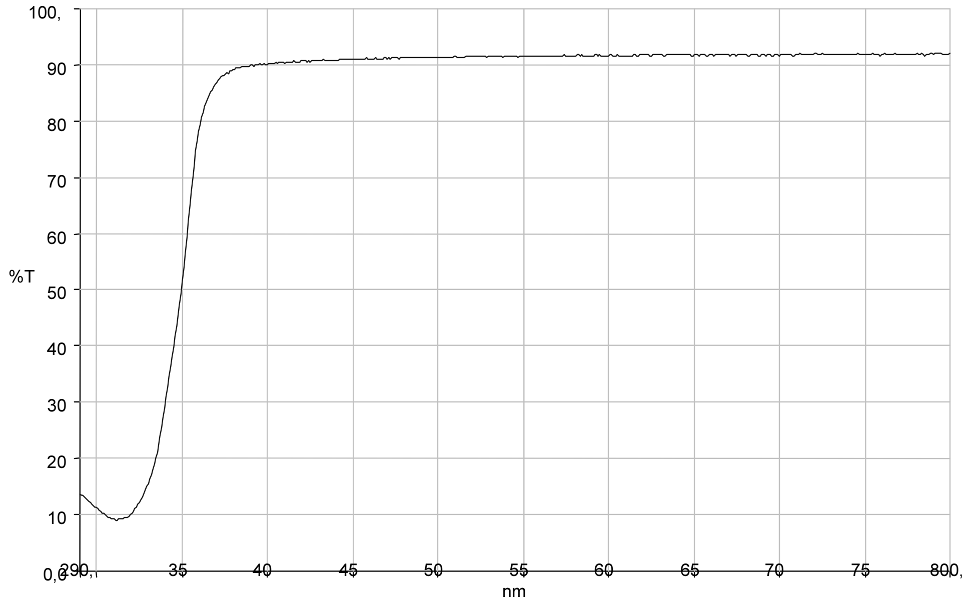


Light transmission of plasticised PVC film

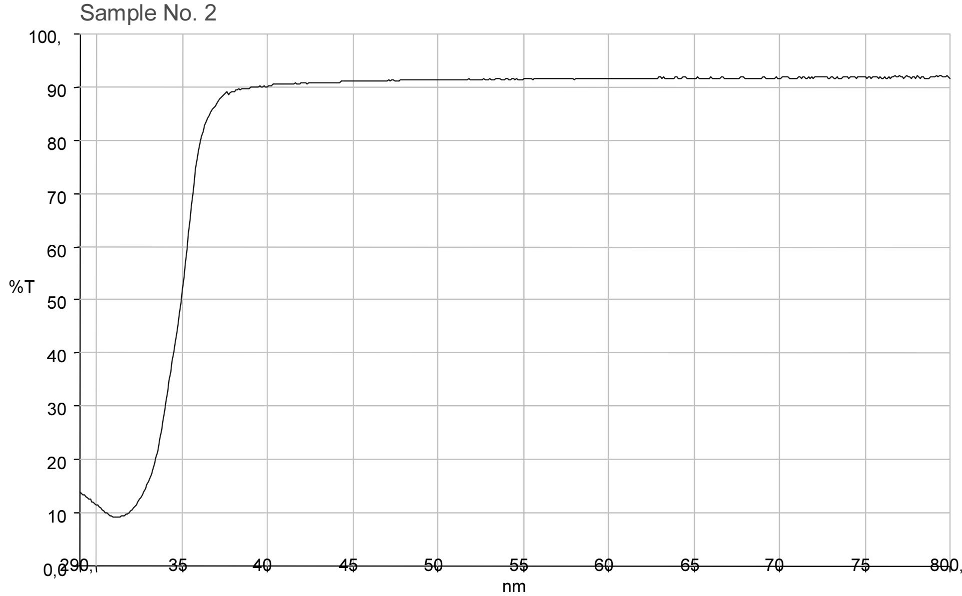
Polyadipate (DP01-042)

3601207750
16.05.2001

Sample No. 1



Sample No. 2

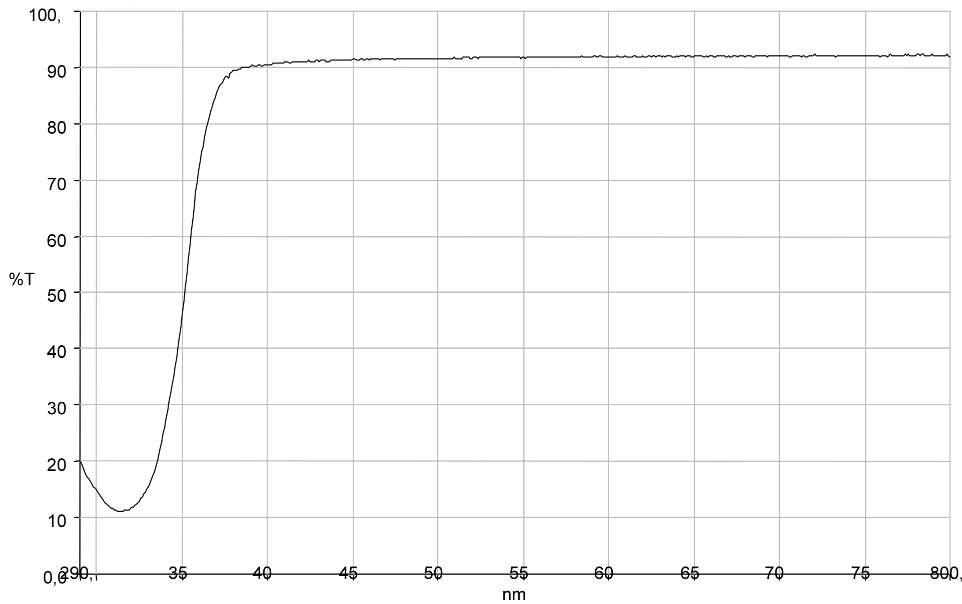


Light transmission of plasticised PVC film

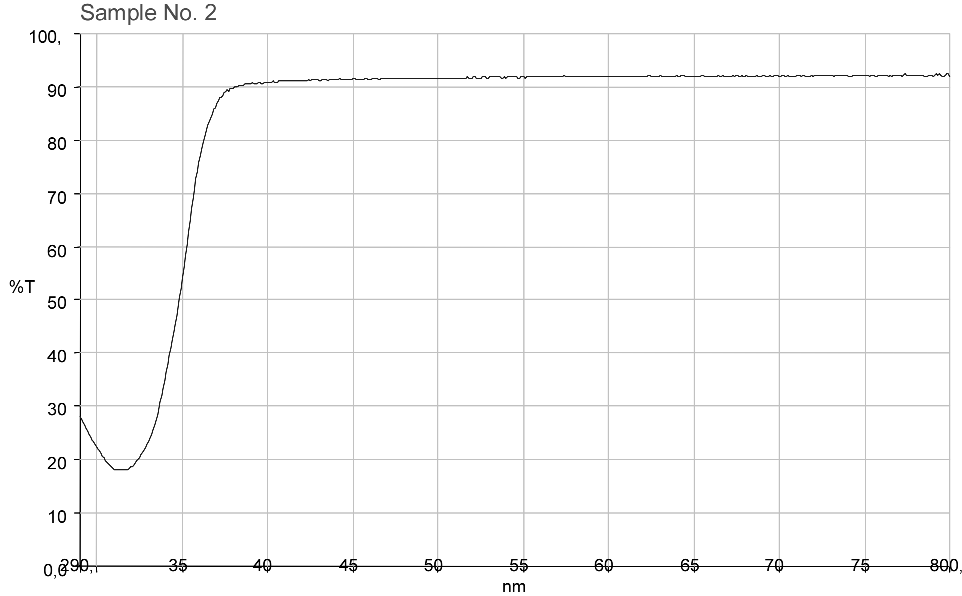
ATBC (DP01-043)

3601207750
16.05.2001

Sample No. 1



Sample No. 2

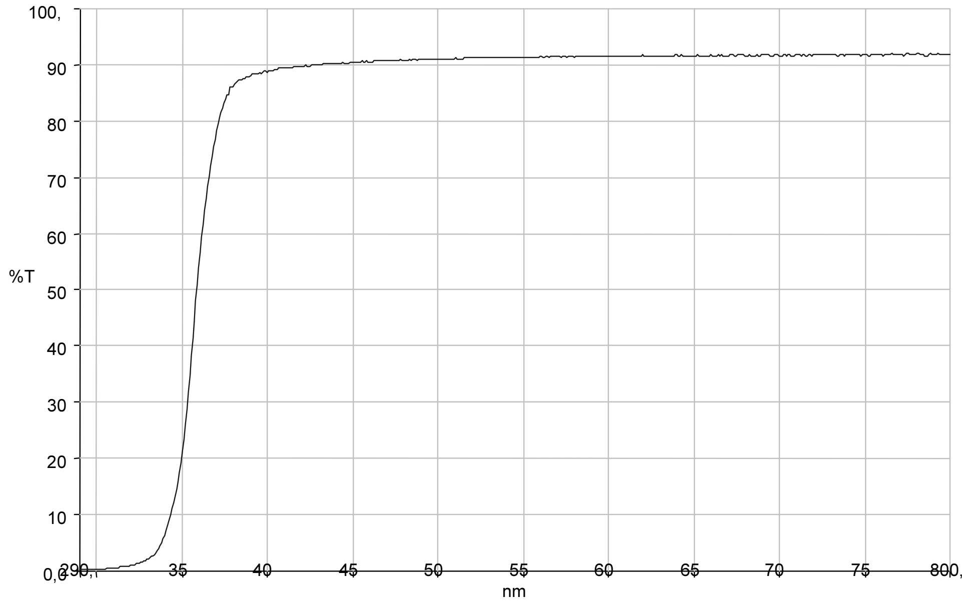


Light transmission of plasticised PVC film

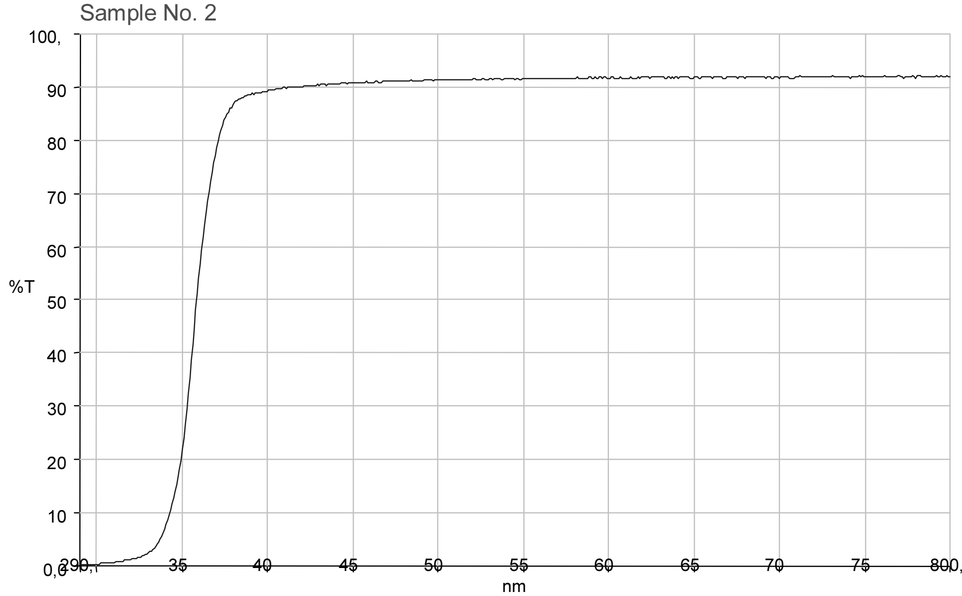
EAC terpolymer (DP01-106)

3601207750
16.05.2001

Sample No. 1



Sample No. 2



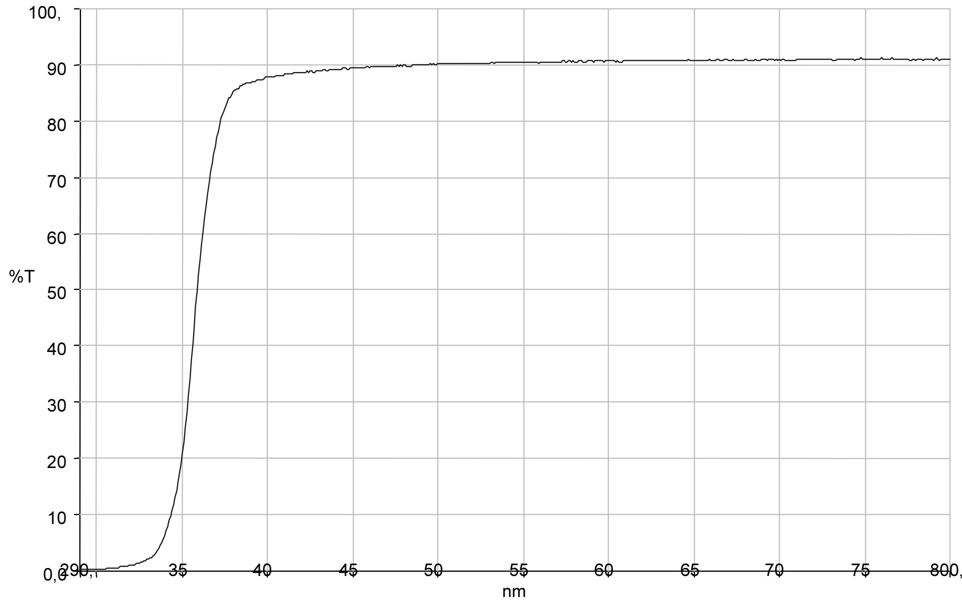
Light transmission of plasticised PVC film

EAC terpolymer (DP01-106) - extra

3601207750

Sample No. 1

16.05.2001



Sample No. 2