

Regulation of Plasticizers Under EU REACH and RoHS

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Abstract

Phthalate plasticizers have been used for many decades in PVC insulation and jacketing of cables. Several of the traditionally used phthalates have known or suspected toxicity issues. The controls on several commonly used phthalate plasticizers for PVC (and other polymer systems) under the European REACH Regulation, and very recently also under the European RoHS, has led to the need for careful evaluation of the composition of PVC insulated wire products produced in, or imported into, the EEA. A further number of plasticizers are under evaluation for possible additional regulatory controls under the REACH evaluation programs over the next years.

With this dynamic regulatory environment regarding major flexible PVC components, EEA producers and importers of wire with PVC insulation or jacketing should fully understand the current and potential regulatory issues associated with each plasticizer, to be sure that their current products are in compliance, and that any plans for reformulation consider future contingencies.

Keywords: Plasticizer; PVC; phthalate; adipate; azelate; trimellitate; sebacate; hexahydrophthalate; terephthalate; REACH; RoHS; Europe; SVHC; insulation; jacketing; regulation; authorization; restriction;

1. Introduction

Phthalate plasticizers are pervasively used in very wide range of industrial, professional and consumer products. These plasticizers have been used for many decades in PVC insulation and jacketing of cables. Many of the traditionally used phthalates have known or suspected endocrine or reproductive effects. The controls on several commonly used phthalate plasticizers for PVC (and other polymer systems) under the European REACH Regulation, and very recently also under the European RoHS, have led to the need for careful evaluation of the composition of flexible PVC products produced in, or articles imported into, the EEA (European Economic Area = European Union, plus Iceland, Liechtenstein and Norway). We will refer to the EEA through the rest of this paper when dealing with the

geographic scope of REACH. A further number of plasticizers of interest in wire and cable are under evaluation for possible additional regulatory controls under the REACH evaluation programs over the next years. Some EU Member States have also proposed expanding the scope of Restrictions on some plasticizers. Other jurisdictions, from the US EPA, to California Proposition 65, to China, to Japan have or are planning regulations on plasticizers used in wire and cable.

With this dynamic regulatory environment regarding major flexible PVC components, EU/EEA producers and importers of wire with PVC insulation or jacketing should fully understand the current and potential regulatory issues associated with each plasticizer, to be sure that their current products are in compliance, and that any plans for reformulation consider future contingencies. Clearly, this also has significance for companies whose wire may be in products exported to the European market.

This paper will review the current regulatory status of PVC plasticizers under REACH and EU RoHS, announced evaluation programs, as well as existing and proposed Restrictions and bans (Authorization). We will review the REACH portion of a matrix of some of the plasticizers listed in current and proposed EU regulations. Comprehensive EU-level regulatory information is necessary to set up current compliance programs, reformulation plans, and specifications to external suppliers, but time only allows review of the REACH and RoHS-related controls.

2. REACH Regulation

REGULATION (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals ("REACH") was passed on December 18, 2006. As an EU "regulation", rather than a "directive", it became law across all of the EU Member States as written. The regulation also established a new EU organization- the European Chemical Agency ("ECHA"). Although it has been 9 years since the passage of REACH, industry (as well as Member States authorities) are still studying, learning, and trying to interpret and comply with this very broad regulatory scheme.. REACH applies to all chemical substances, including those chemicals in "articles"- products in

their final form where the shape and other physical aspects are more critical than the chemical makeup. In the current discussion for example, a PVC polymer, a plasticizer, a filler, etc. are each considered a chemical substance, and a pelletized PVC compound is a mixture of individual substances, whereas an insulated wire or cable is considered an article. The key parts of the regulation are:

2.1 Registration

Each substance must be registered by each EEA manufacturer, or importer (for non-EEA manufacturers) to the EEA market, with certain exceptions. Registration can only be done by an EEA legal entity, so non-EEA companies cannot register by themselves, but must either use an EEA subsidiary, or contract with an EEA company- typically a consultancy or service provider, to register. The company registering for a non-EEA manufacturer is termed an "Only Representative". Alternatively, an EEA end-user or importer can perform the registration. The registration process requires applicants to submit a great deal of technical, process, toxicity and ecotoxicity data. If several companies intend to register the same substances, they are required to compare data and jointly submit the most reliable test results, with companies required to compensate co-registrants that contribute high-quality recent data. A very significant difference from most previous "inventory-type" national regulations is that each legal entity wanting to manufacture or import a substance in the EEA must go through registration. There is no "free ride" for new EEA entrants on a substance registered by other companies. It is significant, though, that only substances manufactured or imported as a substance or in mixture must be registered. Substances in articles are only required to be registered if the substance is intentionally released in the use of an article (i.e. ink in a pen- the ink components are subject to registration.).

The cost of registration is significant, typically up to hundreds of thousands EUROS per registration. There is a fee to be paid to ECHA when the registration is submitted. In addition, as described above, co-registrants must purchase "Letter of Access" from the company that provided the data and often companies will use outside consultants to analyze test data and handle the registration.

2.2 Evaluation

The REACH regulation places the primary responsibility for chemical safety information- data, hazard classification, risk assessment, safe use scenarios, and etc.- on industry. ECHA will evaluate the completeness of the data set that is submitted with the registration, but ECHA together with Member States' authorities may decide to further evaluate specific substances. There are two substance evaluation programs now in operation under REACH- Community Rolling Action Plan ("CoRAP"), and Public Activities Coordination Tool ("PACT").

2.2.1 CoRAP The Community Rolling Action Plan is a rolling three-year program under which ECHA or a Member State can propose a substance for detailed evaluation of hazards and risks. The substances are selected from risk-based criteria and the evaluation will involve all companies that have registered the selected substance. One or possibly two Member States' authorities will take responsibility for leading the evaluation which may simply involve in-depth review of data already submitted by registrants, or may require registrants to provide additional data, and possibly to conduct further testing to more firmly document the hazard and risk (or lack thereof) of a substance and its use. Emphasis is placed on substances with the potential to be a Carcinogen, Mutagen or Reprotoxic (CMR) substance, a Persistent, Bioaccumulative and Toxic (PBT)

substance, a very Persistent and very Persistent and very Bioaccumulative (vPvB) substance, endocrine disruptor, or sensitizer. The evaluation under CoRAP might conclude that the substance is already properly controlled, or it might conclude that further regulatory control measures must be put in place: the substance might get a stricter hazard classification, it might be restricted in use or might be placed on the Candidate List (see later).

2.2.2 PACT The PACT process is somewhat less formal program and is focused on substances where ECHA or a Member State believes there is a need to more thoroughly evaluate a substance for PBT or vPvB properties, or Endocrine Disrupting properties.

2.3 Authorization-

Substances of very high concern are identified in the "Candidate List of substances of very high concern for Authorisation" ("Candidate List" = "SVHC"s) and may eventually be subject to authorization under the REACH Regulation (Annex XIV). Once included in that Annex, the substance cannot be placed on the market or used after a certain date (the so-called "sunset date") unless the company applies for and is granted an authorization.

The Candidate List currently includes 163 substances including 16 phthalates. 31 of the 163 substances are now subject to authorization, of which 4 are phthalate plasticizers.

If authorization is granted, it is valid to the applicant and for the applicant's downstream users, provided they use the substance as described in the authorization. The applicant will receive an authorization number that must be communicated to downstream users. The authorization will be limited in time.

Authorization does not apply to substances in articles (unless the substance is intentionally released from an article). But suppliers of articles (also imported) containing 0.1% or higher of a Candidate List substance must inform their downstream users of the name of the substance, and about safe use of the article. In addition, a notification has to be submitted to ECHA if an article (imported or produced in the EEA) contains 0.1% or more and 1 ton or more per annum of a Candidate List substance.

Applying for authorization is a very costly and time-consuming process- the (non-refundable) application fee to ECHA starts at Euro 53,300 for non-SMEs, and the application must be accompanied by a great deal of exposure data, alternative substance evaluations, economic data, etc. As of June 2015, the only approved authorization for DEHP/DOP is for a masking compound for jet engine turbine blade production.

2.4 Restriction

This part of REACH regulates the manufacture, placing on the market or use of substances (on their own, in mixtures or in articles) and is designed to manage risks that are not addressed by other REACH processes. Restrictions may be limitation in use of a substance or it might be a ban on specific use.

Under the restrictions, the use of a substance is permitted UNLESS specifically prohibited/limited in specified end uses- i.e. DEHP/DOP, DBP and BBP in any article for children, and DINP, DNOP, DIDP, in mouthable articles for children. (For particularly hazardous substances such as asbestos, no uses are allowed.)

2.5 Basis for Evaluating SVHC Content in Articles

One of the current controversies involves the basis for calculating the 0.1% threshold limit for disclosure of SVHCs. The current ECHA interpretation is the SVHC content based on entire article

weight as supplied. However, a number of EEA member states strongly believe that the SVHC content should be based on the weight of an individual component. This is the so-called “Once An Article, Always An Article” approach, or “O5A” for short. The controversy is currently before the European Court of Justice. The O5A interpretation is currently being enforced by its proponent Member States: Germany, France, Austria, Belgium, Denmark, Sweden and Norway (Norway is an EEA member).

Under RoHS, the calculation of Annex II restricted substances is based on the weight of homogeneous material.

To illustrate how the three approaches can apply to wire and cable as part of computer power supply (assuming all permanently assembled into one unit):

Per ECHA REACH: SVHC content based on the weight of assembled power supply (plugs, wires, plus transformer if all permanently connected in one unit)

Per O5A REACH: SVHC content based on wire weight (copper plus insulation and jacket). Other components (transformer parts, etc.) evaluated separately.

RoHS: Annex II content is based separately on composition of insulation excluding the conductor, and each homogeneous component.

3. REACH Regulation of Plasticizers of Interest to Wire and Cable

3.1 Current Controls

Typically, the plasticizer content in thermoplastic PVC insulation and jacket compounds is approximately 30%, so unlike most other organic additives in many polymer systems, plasticizers are a significant proportion of the total plastic.

Some of the main plasticizers under consideration in wire and cable PVC insulation and jacketing applications are (our study is confined to monomeric plasticizers- see list of abbreviations at the end of this paper):

Phthalates*:

DEHP/DOP; Tetra-bromo DEHP, DNOP, DINP, DIBP, 8-10 Phthalate, 9-11 Phthalate, DIDP, DPHP, DIUP, DUP, DTDP

* Note that lower molecular-weight Candidate List phthalates DBP, DIBP and BBP have also been notified to ECHA as being used in wire, cable and/or electrical insulation applications.

Linear Acid Diesters:

DINA, DDA, DTDA, DOS, DIDS, DIDZ

Trimellitates:

TOTM, TNOTM, TINTM, 8-10 TM, TIIDTM

Other Non Ortho-Phthalates:

DOTP, DINCH

Of the listed plasticizers, some are only available in the North American market, some only in Europe, but many are available globally. Most current controls apply to C-3 to C-8 alcohol phthalates.

Controls on wire and cable-range plasticizers under REACH are currently limited to phthalate plasticizers- DEHP/DOP, DINP, DIDP, and DNOP.

- DEHP/DOP is the most severely controlled plasticizer (along with DBP and BBP)- this chemical is subject to Authorization (cannot use in the EEA without application to ECHA and specific approval from the European

Commission), Restriction (cannot be present in any childcare articles or toys), and is a Substance of Very High Concern (SVHC) and thus ECHA and recipients of products containing DEHP/DOP must be informed of its presence if more than 0.1%.

- DNOP, DINP and DIDP are subject to the restriction from presence in childcare articles or toys that can be placed in the mouth. They are NOT SVHCs.
- Although typically considered too volatile for wire and cable, the plasticizers DBP, DIBP and BBP- all SVHCs together with DEHP/DOP- have been notified to ECHA that they are contained in imported wire and/or cable articles.

3.2 Evaluation and Potential Future Controls

A large number of wire and cable-range plasticizers are currently being evaluated by ECHA for possible controls (Restriction, or designation as a SVHC). The wire and cable-range plasticizers now under evaluation programs (CoRAP and/or PACT) include:

Table 1. Wire and Cable-range plasticizers currently under evaluation by ECHA and Member States

9-11 Phthalate	DPHP	Tetra-bromo DEHP/DOP	DIUP/DUP	DTDP
TOTM	DIDZ	DTDA	DINCH	DOTP

The evaluation of a plasticizer does **not** automatically lead to additional controls. In many cases, the authorities ask the registrants to submit additional test data to clarify a concern over a specific health or environmental risk. In the case of DINCH and DOTP, France has initiated PACT evaluation, as these two plasticizers are likely replacements for DEHP/DOP so it is prudent to thoroughly understand the replacements.

Although not a plasticizer itself, a small amount of bisphenol A (0.25 – 0.5%) formerly was added to plasticizers for wire and cable application as a heat stabilizer. It appears that North American and European producers have changed to a less regulatory-challenged heat stabilizer, but it would be prudent to check the heat stabilizer of incoming plasticizers, especially from sources in other parts of the world. Bisphenol A is currently under evaluation both as part of CoRAP and under PACT because of its suspected effect as endocrine disruptor and its wide dispersive use.

Additionally, ECHA is reviewing possibly expanding the current restrictions on DEHP/DOP (as well as DBP, DIBP and BBP) in response to Denmark’s proposal to have the plasticizers restricted from all indoor and direct skin contact applications. ECHA’s evaluation report is due to be issued in January 2016, which may possibly lead to public consultations and eventual further restriction. Note that restrictions apply equally to EEA-produced and imported articles.

4. RoHS Recast Regulation

In March 2015, the European Commission added DEHP/DOP, as well as DBP, DIBP and BBP, to Annex II of RoHS, thus prohibiting their presence in excess of 0.1% in electrical and electronic equipment placed on the EEA market, with effect from July 22 2019 (or July 22 2021 for medical devices, or medical or industrial controls and instruments). Under RoHS, the weight percent calculation is based upon “homogeneous material” thus in the case of wire insulation, the basis would be the composition of the insulation compound alone, excluding the weight of the conductor.

5. Conclusions and Recommendations

Given the current regulatory controls and ongoing evaluations in the European Union, we offer the following conclusions and recommendations for: producers of insulated wire and cable in the EEA; exporters of plasticized compounds to the EEA; exporters of wire and cable products to the EEA; or exporters of assembled electrical/electronic products to the EEA:

- Avoid using DEHP/DOP in any products. Until the new RoHS effective date in 2019, articles (i.e. wire and cable) imported into the EEA which contains more than 0.1% DEHP/DOP must be disclosed to industrial or professional customers within the EEA (and disclosed to consumers within 45 days of a consumer's request), in accordance with REACH. After July 2019, DEHP/DOP, DBP, DIBP, or BBP in excess of 0.1% w/w in any homogeneous plastic or rubber will be RoHS non-compliant (2021 for certain types of equipment).
- Remain aware of the European Court of Justice process to determine if SVHC weight percentage calculations for the purpose of REACH are based on the entire article, or on the individual component (i.e. "OSA").
- Ensure that other compound additives- stabilizers, pigments, etc.- that are purchased pre-dispersed or as masterbatches do not contain the 4 plasticizers (DEHP, DBP, DIBP or BBP).
- When evaluating current regulatory actions on plasticizers, ensure that you are getting accurate, specific plasticizer identification from your supply source. Several of the chemical descriptions in the European regulations are subject

to misinterpretation, unless a specific CAS or EC number is used.

- If exporting base polymers or plastic/rubber compounds to Europe, note that all chemical components- plasticizers, stabilizers, pigments, fillers, etc. need to be registered in the supply chain.
- If exporting base polymers or plastic/rubber compounds to Europe, note that although polymers are exempt from REACH registration, the monomers used to produce imported polymers also must be registered in the supply chain.
- If re-selling wire or cable (i.e. lamp cord, etc.) produced in other world regions to Europe, ensure that you accurately know the composition of the insulation and jacketing to guard against inadvertent liability for non-compliance with SVHC notification or RoHS. Note that DEHP/DOP production in East Asia is still increasing, in contrast to the US and Europe.
- Follow the REACH Evaluation processes (CoRAP and PACT) with regards to critical wire and cable-range plasticizers- especially for higher-temperature-rated wire. Have your technical personnel evaluate alternate plasticizer contingencies. (Note that several flame retardants are also currently controlled or under Evaluation.)
- Finally, remember that in many cases, NGO and public perception is ahead of science and regulation, thus all "phthalates" are often referred to as hazardous. Various "black" and "grey" lists may include plasticizers beyond the regulations.

6. Plasticizer Abbreviations:

DBP: Di normal butyl phthalate

BBP: Butylbenzyl phthalate

DNOP: Di normal octyl phthalate

DINP: Diisononyl phthalate*

9-11 Phthalate: Linear C-9 and C-11 phthalate

DIDP: C 9-11 Branched C-10 rich phthalate*

DIUP/DUP: Diundecyl phthalates*

DINA: Diisononyl adipate

DTDA: Ditridecyl adipate

DIDS: Diisodecyl sebacate

TOTM: Tri 2-ethylhexyl trimellitate

TINTM: Triisononyl trimellitate

TIDTM: Triisodecyl trimellitate

DOTP: di 2-ethylhexyl terephthalate

DIBP: Diisobutyl phthalate

DEHP/DOP: Di 2-ethylhexyl phthalate

Tetra-Bromo DEHP: Bis(2-ethylhexyl) tetrabromophthalate

8-10 Phthalate: Diisononyl phthalate*

DIDP: Diisodecyl phthalate*

DPHP: Dipropylheptyl phthalate

DTDP: Ditridecyl phthalate

DIDA: Diisodecyl adipate

DOS: Di 2-ethylhexyl sebacate

DIDZ: Diisodecyl azelate

TNOTM: tri n-octyl trimellitate

8-10 TM: Mixed C-8 and C-10 trimellitates

DINCH: Diisononyl cyclohexane-1,2-dicarboxylate**

* Note: DINP, DIDP, and DUP each have two separate chemical identities, but generally regulated in generic C-9, C-10, or C-11 alcohol ester groups

** Note: DINCH is a registered trademark of BASF. There are 2 additional REACH pre-registrations by other companies of very similar chemical substances

7. Excerpt of REACH and RoHS Regulatory Data on Plasticizers:

Carbon Chain	Phthalate	Substance Name on List	Authorization Annex XIV	Restriction Annex XVII	SVHC / Candidate List	CoRAP Listing	PACT	Classification	RoHS
8	Yes	Di-2 ethylhexyl Phthalate (DEHP, DOP)	yes	Yes- Entry 51- ECHA to review Restrictions-dossier January 2016	On Candidate List 28 Oct 2008	no		Repr. 1B H360FD (May damage fertility. May damage the unborn child.)	Annex II
8	Yes	Tetrabromo DEHP	no	no	no	Yes- Sweden 2017		Not Classified	
8	Yes	Di n-Octyl Phthalate (DNOP)	no	Yes- Entry 52	no	no		Not Classified	
8	Yes	1,2- benzenedicarboxylic acid, di-C8-10-alkyl esters (8-10 P)	no	no	no	no		Not Classified	
9	Yes	Diisononyl Phthalate, bis(7-methyloctyl)phthalate. (DINP) Note: in the draft review evaluation report from ECHA and in the restrictions list, the two cas numbers 28553-12-0 and 68515-48-0 are linked together both as DINP	no	Yes- Entry 52	no	no		Not Classified	
9	Yes	1,2- benzenedicarboxylic acid, di-C9-11-branched and linear alkyl esters > 80% linear (9-11 P) On CoRAP List!	no	no	no	Yes, 2014-Denmark		Not Classified	
10	Yes	1,2-Benzenedicarboxylic acid, di-C9-11-branched alkyl esters, C10-rich (DIDP) Note: in the draft review evaluation report from ECHA and in the restrictions list, the two cas numbers 26761-40-0 and 68515-49-1 are linked together with both cas numbers both as DIDP	no	Yes- Entry 52	no	no		Not Classified	
10	Yes	Bis(2-propylheptyl) phthalate (DPHP) Note: Although this can also be considered an "isodecyl" phthalate, the Commission has ruled that DPHP is separate and distinct from the two DIDP substances above On CoRAP List!	no	no	no	Yes, 2016-Germany		Not Classified	
11	Yes	Diundecyl Phthalate (DUP) On CoRAP List!	no	no	no	Yes, 2014- DK		Not Classified	
11	Yes	Diundecyl Phthalate, branched and linear (DIUP) On CoRAP List!	no	no	no	Yes, 2014- DK	April 2015 Denmark- PBT	Not Classified	
13	Yes	1,2- benzenedicarboxylic acid, di-C11-14-branched alkyl esters, C13-rich (DTDP) On CoRAP List!	no	no	no	Yes, 2014- DK		Not Classified	
8	No	tris(2-ethylhexyl) benzene-1,2,4-tricarboxylate (TOTM) On CoRAP List!	no	no	no	Yes, 2012- Austria Registrants required to submit environmental test results by Feb 2016		Not Classified	
8	No	triocetyl benzene-1,2,4-tricarboxylate (TNOTM)	no	no	no	no		Not Classified	
9	No	1,2,4-Benzenetricarboxylic acid, mixed decyl and octyl triesters (8-10 TM)	no	no	no	no		Not Classified	
8	No	tris(mixed dodecyl and octyl)benzene-1,2,4-tricarboxylate (8-12 TM)	no	no	no	no		Not Classified	
9	No	triisononyl benzene-1,2,4-tricarboxylate (TINTM)	no	no	no	no		Not Classified	
8	No	Bis(2-ethylhexyl) terephthalate (DOTP, DEHT)	no	no	no	no	September 2014 France (as alternative to DEHP)	Not Classified	
9	No	1,2 Diisononyl cyclohexane dicarboxylate (DINCH)	no	no	no	no	September 2014 France (as alternative to DEHP)	Not Classified	
9	No	Diisononyl Adipate (DINA)	no	no	no	no		Not Classified	
9	No	Triisononyl benzene-1,2,4-tricarboxylate (TINTM)	no	no	no	no		Not Classified	
10	No	diisodecyl sebacate (DIDS)	no	no	no	no		Not Classified	
10	No	diisodecyl adipate (DIDA)	no	no	no	no		Not Classified	
10	No	Trisodecyl Trimellitate (TIDTM)	no	no	no	no		Not Classified	
10	No	Diisodecyl Azelate (DIDZ) On CoRAP List!	no	no	no	Yes, 2013- IT	April 2015 Italy PBT	Not Classified	
13	No	Di isotridecyl Adipate (DTDA) On CoRAP List!	no	no	no	Yes, 2013- Spain	April 2015 Spain PBT	Not Classified	

8. Authors



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Mr. Voskian has a long career in the global chemical industry and chemical regulatory field. At Eastman Chemical Company for 30 years, he held business and general management positions of increasing responsibility in the US and Asia Pacific. Subsequently, he joined Ariel Research/3E Company, a leading US-based chemical regulatory data and services company, with responsibility for business development for Europe and Asia Pacific. Together with Ms. Jytte Syska, he formed Syska Voskian Consulting in 2012. Mr. Voskian holds a Bachelor of Science degree in Chemical Engineering from Lehigh University in the United States, with graduate study at New York University.



Jytte Syska is a partner at Syska Voskian Consulting, providing chemical regulatory compliance services to industry, and is specialised in REACH training and audits.

Ms. Syska is an experienced global chemical regulatory expert with thorough understanding of the chemical regulatory environment and requirements regarding development, production, sale, use and disposal of chemical products and articles, and in how to apply the requirements throughout the product life cycle. She has many years of experience in assessment of processes, systems and training programs for regulatory compliance for companies selling and/or manufacturing chemicals and articles. Previously Ms. Syska worked for 3E Company where she established the outsourced MSDS authoring and regulatory consulting business. She was subsequently appointed President of Ariel Operations with the overall global responsibility for the Ariel Product lines at 3E Company. Earlier in her career she held the position as Director, Occupational Health and Toxicology at the Danish Toxicology Center and as Health and Safety Consultant at an Occupational Health Service Center. Together with Mr. Alfred Voskian, she formed Syska Voskian Consulting in 2012. Ms. Syska lives in Copenhagen, Denmark and holds a master degree in engineering from the Technical University in Denmark.