Syska Voskian Consulting

EU REACH and RoHS
&
Wire and Cable

Toxic Use Reduction Institute

September 25 2013

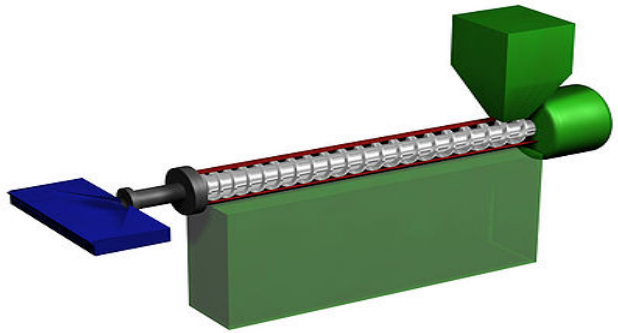
Presentation Outline

Specific impact of REACH on Plasticizers

Other Insulation/Jacketing Components under REACH and RoHS

“O5A” or “Component” Approach to articles

Flexible PVC, Plasticizers and REACH



Typical Flexible PVC Formulation

- Flexible PVC consists of:
  - PVC Resin 100 parts
  - Plasticiser <30 – >100 parts
  - Heat Stabiliser 2 – 8 parts
  - Mineral Filler/Reinforcement – varies
  - Pigments – varies
  - Other additives – varies
- Plasticiser can therefore constitute 20% to more than 50% of the finished product
  - Typically about 25-30% in wire insulation

Simplified PVC Supply Chain

Component (Substance) Producers

- PVC resin
- Plasticizers
- Stabilizers
- Color (Pigments)
- Fillers (clay, talc, etc.)
- Other additives (UV, lubricants, additives, etc.)

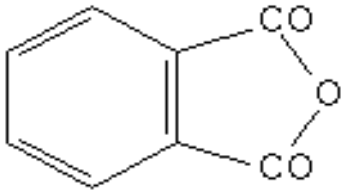
Compounders

- Mix components
- Melt into homogenous plastic for further processing
- Intermediate steps can be color masterbatches or pigment dispersions (pre-dispersed pigments), pre-mixed stabilizer packages, etc.

Molders or other final processors

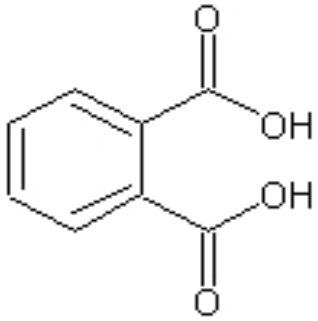
- Wire and Cable Insulation and Jacketing
- Injection mold articles
- Extrude Flexible Sheeting
- Coated fabric/wallpaper
- Cast/molded toys or other articles
- Resilient vinyl flooring

Phthalate Chemistry 101



Phthalic Anhydride

OR

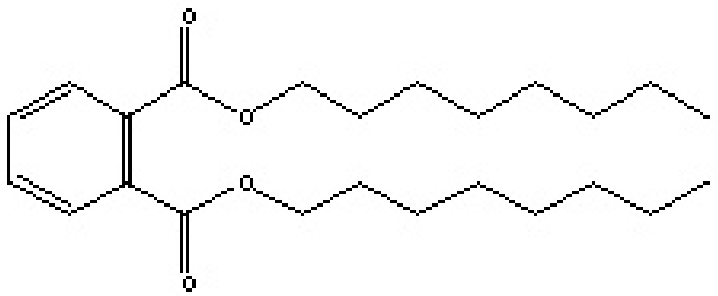


Benzene 1,2 dicarboxylic acid

+ 2

"Alcohol"

=



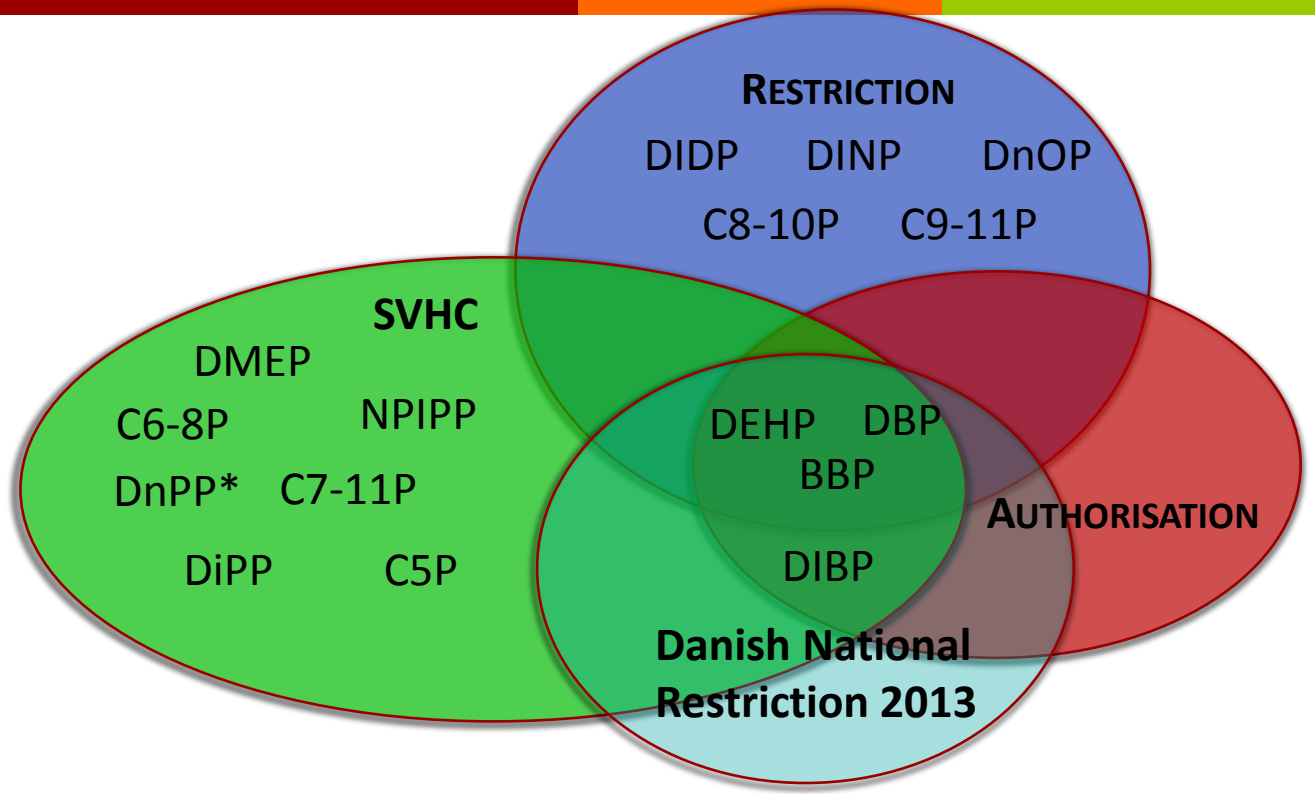
Di "alcohol" Phthalate
or
Ortho phthalate
or
1,2 Benzenedicarboxylic Acid
Di-"alcohol" Alkyl Ester

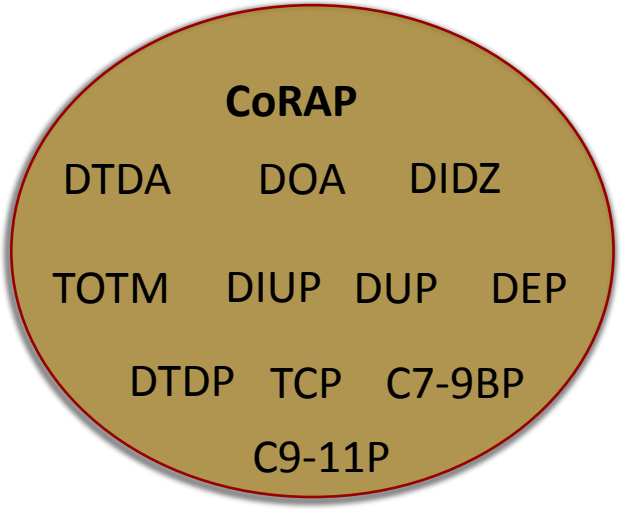
Phthalates and other PVC Plasticizers

- Today's discussion focuses on phthalates commonly used in PVC
  - Most Plasticizer regulatory issues are with phthalate-types
  - Typically 8 carbon alcohols or greater are used in PVC due to processing temperature and permanence
  - We are tracking more than 60 of all types of Plasticizers, of which over 30 are phthalates, which are mentioned in Pre-registration, Registration, CoRAP, or other REACH references
  - Many of the 30+ phthalates have not been registered yet, and thus may not be used commercially in Europe

Carbon Chain	Phthalate	Substance Name on List	Other Names	CAS #	EC #	Authorization Annex XIV	Restriction Annex XVII	SVHC / Candidate List	CoRAP Evaluation	Total Tonnage Band
8	Yes	Di-2 ethylhexyl Phthalate	DOP, DEHP, Bis-2 ethylhexyl Phthalate, LGFlex DOP, DOP, Oxoplast O, Diplast O	117-81-7	204-211-0	yes	Yes- Entry 51	On Candidate List 28 Oct 2008	no	100,000 - 1,000,000
9	Yes	Diisononyl Phthalate, bis(7-methyloctyl)phthalate. 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	DINP, Vestinol 9, Palatinol N, Diplast NS, Di-"isonormal" phthalate	28553-12-0	249-079-5	no	Yes- Entry 52	no	no	100,000 - 1,000,000
9	Yes	1,2-benzenedicarboxylic acid, di-C8-10-branched alkyl esters, C9-rich 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	DINP, Jayflex DINP	68515-48-0	271-090-9	no	Yes- Entry 52	no	no	100,000 - 1,000,000
9	Yes	1,2- benzenedicarboxylic acid, di-C9-11-branched and linear alkyl esters > 80% linear	DIPLAST L 9-11, C9-11P	68515-43-5	271-085-1	no	no	no	Yes- DK	1000-10,000
10	Yes	1,2-Benzenedicarboxylic acid, di-C9-11-branched alkyl esters, C10-rich 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	Jayflex DIDP	68515-49-1	271-091-4	no	Yes- Entry 52	no	no	100,000 - 1,000,000
10	Yes	Bis(2-propylheptyl) phthalate 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	DPHP, Platinol 10P, Oxoplast PH, Diplast RS	53306-54-0	258-469-4	no	no	no	no	100,000 - 1,000,000
11	Yes	Diundecyl Phthalate	DUP, Diplast L 11, Diplast 11/ST	3648-20-2	222-884-9	no	no	no	Yes- DK	1000-10,000
11	Yes	Diundecyl Phthalate, branched and linear	DUP, Jayflex DIUP	85507-79-5	287-401-6	no	no	no	Yes- DK	1000-10,000
8	Non-Phthalate	Bis (2-ethylhexyl) Adipate	DOA, Sicol 250, Flexol A 26, Vestinaol OA, Effomoll DOA, Plastomoll DOA, Truflex DOA, Monoplex DOA, Di Plast D, many more	103-23-1	203-090-1	no	no	no	Proposed- FI 2013	10,000 - 100,000
8	Non-Phthalate	tris(2-ethylhexyl) benzene-1,2,4-tricarboxylate	Trioctyl Trimellitate, TOTM, diplast TM, LGFlex TOTM, Cereplast TOTM	3319-31-1	222-020-0	no	no	no	Yes- Austria	10,000 - 100,000
	Non-Phthalate	triisononyl benzene-1,2,4-tricarboxylate	Triisononyl Trimellitate TINTM	53894-23-8	258-847-9				no	Not Registered
8	Non-Phthalate	Bis(2-ethylhexyl) terephthalate	DOTP, Eastman DOTP, DEHT, Eastman 168 GL300, GL100	6422-86-2	229-176-9	no	no	no	no	10,000 - 100,000
9	Non-Phthalate	Hexamoll DINCH NOTE: The registration is in the BASF Tradename, although structure should be very close to EC 610-353-8 and 605-439-8			431-890-2	no	no	no	no	CONFIDENTIAL!

Multiple Regulatory Controls





*= Submitted Intention by Member State

Some Inconsistencies!

- DEHP (Substance subject to Authorisation)
  - Could not be **used in the EU,** as of 2015, to make PVC wire insulation/jacket (unless authorisation has been obtained)
  - Import of wires with DEHP in the insulation, or as part of an article, might not even require information in the supply chain (if <0.1% w/w of total weight of article, subject to O5A caveat)

More Uncertainty!

- Search on the ECHA dissemination website for “phthalate” will not list all phthalates as some are listed with other chemical names:
  - Example: 8 of the 11 phthalates on the candidate list are listed as “phthalate” the other three are listed as “1,2 benzenedicarboxylic acid …….”
- Generic Substance Listings “overlap”- i.e.:
  - 1,2- benzenedicarboxylic acid, Di-C7-11- branched and linear alkyl ester (on Candidate List/SVHC)
  - 1,2- benzenedicarboxylic acid, di-C8-10-alkyl esters (not on Candidate List nor under CoRAP Evaluation)

Specifically for Wire and Cable

- While DEHP has decreased greatly in wire insulation and jacketing in North America and Europe, it may still be used in Asia for low voltage/non-demanding applications. See also next slide on colorants
- Several high-temperature phthalate and non-phthalate Plasticizers for wire insulation are on the CoRAP list for evaluation. Important to monitor status of evaluations, and prepare contingency plans

Asian DEHP Production

- While DEHP (and DBP, BBP) production in Europe and North America has decreased markedly, it remains large in Asia Pacific:
  - China: > 500 M lb. annual DEHP production
  - Japan/Taiwan/Korea: approx 750 M lb. annual DEHP production
  - Rest of Asia: approx 750 M lb. annual DEHP

∴ DEHP continues to be used widely as a general purpose Plasticizer for PVC, and volume is still growing

Additional Caution

- Perhaps mostly for imported articles:
  - A non-EU supplier may disclose or otherwise assure compliance for the plasticizer used to produce a flexible PVC article
  - However, pigments are typically pre-dispersed in plasticizer for precise and uniform color appearance, especially for thin-film or PVC coatings
  - Often, the pigment dispersions or color masterbatches are purchased from specialized colorant firms, who may use DEHP, DBP, etc. as a dispersing medium, and thus inadvertently introduce more than 0.1% of an SVHC or Restricted substance to the finished article

RoHS and Plasticizers

- EU RoHS “Recast” (Directive 2011/65/EU)
  - Requires the list of substances be reviewed for amendment no later than 22 July 2014
  - The Directive preamble recommends DBP, BBP, and DEHP for priority consideration to be included under RoHS restriction

Additional Components to Watch For

- Heat Stabilizers (PVC)
  - Lead stabilizer- very effective in wire & cable insulation, but may exceed RoHS and REACH thresholds
  - Barium/Cadmium/Zinc stabilizers- no longer widely used, but:
    - REACH Restriction (Article 23):

      Cadmium- Shall not be used to stabilise the following mixtures or articles manufactured from polymers or copolymers of vinyl chloride:

      -insulation for electrical wiring
    - *RoHS-*

      Cadmium is one of the 6 Chemical groups listed, and with a 0.01% threshold

Flame Retardants

- Antimony Oxide
  - Although not controlled under REACH, Sb_2O_3 is CLP Classified as Carcinogenic Category 2
  - High smoke generation upon burning
- Brominated Aromatics
  - (Poly)brominated Biphenylethers are listed in RoHS
  - Brominated Biphenylethers are listed as Persistent Organic Pollutants under Stockholm Convention
  - DecaBDE is on REACH Candidate List
  - Polybrominated Biphenyls are also listed in RoHS
  - Not typically used in PVC or Polyolefins. Possibly in Rubber or EPDM

Flame Retardants

- Brominated Cylcoaliphatics
  - Hexabromocyclododecane is on Authorization List
- Short Chain Chlorinated Paraffins (SCCP)
  - Raises chlorine content, and also acts as plasticizer
  - SCCPs are on the REACH Candidate List
- Aryl Phosphates
  - TCP and TPP are on CoRAP Evaluation

Additional Components to Watch For

- UV Absorbers (PVC, Polyolefins)
  - Three benzotriazol UV stabilizers have been proposed for Candidate List (SVHC) by Germany
  - Alternates widely available
- Inorganic Pigments (All)
  - May contain SVHC metals- lead, cadmium
  - May contain hexavalent chromium

"O5A"- Additional Uncertainty!

- "**O**nce **A**n **A**rticle, **A**lways **A**n **A**rticle" = O5A

  Also referred to as "Component Approach"

- 6 EU Member States adopt this approach to evaluating the calculations on SVHCs in Articles (Germany, France, Austria, Belgium, Sweden, and Denmark, plus Norway- EEA Member)

- Similar approach to RoHS

O5A

- The basis for determining whether a SVHC is greater than the typical 0.1% threshold is determined when an article is first created. The basis does not change when the initial article is assembled into a larger article.
- *"The 0.1% trigger limit thus apply to each object – within an assembled article – that fulfils the definition of an article in REACH, and that was an article already before the assembly."*[1]
- Therefore, under O5A, SVHCs in a wire or a cable will be evaluated based upon just the piece of wire or cable, not based upon the entire assembly it may be attached to, even if soldered connections.

[1] "Guidance for Suppliers of Articles The REACH duties To inform about candidate list substances" July 2013

O5A

- European Chemical Agency does NOT agree with O5A approach- will probably end up in European courts
- O5A Member States have NOT indicated that they will begin inspecting or enforcing REACH compliance based upon O5A

Enforcement

- Enforcement regarding articles for content of SVHCs and substances for authorisation is still in its beginning stage
- Experience from the restrictions of phthalates in toys: RAPEX - the EU rapid alert system for consumer products

  (http://ec.europa.eu/consumers/dyna/rapex/rapex_archives_en.cfm)

Summary

- Choice of plasticizers and other wire insulation components needs to consider processing and end product performance requirements
- In addition, the current controls under REACH (Authorisation, Restriction, SVHC/Candidate List) and RoHS MUST also be carefully evaluated for products destined for Europe
- The science and especially reproductive toxicity testing of plasticizers is very dynamic
  - Closely follow evaluations (i.e. CoRAP) and regulatory proposals on components you currently use (or your suppliers use), as well as potential substitutes
  - In many cases, in-depth analysis of plasticizer chemical description in regulations is required. The use of generic chemical descriptions often overlap
- As always, politics and public perception also apply!

Syska Voskian Consulting

A Danish – US consultancy with global regulatory expertise and broad chemical industry experience

- **REACH for Articles**
  - Establish compliance processes up and down the supply chain
  - Review components for priority compliance review and action
  - Plasticizers Under REACH
    - Specific regulatory analysis of plasticizers and flame retardants
- **REACH Training & Internal Audits**
  - Prepare for Member State enforcement
  - Support organisation-wide understanding of REACH and the impact on its business
- **REACH in the Workplace**
  - Application of suppliers' Exposure Scenarios to workplace hygiene practices and existing work place risk assessments
- **Corporate Compliance Systems**
  - Within Europe only: Lisam System's ExESS SDS and Chemical Management System

Questions?

- ***Please note that Syska Voskian Consulting does not take any position on the scientific basis or Authorities' decisions on any substance***
- ***Our consultancy supports clients' understanding of regulations, and strategies to comply with current and announced future regulations***

Thank You

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