



REACH for the downstream user

Making it work for the business

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The Smithers RAPRA RubberChem 2010 Conference, Vienna, Austria



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Clwyd Compounders Ltd.

- Established in 1979
- Specialise in the design, development and manufacture of rubber compounds
- Handle all types of heat curable elastomers
- > 700 ingredients
- >7000 formulations, including many with “no change” requirements
- Up to 20 ingredients per formulation





REACH- the aims

- To provide a high level of protection of human health and the environment from the use of chemicals (substances).
- To make manufacturers and importers who place chemicals on the market responsible for understanding and managing the risks associated with their use.
- To allow free movement substances in the EU market.
- To enhance innovation in and the competitiveness of the EU chemicals industry.
- To promote a standardised approach to the testing and assessment of the hazardous properties of substances



REACH- Registration

“One substance, one registration”

Dossiers to be submitted by manufacturers or importers of substance, acting in groups.

Required for all new substances from Dec 2008, and for existing substances from 1 of 3 “phase in” deadlines- Dec 2010, June 2013, June 2018.

To include properties and proposed hazard ratings, together with studies and test results supporting the ratings given, and **description of uses** of the substance.



REACH - use descriptor examples

SU 10- Formulators

SU11- Manufacturers
of rubber products

PC 32- Polymer
Preparations &
compounds

PROC 5- Mixing or
blending in batches..
PROC 21- Low energy
manipulation of bound
substances...

ERC 3- Bound into matrix
ERC 10A/B - Wide
dispersive outdoor/
indoor use of long life
articles ...

Article type in service & waste life eg AC2- Machinery



REACH- evaluation...

Carried out by the European Chemicals Agency (ECHA) on

Registration Dossier information-

- Compliance/ completeness checking.
- Evaluation of testing proposals (for substances > 100tpa)

Annex XV Dossier information-

For certain substances, Competent Authorities of Member States may express concerns in respect of human health or environmental hazards of particular substances by submitting an Annex XV dossier



REACH- authorisation

First List-
Nov. 2008

Annex XV dossiers-

May be prepared where substances are

- Carcinogenic, Mutagenic or toxic to Reproduction (CMR) classified in category 1 or 2.
- Persistent, Bio accumulative and Toxic (PBT) or very Persistent and very Bio accumulative (vPvB)
- Causing an equivalent level of concern e.g. endocrine disrupters

If evaluation confirms these concerns, ECHA will add the substance(s) to the **Candidate List**

for detailed evaluation as a potential

Substance of Very High Concern (SVHC)

More testing and study will then be required.

To date, 46 on
Candidate List



REACH- authorisation

1st 7 SVHC
Listed in 2009

SVHC- the “Annex XIV” list

The use of SVHC will be evaluated in terms of socio-economic need for the proposed use(s), and the adequacy of hazard and exposure control measures
For listed substances, two dates are set;

Application date- by which producers must apply for permission to use the SVHC for specific purposes, with appropriate hazard control measures.

Sunset date- after which ECHA will authorise the SVHC for specific use(s) only (as above), or require that it be phased out.

2 -3 yrs
after listing

4 yrs
after listing



REACH – communication

Pre-REACH- manufacturer to user

- Safety data sheets (SDS) & labels provided information.
- Dangerous Substances Directive (DSD) & Dangerous Preparations Directive (DPD) enabled standardised classifications for many substances & preparations.

Post REACH- communication must be 2-way

Builds on above systems but

- Onus on manufacturers & users to assess hazards in light of actual uses of substances & preparations.
- Extended SDS required for all substances classified as hazardous and supplied at >10tpa
- Extensive requirements for SVHC

For Article producers, if articles contain SVHC &/or Candidate List substances, information must be provided to consumers on request, and from June 2011, also directly to ECHA.

REACH- why communicate?



- REACH forces us to address the customers need to know, for a public fearful of chemicals, and a press eager for stories...



REACH –communication 2011

From 1-6-2011 there are updated requirements for substances in articles;

Manufacturers of Articles containing >0.1%w/w of a Candidate List material must inform ECHA of

- The type of article**
- The amount of candidate list material present**
- The function of the candidate list substance within the article**



REACH- implementation to date

- **Identification of substances-**
 - Many raw materials are preparations
 - Will they be registered/ for what uses.
- **Identify Candidate List/ SVHC substances-**


DOP (DEHP) appeared as potential Candidate list substance in summer 2008

 - Removed from Clwyd preparations by Nov 2008
- **Review SDS/ Article 32 information & communicate to customers**
 - Able to offer re-assurance!



REACH- communications to date

- **Appoint a Reachrep**
- **Communicate about intentions to register substances & intended uses**
- **SDS- Requirements defined in UK under CHIP**
(Chemical Hazard Information for Packaging & Supply Legislation)
 - for substances & preparations, as defined under DSD or DPD
 - For preparations containing a DSD substance at >1% w/w
 - For preparations containing Candidate List or SVHC substances at > 0.1% w/w, to enable consumer notification of SVHC in articles
- **Provide “Article 32” information**
 - For preparations not identified above, which still requiring some “safe handling” information.



REACH – major changes to SDS & labelling

CLP -Classification, Labelling & Packaging of Substances & Mixtures, EC 1272/20080.

Jan 2011-

- Manufacturers of registered substances must label and package them under CLP, and classify them (on the Safety data sheet) under both CLP and previous legislation (DSD).
- Manufacturers must notify their classifications to ECHA
- Formulators must continue to label and package under (DSD/DPD), they may also classify them under CLP.

June 2015

- Formulators must label and package their formulations under CLP



Transition to CLP –

- **New language and symbols-**
 - “Dangerous” become “hazardous”, preparations become mixtures.
 - Hazard statements and precautionary statements replace risk and safety phrases
 - Wider range of hazard classifications and symbols will be available
- **Substances already classified under DSD-**
 - 4000 substances have been “translated” into the new framework (Table 3.1 of Annex VI to CLP). These classifications must now be considered as minima.
- **Extended SDS-**
 - For hazardous substances produced at >10tpa, SDS to include “exposure scenarios”.





CLP- Implementation issues

New SDS and labelling will be received with registered substances from Jan 2011

- Staff training
- Review SDS
 - Check hazard classifications
 - Extended SDS may be required where hazardous substances are present
 - Communicate with customers & suppliers as required

SDS for mixtures

- Re-writes/ more SDS may be needed in 2012
- Major review and amendment of all classification, labelling and SDS must be completed by 2015



REACH- SVHC issues

For downstream users, presence of a Candidate list substance/ SVHC in a product has major implications

- Health & Safety considerations for staff in the business
- Evaluation – Authorisation – Restrictions on Use/ Ban. Long period of uncertainty, likely need for re-formulation where this poses a problem.

Member States submit requests for SVHCs- politics will be a factor as well as chemistry...

Downstream user strategy- Review uses of potential SVHC materials and eliminate or substitute wherever possible



REACH- future SVHCs?

- **Criteria for Candidate List or SVHC**
 - CMR under DSD- approx 1000 substances
- **GADSL (Global Automotive Declarable Substances List)**
 - American Chemistry Inc, describes over 100 substances & groups which are either prohibited or declarable for use in cars.
- **The SIN (Substitute It Now) list**
 - Created by Chemsec with backing of many NGOs and some major companies producing consumer products
 - 356 substances, (311 CMRs)

Includes all lead compounds

Includes DINP & ETU



The SIN list- gaining influence?

From PRW.com, Wednesday, 4th May 2011

ChemSec wants to catch 22 in extended Reach

Environment lobby group ChemSec, based in Göteborg, Sweden, has called on the European Union to add 22 substances to the Reach Regulation, which it claims are endocrine-disruptors... *this includes TMTD*

From PRW.com Monday, 9th May 2011

Green groups take toxic action against ECHA

Two green lobby organisations ClientEarth and ChemSec are taking legal action against the European Chemicals Agency (ECHA) for its alleged refusal to release the names of companies producing *some of the most dangerous chemicals in the EU market.*

The 356 chemicals at the heart of the debate are on ChemSec SIN (Substitute it Now!) list, which comprises substances classified as Substances of Very High Concern under the Reach Regulation



SVHCs- too slow a process ?

- 1000+ substances were *potentially* SVHC- CMR or environmental hazards under DSD
REACH has added more- the “substances of equivalent concern” such as endocrine disruptors
- Since 2008,
 - 46 put on candidate list (Annex XV dossiers have been prepared)
 - 15 declared SVHC (Annex XIV list)
- First sunset dates (decision on authorisation or ban of particular SVHCs)- 2014/5

Chemsec want all 378 “SIN list” substances declared SVHC now.



Clwyd approach to accelerator issues

ETU- toxic for reproduction, cat.2. Clwyd does not use it, we have several substitutes, none of which is ideal.

We have also joined an EU project www.saferubber.eu which aims to design a safe alternative.

TMTD- Harmful, may cause damage to organs through respiratory exposure, Also harmful to the aquatic environment.

Clwyd are minimising use in new compounds, but have not yet substituted in existing formulations.

In rubber articles, due to low levels used, could assume residual substance present would be $>0.1\%$. But bloom is a known issue with TMTD, and if present on the surface, this would present a risk disproportionate to its actual presence in the compound.



Case Study- phthalate substitution

Why substitute ?

- Have a “bad press” generally
- DOP/DEHP (di-ethyl hexyl phthalate) + 3 others are SVHC, with Sunset Dates in 2013.

DINP di-iso-nonyl phthalate, replaced DEHP in 2008, BUT

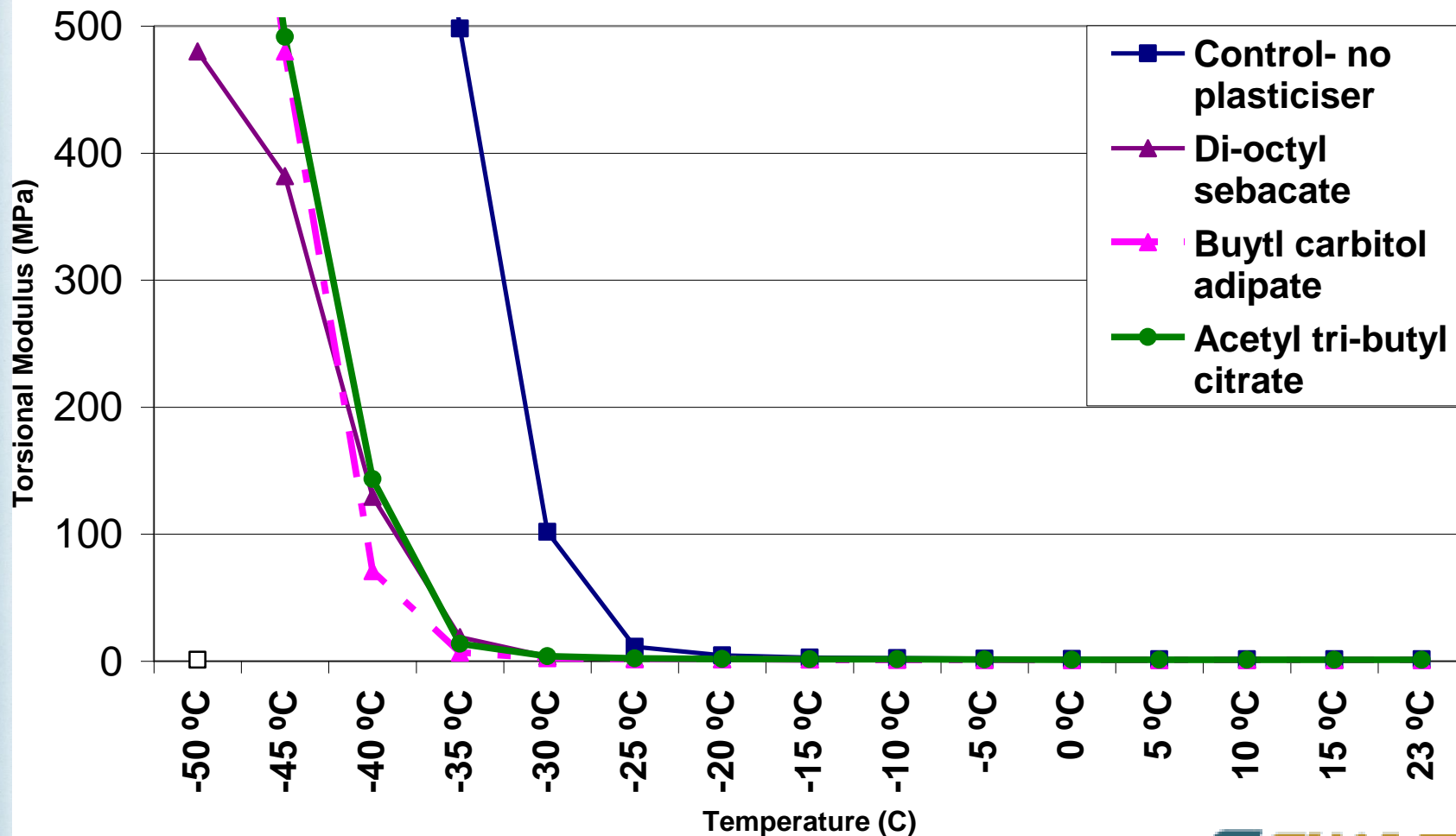
- on ECHA priority 2 list for investigation
- on “SIN” list
- widely used

Current Project- Evaluation of Citrates

- Used in plastics for over 40 years, clean bill of health in respect of REACH
- Initially evaluated due to low temperature properties
- Possible alternative to phthalates?



Low temperature flexibility of 60 IRHD HNBR compounds containing different plasticisers



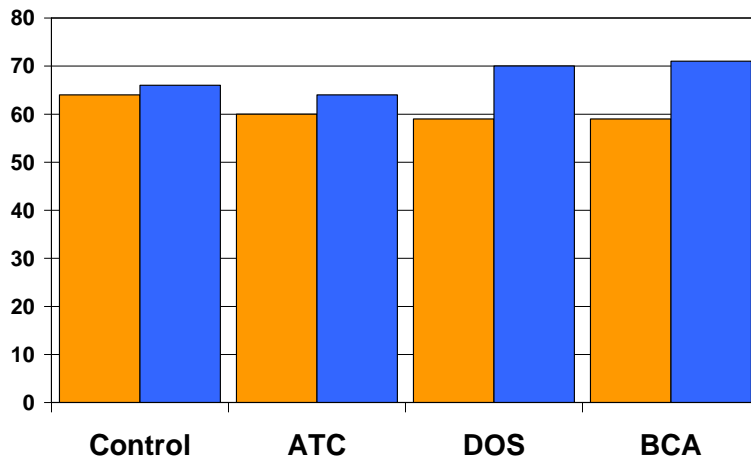


Performance of Citrate Ester Plasticiser in HNBR

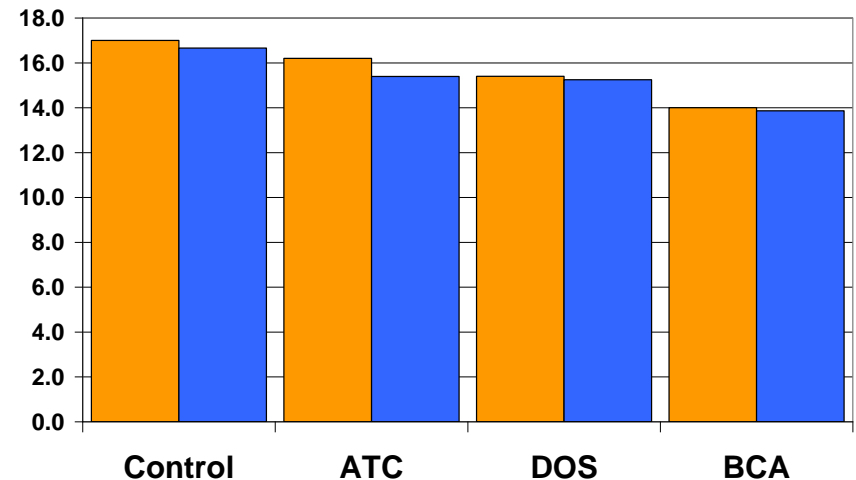
Test results for
No plasticiser- Control
ATC- Acetyl Tributyl Citrate
DOS-Di-octyl sebacate
BCA- Butyl carbitol adipate

■ before ageing ■ after 168hr @ 150C

Hardness (IRHD)



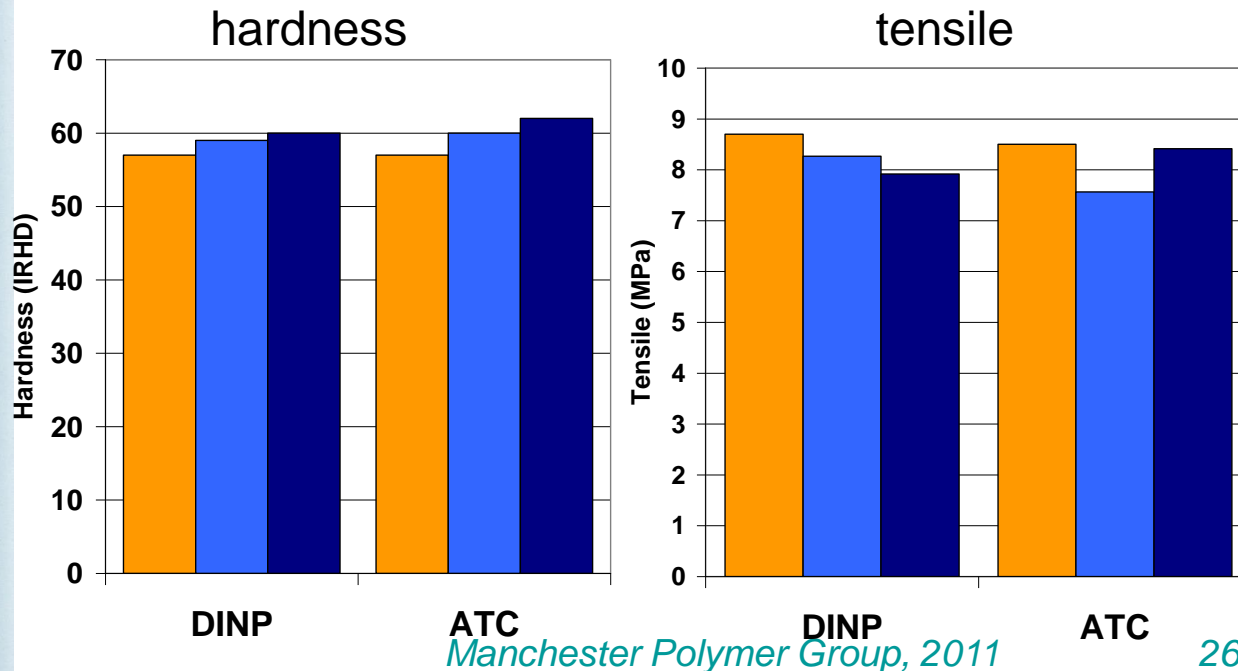
Tensile (Mpa)





Comparison of DINP and Citrate in 60 IRHD NBR

Formulation-	Medium acrylonitrile, sulphur cured	
Plasticiser-	DINP	Acetyl tri-butyl citrate (ATC)
Hardness-	57	57
Comp. set % (24hr @ 70C)-	21	21
Results for ageing in hot air-		





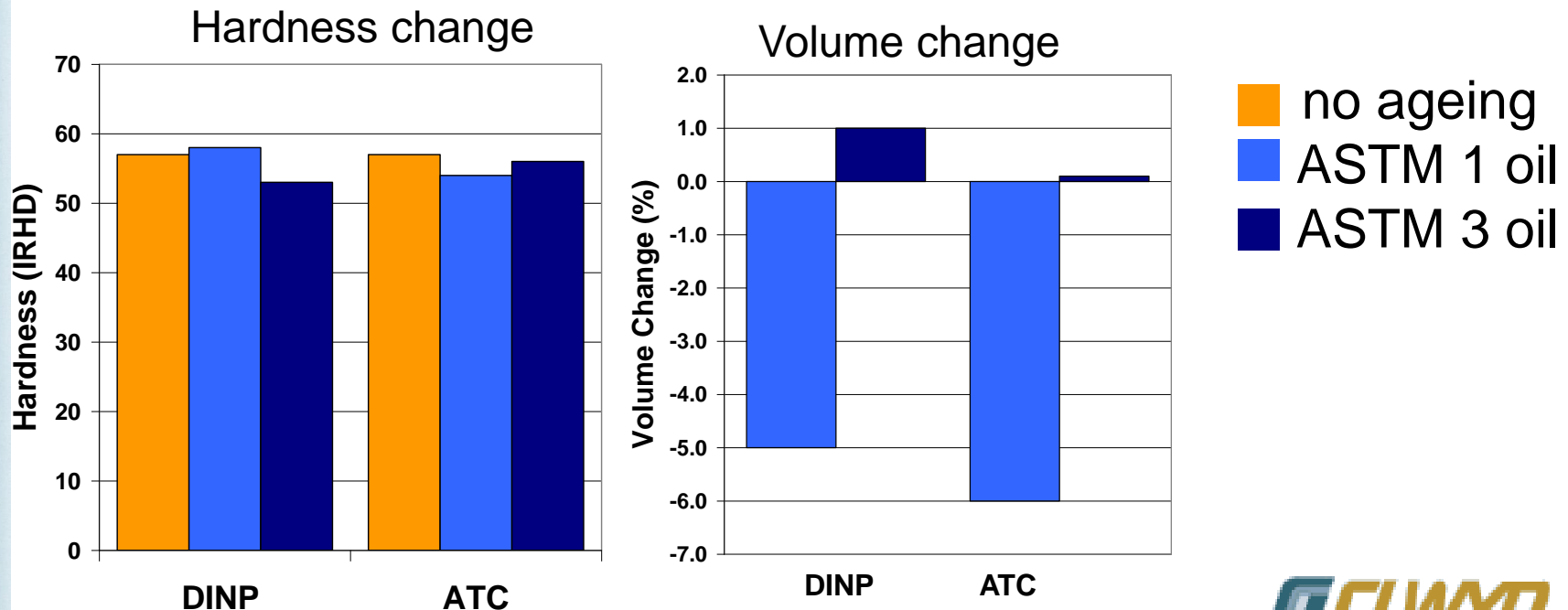
Comparison of DINP and Citrate in 60 IRHD NBR

Corrosion

(168hr @ 70C, carbon steel & copper) - both pass

Oil resistance-

Results after ageing for 70hr @ 70C





Comparison of DINP & Citrate in 40 IRHD NBR

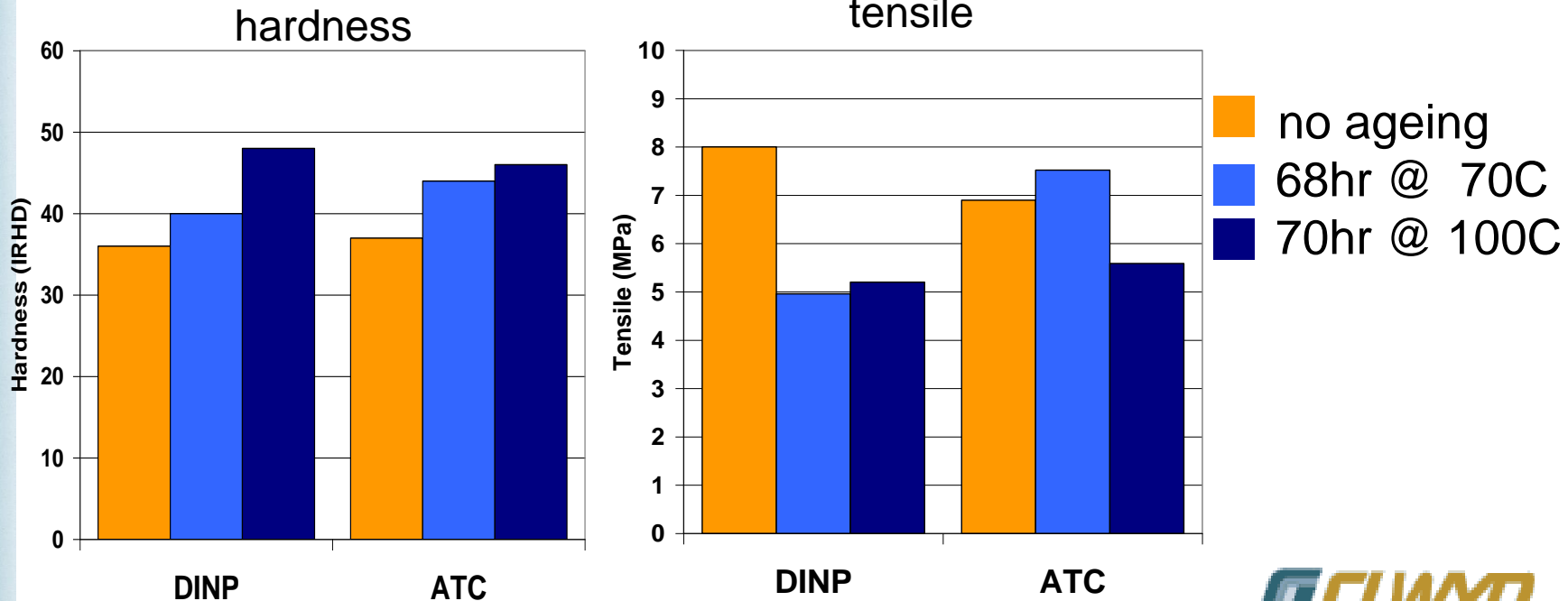
Formulation- Medium acrylonitrile, sulphur cured

Plasticiser- DINP Acetyl tri-butyl citrate (ATC)

Hardness- 36 37

Comp. set % (24hr @ 70C)- 24 35

Results for ageing in hot air-





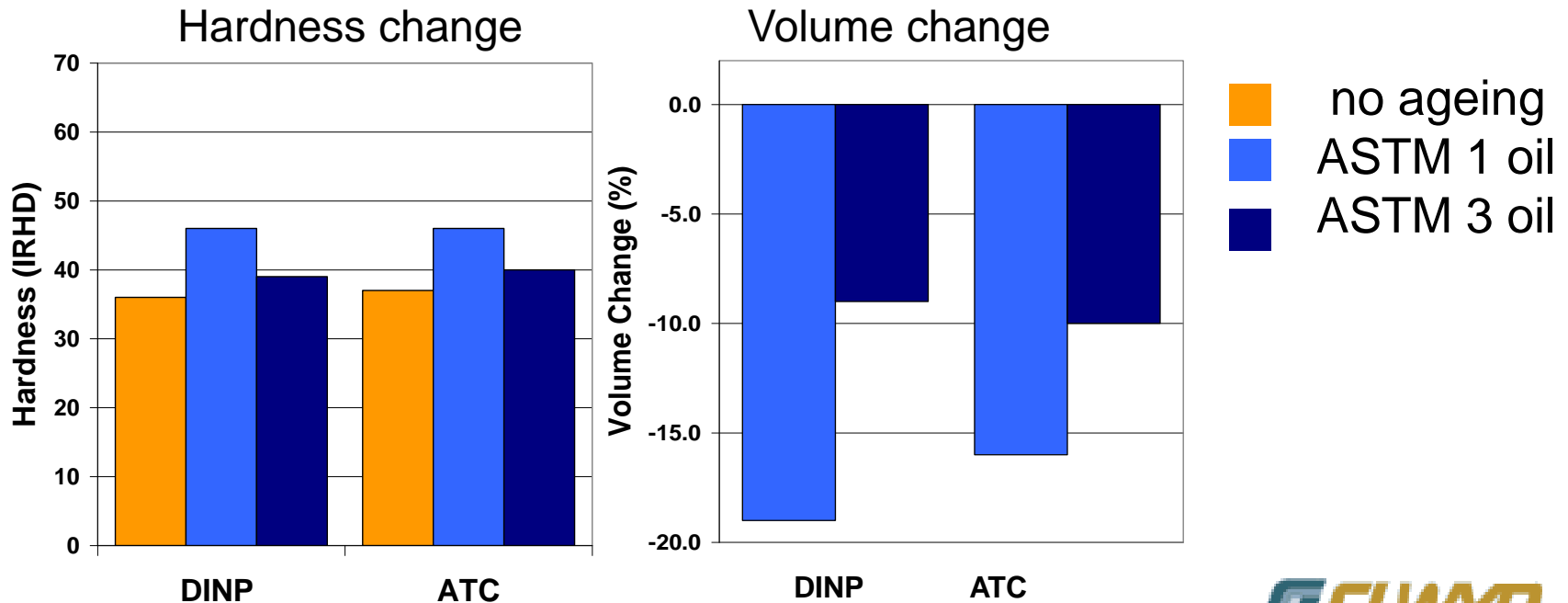
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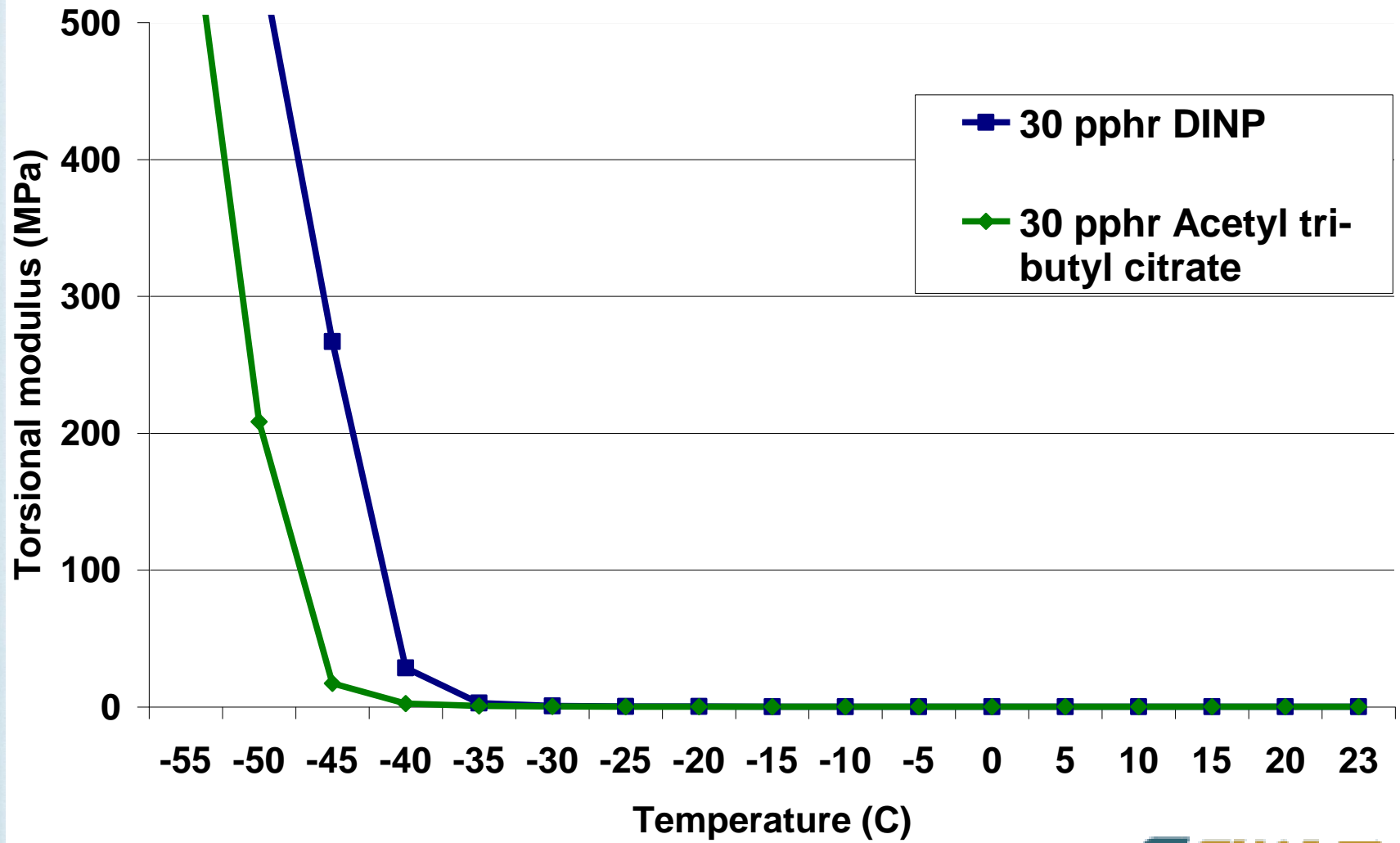
Oil resistance-

Results after ageing for 70hr @ 70C





Low temperature flexibility of 40 IRHD NBR (Gehman test)





Case Study conclusion

- Tri-butyl O-acetyl citrate (Citrofol B2) has a very useful range of properties, and is potentially a general purpose plasticiser which could replace DINP.
- Long term testing is now in hand
 - Compatability testing
 - Metal bonding trials
 - More work needed to establish best working temperature range
- Higher molecular weight citrates have also been sourced- may give improved heat ageing



REACH- Keep it simple

- The key for SMEs- understand the basics, focus on a step at a time approach
- Let the majors lead- SME's can't afford to invent the wheel!
- For a formulator, the key needs are-
 - A robust system for picking up changes in supplier data sheets
 - Be pro-active in identifying likely SVHC issues



And finally

In mature economies, consumer safety is rightly a prime driver of product development

REACH is a tool

It is down to us all to make good use of it

Thank you for listening

ANY QUESTIONS