

REACH
THE NEW
LEGISLATION
AND
MANUFACTURE OF
COMPOSITES
OUTSIDE THE EU

REACH – THE BASICS

REACH requires all substances manufactured in the EU in a quantity greater than 1 tonne per annum (tpa) to be registered. The obligation is with the manufacturer or importer to register the substance and this includes an assessment that the uses within the EU market are safe.

Composites are mixtures of polymers with substances and can be considered as preparations under REACH terminology. If the composite is to be exported to the EU then the monomers within the polymer and other, non-chemically bound substances, need to be registered if the volume of the particular substance exported is greater than 1 tpa.

The affect this will have to the export of composites to the EU can be split into 3 main areas:

1. All suppliers sourcing material from within the EU must confirm the product will be available after REACH registration deadlines
2. The composition of all products exported to the EU must be assessed and qualifying substances registered for customer uses.
3. Any appropriate risk management measures to ensure safe use must be communicated to customers

This guide applies to the supply of the following materials from Lucite International:

Avron
Composites
Repair resin

This guide contains sections detailing the obligations throughout the supply chain and is split into purchasing, manufacturing and sales.

The key milestones in the REACH timeline are as follows:

1 June 2007	Legislation enters into force (EIF).
1 June 2008	Pre-registration begins.
1 December 2008	Pre-registration ends.
1 December 2010	Registration deadline for substances placed on the market in quantities over 1000 tonnes per annum, or substances of very high concern.
1 June 2013	Registration deadline for substances placed on the market in the range of 100–1000 tonnes per annum.
1 June 2018	Registration deadline for substances in quantities of 1–100 tonnes per annum.

REACH applies to all substances manufactured or imported into the EU in a quantity >1tpa. Registration is by the entity placing the substance on the market but this requires detailed communication of uses and risk management measures up and down the supply chain. As a result there could be effects seen throughout the supply chain. From the perspective of a non-EU manufacturer there are some key points to consider:

1. Purchasing of raw materials
2. Manufacture of products registered under REACH
3. Supply of products to customers ('Downstream Users')

PURCHASING OF RAW MATERIALS

The REACH process is phased according to the volume and hazards of the individual substance. However, each legal entity manufacturing or importing a material in the EU must register. As a result, if a raw material is purchased within the EU, it should be confirmed that the supplier is intending to register the manufacture of that substance to ensure continuity of supply. The following are the checks that should be made:

1. All suppliers sourcing material from within the EU must confirm the product will be available after REACH registration deadlines
2. Any new EU supplier must confirm that supply of the material will not be affected by REACH.

As REACH registration obligations are phased the questions we should be asking suppliers and the steps we should take are dependent upon the REACH timeline. The following pages indicate the requirements according to timing.

PURCHASING SUBSTANCES FROM AN EU SUPPLIER

PRIOR TO 1st JUNE 2008

REACH Obligations: No obligation to register, preparation phase

Confirm with supplier:

1. Substances purchased will be pre-registered
2. Determine anticipated registration deadlines
3. Review with supplier if material contains a substance that may be listed as a substance of high concern and potentially require authorisation in the future

1st JUNE 2008 – 1st DECEMBER 2008

REACH Obligations: Pre-registration phase. Existing substances need to be pre-registered to allow manufacturing in the EU to continue and to take advantage of the phase-in registration process. New substances should be registered before being manufactured in the EU.

Confirm with supplier:

1. Existing substances have been pre-registered under REACH and will continue to be supported
2. Registration due date for potential next milestone that could affect manufacturing in the EU

AFTER 1st DECEMBER 2008

REACH Obligations: Existing substances should be pre-registered or registered to allow manufacturing in the EU to continue. Pre-registration is not a guarantee of registration hence it is important to review deadlines with the manufacturer. New substances should be registered before being manufactured in the EU.

Confirm with supplier:

1. Substances purchased will be pre-registered
2. Determine anticipated registration deadlines
3. Review with supplier if material contains a substance that may be listed as a substance of high concern and potentially require authorisation in the future

MANUFACTURE OF COMPOSITES OUTSIDE THE EU UNDER REACH

The manufacturing process for production of composites outside the EU does not require registration under REACH. However, if changes to the manufacturing process affect composition of a product exported to the EU then there may be some checks required.

CHANGE TO EXISTING PRODUCT COMPOSITION OR MANUFACTURE OF A DIFFERENT PRODUCT

Ensuring products exported to the EU are compliant with REACH requires identification and registration of qualifying substances. Changes to composition may mean that the obligations change. This may be due to the introduction of a new substance, or the increase in volume of a substance being exported to the EU. Hence, if the manufacturing process changes such that the composition is altered then the new specification should be checked against the registration. If the change takes this outside the original limits then it should be treated as manufacture of a different product. In summary:

1. Introduction of a completely new substance into a composite
This will require that substance to be registered before the product can be exported to the EU. If it already exists as a substance in the EU then it may be pre-registered and the registration requirements phased. However, if it is a completely new substance to the EU then it will need to be fully registered before it can be exported to the EU.
2. Change to concentrations of existing substances
If a product composition changes then the amount of an individual substance exported to the EU may change. In this case, the volumes must be assessed to ensure that the correct substances are pre-registered and registered, and that registrations are updated if there is a change to the volume band originally declared.

REGISTRATION OF COMPOSITES UNDER REACH

REACH requires the individual substances to be registered. In the case of a composite this requires both the polymer content and the other substances in the mixture to be assessed.

All individual substances imported into the EU in a quantity >1tpa may be subject to registration. Although the obligation for registration is with the legal entity responsible for import of the substances into the EU, a non-EU manufacturer can nominate an only representative in the EU to complete the registration on their behalf. For Lucite International products identified as exported to the EU the registration will be completed in the UK.

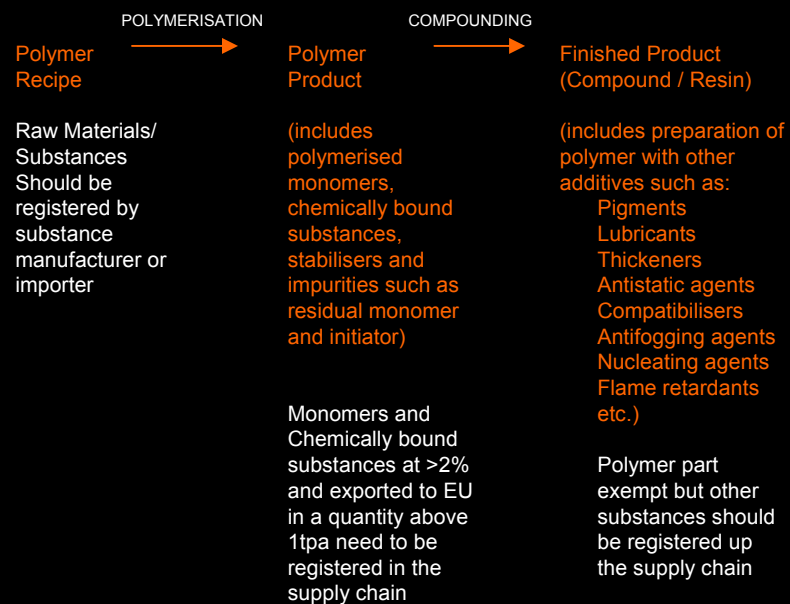
In order to complete these registrations fully the composition of the product needs to be reviewed. Component substances should be assessed and registered as identified. The polymer content required further assessment as outlined in the following page.

REGISTRATION REQUIREMENTS FOR NON-EU POLYMERS

Polymers themselves are exempt from REACH registration. However, the monomers need to be registered and many products are compounds of polymers with additives such as pigments, stabilisers, antistatic agents etc.

The quantity of any heat or light stabiliser or antioxidant added to a polymer to preserve stability is considered part of the polymer and hence exempt. However, any unbound substances such as pigments must be treated as constituents of a preparation. As such these substances are being placed back on the market and customer uses should be fed back to the original manufacturer or importer to include these in their registration dossiers.

The diagram below aims to show the registration requirements for polymers exported to the EU:



SALE OF COMPOSITES FOLLOWING REACH

REACH applies to substances manufactured or imported into the EU. The effect this could have to downstream users of composites will be dependent upon how and where the material is to be used.

Use of non-EU manufactured composites outside the EU

The use of substances outside the EU is not subject to REACH. However, if the composite is used to manufacture a product that is then exported to the EU the customer may have some obligations. For example, a sink would be classified as an article under REACH. Although the export of a sink to the EU would not require registering there are implications if the bath contains substances of high concern and hence the bath manufacturer may seek reassurances on composition of the composite. More details of these implications are assessed in the guide 'MANUFACTURE OF ARTICLES OUTSIDE THE EU'

Use of non-EU manufactured composites in the EU

REACH requires each legal entity importing a substance in a quantity over 1 tpa to register that substance. In the case of non-EU manufactured substances, the obligation is with the importer to complete the registration unless they can demonstrate the substance has been registered within the supply chain.

If a legal entity importing a substance to the EU fails to meet the REACH registration timelines then it will be illegal for that legal entity to import that substance into the EU until they have completed the full registration.

The next pages look to review the registration timeframes associated with REACH, the effect that may have to customers of non-EU manufactured substances and the schedule for meeting the phased obligations.

USE OF SUBSTANCES IN PREPARATIONS

Prior to 1st June 2008

Substances can be manufactured, imported and placed on the market as existing procedures

1st June 2008 – 1st December 2008

New substances will have to be registered under REACH and sold according to the recommendations in the use and exposure assessments included on the extended safety datasheet.

Existing substances should be going through pre-registration and can continue to be sold as existing procedures.

After 1st December 2008

New substances will have to be registered under REACH and sold according to the recommendations in the use and exposure assessments included on the extended safety datasheet.

Existing substances can be sold as normal if they are pre-registered and the registration date is due in the future. After registration they should be sold in Europe according to the recommendations in the use and exposure assessments included on the extended safety datasheet. For a preparation of several substances, the appropriate risk management measures should be identified on the single safety datasheet.

Specific Downstream User obligations under REACH will vary depending upon how the substance is used. Whilst this booklet covers the manufacture of composites outside the EU, we have prepared a number of similar booklets for our downstream operations that can be used to review other more specific issues. These are:

MANUFACTURE OF SUBSTANCES IN THE EU

MANUFACTURE OF POLYMERS / RESINS IN THE EU

MANUFACTURE OF COMPOSITES IN THE EU

MANUFACTURE OF ACRYLIC SHEET IN THE EU

DISTRIBUTION OF ACRYLIC SHEET IN THE EU

MANUFACTURE OF SUBSTANCES OUTSIDE THE EU

MANUFACTURE OF POLYMERS / RESINS OUTSIDE THE EU

MANUFACTURE OF ACRYLIC SHEET OUTSIDE THE EU

GENERIC OBLIGATIONS FOR DOWNSTREAM USERS

There are a number of generic obligations under REACH for users of substances. These may have additional implications that should be considered.

1. DECLARATION OF USE AND EXPOSURE SCENARIO

The registrant of a substance may, depending upon properties and volume, have to submit a dossier that includes an assessment of each identified use against the toxicology data and propose appropriate risk management measures. These are then required to be communicated through the extended safety datasheet (eSDS).

Exposure scenarios can be communicated by the customer (and a distributor is obliged to pass that information back up the supply chain) or developed by the manufacturer (possibly through trade associations).

2. IMPLEMENTATION OF RISK MANAGEMENT MEASURES

A downstream user must implement the risk management measures highlighted against the appropriate exposure scenario in the eSDS. If the list of scenarios does not cover that particular use then the customer either needs to declare it to the agency themselves (may be preferred due to reasons of confidentiality) or get the original registrant to conduct the assessment and update the dossier and the eSDS. A distributor may want to take the option of assessing downstream uses themselves rather than declaring these to their supplier. For registered substances, this needs to be done within a month of supply.

3. COMMUNICATION OF INFORMATION IN THE SUPPLY CHAIN

The effect of (1) and (2) is a lot of information needs to be passed through the supply chain. Supplementary to this booklet is REACH: THE NEW LEGISLATION AND YOU: INFORMATION THROUGH THE SUPPLY CHAIN that provides a more detailed assessment

4. TIMESCALES

Registration timeframes are according to the volume manufactured or imported by the registrant. It is important to note that, if the substance is supplied in a low volume by a distributor, the timeframe might be sooner than anticipated. Registration of LI monomers will be by 1st December 2010.

FREQUENTLY ASKED QUESTIONS ABOUT REACH

1. When do you need to generate an exposure scenario?

Exposure scenarios are required for the registration phase for substances manufactured or imported in a quantity ≥ 10 tpa (Article 10, 14.1) and classified as dangerous according to directive 67/548/EEC or Directive 199/45/EC or is assessed to be a PBT or vPvB (Annex I (0.6)).

2. What happens if my use is not covered by my supplier's registration?

A downstream user may make a request in writing for a use to be included. For phase-in substances this request must be made 12 months before the registration is due (Article 37.3). For registered substances, the supplier must complete the exposure assessment the later of prior to next supply (if the request was made at least 1 month before supply) or within 1 month (Article 37.3). A downstream user may prepare their own chemical safety report for any use outside the conditions described in an exposure scenario and this must be done within 12 months of receiving the registration number from the supplier (Article 37.4, 39.1).

3. What happens if my supplier fails to pre-register?

If a substance does not appear on the list of those pre-registered and published by the Agency by 1 January 2009 (i.e. no-one pre-registers) then a downstream user may notify the Agency of his interest and details of his current supplier. The Agency shall publish the name of this substance on its website in the event that there maybe a potential registrant (Article 28.5). Otherwise, it would be possible to look for an alternative supplier who has pre-registered, or to consider manufacturing or importing the substance. In the latter case, it is possible to submit a late pre-registration for that substance if completed within 6 months of first manufacture or import (Article 28.6) as long as it is more than 12 months before you would be due to fully register your volume. This option would allow import for 6 months whilst an alternative was sought.

4. What happens if I want to introduce a new use for a registered substance?

A downstream user may make a use known to the supplier and, if an exposure assessment is required, the supplier must provide that information before next supply or within 1 month of the request (Article 37.3). If a downstream user decides to register the new use directly to the Agency (potentially for reasons of confidentiality) then that assessment is required within 6 months (Article 38, 39.2)

5. What happens if I want to start manufacturing or importing a substance after pre-registration has ended?

See Q3.

6. How do I pre-register a substance?

IT tools are available from the ECB website which links from the ECHA website (see further info section for link). The system to be used for collating the data required for registration is IUCLID5 and is available as a free download from the website. Systems are being developed to allow this data to be submitted for pre-registration.

DEFINITION OF SOME COMMON REACH ACRONYMS

C&L	Classification and Labelling	IUCLID	International Uniform Chemical Information Database
CA	Competent Authority	LEO	Legal Entity Organisation
CAS	Chemical Abstracts Service Number	M/I	Manufacturer / Importer
CMR	Carcinogen, Mutagen or Reproductive Toxin	MS	Member State
CSA	Chemical Safety Assessment	MSDS	Material Safety Data Sheet
CSR	Chemical Safety Report	NLP	No Longer Polymers
DNEL	Derived No Effect Level	OECD	Organisation for Economic Co-operation and Development
DU	Downstream User	OSOR	One Substance One Registration
DUNS	D&B Unique Numbering System	PBT	Persistent, Bioaccumulative and Toxic
EBW	Exposure Based Waiving	PNEC	Predicted No Effect Concentration
EC	European Commission	PPORD	Product and Process Orientated Research and Development
ECHA	European Chemicals Agency	QSAR	Qualitative Structure Activity Relationship
EC No	EINECS or ELINCS Number	REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
EIF	Entry into Force	RIP	REACH Implementation Project
EINECS	European Inventory of Existing Chemical Substances	RMM	Risk Management Measure
ELINCS	European List of Notified Chemical Substances	RSS	Robust Study Summary
EP	European Parliament	SEA	Socio Economic Analysis
ES	Exposure Scenario	SIEF	Substance Information Exchange Forum
eSDS	Extended Safety Data Sheet	SME	Small and Medium Sized Enterprise
EU	European Union	SPORT	Strategic Partnership on REACH Testing
GHS	Global Harmonised System	SVHC	Substances of Very High Concern
GLP	Good Laboratory Practice	TGD	Technical Guidance Document
HPV	High Production Volume	vPvB	Very Persistent and Very Bioaccumulative

FURTHER SUPPORT FOR REACH

There are a number of REACH service providers available. Listed below are some additional sources of support to help you understand your obligations under REACH:

UK Chemical Industries Association REACH Service:

www.reachready.co.uk

UK National Competent Authority:

www.hse.gov.uk/reach

CEFIC REACH Service:

www.reachcentrum.eu

European Chemicals Agency:

www.echa.europa.eu

For more information on preparations for REACH within Lucite International:

www.reach-and-you.info

For more information about Lucite International:

www.luciteinternational.co.uk

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