

REACH
THE NEW
LEGISLATION
AND
MANUFACTURE OF
SUBSTANCES
IN 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. This registration must include an assessment that the uses within the EU market are safe according to the toxicology data for that substance. How this affects the manufacturing of substances in the EU is three-fold:

- 1.All raw materials should be registered for our own and potentially our customers uses
- 2.Any risk management measures prescribed by our raw material suppliers should be implemented at our manufacturing sites and, if necessary, communicated to customers
- 3.All products should be registered for all downstream uses and customers informed of any appropriate risk management measures

This guide contains sections detailing the obligations throughout the supply chain and is split into purchasing, manufacturing and sales. It applies to the manufacture of the following materials at Lucite International:

Acetone Cyanohydrin
Ammonium Sulphate
i-Butyl Methacrylate
n-Butyl Methacrylate
Hydrogen Cyanide
Methyl Methacrylate
Methacrylic Acid

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 must register. As a result each supplier must register every substance and we cannot rely on the fact the one supplier having registered meaning that an alternative supplier is approved. Consequently the following processes must be in place:

1. Existing suppliers must confirm all the products they supply are compliant with REACH
2. Existing suppliers must also confirm that any additional products that they are asked to supply are compliant with REACH
3. Any new supplier of an existing raw material must confirm that their supply of that material is compliant to REACH
4. Any supplier of a new raw material must confirm that the supply of that material is compliant to 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.

PRIOR TO 1st JUNE 2008

REACH Obligations: No obligation to register, preparation phase

Confirm with supplier:

1. All substances requiring registration have been identified
2. Supplier will pre-register all relevant substances
3. Non-EU supplier will nominate an 'only representative' based in the EU to fulfil the obligations of registration
4. Anticipated registration due dates for substances (1st June 2008, 1st December 2010, 1st June 2013 or 1st June 2018)
5. How supplier will identify and review use and exposure scenarios and communicate risk management measures.
6. Indicate if the product contains any substance that may be listed as a substance of high concern and potentially require authorisation in the future

If the supplier is unable to answer any of the above then an alternative or second supplier should be identified as a precaution.

1ST JUNE 2008 – 1ST DECEMBER 2008

REACH obligations: Pre-registration existing substances
Registration new substances

During this time a supplier must:

1. Confirm pre-registration or exemption from REACH
2. Confirm pre-registration numbers
3. Confirm registration due dates
4. Indicate next steps for identification of use and exposure scenarios
5. Indicate if the product contains any substance that may be listed as a substance of high concern and potentially require authorisation in the future

If the supplier is unable to answer any of the above then an alternative or second supplier should be identified as a precaution.

AFTER 1ST DECEMBER 2008

REACH Obligations: All substances not exempt from REACH should now either be pre-registered or registered.

A substance can now have one of the following status:

- Pre-registered
- Registered
- Exempt for registration

Status	Purchasing Responsibilities
Pre-registered	<ol style="list-style-type: none">1. Confirm pre-registration number2. Confirm registration due date3. Ensure supplier has been sent list of use and exposure scenarios4. Set follow-up date with supplier5. Confirm if product contains a substance of high concern *
Registered	<ol style="list-style-type: none">1. Confirm registration number(s) with supplier2. Confirm where all identified (manufacturing and downstream user) use and exposure scenarios are covered in suppliers eSDS3. Update MSDS with new eSDS4. Confirm if product contains a substance of high concern *
Exempt from REACH registration	<ol style="list-style-type: none">1. Ensure systems are updated to confirm exempt then no further action2. Confirm if product contains a substance of high concern *

NO MATERIAL SHOULD BE PURCHASED UNLESS IT HAS A REGISTRATION NUMBER, A PRE-REGISTRATION NUMBER WITH A REGISTRATION DUE DATE SOMETIME IN THE FUTURE OR IS CONFIRMED BY THE SUPPLIER AS EXEMPT FROM REACH

*If the product contains a substance of high concern it may need to be authorised or substituted in the future. The supplier should indicate plans regarding authorisation and manufacturing teams informed for potential requirement for substitution

MANUFACTURE OF SUBSTANCES IN EU UNDER REACH

All substances manufactured in a quantity ≥ 1 tpa will need to be assessed under REACH. Unless exempt, substances will not be available and should not be placed on the market after 1st December 2008 unless they are either pre-registered or registered. This can have a number of effects on manufacturing processes and can be grouped into the following areas:

1. Use of existing raw materials
2. Control of changes within the manufacturing process
 - Introduction of new raw materials
 - Change of use of existing raw material
 - Change to process to affect storage and transport of intermediates
3. Manufacture of new product or change to existing product composition

The requirements of REACH for the above cases are covered in the following pages.

USE OF EXISTING RAW MATERIALS

REACH registration requirements are phased and different suppliers may be required to register at different times. The first check is to confirm it is compliant with REACH which may mean that it is pre-registered or registered. The purchasing checks should ensure that substances are compliant from each supplier. Those pre-registered and due registration at a later date can be used according to site procedures. However, if any supplier has registered in excess of 10tpa then they will have carried out a chemical safety assessment to ensure that suitable risk management measures are recommended for each identified use of the substance. These are to be included in an extended safety datasheet (eSDS). The downstream user is required to implement those risk management measures. Hence, before using a substance on a manufacturing site we will be required to check:

1. The manufacturer has registered the substance for the intended use (this will be on the eSDS when the manufacturer has fully registered)
2. The appropriate risk management measures as specified in the extended safety datasheet are being implemented
3. Any changes to use or new use of substances are checked against the safety datasheet and appropriate risk management measures are applied or, if not covered, are reviewed with the supplier before the new use is implemented

REACH does include the requirement for authorisation for use of the substances of highest concern and there is the potential for these to be phased out and result in compositional changes of products or preparations that might not obviously be affected. This may include process consumable materials where performance in the process is affected by composition. To mitigate against this purchasing teams have been asked to check if materials or articles contain potential substances of high concern.

CONTROL OF CHANGES WITHIN MANUFACTURING

1. INTRODUCTION OF NEW RAW MATERIALS

From 1st December 2008 all substances should have been assessed under REACH and should either be pre-registered, registered or confirmed as exempt from the regulation. Any new raw material needs to be checked with the supplier to confirm they comply with the requirements and all proposed uses need to be reviewed with the supplier to verify that they are supported before the substance is introduced and used.

2. CHANGE OF USE OF EXISTING RAW MATERIAL

- All new uses of a pre-registered substance should be declared to the purchasing team and reviewed with the supplier to confirm it will be added to the registration dossier
- All new uses of a previously registered substance should be checked against the eSDS to confirm the appropriate risk management measures.
- If a new use is not included on the eSDS then it must be reviewed with the supplier and the registration updated before the new use is implemented.

3. CHANGE OF PROCESS AND HANDLING OF INTERMEDIATES

REACH requires isolated intermediates to be registered, although the information requirements are reduced. Should a new substance be isolated from the process and stored on site then a new registration will be required.

If an intermediate previously stored only on site is to be transported off-site then the information requirements are increased and the registration dossier needs to be updated prior to transport of the substance.

CHANGE TO EXISTING PRODUCT COMPOSITION OR MANUFACTURE OF A DIFFERENT PRODUCT

Registration of substances under REACH requires confirmation of composition early in the process. Should the manufacturing process change such that the composition is altered 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.

Introduction of a different product will require a separate registration under REACH. If this is a substance classified as existing under previous legislation then it is possible that this could be pre-registered and given a phase-in registration timeframe according to volume. However, if this is a completely new substance then it will require immediate registration.

SALE OF MATERIAL UNDER REACH

The substances we manufacture within the EU will be pre-registered and supported through the REACH registration process. The key milestones for us to achieve this are:

Prior to 1 st June 2008	<ul style="list-style-type: none"> Confirm list of substances manufactured in EU Identify on-site isolated and transported intermediates Compile available toxicology data Prepare generic EU use descriptions 	<ul style="list-style-type: none"> ✓ ✓ ✓ ✓
1 st June – 1 st December 2008	<ul style="list-style-type: none"> Pre-registration Continue to develop use scenarios into exposure scenarios as per technical guidance Enter into Pre-SIEFs 	
December 2008	<ul style="list-style-type: none"> Confirmation of status to sales team Pre-registration numbers to be available 	
1 st Jan 2009	<ul style="list-style-type: none"> Enter into SIEFs 	
2009	<ul style="list-style-type: none"> Share data requirements within SIEF Collate all exposure scenarios Agree risk management measures with downstream users Prepare registration dossier Update safety data sheet 	
1 st December 2010	<ul style="list-style-type: none"> Latest Registration Updated safety datasheet to be sent to customers 	

Customers will also require reassurance that their use and exposure scenarios will be included in our chemical safety assessments and incorporated onto our material safety datasheet. The level of support required will depend upon their position in the supply chain and the following pages aim to support this.

DOWNSTREAM USE OF SUBSTANCES

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. This includes our EU manufactured substances.

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.

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

MANUFACTURE OF COMPOSITES IN THE EU

MANUFACTURE OF POLYMERS / RESINS 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 COMPOSITES 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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