

REACH
THE NEW
LEGISLATION
AND
MANUFACTURE OF
ACRYLIC SHEET
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. It is the obligation of the manufacturer or importer of the substance to complete the registration.

Acrylic sheet can be classified as an article i.e. the shape and surface of the sheet determines its' function to a greater extent than chemical composition. As such, it is not a substance and it is exempt from registration. However, there are some obligations associated with substances in articles and as such the export of acrylic sheet to the EU is not exempt from the effects of REACH. The main considerations are as follows:

1. Raw materials purchased from within the EU containing substances subject to REACH should be registered and confirmed as available.
2. Any substance contained within an article exported to the EU and intended to be released should be registered for those downstream uses. These uses should be identified and included in the substance registration by the article importer.
3. Any Substance of Very High Concern (SVHC) that may be on the candidate list for authorisation and present in the article at greater than 0.1% must be identified and requires notification.

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

Lucite Sheet Grades
Perspex Sheet Grades

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 EU market in quantities over 1000 tonnes per annum, or substances of very high concern.
1 June 2013	Registration deadline for substances placed on the EU 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 and includes any substance that is intended to be released from an article. 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 registration 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, 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.

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

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 ACRYLIC SHEET OUTSIDE THE EU UNDER REACH

Manufacturing of acrylic sheet outside the EU does not require registration under REACH. There are also no obligations to ensure that your use of a substance is covered by an extended safety datasheet (eSDS). However, if changes to the manufacturing process affect the composition of product exported to the EU then there may be some checks required.

CHANGE TO EXISTING PRODUCT COMPOSITION OR MANUFACTURE OF A DIFFERENT PRODUCT

Export of Acrylic Sheet to the EU requires the following:

1. Registration of any substances intended to be released from the sheet if the total amount of that substance exported is >1tpa
2. Notification of any substance identified as being of high concern and on the prioritisation list in the EU if in a concentration of >0.1% in the article and exported to the EU in a quantity of >1tpa. These high concern substances will not be listed until June 2009, although will include category 1 & 2 Carcinogens, Mutagens or Reprotoxins and substances classified as either very Persistent and very Bioaccumulative or Persistent, Bioaccumulative and Toxic.
3. Provision of information to the recipient of the article enough information to ensure safe use and handling if the article contains >0.1% of a substance on the prioritisation list.

If there are any changes in manufacturing that affect the composition of the article, e.g. change in pigment, then it must be confirmed if the level of a substance of high concern is increased or if the substance is intended to be released upon use.

SALE OF ARTICLES FOLLOWING REACH

Customers of Acrylic Sheet manufactured outside the EU and intending to export that material to the EU will require confirmation that:

1. Any substance intended to be released has been registered for the uses within the EU (there are no examples of this requirement for Lucite International Acrylic Sheet)
2. Whether the sheet contains a substance of high concern on the European Chemicals Agency Prioritised List
3. What, if any, risk management measures are required to safely use the article if it contains a substance of high concern.

Regulatory statements for currently provided will be updated to include an assessment against REACH.

DOWNSTREAM USE OF ARTICLES

Any article manufactured outside the EU, whether Acrylic Sheet or a Perspex bath, will have the same obligations if exported to the EU. Assessments should include whether a substance is contained within the article and intended to be released (e.g. ink in a printer cartridge) in which case the substance needs to be registered, or whether the article contains a substance of very high concern requiring notification.

The details for export of articles to the EU are covered in this booklet. However, an article manufacturer may also supply or purchase other substances from the EU. The other booklets within this series may provide additional useful information. These are:

MANUFACTURE OF SUBSTANCES IN THE EU

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 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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