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REACH Fact Sheet

REACH (Registration, Evaluation, Authorization and Restriction of Chemicals) is the European Union regulatory framework for chemicals management. REACH requires that manufacturers and importers of substances to the EU (in quantities of more than one metric ton per year) disclose information on the properties of their substances, including the risk to humans and the environment associated with use. Information on appropriate risk reduction measures must also be provided.

REACH Philosophy

- Industry assesses, communicates, and manages risk. REACH registration is required for EU market access (no data – no market).
- Manufacturers and importers of substances have to collect information on substance properties, product applications and exposure to users and the environment. Besides they have to assess and communicate risk management measures within the supply chain.
- Downstream users, e.g., customers, inform suppliers about uses and use conditions.
- Substance registration provides evidence to authorities that the supply chain applies the process.
- Specific hazardous chemicals are regulated separately.

Substances

Substances need to be registered by each manufacturer or importer legal entity. Products may include multiple substances, and those substances are registered individually and can include multiple uses. Under certain conditions, the registration of certain substances can be delayed provided a (late) pre-registration has been completed by the manufacturer. These substances are referred to as "phase-in" substances.

Polymers

- Polymers are not exempted from the scope of REACH but are exempted from registration requirements.
- However, monomers, as well as any other substances that have been reacted into the polymer backbone, must be registered if a polymer produced in or imported into the EU consists of 2% or more by weight of such monomers or other substances, and if the volume of monomers or other substances in reacted form exceeds 1 metric ton per year.
- Polymer additives need to be registered if they are manufactured or imported on their own or in compounded form in volumes of 1 metric ton or more per year.

Timeline

- REACH approved by European Council December 18, 2006.
- REACH entry into force and registration timelines began on June 1, 2007.
- European Chemical Agency (ECHA, headquartered in Helsinki, the agency created to oversee REACH) operational as of June 1, 2008.
- Pre-registration of phase-in substances began on June 1, 2008 and ended on December 1 2008.
- Late-pre-registration is allowed under specific circumstances.
- Registration deadlines of phase-in substances (must have been pre-registered):
- Volumes > 1000 tons/yr., CMRs 1&21 > 1 ton/yr. and R50/532 > 100 tons/yr.: Dec. 1, 2010.
- Volumes > 100 tons/yr.: June 1, 2013.
- Volumes > 1 ton/yr.: June 1, 2018.

[1] CMRs 1&2: substances classified as carcinogen, mutagen, or reprotoxic category 1 or 2.

[2] R50/53: substances very toxic to aquatic organisms which may cause long-term adverse effects in the aquatic environment

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Registration

- Registrants collect, submit substance hazard, uses and risk information to the ECHA (dossier), which includes registrant identity, substance identity, volume data; substance hazard data; testing proposal for generation of additional data, if applicable; uses of the substance; a chemical safety assessment/report (which can include hazard, exposure and risk assessment) for substances of 10 tons/yr. or more; classification and labeling information; and information about safe handling and uses.
- Costs associated with registration include those for substance data generation and/or purchase from SIEF members, dossier generation, and registration fees.
- ECHA assigns a registration number after a dossier completeness check.
- There are reduced registration requirements for isolated intermediates - substances that are consumed or transformed into another substance and are not present in the final manufactured substance. Down steam users of isolated intermediates are required to handle those substances under strictly controlled conditions. Reduced requirements do not apply to monomers.

Evaluation by Authorities

- Compliance check of registration dossiers and check of testing proposals.
- Substance evaluation and possible request for further information based on risk to human health or the environment.

Authorization

- Authorization includes identification of substances that are banned for general use.
- It also includes authorization of specific uses of such substances banned for general use 1) under defined risk management regimes or 2) based on socio-economic justification.
- Authorization requests should include an analysis of alternatives, a substitution plan when a suitable alternative is available, and information about any relevant R & D activities for the application.
- Authorization must be renewed periodically as specified in the authorization decision.

Safety Data Sheet (SDS), Extended Safety Data Sheet (eSDS) and Labels

- As of June 1, 2007, some format changes and content additions apply to SDSs.
- The extended SDS (eSDS) will be the primary tool for information transfer along the supply chain
- Extended SDSs under REACH add relevant exposure scenarios based on chemical safety assessments performed according to registration requirements.
- As needed, extended SDSs (eSDSs) will be developed for preparations (products that contain multiple substances) as well as individual substances. Note, eSDS are only required for substances that are sold in quantities of more than 10 tonnes per year and are classified as hazardous.
- By 1 June 2015, CLP, the Regulation (EC) No 1272/2008 on classification, labelling and packaging (CLP) of substances and mixtures replaces DPD (Dangerous Preparations Directive) for the classification, labelling and packaging of mixtures.

If the exposure scenarios communicated via the safety data sheet do not cover the use(s) of the downstream user, it means that the registrant has not covered the particular use(s) in the registration. The downstream user has the option either to make the use known to a supplier within 12 months after receipt of a registration number communicated to him in the Safety Data Sheet (Article 39(1)), or to develop his own Chemical Safety report within 6 months after receipt of a registration number communicated to him in the Safety Data Sheet (Article 39(2)). The downstream user can continue the product use in the meantime.

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Substance Evaluation and the Community Rolling Action Plan (CoRAP)

Member States evaluate certain substances to clarify whether their use poses a risk to human health or the environment. The objective is to request further information from the registrants of the substance to verify the suspected concern, if necessary.

In cooperation with the Member States, ECHA defines risk-based criteria and then selects the substances that are to be evaluated. The selected substances are listed by ECHA in the community rolling action plan (CoRAP) following the opinion of the Member State Committee. An evaluating Member State will be designated for each substance on the final CoRAP. The substance evaluation process assesses all registration dossiers from all registrants specific to the same substance, i.e. in order to take into account the combined exposure. Other available sources of information are also considered. The evaluating Member State has 12 months from the publication of the CoRAP to decide whether it needs to request further information from the registrants to clarify the concern.

Trinseo REACH Implementation Steps / Timing for Suppliers / Customer Interaction

Pre-registration: Trinseo Europe had duly pre-registered before the end of the preregistration period the substances contained in the Trinseo products. Trinseo is taking the actions needed to comply with pre-registration and registration compliance requirements to assure a continued supply.

Registration: Trinseo has successfully completed the first and second phases of registrations for all substances it manufactures in Europe or imports into Europe.

We are now focusing on preparing for the coming registration deadline in 2018 by:

- Engaging in SIEF and consortia discussions.
- Working on downstream use identification/ exposure scenarios for substance registration.

Authorization: Trinseo is duly fulfilling its obligations resulting from the publication of the ECHA Candidate list. Information on Trinseo products containing substances on the Candidate list (SVHCs) above reportable limits can be found on the Safety Data Sheets (SDS). Trinseo is proactively sending these updated data sheets to all customers currently purchasing concerned products. Most recent versions can be obtained from the Customer Information Group (CIG).

Sources of Additional Information: The European Chemical Agency provides detailed guidance information on the EU REACH regulation and CLP through their web-pages (refer to http://echa.europa.eu/support/guidance-on-reach-and-clp-implementation).

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North America	
U.S.	+1-855-TRINSEO (+1-855-874-6736)
U.S. & Canada	+1-989-633-1718
Latin America	
Brazil	+55-11-5184-8722
Argentina, Chile, South Region of LAA	+54-11-4319-0100
Mexico, Colombia, North Region of LAA	+52-55-5201-4700
Europe/Middle East/Africa	+800-444-11-444
	+31-11567-2601
Asia Pacific	+603-7965-53-19
China	+86-21-3851-1017
Email	CIG@trinseo.com

www.trinseo.com

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Trinseo and its affiliated companies have a fundamental concern for all who make, distribute, and use their products and for the environment in which we live. This concern is the basis for our Product Stewardship philosophy by which we assess the safety, health, and environmental information on our products so that appropriate steps may be taken to protect employee and public health and our environment. The success of our product stewardship program rests with each and every individual involved with Trinseo products – from the initial concept and research, to manufacture, use, sale, disposal, and recycle of each product.

CUSTOMER NOTICE

Customers are responsible for reviewing their manufacturing processes and their applications of Trinseo products from the standpoint of human health and environmental quality to ensure that Trinseo products are not used in ways for which they are not suitable. Trinseo personnel are available to answer questions and to provide reasonable technical support. Trinseo product literature, including safety data sheets, should be consulted prior to the use of Trinseo products. Current safety data sheets are available from Trinseo.

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