



# REACHing out to you

An Introduction to the EU's new Chemicals Legislation



December 13, 2010

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## REACH - for health and the environment

AkzoNobel Chelates supports the main objective of REACH, an improved protection of human health and the environment from the risk of chemicals. This is consistent with our commitment to Product Stewardship — the responsible and ethical management of the health, safety and environmental aspects of a product throughout its total life cycle. AkzoNobel Chelates has been working towards the aim of REACH for several years, via the Responsible Care program, the High Production Volume chemicals testing program in the US and the extensive risk assessments on EDTA and NTA under the European Existing Substances Regulation.

A key priority in the implementation of REACH is close cooperation and coordination with our customers and suppliers, to ensure that the required information is exchanged between all players in the supply chain.

We are well positioned and committed to support our customers in making this challenging task a success. We will also continue to provide input to the EU institutions, to contribute to the development of a workable REACH legislation.

## What is REACH?

The European Community has reformed the previous European legislations for 'existing' (EINECS) and 'new' (ELINCS) substances, into one new uniform regulatory system for the Registration, Evaluation, Authorization and restrictions of Chemicals (REACH). The REACH regulation came into force on June 1<sup>st</sup>, 2007. REACH makes manufacturers, importers and their customers responsible for the safe use of chemicals. The producers and importers have to assess the risks of their substances over the entire supply chain and have to demonstrate that those risks are properly managed. The authorities will control this process by means of the registration dossiers to be submitted by the producers or importers and take additional measures on highly dangerous substances, where needed.

REACH is;

- providing an improved protection to human health and the environment
- increasing knowledge about the properties and uses of existing substances
- establishing an efficient risk assessment process
- requiring the registration of all substances manufactured or imported in quantities of 1 ton or more per year

## How will REACH work?

Registration requires gathering data on physicochemical, toxicological and ecotoxicological properties of substances as well as specifying individual identified uses and assessments of the associated risks and safety measures connected to these uses. Manufacturers and importers have to submit this information to the European Chemicals Agency (ECHA) in Helsinki.

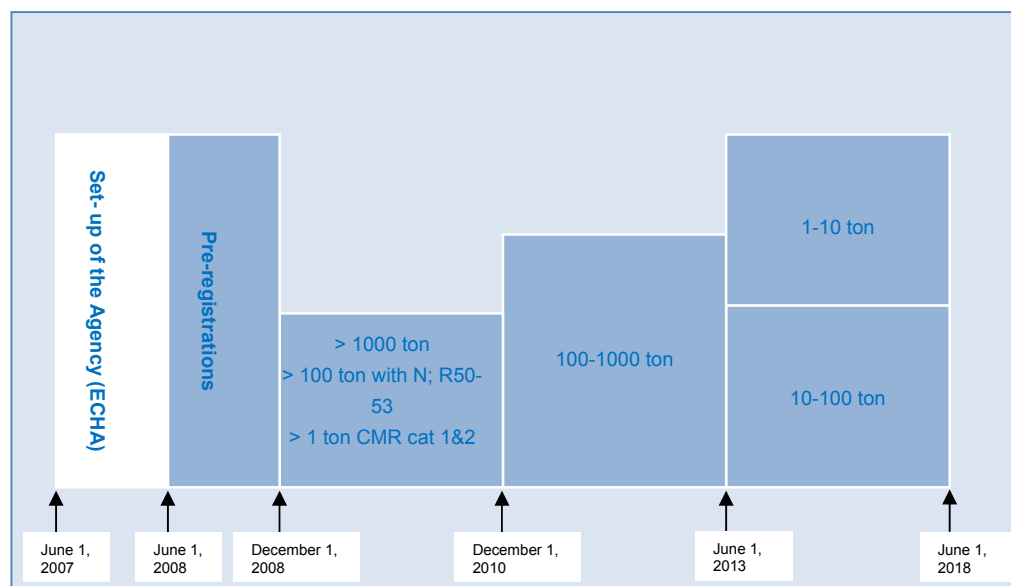
Essential parts of the [registration](#) dossier are:

- a Technical Dossier (for substances > 1 ton/y)
- a Chemical Safety Report (for substances > 10 ton/y)

The agency may then check that the registration dossier complies with the REACH Regulation and must evaluate testing proposals to ensure that the assessment of the chemical substances will not result in unnecessary animal testing. Where appropriate, authorities may select substances for an in-depth [evaluation](#). Substances of very high concern shall not be used and have to be replaced by safer alternatives unless they get an [authorisation](#) for certain uses. Substances of very high concern are defined as carcinogenic, mutagenic or reproductive toxicants; substances that are persistent, bio accumulative and toxic; or substances of equivalent concern. In addition the authorities may impose [restrictions](#) on the manufacture, use or marketing of substances causing an unacceptable risk to human health or the environment.

## The main stages of REACH

REACH includes a 'no data, no market' principle. Manufacturers and importers have to present data and register all substances that they produce or import at volumes of one ton per year or more. 'New' substances that were already notified under the previous legislation will be considered as being registered and receive a registration number. After pre-registration the 'existing' substances (now being mentioned phase-in substances) are granted with a delayed registration period on a phased basis over a period of 11 years.



### Pre-registration phase & number

The period in which substances could be pre-registered ended on November 30, 2008. All substances in the tables (see appendix) have been successfully submitted in the pre-registration database, a pre-registration number was assigned to each separate substance and legal entity combination.

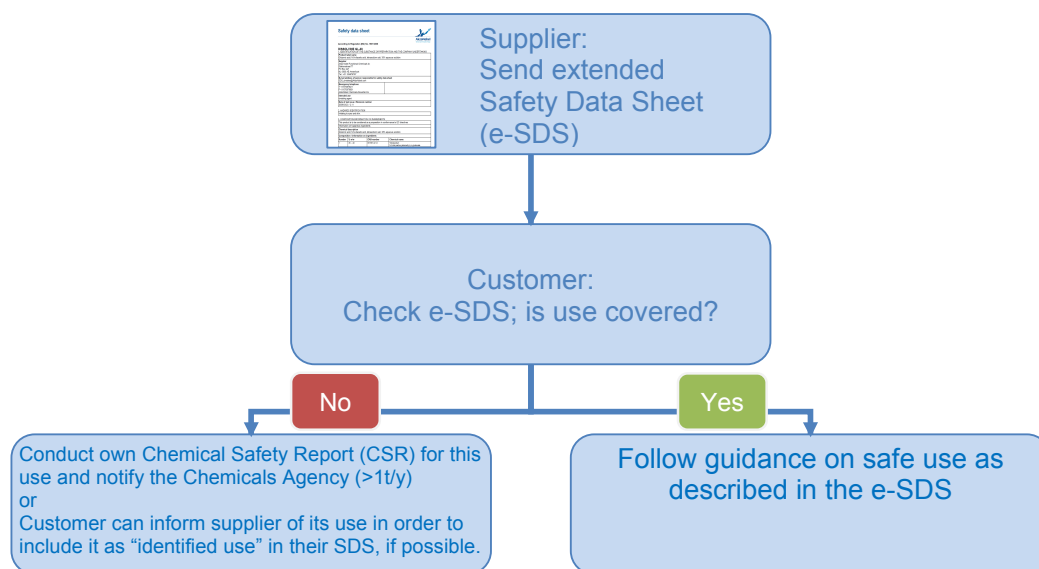
There is no legal requirement to provide pre-registration numbers in the supply chain. Pre-registration numbers will not be published by AkzoNobel, nor will AkzoNobel provide these numbers on request.

### First registration phase

The period in which substances could be registered for the volume band >1000 ton pended on November 30, 2010. AkzoNobel submitted all registration dossiers for substances >1000 ton/year. A registration number is assigned to each registration by the Agency (ECHA). These numbers will be communicated to our customers via the Safety Data Sheet. An overview of all available numbers can be found in the tables in the appendix.

### Information flow

Under the REACH legislation the final target for information transfer to downstream users (customers) will be the new extended Safety Data Sheet (e-SDS) including the relevant exposure scenarios from the Chemical Safety Report covering all identified uses.

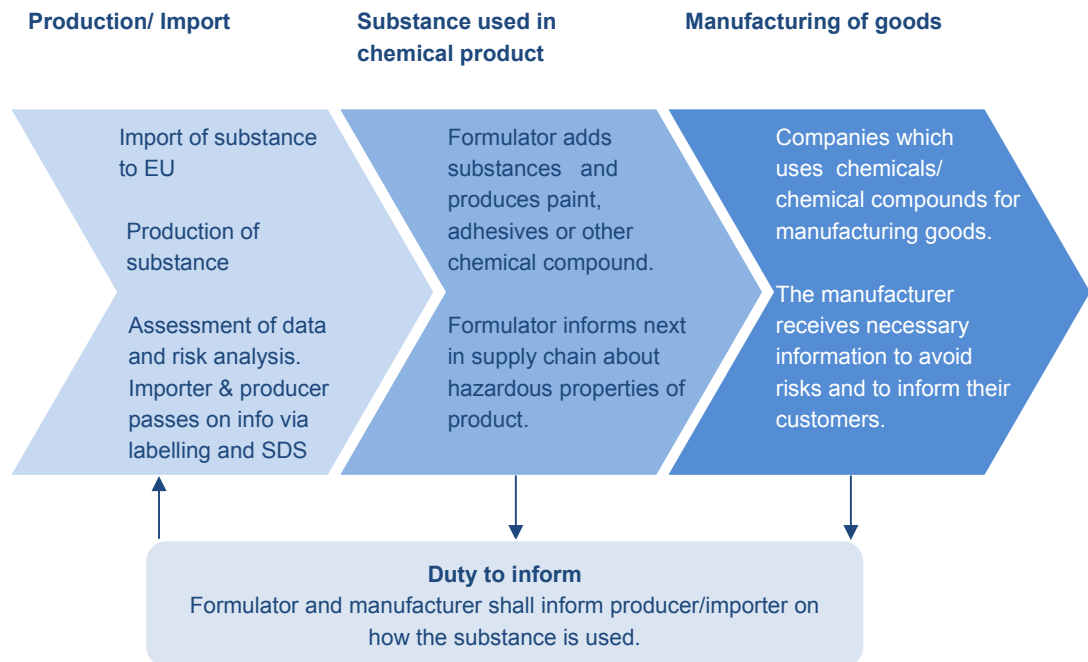


An explanatory manual on Chelates Exposure Scenarios is also available on the website [www.dissolvine.com](http://www.dissolvine.com).

## Communication

The formation and communication within consortia (= groups of producers/importers of a substance) is a key issue within REACH, and our long experience as an active member of chemical industry associations means that we are prepared for the procedures and tasks that will be required. This is also of great significance for the obligatory SIEFs (Substance Information Exchange Forums) that are formed at the end of the pre-registration period.

Also the communication over the supply chain is a very important part of REACH. Downstream users (customers) have the duty to inform the producer on the use of a substance, or have to register their specific use themselves.



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## How we can help you

In order to keep the administrative burden of the interactive communication between suppliers and downstream users to a minimum we have developed Exposure Scenarios (ESs) for all known applications of our products, based on our in-house knowledge. This is fully in line with the proposals/ recommendations done by CEFIC on communication in the supply chain.

We have communicated the (draft) Exposure Scenarios for the TIER 1 substances to most of our customers for their review on whether their uses are covered and on the appropriateness of the use description and possible risk management measures. We will continue with this working method for the TIER 2 and TIER 3 substances.

For your convenience we have developed an explanatory manual on the Chelates Generic Exposure Scenarios, this manual is available on our website [www.dissolvine.com](http://www.dissolvine.com).

In the tables in the appendix you will find an overview of the pre-registered substances, the intended registration dates and, if available, the REACH registration numbers.

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## Appendix 1: EDTA Chelating Agents

Dissolvine ®	Chemical formula	CAS registry number & INCI name	EC Number	Pre-registered	Registration deadline	Registration number
E-39 (-K)	EDTA-Na <sub>4</sub>	64-02-8 & Tetrasodium EDTA	200-573-9	Yes	2010	AB: 01-2119486762-27-0003  BV: 01-2119486762-27-0004
100-S						
NA						
NA-X						
220-S						
240-S						
NA3-36	EDTA-Na <sub>3</sub> H	150-38-9 & Trisodium EDTA	205-758-8	Yes	2018	Not available yet
NA2	EDTA-Na <sub>2</sub> H <sub>2</sub> Dihydrate	Anhydrous: 139-33-3 & Disodium EDTA	205-358-3	Yes	2010	01-2119486775-20-0001
NA2-S						
NA2-P						
E-Ca-10	EDTA-Na <sub>2</sub> Ca Dihydrate	Anhydrous: 62-33-9 & Calcium Disodium EDTA	200-529-9	Yes	2013	Not available yet
AM4-50	EDTA-(NH <sub>4</sub> ) <sub>4</sub>	22473-78-5	245-022-3	Yes	2018	Not available yet
AM3-40	EDTA-(NH <sub>4</sub> ) <sub>3</sub> H	15934-01-7	240-073-8	Yes	2018	Not available yet
AM2-45	EDTA-(NH <sub>4</sub> ) <sub>2</sub> H <sub>2</sub>	20824-56-0 & Diammonium EDTA	244-063-4	Yes	2018	Not available yet
K4-50	EDTA-K <sub>4</sub>	5964-35-2	227-743-5	Yes	2018	Not available yet
K4-100-S						
K3-123-S	EDTA-K <sub>3</sub> H	17572-97-3 & Tripotassium EDTA	241-543-5	Yes	2018	Not available yet
Z	EDTA-H <sub>4</sub>	60-00-4 & EDTA	200-449-4	Yes	2010	01-2119486399-18-0001
Z-S						

## Appendix 2: Other Chelating Agents

Dissolvine <sup>®</sup>	Chemical formula	CAS registry number & INCI name	EC Number	Pre-registered	Registration deadline	Registration number
A-40 (-K)	NTA-Na <sub>3</sub>	5064-31-3 & Trisodium NTA	225-768-6	Yes	2010	01-2119519239-36-0003
A-150-S						
A-92						
GL-38	GLDA-Na <sub>4</sub>	51981-21-6 & Tetrasodium Glutamate Diacetate	257-573-7	Yes	2010	01-2119493601-38-0000
GL-47-S						
GL-PD (-S)						
D-40 (-K)	DTPA-Na <sub>5</sub>	140-01-2 & Pentasodium Pentate	205-391-3	Yes	2010	AB: 01-2119474445-33-0003 BV:01-2119474445-33-0004
D-50 (-K)						
D-88						
D-K5-40	DTPA-K <sub>5</sub>	7216-95-7	404-290-3	Yes	2013	Not available yet
DZ	DTPA-H <sub>5</sub>	67-43-6 & Pentetic Acid	200-652-8	Yes	2010	01-2119497281-34-0000
H-40 (-K)	HEDTA-Na <sub>3</sub>	139-89-9 & Trisodium HEDTA	205-381-9	Yes	2013	Not available yet
H-88-X	HEDTA-Na <sub>3</sub> 2.5 hydrate	Anhydrous: 139-89-9 & Trisodium HEDTA				
EDG	EDG-Na <sub>2</sub>	135-37-5	205-187-4	Yes	2018	Not available yet
PDZ	PDTA-H <sub>4</sub>	1939-36-2	400-400-9	ELINCS notified	ELINCS Notified	01-0000015036-78-0003
CSA	Sodium glucoheptonate	31138-65-5 (Also 13007-85-7) & Sodium Gluceptate	250-480-2	Yes	2013	Not available yet

### Appendix 3: Metal Chelates

Dissolvine®	Chemical formula	CAS registry number & INCI name	EC Number	Pre-registered	Registration deadline	Registration number
E-CA-3	[EDTA.Ca] Na <sub>2</sub>	Anhydrous: 62-33-9	200-529-9	Yes	2013	Not available yet
E-CA-10	[EDTA.Ca] Na <sub>2</sub> .2H <sub>2</sub> O					
E-CU-8	[EDTA.Cu] (NH <sub>4</sub> ) <sub>2</sub>	67989-88-2	268-018-3	Yes	2018	Not available yet
E-CU-9						
E-CU-15	[EDTA.Cu] Na <sub>2</sub>	14025-15-1 & Disodium EDTA-Copper	237-864-5	Yes	2013	Not available yet
E-MG-3	[EDTA.Mg] Na <sub>2</sub>	14402-88-1	238-372-3	Yes	2018	Not available yet
E-MG-6						
E-MN-6	[EDTA.Mn] K <sub>2</sub>	68015-77-0	268-144-9	Yes	2013	Not available yet
E-MN-13	[EDTA.Mn] Na <sub>2</sub>	15375-84-5	239-407-5	Yes	2010	01-2119493600-40-0000
E-FE-6	[EDTA.Fe] K	54959-35-2	259-411-0	Yes	2018	Not available yet
E-FE-13	[EDTA.Fe] Na <sub>2</sub> .3H <sub>2</sub> O	15708-41-5	239-802-2	Yes	2010	01-2119487279-21-0003
E-ZN-9	[EDTA.Zn] (NH <sub>4</sub> ) <sub>2</sub>	67859-51-2	267-400-7	Yes	2013	Not available yet
E-ZN-15	[EDTA.Zn] Na <sub>2</sub>	14025-21-9	237-865-0	Yes	2013	Not available yet
AMFE-50	[EDTA.Fe] NH <sub>4</sub> .NH <sub>4</sub> OH	68413-60-5	270-232-7	Yes	2010	01-2119496227-29-0000
AMFE-52						
AMFE-54						
D-FE-3	[DTPA.Fe] Na <sub>2</sub>	19529-38-5	243-136-8	Yes	2013	Not available yet
D-FE-7						
D-FE-6	[DTPA.Fe] (NH <sub>4</sub> ) <sub>2</sub>	85959-68-8	289-064-0	Yes	2013	Not available yet
D-FE-6-P						
D-FE-11	[DTPA.Fe] H Na	12389-75-2	235-627-0	Yes	2013	Not available yet
H-FE-4.5	[HEDTA.Fe]	17084-02-5	241-142-5	Yes	2013	Not available yet
H-FE-9						
H-FE-13						
Q-products	[EDDHA.Fe] Na	84539-55-9	283-044-5	Yes	2010	01-2119487279-21-0003
M-products	[EDDHMA.Fe] Na	84539-53-7	283-041-9	Yes	2013	Not available yet
MP	[PDTA.Fe] K	124268-99-1	405-680-6	Yes	2018	Not available yet

## Appendix 4: EC Substance numbers and names

EC Number	EC Substance name
200-449-4	Edetic acid
200-529-9	Sodium calcium edetate
200-573-9	Tetrasodium ethylenediaminetetraacetate
200-652-8	N-carboxymethyliminobis(ethylenenitrilo)tetra(acetic acid)
205-187-4	Disodium 2-hydroxyethyliminodi(acetate)
205-355-7	Nitilotriacetic acid
205-358-3	Disodium dihydrogen ethylenediaminetetraacetate
205-381-9	Trisodium 2-(carboxylatomethyl(2-hydroxyethyl)amino)ethyliminodi(acetate)
205-391-3	Pentasodium (carboxylatomethyl)iminobis(ethylenenitrilo)tetraacetate
205-758-8	Trisodium hydrogen ethylenediaminetetraacetate
225-768-6	Trisodium nitilotriacetate
227-743-5	Tetrapotassium ethylenediaminetetraacetate
235-627-0	Sodium hydrogen [N,N-bis[2-[bis(carboxymethyl)amino]ethyl]glycinato(5-)]ferrate(2-)
237-864-5	Disodium [[N,N'-ethylenebis[N-(carboxymethyl)glycinato]](4-)-N,N',O,O',ON,ON']cuprate(2-)
237-865-0	Disodium [[N,N'-ethylenediylbis[N-(carboxylatomethyl)glycinato]](4-)-N,N',O,O',ON,ON']zincate(2-)
238-372-3	Disodium [[N,N'-ethylenebis[N-(carboxymethyl)glycinato]](4-)-N,N',O,O',ON,ON']magnesate(2-)
239-407-5	Disodium [[N,N'-ethylenebis[N-(carboxymethyl)glycinato]](4-)-N,N',O,O',ON,ON']manganate(2-)
239-802-2	Sodium feredetate
240-073-8	Triammonium hydrogen ethylenediaminetetraacetate
241-142-5	[N-[2-[bis(carboxymethyl)amino]ethyl]-N-(2-hydroxyethyl)glycinato(3-)]iron
241-543-5	Tripotassium hydrogen ethylenediaminetetraacetate
243-136-8	Disodium [N,N-bis[2-[bis(carboxymethyl)amino]ethyl]glycinato(5-)]ferrate(2-)
244-063-4	Diammonium dihydrogen ethylenediaminetetraacetate
244-302-2	Ammonium [[N,N'-ethylenebis[N-(carboxymethyl)glycinato]](4-)-N,N',O,O',ON,ON']ferrate(1-)
245-022-3	Tetraammonium ethylenediaminetetraacetate
250-480-2	Sodium glucoheptonate
257-573-7	Tetrasodium N,N-bis(carboxylatomethyl)-L-glutamate
259-411-0	Potassium [[N,N'-ethylenebis[N-(carboxymethyl)glycinato]](4-)-N,N',O,O',ON,ON']ferrate(1-)
267-400-7	Diammonium [[N,N'-ethylenebis[N-(carboxylatomethyl)glycinato]](4-)-N,N',O,O',ON,ON']zincate(2-)
268-018-3	Diammonium [[N,N'-ethylenebis[N-(carboxymethyl)glycinato]](4-)-N,N',O,O',ON,ON']cuprate(2-)
268-144-9	Dipotassium [[N,N'-ethylenebis[N-(carboxymethyl)glycinato]](4-)-N,N',O,O',ON,ON']manganate(2-)
270-232-7	Diammonium [[N,N'-ethylenebis[N-(carboxymethyl)glycinato]](4-)-N,N',O,O',ON,ON']hydroxyferrate(2-)
283-041-9	Acetic acid, oxo-, sodium salt, reaction products with cresol and ethylenediamine, iron sodium salts
283-044-5	Acetic acid, oxo-, sodium salt, reaction products with ethylenediamine and phenol, iron sodium salts
289-064-0	Diammonium [N,N-bis[2-[bis(carboxymethyl)amino]ethyl]glycinato(5-)]ferrate(2-)
400-400-9	N,N'-propylene-1,3-diylbis[N-(hydroxycarbonylmethyl)glycine]
400-660-3	Ammonium iron(III) trimethylenediaminetetraacetate hemihydrate
404-290-3	Diethylenetriaminopentaacetic acid, pentapotassium salt
405-680-6	Potassium iron(III) 1,3-propanediamine-N,N,N',N'-tetraacetate hemihydrate