

REACH registration – how the information is generated and used

Session 18c

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ECHA

REACH registration – a significant undertaking

Over 13 000 unique substances registered to date



- What information is generated and submitted in the registration?
- What is the information used for?
- What can occupational hygienists do before and after registration?

What information is submitted in the REACH registration of substances?

Hazard

- Physical and chemical properties
- Classification and labelling
- Environmental and human health hazard assessment

Risk

- How much is used
- How and where it is used
- How risk is controlled
- Environmental and human health exposure assessment

- Next and last registration deadline is **2018**
- Registration and updates can be made at any time

What is REACH registration information used for?

Regulatory Decisions

- Authorisation
- Restriction
- Harmonised classification

Information to users of Chemicals

- Safety data sheets and exposure scenarios
- Uses that are advised against
- Advice to consumers
- Dissemination advice on ECHA website

Substance information from REACH registration (New format on ECHA website later in 2015)

4,4'-isopropylidenediphenol

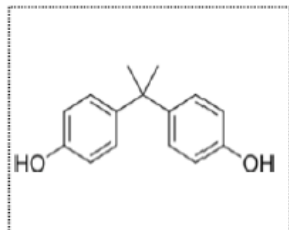
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Infocard – last updated 03/06/2014

2,2-bis (4-hydroxyphenyl) propane; 2,2-di(4-hydroxyphenyl)propane; 4,4' isopropylidenediphenol; Biphenol A; Bisferol A; **BPA**; C006780; DIAN; ...

Substance Identity

EC Number 201-245-8
CAS Number 80-05-7
Molecular Formula C15H16O2



Critical properties



Safety classification & labelling



Danger! This substance causes serious eye damage, is suspected of damaging fertility or the unborn child, may cause respiratory irritation, may cause an allergic skin reaction and is toxic to aquatic life with long lasting effects.

The above is based on the Harmonised Classification and Labelling (ATP1) approved by the European Union and Classification and Labelling provided by companies to ECHA in REACH registrations.

Regulatory actions

Substance included in the [Community Rolling Action Plan \(CoRAP\)](#).

About this substance

This substance is a High Production Volume chemical; per year 1,000,000+ tonnes are manufactured and/or imported in the European Economic Area.

This substance can be found in products with material based on: plastic (e.g. food packaging and storage, toys, mobile phones), and paper (e.g. tissues, feminine hygiene products, nappies, books, magazines, wallpaper).

This substance is used in the following products: coating products, fillers, putties, plasters, modelling clay, and adhesives and sealants. This substance has an industrial use resulting in manufacture of another substance (use of intermediates).

This substance is used in the following areas: formulation of mixtures and/or re-packaging, and building & construction work. This substance is used in for the manufacture of: plastic products, electrical, electronic and optical equipment, bulk chemicals, machinery and vehicles, and pulp, paper and paper products.

Release to the environment of this substance is likely to occur from industrial use: in the production of articles, formulation in materials, as an intermediate step in further manufacturing of another substance (use of intermediates), formulation of mixtures, and manufacturing of the substance. Other release to the environment of this substance is likely to occur from: indoor use in long-life materials with low release rate (e.g. flooring, furniture, toys, construction materials, curtains, foot-wear, leather products, paper and cardboard products, electronic equipment), outdoor use in long-life materials with low release rate (e.g. metal, wooden and plastic construction and building materials), indoor use (e.g. machine wash liquids/detergents, automotive care products, paints and coating or adhesives, fragrances and air fresheners), and outdoor use.

Precautions and Safe Use

Precautions suggested by manufacturers and importers of this substance can be found [here](#); Guidance provided by manufacturers and importers on the safe use of the substance can be found [here](#).

4,4'-isopropylidenediphenol – European Chemicals Agency Infocard – last updated 18/02/2014

More

- Infocard gives simple high level overview of a substance
- Understandable to the broadest possible audience
- More detailed profiles will also be available

Chemical risk assessment



Chemical Agents Directive: Site based assessment, all chemical agents

REACH registration: Scenario based assessment, substance based

REACH registration chemical safety report (CSR)

Sections 1-8 Hazard

- Substance ID, uses, physical and chemical properties/classification and labelling/hazard assessment

Section 9 Exposure Assessment

- Exposure scenarios for all uses to be assessed
- Often based on sector information (use maps)
- Often exposure modelling (ECETOC TRA, Stoffenmanager, ART, EMKG)

Section 10 Risk Characterisation

- Quantitative or qualitative
- Risk characterisation ratio (RCR) = exposure estimate/DNEL

Chemical safety reports in REACH – three “types”

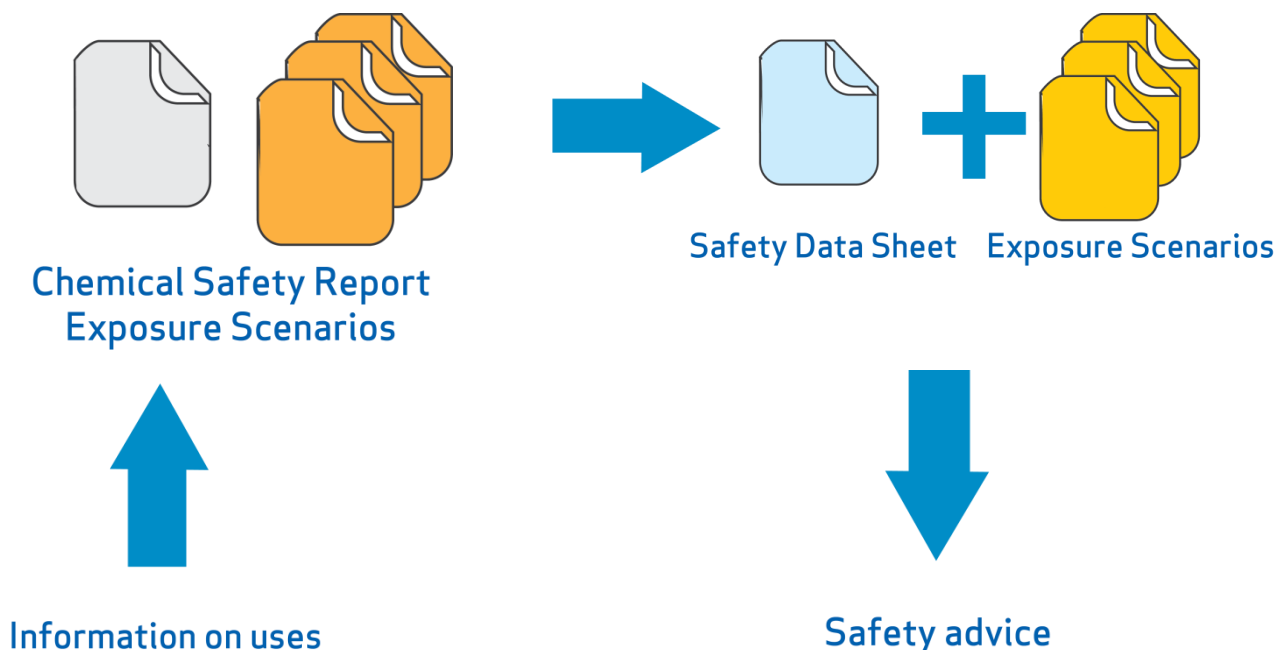
- **Registration CSR**
 - CSR required for registrations >10 tonne/year
 - Exposure assessment/risk characterisation when hazard identified for uses
- **Application for authorisation CSR**
 - More site specific than registrant CSR
- **Downstream user CSR**
 - When use not covered in registrant’s exposure scenario
 - DU CSR not as comprehensive as registrant CSR
 - Practical guide later in 2015

Occupational hygienists can promote good quality CSRs within REACH



Information in the supply chain

Registrants



Customers (Downstream users)

Information to registrants

Registrants



Registration dossier



Chemical Safety Report
Exposure Scenarios



Information on uses

Substance		CAS No.		EC No.		ECHA No.		REACH No.		Sector Use Maps	
Substance 1	Substance 2	123456	789012	1234	5678	9012	3456	7890	1234	5678	9012
Substance 3	Substance 4	345678	901234	5678	9012	3456	7890	1234	5678	9012	3456
Substance 5	Substance 6	901234	567890	3456	7890	1234	5678	9012	3456	7890	1234

Sector Use
Maps

Downstream users/Sector organisations

Information from registrants

Registrants



Formulators

Downstream users / Consumers

Some steps being taken to improve information to users of chemicals



Information on uses

- Develop guidance, tools and sector use maps for chemical safety assessment (CSA)
- Develop harmonised communication of exposure scenarios (ES)



Safety advice

- Build on existing risk management advice, such as control sheets
- Use REACH information to support other compliance activities
- Help formulators provide realistic and relevant safe use information for mixtures

<http://echa.europa.eu/csr-es-roadmap>

Next talks

Summary – what occupational hygienists do

- Develop good quality chemical safety reports (registration, authorisation, downstream user)
- Participate in regulatory risk management processes (public consultation, awareness, substitution)
- Use registration information to support safe use of chemicals (SDS, exposure scenario, ECHA's website)
- Integrate REACH/CLP information and activities with current environmental health and safety practice



Further information



echa.europa.eu/downstream
echa.europa.eu/reach-2018

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