

NIVA webinar 'Short introduction into REACH'
December 5, 2023
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REACH and OSH
or
OSH and REACH



Regulations vs Directives

Regulations (e.g. REACH)

‘Regulations are legal acts that apply automatically and uniformly to all EU countries as soon as they enter into force, without needing to be transposed into national law. They are binding in their entirety on all EU countries.’

Directives (e.g. all EU OSH Legislation)

‘Directives require EU countries to achieve a certain result, but leave them free to choose how to do so. EU countries must adopt measures to incorporate them into national law (transpose) in order to achieve the objectives set by the directive. National authorities must communicate these measures to the European Commission.’

Quotes from: https://commission.europa.eu/law/law-making-process/types-eu-law_en

EU Occupational safety and health legislation works by

Directives

The EU-wide legal frame for use and handling of chemicals at work places is set in several directives

- Directive 98/24/EC (the Chemical Agents Directive, CAD)
- Directive 2004/37/EC (the Carcinogens and Mutagens Directive, CMD)

Other directives add to this, e.g. several articles of these:

- Personal Protective Equipment (Dir 2016/425)
- Minimum requirements at workplaces (Dir 89/654)
- Use of work equipment (2009/104)

Complete overview on relevant OSH legislation:
<https://osha.europa.eu/en/safety-and-health-legislation>



REACH – Objectives

- **EU-Commission/DG ENV:**to protect human health and the environment from the risks that can be posed by chemicals. This is done by better and earlier identification of the intrinsic properties of chemical substances and by taking measures, such as phasing out or restricting substances of very high concern. REACH also aims to enhance innovation and the competitiveness of the EU chemicals industry.
- **EU-Commission/DG GROW:** The main aims of REACH are to ensure a high level of protection for human health and the environment, including the promotion of alternative test methods, as well as the free circulation of substances on the internal market and the enhancement of competitiveness and innovation.
- **ECHA:** REACH is a regulation of the European Union, adopted to improve the protection of human health and the environment from the risks that can be posed by chemicals, while enhancing the competitiveness of the EU chemicals industry.

REACH – National implementation level

- **RIVM (NL):** The aim of REACH is to place chemical substances safely on the European market and thus protect the health of people and the environment among other things. REACH describes what companies and governments must comply with regarding dealing with chemical substances.
- **KEMI:** The REACH Regulation includes rules on the registration of substances, bans or other restrictions on substances, authorisation requirements for particularly dangerous substances and rules on informing customers.

Description of EU OSH-Legislation

EU-Commission/DG EMPL:

Health and safety at work is one of the areas where the EU has had the biggest impact – with a solid legal framework covering the maximum number of risks with the minimum number of regulations.

As set out by principle 10 of the European Pillar of Social Rights, workers have the right to a high level of protection of their health and safety at work.

They have the right to a working environment adapted to their professional needs and which enables them to prolong their participation in the labour market.

Positive impacts of REACH on workplace use of chemicals

Positive impact for work places

Direct impacts:

More data, expert review, restrictions of certain substances, authorisation for certain uses, support of substitution, exchange of data up and down the supply chain

Indirect impact: Elimination of several chemicals in advance of registration date, i.e. no registration - no data - no market, more consideration about the use of chemicals in general, substitution efforts

Positive impacts of REACH on workplace use of chemicals

More assessments of chemicals, currently 104.000 registrations for 23.000 substances (oct 2023)

Most frequently registered Substances	# Registrations
ethanol	732
calcium dihydroxide	586
iron	570
ethylene oxide	549
ethylene	493
Charcoal	476
aluminium oxide	446
aluminium	402
styrene	383
methyloxirane	378
silicon dioxide	373

https://echa.europa.eu/documents/10162/2741157/registration_statistics_en.pdf/58c2d7bd-2173-4cb9-eb3b-a6bc14a6754b?t=1686750748164

REACH - groups of substances not covered

Radioactive substances, waste, and substances which are used for military purposes. Substances in temporary storage under customs supervision.

Annex V substances like most vegetable fats and oils, glass, ceramics, hydrogen and oxygen, coke, cement, mineral ores, by-products, etc. etc.

Non-isolated intermediates that during synthesis are not intentionally removed from the synthesis equipment are exempted, for isolated intermediates, a simplified registration applies. (REACH exemptions are listed in the REACH Annex IV –e.g. nitrogen and water - and Annex V.

Impact of REACH on workplace use of chemicals

Weaker impact of REACH

**Process generated substances – e.g. dust and dirt mixtures, welding, cutting, grinding – are difficult to cover (mention OEL-Work of ECHA).
Workplaces with exposure to unknown mixtures – waste collection and recycling – are hard to cover.**

In short: where the chemical composition of the exposure is unknown an (immediate) improvement via regulation of chemicals is hardly possible - application of preventive OSH-measures is the adequate solution

REACH approach - Chemical safety reports and Exposure scenarios

Chemical Safety Report

Quote from ECHA:

‘The chemical safety report documents the chemical safety assessment undertaken as part of the REACH registration process, and is the key source from which the registrant provides information to all users of chemicals through the exposure scenarios. It also forms a basis for other REACH processes including substance evaluation, authorisation and restriction.’


Exposure scenarios

Quote from ECHA:

‘An exposure scenario is a set of conditions that describe how a substance is manufactured or used, and the measures necessary to control exposure to humans and releases to the environment.’

Implementation of REACH – SDS examples

New extended Safety Data Sheet - Identified and unidentified uses

 www.sigmaldrich.com

SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Version 6.11
Revision Date 09.08.2023
Print Date 09.08.2023
GENERIC EU MSDS - NO COUNTRY SPECIFIC DATA - NO OEL DATA

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifiers

Product name : Ethanol absolute for analysis EMSURE®
ACS,ISO,Reag. Ph Eur

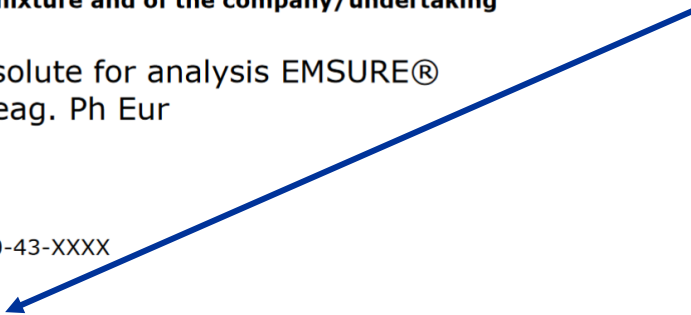
Product Number : 100983
Brand : Millipore
Index-No. : 603-002-00-5
REACH No. : 01-2119457610-43-XXXX
CAS-No. : 64-17-5

1.2 Relevant identified uses of the substance or mixture and uses advised against

Identified uses : Reagent for analysis, Chemical production

1.3 Details of the supplier of the safety data sheet

Company : Merck KGaA
Frankfurter Str. 250



Implementation of REACH – SDS examples

New extended Safety Data Sheet –

International version

8. Exposure controls

OEL limit-value 8 hours is

Denmark 1900 mg/m³

Finland 1900 mg/m³

Sweden 1000 mg/m³

Norway 950 mg/m³

Germany 380 mg/m³

Source:

https://limitvalue.ifa.dguv.de/WebForm_ueliste2.aspx

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Ingredients with workplace control parameters

Derived No Effect Level (DNEL)

Application Area	Routes of exposure	Health effect	Value
Worker DNEL, acute	inhalation	Local effects	1900 mg/m ³
Worker DNEL, longterm	dermal	Systemic effects	
Worker DNEL, longterm	inhalation	Systemic effects	950 mg/m ³
Consumer DNEL, acute	inhalation	Local effects	950 mg/m ³
Consumer DNEL, longterm	dermal	Systemic effects	
Consumer DNEL, longterm	inhalation	Systemic effects	114 mg/m ³
Consumer DNEL, longterm	oral	Systemic effects	

Predicted No Effect Concentration (PNEC)

Compartment	Value
Fresh water	0,96 mg/l
Sea water	0,79 mg/l
Fresh water sediment	3,6 mg/kg

Implementation of REACH – SDS examples

New extended Safety
Data Sheet

Exposure controls

National version

ABSCHNITT 8: Begrenzung und Überwachung der Exposition/Persönliche Schutzausrüstungen

8.1 Zu überwachende Parameter

Bestandteile mit arbeitsplatzbezogenen, zu überwachenden Grenzwerten

Inhaltsstoff	CAS-Nr.	Zu überwachende Parameter	Wert	Grundlage
Ethanol	64-17-5	AGW	200 ppm 380 mg/m ³	Deutschland. TRGS 900 - Arbeitsplatzgrenzwerte
	Anmerkung	Ein Risiko der Fruchtschädigung braucht bei Einhaltung des Arbeitsplatzgrenzwertes und des biologischen Grenzwertes (BGW) nicht befürchtet zu werden		

Abgeleitete Expositionshöhe ohne Beeinträchtigung (DNEL)

Anwendungsbereich	Expositionsweg	Auswirkung auf die Gesundheit	Wert
Arbeiter DNEL, akut	Inhalativ	Lokale Effekte	1900 mg/m ³

Implementation of REACH – SDS examples

Info on Bisphenol?



SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

GENERIC EU MSDS - NO COUNTRY SPECIFIC DATA - NO OEL DATA

Version 7.2
Revision Date 14.09.2023
Print Date 03.12.2023

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifiers

Product name : Bisphenol A

Product Number : 239658
Brand : Aldrich
Index-No. : 604-030-00-0
REACH No. : A registration number is not available for this substance as the substance or its uses are exempted from registration, the annual tonnage does not require a registration or the registration is envisaged for a later registration deadline.

CAS-No. : 80-05-7

Page: 1/19

BASF safety data sheet. This is a translation of the country-specific safety data sheet into a language other than that required by law. This document does not replace the safety data sheet provided according to Regulation (EC) No 1907/2006.

Date / Revised: 02.10.2023
Date previous version: 29.08.2023
Date / First version: 29.08.2023

Version: 2.0
Previous version: 1.0

Product: **Bisphenol A, 34 weight% in TriethyleneMonomethylether(MTG)**

(ID no. 30604079/SDS_GEN_DE/EN)

Date of print 20.11.2023

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

**Bisphenol A, 34 weight% in
TriethyleneMonomethylether(MTG)**

UFI: Y1PY-N0DE-5001-497M

1.2. Relevant identified uses of the substance or mixture and uses advised against

Recommended use: Chemical

ECHA's data offers

Substance data: <https://echa.europa.eu/information-on-chemicals/registered-substances>

CLP - Classification, Labelling and Packaging

All substances: 237,655, harmonised: 4,754

SCIP Database

Articles containing substances of very high concern (SVHCs) on the Candidate List at a concentration above 0.1% weight by weight (w/w) placed on the EU market notified according to Article 9(1)(i) of the Waste Framework Directive 2008/98/EC

<https://echa.europa.eu/scip-database>

Chemical legislation finder – in future

To improve from my point of view

Enforcement/ Implementation of REACH

Better data and better exposure scenarios (not only based on calculation models)

Higher ranking of safety concerns

REACH and OSH or OSH and REACH

Thanks for listening!

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