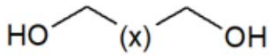
Assessment of regulatory needs

Authority: European Chemicals Agency (ECHA)

Group Name: Linear diols

General structure:



Revision history

Version	*Date*	*Description*
1.0	14 February 2023	

Substances within this group:

EC/List number	CAS number	Substance name	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y)[1]
203-786-5	110-63-4	butane-1,4-diol	Full, >1000
203-854-4	111-29-5	pentane-1,5-diol	Full, 100-1000
203-975-2	112-47-0	decane-1,10-diol	Full, 10-100
207-997-3	504-63-2	propane-1,3-diol	Full, >1000
211-074-0	629-11-8	hexane-1,6-diol	Full, >1000
223-517-5	3937-56-2	nonane-1,9-diol	Full, not (publicly) available
227-133-9	5675-51-4	dodecane-1,12-diol	Full, 10-100

This table does not contain group members that are only notified under the CLP Regulation. However, the list is not necessarily exhaustive. Should further regulatory risk management action on one or more substances in the group be considered, ECHA may make an additional search for related C&L notified substances to be included in the group and develop an assessment of regulatory needs for them.

[1] Note that the total aggregated tonnage band may be available on ECHA's webpage at https://echa.europa.eu/information-on-chemicals/registered-substances

Contents

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The author does not accept any liability with regard to the use that may be made of the information contained in this document. Usage of the information remains under the sole responsibility of the user. Statements made or information contained in the document are without prejudice to any further regulatory work that ECHA, the Member States or other regulatory agencies may initiate at a later stage. Assessment of regulatory needs and their conclusions are compiled on the basis of available information and may change in light of newly available information or further assessment.

Foreword

The purpose of the assessment of regulatory needs of a group of substances is to help authorities conclude on the most appropriate way to address the identified concerns for a group of substances or a single substance, i.e. the combination of the regulatory risk management instruments to be used and any intermediate steps, such as data generation, needed to initiate and introduce these regulatory measures.

An assessment of regulatory needs can conclude that regulatory risk management at EU level is required for a (group of) substance(s) (e.g. harmonised classification and labelling, Candidate List inclusion, restriction, other EU legislation) or that no regulatory action is required at EU level. While the assessment is done for a group of substances, the (no) need for regulatory action can be identified for the whole group, a subgroup or for single substance(s).

The assessment of regulatory needs is an important step under ECHA's Integrated Regulatory Strategy. However, it is not part of the formal processes defined in the legislation but aims to support them.

The assessment of regulatory needs can be applied to any group of substances or single substance, i.e., any type of hazards or uses and regardless of the previous regulatory history or lack of such. It can be done based on a different level of information. A Member State or ECHA can carry out this case-by-case analysis. The starting point is available information in the REACH registrations and any other REACH and CLP information. However, a more extensive set of information can be available, e.g. assessment done under REACH/CLP or other EU legislation, or can be generated in some cases (e.g. further hazard information under dossier evaluation). Uncertainties associated to the level of information used should be reflected in the documentation. It will be revisited when necessary. For example, after further information is generated and the hazard has been clarified or when new insights on uses are available. It can be revisited by the same or another authority.

The responsibility for the content of this assessment rests with the authority that developed it. It is possible that other authorities do not have the same view and may develop further assessment of regulatory needs. The assessment of regulatory needs does not yet initiate any regulatory process but any authority can consequently do so and should indicate this by appropriate means, such as the Registry of Intentions.

For more information on Assessment of regulatory needs please consult ECHA website[2].

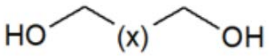
[2] https://echa.europa.eu/understanding-assessment-regulatory-needs

Glossary

ARN	Assessment of Regulatory Needs
CCH	Compliance Check
CLH	Harmonised classification and labelling
CMR	Carcinogenic, mutagenic and/or toxic to reproduction
DEv	Dossier evaluation
ED	Endocrine disruptor
NONS	Notified new substances
OEL	Occupational exposure limit
OSII or TII	On-site isolated intermediate or transported isolated intermediate
PBT/vPvB	Persistent, bioaccumulative and toxic/very persistent and very bioaccumulative
RMOA	Regulatory management options analysis
RRM	Regulatory risk management
SEv	Substance evaluation
STOT RE	Specific target organ toxicity, repeated exposure
SVHC	Substance of very high concern

1 Overview of the group

ECHA has grouped together structurally similar substances based on the presence of the two hydroxyl groups in each of the ends of a linear saturated hydrocarbon chain. The length of the hydrocarbon chain in the substances of the group varies from C3 to C12. General structure of the linear diols is shown in the figure below.



The group covers seven well defined mono-constituent substances, all having a full registration.

Based on information reported in the REACH registration dossiers, the substances of the group are mainly used in industrial settings, as intermediates, solvents, binding, lubricating and surface-active agents, processing and reprographic aids, adhesives and are used in pharmaceuticals, cosmetics and as laboratory agents.

Widespread professional and consumer uses are also reported in coatings, inks, antifreeze agents, lubricant agents, cleaning products, cosmetics and personal care products, construction chemicals where potential for exposure and release to the environment cannot be excluded. Article service life is reported in the use of coatings, construction chemicals, and articles made of 1,4 butanediol containing polymers. Release to the environment via the articles containing the substance

Together with γ-butyrolactone (GBL), 1,4-butanediol (1,4-BD, EC 203-786-5) is precursor of γ-hydroxybutyrate, more commonly known as GHB or the "date rape" drug, classified as a narcotic since 1999. Since this date, there has been a perceptible increase in the recreational use of these two precursors that are rapidly metabolised into GHB in the body after ingestion, causing similar sensations and enabling the law on GHB to be circumvented. Considering in particular that these substances are easy to obtain and can be sold to the general public for various uses (solvents, automotive cleaners, etc.) including at high concentrations, France decided to prohibit the supply and sale to the public of GBL and 1,4-BD either as raw materials, or in manufactured goods containing a concentration greater than 10% and a volume of more than 100 mL. This ban has been effective since 2 September 2011[3]. In addition, France submitted a RMOA in 2011 and proposed restriction under REACH to deal with misuse of the substance (cleaning solvents, nail varnish removers, paint strippers, etc) purchased via professional or home use[4]. Doubts were expressed on whether limiting the concentration in mixtures available to the general population via a REACH restriction would have a significant impact on the abuse.

In December 2020 Germany submitted an intention[5] to prepare a CLH for 1,4-BD with proposed harmonised classification for acute toxicity and specific target organ toxicity - single exposure.

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[3] French decree « Arrêté du 2 septembre 2011 portant application d'une partie de la réglementation des stupéfiants à la gamma-butyrolactone (GBL), au 1,4-butanediol (1,4 BD) et aux produits qui en contiennent »

[4] ANSES opinion available at https://www.anses.fr/en/system/files/REACH2010sa0319.pdf

[5] https://echa.europa.eu/registry-of-clh-intentions-until-outcome/-/dislist/details/0b0236e185c26a66

Note on the scope of ECHA's assessment of regulatory needs

Regarding hazards, the focus of ECHA's assessment is on CMR (carcinogenic, mutagenic and/or toxic to reproduction), sensitiser, ED (endocrine disruptor), PBT/vPvB or equivalent (e.g. substances being persistent, mobile and toxic), aquatic toxicity hazard endpoints and therefore only those are reflected in the table in section 3. This does not mean that the substances do not have other known or potential hazards. In some specific cases, where ECHA identifies a need for regulatory risk management action at EU level for other hazards (e.g. neurotoxicity, STOT RE), such additional hazards may be addressed in the assessment. An overview of classification is presented in Annex 1.

On the exposure side, ECHA is mainly using the information on uses reported in the registration dossiers (IUCLID) as a proxy for assessing the potential for exposure to humans and releases to the environment. The potential for release / exposure is generally considered high for "widespread" uses, i.e. professional and consumer uses and uses in articles. For these uses, normally happening at many places, the expected level of control is *à priori* considered limited. The chemical safety reports are not necessarily consulted and no quantitative exposure assessment is performed at this stage.

2 Justification for the need for regulatory risk management action at EU level

Based on currently available information, there is a need for (further) EU regulatory risk management – restriction for potential reproductive toxicity hazard due to the potential for release/ exposure of the substance EC 203-786-5.

1,4-butanediol (EC 203-786-5) is known to have effects on the central nervous system and is appropriately self-classified as STOT SE3 (H336 May cause drowsiness or dizziness). The toxicity of 1,4-butanediol in animals and humans is linked to its metabolism into γ-hydroxybutyric acid (GHB), a naturally occurring neurotransmitter and a psychoactive drug (OECD SIDS, 1999). For developmental toxicity, the effects of the substance on the central nervous system indicate a potential for such effects during gestation and early life stages and therefore a potential hazard for reproductive toxicity is flagged for this substance. For this reason, a compliance check (CCH) is suggested to clarify the hazard.

The first step of the regulatory risk management action proposed, should the hazard exist, is the confirmation of hazard via harmonised classification (CLH) as Repr 1B for 1,4-butanediol (EC 203-786-5).

CLH i) will require company level risk management measures (RMM) under EU legislation for workers, to be in place, ii) is needed or highly recommended for further regulatory processes under REACH and iii) is a prerequisite to restrict the

presence of the substances in consumer mixtures, by means of the restriction entry 30.

CLH will also support regulatory action under other regulations. For instance, in this specific case harmonised classification as Repr 1B will trigger:

- regulatory action under the Cosmetic products regulation (EC) No 1223/2009, since CMR cat. 1 are restricted by this regulation;
- the restriction of use of these substances in toys. According to the safety requirements set for chemicals in toys under the Toy Safety Directive (2009/48/EC), substances or mixtures that are classified as CMR category 1 shall not be used in toys, in components of toys or in micro-structurally distinct parts of toys unless they meet the criteria for a derogation. In addition, harmonised classification will facilitate conformity assessment and declaration, particularly when the toy manufacturer bearing obligations is located outside the EU and therefore self-classification in registration dossiers is not applicable to them.

Professional uses of the substance in coatings, paints, thinners, paint removers, adhesives, including treatment of articles by dipping and pouring are expected to be widespread (at many sites and by many users) with relatively low levels of operational controls and risk management measures but with often frequent exposures with a long duration. In addition, professional users may be self-employed and therefore not covered by occupational safety and health (OSH) legislation.

Consumers may be co-exposed to the substances used by professionals (e.g. house painters).

Therefore, a **restriction of the substance as such or in mixtures (concentration limit in mixtures) used by professionals** is suggested after CLH.

Restriction of professional uses is preferred over authorisation as it is considered to be more efficient and effective to introduce controls at the level of placing on the market rather than at the level of uses.

In addition, the use of the most harmful substances by professional workers has been recognised as an area of concern under the European Commission's Chemicals Strategy for Sustainability[6] which aims to extend to professional users under REACH the level of protection granted to consumers.

Moreover, **restricting substances in articles** made of 1,4-butanediol containing polymers used by professionals or consumers should be considered in the context of the restriction of professional uses as potential exposure from articles needs further investigation first.

Based on currently available information, there is no need for (further) EU regulatory risk management for all the other substances in the group.

Based on ECHA's assessment of currently available hazard information, no potential hazards were identified for human health. These conclusions are based on the available experimental data (negative *in vivo* skin sensitisation studies, negative *in vitro* and *in vivo* mutagenicity studies, available systemic toxicity studies, negative PNDT studies, RDT and reproductive toxicity studies) and the structural similarity among the different substances of the group. CCH will be opened for all the

[6] European Commission, *Chemical Strategy for Sustainability Towards a Toxic-Free Environment*, available at https://ec.europa.eu/environment/pdf/chemicals/2020/10/Strategy.pdf

substances to examine validity of read-across adaptations, where used, and the necessity of further data generation to confirm low hazard.

Substances belonging to this group can be generally considered as of low hazard for the environment. Nevertheless, regarding aquatic toxicity, all the substances present incomplete dataset for long term studies. These studies could be requested for all the substances, where possible. However, it is unlikely that this information would reveal high long-term aquatic toxicity or affect the classification of those substances. Based on short-term aquatic studies provided for dodecane-1,12-diol EC 227-133-9 it can be concluded that the substance requires environmental classification (Aquatic Acute 1, Aquatic Chronic 1 with M-factor). The screening also revealed possible trend in aquatic toxicity for decane-1,10-diol EC 203-975-2 and EC 223-517-5 (chronic effects observed and the substance is currently self-classified as Aquatic Chronic 3, H412). As the effects seem to appear only from alkyl chain length C9 it is very likely that the substances with shorter alkyl chain length (C3-C6) are of low toxicity.

Therefore, it is proposed that there is currently no need for EU-wide regulatory risk management.

It is expected that following data generation for aquatic toxicity registrants would adequately self-classify the substances and implement necessary RMMs to ensure safe use. Therefore, it is proposed that there is currently no need for EU-wide regulatory risk management.

3 Conclusions and actions

The conclusions and actions proposed in the table below are based on the REACH and CLP information available at the time of the assessment by ECHA. The main source of information is the registration dossiers. Relevant public assessments may also be considered. When new information (e.g. on hazards through evaluation processes, or on uses) will become available, the document will be updated and conclusions and actions revisited

EC number	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
203-786-5	Known or potential hazard for reproductive toxicity	No hazard or unlikely hazard	Industrial, widespread professional and consumer uses as intermediate, solvent, binding agent in polymer production, coatings, paints, thinners, paint removers, adhesives, including treatment of articles by dipping and pouring. Potential for exposure and release in the environment. Exposure and release to the environment via the articles containing the	**Need for EU RRM: Restriction** <u>Justification:</u> The harmonised classification as Repr. 1B would trigger the restriction entry 30 and by that ensure that the substances are not included in consumer mixtures above the limits specified in that entry. The reported professional uses are widespread (at many sites and many users) with relatively low levels of operational controls and risk management	**First step:** CCH **Next steps (if hazard confirmed):** CLH Restriction

			substance cannot be excluded.	measures but with often frequent exposures with a long duration. Restriction of professional uses is preferred over authorisation as it is considered to be more efficient and effective to introduce controls at the level of placing on the market rather than at the level of uses.	
203-854-4 203-975-2 207-997-3 211-074-0 223-517-5 227-133-9	No hazard or unlikely hazard	Known or potential hazard for aquatic toxicity for ECs 203-975-2, 223-517-5, 227-133-9	Industrial, widespread professional and consumer uses as solvent, laboratory agent, binding agent in coatings, inks, antifreeze, lubricants, cleaning products, cosmetics and personal care products, construction chemicals. Potential for exposure and	**Currently no need for EU RRM** <u>Justification:</u> Overall, no or unlikely hazard that would lead to concern for the reported uses. Self classification for aquatic toxicity followed by implementation of necessary RMMs should be sufficient	**First step:** CCH

			release to the environment.	to ensure safe use for environment	

Annex 1: Overview of classifications

Data extracted on 11.06.2020

EC No	Substance name	Harmonised classification	Classification in registrations
203-786-5	butane-1,4-diol	-	Acute Tox. 4, H302 STOT SE 3, H336
203-854-4	pentane-1,5-diol	-	-
203-975-2	decane-1,10-diol	-	-
207-997-3	propane-1,3-diol	-	-
211-074-0	hexane-1,6-diol	-	-
223-517-5	nonane-1,9-diol	-	Aquatic Chronic 3, H412
227-133-9	dodecane-1,12-diol	-	-

Annex 2: Overview of uses based on information available in registration dossiers

Data extracted on 11.06.2020

Main types of applications structured by product or article types	203-786-5	203-854-4	203-975-2	207-997-3	211-074-0	223-517-5	227-133-9
Intermediate	I	I	I	I		I	I
Polymer production	I			I	F, I	I	I
Cleaning and auxiliary agents		F, I, **P**, **C**			F, I, **C**, **A**		
Coatings (paints, inks, toner)	I, **P**, **C**	F, I, **P**, **C**, **A**		I, **P**, **C**	F, I, **C**, **A**		
Construction chemical		I, **P**, **C**, **A**			I, **P**, **C**, **A**		
Lubricants and waxes		I, **P**, **C**		I, **P**, **C**			
Antifreeze agent				I, **P**, **C**			
Cosmetics and personal hygiene		**P**, **C**, **A**		F, **P**, **C**	**C**, **A**		
Plasters					**C**		
Laboratory chemicals	I,				**P**	I	
Use articles made of polymers based containing 1,4-butanediol	F, I, **P**, **C**, **A**			F			

F: formulation, I: industrial use, P: professional use, C: consumer use, A: article service life; P, C and A are highlighted in red to indicate widespread use with potential for exposure/release

Annex 3: Overview of completed or ongoing regulatory risk management activities

Data extracted on 28.05.2020

EC / List number	RMOA	Authorisation		Restriction	CLH	Actions not under REACH / CLP
		Candidate list	Annex XIV	Annex XVII	Annex VI (CLP)	
203-786-5	YES					

There are no relevant completed or ongoing regulatory risk management activities for the other substances.