Assessment of regulatory needs

Authority: European Chemicals Agency (ECHA)

Group Name: Dibenzoates

General structure:

Revision history

Version	*Date*	*Description*
1.0	1 December 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]
202-338-6	94-49-5	ethylene dibenzoate	Full, not (publicly) available
204-407-6	120-55-8	oxydiethylene dibenzoate	Full, >1000
204-408-1	120-56-9	ethylenebis(oxyethylene) dibenzoate	C&L notification
224-081-9	4196-89-8	2,2-dimethylpropane-1,3-diyl dibenzoate	Full, not (publicly) available
242-894-7	19224-26-1	propane-1,2-diyl dibenzoate	Full, >1000
248-258-5	27138-31-4	oxydipropyl dibenzoate	Full, >1000
416-230-3[2]	35541-81-2	A mixture of: cis-1,4-dimethylcyclohexyl dibenzoate; trans-1,4-dimethylcyclohexyl dibenzoate	NONS
609-138-1	35541-81-2	A mixture of: cis-1,4-Dimethylcyclohexyl dibenzoate and trans-1,4-Dimethylcyclohexyl dibenzoate	C&L notification
907-434-8[2]	-	Reaction mass of ethylenebis(oxyethylene) dibenzoate and oxydiethylene dibenzoate and oxydipropyl dibenzoate	Full, not (publicly) available
907-437-4	-	Reaction mass of 2-[2-(benzoyloxy)ethoxy]ethyl benzoate.and oxydipropyl dibenzoate	Full, not (publicly) available

This table contains also group members that are only notified under the CLP Regulation, however, the list is not necessarily exhaustive.

[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

[2] When a dossier is submitted without EC number, REACH-IT automatically assigns a List number to the dossier. Sometimes, due to IT technical limitations, duplicate List numbers are created. In this group the following are considered duplicate entries: List nr 907-434-8 and EC 416-230-3. In general EC numbers take precedence over List numbers.

Contents

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Foreword

The assessment of regulatory needs of a group of substances is an iterative, informal process to help authorities consider the most appropriate way to address an identified concern for a group of substances or a single substance and decide whether further regulatory risk management activities are necessary.

The grouping is mainly based on structural similarity and associations made by the registrants between substances through read-across and category approaches as well as category associations from external sources (e.g. OECD categories)[3]. These methods are different from grouping as defined in Section 1.5 of Annex XI to REACH because the scope and intended use of ECHA's grouping is different. Thus, in this context, grouping does not aim to validate read-across and category approaches according to the Annex XI requirements but rather to support a faster and more consistent approach for regulating chemicals and avoid regrettable substitution.

The focus of the assessment is largely based on information available in the registration dossiers and on properties requiring regulatory risk management action at EU level[4]. The information reported on uses is from the registration dossiers (IUCLID) and is used as a proxy for assessing how widespread uses are and whether potential for exposure to humans and releases to the environment can be expected. The chemical safety reports are not necessarily consulted and no quantitative exposure assessment is performed at this stage.

The outcome of these assessments are proposals for immediate (the first action) and subsequent regulatory action(s), including the foreseen ultimate regulatory action (last foreseen regulatory action) to address the identified concern(s) in case the potential hazards are confirmed. For example, further data generation through compliance check is suggested as a first action, to confirm the identified hazard.

Where hazards are confirmed, regulatory risk management actions could be considered for the whole group, for a subgroup or for individual substances within the group. The robustness of the group depends on the stage of assessment and the level of certainty this stage requires. For example, the needs for grouping under restriction may differ from the needs for grouping for the purpose of harmonised classification. Group membership is reconsidered accordingly throughout the iterative assessment of regulatory needs, for example, after further information is generated and the hazard has been clarified or when new insights on uses and risks are available.

The assessment of regulatory needs in itself does not represent a regulatory action, but rather a preparatory step to consider further possible regulatory actions at the level of individual substances or groups/subgroups of substances.

[3] Working with Groups - ECHA (europa.eu)

[4] Regarding hazard properties the focus is for instance 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 report. This does not mean that the substances do not have other known or potential hazards. In some specific cases, ECHA may consider additional hazards (e.g. neurotoxicity, STOT RE).

Publication of ARNs makes it easier for companies to follow the latest status of their substances of interest, anticipate potential regulatory actions and make strategic choices in their chemicals portfolio.

For more information on assessments of regulatory needs please consult ECHA's website[5].

[5] 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
TPE	Testing proposal evaluation

1 Overview of the group

Explanations on the scope of this assessment is available in the foreword to this document. Please read it carefully before going through the report

ECHA has grouped together structurally similar substances based on the presence of the dibenzoate moiety.

In particular, the dibenzoate group was built based on similarity with substances 2,2-dimethylpropane-1,3-diyl dibenzoate (EC 224-081-9) and Reaction mass of oxydiethylene dibenzoate and oxydipropyl dibenzoate (EC 907-437-4), mapped in PLASI (plastic additives initiative[6]) as among those ranked as high in the potential for release from plastics. Group members are based on structural similarity and read-across/category links made by registrants.

The group consists of 9 substances, out of which 7 have a full registration within REACH, 1 is a NONS and 1 is only notified under the CLP Regulation.
Based on information reported in the REACH registration dossiers, 6 of the fully registered substances are used as plasticisers, and they all have at least one widespread use (involving professional users and/or consumers). This includes use in dyes, cleaning agents, adhesives and sealants and as carriers for agrochemicals. 1 of the registered substances (EC 202-338-6) is only used as a stabiliser, while for the NONS (EC 416-230-3), where registration information is very limited, a wider search indicates use as a potential food additive, adhesive and in coatings.

Substances EC 204-407-6 and EC 248-258-5 were subject to substance evaluation due to potential reproductive toxicity effects. The evaluating Member State concluded that the substances do not have reproductive toxicity hazard[7,8].

[6] https://echa.europa.eu/plastic-additives-initiative

[7] Substance Evaluation conclusion document EC 204-407-6, 3 August 2020

[8] Substance Evaluation conclusion document EC 248-258-5, 3 August 2020

2 Conclusions and proposed actions

The conclusions and actions proposed in the table below are based mainly on the REACH and CLP information available at the time of the assessment by ECHA. The conclusions are preliminary suggestions from a screening-level assessment done by ECHA with the aim to propose the next steps for further work (e.g., strengthening of the hazard conclusions, clarification of the uses and/or potential for exposure). 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 may be updated, and conclusions and actions revisited.

EC/List no	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Suggested regulatory actions
202-338-6 **204-407-6** **204-408-1** **224-081-9** **242-894-7** **248-258-5** **416-230-3/List 609-138-1** **907-434-8** 907-437-4	Known or potential hazard for skin sensitisation for EC 242-894-7	Known or potential hazard for aquatic toxicity for EC 202-338-6, 248-258-5, 416-230-3 and List 907-437-4	Industrial, widespread professional, consumer uses and article service life mainly as plasticisers in polymer preparations and compounds, in dyes, cleaning agents, adhesives and sealants and as carriers for agrochemicals. Potential for exposure to workers, consumers and release in the environment for all	CCH ECs/Lists 202-338-6, 204-407-6, 224-081-9, 242-894-7, 248-258-5, 907-434-8 and 907-437-4 **Potential last action:** **Currently no need for EU RRM** Justification: Overall, no or unlikely hazard that would lead to concern for the reported uses. Harmonised/self-classification (will) require company level risk management measures (RMM) for workers and for environment to be in place.

EC / List no	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Suggested regulatory actions
			fully registered substances.	The concern related to the presence of skin sensitisers in consumer mixtures is under investigation.

3 Justification for the no need for regulatory risk management action at EU level

Currently no need to suggest (further) regulatory risk management actions for all substances in the group

Based on ECHA's assessment of hazard information currently available in the registration dossiers no or unlikely hazard for human health was identified for all the substances of the group, except for EC 242-894-7. However, some of the substances have data gaps or present read-across adaptations to be further evaluated.

While all group member substances were tested and have negative data on skin sensitisation, only EC 242-894-7 shows positive test results for skin sensitisation (OECD TG 429 Local Lymph Node Assay). Based on the information available, classification for Skin sens. 1B appears to be warranted for the substance EC 242-894-7. Such classification is however not reported in the registration dossiers. Registrants are invited to consider the information available, self-classify the substance, and update their registration dossiers and Safety Data Sheets accordingly.

For industrial and professional uses, sufficient and consistent self-classification by registrants should require company level risk management measures (RMM) to be in place for workers.

Adequate product labelling should in principle provide consumers with sufficient information to manage risks arising from the use of mixtures containing the substance EC 242-894-7.

For the use of the substance in cosmetics, sufficient and consistent self-classification by registrants would inform on the need or not for classification of the final product and safety assessment to be done according to Cosmetic product regulation (EC) No 1223/2009.

However, there is a concern related to skin sensitisers (potentially) present in consumer mixtures and the need to further investigate whether further regulatory actions are needed and what would be the best options to address this concern.

Such concern has already been identified in other groups of substances and was brought for further discussion to Member States. Work is ongoing on this generic issue by both Member States and ECHA which may affect the regulatory actions on substances in this group.

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

With respect to environmental hazard, 4 group members are (self)classified as hazardous to the aquatic environment (EC 202-338-6, EC 248-258-5, EC 416-230-3 and List 907-437-4). EC 202-338-6, EC 242-894-7, EC 224-081-9 and List 907-434-8 show low potential for aquatic toxicity, however, due to data gaps on long-term aquatic toxicity compliance checks need to be initiated to clarify the hazard. All substances in the group except EC 416-230-3 are unlikely PBT/vPvB based on experimental data available (not readily biodegradable). EC 416-230-3 meets screening criteria for P (substance is not readily biodegradable) and B (log Kow >3.73), and there is no data on long-term aquatic toxicity available. Consequently,

there is potential PBT/vPvB concern for this substance, but due to its registration status data generation cannot be requested.

In summary, compliance check is proposed for clarifying hazard of the following group members with active REACH registration: ECs/Lists 202-338-6, 204-407-6, 224-081-9, 242-894-7, 248-258-5, 907-434-8 and 907-437-4.

It is expected that following data generation for aquatic toxicity registrants would adequately self-classify the substances. The self-classification will require company level risk management measures (RMM) for environment to be in place. Therefore, it is proposed that there is currently no need for EU-wide regulatory risk management.

Annex 1: Overview of classifications

Data extracted on 14.09.2020

EC/ List No	Substance name	Harmonised classification	Classification in registrations
202-338-6	Ethylene dibenzoate	-	Aquatic Chronic 2 H411: Toxic to aquatic life with long lasting effects
204-407-6	Oxydiethylene dibenzoate	-	-
204-408-1	Ethylenebis(oxyethylene) dibenzoate	-	-
224-081-9	2,2-dimethylpropane-1,3-diyl dibenzoate	-	-
242-894-7	Propane-1,2-diyl dibenzoate	-	-
248-258-5	oxydipropyl dibenzoate	-	Aquatic Chronic 3 H412: Harmful to aquatic life with long lasting effects
416-230-3	A mixture of: cis-1,4-dimethylcyclohexyl dibenzoate; trans-1,4-dimethylcyclohexyl dibenzoate	Aquatic Chronic 4 H413: May cause long lasting harmful effects to aquatic life	-
609-138-1	A mixture of: cis-1,4-Dimethylcyclohexyl dibenzoate and trans-1,4-Dimethylcyclohexyl dibenzoate	-	-
907-434-8	Reaction mass of ethylenebis(oxyethylene) dibenzoate and oxydiethylene dibenzoate and oxydipropyl dibenzoate	-	-

EC/ List No	Substance name	Harmonised classification	Classification in registrations
907-437-4	Reaction mass of 2-[2-(benzoyloxy)ethoxy]ethyl benzoate.and oxydipropyl dibenzoate	-	Aquatic Chronic 3 H412: Harmful to aquatic life with long lasting effects

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

Data extracted on 14.07.2023

Main types of applications structured by product or article types	202-338-6	204-407-6	224-081-9	242-894-7	248-258-5	907-434-8	907-437-4
PC 20: Products such as ph-regulators, flocculants, precipitants, neutralisation agents			I				
PC 27: Plant protection products		**C**			**P, C**	I, **C**	
PC 35: Washing and cleaning products		**P, C**	I		**P, C**	**P, C**	**P, C**
PC 8: Biocidal products (e.g. disinfectants, pest control)		**C**			**P, C**		
PC 39: Cosmetics, personal care products		**C, A**		F, **P, C**	F, I, **C, A**		
PC 15: Non-metal-surface treatment products						I, **C**	
PC 24: Lubricants, greases, release products		I, **P, A**			F, I, **P, A**		
PC 32: Polymer preparations and compounds	I, **P**	F, I, **C, A**	F, I, **C, A**	F, I, **P, C, A**	F, I, **P, C, A**	F, I, **C, A**	F, I, **A**
PC 1: Adhesives, sealants		F, I, **P, C, A**	F, I, **P, C, A**	F, I, **P, C, A**	F, I, **P, C, A**	F, I, **P, C**	F, I, **P, C, A**
PC 9c: Finger paint		**C**			**C**	**C**	**C**
PC 9b: Fillers, putties, plasters, modelling clay		F, I, **P, C**			F, I, **P, C**	F, I, **P, C**	F, I, **P, C**
PC 9a: Coatings and paints, thinners, paint removes		F, I, **P, C, A**	F, I, **P, C, A**	F, I, **P, C, A**	F, I, **P, C, A**	F, I, **P, C, A**	F, I, **P, C, A**
PC 18: Ink and toners		F, I, **P, C, A**		**P, C**	F, I, **P, C, A**	F, I, **P, C**	F, I, **P, C**
PC 34: Textile dyes, and impregnating products		F, I					
PC 23: Leather treatment products						I, **C**	
PC 14: Metal surface treatment products						I, **C**	
PC 7: Base metals						I, **C**	

Main types of applications structured by product or article types	202-338-6	204-407-6	224-081-9	242-894-7	248-258-5	907-434-8	907-437-4
and alloys							
PC 21: Laboratory chemicals	F, I, **P**	F, I, **P**	F, I, **P**	F, I, **P**	F, I, **P**	F, I, **P**	F, I, **P**

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 14.09.2020

There are no relevant completed or ongoing regulatory risk management activities for any of substances.