

Assessment of regulatory needs

Authority: European Chemicals Agency (ECHA)

Date: 31 March 2022

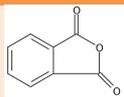
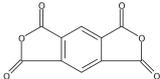
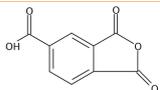
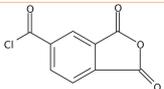
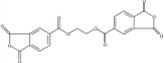
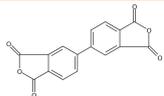
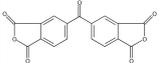
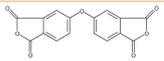
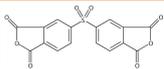
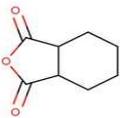
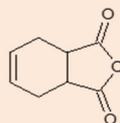
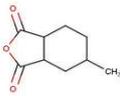
Group Name: Phthalic anhydrides and hydrogenated phthalic anhydrides

General structure: -

Revision history

| <i>Version</i> | <i>Date</i> | <i>Description</i> |
|----------------|---------------|-------------------------------|
| 1.0 | 31 March 2022 | First version for publication |
| | | |

Substances within this group:

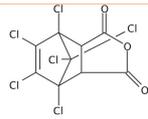
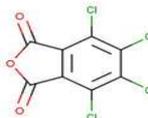
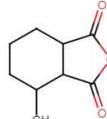
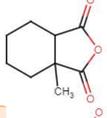
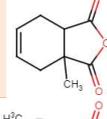
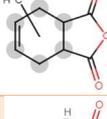
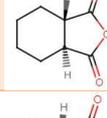
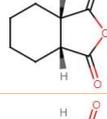
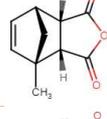
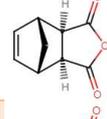
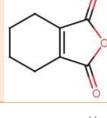
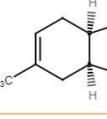
| EC/List number | CAS number | Substance name [and substance name acronyms] | Chemical structures | Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) ¹ |
|----------------|------------|---|---|--|
| 201-607-5 | 85-44-9 | Phthalic anhydride [PA] |  | Full, >1000 |
| 201-898-9 | 89-32-7 | Benzene-1,2:4,5-tetracarboxylic dianhydride [PMDA] |  | Full, 100-1000 |
| 209-008-0 | 552-30-7 | Benzene-1,2,4-tricarboxylic acid 1,2-anhydride [TMA] |  | Full, >1000 |
| 214-874-8 | 1204-28-0 | 4-chloroformylphthalic anhydride [TMAC] |  | Full, 10-100 |
| 217-062-1 | 1732-96-3 | Ethylene bis[1,3-dihydro-1,3-dioxoisobenzofuran-5-carboxylate] [TMEG] |  | Full, not (publicly) available |
| 219-342-9 | 2420-87-3 | 4,4'-biphtalic dianhydride [BPDA] |  | Full, not (publicly) available |
| 219-348-1 | 2421-28-5 | Benzophenone-3,3':4,4'-tetracarboxylic dianhydride [BTDA] |  | Full, 100-1000 |
| 412-830-4 | 1823-59-2 | 4,4'-oxydiphthalic anhydride [ODPA] |  | Full, not (publicly) available |
| 807-101-6 | 2540-99-0 | 5,5'-sulfonylbis(2-benzofuran-1,3-dione) [DSDA] |  | Full, not (publicly) available |
| 201-604-9 | 85-42-7 | cyclohexane-1,2-dicarboxylic anhydride [HHPA] |  | Full, >1000 |
| 201-605-4 | 85-43-8 | 1,2,3,6-tetrahydrophthalic anhydride [THPA D4] |  | Full, >1000 |
| 243-072-0 | 19438-60-9 | hexahydro-4-methylphthalic anhydride [4-MHHPA] |  | Full, >1000 |

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>

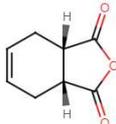
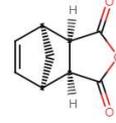
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| | | | | |
| 251-823-9 | 34090-76-1 | tetrahydro-4-methylphthalic anhydride [4-MTHPA] | | Full, >1000 |
| 226-247-6 | 5333-84-6 | 1,2,3,6-tetrahydro-3-methylphthalic anhydride [3-MTHPA DA] | | Full, not (publicly) available |
| 246-644-8 | 25134-21-8 | 1,2,3,6-tetrahydromethyl-3,6-methanophthalic anhydride [METH] | | Full, 100-1000 |
| 247-094-1 | 25550-51-0 | hexahydromethylphthalic anhydride [MHHPA] | | Full, 100-1000 |
| 234-290-7 | 11070-44-3 | tetrahydromethylphthalic anhydride [MTHPA] | | Full, >1000 |
| 247-570-9 | 26266-63-7 | tetrahydrophthalic anhydride [THPA] | | Full, not (publicly) available |
| 222-323-8 | 3425-89-6 | 1,2,3,6-tetrahydro-4-methylphthalic anhydride [4-MTHPA D4] | | TII or OSII, not (publicly) available |
| 212-557-9 | 826-62-0 | 1,2,3,6-tetrahydro-3,6-methanophthalic anhydride | | TII or OSII, not (publicly) available |
| 429-060-1 | - | EPICURE YH306 | not (publicly) available | TII or OSII, not (publicly) available |

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| 204-077-3 | 115-27-5 | 1,4,5,6,7,7-hexachloro-8,9,10-trinorborn-5-ene-2,3-dicarboxylic anhydride [chlorendic anhydride] |  | Full, not (publicly) available |
| 211-185-4 | 632-79-1 | tetrabromophthalic anhydride [TBPA] |  | Full, not (publicly) available |
| 204-171-4 | 117-08-8 | tetrachlorophthalic anhydride [TCPA] |  | Full, 100-1000 |
| 260-566-1 | 57110-29-9 | Hexahydro-3-methylphthalic anhydride |  | C&L notified |
| 256-356-4 | 48122-14-1 | Hexahydro-1-methylphthalic anhydride |  | C&L notified |
| 255-853-3 | 42498-58-8 | 2,3,5,6-tetrahydro-2-methylphthalic anhydride |  | C&L notified |
| 247-830-1 | 26590-20-5 | 1,2,3,6-tetrahydromethylphthalic anhydride |  | C&L notified |
| 238-009-9 | 14166-21-3 | trans-cyclohexane-1,2-dicarboxylic anhydride |  | C&L notified |
| 236-086-3 | 13149-00-3 | cis-cyclohexane-1,2-dicarboxylic anhydride |  | C&L notified |
| 620-411-4 | 123748-85-6 | 8,9-dinorborn-5-ene-2,3-dicarboxylic anhydride |  | C&L notified |
| 220-384-5 | 2746-19-2 | (1α,2α,3β,6β)-1,2,3,6-tetrahydro-3,6-methanophthalic anhydride |  | C&L notified |
| 219-374-3 | 2426-02-0 | 3,4,5,6-tetrahydrophthalic anhydride |  | C&L notified |
| 216-906-6 | 1694-82-2 | cis-1,2,3,6-tetrahydro-4-methylphthalic anhydride |  | C&L notified |

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| 213-308-7 | 935-79-5 | cis-1,2,3,6-tetrahydrophthalic anhydride |  | C&L notified |
| 204-957-7 | 129-64-6 | Endo-3,6-methylene-1,2,3,6-tetrahydrophthalic anhydride |  | C&L notified |

This table contains also 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.

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DISCLAIMER

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 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, 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 website².

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 |
| CSR | Chemical Safety Report |
| 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 |
| TWA | Time-weighted average |

1 Overview of the group

ECHA has grouped together substances based on the presence of at least one phthalic anhydride (PA) or hydrogenated PA moiety. Additional functionalities may be present in the structure of the group members. The group is composed of 36 substances out of which 24 are registered and 12 are only notified under the CLP Regulation.

The group can be described as consisting of substances with a PA moiety that may be further functionalised with an anhydride, carboxylic acid, halide or acyl halide group. Where more than one PA moiety is present, the PAs are bonded with each other directly or through an ethylene dicarboxylate, keto, ether or sulfonyl bridge. Other substances in this group have partially or fully hydrogenated PA. Some of the hydrogenated substances display a methylene bridged bicyclic structure, one of them being chlorinated. Aliphatic substituents may also be present.

The main hazards of the group are respiratory and skin sensitisation. Many of the substances in the group have a harmonised classification as skin sensitiser and respiratory sensitiser (see Annex 1). HHPA³, MHHPA⁴ and TMA (EC 209-008-0) are included in the Candidate List for their respiratory sensitising properties (Article 57(f) - human health) and were recommended for inclusion in the Authorisation List.

Based on information reported in the REACH registration dossiers, most substances in the group have only industrial uses (mainly as intermediate and monomer) in adhesives and sealants, coatings, paints and inks, lubricants and greases, textile treatment products, dyes and in the production of polymeric resins. Halogenated anhydrides (TBPA, TCPA and chlorendic anhydride) are also used as flame retardants. HHPA, MHHPA and TMA have been prioritised for inclusion into Annex XIV of REACH due to high use volume, wide dispersiveness of uses (use at industrial sites) and potential for regrettable substitution (grouping with substances having similar structure and similar uses). The same use and exposure considerations apply also to other substances of this group. Potential for exposure for human health and the environment is confirmed for all registered substances in the group. All substances have industrial uses. However, there are uncertainties on the effectiveness of RMM considered by registrants in their CSRs to reduce exposure to workers and limit releases to the environment.

Professional uses (e.g. use of bi-component adhesives, as hardener for epoxy resins) are reported for 4 substances in the group (EC 201-607-5; EC 201-898-9; EC 209-008-0; EC 219-348-1), thus exposure of self-employed workers is expected. Consumer exposure is also possible based on the reported consumer use for 4 substances (EC 201-607-5; EC 201-898-9; EC 246-644-8; EC 247-094-1) mainly in coatings, paints and inks, with no specific information in 1 case (EC 247-094-1). Registrants included article service life for two substances, mainly in coatings, paints and inks. Article service life could possibly be relevant to other substances. Although no information is available on possible presence of unreacted form of these substances in polymers, their releases from polymer articles and subsequent exposure to consumers cannot be excluded.

³ The Candidate List entry for HHPA covers EC 201-604-9, 236-086-3 and 238-009-9

⁴ The Candidate List entry for MHHPA covers EC 243-072-0, 247-094-1, 256-356-4 and 260-566-1

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 (no) 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 known or potential skin and respiratory sensitising properties due to the potential for exposure to all substances in the group.

All substances in this group have known or potential skin and respiratory sensitising properties.

A group restriction is considered as the best option to address the exposure of workers and consumers to these substances. The aim of the restriction would be to ban the substances in mixtures handled by professional users and by consumers through a low concentration limit. Moreover, restricting substances in articles used by professionals or consumers should be considered in the context of the restriction of consumer/professional uses. It can be considered to restrict targeted industrial uses. Compared with authorisation, a restriction would allow for more flexibility in setting conditions and possible derogations for uses where the necessary RMMs to ensure safe use at the workplace are considered to be in place.

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 Sustainability⁵ which aims to extend to professional users under REACH the level of protection granted to consumers.

Authorisation may be considered as a RRM for this group to address the risk of workers based on the following:

- consistency with the regulatory measure already proposed for these substances, recommended for inclusion into Annex XIV (Authorisation List): the substances are likely to be used to substitute other substances with similar structure (e.g. HHPA and MHPA) which are already included in the candidate list of REACH and recommended for inclusion in Annex XIV of REACH (9th recommendation October 2019); and
- the predominance of industrial uses among all the substances of the group.

Authorisation might be considered for uses excluded from the scope of the restriction (e.g. industrial uses). However, most of the uses are intermediate uses and thus not in the scope of authorisation. The number of uses that would be in the scope of authorisation would be further reduced when authorisation would be implemented following a restriction. Moreover, discussions are still ongoing among Member States, the Commission and ECHA about the most appropriate EU RRM option for the substances that ECHA recommended for inclusion in Annex XIV. Therefore, the Commission considered it appropriate to postpone the inclusion of those substances in Annex XIV.

As alternative risk management option to authorisation for industrial uses, the establishment of an EU-wide exposure limit for workers under Occupational Health and Safety (OSH) legislation or REACH was also considered. Currently national OELs (8h TWA) are available in Finland for HHPA, MHPA and TCPA (EC 204-171-4). Several Member States have established OELs for TMA and PA (EC 201-607-5), however variability among those values is significant. Furthermore, the Member State Committee, in the report on inclusion of TMA (EC 209-008-0) in the Candidate List of SVHC, concluded that current data do not allow the establishment of safe threshold for exposure. Usually, epidemiological data may not be available or allow for establishing a dose response for respiratory sensitisers. Consequently, it may be difficult to establish a safe level of exposure for a respiratory sensitiser.

As a first step, it is proposed that CLH proposals are initiated and submitted jointly for respiratory and skin sensitisation for all substances in the group that do not yet have CLH covering these hazards. CLH as Resp. Sens. and Skin Sens. should be addressed by company level risk management measures (RMM) under OSH legislation for industrial workers, though it is not considered sufficiently protective for professionals and consumers. This action could run in parallel to the preparation of the group restriction, in order not to delay the action toward a minimization of professional and consumer exposure to respiratory and skin sensitisers.

In parallel, data generation is needed to clarify mutagenicity observed for 1 substance (TMAC, EC 214-874-8) and reproductive toxicity, since current information on hazard is not sufficient to conclude on this hazard for 10 substances. Should the hazard exist, the confirmation of hazard via the group harmonised classification will be reassessed. CLH as Repr. Cat 1 and/or Muta. Cat 1 i) will trigger company level risk management measures (RMM) under OSH legislation for workers, 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

⁵ European Commission, *Chemical Strategy for Sustainability Towards a Toxic-Free Environment*, available at <https://ec.europa.eu/environment/pdf/chemicals/2020/10/Strategy.pdf>

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consumer mixtures, by means of the restriction entry 29 and/or 30 of REACH Annex XVII.

None of the substances in the group need further EU regulatory risk management actions at the moment due to environmental hazard (no PBT/vPvB hazard for any of the registered substances in the group; low environmental hazards and/or correct (self-) classification in place).

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

| Subgroup name, EC number, substance name | Human Health Hazard | Environmental Hazard | Relevant use(s) & exposure potential | Last foreseen action | Action |
|---|--|--|--|---|---|
| 214-874-8, TMAC 217-062-1, TMEG 219-348-1, BTDA 219-342-9, BPDA 412-830-4, ODPA 807-101-6, DSDA 246-644-8, METH 204-077-3, chlorendic anhydride 211-185-4, TBPA 429-060-1, EPICURE YH306 | Known or potential hazard for skin sensitisation and respiratory sensitisation (except unlikely skin sensitisation for ODPA and DSDA) Known or potential hazard for mutagenicity TMAC for reproductive toxicity TMA Inconclusive hazard for carcinogenicity and STOT RE | No hazard or unlikely hazard for all with few exceptions: Known or potential hazard for aquatic toxicity <ul style="list-style-type: none"> • PA • PMDA • ODPA • THPA D4 | Industrial uses mainly as intermediate and monomer in adhesives and sealants, coatings, paints and inks, lubricants, production of polymeric resins. Professional uses as hardener for epoxy resins, use of bi-component adhesives. Consumer use and article service life in coatings, paints and inks. Potential for exposure for | Need for EU RRM: Restriction <u>Justification:</u> 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. Potential exposure from articles needs further investigation, restriction for use | First step: CLH and in parallel Restriction (and in parallel: <ul style="list-style-type: none"> • CCH <ul style="list-style-type: none"> • METH • TBPA • await for data being generated for TMAC) First step: Restriction |
| 201-607-5, PA 201-898-9, PMDA | | | | | |

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| Subgroup name, EC number, substance name | Human Health Hazard | Environmental Hazard | Relevant use(s) & exposure potential | Last foreseen action | Action |
|---|---|----------------------|--------------------------------------|---|---|
| 209-008-0, TMA | <ul style="list-style-type: none"> • HHPA • THPA D4 • TCPA • TBPA • 3-MTHPA DA • MTHPA • METH • 4-MTHPA • MHHPA (only for carcinogenicity) | | human health and the environment. | <p>in articles to be considered together with the restriction of professional uses.</p> <p>Industrial uses to be considered as part of the restriction.</p> | <p>(and in parallel</p> <ul style="list-style-type: none"> • CCH for <ul style="list-style-type: none"> • TMA • HHPA • THPA D4 • TCPA • TBPA • MTHPA DA • MTHPA • METH • MHHPA • await for data being generated for PMDA) |
| 201-604-9, HHPA | | | | | |
| 201-605-4, THPA D4 | | | | | |
| 243-072-0, 4-MHHPA | | | | | |
| 251-823-9, 4-MTHPA | | | | | |
| 226-247-6, 3-MTHPA DA | | | | | |
| 247-094-1, MHHPA | | | | | |
| 234-290-7, MTHPA | | | | | |
| 247-570-9, THPA | | | | | |
| 222-323-8, 4-MTHPA D4 | | | | | |
| 212-557-9, 1,2,3,6-tetrahydro-3,6-methanophthalic anhydride | | | | | |
| 204-171-4, TCPA | | | | | |
| 260-566-1, Hexahydro-3-methylphthalic anhydride | | | | | |

ASSESSMENT OF REGULATORY NEEDS

| Subgroup name, EC number, substance name | Human Health Hazard | Environmental Hazard | Relevant use(s) & exposure potential | Last foreseen action | Action |
|---|---------------------|----------------------|--------------------------------------|----------------------|--------|
| 256-356-4, Hexahydro-1-methylphthalic anhydride | | | | | |
| 255-853-3, 2,3,5,6-tetrahydro-2-methylphthalic anhydride | | | | | |
| 247-830-1, 1,2,3,6-tetrahydromethylphthalic anhydride | | | | | |
| 238-009-9, trans-cyclohexane-1,2-dicarboxylic anhydride | | | | | |
| 236-086-3, cis-cyclohexane-1,2-dicarboxylic anhydride | | | | | |
| 620-411-4, 8,9-dinorborn-5-ene-2,3-dicarboxylic anhydride | | | | | |
| 220-384-5, (1 α ,2 α ,3 β ,6 β)-1,2,3,6-tetrahydro-3,6-methanophthalic anhydride | | | | | |

ASSESSMENT OF REGULATORY NEEDS

| Subgroup name, EC number, substance name | Human Health Hazard | Environmental Hazard | Relevant use(s) & exposure potential | Last foreseen action | Action |
|--|---------------------|----------------------|--------------------------------------|----------------------|--------|
| 219-374-3, 3,4,5,6-tetrahydrophthalic anhydride | | | | | |
| 216-906-6, cis-1,2,3,6-tetrahydro-4-methylphthalic anhydride | | | | | |
| 213-308-7, cis-1,2,3,6-tetrahydrophthalic anhydride | | | | | |
| 204-957-7, Endo-3,6-methylene-1,2,3,6-tetrahydrophthalic anhydride | | | | | |

Annex 1: Overview of classifications

Data extracted on 22/10/2020

| EC/ List No | Substance name | Harmonised classification | Classification in registrations | Classification in C&L notifications |
|------------------|---|---|---------------------------------|--|
| 201-607-5 | Phthalic anhydride | Acute Tox. 4 (H302) Skin Irrit. 2 (H315) Eye Dam. 1 (H318) Resp. Sens. 1 (H334) Skin Sens. 1 (H317) STOT SE 3 (H335) | | |
| 201-898-9 | Benzene-1,2:4,5-tetracarboxylic dianhydride | Eye Dam. 1 (H318) Resp. Sens. 1 (H334) Skin Sens. 1 (H317) | | |
| 209-008-0 | Benzene-1,2,4-tricarboxylic acid 1,2-anhydride | Eye Dam. 1 (H318) Resp. Sens. 1 (H334) Skin Sens. 1 (H317) STOT SE 3 (H335) | | |
| 214-874-8 | 4-chloroformylphthalic anhydride | | | Resp. Sens. 1** (H334) Skin Sens. 1** (H317) |
| 217-062-1 | Ethylene bis[1,3-dihydro-1,3-dioxisobenzofuran-5-carboxylate] | | | Resp. Sens. 1** (H334) Skin Sens. 1** (H317) |
| 219-342-9 | 4,4'-bipthalic dianhydride | | Eye Irrit. 2 H319 | "STOT Single Exp. 3 H335, affected organs: respiratory tract[2 out of 10] STOT Single Exp. 3 H335, affected organs: respiratory system[2 out of 10] STOT Single Exp. 3 H335, |

ASSESSMENT OF REGULATORY NEEDS

| EC/ List No | Substance name | Harmonised classification | Classification in registrations | Classification in C&L notifications |
|------------------|---|--|--|---|
| | | | | affected organs: [1 out of 10] Skin Irrit. 2 H315[5 out of 10]" |
| 219-348-1 | Benzophenone -3,3':4,4'-tetracarboxylic dianhydride | | | Skin Sens. 1** (H317) |
| 412-830-4 | 4,4'-oxydiphthalic anhydride | | | Aquatic chronic 3 (H412) |
| 807-101-6 | 5,5'-sulfonylbis(2-benzofuran-1,3-dione) | | Eye Irrit. 2 H319 | |
| 201-604-9 | HHPA | Eye Dam. 1 H318 Skin Sens. 1 H317 Resp. Sens. 1 H334 | Eye Dam. 1 H318 Skin Sens. 1 H317 Resp. Sens. 1 H334 | Skin Irrit. 2 H315 Eye Irrit. 2 H319 STOT SE 3 H335 (bronchia) (Inhalation) STOT SE 3 H336 (narcotic effect) |
| 201-605-4 | THPA D4 | Eye Dam. 1 H318 Skin Sens. 1 H317 Resp. Sens. 1 H334 Aquatic Chronic 3 H412 | Eye Dam. 1 H318 Skin Sens. 1 H317 Resp. Sens. 1 H334 Aquatic Chronic 3 H412 | Aquatic Chronic 1 H410 Skin Corr. 1B H314 |
| 243-072-0 | 4-MHHPA | Eye Dam. 1 H318 Skin Sens. 1 H317 Resp. Sens. 1 H334 | Eye Dam. 1 H318 Skin Sens. 1 H317 Resp. Sens. 1 H334 | Skin Irrit. 2 H315 |
| 251-823-9 | 4-MTHPA | Eye Dam. 1 H318 Skin Sens. 1 H317 Resp. Sens. 1 H334 | Eye Dam. 1 H318 Skin Sens. 1 H317 Resp. Sens. 1 H334 | Skin Irrit. 2 H315 |
| 226-247-6 | 3-MTHPA DA | Eye Dam. 1 H318 Skin Sens. 1 H317 | Eye Dam. 1 H318 | Skin Irrit. 2 H315 |

ASSESSMENT OF REGULATORY NEEDS

| EC/ List No | Substance name | Harmonised classification | Classification in registrations | Classification in C&L notifications |
|------------------|----------------|--|--|--|
| | | Resp. Sens. 1 H334 | Skin Sens. 1 H317 Resp. Sens. 1 H334 | Eye Irrit. 2 H319 |
| 246-644-8 | METH | | Acute Tox. 4 H302 Skin Irrit. 2 H315 Skin Sens. 1 H317 Eye Dam. 1 H318 Acute Tox. 3 H331 Resp. Sens. 1 H334 | Skin Corr. 1B H314 Eye Irrit. 2 H319 STOT SE 3 H335 (Inhalation) Acute Tox. 4 H332 |
| 247-094-1 | MHHPA | Eye Dam. 1 H318 Skin Sens. 1 H317 Resp. Sens. 1 H334 | Eye Dam. 1 H318 Skin Sens. 1 H317 Resp. Sens. 1 H334 | |
| 234-290-7 | MTHPA | Eye Dam. 1 H318 Skin Sens. 1 H317 Resp. Sens. 1 H334 | Eye Dam. 1 H318 Skin Sens. 1 H317 Resp. Sens. 1 H334 | Acute Tox. 4 H302 Aquatic Chronic 3 H412 Acute Tox. 4 H312 |
| 247-570-9 | THPA | Eye Dam. 1 H318 Skin Sens. 1 H317 Resp. Sens. 1 H334 Aquatic Chronic 3 H412 | Eye Dam. 1 H318 Skin Sens. 1 H317 Resp. Sens. 1 H334 Aquatic Chronic 3 H412 Acute Tox. 4 H302 | Aquatic Chronic 1 H410 Skin Corr. 1B H314 |
| 222-323-8 | 4-MTHPA D4 | Eye Dam. 1 H318 Skin Sens. 1 H317 Resp. Sens. 1 H334 | Eye Dam. 1 H318 Skin Sens. 1 H317 Resp. Sens. 1 H334 | |
| 212-557-9 | | Eye Dam. 1 H318 Skin Sens. 1 H317 Resp. Sens. 1 H334 | Eye Dam. 1 H318 Skin Sens. 1 H317 Resp. Sens. 1 H334 | |

ASSESSMENT OF REGULATORY NEEDS

| EC/ List No | Substance name | Harmonised classification | Classification in registrations | Classification in C&L notifications |
|------------------|---|--|--|---|
| 429-060-1 | | | | |
| 204-077-3 | chlorendic anhydride | Skin Irrit. 2 H315 Eye Irrit. 2 H319 STOT SE 3 H335 | Skin Irrit. 2 H315 Skin sens. 1 H317 Eye Irrit. 2A H319 Carc. 2 H351 (Oral) STOT SE 3 H335 STOT RE 2 H373 Aquatic chronic 3 H412 | Carc. 1A H350 Aquatic Chronic 4 H413 Aquatic Chronic 1 H410 |
| 211-185-4 | TBPA | | Skin sens. 1 H317 | Skin Irrit. 2 H315 Eye Irrit. 2 H319 |
| 204-171-4 | TCPA | Eye Dam. 1 H318 Skin Sens. 1 H317 Resp. Sens. 1 H334 Aquatic Acute 1 H400 Aquatic Chronic 1 H410 | Eye Dam. 1 H318 Skin Sens. 1 H317 Resp. Sens. 1 H334 Aquatic Acute 1 H400 Aquatic Chronic 1 H410 Aquatic Acute 3 H402 Aquatic Chronic 3 H412 | For impurities: Carc. 1B H350 STOT RE 2 H373 (not known) |
| 260-566-1 | Hexahydro-3-methylphthalic anhydride | Eye Dam. 1; Skin Sens. 1; Resp. Sens. 1 | | |
| 256-356-4 | Hexahydro-1-methylphthalic anhydride | Eye Dam. 1; Skin Sens. 1; Resp. Sens. 1 | | |
| 255-853-3 | 2,3,5,6-tetrahydro-2-methylphthalic anhydride | Eye Dam. 1; Skin Sens. 1; Resp. Sens. 1 | | |
| 247-830-1 | 1,2,3,6-tetrahydromethylphthalic anhydride | Eye Dam. 1; Skin Sens. 1; Resp. Sens. 1 | | |
| 238-009-9 | trans-cyclohexane-1,2- | Eye Dam. 1; Skin Sens. 1; Resp. Sens. 1 | | |

ASSESSMENT OF REGULATORY NEEDS

| EC/ List No | Substance name | Harmonised classification | Classification in registrations | Classification in C&L notifications |
|------------------|--|---|---------------------------------|-------------------------------------|
| | dicarboxylic anhydride | | | |
| 236-086-3 | cis-cyclohexane-1,2-dicarboxylic anhydride | Eye Dam. 1; Skin Sens. 1; Resp. Sens. 1 | | |
| 620-411-4 | 8,9-dinorborn-5-ene-2,3-dicarboxylic anhydride | Acute Tox. 4; Skin Irrit. 2; Eye Irrit. 2; STOT SE 3; Resp. Sens. 1 | | |
| 220-384-5 | (1 α ,2 α ,3 β ,6 β)-1,2,3,6-tetrahydro-3,6-methanophthalic anhydride | Eye Dam. 1; Skin Sens. 1; Resp. Sens. 1 | | |
| 219-374-3 | 3,4,5,6-tetrahydrophthalic anhydride | Eye Dam. 1; Skin Sens. 1; Resp. Sens 1; 1Aquatic Chronic 3 | | |
| 216-906-6 | cis-1,2,3,6-tetrahydro-4-methylphthalic anhydride | Eye Dam. 1; Skin Sens. 1; Resp. Sens. 1 | | |
| 213-308-7 | cis-1,2,3,6-tetrahydrophthalic anhydride | Eye Dam. 1; Skin Sens. 1; Resp. Sens 1; 1Aquatic Chronic 3 | | |
| 204-957-7 | Endo-3,6-methylene-1,2,3,6-tetrahydrophthalic anhydride | Eye Dam. 1; Skin Sens. 1; Resp. Sens. 1 | | |

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

Data extracted on 22/10/2020

| Main applications structured by product or article types Substances EC/List | PC 9a: Coatings and paints, thinners, paint removes | PC 21: Laboratory chemicals | PC 1: Adhesives, sealants | PC 19: Intermediate | PC 32: Polymer preparation and compounds | PC 30: photochemicals |
|--|---|-----------------------------|---------------------------|---------------------|--|-----------------------|
| 201-607-5 | F, I, P, C, A | F, I, P, C, A | F, I | I | I | |
| 201-898-9 | F, I, P, C, A | | | F, I | F, I | |
| 209-008-0 | | P | | F, I | F, I | |
| 217-062-1 | | | | | I | |
| 219-342-9 | | | | | I | |
| 219-348-1 | I, P | | | I | I | |
| 412-830-4 | | | | | | I |
| 807-101-6 | | | | I | | |
| 201-604-9 | I | | I | I, P | F, I, P | |
| 201-605-4 | | | I | F, I | F, I | |
| 243-072-0 | | | I | I | I | |
| 251-823-9 | | | I | F, I | F, I | |
| 226-247-6 | | | | I | F, I | |
| 246-644-8 | I, C | | I | I | I | |
| 247-094-1 | | | I | I | F, I, P, C | |
| 234-290-7 | | | | I | I | |

ASSESSMENT OF REGULATORY NEEDS

| | | | | | | |
|------------------|---|--|--|------|------|--|
| 247-570-9 | | | | | I | |
| 222-323-8 | | | | I | F, I | |
| 212-557-9 | | | | | F, I | |
| 204-077-3 | | | | F, I | I | |
| 211-185-4 | | | | I | I | |
| 204-171-4 | I | | | | F, I | |

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 14/12/2020

| EC/List number | RM OA | Authorisation | | Restriction* | | CLH | Actions not under REACH/CLP |
|----------------|-------|----------------|-----------|--------------|----------------|-----|-----------------------------|
| | | Candidate list | Annex XIV | Annex XVII | Annex VI (CLP) | | |
| 201-607-5 | | | | | | Yes | |
| 201-898-9 | | | | | | Yes | |
| 209-008-0 | Yes | Yes** | | | | | |
| 214-874-8 | | | | | | Yes | |
| 217-062-1 | | | | | | Yes | |
| 219-348-1 | | | | | | Yes | |
| 412-830-4 | | | | | | Yes | NONS |
| 201-604-9 | | Yes | | | | Yes | |
| 201-605-4 | | | | | | Yes | |
| 243-072-0 | | Yes | | | | Yes | |
| 251-823-9 | | | | | | Yes | |
| 226-247-6 | | | | | | Yes | |
| 247-094-1 | | Yes | | | | Yes | |
| 234-290-7 | | | | | | Yes | |
| 247-570-9 | | | | | | Yes | |
| 222-323-8 | | | | | | Yes | |
| 212-557-9 | | | | | | Yes | |
| 429-060-1 | | | | | | | NONS |
| 204-077-3 | | | | | | Yes | |
| 204-171-4 | | | | | | Yes | |
| 260-566-1 | | | | | | Yes | |
| 256-356-4 | | | | | | Yes | |
| 255-853-3 | | | | | | Yes | |
| 247-830-1 | | | | | | Yes | |
| 238-009-9 | | | | | | Yes | |
| 236-086-3 | | | | | | Yes | |
| 620-411-4 | | | | | | Yes | |
| 220-384-5 | | | | | | Yes | |
| 219-374-3 | | | | | | Yes | |
| 216-906-6 | | | | | | Yes | |
| 213-308-7 | | | | | | Yes | |
| 204-957-7 | | | | | | Yes | |

*Some of the broad restriction entries in the Annex XVII of REACH are not represented in the overview, e.g. when the scope of the restriction is defined by its classification or the substance identification is broad (e.g. entries 3, 28-30 and 40).

** Included in draft 10th proposal for prioritization of substances into Annex XIV (consultation ongoing until June 2020)

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