Assessment of regulatory needs

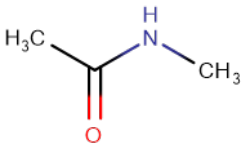
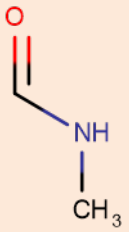
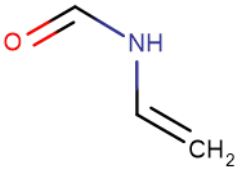
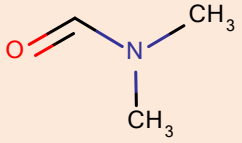
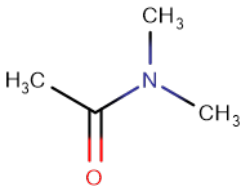
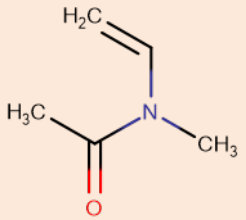
Authority: European Chemicals Agency (ECHA)

Group Name: Aliphatic secondary and tertiary amides

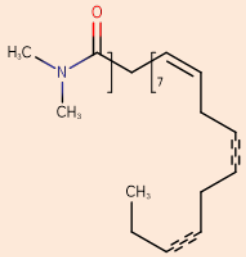
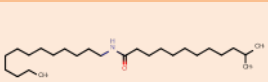
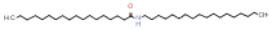
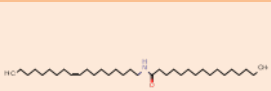
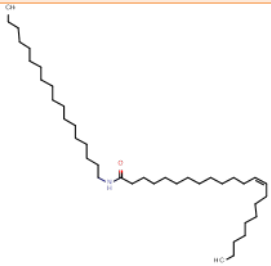
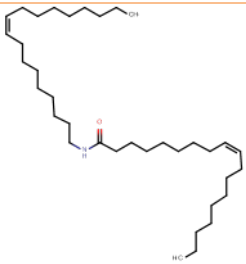
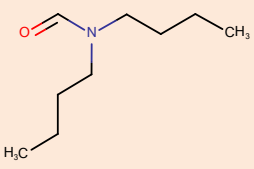
Revision history

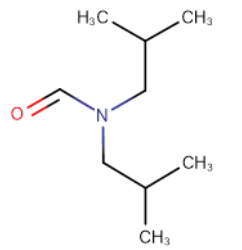
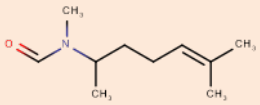
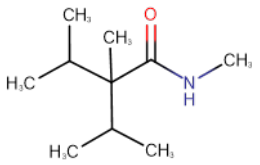
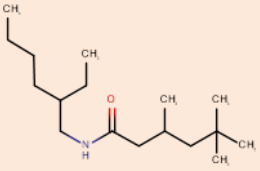
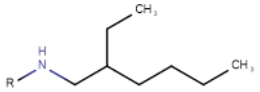
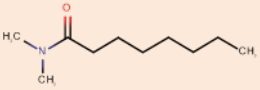
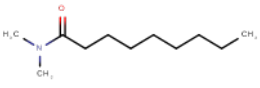
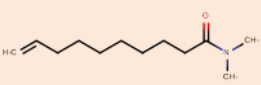
Version	*Date*	*Description*
1.0	10 February 2023	

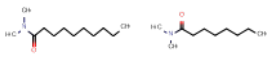
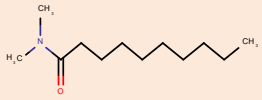
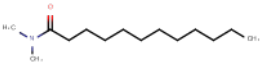
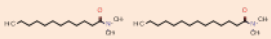
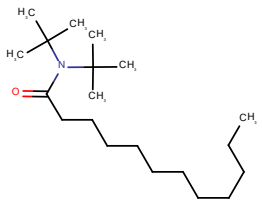
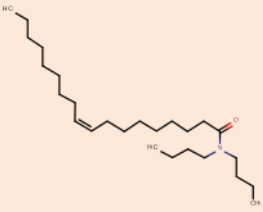
Substances within this group:

EC / List number	CAS number	Substance name (and / or Substance name acronyms)	Chemical structures	Registration status (full, OSII or TII, NONS), highest tonnage band among all the registrations (t / y) [1]
Sub-group 1				
201-182-6	79-16-3	N-methylacetamide		OSII or TII
204-624-6	123-39-7	N-methylformamide		OSII or TII
236-102-9	13162-05-5	N-vinylformamide		Full, not (publicly) available
200-679-5	68-12-2	N,N-dimethylformamide (DMF)		Full, >1000
204-826-4	127-19-5	N,N-dimethylacetamide (DMAC)		Full, >1000
221-698-5	3195-78-6	N-methyl-N-vinylacetamide		Full, 10-100
Sub-group 2				

[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

EC/List number	CAS number	Substance name (and/or Substance name acronyms)	Chemical structures	Registration status (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) [1]
269-665-4	68308-74-7	Amides, tall-oil fatty, N,N-di-Me		Full, not (publicly) available
Sub-group 3				
435-780-5	-	N-isotridecyl-iso-tridecanamide		Cease manufacture
236-276-6	13276-08-9	N-octadecylstearamide		Full, 100-1000
240-367-6	16260-09-6	(Z)-N-octadec-9-enylhexadecan-1-amide		Full, 100-1000
233-226-5	10094-45-8	(Z)-N-octadecyldocos-13-enamide		Full, 100-1000
276-974-8	72901-31-6	Dioleamide		Full, 10-100
Sub-group 4				
212-090-0	761-65-9	N,N-dibutylformamide		Full, not (publicly) available

EC / List number	CAS number	Substance name (and / or Substance name acronyms)	Chemical structures	Registration status (full, OSII or TII, NONS), highest tonnage band among all the registrations (t / y) [1]
219-983-4	2591-76-6	N,N-bis(2-methylpropyl)formamide		OSII or TII
917-791-1	-	N-methyl-N-(6-methylhept-5-en-2-yl)formamide		OSII or TII
256-974-4	51115-67-4	2-isopropyl-N,2,3-trimethylbutyramide		Full, 1-10
810-288-7	1700656-13-8	Hexanamide, N-(2-ethylhexyl)-3,5,5-trimethyl-		Full, 100-1000
298-613-3	93820-33-8	N-(2-ethylhexyl)isononan-1-amide		Inactive
214-272-5	1118-92-9	N,N-dimethyloctanamide		Full, 100-1000
612-975-5	6225-08-7	N,N-dimethylnonanamide		Full, not (publicly) available
806-919-0	1356964-77-6	N,N-dimethyldec-9-enamide		Full, not (publicly) available

EC/List number	CAS number	Substance name (and/or Substance name acronyms)	Chemical structures	Registration status (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) [1]
909-125-3*	-	Reaction mass of N,N-dimethyldecan-1-amide and N,N-dimethyloctanamide		Full, >1000
238-405-1	14433-76-2	N,N-dimethyldecan-1-amide		Full, >1000
221-117-5	3007-53-2	N,N-dimethyldodecanamide		Full, not (publicly) available
944-968-0	-	Reaction mass of N,N-dimethyldodecanamide and N,N-dimethyltetradecanamide		Full, 10-100
438-530-3	5343-44-2	N,N-dibutyldodecanamide		Full, not (publicly) available
227-410-4	5831-80-1	N,N-dibutyloleamide		OSII or TII

* earlier identifier List 614-052-2

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

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 the 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
PPP	Plant Protection Products
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 27 structurally similar substances based on the presence of the secondary or tertiary amide moiety. The group consists of 11 secondary aliphatic amides and 16 tertiary aliphatic amides. The alkyl chains vary from C1 (methyl) to C18 and can be linear, branched or containing unsaturated bonds.

The substances in the group have been further divided into 4 sub-groups based on the potential hazards, hence, each sub-group may contain different amides from the chemistry point of view:

Sub-group 1 includes structurally similar short-chain secondary and tertiary aliphatic amides with known or potential reproductive toxicity hazard:

- Secondary amides: N-methylacetamide (EC 201-182-6), N-methylformamide (EC 204-624-6) and N-vinylformamide (EC 236-102-9).
- Tertiary amides: N,N-dimethylformamide (DMF) (EC 200-679-5), N,N-dimethylacetamide (DMAC) (EC 204-826-4) and N-methyl-N-vinylacetamide (EC 221-698-5).

Sub-group 2 includes a single substance, a long-chain tertiary aliphatic amide with potential reproductive toxicity hazard: Amides, tall-oil fatty, N,N-di-Me (EC 269-665-4).

Sub-group 3 includes structurally similar long-chain secondary aliphatic amides with potential PBT/vPvB hazard: (Z)-N-octadecyldocos-13-enamide (EC 233-226-5), N-octadecylstearamide (EC 236-276-6), (Z)-N-octadec-9-enylhexadecan-1-amide (EC 240-367-6), Dioleamide (EC 276-974-8) and N-isotridecyl-iso-tridecanamide (EC 435-780-5).

Subgroup 4 includes other secondary and tertiary aliphatic amides (total number of carbons C9-C20; exception EC 227-410-4 with total number of carbons C26) and unlikely hazards, except known skin sensitisation and/or aquatic toxicity for several substances:

Two secondary aliphatic amides, EC 201-182-6 and EC 204-624-6, and two tertiary aliphatic amides, EC 200-679-5 (DMF) and EC 204-826-4 (DMAC), are known reproductive toxicants with a harmonised classification as Repr. 1B (H360D***). EC 236-102-9 is self-classified as Repr. 1B (H360FD) based on an impurity (Formamide, EC 200-842-0).

EC 201-182-6, EC 200-679-5 (DMF) and EC 204-826-4 (DMAC) are placed on the Candidate List of substances of very high concern for authorisation, with EC 200-679-5 and EC 204-826-4 also being recommended for inclusion in Annex XIV. In addition, for EC 200-679-5 (DMF) a restriction proposal has been prepared by Italy[3]. The restriction includes harmonised DNELs to reduce inhalation and dermal exposure to DMF at workplaces, similar to the restriction for N-methylpyrrolidone (NMP[4], not a group member). The Netherlands intend to restrict EC 204-826-4 (DMAC) and N-ethylpyrrolidone (NEP[5], not a group member) similarly to DMF and NMP[6].

[3] https://echa.europa.eu/registry-of-restriction-intentions/-/dislist/details/0b0236e18213ec9e

[4] EC 212-828-1; entry 71 of Annex XVII

[5] EC 220-250-6

[6] https://echa.europa.eu/registry-of-restriction-intentions/-/dislist/details/0b0236e1844d552a

Based on information reported in the REACH registration dossiers, the majority of substances in the group have reported industrial and widespread professional and consumer uses. Main applications are in biocides, in plant protection products (PPP), washing/cleaning products, polishes and waxes, coatings/inks, surface treatment products, textiles/leather, cosmetics and personal care products. Substances with long carbon chain are, in addition to solvent and intermediate uses, also used as lubricants, detergents, process regulators, softener and/or as co-formulants in PPP. Therefore, these substances are expected to have a high exposure potential both for humans (workers and consumers) and the environment. Furthermore, considering structural similarities, many substances are likely substitutes to each other.

Three tertiary aliphatic amides EC 200-679-5 (DMF), EC 204-826-4 (DMAC) and EC 221-698-5 are so called polar aprotic solvents[7]. Industrial uses in pharmaceutical and agrochemical applications, in the production of artificial leather and fibres, in polymerisation, in coatings and paints, as intermediate and as laboratory chemicals are reported for these substances. Two secondary aliphatic amides (EC 201-182-6 and 204-624-6) have only intermediate registrations. However, worker exposure potential is expected to be high for these substances when used as solvent.

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.

[5] Polar aprotic solvents are substances that cannot act as hydrogen bond donors (do not have O-H or N-H bonds) and have a high dielectric constant. These properties are relevant to their use as solvents in organic chemistry and, because of their similarity, make them to a certain degree, interchangeable between each other.

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 reproductive toxicity hazards due to the potential for release/ exposure of EC 200-679-5 (DMF), EC 204-826-4 (DMAC) and EC 221-698-5 (members of sub-group 1).

EC 200-679-5 (DMF) and EC 204-826-4 (DMAC) are known reprotoxic substances with a harmonised classification as Repr. 1B. EC 221-698-5 is also a potential reproductive toxicant, but further data generation is needed to confirm the hazard. In case no conclusion can be reached on reproductive toxicity based on data generated under CCH, the substance may be proposed for substance evaluation (SEv).

EC 200-679-5 (DMF) and EC 204-826-4 (DMAC) are already placed on the Candidate List. In addition, DMF has a RAC/SEAC Opinion on a restriction proposal, which is similar to EC 212-828-1 (NMP) and includes harmonised DNELs for limiting inhalation and dermal exposure to DMF in the workplace. The Netherlands has also made a similar restriction intention for DMAC[8]. EC 221-698-5 is structurally very similar to DMF and DMAC and also belongs to a group called polar aprotic solvents[5], with very specific properties and uses in industry. Currently identified uses for EC 221-698-5 reported in the registration dossiers are limited to formulation of personal care products (formulation of contact lenses), polymerisation (no article service life identified) and use as laboratory chemical. If, following further data generation, EC 221-698-5 is concluded to meet the classification criteria as Repr. 1B, it is proposed to consider a restriction similar to EC 204-826-4 (DMAC) and EC 220-250-6 (NEP).

Considering that several structurally similar substances have CLH for Repr. 1B (DMF, DMAC, NEP and NMP), and to avoid potentially substitution to other aprotic solvents with likely similar hazardous properties, it is proposed to consider including in a possible restriction proposal for EC 221-698-5 also some notified substances that are structurally similar short carbon chain tertiary amides (i.e. other aprotic solvent type substances) listed in Annex 4 to this report.

Based on currently available information, there is a need for (further) EU regulatory risk management – authorisation for reproductive toxicity hazards due to the potential for release/ exposure of EC 269-665-4 (sub-group 2).

EC 269-665-4 is a potential reproductive toxicant, supported by positive results from a screening study. However, data generation is needed to confirm the presence of reproductive and developmental toxicity hazard and CCH is proposed as a first step.

This substance is used as a dispersant in many industrial applications such as washing and cleaning products, water treatment products and paper, board and leather treatment products.

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**.

CLH i) will require company level risk management measures (RMM) 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 28, 29, 30.

[8] https://echa.europa.eu/registry-of-restriction-intentions/-/dislist/details/0b0236e1844d552a

CLH will also support regulatory action under other regulations. For instance, in this specific case:

- harmonised classification as CMR cat. 1 will impact the authorisation of biocidal products containing the substances, if present at concentrations above the relevant specific concentration limits for mixtures.

Following CLH, SVHC identification and later authorisation is proposed, since it is plausible that safer alternatives are available for the substance and that it may be substituted. Since there are only industrial applications as a dispersant in several industrial sectors, and only one registrant, it is considered that authorisation may be an appropriate regulatory risk management option.

Based on currently available information, there is a need for (further) EU regulatory risk management – restriction for PBT/vPvB hazards due to the potential for release/ exposure for all sub-group 3 members.

Based on ECHA's assessment of hazard information currently available in the registration dossiers and considerations of structural similarity and presence of common functional moiety all the substances in sub-group 3 have (potentially) the following environmental hazards: PBT/vPvB. Furthermore, the substances in the sub-group are likely interchangeable due to strong structural similarity.

Three of the substances (EC 233-226-5, EC 236-276-6 and EC 240-367-6) are high tonnage substances (100-1000 tpa) and the exposure potential for environment is high due to numerous professional and consumer uses reported in the registration dossiers. Data generation is currently ongoing for these substances and therefore it is proposed to await the data requested.

The first step of the regulatory risk management action proposed, should the hazard exist, is the confirmation of hazard via SVHC identification and inclusion on the Candidate List as PBT/vPvB.

SVHC identification is highly recommended as a step prior to restriction. In addition, SVHC identification brings immediate obligations for suppliers of the substances such as (i) supplying a safety data sheet and communicating on the safe use of the substances, (ii) responding to consumer requests within 45 days and (iii) notifying ECHA if the article they produce contains the substance above regulatory threshold.

Furthermore, PBT identification introduces further restrictions via the biocidal product regulation and under the detergent regulation.

Confirmation of the hazard properties via SVHC identification is not considered sufficient to minimise potential releases of the substances in the environment. A restriction is seen as the most appropriate option as potential for exposure is expected from consumer, professional and industrial uses, such as uses in paints, coatings, inks and toners.

Releases to the environment from consumer uses cannot be avoided.

Widespread professional uses are typically non-contained and non-automated leading to releases to the environment.

Therefore, a restriction of the substances as such or in mixtures (concentration limit in mixtures) used by consumers, professional and industrial workers is suggested after SVHC identification, with the aim to minimise exposures and emissions to humans and the environment.

The use of PBT and vPvB substances by consumers and professional workers has been recognised as an area of concern under the European Commission's Chemicals Strategy for Sustainability[9].

Based on ECHA's assessment of currently available hazard information, no potential hazards were identified for human health.

Based on currently available information, there is no need for (further) EU regulatory risk management for EC 201-182-6, EC 204-624-6 and EC 236-102-9 of sub-group 1 and all sub-group 4 members.

EC 201-182-6 and EC 204-624-6 (members of sub-group 1) have intermediate registrations and the exposure potential is expected to be low. EC 201-182-6 is already on the Candidate List and, for EC 204-624-6, the RMOA performed by the DE CA concluded that there is no need for further actions due to the intermediate registration and regarding import to, manufacture and use within EU, exposure of consumers is highly unlikely. On this basis, it is concluded that no EU-wide regulatory risk management is needed at the moment for these substances. However, changes in the registration status would need to be followed.

The self-classification by registrants for EC 236-102-9 (member of sub-group 1) as Repr. 1B is based on on the presence of an impurity (formamide EC 200-842-0). The highest tonnage band is >1000 t/year and it is used only in industrial polymerisation. It is expected that the current self-classification by registrants is sufficient for risk management under industrial settings.

The substances in sub-group 4 are unlikely CMR or PBT/vPvB substances. Some of the substances may have aquatic toxicity properties. Most of them have widespread uses in plant protection, washing and in cleaning products and in polishes and waxes. It is proposed to initiate CCH to verify the presence or absence of hazards for five of the substances. Two substances (EC 438-530-3 and List 810-288-7) are skin sensitisers (Skin Sens. 1) and have only industrial uses. For industrial and professional uses, sufficient and consistent self-classification by registrants should require adequate risk management measures to be in place according to workplace legislation.

Adequate product labelling should in principle provide consumers with sufficient information to manage risks arising from the use of mixtures containing EC 438-530-3 and List 810-288-7.

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

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

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
200-679-5 204-826-4 221-698-5	Known or likely hazard for reproductive toxicity	No hazard or unlikely hazard	Industrial uses as polar aprotic solvent e.g. in pharmaceutical applications and in polymerisation processes. High worker exposure potential for solvent uses.	**Need for EU RRM: Restriction** Justification: High exposure potential for solvent uses at the workplace cannot be excluded. Restriction of (targeted) industrial uses to minimise workplace exposure.	**First step:** CCH for EC 221-698-5 **Next steps (if hazard confirmed):** Restriction for EC 221-698-5
Sub-group 2: 269-665-4	Known or likely hazard for reproductive toxicity Skin Sens. 1 Inconclusive hazard for STOT RE and ED	No hazard or unlikely hazard	Industrial uses as dispersant in many industrial applications. High exposure potential to workers and the environment.	**Need for EU RRM: Authorisation** Justification: Authorisation is considered the most appropriate regulatory risk management option	**First step:** CCH **Next steps (if hazard confirmed):** potentially followed by CLH

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
				for the time being, as there is a number of industrial applications as dispersant in several industrial sectors and only one registrant.	potentially followed by SVHC identification
Sub-group 3: 435-780-5 236-276-6 240-367-6 233-226-5 276-974-8	No hazard or unlikely hazard	Known or likely hazard for PBT/vPvB	Wide dispersive uses in e.g. biocides, cleaning and washing products, in coatings and paints. High exposure potential to humans and the environment.	**Need for EU RRM: Restriction** Justificiation: Releases to the environment from consumer and widespread professional uses cannot be avoided. Widespread professional uses are typically non-contained and non-automated leading to releases to the environment. Restriction of professional uses is preferred over authorisation as it is considered to be	**First step:** Await outcome of ongoing CCH on EC 233-226-5, 236-276-6 and 240-367-6 **Next steps (if hazard confirmed):** potentially followed by SVHC identification

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
				more efficient and effective to introduce controls at the level of placing on the market rather than at the level of uses.	
201-182-6 204-624-6 236-102-9	Known or likely hazard for reproductive toxicity	No hazard or unlikely hazard	Two substances are having only intermediate registrations and one is used only as a monomer in polymerisation. Low exposure potential to humans/environment.	**Currently no need for EU RRM**	No action. The changes in uses and in the registration status are followed.
Sub-group 4: 212-090-0 219-983-4 917-791-1 256-974-4 810-288-7 298-613-3 214-272-5	No hazard or unlikely hazard (except known skin sensitisation for 438-530-3 and 810-288-7)	Known or likely hazard for aquatic toxicity for some substances	Wide dispersive uses e.g. in plant protection products, in washing and cleaning and in polishes and waxes. High exposure potential to humans and the environment.	**Currently no need for EU RRM**	CCH for 212-090-0, 221-117-5, 806-919-0, 810-288-7 and 944-968-0 Await the outcome of ongoing CCH on 238-405-1.

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
612-975-5 806-919-0 909-125-3 238-405-1 221-117-5 944-968-0 438-530-3 227-410-4					

Annex 1: Overview of classifications

Data extracted on 2 February 2021

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations
201-182-6	79-16-3	N-methylacetamide	***Repr. 1B H360 D***	*Repr. 1B H360*
204-624-6	123-39-7	N-methylformamide	***Repr. 1B H360 D*** ***Acute Tox. 4 H312***	*Acute Tox. 4 H312* *Repr. 1B H360, specific effect:May damage the unborn child* *Eye Irrit. 2 H319* *Repr. 1B H360*
236-102-9	13162-05-5	N-vinylformamide	-	*Repr. 1B H360* *Self React. Type G* *Acute Tox. 4 H302* *Eye Damage 1 H318* *STOT Rep. Exp. 2 H373*
200-679-5 **(DMF)**	68-12-2	N,N-dimethylformamide	***Repr. 1B H360 D*** ***Acute Tox. 4 H312*** ***Acute Tox. 4 H332*** ***Eye Irrit. 2 H319***	*Repr. 1B H360, specific effect:H360D "May damage the unborn child".* *Flam. Liquid 3 H226* *Acute Tox. 4 H312* *Acute Tox. 4 H332* *Eye Irrit. 2 H319*
204-826-(DMAC)	127-19-5	N,N-dimethylacetamide	***Repr. 1B H360 D*** ***Acute Tox. 4 H312*** ***Acute Tox. 4 H332***	*Repr. 1B H360, specific effect:H360D: may damage the unborn child* *Acute Tox. 4 H312* *Acute Tox. 4 H332* *Eye Irrit. 2 H319*
221-698-5		N-methyl-N-vinylacetamide	-	*Acute Tox. 4 H302* *Acute Tox. 4 H312* *Eye Irrit. 2 H319* *STOT Rep. Exp. 1 H372, affected organs: liver, kidney, respiratory tract*
269-665-4		Amides, tall-oil fatty, N,N-di-Me	-	*Skin Sens. 1B H317* *Aquatic Acute 1 H400* *Aquatic Chronic 3 H412*
435-780-5		N-isotridecyl-iso-tridecanamide	-	*Not classified*
236-276-6		N-octadecylstearamide	-	*Aquatic Chronic 4 H413*

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations
240-367-6		(Z)-N-octadec-9-enylhexadecan-1-amide	-	-
233-226-5		(Z)-N-octadecyldocos-13-enamide	-	*Not self-classified*
276-974-8		Dioleamide	-	*Not self-classified*
212-090-0		N,N-dibutylformamide	-	*Acute Tox. 4 H302* *Acute Tox. 3 H311* *Skin Corr. 1C H314* *Eye Damage 1 H318* *Aquatic Chronic 3 H412*
219-983-4		N,N-bis(2-methylpropyl)formamide	-	*Eye Damage 1 H318* *Acute Tox. 4 H302*
917-791-1		N-methyl-N-(6-methylhept-5-en-2-yl)formamide	-	*Eye Irrit. 2 H319* *Skin Irrit. 2 H315* *Acute Tox. 4 H302*
256-974-4		2-isopropyl-N,2,3-trimethylbutyramide	-	*Acute Tox. 4 H302*
810-288-7		Hexanamide, N-(2-ethylhexyl)-3,5,5-trimethyl	-	*Skin Sens. 1 H317*
298-613-3		N-(2-ethylhexyl)isononan-1-amide	-	*Aquatic Acute 1 H400* *Aquatic Chronic 2 H411*
214-272-5		N,N-dimethyloctanamide	-	*Skin Irrit. 2 H315* *Eye Damage 1 H319*
612-975-5		N,N-dimethylnonanamide	-	*Skin Irrit. 2 H315* *Eye Irrit. 2A H319*
806-919-0		N,N-dimethyldec-9-enamide	-	*Acute Tox. 4 H302* *Skin Irrit. 2 H315* *Eye Irrit. 2 H319* *STOT Single Exp. 3 H335, affected organs: Respiratory system* *Aquatic Chronic 3 H412*
909-125-3		Reaction mass of N,N-dimethyldecan-1-amide and N,N-dimethyloctanamide	-	*Skin Irrit. 2 H315* *Eye Damage 1 H318* *STOT Single Exp. 3 H335, affected organs: Respiratory system*
238-405-1		N,N-dimethyldecan-1-amide	-	*Skin Irrit. 2 H315* *Eye Irrit. 2 H319*

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations
				STOT Single Exp. 3 H335, affected organs: Respiratory system *Aquatic Chronic 3 H412*
221-117-5		N,N-dimethyldodecanamide	-	*Skin Irrit. 2 H315* *Eye Irrit. 2 H319* *Aquatic Acute 1 H400* *STOT Single Exp. 3 H335, affected organs: Respiratory system* *Aquatic Chronic 3 H412*
944-968-0		Reaction mass of N,N-dimethyldodecanamide and N,N-dimethyltetradecanamide	-	*Skin Irrit. 2 H315* *Eye Irrit. 2 H319* *Aquatic Acute 1 H400* *STOT Single Exp. 3 H335, affected organs: Respiratory system* *Aquatic Chronic 3 H412*
438-530-3		N,N-dibutyldodecanamide	-	*Skin Irrit. 2 H315* *Skin Sens. 1 H317* *Aquatic Acute 2*
227-410-4		N,N-dibutyloleamide	-	*Skin Irrit. 2 H315*

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

Data extracted on 2 February 2021

Table. Reported uses for sub-groups 1 and 2.

Main types of applications structured by product or article types	EC 200-679-5 (DMF)	EC 204-826-4 (DMAC)	EC 221-698-5	EC 201-182-6	EC 204-624-6	EC 236-102-9	EC 269-665-4
PC 20: Products such as ph-regulators, …	I	F, I, **P**					I
PC 37: Water treatment chemicals							I
PC 35: Washing and cleaning products							I
PC 8: Biocidal products							I
PC 27: Plant protection products	I						
PC 28: Perfumes, fragrances	I						
PC 39: Cosmetics, personal care products			F				
PC 29: Pharmaceuticals	I	I		I			
PC 32: Polymer preparations and compounds	I	I	I			I	I
PC 1: Adhesives, sealants	I						
PC 18: Ink and toners							I
PC 9a: Coatings and paints etc	I	F, I					
PC 34: Textile dyes, and impregnating products	I						

Main types of applications structured by product or article types	EC 200-679-5 (DMF)	EC 204-826-4 (DMAC)	EC 221-698-5	EC 201-182-6	EC 204-624-6	EC 236-102-9	EC 269-665-4
PC 26: Paper and board treatment products		**I, A**					I
PC 23: Leather treatment products	I						I
PC 21: Laboratory chemicals	I, **P**	F, I, **P**	I	I			
PC 19: Intermediate	I	I	I	I	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

Table. Reported uses for sub-group 3.

Main types of applications structured by product or article types	EC 233-226-5	EC 236-276-6	EC 240-367-6	EC 276-974-8	EC 435-780-5
PC 20: Products such as ph-regulators, ...	F, I		F, I		
PC 37: Water treatment chemicals	I		I		
PC 12: Fertilisers		F, **P, C**			
PC 35: Washing and cleaning products	F, I, **P**		F, I, **P, C**		
PC 8: Biocidal products	I, **P, C**		I, **P, C**		
PC 28: Perfumes, fragrances	I, **C**		I, **C**		
PC 3: Air care products	**C**		**C**		
PC 39: Cosmetics, personal care products	F, I, **P, C**		F, I, **P, C**		
PC 29: Pharmaceuticals	I, **P**		I, **P**		
PC 31: Polishes and wax blends	**P, C**		P, **C**		
PC 15: Non-metal-surface treatment products				I	
PC 24: Lubricants, greases, release products	F, I, **P, C**		F, I, **P, C**		
PC 25: Metal working fluids	F, I, **P**		F, I, **P**		
PC 32: Polymer preparations	F, I, **C, A**		F, I, **C**		
PC 1: Adhesives, sealants	F, I, **P, C**		F, I, **P, C**		
PC 9b: Fillers, putties, plasters etc	**C**	**C**	**C**		
PC 9a: Coatings and paints etc	F, I, **P, C, A**	F, I, **P, C**	F, I, **P, C**		
PC 18: Ink and toners	F, I ,**P, C**	F, I, **P, C**	F, I, **P, C**		

Main types of applications structured by product or article types	EC 233-226-5	EC 236-276-6	EC 240-367-6	EC 276-974-8	EC 435-780-5
PC 26: Paper and board treatment products	I		I		
PC 34: Textile dyes, and impr. products	F, I, **A**		F, I, **A**		
PC 23: Leather treatment products	F, I, **P, C**		F, I, **P, C**		
PC 14: Metal surface treatment products	I		I		
PC 21: Laboratory chemicals	F, I, **P**		F, I, **P**		
PC 19: Intermediate	I		I		
PC 40: Extraction agents					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

Table: Reported uses for sub-group 4 (without intermediate registrations and EC 298-613-3).

Main types of applications structured by product or article types	212-090-0	214-272-5	221-117-5	238-405-1	256-974-4	438-530-3	612-975-5	810-288-7	806-919-0	909-125-3	944-968-0
PC 20: Products such as ph-regulators, ...								I			
PC 37: Water treatment chemicals									F, I		
PC 12: Fertilisers		**P, C**		**C**			**C**			**P, C**	
PC 27: Plant protection products	I	F, I, **P, C**	F, **P, C**	F, **P, C**			F, **P, C**		F, **P, C**	F, **P, C**	**P, C**
PC 35: Washing and cleaning products				F, I, **P, C**	I, **P, C**				F, I, **P, C**	I, **P, C**	F, I, **P, C**
PC 8: Biocidal products					**C**				F, **C**		F, I, **P, C**
PC 28: Perfumes, fragrances					**C**						
PC 3: Air care products					**C**				**C**		F, **C**
PC 39: Cosmetics, personal care products					**C**			F	F, **P**		
PC 31: Polishes and wax blends				**C**	**P, C**				F, **P, C**		F, **P, C**
PC 25: Metal working fluids									F, I		

Main types of applications structured by product or article types	212-090-0	214-272-5	221-117-5	238-405-1	256-974-4	438-530-3	612-975-5	810-288-7	806-919-0	909-125-3	944-968-0
PC 32: Polymer preparation								F, I		F	
PC 9a: Coatings and paints										I, **P**, **C**	
PC 26: Paper and board treatment products						I, **A**				I	
PC 34: Textile dyes, and impreg. Products								F, I		I	
PC 23: Leather treatment products								F, I			
PC 21: Laboratory	I	I		I					F, **P**		
PC 19: Intermediate	I				I					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 updated on 21 February 2021

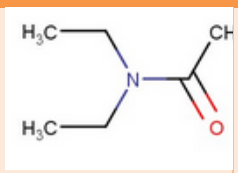
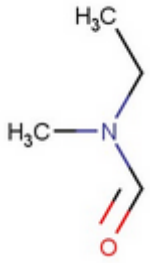
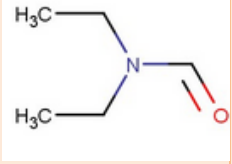
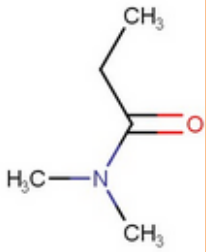
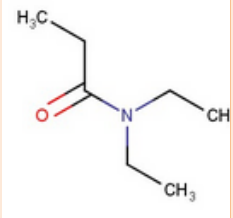
EC / List number	RMOA	Authorisation		Restriction*	CLH	Actions not under REACH / CLP
		Candidate list	Annex XIV	Annex XVII	Annex VI (CLP)	
200-679-5 (DMF)	YES	YES	Rec. inclusion	YES	YES	-
201-182-6	YES	YES	-	-	YES	-
204-624-6	YES		-	-	YES	-
204-826-4 (DMAC)	YES	YES	Rec. inclusion	YES	YES	-

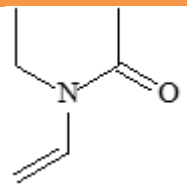
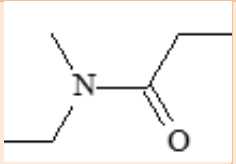
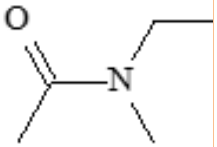
*Some of the broad restriction entries in the Annex XVII of REACH are not represented in the overview, e.g. when the scope of the restriction is defined by its classification or the substance identification is broad (e.g. entries 3, 28-30 and 40).

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

Annex 4: Non exhaustive list of substances in the C&L inventory that may fall into the group definition

The following polar aprotic solvent substances are structurally very similar to substances in sub-group 1.

EC/List number	CAS number	Substance name	Chemical structures [and/ or] Substance name acronyms	Remarks
211-685-2	685-91-6	N,N-diethylacetamide		
800-174-5	28860-25-5	N-Ethyl-N-methylformamide		
210-533-2	617-84-5	N,N-diethylformamide		
212-064-9	758-96-3	N,N-dimethylpropionamide		
625-387-9	1114-51-8	N,N-Diethyl-propanamide		

EC / List number	CAS number	Substance name	Chemical structures [and / or] Substance name acronyms	Remarks
NA	3195-79-7	N-ethenyl-N-ethyl-acetamide	 EVAC	No CL notification
NA	98278-03-6	N-ethyl-N-methyl-propanamide	 EMPA	No CL notification
NA	38806-26-7	N-ethyl-N-methyl-acetamide	 EMAC	No CL notification