

## Assessment of regulatory needs

**Authority: ECHA**

**Date: 26 April 2021**

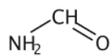
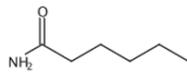
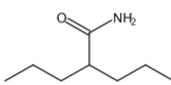
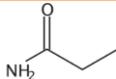
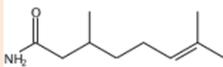
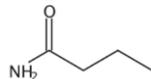
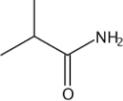
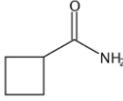
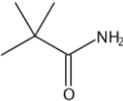
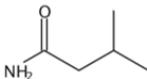
**Group Name: Aliphatic primary amides**

**General structure: -**

### Revision history

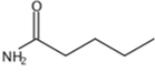
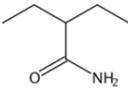
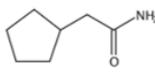
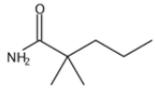
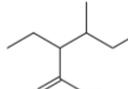
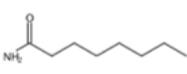
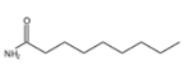
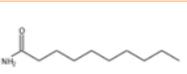
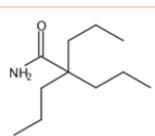
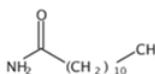
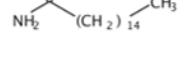
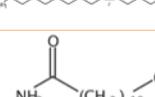
<i>Version</i>	<i>Date</i>	<i>Description</i>
<b>1.0</b>	26 April 2021	

**Substances within this group: 34 (of which 11 registered)**

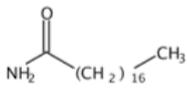
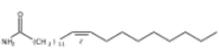
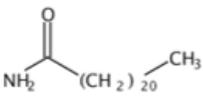
EC number	CAS number	Substance name	Chemical structure	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) <sup>1</sup>
<b>Sub-group 1</b>				
200-842-0	75-12-7	Formamide		Full 1-10; OSII or TII
<b>Sub-group 2</b>				
200-473-5	60-35-5	Acetamide	Not (publicly) available	Not (publicly) available
211-024-8	628-02-4	Hexanamide		Not registered
219-394-2	2430-27-5	Valpromide		Not registered
<b>Sub-group 3</b>				
201-172-1	79-05-0	Propionamide		Not (publicly) available
615-913-5	73127-86-3	3,7-Dimethyl-6-octenamide		Not (publicly) available
208-776-4	541-35-5	Butyramide		Not registered
209-265-9	563-83-7	Isobutyramide		Not registered
622-833-4	1503-98-6	Cyclobutanecarboxamide		Not registered
212-043-4	754-10-9	Pivalamide		Not registered
208-781-1	541-46-8	Isovaleramide		Not registered

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

## ASSESSMENT OF REGULATORY NEEDS

EC number	CAS number	Substance name	Chemical structure	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) <sup>1</sup>
210-974-0	626-97-1	Valeramide		Not registered
682-909-8	1114-38-1	2-Ethylbutyramide		Not registered
821-461-1	933-04-0	2-cyclopentylacetamide		Not registered
236-083-7	13146-36-6	2,2-dimethylvaleramide		Not registered
224-033-7	4171-13-5	Valnoctamide		Not registered
211-066-7	629-01-6	Octanamide		Not registered
214-297-1	1120-07-6	Nonan-1-amide		Not registered
219-029-7	2319-29-1	Decan-1-amide		Not registered
257-630-6	52061-73-1	Valdipromide		Not registered
214-298-7	1120-16-7	Lauramide		Not registered
622-239-5	34778-57-9	Tridecanamide		Not registered
211-343-2	638-58-4	Myristamide		Not registered
211-095-5	629-54-9	Palmitamide		Not registered
206-103-9	301-02-0	Oleamide		Not registered
257-152-8	51360-63-5	Icosanamide		Not registered

## ASSESSMENT OF REGULATORY NEEDS

EC number	CAS number	Substance name	Chemical structure	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) <sup>1</sup>
<b>Sub-group 4</b>				
931-695-7	63163-80-4	Amides, C16-C18 (even numbered)		Full 1000+; OSII or TII
204-693-2	124-26-5	stearamide		Full 1000+
931-801-1	Not (publicly) available	Amides, C18 (unsaturated)		Full 1000+
938-869-1	1469982-93-1	Amides, C18 and C18-unsatd.		Not (publicly) available
942-773-5	Not (publicly) available	Amides, C18, branched and linear		Not (publicly) available
204-009-2	112-84-5	(Z)-docos-13-enamide		Full 1000+
221-304-1	3061-75-4	docosanamide		Full 100-1000

This table contains also group members that are only notified under the CLP Regulation. However, the list is currently non-exhaustive. Should further regulatory 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 for them.

**Contents**

**Foreword** ..... 7

**Glossary** ..... 8

**1 Overview of the group** ..... 9

**2 Justification for the need for regulatory risk management action at EU level** ..... 10

**3 Conclusions and actions** ..... 12

**Annex 1: Harmonised classifications and self-classifications reported by registrants** ..... 16

**Annex 2: Overview of uses based on information available in registration dossiers** ..... 20

**Annex 3: Overview of completed or ongoing regulatory risk management activities** ..... 22

## **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 website.<sup>2</sup>

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<sup>2</sup> <https://echa.europa.eu/understanding-assessment-regulatory-needs>

## Glossary

ANSES	L'Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (The French Agency for Food, Environmental and Occupational Health & Safety)
CCH	Compliance check
CLH	Harmonised classification and labelling
CMR	Carcinogenic, mutagenic and/or toxic to reproduction
DEv	Dossier evaluation
ED	Endocrine disruptor
EVA	Ethylene vinyl acetate
NONS	Notified new substances
OEL	Occupational exposure limit
OSH	Occupational safety and health
OSII or TII	On-site isolated intermediate or transported isolated intermediates
PBT/vPvB	Persistent, bioaccumulative and toxic/very persistent and very bioaccumulative
RMM	Risk management measures
RMOA	Regulatory management options analysis
RRM	Regulatory risk management
SCC	Strictly controlled conditions
SEv	Substance evaluation
STOT RE	Specific target organ toxicity, repeated exposure
SVHC	Substance of very high concern
UVCB	Substances of unknown or variable composition, complex reaction products or biological materials

## 1 Overview of the group

ECHA has grouped together structurally similar substances based on the presence of the aliphatic primary amide moiety. The group consists of 34 primary amides with aliphatic carbon chain lengths C1-C22. Among the eleven substances that are registered, seven are well-defined, mono constituent and four are UVCB substances (Substances of Unknown or Variable composition, Complex reaction products or Biological materials). In addition, there is one non-registered group member for which all the substance identifiers are confidential. Two of the registered substances contain branched chains (mainly methyl-branched), and four substances contain unsaturated bonds. The non-registered substances are linear or branched C4 to C20 amides, two of which contain cyclic structures.

The substances in the group have been further divided into four sub-groups. The division is based on the potential hazards and the current uses:

Sub-group 1: Formamide (C1);

Sub-group 2: Acetamide (C2), hexanamide (C6) and valpromide (C8);

Sub-group 3: Propionamide (C3) and 3,7-dimethyl-6-octenamide (C10) together with the C4 to C20 notified (non-registered) substances;

Sub-group 4: C16 to C22 registered substances (at tonnages >100 t/y).

As for the hazards within the group, formamide has a harmonised classification for Repr. 1B (H360D) and acetamide for Carc. 2 (H351). Formamide is included in the Candidate list. In addition, one notifier has classified valpromide as Repr. 1A (H360Df).

### 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.

Based on information reported in the REACH registration dossiers, the registered substances with carbon chain lengths C1-C10 (formamide, acetamide, propionamide and 3,7-dimethyl-6-octenamide) are used only as intermediates in industrial settings or as solvent or reagent chemical in laboratory conditions.

Therefore, these substances are expected to have a low exposure potential for workers and the environment, and no consumer uses or article service lives are identified. Nonetheless, formamide has been found in different ethylene vinyl acetate (EVA) mats (puzzle, exercise and fitness mats) and toys. Formamide, present in these articles, is likely a by-product of the blowing agent used to produce the articles.

The registered substances with carbon chain lengths C16-C22 have widespread uses. All are used in polymer production, and article service lives of rubber and plastic articles are identified in the registration dossiers. Many of the substances are also used in coatings, inks, adhesives, lubricants and greases. Some substances have wider use profiles including uses in textiles, laundry and dishwasher products, disinfecting products and air fresheners (e.g. as slip and antiblock agents, surfactants and processing aids). Therefore, these substances are expected to have a high exposure potential both for humans (workers and consumers) and the environment.

## 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** to address the potential Repr. 1B hazards and the potential for release/ exposure of formamide (EC 200-842-0) from articles.

Formamide has a harmonised classification (CLH) as Repr. 1B.

CLH i) will trigger company level risk management measures (RMM) under occupational safety and health (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 consumer mixtures when present in concentration above 0.3%, by means of the restriction entry 30 of REACH Annex XVII. Therefore, the uses of formamide in mixtures such as glues is already regulated.

However, consumer articles in which formamide may be present (both intentionally or non-intentionally) are currently not regulated. Formamide has been confirmed to be released from ethylene vinyl acetate (EVA) based consumer articles (fitness mats, puzzle mats, toys). It has not been added intentionally to the EVA articles but instead, it is considered to be a likely by-product of the blowing agent (azodicarbonamide or tosylsemicarbazide) used to manufacture these consumer products<sup>3</sup>. It is considered that exposure to formamide from those consumer articles should be investigated further and it is proposed to do this under the restriction process. The French Agency for Food, Environmental and Occupational Health & Safety (ANSES) investigated the uses of formamide in consumer goods and health risks related to formamide in children's foam puzzle mats. Following the publication of the ANSES report, the EU "Toys" Directive (2009/48/EC<sup>4</sup>) concerning the specific limit values for chemicals used in toys, was amended (2015) and a specific limit value was set for formamide. The emission limit was set to 20 µg/m<sup>3</sup> after 28 days in foam toy materials containing more than 200 mg formamide per kg of foam. The presence of formamide in those other consumer articles may need to be restricted in a similar way as for toys.

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<sup>3</sup> Annex XV dossier submitted by the Federal Institute for Occupational Safety and Health in Germany: <https://echa.europa.eu/documents/10162/4359a048-0988-4338-becc-6c0a3d411073>

<sup>4</sup> Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys (Text with EEA relevance). <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02009L0048-20171124>

Formamide has been identified as a Substance of Very High Concern (SVHC) and it is included in the Candidate list. Therefore, authorisation could be an option to manage the risk linked to the presence of formamide present in consumer articles via Art. 69(2). However, formamide is for the time being not included on the Authorisation List (Annex XIV) and therefore it will take time before any action can be initiated. Furthermore, formamide has only professional use as reagent chemical with low volume <10 t/y under the scope of authorisation. The identified industrial and professional uses of formamide for analytical purposes may fall under the exemption of Scientific and Research Development.

As the source of formaldehyde is actually the blowing agent it would be good to reflect when the possibility to restrict formamide is further investigated whether regulating the blowing agents could be an alternative option to regulate presence of formamide in articles.

**Based on currently available information, there is no need for (further) EU regulatory risk management** for substances in the subgroups 2 and 3.

Acetamide has a harmonised classification for carcinogenicity (Carc. 2), is registered only at 1-10 t/y and used in manufacture of nitrification inhibitors in industrial settings and in intermediate uses under strictly controlled conditions (SCC). Hence it has limited potential for exposure for humans and release to the environment.

Effects of reproductive toxicity are also reported in the literature. However, since the substance is registered only at Annex VII level requirement, the potential for reproductive toxicity cannot be clarified under CCH. Based on the current use pattern of the substance, it is unlikely that the substance would be a good candidate for substance evaluation.

For hexanamide, the available evidence indicates a potential carcinogenic hazard while notifiers of valpromide report a classification as Repro. 1A. However, as the substances are not registered, there is currently no need for additional regulatory action.

Propionamide is registered at 1-10 t/y (Annex VII) and 3,7-dimethyl-6-octenamide is registered as intermediate so low potential for exposure is expected for these substances.

Six substances may have potential PBT/vPvB properties (i.e. pivalamide, cyclobutane carboxamide, 2,2-dimethyl valeramide, valnoctamide, valdipromide and 2-cyclopentyl acetamide). However, none of these substances are currently registered so this potential hazard cannot be investigated further.

Any changes in the registration status and/or tonnage bands need to be followed since it may change the information requirements for the substances.

**Based on currently available information, it is not possible to assess the need for regulatory risk management of substances in subgroup 4** as information on hazard is not sufficient to conclude on carcinogenicity, mutagenicity, and reproductive toxicity and aquatic toxicity of those substances. The needs for regulatory risk management action on those substances will be assessed after generation of data is completed (CCH).

### 3 Conclusions and actions

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

EC number	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
<b>Subgroup 1</b>					
<b>200-842-0</b>	Known or potential hazard for carcinogenicity and reproductive toxicity	No hazard or unlikely hazard	Industrial uses (intermediate, solvent and chemical reagent), low potential for exposure for workers and consumers. Potential for exposure for consumers from consumer articles, e.g. ethylene vinyl acetate (EVA) based fitness mats, puzzle mats and toys. 200-842-2 is considered to be a likely by-product of the blowing agent (azodicarbonamide or tosylsemicarbazide) used to manufacture these consumer products.	<b>Need for EU RRM: Restriction</b>  <u>Justification:</u> Potential exposure from the use of articles by consumers. The presence of formamide in toys is already restricted by the use of a specific limit value. There is similar concern with other articles and it is suggested to consider restricting those other articles. The substance is already on the Candidate list, however, to wait for the substance to be on the authorisation list would delay the action on articles.	<b>First step: Restriction</b>

ASSESSMENT OF REGULATORY NEEDS

EC number	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
<b>Subgroup 2 and 3</b>					
<b>200-473-5</b>	Known or potential hazard for carcinogenicity and reproductive toxicity	No hazard or unlikely hazard	Industrial use (intermediate under SCC, intermediate, reagent chemical, laboratory use), low potential for exposure.	<b>Currently no need for EU RRM</b>  <u>Justification:</u> According to the reported uses, low exposure potential and a limited release to the environment can be assumed. In addition, due to low tonnage no data generation is possible to clarify the hazards currently.	No action  Actions (including data generation) will be re-considered when the assessment will be revisited if the registration status changes.
<b>615-913-5</b>	Inconclusive hazard	Known or potential hazard for aquatic toxicity			
<b>201-172-1</b>	No hazard or unlikely hazard	No hazard or unlikely hazard			
<b>211-024-8</b>	Known or potential hazard for carcinogenicity	Known or potential hazard for aquatic toxicity	No information available (no registration)	<b>Currently no need for EU RRM</b>  <u>Justification:</u> no registration	No action  Actions (including data generation) will be re-considered when the assessment will be revisited if the registration status changes.
<b>219-394-2</b>	Known or potential hazard for reproductive toxicity				
<b>208-776-4</b>	Inconclusive hazard				
<b>209-265-9</b>					
<b>208-781-1</b>					
<b>210-974-0</b>					

ASSESSMENT OF REGULATORY NEEDS

EC number	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
<b>682-909-8</b> <b>211-066-7</b> <b>214-297-1</b> <b>219-029-7</b> <b>214-298-7</b> <b>622-239-5</b> <b>211-343-2</b> <b>211-095-5</b> <b>206-103-9</b> <b>937-972-9</b> <b>257-152-8</b>					
<b>212-043-4</b> <b>622-833-4</b> <b>236-083-7</b> <b>224-033-7</b> <b>257-630-6</b> <b>821-461-1</b>		Known or potential hazard for aquatic toxicity inconclusive hazard for PBT/ vPvB			

ASSESSMENT OF REGULATORY NEEDS

EC number	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
<b>Subgroup 4</b>					
<b>204-009-2</b>	No hazard or unlikely hazard for carcinogenicity and inconclusive hazard for reproductive toxicity	Inconclusive for aquatic toxicity	Widespread uses e.g. in polymer production (plastic and rubber), lubricant & greases, coatings & adhesives; high potential for exposure for workers and consumers.	<b>Currently not possible to assess the regulatory needs</b>  <u>Justification:</u> Hazard potential needs to be clarified first.	CCH
<b>204-693-2</b>					
<b>931-695-7</b>					
<b>931-801-1</b>					
<b>938-869-1</b>					
<b>942-773-5</b>					
<b>221-304 -1</b>					

## Annex 1: Harmonised classifications and self-classifications reported by registrants

Data extracted on 12 May 2020.

EC No	Substance name	Harmonised classification	Classification in registrations	Classification in C&L notifications
<b>200-842-0</b>	Formamide	<i>Repr. 1B H360D</i>	<i>Repr. 1B H360D Carc. 2 H351 STOT RE 2 H373</i>	-
<b>200-473-5</b>	Acetamide	<i>Carc. 2 H351</i>	<i>Carc. 2 H351</i>	-
<b>211-024-8</b>	Hexanamide	-	-	<i>Skin Irrit. 2 H315 Eye Irrit. 2 H319 STOT SE 3 H335</i>
<b>219-394-2</b>	Valpromide	-	-	<i>Repr. 1A H360Df Acute Tox. 4 H302</i>
<b>201-172-1</b>	Propionamide	-	<i>Eye irrit. 2 H319</i>	-
<b>615-913-5</b>	3,7-Dimethyl-6-octanamide	-	<i>Not classified</i>	-
<b>208-776-4</b>	Butyramide	-	-	<i>Acute Tox. 4 H302</i>
<b>209-265-9</b>	Isobutyramide	-	-	-
<b>622-833-4</b>	Cyclobutane carboxamide	-	-	<i>Acute Tox. 4 H302 Eye Irrit. 2 H319</i>
<b>212-043-4</b>	Pivalamide	-	-	<i>Acute Tox. 4 H302</i>

ASSESSMENT OF REGULATORY NEEDS

EC No	Substance name	Harmonised classification	Classification in registrations	Classification in C&L notifications
<b>208-781-1</b>	Isovaleramide	-	-	<i>Acute Tox. 4 H302 Eye Irrit. 2 H319 STOT SE 3 H335</i>
<b>210-974-0</b>	Valeramide	-	-	<i>Acute Tox. 4 H302 Skin Irrit. 2 H315 Eye Irrit. 2 H319 STOT SE 3 H335</i>
<b>682-909-8</b>	2-ethylbutyramide	-	-	<i>Acute Tox. 4 H302</i>
<b>821-461-1</b>	2-cyclopentyl acetamide	-	-	<i>Acute Tox. 4 H302 Skin Irrit. 2 H315 Eye Irrit. 2 H319 STOT SE 3 H335</i>
<b>236-083-7</b>	2,2-dimethyl valeramide	-	-	-
<b>224-033-7</b>	Valnoctamide	-	-	<i>Acute Tox. 4 H302</i>
<b>211-066-7</b>	Octanamide	-	-	<i>Skin Irrit. 2 H315 Eye Irrit. 2 H319</i>
<b>214-297-1</b>	Nonan-1-amide	-	-	<i>Acute Tox. 4 H302</i>
<b>219-029-7</b>	Decan-1-amide	-	-	<i>Acute Tox. 4 H302 Skin Irrit. 2 H315 Eye Irrit. 2 H319 STOT SE 3 H335</i>

ASSESSMENT OF REGULATORY NEEDS

EC No	Substance name	Harmonised classification	Classification in registrations	Classification in C&L notifications
<b>257-630-6</b>	Valdipromide	-	-	<i>Acute Tox. 4 H302</i>
<b>214-298-7</b>	Lauramide	-	-	<i>Aquatic chronic 4 H413 Not classified</i>
<b>622-239-5</b>	Tridecanamide	-	-	<i>Aquatic chronic 4 H413</i>
<b>211-343-2</b>	Myristamide	-	-	<i>Skin Irrit. 2 H315 STOT SE 3 H335 Aquatic chronic 4 H413</i>
<b>211-095-5</b>	Palmitamide	-	-	<i>Aquatic chronic 4 H413  Not classified</i>
<b>206-103-9</b>	Oleamide	-	-	-
<b>937-972-9</b>	Octadecanamide	-	-	-
<b>257-152-8</b>	Icosanamide	-	-	-
<b>931-695-7</b>	Amides, C16-C18 (even numbered)	-	<i>Not classified</i>	-
<b>204-693-2</b>	octadecanamide	-	<i>Not classified</i>	-
<b>931-801-1</b>	Amides, C18 (unsaturated)	-	<i>Not classified</i>	-

## ASSESSMENT OF REGULATORY NEEDS

EC No	Substance name	Harmonised classification	Classification in registrations	Classification in C&L notifications
<b>938-869-1</b>	Amides, C18 (saturated and unsaturated)	-	<i>Not classified</i>	-
<b>942-773-5</b>	Amides, C18 (branched and linear)	-	<i>Not classified</i>	-
<b>221-304 -1</b>	Docosanamide	-	<i>Not classified</i>	-
<b>204-009-2</b>	(Z)-docos-13-enamide	-	<i>Not classified</i>	-

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

Data extracted on 12 May 2020.

Main types of applications structured by product or article types	200-342-0	200-473-5	201-172-1	615-913-5	931-695-7	204-693-2	931-801-1	938-869-1	942-773-5	221-304-1	204-009-2
Manufacturing of nitrification inhibitors		I									
Use as an intermediate	I	I	I	I	I	I	I	I	I	I	I
Solvent in laboratory analysis	I										I
Reagent chemical	F, I, P		F, I, P								F, I, P
Laboratory chemical	F, I, P		F, I, P								F, I, P
Articles and materials containing fatty acids as slip and antiblocking agents								F, I, P, C, A			
Paper					I, P, C, A		I, P, C, A				
Rubber					F, I, P, C, A	C, A	F, I, P, C, A		F, I, A*	F, I, P, C, A	
Plastics					F, I, P, C, A	F, I, P, C, A	F, I, P, C		F, I, A	F, I, P, C, A	
Resin											
Metal working fluids, lubricants and greases							F, I, P, C			F, I, P, C	
Coatings/inks and adhesives					F, I, P, C	F, I, P, C	F, I, P, C			F, I, P, C	
Use in textiles										F, I, P, C, A	

ASSESSMENT OF REGULATORY NEEDS

Main types of applications structured by product or article types	200-342-0	200-473-5	201-172-1	615-913-5	931-695-7	204-693-2	931-801-1	938-869-1	942-773-5	221-304-1	204-009-2
<b>Air fresheners, polishes, laundry and dishwasher products, hand cleaners/ skin disinfectants, medical devices</b>										F, I, P, C, A	

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 12 May 2020.

EC number	RMOA	Authorisation		Restriction*		CLH	Actions not under REACH/ CLP
		Candidate list	Annex XIV	Annex XVII	Annex VI (CLP)		
<b>200-842-0</b>	YES	YES	x				

\*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.