Assessment of regulatory needs

Authority: ECHA

Date: 21 October 2020

Group Name: Methylene diphenyl ureas

General structure: -

Revision history

Version	*Date*	*Description*
1.0	**21 October 2020**	

Substances within this group:

EC/List number	CAS number	Substance name [and Substance name acronyms (*)]	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y)[1]
Linear primary amines			
406-690-3	43136-14-7	3,3'-dioctadecyl-1,1'-methylenebis(4,1-phenylene)diurea [MDI/ODA]	10+ t/y, NONS
414-980-6	Not (publicly) available	KY-WPH	NONS
416-600-4	Not (publicly) available	1,1'-(methylenedi-4,1-phenylene)bis(3-butylurea) [HAT-ISO]	1,000+ t/y, NONS
430-930-6	1266545-64-5	reaction product of diphenylmethanediisocyanate, octylamine and oleylamine (molar ratio 1:1.86:0.14) [UREA 1]	10+ t/y
445-760-8	Not (publicly) available	N,N''-(methylenedi-4,1-phenylene)bis[N'-octyl]urea [KY-EU]	100 – 1,000 t/y
451-060-3	122886-55-9	N,N''-(methylenedi-4,1-phenylene)bis[N'-octylurea] [KY-UN]	10 – 100 t/y
812-490-0	1312943-21-7	1-Dodecanamine, reaction products with 1,1'-methylenebis[4-isocyanatobenzene] and 1-octanamine	100 – 1000 t/y
812-491-6	1312943-23-9	1-Octadecanamine, reaction products with 1,1'-methylenebis[4-isocyanatobenzene] and 1-octanamine	Not (publicly) available
905-837-3	Not (publicly) available	Reaction mass of 4,4'-methylenediphenyl diisocyanate and Amines, soya alkyl	Not (publicly) available
Cyclic or cyclic and linear primary amines			
406-370-3	58890-25-8	3,3'-dicyclohexyl-1,1'-methylenebis(4,1-phenylene)diurea [MDI/CHA]	10 – 100 t/y, NONS
406-530-2	Not (publicly) available	A mixture of: 3,3'-dicyclohexyl-1,1'-methylenebis(4,1-phenylene)diurea; 3-cyclohexyl-1-(4-(4-(3-octadecylureido)benzyl)phenyl)	10 – 100 t/y, NONS

[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 Substance name acronyms (*)]	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y)[1]
		urea; 3,3'-dioctadecyl-1,1'-methylenebis(4,1-phenylene)diurea [MDI/CHA/ODA]	
406-540-7	Not (publicly) available	MDI/CHA/SA	NONS
406-550-1	Not (publicly) available	A mixture (1:2:1) of: bis(N-cyclohexyl-N'-phenyleneureido)methylene; bis(N-octadecyl-N'-phenyleneureido)methylene; bis(N-dicyclohexyl-N'-phenyleneureido)methylene [MDI]	NONS
430-980-9	Not (publicly) available	reaction product of diphenylmethanediisocyanate, octylamine, oleylamine and cyclohexylamine (1:1.58:0.32:0.097) [UREA 7]	NONS
434-210-2	Not (publicly) available	Diurea reaction product of 4,4'-methylene diphenyl diisocyanate with a mixture of tallow amine and cyclohexyl amine [POLYUREA GREASE THICKENER]	Not (publicly) available, NONS
Not (publicly) available	Not (publicly) available	Reaction products of cyclohexylamine, alkan-1-amine and 1,1'-methanediylbis(4-isocyanatobenzene)	Not (publicly) available
Not (publicly) available	Not (publicly) available	Reaction products of cyclohexylamine and 4-alkylaniline and 1,1'-methanediylbis(4-isocyanatobenzene)	Not (publicly) available
926-119-6	Not (publicly) available	Reaction product of 4,4'-methylenediphenyl diisocyanate (MDI) (101-68-8), Octylamine (111-86-4) and Cyclohexylamine (108-91-8)	Not (publicly) available
Aromatic primary amines			
423-070-8	Not (publicly) available	N,N''-(methylenedi-4,1-phenylene)bis[N'-cyclohexylurea]; N-(4-[[4-[[(phenylamino)carbonyl]amino]phenylmethyl]phenyl]-N'-cyclohexylurea; reaction mass of: N,N''-(methylenedi-4,1-phenylene)bis[N'-phenylurea] [KY-RB]	Not (publicly) available

EC/List number	CAS number	Substance name [and Substance name acronyms (*)]	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y)[1]
429-380-1	133336-92-2	N,N''-(methylenedi-4,1-phenylene)bis[N'-(4-methylphenyl)urea] [KY-AF]	Not (publicly) available
451-130-3	Not (publicly) available	MDI/CHA/PTL	NONS
926-809-7	Not (publicly) available	Reaction product of 4,4'-methylenediphenyl diisocyanate (MDI) (101-68-8) and p-Toluidine (106-49-0)	Not (publicly) available
Other structures			
231-034-6	7417-99-4	N,N'-(methylenedi-p-phenylene)bis(aziridine-1-carboxamide)	100-1,000 t/y
423-370-9	10097-09-3	Urea, N,N''-(methylenedi-4,1-phenylene)bis[N',N'-dimethyl- [OMICURE 52 OMICURE 52M]	Not (publicly) available, NONS
923-615-4	Not (publicly) available	Reaction product of 4,4'-methylenediphenyl diisocyanate (MDI) (101-68-8), Hexamethylenediamine (124-09-4) and Cyclohexylamine (108-91-8)	Not (publicly) available
924-043-8	Not (publicly) available	Reaction product of 4,4'-methylenediphenyl diisocyanate, ethylenediamine and dodecylamine	Not (publicly) available
928-226-3	1179884-99-1	1-Octadecanamine, reaction products with 1,1'-methylenebis[4-isocyanatobenzene]	Not (publicly) available

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

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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 different level of information. A Member State or E CHA 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[2].

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

Glossary

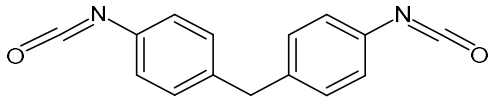
ARN	Assessment of Regulatory Needs
CCH	Compliance Check
CLH	Harmonised classification and labelling
CMR	Carcinogenic, mutagenic and/or toxic to reproduction
Dev	Dossier evaluation
ED	Endocrine disruptor
MSCA	Member State Competent Authority
NONS	Notified new substances
OEL	Occupational exposure limit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

1 Overview of the group

ECHA has grouped together structurally similar substances based on the presence of the moiety shown in the figure below.

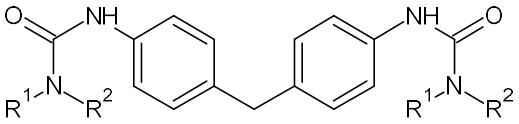
The group comprises of 27 "diureas" substances manufactured from:

- MDI (1,1'-methylenebis(4-isocyanatobenzene as a major constituent; the isomer 1-isocyanato-2-(4-isocyanatobenzyl)benzene may be present, but its concentration is not mentioned in registration dossiers):



- and different amines: primary aliphatic amines, primary alicyclic amines, primary aromatic amines, secondary aliphatic amines and one particular cyclic amine (aziridine)

General formula for this type of diureas:



R1 = alkyl, aryl
R2 = H or alkyl
R1 and R2 = cyclo

A few diureas involve the use of diamines (ethylenediamine and hexamethylene diamine) as starting materials.

The group is divided in four subgroups, based on the type of amines used as starting materials:

- Linear primary amines: 10 substances
- Cyclic or cyclic and linear primary amines: 8 substances
- Aromatic primary amines: 4 substances
- Other structures: 5 substances

These subgroups are shown in the comprehensive table starting with the first page of the report.

Based on information reported in the REACH registration dossiers, most substances in the group are used as thickener or viscosity modifier in lubricants and greases. One substance (EC 416-600-4) is as well used for adhesives, sealants, coatings, paints, fillers or putties. Two other substances (EC 231-034-6 and 423-370-9) are reactive and used as cross-linking agent or hardener for resins. Uses in industrial settings but also widespread uses by professional workers are considered relevant for all substances (see also Annex 2). For a number of substances also consumer uses, and article service life are reported. Exposure to consumers and professional workers is expected as well as releases to the environment from the reported uses. For the main application as thickeners in lubricants and greases, the substances

could potentially substitute each other, while for the other uses a potential interchangeability is assumed to be uncertain or unlikely.

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

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

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

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

Based on currently available information, there is a need for (further) EU regulatory risk management –restriction combined with authorisation for mutagenicity hazard due to the potential for release / exposure of the substance N,N'-(methylenedi-p-phenylene)bis(aziridine-1-carboxamide) (EC 231-034-6).

Substance EC 231-034-6 is self-classified by the registrant as Muta. 2 based on positive results obtained in an Ames test. Based on ECHA's assessment of currently available hazard information, the substance may merit a classification in a more severe hazard category for mutagenicity. However, compliance check (CCH) and potential data generation is needed first to clarify the hazard.

Should the requested data clarify that classification as Muta. 1B is warranted, the first step of the regulatory risk management (RRM) action proposed is the confirmation of the hazard via harmonised classification (CLH).

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

The substance is reactive and used in industrial settings as cross-linking agent or hardener for resins and in uses by professional workers. Some of the professional uses (e.g., coatings, adhesives) are expected to be widespread (at many sites and by many users). Widespread professional uses are expected to be with relatively low levels of operational controls and risk management measures but with often frequent exposures with a long duration. In addition, professional users may be self-employed and therefore not covered by occupational safety and health (OSH) legislation.

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

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

In addition, the use of the most harmful substances by professional workers has been recognised as an area of concern under the European Commission's Chemicals Strategy for Sustainability[3] which aims to extend to professional users under REACH the level of protection granted to consumers.

For industrial uses where potential for exposure cannot be excluded **it is suggested to use authorisation**. After being classified as Muta. 1B, SVHC identification could be initiated followed by inclusion in the Authorisation list to push for substitution.

As alternative to SVHC and authorisation, setting an EU-wide exposure limit for workers under OSH or REACH for industrial uses could also be considered. These conclusions will be revisited after clarification of the hazardous properties.

Based on currently available information, it is not possible to assess the need for regulatory risk management as information on hazard is not sufficient to conclude on potential PBT/vPvB properties of the substance EC 445-760-8 in the group.

Based on information available in the registration dossiers, the substance EC 445-760-8 fulfils the screening criteria for being P/vP, however, no firm conclusions are possible on B or T properties. Two compliance checks (CCH) are ongoing and will support clarifying the hazardous properties of the substance.

Furthermore, this substance has a harmonised classification as Resp. Sens. 1, Aquatic Acute and Chronic 1 (M = 100) and Eye Dam. 1.

There is lack of data for respiratory sensitisation in the registration dossiers. There is also no information available publicly on potential respiratory health effects of this substance. Furthermore, the registrant mentioned that medical reports of plant workers as well do not indicate this hazard. Based on this and the fact that no further data can be requested under CCH to substantiate the current harmonised classification, no further action is proposed in relation to respiratory sensitisation.

Similarly, also the basis for harmonised classification as Aquatic Acute and Chronic 1 could not be verified based on the information in the registration dossiers. Available data indicate no aquatic toxicity up to the level of water solubility.

Although data on which the harmonised classification was based is not publicly available and registrants argue that the substance does not fulfil the criteria for such severe hazard classification, the harmonised classification according to Annex VI of the CLP Regulation is legally binding. Some uncertainty remains in particular on the long-term aquatic toxicity and subsequently the existing chronic hazard classification of the substance which will be clarified by the ongoing CCH.

Industry has the possibility to submit a CLH proposal via a Member State Competent Authority (MSCA) to initiate the revision of the existing harmonised entry in Annex VI to CLP. Based on the outcome of such CLH proposal further EU regulatory risk management (RRM) might be needed.

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

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

Four substances (EC 406-370-3, 406-550-1, 429-380-1 and Reaction products of cyclohexylamine and 4-alkylaniline and 1,1'-methanediylbis(4-isocyanatobenzene)) are classified (harmonised or self-classification) as Skin Sens 1. They are used as thickeners in lubricants and greases in industrial settings but also by professional workers and substance EC 406-370-3 as well by consumers.

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 substance EC 406-370-3.

However, there is a concern related to skin sensitisers (potentially) present in consumer mixtures and the need to further investigate whether further regulatory actions are needed and what would be the best options to address this concern. Such concern has been already identified in other groups of substances and was brought for further discussion to Member States. Work is ongoing on this generic issue by both Member States and ECHA which may affect the regulatory actions on substances in this group.

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

Note that in addition, several substances in the group potentially contain as constituent or impurity substances with harmonised classification as respiratory sensitiser, skin sensitiser or carcinogen at concentrations above specific/generic concentration limits under the CLP Regulation leading to the potential classification of the parent substances. Such classification has not always been followed by all registrants; however, it is to be noted that this might be the case for only some compositions registered for a substance under one of the EC/List numbers or for all compositions registered for a substance.

Based on ECHA's assessment of currently available hazard information, no potential hazards were identified for human health or the environment. Therefore, and because of already existing regulatory risk management measures, no additional regulatory actions are proposed for the time being. However, registrants should adequately classify the substances based on constituents/impurities present in the substances in concentrations above regulatory thresholds.

Uncertainty about substance composition and classification

For a number of substances included in this group only limited compositional information is available. In particular, certain reaction products only generically specify impurities inherited from the starting materials and manufacturing process. These impurities could be present at rather high concentrations. Some of these starting materials carry a harmonised classification. For example, ethylenediamine (EC 203-468-6) has a CLH for Resp. and Skin Sens. 1 and is listed as SVHC on the Candidate List, p-toluidine (EC 203-403-1) has a CLH for Carc. 2, Skin Sens. 1, Aquatic Acute 1 or cyclohexylamine (EC 203-629-0) has a CLH for Repr. 2, H361f. The limited level of information available on the composition of some substances does not allow to derive firm conclusions on whether or not the presence of these impurities would warrant classification of these registered substances.

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
231-034-6	Known or potential hazard for mutagenicity	No hazard or unlikely hazard for PBT/vPvB Known or potential hazard for aquatic toxicity	Industrial and widespread professional uses as cross-linker for resins (e.g., coatings, adhesives); potential for exposure to professional workers.	**Need for EU RRM: Restriction potentially combined with authorisation** <u>Justification</u>: The reported professional uses are widespread (at many sites and many users) with relatively low levels of operational	**First step:** CCH **Next steps (if hazard confirmed):** CLH Restriction for professional uses potentially combined with SVHC identification followed by authorisation

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
				controls and risk management measures but with often frequent exposures with a long duration. Restriction of professional uses is preferred over authorisation as it is considered to be more efficient and effective to introduce controls at the level of placing on the market rather than at the level of uses. For industrial uses, authorisation is suggested as the most appropriate option but may need to be revisited once the hazard is clarified based on further assessment.	
445-760-8	Known or potential hazard for	Inconclusive hazard for PBT/vPvB	Industrial and professional uses in	**Currently not possible to assess**	CCH

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
	respiratory sensitisation	Known or potential hazard for aquatic toxicity	lubricants and greases.	**the regulatory needs**	
429-380-1, **Reaction products of cyclohexylamine and 4-dodecylaniline and 1,1'-methanediylbis(4-isocyanatobenzene),** **406-370-3 ,** **406-550-1**	Known or potential hazard for skin sensitisation	Known or potential hazard for aquatic toxicity	Widespread uses as thickeners in lubricants and greases in industrial settings, by professional workers and consumers.	**Currently no need for EU RRM** Justification: 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 the substances.	No action

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
				Harmonised/self-classification followed by implementation of necessary RRMs should be sufficient to ensure safe use for environment	
434-210-2	No hazard or unlikely hazard	No hazard or unlikely hazard	Industrial, professional and consumer uses in lubricants and greases.	**Currently no need for EU RRM** <u>Justification</u>: Overall, no or unlikely hazard that would lead to concern for the reported uses. Potential presence of classified constituent/impurity leading to the classification of the parent substances to be considered by registrants.	
430-930-6	No hazard or unlikely hazard	Known or potential hazard for aquatic toxicity	Industrial and professional uses in lubricants and greases.		
406-530-2, 406-540-7, 414-980-6	No hazard or unlikely hazard	Known or potential hazard EC 406-530-2 has a	Industrial, for some substances also professional and consumer uses in lubricants and greases.		
812-490-0, 812-491-6, 926-119-6	No hazard or unlikely hazard	No hazard or unlikely hazard	Industrial, professional and consumer uses in		

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
			lubricants and greases.		
406-690-3, 423-070-8, 423-370-9, 430-980-9, 451-060-3, 451-130-3, **Reaction products of cyclohexanamine, docosan-1-amine and 1,1'-methanediylbis(4-isocyanatobenzene)**	No hazard or unlikely hazard	Known or potential hazard for aquatic toxicity	Industrial, for some substances also professional and consumer uses in lubricants and greases.		
416-600-4	No hazard or unlikely hazard	Known or potential hazard for aquatic toxicity Self-classified as Aquatic Chronic 4.	Industrial, professional, consumer and article service life use in adhesives, sealants, coatings, paints, fillers or putties.		
905-837-3, 923-615-4, 924-043-8, 928-226-3	No hazard or unlikely hazard	No hazard or unlikely hazard	Industrial, professional and consumer uses in lubricants and greases.		

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
926-809-7	No hazard or unlikely hazard	No hazard or unlikely hazard	Industrial, professional and consumer uses in lubricants and greases.		

Annex 1: Overview of classifications

Data extracted on 28 May 2020.

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations
406-690-3	43136-14-7	3,3'-dioctadecyl-1,1'-methylenebis(4,1-phenylene)diurea	*Aquatic Chronic 4, H413*	*Aquatic Chronic 4, H413*
414-980-6	Not (publicly) available	KY-WPH	*Not included in Annex VI*	*No IUCLID 5(6) dossier*
416-600-4	Not (publicly) available	1,1'-(methylenedi-4,1-phenylene)bis(3-butylurea)	*Not included in Annex VI*	*Aquatic Chronic 4, H413*
430-930-6	1266545-64-5	reaction product of diphenylmethanediisocyanate, octylamine and oleylamine (molar ratio 1:1.86:0.14)	*Aquatic Chronic 4, H413*	*Aquatic Chronic 4, H413*
445-760-8	Not (publicly) available	N,N''-(methylenedi-4,1-phenylene)bis[N'-octyl]urea	*Eye Dam. 1, H318* *Resp. Sens. 1, H334* *Aquatic Acute 1, H400* *Aquatic Chronic 1, H410 (M=100)*	*Eye Dam. 1, H318* *Resp. Sens. 1, H334* *Aquatic Acute 1, H400* *Aquatic Chronic 1, H410*
451-060-3	122886-55-9	N,N''-(methylenedi-4,1-phenylene)bis[N'-octylurea]	*Aquatic Chronic 4, H413*	*Aquatic Chronic 4, H413*
812-490-0	1312943-21-7	1-Dodecanamine, reaction products with 1,1'-methylenebis[4-isocyanatobenzene] and 1-octanamine	*Not included in Annex VI*	*Not classified*
812-491-6	1312943-23-9	1-Octadecanamine, reaction products with 1,1'-methylenebis[4-isocyanatobenzene] and 1-octanamine	*Not included in Annex VI*	*Not classified*

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations
905-837-3	Not (publicly) available	Reaction mass of 4,4'-methylenediphenyl diisocyanate and Amines, soya alkyl	*Not included in Annex VI*	*Not classified*
406-370-3	43136-14-7	3,3'-dicyclohexyl-1,1'-methylenebis(4,1-phenylene)diurea	*Aquatic Chronic 4, H413*	*Skin Sens. 1, H317* *Aquatic Chronic 4, H413*
406-530-2	Not (publicly) available	A mixture of: 3,3'-dicyclohexyl-1,1'-methylenebis(4,1-phenylene)diurea; 3-cyclohexyl-1-(4-(4-(3-octadecylureido)benzyl)phenyl)urea; 3,3'-dioctadecyl-1,1'-methylenebis(4,1-phenylene)diurea	*Aquatic Chronic 4, H413*	*Aquatic Chronic 4, H413*
406-540-7	Not (publicly) available	MDI/CHA/SA	*No information*	*No information*
406-550-1	1266545-64-5	A mixture (1:2:1) of: bis(N-cyclohexyl-N'-phenyleneureido)methylene; bis(N-octadecyl-N'-phenyleneureido)methylene; bis(N-dicyclohexyl-N'-phenyleneureido)methylene	*Skin Sens. 1, H317* *Aquatic Chronic 4, H413*	*Skin Sens. 1, H317* *Aquatic Chronic 4, H413*
430-980-9	Not (publicly) available	reaction product of diphenylmethanediisocyanate, octylamine, oleylamine and cyclohexylamine (1:1.58:0.32:0.097)	*Aquatic Chronic 4, H413*	*Aquatic Chronic 4, H413*
434-210-2	122886-55-9	Diurea reaction product of 4,4'-methylene diphenyl diisocyanate with a mixture of tallow amine and cyclohexyl amine	*Not included in Annex VI*	*Not classified*
Not (publicly) available	Not (publicly) available	Reaction products of cyclohexylamine, alkan-1-amine and 1,1'-methanediylbis(4-isocyanatobenzene)	*Not included in Annex VI*	*Aquatic Chronic 4, H413*
Not (publicly) available	Not (publicly) available	Reaction products of cyclohexylamine and 4-alkylaniline and 1,1'-methanediylbis(4-isocyanatobenzene)	*Not included in Annex VI*	*Skin Sens. 1, H317* *Aquatic Chronic 4, H413*
926-119-6	Not (publicly) available	Reaction product of 4,4'-methylenediphenyl diisocyanate (MDI) (101-68-8), Octylamine (111-86-4) and Cyclohexylamine (108-91-8)	*Not included in Annex VI*	*Flam. Sol. 1, H228*

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations
423-070-8	Not (publicly) available	N,N''-(methylenedi-4,1-phenylene)bis[N'-cyclohexylurea]; N-(4-[[4-[[(phenylamino)carbonyl]amino]phenylmethyl]phenyl]-N'-cyclohexylurea; reaction mass of: N,N''-(methylenedi-4,1-phenylene)bis[N'-phenylurea]	*Aquatic Chronic 4, H413*	*Aquatic Chronic 4, H413*
429-380-1	133336-92-2	N,N''-(methylenedi-4,1-phenylene)bis[N'-(4-methylphenyl)urea]	*Skin Sens. 1, H317* *Aquatic Chronic 4, H413*	*Skin Sens. 1, H317* *Aquatic Chronic 4, H413*
451-130-3	Not (publicly) available	MDI/CHA/PTL	*Not included in Annex VI*	*Not classified*
926-809-7	Not (publicly) available	Reaction product of 4,4'-methylenediphenyl diisocyanate (MDI) (101-68-8) and p-Toluidine (106-49-0)	*Not included in Annex VI*	*Flam. Sol. 1, H228*
231-034-6	7417-99-4	N,N'-(methylenedi-p-phenylene)bis(aziridine-1-carboxamide)	*Not included in Annex VI*	*Muta. 2, H341* *Acute Tox. 4, H302* *Aquatic Acute 1, H400* *Aquatic Chronic 1, H410*
423-370-9	10097-09-3	Urea, N,N''-(methylenedi-4,1-phenylene)bis[N',N'-dimethyl-	*Not included in Annex VI*	*Aquatic Chronic 3, H412*
923-615-4	Not (publicly) available	Reaction product of 4,4'-methylenediphenyl diisocyanate (MDI) (101-68-8), Hexamethylenediamine (124-09-4) and Cyclohexylamine (108-91-8)	*Not included in Annex VI*	Not (publicly) available
924-043-8	Not (publicly) available	Reaction product of 4,4'-methylenediphenyl diisocyanate (202--966-0), ethylenediamine (203-468-6) and dodecylamine (204-690-6)	*Not included in Annex VI*	*Not Classified*
928-226-3	1179884-99-1	1-Octadecanamine, reaction products with 1,1'-methylenebis[4-isocyanatobenzene]	*Not included in Annex VI*	*Not Classified*

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

Data extracted on 28 May 2020.

Main types of applications structured by product or article types	Lubricants, greases (open and closed systems)	Cross-linker/ hardener for resins (epoxy, PU, acrylic) used in coatings or adhesives	Adhesives, sealants	Coatings, paints	Fillers, putties, plasters, modelling clay
231-034-6		F, I, **P**			
423-370-9		F, I			
416-600-4			F, I, **P**, **C**, **A**	F, I, **P**, **C**, **A**	F, I, **P**, **C**, **A**
406-370-3	F, I, **P**, **C**, **A**				
406-530-2	F, I, **P**, **C**, **A**				
406-540-7	I, **P**				
406-550-1	I				
406-690-3	F, I, **P**, **C**, **A**				
414-980-6	I				
423-070-8	I, **P**, **A**				
429-380-1	I, **P**				
430-930-6	F, I, **P**				
430-980-9	F, I, **P**				
434-210-2	F, I, **P**, **C**				
445-760-8	I, **P**, **A**				
451-060-3	F, I, **P**, **C**, **A**				

451-130-3	I, **P**				
Reaction products of cyclohexan amine, docosan-1-amine and 1,1'-methanediylbis(4-isocyanato benzene)	I				
Reaction products of cyclohexylamine and 4-dodecyl aniline and 1,1'-methanediylbis(4-isocyanato benzene)	I				
812-490-0	F, I, **P**, **C**				
812-491-6	F, I, **P**, **C**				
905-837-3	F, I, **P**, **C**				
923-615-4	F, I, **P**, **C**				
924-043-8	F, I, **P**, **C**				
926-119-6	F, I, **P**, **C**				
926-809-7	F, I, **P**, **C**				
928-226-3	F, I, **P**, **C**				

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

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

Data extracted on 28 May 2020.

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