Assessment of regulatory needs

Authority: European Chemicals Agency (ECHA)

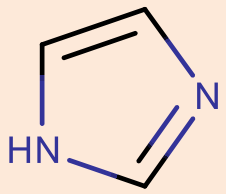
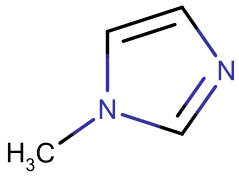
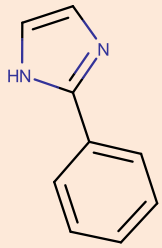
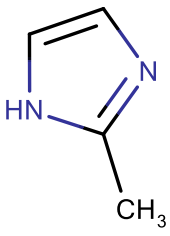
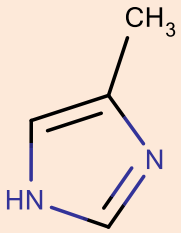
Date: 7 December 2021

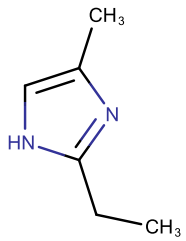
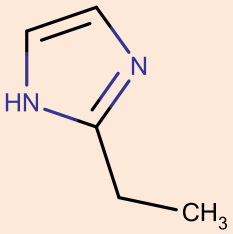
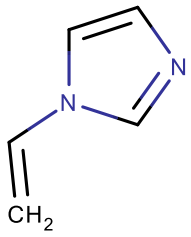
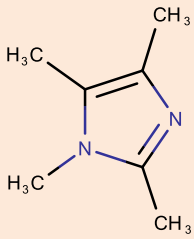
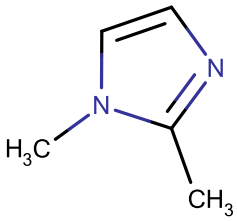
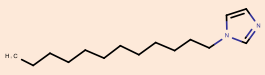
Group Name: Imidazoles

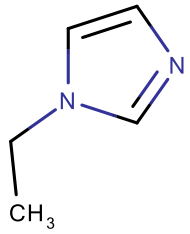
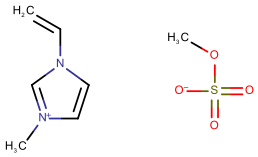
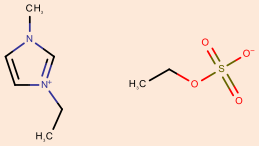
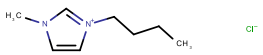
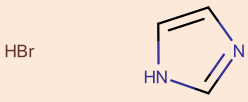
Revision history

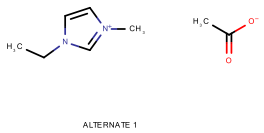
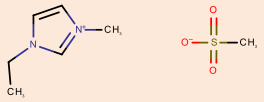
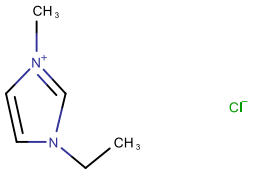
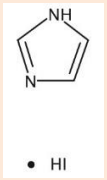
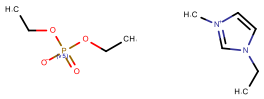
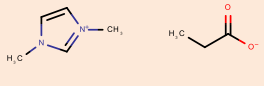
Version	*Date*	*Description*
1	7 December 2021	First version prepared by ECHA

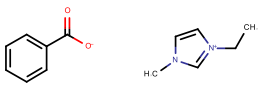
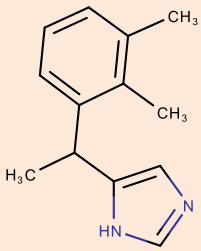
Substances within this group:

EC/List number	CAS number	Substance name	Chemical structure	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y)
206-019-2	288-32-4	imidazole		Full, 100-1000 t/y
210-484-7	616-47-7	1-methylimidazole		Full, 100-1000 t/y
211-581-7	670-96-2	2-phenylimidazole		Full, 1-10 t/y
211-765-7	693-98-1	2-methylimidazole		Full, 100-1000 t/y
212-497-3	822-36-6	4-methylimidazole		Intermediate, tonnage N/A

213-234-5	931-36-2	2-ethyl-4-methylimidazole		Full, tonnage N/A
214-011-5	1072-62-4	2-ethylimidazole		Full, tonnage N/A
214-012-0	1072-63-5	1-vinylimidazole		Full, tonnage N/A
217-100-7	1739-83-9	1,2,4,5-tetramethyl-1H-imidazole		Full, tonnage N/A
217-101-2	1739-84-0	1,2-dimethylimidazole		Full, tonnage N/A
224-314-4	4303-67-7	1-dodecyl-1H-imidazole		Full, tonnage N/A

230-403-9	7098-07-9	1-ethyl-1H-imidazole		Full, tonnage N/A
245-589-7	23328-87-2	2-heptadecyl-1H-imidazole		Full, tonnage N/A
247-832-2	26591-72-0	3-methyl-1-vinyl-1H-imidazolium methyl sulphate		Full, 100-1000 t/y
460-100-9	342573-75-5	1-Ethyl-3-methylimidazolium ethylsulfate		Full, tonnage N/A
460-120-8	79917-90-1	3-butyl-1-methyl-1H-imidazol-3-ium chloride		NONs, tonnage N/A
483-310-2	101023-55-6	1H-Imidazole, hydrobromide (1:1)		Full, tonnage N/A

604-344-8	143314-17-4	1-ethyl-3-methyl-1H-imidazol-3-ium acetate		Full, tonnage N/A
604-453-0	145022-45-3	1-ethyl-3-methyl-1H-imidazolium methanesulfonate (1:1)		Full, tonnage N/A
613-739-4	65039-09-0	1H-Imidazolium, 3-ethyl-1-methyl-, chloride (1:1)		Full, tonnage N/A
684-693-0 **ELINCS (The European List of Notified Chemical Substances) 460-240-2**	68007-08-9	Imidazole hydroiodide		Notified C&L
684-879-1	848641-69-0	1-ethyl-3-methyl-1H-imidazol-3-ium diethyl phosphate		Full, tonnage N/A
691-156-4	1307233-42-6	1,3-Dimethyl-1H-imidazol-3-ium propionate		Full, tonnage N/A

695-723-7	150999-33-0	3-ethyl-1-methyl-1H-imidazol-3-ium benzoate		Full, tonnage N/A
811-718-6	86347-14-0	1*H*-Imidazole, 5-[1-(2,3-dimethylphenyl) ethyl]-		Notified C&L

This table also contains group members that are not registered (yet) but have a C&L notification under the CLP Regulation. However, the list is currently non-exhaustive. Once further regulatory risk management action on one or more registered substances is being considered, ECHA will make an extensive search for related C&L notified substances to be included in the group and develop a regulatory strategy 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 voluntary, i.e., it is not part of the 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[1].

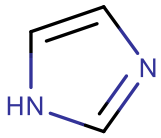
[1] https://echa.europa.eu/understanding-assessment-regulatory-needs

Glossary

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
PMT	Persistent, mobile in water and toxic
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 structurally similar substances based on the presence of the imidazole moiety shown in the figure below.



Substances that form this group have an imidazole fragment. The imidazole ring may be substituted with hydrocarbon chains or rings and substitution point may be on the nitrogen or on the carbon. Imidazolium salts are also included in the group.

Most of the substance (25 in total) are mono constituents with a full registration and relatively small joint submission or individual registrations.

Some of the substances in the group contain hazardous imidazole derivatives (Reproductive toxicant 1B) as impurities. However, the substances containing these impurities are also hazardous themselves (Reproductive toxicant 1B) or the concentrations of the impurities are low, and therefore, would not have an impact on the regulatory needs. For the substance 2-ethyl-4-methylimidazole (EC 213-234-5), there is a CLH intention for carcinogenicity, reproductive toxicity and germ cell mutagenicity, and the substance is reported to contain 4-methyl imidazole (EC 212-497-3) as an impurity. For 4-Methyl imidazole the Committee for Risk Assessment (RAC) has adopted the Opinion for the proposed harmonised classification as Repr. 1B, H360Fd and Carc. 1B, H350.

Based on information reported in the REACH registration dossiers, most of the substances of the group are used in industrial setting as intermediates. Other commonly reported uses/applications are in polymer preparation and compounds; coating and paints, thinners, paint removers; and laboratory chemicals in industrial setting. Ten out of 23 substances are widespread mostly professional uses, but one substance is used by consumers and another one is likely to be present in plastic articles. There is a high potential for exposure especially to professional workers but also to consumers for the uses in polymer preparations and compounds; coatings and paints, thinners, paint removers; adhesives and sealants. In addition, one substance is used by professionals in mixing and/or application of dental materials where potential for exposure to workers exists. According to a 2018 EU SDS, the substance is used in a 2 component (base and catalyst) quick refill product for use by dental care professionals only. In this context exposure to patients cannot be excluded.

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

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

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

2 Justification for the (no) need for regulatory risk management action at EU level

In this section, substances have been distributed in groups according to the need or no need for regulatory risk management action at EU level and last action foreseen based on variations in hazard conclusions, uses and the current regulatory risk management already in place. It should be noted that the foreseen regulatory need is a working hypothesis based on current assumptions and experiences and may be revisited and adapted at subsequent iterations of the assessment (e.g., when additional information becomes available after a CCH).

Harmonised classification for reproductive toxicity is proposed (either as a step in the regulatory actions or as the last action foreseen) for the following substances: 1-methylimidazole (EC 210-484-7), 2-ethylimidazole (EC 214-011-5), 1-ethyl-1H-imidazole (EC 230-403-9), and 1H-Imidazole, hydrobromide (1:1) (EC 483-310-2). For EC 210-484-7, 214-011-5, 230-403-9, a group approach could be taken for the CLH based on structural read across to other imidazoles that already have a harmonised classification for reproductive toxicity. For EC 483-310-2 the known hazard stems from the bromide ion and therefore, CLH should be done separately.

Based on currently available information, there is a need for (further) EU regulatory risk management – restriction and/or authorisation for imidazole (EC 206-019-2), 1-methylimidazole (EC 210-484-7), and 2-ethyl-4-methylimidazole (EC 213-234-5) for reproductive toxicity, endocrine disruption (ED) for human health and in some cases carcinogenicity, skin sensitiser hazards due to the potential for release / exposure.

Reproductive toxicity is the main hazard identified for these substances and is therefore taken as the driver for the need for further action. Imidazole (EC 206-

019-2) and the alkyl substituted imidazoles 1-vinyl (EC 214-012-0), 2-methyl (EC 211-765-7), and 4-methyl imidazole (EC 212-497-3) are known to induce developmental toxicity (aneurysms and offspring viability) with existing Repr. 1B classifications. Therefore, the alkyl substituted imidazoles such as 1-methyl imidazole (EC 210-484-7) are expected to have a potential to cause developmental toxicity (currently self-classified as Repr. 2). Alkylated imidazoles are also associated with potential carcinogenicity and endocrine activity. However, compared to the reproductive toxicity, data availability and the target organs related to the carcinogenicity and on endocrine system are less consistent within the group, weakening the structure-based approach for the regulatory risk management. Furthermore, EC 213-234-5 is reported to contain 4-methyl imidazole (EC 212-497-3). For 4-Methyl imidazole the Committee for Risk Assessment (RAC) has adopted the Opinion for the proposed harmonised classification as Repr. 1B, H360Fd and Carc. 1B, H350 .

Substances EC 206-019-2, EC 210-484-7, and EC 213-234-5 are used by professional workers in e.g., coatings and paints or polymer preparation where exposure is likely (roller application, non-industrial spraying, hand-mixing with only PPE). These substances are also used by professional workers as laboratory chemicals. The potential for exposure in this type of use is generally considered to be relatively low. In addition, the substances are used in industrial settings in e.g., coatings and paints, polymer preparations and compounds, metal surface treatments applications where there is a potential for exposure to workers (industrial spraying, dipping & pouring, roller application and brushing). From the data screened it seems unlikely that these substances would be included in the final articles manufactured.

A substance evaluation on imidazole (EC 206-019-2) was concluded by UK in 2018[2]. The general conclusion was that there is no need for follow-up regulatory action[3]. However, the substance has a full registration for 100-1000 t/y and although this includes uses as intermediate, the actual split of tonnage across the different uses is not reported. Professional uses are typically widespread (at many sites and many users) with relatively low levels of operational controls and risk management measures but with typically frequent exposures with a long duration.

In addition, professional users may be self-employed and therefore not covered by Occupational Health and Safety (OSH) legislation. 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[4] which aims to extend to professional users under REACH the level of protection granted to consumers.

The reproductive toxicity hazard identified combined with the potential for exposure should be addressed by regulatory risk management action at EU level. A combination of restriction and authorisation is proposed. Restriction should address

[2] https://echa.europa.eu/documents/10162/572435f5-76b7-6145-1672-565f884f8637

[3] The majority of the registered tonnage is supplied for use as an intermediate and most intermediate use takes place under strictly controlled conditions. In their evaluation, using their own DNELs and taking a precautionary approach to the exposure assessment, the eMSCA obtained RCRs > 1 for some activities covered by the scenarios for industrial and professional use of products containing up to 3% imidazole. The eMSCA did not consider that these RCRs provide evidence for an unacceptable risk and concluded that no further regulatory action was necessary.

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

the professional uses while authorisation should address the industrial uses. These measures will also address the other hazards identified for these substances.

Based on currently available information, there is a need for (further) EU regulatory risk management – CLH for 2-ethylimidazole (EC 214-011-5), 1-ethyl-1H-imidazole (EC 230-403-9), and 1H-Imidazole, hydrobromide (1:1) (EC 483-310-2) for carcinogenicity, reproductive toxicity, ED due to the potential for release / exposure.

Reproductive toxicity is the main hazard identified for these and is therefore taken as the driver for the need for further action. Imidazole (EC 206-019-2) and the alkyl substituted imidazoles 1-vinyl (EC 214-012-0), 2-methyl (EC 211-765-7), and 4-methyl imidazole (EC 212-497-3) are known to induce developmental toxicity (aneurysms and offspring viability) with existing or proposed Repr. 1B classifications. Therefore, the alkyl substituted imidazole derivatives such as EC 214-011-5 and EC 230-403-9 are expected to have a potential to cause developmental toxicity. Alkylated imidazoles are also associated with potential carcinogenicity and endocrine activity. The reproductive toxicity hazard for the EC 483-310-2 stems from the bromide.

Harmonised classification is proposed as the final action as it should be sufficient to address the current concern or trigger additional actions under other legislations.

EC 214-011-5 and 230-403-9 are currently only used as intermediate in industrial setting. The potential for exposure in this type of use is generally considered to be low. However, both substances are structurally similar to other substances in the group and for which the same reproductive toxicity hazard has been identified. Although it is difficult to conclude on the potential for EC 214-011-5 and 230-403-9 to be used as alternatives for these other substances, this cannot be excluded. CLH for EC 214-011-5 and 230-403-9 will ensure that the correct information is communicated in the supply chain and prevent potential regrettable substitution.

EC 483-310-2 is registered at a low tonnage and only for the use as a laboratory chemical by professional workers. The potential for exposure in this type of use is generally considered to be relatively low. The reproductive toxicity hazard is linked to the presence of the Br ion however current self-classification reports no hazard. CLH would help to ensure that the correct information is communicated in the supply chain.

Based on currently available information, there is no need for (further) EU regulatory risk management for all remaining substances **EC 211-581-7, 245-589-7, 224-314-4, 211-765-7, 214-012-0, 212-497-3, 217-100-7, 217-101-2, 604-344-8, 247-832-2, 460-100-9, 460-120-8, 604-453-0, 613-739-4, 684-879-1, 691-156-4, 695-723-7**

Some of these substances do have known or potential hazard (e.g., reproductive toxicity, skin sensitiser) but either the concern has already been/is being addressed (for example candidate listing for reproductive toxicity for 2-methylimidazole (EC 211-765-7) and 1-vinylimidazole (EC 214-012-0) or CLH for 4-methylimidazole (EC 212-497-3)), correct self-classification is sufficient to protect the workers (e.g. 1-ethyl-3-methyl-1H-imidazol-3-ium acetate (EC 604-344-8)) or the type of uses registered combined with low potential for exposure or the low tonnage do not lead to the need for (further) EU regulatory risk management (e.g. 1,2,4,5-tetramethyl-

1H-imidazole (EC 217-100-7)). The detail situation for each substance is presented in the table below

EC 224-314-4 is registered at a low tonnage (1-10 t/y) and only for the use by professional workers in mixing and application of dental materials where potential for exposure to the professionals as well as to the patients cannot be excluded. The substance is a suspected CMR based on the presence of imidazole structure. However, due to the low tonnage registration (one registrant only), compliance check would not provide the required information to further explore the hazard and the priority to initiate substance evaluation would be low. However, if the registration status changes for this substance, data generation and actions will be re-considered when the assessment will be revisited. It should be noted that if the reproductive toxicity hazard was to be confirmed for 1-dodecyl-1H-imidazole (EC 224-314-4) at some point, the hazard could potentially be extended also to 2-heptadecyl-1H-imidazole (EC 245-589-7).

CCH is proposed for EC 217-100-1 to confirm skin sensitisation hazard. For industrial and professional uses, sufficient and consistent self-classification by registrants should trigger adequate risk management measures 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 217-100-1. However, there is a concern related to skin sensitisers present in consumer mixtures and the need to further investigate whether further regulatory actions are needed and what would be the best options to address this concern. Such concern has already been identified in other groups of substances and was brought for further discussion to Member States. Work is ongoing on this generic issue by both Member States and ECHA which may affect the regulatory actions on substances in this group.

The rest of the substances have no or unlikely hazards. CCH on EC 247-832-2 is proposed to confirm the low hazard.

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
206-019-2	Known or potential hazard for reproductive toxicity for ED	No hazard or unlikely hazard	PROF uses where potential for exposure is likely (coatings & paints, polymer preparation) IND uses where potential for exposure exists (coatings & paints, polymer preparation, metal surface treatments)	Need for EU RRM: Combination of restriction and authorisation Justification: The reproductive toxicity hazard identified combined with the potential for exposure should be addressed by regulatory risk management action at EU level. Restriction should address the professional uses while authorisation should address the industrial uses.	**First step:** Restriction for professional uses. Followed by SVHC identification and authorisation for industrial uses
210-484-7	Known or potential hazard for reproductive toxicity		PROF uses where potential for exposure is likely (polymer preparation) IND uses where potential for exposure exists (coatings &		**First step:** CLH for reproductive toxicity. Followed by restriction for professional uses Followed by SVHC identification and

			paints, polymer preparation)		authorisation for industrial uses
213-234-5	Known or potential hazard for skin sensitisation and for carcinogenicity for reproductive toxicity for ED		PROF uses where potential for exposure is likely (polymer preparation) IND uses where potential for exposure exists (polymer preparation)		**First step:** Await outcome of on-going CLH on impurity (EC 212-497-3) **Next steps (if hazard confirmed):** Restriction for professional uses Followed by SVHC identification and authorisation for industrial uses
214-011-5 230-403-9	Known or potential hazard for carcinogenicity for reproductive toxicity for ED	No hazard or unlikely hazard for EC 214-011-5 Known or potential hazard for aquatic toxicity for EC 230-403-9	IND uses where potential for exposure is limited (intermediate), structural similarity to other substance in the group imply a potential for regrettable substitution	Need for EU RRM: CLH Justification: Harmonised classification should be sufficient to address the current concern, prevent regrettable substitution and trigger additional actions under other legislations.	**First step:** CLH for reproductive toxicity
483-310-2	Known or potential hazard	No hazard or unlikely hazard	PROF use where potential for exposure		

	for reproductive toxicity for ED for STOT RE		to workers is limited (laboratory)		
211-581-7 245-589-7	Known or potential hazard for carcinogenicity for reproductive toxicity for ED for skin sensitisation	No hazard or unlikely hazard	IND uses where potential for exposure exists (coatings & paints)	Currently no need for EU RRM Justification: limited potential for exposure combined with low tonnage and weaker structural similarity. Correct self-classification for skin sensitisation is sufficient for workers	**First step:** CCH to confirm skin sensitisation
224-314-4	Known or potential hazard for carcinogenicity for reproductive toxicity for ED for skin sensitisation (based on self-classification)	Known or potential hazard for aquatic toxicity	PROF uses where potential for exposure is possible (dental application)	Currently no need for EU RRM Justification: limited potential for exposure combined with low tonnage and weaker structural similarity. Correct self-classification for skin	**First step:** No action

				sensitisation is sufficient for workers	
211-765-7 214-012-0	Known or potential hazard for carcinogenicity (EC 211-765-7 only) for reproductive toxicity for ED	No hazard or unlikely hazard	Mostly IND uses in various applications. PROF use where potential for exposure is likely (coatings & paints) for EC 211-765-7	Currently no need for EU RRM Justification: the substances have already been included in the candidate list for authorisation.	
212-497-3			Intermediate registration	Currently no need for EU RRM Justification: the ongoing CLH proposal for reproductive toxicity will prevent regrettable substitution.	
217-100-7	Known or potential hazard for carcinogenicity for reproductive toxicity for ED for skin sensitisation		IND use where potential for exposure is limited (use of non-reactive processing aid at industrial site (no inclusion into or onto article), closed continuous or batch process with	Currently no need for EU RRM Justification: limited potential for exposure combined with low tonnage and weaker structural similarity.	

			occasional controlled exposure). Weaker structural similarity to other imidazoles with concern therefore lower potential for hazard.		
217-101-2	Known or potential hazard for skin sensitisation		PROF/CONS uses in washing and cleaning products, polymers, adhesive and sealants, coatings and paints. IND uses in laboratory, intermediates.	Currently no need for EU RRM Justification: the use by consumers is to be covered by the generic restriction on skin sensitisers in consumer products. Correct self-classification is sufficient for workers.	
604-344-8			IND uses in various applications.	Currently no need for EU RRM Justification: correct self-classification is sufficient for workers.	
247-832-2 460-100-9	No hazard or unlikely hazard	Known or potential hazard	Mostly IND/PROF uses in various applications.	Currently no need for EU RRM	**First step:** CCH For 247-832-2 to confirm low hazard

460-120-8 604-453-0 613-739-4 684-879-1 691-156-4 695-723-7		for aquatic toxicity for EC 247-832-2 and 604-453-0 No hazard or unlikely hazard For the other substances		Justification: no hazard or unlikely hazard.	

Annex 1: Harmonised classifications and self-classifications reported by registrants (reporting performed on September 2021)

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations
206-019-2	288-32-4	imidazole	Acute tox 4 (H302), Skin corr. 1C (H314), Repr. 1B (H360D)	Repr. 1B H360, specific effect:unborn child Acute Tox. 4 H302 Skin Corr. 1C H314 Eye Damage 1 H318 Repr. 1B H361, specific effect:H361D Repr. 1B H360, specific effect:D Skin Corr. 1B H314 Repr. 2 H361, specific effect:Unborn child
210-484-7	616-47-7	1-methylimidazole	Acute Tox. 4 * Acute Tox. 4 * Skin Corr. 1B	Acute Tox. 4 H302 Acute Tox. 3 H311 Skin Corr. 1B H314 Eye Damage 1 H318
211-581-7	670-96-2	2-phenylimidazole		Acute Tox. 4 H302

211-765-7	693-98-1	2-methylimidazole	Repr. 1B, H360Df	Carc. 2 H351 Repr. 1B H360, specific effect:H360Df: May damage the unborn child and suspected of damaging fertility. Acute Tox. 4 H302 Skin Corr. 1C H314 Eye Damage 1 H318

212-497-3	822-36-6	4-methylimidazole	Carc. 1B (H350), Repr. 1B (H360Fd). Adopted by RAC.	Acute Tox. 4 H302 Eye Irrit. 2 H319 Acute Tox. 4 H312 STOT Single Exp. 3 H335, affected organs: UPPER TRACT Skin Irrit. 2 Skin Corr. 1B H314
213-234-5	931-36-2	2-ethyl-4-methylimidazole	CLH intention (CMR)	Carc. 2 H351 Acute Tox. 4 H302 Skin Corr. 1B H314 Skin Irrit. 2 H315 Eye Damage 1 H318 Skin Sens. 1B H317
214-011-5	1072-62-4	2-ethylimidazole		Acute Tox. 4 H302 Skin Irrit. 2 H315 Eye Damage 1 H318

214-012-0	1072-63-5	1-vinylimidazole	Repr. 1B; H360D: C ≥ 0,03 %	Repr. 1B H360, specific effect:Developmental toxicity, specific concentration: >=.03 Acute Tox. 4 H302 Eye Damage 1 H318
217-100-7	1739-83-9	1,2,4,5-tetramethyl-1H-imidazole		Eye Damage 1 H318
217-101-2	1739-84-0	1,2-dimethylimidazole	Acute Tox. 4 * Skin Irrit. 2 Eye Dam. 1	Acute Tox. 4 H302 Skin Irrit. 2 H315 Eye Damage 1 H318 Skin Sens. 1B H317
224-314-4	4303-67-7	1-dodecyl-1H-imidazole		Acute Tox. 4 H302 Eye Irrit. 2 H319 Skin Sens. 1A H317 Aquatic Acute 1 H400, M-factor: 100.00 Aquatic Chronic 1 H410, M-factor: 10.00
230-403-9	7098-07-9	1-ethyl-1H-imidazole		Acute Tox. 4 H302 Skin Irrit. 2 H315 Eye Damage 1 H318 Aquatic Chronic 3 H412
245-589-7	23328-87-2	2-heptadecyl-1H-imidazole		-
247-832-2	26591-72-0	3-methyl-1-vinyl-1H-imidazolium methyl sulphate		Aquatic Acute 3 H402 Aquatic Chronic 3 H412

460-100-9	-	460-100-9		-
460-120-8	-	3-butyl-1-methyl-1H-imidazol-3-ium chloride		Eye Irrit. 2 H320 Skin Irrit. 2 H315 STOT Rep. Exp. 2 H373, affected organs: heart Aquatic Chronic 2 H411 Acute Tox. 3 H301 Aquatic Acute 2
483-310-2	-	483-310-2		-
604-344-8	143314-17-4	1-ethyl-3-methyl-1H-imidazol-3-ium acetate		Skin Irrit. 2 H315 Skin Sens. 1B H317
604-453-0	145022-45-3	1-ethyl-3-methyl-1H-imidazolium methanesulfonate (1:1)		Skin Sens. 1B H317 Aquatic Acute 3 H402 Aquatic Chronic 3 H412
613-739-4	65039-09-0	613-739-4		Acute Tox. 4 H302 Eye Irrit. 2B H319
684-693-0	68007-08-9	684-693-0		-

684-879-1	848641-69-0	1-ethyl-3-methyl-1H-imidazol-3-ium diethyl phosphate		-
691-156-4	1307233-42-6	1,3-Dimethyl-1H-imidazol-3-ium propionate		-
695-723-7	150999-33-0	3-ethyl-1-methyl-1H-imidazol-3-ium benzoate		Eye Damage 1 H318
811-718-6	86347-14-0	811-718-6		-

Annex 2: Overview of uses based on information available in registration dossiers (September 2021)

Main types of applications	206-019-2	210-484-7	211-581-7	211-765-7	212-497-3	213-234-5	214-011-5	214-012-0	217-100-7	217-101-2	224-314-4	230-403-9	245-589-7	247-832-2	460-100-9	460-120-8	483-310-2	604-344-8	604-453-0	613-739-4	684-879-1	691-156-4	695-723-7
PC 20: Products such as ph-regulators, flocculants, precipitants, neutralisation agents	f, i, p,	i,							i,														
PC 2: Adsorbents																					i, p,		
PC 27: Plant protection products		i,																					
PC 35: Washing and cleaning products										i, p,													
PC 29: Pharmaceuticals		i,																					
PC 16: Heat transfer fluids																						i, p,	
PC 13: Fuels																		i,					
PC 32: Polymer preparations and compounds	i,	i, p,		i,		i, p,		i,		i, p, c,				i,	i, a,			i,					i, p,
PC 1: Adhesives, sealants			i,							i, p, c,													f, i, p,
PC 9a: Coatings and paints, thinners, paint removes	p,	i,	f, i,	f, i, p,						i, p, c,			f, i,										f, i, p,

Main types of applications	206-019-2	210-484-7	211-581-7	211-765-7	212-497-3	213-234-5	214-011-5	214-012-0	217-100-7	217-101-2	224-314-4	230-403-9	245-589-7	247-832-2	460-100-9	460-120-8	483-310-2	604-344-8	604-453-0	613-739-4	684-879-1	691-156-4	695-723-7
PC 18: Ink and toners																							f, i, p,
PC 26: Paper and board treatment products																		i,					
PC 34: Textile dyes, and impregnating products																		i,					
PC 14: Metal surface treatment products	i,																						
PC 21: Laboratory chemicals	f, i, p,	f, i, p,		i,		i, p,		i,		i,							p,		i,				
PC 19: Intermediate	i,	i,		i,	i,	i,	i,	i,		i,		i,		i,						i,			
PC 40: Extraction agents																					i, p,		
PC41: Oil and gas exploration or production products		i,																					
Dental application											f, p,												

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

Annex 3: Overview of completed or ongoing regulatory risk management activities (September 2021)

EC / List numbers	RMOA	Authorisation		Restriction	CLH	Actions not under REACH/ CLP*
		Candidate List	Annex XIV	Annex XVII	Annex VI (CLP)	
206-019-2					YES	
211-765-7	YES	YES	YES**		YES	
212-497-3					YES	
213-234-5					YES	
214-012-0	YES	YES	YES**		YES	
460-100-9						NONS, tpa upgraded
460-120-8						NONS, claimed, no upgrade
483-310-2						NONS, tpa upgraded

(*) Please report here when the substance falls under PPP, BPR, NONS, RAR or POPs (Stockholm convention) legislation

(**) Not yet included in Annex XIV

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