

Assessment of regulatory needs

Authority: European Chemicals Agency (ECHA)

Date: 31.5.2022

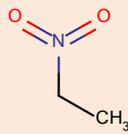
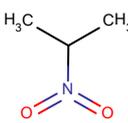
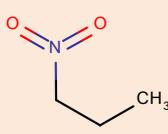
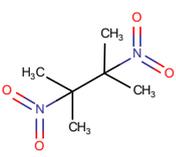
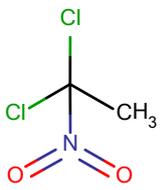
Group Name: Nitroalkanes

General structure: -

Revision history

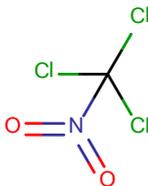
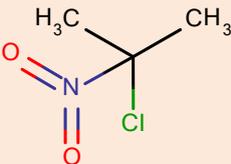
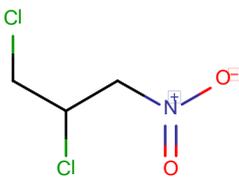
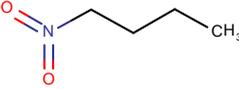
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1.0	12.9.2022	

Substances within this group:

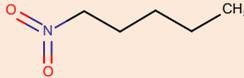
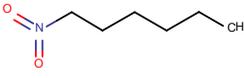
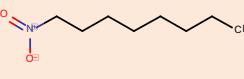
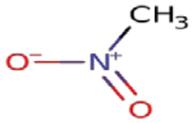
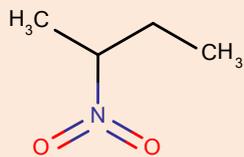
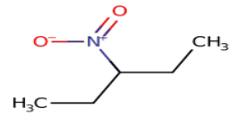
EC/List number	CAS number	Substance name	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) ¹
Registered nitroalkanes				
200-876-6	75-52-5	nitromethane		Full, 100-1000
201-188-9	79-24-3	nitroethane		Full, 100-1000
201-209-1	79-46-9	2-nitropropane		Full, 0-10
203-544-9	108-03-2	1-nitropropane		Full, 100-1000
223-569-9	3964-18-9	2,3-dimethyl-2,3-dinitrobutane		OSII or TII
Chlorinated nitroalkanes (non-registered, C&L notified)				
209-854-0	594-72-9	1,1-dichloro-1-nitroethane		Not registered (C&L notification)

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>

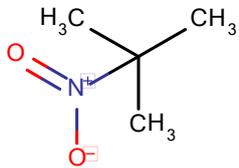
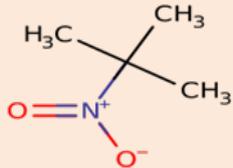
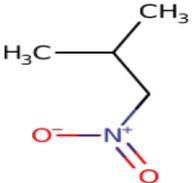
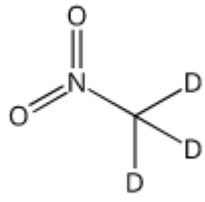
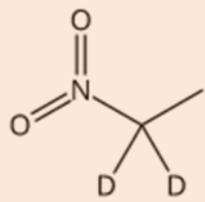
ASSESSMENT OF REGULATORY NEEDS

EC/List number	CAS number	Substance name	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) ¹
209-990-0	600-25-9	1-chloro-1-nitropropane		Not registered (C&L notification)
200-930-9	76-06-2	trichloronitromethane		Not registered (C&L notification)
209-853-5	594-71-8	2-chloro-2-nitropropane		Not registered (C&L notification)
661-417-7	88947-51-7	1,2-dichloro-3-nitropropane		Not registered (C&L notification)
Non-registered nitroalkanes (C&L notified)				
210-980-3	627-05-4	1-nitrobutane		Not registered (C&L notification)

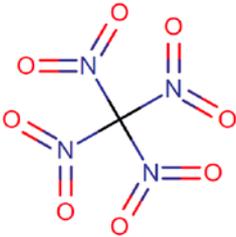
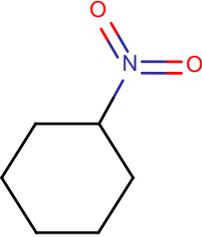
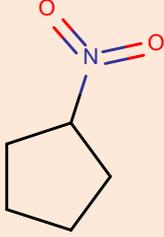
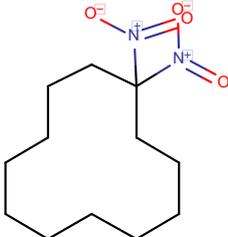
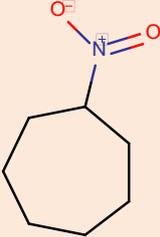
ASSESSMENT OF REGULATORY NEEDS

EC/List number	CAS number	Substance name	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) ¹
211-025-3	628-05-7	1-nitropentane		Not registered (C&L notification)
211-467-7	646-14-0	1-nitrohexane		Not registered (C&L notification)
659-737-7	629-37-8	1-nitrooctane		Not registered (C&L notification)
684-185-9	23717-53-5	Nitromethane-15N		Not registered (C&L notification)
209-989-5	600-24-8	2-nitrobutane		Not registered (C&L notification)
863-298-9	551-88-2	3-nitropentane		Not registered (C&L notification)

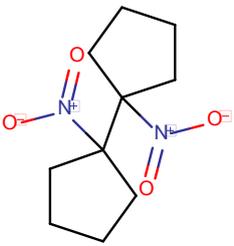
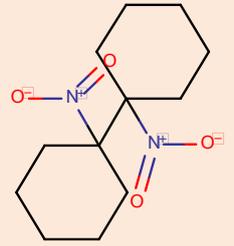
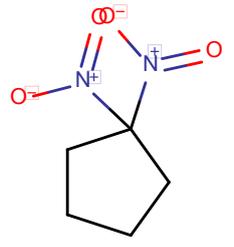
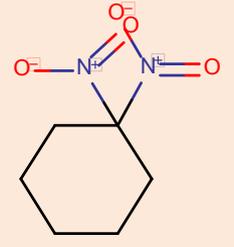
ASSESSMENT OF REGULATORY NEEDS

EC/List number	CAS number	Substance name	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) ¹
684-723-2	600-40-8	1,1-dinitroethane		Not registered (C&L notification)
209-851-4	594-70-7	nitro-tert-butane		Not registered (C&L notification)
685-812-9	74228-29-8	2-methyl-2-nitropropane-15N		Not registered (C&L notification)
830-037-5	625-74-1	2-methyl-1-nitropropane		Not registered (C&L notification)
235-892-2	13031-32-8	nitro(2H3)methane		Not registered (C&L notification)
686-064-6	13031-33-9	nitroethane-1,1-d2		Not registered (C&L notification)

ASSESSMENT OF REGULATORY NEEDS

EC/List number	CAS number	Substance name	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) ¹
208-094-7	509-14-8	tetranitromethane		Not registered (C&L notification)
214-354-0	1122-60-7	nitrocyclohexane		Not registered (C&L notification)
219-884-6	2562-38-1	nitrocyclopentane		Not registered (C&L notification)
659-766-5	84065-76-9	1,1-dinitrocyclododecane		Not registered (C&L notification)
659-779-6	2562-40-5	1-nitrocycloheptane		Not registered (C&L notification)

ASSESSMENT OF REGULATORY NEEDS

EC/List number	CAS number	Substance name	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) ¹
659-817-1	65261-04-3	1,1'-dinitrodicyclopentyl		Not registered (C&L notification)
659-836-5	1636-37-9	1,1'-dinitrodicyclohexyl		Not registered (C&L notification)
659-870-0	10515-17-0	1,1-dinitrocyclopentane		Not registered (C&L notification)
659-875-8	4028-15-3	1,1-dinitrocyclohexane		Not registered (C&L notification)

This table also contains group members that are only notified under the CLP Regulation.

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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 ECHA can carry out this case-by-case analysis. The starting point is available information in the REACH registrations and any other REACH and CLP information. However, more extensive set of information can be available, e.g. assessment done under REACH/CLP or other EU legislation, or can be generated in some cases (e.g. further hazard information under dossier evaluation). Uncertainties associated to the level of information used should be reflected in the documentation. It will be revisited when necessary. For example, after further information is generated and the hazard has been clarified or when new insights on uses are available. It can be revisited by the same or another authority.

The responsibility for the content of this assessment rests with the authority that developed it. It is possible that other authorities do not have the same view and may develop further assessment of regulatory needs. The assessment of regulatory needs does not yet initiate any regulatory process but any authority can consequently do so and should indicate this by appropriate means, such as the Registry of Intentions.

For more information on Assessment of regulatory needs please consult ECHA website².

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

Glossary

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

1 Overview of the group

ECHA has grouped together structurally similar substances based on the presence of nitro groups in alkanes. The group also covers chlorinated nitroalkanes.

The group consists of thirty-two substances in total. Five nitroalkanes are registered, of which four are linear or branched nitroalkanes with short carbon chain ($C < 4$) with full (article 10) registrations and one is a branched dinitroalkane with an intermediate registration.

Three of the five, nitroalkanes (*registered*) have besides industrial use in formulation, widespread consumer- and professional use in anti-freeze and de-icing products, polishes, wax blend, adhesives/sealants, paints coatings and /or fuel additives with potential for exposure/release. The other two substances have low potential for exposure and are used as laboratory chemical and/or intermediate. For these three nitroalkanes a CLH proposal is submitted by the Belgium Authority concerning the hazard classes: carcinogenicity, reproductive toxicity and STOT RE (effects on blood and on the central nervous system).

The group also contains five chlorinated nitroalkanes, which are not registered and only notified in the C&L Inventory.

Finally, the group contains twenty-seven nitroalkanes (*not registered*), which are only notified in the C&L Inventory. These substances concern nitroalkanes with longer alkyl chain ($C \geq 4$) linear or branched, cyclic nitroalkanes and two deuterated and one nitrogen-15 nitroalkanes. Some of the substances have multiple nitro groups.

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 - for potential reproductive toxicity, carcinogenicity, ED and STOT RE (effects on blood and on the central nervous system) for three nitroalkanes (**registered**) due to the potential for release/exposure for consumer and professional use (**EC 203-544-9, EC 201-188-9 and EC 200-876-6**).

Based on ECHA's assessment of currently available hazard information, it is considered that most substances in the group present the following (known or) potential human health hazards: carcinogenicity, reproductive toxicity (developmental toxicity for all substances in the group and effects on sexual function and fertility), endocrine disruption (thyroid effects) and systemic toxicity following repeated dose exposure (effects on blood and central nervous system). These hazards are identified based on effects observed with the registered group members and open literature information on the potential mechanism of action of nitroalkanes and their respective metabolites. Regarding endocrine disruption, nitroalkanes metabolise *in vivo* to nitrite which likely interferes with iodine uptake and can lead to thyroid dysfunction; therefore, there is potential hazard for endocrine disruption for all substances in the group. However, this conclusion is made with a certain degree of uncertainty, as it depends on homeostatic mechanisms for the iodine uptake and due to the data on the other registered nitroalkanes not investigating thyroid effects in order to allow for a better evaluation of this subgroup of nitroalkanes. At this stage no further action is proposed for endocrine disruption for human health. Based on structural similarity, these findings are extrapolated to the substances where there is limited or no information available for these endpoints.

Regarding environment, most substances have (known or) potential aquatic toxicity and potential hazard for persistency, mobility and toxicity. At this stage endocrine disruption potential (thyroid modality) is not extrapolated to environment as the potential of nitrate mediated thyroid effect might not be relevant for environment taking into account the abundance of nitrate in environmental compartments, the volatility of nitroalkanes therefore leading to low exposure potential; in addition, no information is available on metabolism of nitroalkanes in aquatic species to support extrapolation of nitrate mediated endocrine potential.

Regulatory risk management actions are already under consideration for nitromethane (EC 200-876-6), nitroethane (EC 201-188-9), 1-nitropropane (EC 203-544-9)), in the form of CLH-proposals submitted by the Belgian Competent Authority, for the following hazard classes: carcinogenicity (for nitromethane), reproductive toxicity and STOT RE (effects on blood and on the central nervous system) (for all three substances). These three registered nitroalkanes and three of five chlorinated nitroalkanes have harmonised classification for acute toxicity. In addition, most of the ones which are only notified in the C&L Inventory have notified classification for acute toxicity.

Based on the information reported in the REACH registration dossiers, the substances EC 203-544-9 and EC 201-188-9 have widespread and wide dispersive

consumer- and professional uses as anti-freeze and de-icing product, polishing and wax blends, lubricants, greases, fingers paints, plasters, fillers, coatings and paints and ink and toners. EC 200-876-6 has widespread and wide dispersive consumer- and professional use as air care products, cosmetics, personal care products and in fuels. All three substances are also used in industrial settings, of which EC 200-876-6 is mainly used in formulations. Therefore, these three substances are proposed for regulatory risk management.

The first step of the regulatory risk management action proposed, should the hazard exist, is the confirmation of hazard via harmonised classification (CLH) (already proposed by the Belgium Competent authority) as Repr. 1B/ Carc. 1. If the hazard is confirmed it i) will require company level risk management measures (RMM) under the OSH legislation for workers, to be in place, ii) is needed or highly recommended for further regulatory processes under REACH and iii) is a prerequisite to restrict the presence of the substances in consumer mixtures, by means of the restriction entry 28, 29, 30. CLH will also support regulatory action under other regulations. For instance, in this specific case for EC 200-876-6 harmonised classification as CMR cat. 1 will trigger regulatory action under the Cosmetic products regulation (EC) No 1223/2009 for uses in cosmetics, since CMR cat. 1 are restricted by this regulation.

The professional uses as anti-freeze and de-icing product, polishing and wax blends, lubricants, greases, fingers paints, plasters, fillers, coatings and paints, fuels and ink and toners are expected to be widespread (at many sites and by many users). Professional use is often wide-dispersive with sometimes frequent exposures with a long duration. Despite company level risk management measures under OSH, i.e. training, relatively low levels of operational controls and risk management measures can occur. . 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 for the three substances.

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 Sustainability¹ which aims to extend to professional users under REACH the level of protection granted to consumers.

Moreover, restricting substances in articles used by professionals or consumers (possibly for substances EC 203-544-9 and EC 201-188-9) should be considered in the context of the restriction of professional uses as potential exposure from articles needs further investigation first. The restriction may also address industrial uses, such as the industrial use of EC 203-544-9 and EC 201-188-9 as adhesives, sealants, inks and toners. Alternatively, further actions such as establishing an EU-wide OEL or authorisation may be considered. These substances have industrial uses across several use categories (similar to the professional uses) which would be controlled in the countries where there is a national OEL³, but not on the EU level, so the derivation of an EU wide OEL could be considered in the future.

³ GESTIS International Limit values for nitromethane, nitroethane, 1-nitropropane

The substances EC 200-876-6 and EC 201-188-9 are T (based on CLH proposals as Carc and/or Repro and STOT RE), potentially P/vP and expected to be very mobile in the environment. Compliance check is proposed to clarify the potential persistency of the substances, as well as to clarify hazards to the aquatic environment. Depending on the outcome of the ongoing regulatory processes (CLH), the need to investigate ED potential for Human Health will be revisited. However, for the time being no further EU regulatory risk management is proposed for these substances until confirmation of the hazard properties which should help identifying what the main protection goals are for these specific substances. The persistency, mobility and toxicity properties will be considered when developing the restriction proposal.

Concerning the potential hazard for aquatic toxicity, it is expected that registrants would adequately self-classify these two substances and then implement the relevant risk management measures which would be sufficient to ensure safe use in accordance with environmental legislation.

Based on currently available information – no exposure potential – there is no need for (further) EU regulatory risk management for all other substances in the group as they are either not registered or two are registered substances with intermediate uses (EC 223-569-9) and laboratory uses under strictly controlled conditions (EC 201-209-1). EC 201-209-1 has harmonised classification as Carc. 1B and is self-classified as Muta. 2.

The hazards identified for the registered nitroalkanes are extrapolated on the basis of structural similarity and potential similar metabolism to the remaining substances in the group. Genotoxicity is identified as additional hazard for the non-registered secondary nitroalkanes and chlorinated nitroalkanes.

However, based on structural similarity to the registered nitroalkanes, **EC/List 201-209-1, 210-980-3, 211-025-3, 211-467-7, 659-737-7, 863-298-9, 209-989-5, 209-851-4, 685-812-9, 830-037-5** might be regrettable substitutes in the future and therefore are possibly alerted for restriction

The assumed interchangeability between substances is not based on actual evidence that such replacement can or will happen in practise, nor that it may be economically feasible. It is rather based on reasonable worst-case preliminary assumptions built on structural similarity. If the registration status or use changes, data generation and potentially follow up actions will be re-considered when the assessment will be revisited.

The structurally similar substances with nitrogen 15N (List 684-185-9) and the two with deuterium (List 686-064-6 and EC 235-892-2), are not to be included for possible restriction in the future, as these substances are probably produced for very specific uses (e.g. NMR analysis) and are therefore not expected to be potential substitutes.

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
Registered nitroalkanes					
203-544-9 201-188-9 200-876-6	Known or potential hazard for reproductive toxicity, carcinogenicity, ED and STOT RE for all substances	Known or potential hazard for aquatic toxicity for EC 201-188-9, EC 200-876-6 Known or potential hazard for persistency, mobility and toxicity for all three substances (T, very mobile, and potentially P/vP)	Nitromethane (EC 200-876-6) indicated in formulation or re-packing and at industrial sites; air care products, fuels, cosmetics and personal care products, Indoor use/outdoor as processing aid Nitropropane/nitroethane (EC 203-544-9/EC 201-188-9): industrial sites, antifreeze, washing/cleaning products/lubricants/adhesives/paints/fillers	Need for EU RRM: Restriction for EC 203-544-9; EC 201-188-9; EC 200-876-6 <u>Justification:</u> The harmonised classification as Repr. 1B/ Carc. 1 would trigger the restriction entry 28, 29, 30 and by that ensure that the substances are not included in consumer mixtures above the limits specified in that entry. The reported professional uses are widespread (at many sites and many users) with relatively low levels of	First step: CCH to clarify P/vP and aqua tox for EC 200-876-6 and EC 201-188-9. Next steps (if hazard confirmed) CLH (proposal by BE) Restriction

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Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
				<p>operational controls and risk management measures but with often frequent exposures with a long duration.</p> <p>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.</p> <p>Potential exposure from articles needs further investigation, restriction for use in articles to be considered together with the restriction of professional uses.</p>	
<p>223-569-9 201-209-1</p>	<p>Known or potential hazard for reproductive toxicity for STOT RE for carcinogenicity</p>	<p>Known or potential hazard for aquatic toxicity and for persistency, mobility and toxicity</p>	<p>EC 223-569-9 Industrial use only as intermediate</p>	<p>Currently no need for EU RRM</p> <p>Justification: According to the reported uses, low</p>	<p>No action</p>

ASSESSMENT OF REGULATORY NEEDS

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
	for ED for all substances. for mutagenicity only for EC 201-209-1		EC 201-209-1 (2-nitropropane) Used for laboratory chemicals, closed systems	potential for exposure to both human health and environment is expected.	
Non-registered substances (C&L notified)					
200-930-9	Known or potential hazard for carcinogenicity for reproductive toxicity for ED for STOT RE for all substances in the group. for mutagenicity only for EC 200-930-9, EC 209-990-0, EC 209-854-0, EC 661-417-7, EC 209-853-5, EC 863-298-9, EC 209-989-5 and EC 208-094-7.	Known or potential hazard for aquatic toxicity and for persistency, mobility and toxicity	No registered use	Currently no need for EU RRM <u>Justification:</u> Therefore, no EU regulatory risk management action is currently proposed for any of the aforementioned substances due to low exposure potential- no registration. The following substances have structural similarity with registered nitroalkanes, so are flagged for possible restriction due to regrettable substitution: EC/List: 210-980-3, 211-025-3, 211-467-7, 659-737-7, 863-298-9, 209-989-5, 209-851-4, 685-812-9, 830-037-5	No action
209-990-0					
209-854-0					
661-417-7					
209-853-5					
210-980-3					
211-025-3					
211-467-7					
659-737-7					
684-185-9					
209-989-5					
863-298-9					
684-723-2					

ASSESSMENT OF REGULATORY NEEDS

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
209-851-4					
685-812-9					
830-037-5					
235-892-2					
686-064-6					
208-094-7					
214-354-0					
219-884-6					
659-766-5					
659-779-6					
659-817-1					
659-836-5					
659-870-0					
659-875-8					

Annex 1: Overview of classifications

Data extracted on 26/01/2022.

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations
200-876-6	75-52-5	nitromethane	<i>Flam. Liquid 3 H226 Acute Tox. 4 H302</i>	<i>Carc. 2 H351 Repr. 2 H361, Flam. Liquid 3 H226 Acute Tox. 4 H302 Acute Tox. 4 H332</i>
200-930-9	76-06-2	trichloronitromethane	<i>Acute Tox. 4 H302 Skin Irrit. 2 H315 Eye Irrit. 2 H319 Acute Tox. 2 H330 STOT SE 3 H335</i>	-
201-188-9	79-24-3	nitroethane	<i>Flam. Liq. 3 H226 Acute Tox. 4 H302 Acute Tox. 4 H332</i>	<i>Repr. 2 H361 Flam. Liquid 3 H226 Acute Tox. 4 H302 Acute Tox. 4 H332 Aquatic Chronic 3 H412</i>
201-209-1	79-46-9	2-nitropropane	<i>Flam. Liq. 3 H226 Acute Tox. 4 H302 Acute Tox. 4 H332 Carc. 1B H350</i>	<i>Carc. 1B H350 Muta. 2 H341 Flam. Liquid 3 H226 Acute Tox. 4 H302 Acute Tox. 3 H331 Acute Tox. 4 H332 Aquatic Chronic 3 H412</i>
203-544-9	108-03-2	1-nitropropane	<i>Flam. Liq. 3 H226 Acute Tox. 4 H302 Acute Tox. 4 H312 Acute Tox. 4 H332</i>	<i>Flam. Liquid 3 H226 Acute Tox. 4 H302 Acute Tox. 4 H312 Acute Tox. 4 H332 Acute Tox. 3 H331</i>
209-854-0	594-72-9	1,1-dichloro-1-nitroethane	<i>Acute Tox. 3 H301 Acute Tox. 3 H311 Acute Tox. 3 H331</i>	-
209-990-0	600-25-9	1-chloro-1-nitropropane	<i>Acute Tox. 4 H302 Acute Tox. 4</i>	-
223-569-9	3964-18-9	2,3-dimethyl-2,3-dinitrobutane	-	<i>Acute Tox. 2 H300</i>

(*) the number in brackets indicates the number of notifications received. Each notification can represent a group of notifiers, therefore the number may differ from the C&L inventory which displays number of notifiers.

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

Data extracted on 11/01/2022.

Main types of applications structured by product or article types	EC/ List 200-876-6	EC/ List 201-188-9	EC/ List 201-209-1	EC/ List 203-544-9	EC/ List 223-569-9
Products such as ph-regulators, flocculants, precipitants, neutralisation agents	I, P				
Anti-freeze and de-icing products		C		C	
Washing and cleaning products				I, P	
Air care products	F, P, C,				
Cosmetics, personal care products	F, P, C				
Polishes and wax blends		C		C	
Lubricants, greases, release products		C		C	
Fuels	F, P, C				
Adhesives, sealants		F, I, C		C	
Finger paint				C	
Fillers, putties, plasters, modelling clay		C		C	
Coatings and paints, thinners, paint removes		F, I, P, C		I, P, C	
Ink and toners		F, I			
Laboratory chemicals	F, I, P		I, P		
Intermediate	I	I		I	I

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

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

Data extracted on 27/01/2022.

EC/List number	RMOA	Authorisation		Restriction*		CLH	Actions not under REACH/ CLP
		Candidate list	Annex XIV	Annex XVII	Annex VI (CLP)		
200-876-6	-	-	-	-	-	YES	-
200-930-9	-	-	-	-	-	YES	PIC, Reg. (EC) No 1107/2009
201-188-9	-	-	-	-	-	YES	-
201-209-1	-	-	-	-	-	YES	PIC
203-544-9	-	-	-	-	-	YES	-
209-854-0	-	-	-	-	-	YES	-
209-990-0	-	-	-	-	-	YES	-

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

There are no relevant completed or ongoing regulatory risk management activities for EC 223-569-9.