

Assessment of regulatory needs

Authority: European Chemicals Agency (ECHA)

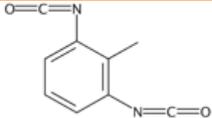
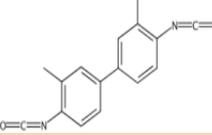
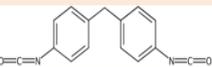
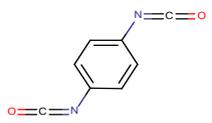
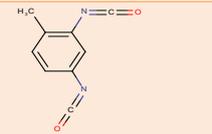
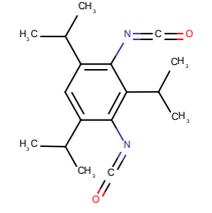
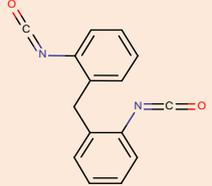
Group Name: Isocyanates

General structure: $R(N=C=O)_n$

Revision history

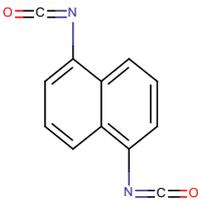
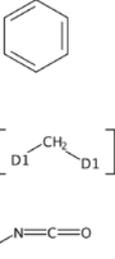
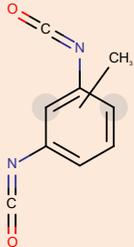
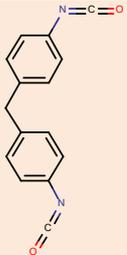
<i>Version</i>	<i>Date</i>	<i>Description</i>
1.0	28 June 2023	

Substances within this group

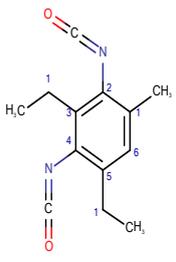
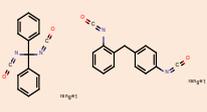
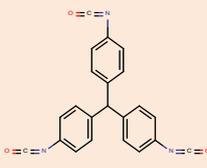
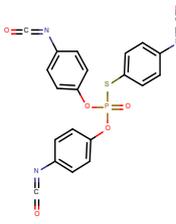
EC/List number	CAS number	Substance name; acronyms	Chemical structures	Registration type (full/OSII/TII/NONS), highest tonnage band among all the registrations (t/y) ¹
SUBGROUP 1				
Aromatic polyisocyanates and their oligomers				
Subgroup 1.1: Aromatic di-isocyanates				
202-039-0	91-08-7	2-methyl-m-phenylene diisocyanate; 2,6-TDI		Full 1-10 tpa
202-112-7	91-97-4	3,3'-dimethylbiphenyl-4,4'-diyl diisocyanate; TODI		Full 100-1000 tpa
202-966-0	101-68-8	4,4'-methylenediphenyl diisocyanate; 4,4'-MDI		Full > 1000 tpa
203-207-6	104-49-4	p-phenylene diisocyanate; PPDI		Full 100-1000 tpa
209-544-5	584-84-9	4-methyl-m-phenylene diisocyanate; 2,4-TDI		Full > 1000 tpa
218-485-4	2162-73-4	2,4,6-triisopropyl-m-phenylene diisocyanate; TRIDI		Full 100-1000 tpa
219-799-4	2536-05-2	2,2'-methylenediphenyl diisocyanate; 2,2'-MDI		Full > 1000 tpa

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>

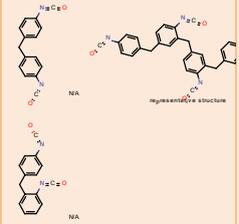
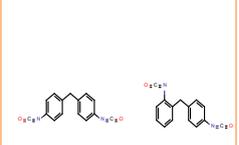
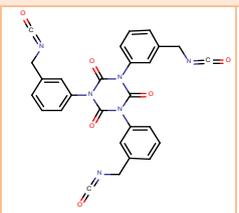
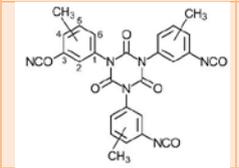
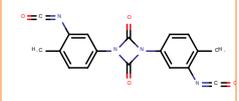
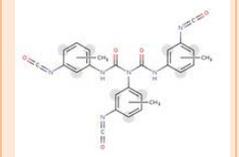
ASSESSMENT OF REGULATORY NEEDS

EC/List number	CAS number	Substance name; acronyms	Chemical structures	Registration type (full/OSII/TII/NONS), highest tonnage band among all the registrations (t/y) ¹
221-641-4	3173-72-6	1,5-naphthylene diisocyanate; NDI		Full >1000 tpa
227-534-9	5873-54-1	o-(p-isocyanatobenzyl)phenyl isocyanate; 2,4-MDI		Full >1000 tpa
247-714-0	26447-40-5	Methylenediphenyl diisocyanate; MDI		Cease manufacture
247-722-4	26471-62-5	m-tolylidene diisocyanate; m-TDI		Full >1000 tpa
298-531-8	93805-48-2	Ureylenebis(p-phenylenemethylene-p-phenylene) diisocyanate	Not (publicly) available	Not registered
618-498-9	9016-87-9	Isocyanic acid, polymethylenepolyphenylene ester		C&L Notification

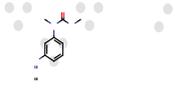
ASSESSMENT OF REGULATORY NEEDS

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813-050-0	2162-70-1	1,3-diethyl-2,4-diisocyanato-5-methylbenzene; DETDI		Full 1-10 tpa
905-806-4	-	Reaction mass of 4,4'-methylenediphenyl diisocyanate and o-(p-isocyanatobenzyl)phenyl isocyanate		Full 100-1000 tpa
Subgroup 1.2: Aromatic tri-isocyanates				
219-351-8	2422-91-5	methylidynetri-p-phenylene triisocyanate		Full 1-10 tpa
223-981-9	4151-51-3	tris(p-isocyanatophenyl) thiophosphate		Full 100-1000 tpa
Subgroup 1.3: MDI oligomers				
500-040-3	25686-28-6	4,4'-Methylenediphenyl diisocyanate, oligomers		Full >1000 tpa

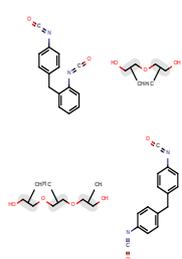
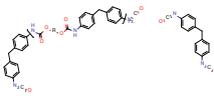
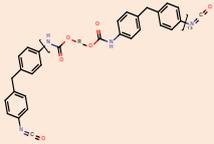
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500-079-6	32055-14-4	Formaldehyde, oligomeric reaction products with aniline and phosgene		Full >1000 tpa
500-297-1	109331-54-6	4,4'-Methylenediphenyl diisocyanate, oligomeric reaction products with 2,4'-diisocyanatodiphenylmethane		Full 100-1000 tpa
Subgroup 1.4: TDI oligomers				
247-840-6	26603-40-7	(2,4,6-trioxotriazine-1,3,5(2H,4H,6H)-triy)l tris(methyl-m-phenylene) isocyanate		C&L notification
938-708-5		m-TDI oligomers, isocyanurate		Full 100-1000 tpa
247-953-0	26747-90-0	2,4-dioxo-1,3-diazetidene-1,3-bis(methyl-m-phenylene) diisocyanate; 2,4-TDI dimer		Full 10-100 tpa
500-299-2	110839-12-8	Toluene diisocyanate, oligomeric reaction products with water		Not registered

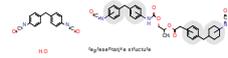
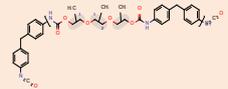
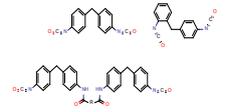
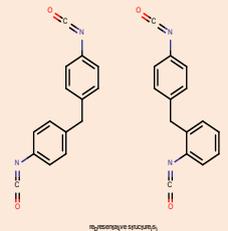
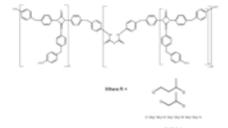
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701-017-2	-	Toluene-2,4(6)-diisocyanates and oligomeric reaction products of toluene-2,4(6)-diisocyanates and toluene-2,4(6)-diamines, containing biuret derivatives		Full >1000 tpa
SUBGROUP 2 MDI polyurethanes				
500-119-2	52747-01-0	Propanol, [(1-methyl-1,2-ethanediyl)bis(oxy)]bis-, polymer with 1,1'-methylenebis[4-isocyanatobenzene]		C&L notification
500-142-8	59952-43-1	Propanol, oxybis-, polymer with 1,1'-methylenebis[4-isocyanatobenzene]		C&L notification
500-262-0	-	Propanol, [(1-methyl-1,2-ethanediyl)bis(oxy)]bis-, polymer with 1-isocyanato-2-[(4-isocyanatophenyl)methyl]benzene and 1,1'-methylenebis[4-isocyanatobenzene]		C&L notification
500-270-4	88288-99-7	4,4'-Methylenediphenyl diisocyanate, oligomeric reaction products with 2,4'-diisocyanatodiphenylmethane and oxydipropanol		C&L notification
500-312-1	123714-19-2	4,4'-Methylenediphenyl diisocyanate, oligomeric reaction products with butane-1,3-diol, 2,4'-diisocyanatodiphenylmethane, [(methylethylene)bis(oxy)]dipropanol and propane-1,2-diol		C&L notification

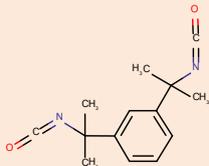
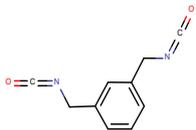
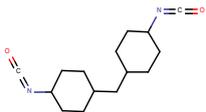
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500-313-7	-	4,4'-Methylenediphenyl diisocyanate, oligomeric reaction products with butane-1,3-diol, 2,4'-diisocyanatodiphenylmethane, 1,1'-methylenebis(4-isocyanatobenzene) homopolymer, [(methylethylene)bis(oxy)] dipropanol and propane-1,2-diol		Full >1000 tpa
500-439-2	-	4,4'-Methylenediphenyl diisocyanate, oligomeric reaction products with 2,4'-diisocyanatodiphenylmethane, [(methylethylene)bis(oxy)] dipropanol and oxydipropanol		C&L notification
701-029-8	-	1-isocyanato-2(or 4)-(4-isocyanatobenzyl)benzene and their reaction products with [(methylethylene)bis(oxy)] dipropanol and butane-1,3-diol and propylene glycol		Full >1000 tpa
701-040-8	-	1,1'-Methylenebis(4-isocyanatobenzene) and oligomeric reaction products of 1,1'-methylenebis(4-isocyanatobenzene) and oxydipropanol		Full >1000 tpa
701-041-3	-	1,1'-Methylenebis(4-isocyanatobenzene) and oligomeric reaction products of 1,1'-methylenebis(4-isocyanatobenzene) and oxydipropanol and oligomerization reaction products of oxydipropanol		Full >1000 tpa

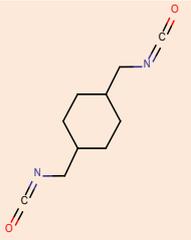
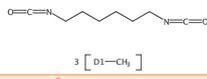
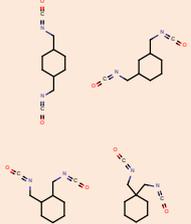
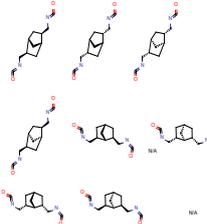
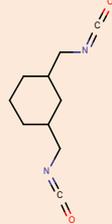
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701-072-2	-	4,4'-methylenediphenyl diisocyanate and its oligomeric reaction products with oxydipropanol and [(methylethylene)bis(oxy)] dipropanol		Full >1000 tpa
701-124-4	-	1,1'-Methylenebis(4-isocyanatobenzene) and its oligomeric reaction products with [(methylethylene)bis(oxy)] dipropanol		Full >1000 tpa
701-173-1	-	1,1'-methylenebis(4-isocyanatobenzene) and its oligomeric reaction products with butane-1,3-diol, 2,2'-oxydiethanol and propane-1,2-diol		Full >1000 tpa
701-276-1	-	4,4'-methylenediphenyldiisocyanate and 2,4'-diisocyanatodiphenylmethane and their oligomerisation reaction products with 2,2'-oxydiethanol, propane-1,2-diol and butane-1,3-diol		Full 100-1000 tpa
701-393-8	-	1,1'-Methylenebis(4-isocyanatobenzene) and 1,1'-methylenebis(4-isocyanatobenzene) homopolymer and their reaction products with [(methylethylene)bis(oxy)] dipropanol and butane-1,3-diol and propane-1,2-diol		Full >1000 tpa
941-496-7	-	Reaction products of 1,1'-methylenebis(4-isocyanatobenzene) with 2,2'-[(methylethylene)bis(oxy)] di(methylethanol), butane-		Full 100-1000 tpa

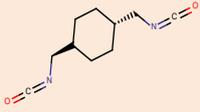
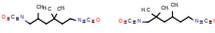
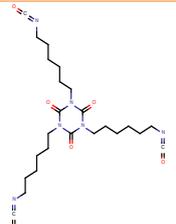
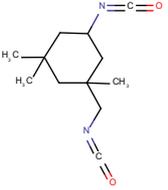
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		1,3-diol and propane-1,2-diol		
SUBGROUP 3				
Aliphatic polyisocyanates and their oligomers				
Subgroup 3.1: Aliphatic di-isocyanates (including also aralkyl and cycloalkyl-alkyl di-isocyanates)				
212-485-8	822-06-0	hexamethylene diisocyanate; HDI		Full > 1000 tpa
220-474-4	2778-42-9	1,3-bis(1-isocyanato-1-methylethyl)benzene; m-TMXDI		Full > 1000 tpa
222-852-4	3634-83-1	1,3-bis(isocyanatomethyl)benzene; XDI		Full 100-1000 tpa
223-861-6	4098-71-9	3-isocyanatomethyl-3,5,5-trimethylcyclohexyl isocyanate; IPDI		Full 100-1000 tpa
225-863-2	5124-30-1	4,4'-methylenedicyclohexyl diisocyanate; H12-MDI		Full > 1000 tpa

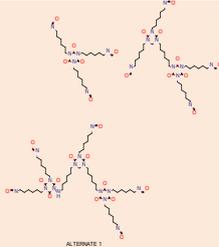
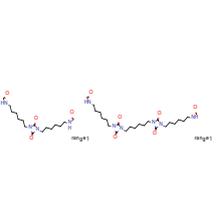
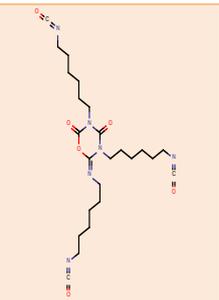
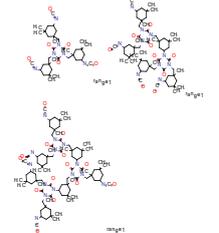
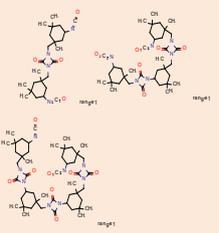
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233-757-2	10347-54-3	1,4-bis(isocyanatomethyl)cyclohexane		C&L notification
249-151-6	28679-16-5	trimethylhexa-1,6-diyl diisocyanate		C&L notification
255-693-4	42170-25-2	bis(isocyanatomethyl)cyclohexane		C&L notification
411-280-2	74091-64-8	2,5-bis-isocyanatomethyl-bicyclo[2.2.1]heptane; NBDI		NONS 100-1000 tpa
609-567-4	38661-72-2	1,3-bis(isocyanatomethyl)cyclohexane		Full 10-100 tpa
807-040-5	4538-42-5	1,5-Diisocyanatopentane; PDI		Full >1000 tpa

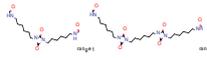
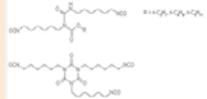
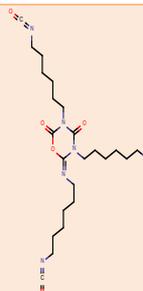
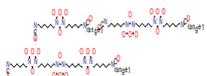
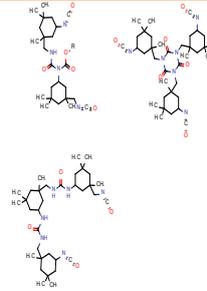
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825-609-6	98458-83-4	trans-1,4-bis(isocyanatomethyl)cyclohexane		Full 10-100 tpa
915-277-1 691-431-9		2,2(4),4-Trimethylhexane-1,6-diisocyaanate		Full 100-1000 tpa
Subgroup 3.2: Aliphatic di-isocyanates oligomers				
223-242-0	3779-63-3	(2,4,6-trioxotriazine-1,3,5(2H,4H,6H)-triy)tris(hexamethylene)isocyanate		Full 100-1000 tpa
500-060-2	28182-81-2	Hexamethylene diisocyanate, oligomers	 Structure represents monomer	C&L notification
500-125-5	53880-05-0	3-Isocyanatomethyl-3,5,5-trimethylcyclohexyl isocyanate, oligomers	 Structure represents monomer	C&L notification

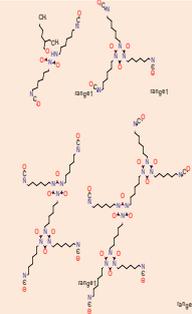
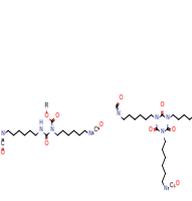
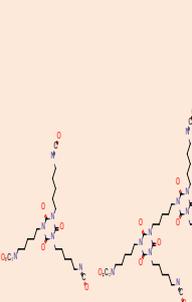
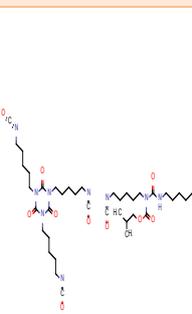
ASSESSMENT OF REGULATORY NEEDS

EC/List number	CAS number	Substance name; acronyms	Chemical structures	Registration type (full/OSII/TII/NONS), highest tonnage band among all the registrations (t/y) ¹
931-274-8	-	Oligomerisation products of 1,6-diisocyanatohexane, isocyanurate type		Full >1000 tpa
931-288-4	-	HDI oligomers, uretdione		Full >1000 tpa
931-297-3	-	HDI oligomers, iminoxadiazindione		Full >1000 tpa
931-312-3	-	3-Isocyanatomethyl-3,5,5-trimethylcyclohexyl isocyanate homopolymer, isocyanurate type		Full >1000 tpa
938-351-5	-	3-Isocyanatomethyl-3,5,5-trimethylcyclohexyl isocyanate homopolymer, uretdione type		OSII or TII

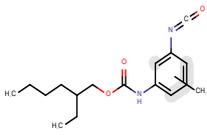
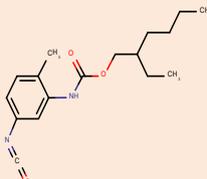
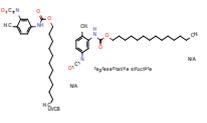
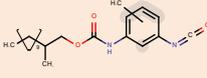
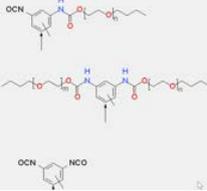
ASSESSMENT OF REGULATORY NEEDS

EC/List number	CAS number	Substance name; acronyms	Chemical structures	Registration type (full/OSII/TII/NONS), highest tonnage band among all the registrations (t/y) ¹
939-340-8	-	Oligomerisation products of 1,6-diisocyanatohexane, biuret type		Full >1000 tpa
939-657-1	-	HDI oligomers, allophanate		Full 100-100 tpa
Subgroup 3.3: Iminoxadiazindione and Oxadiazintrione (aliphatic diisocyanate oligomers with CO2 as another reactant)				
931-297-3	-	HDI oligomers, iminoxadiazindione		Full >1000 tpa
942-994-7	-	HDI oligomers, oxadiazintrione		Full 1-10 tpa
Subgroup 3.4: Allophanates (reaction products of urethanised isocyanates with isocyanates)				
933-047-9	-	Oligomerisation products of 3-isocyanatomethyl-3,5,5-trimethylcyclohexyl isocyanate and butan-1-ol and pentan-1-ol and 2-ethylhexan-1-ol, allophanate type		Full 100-1000 tpa

ASSESSMENT OF REGULATORY NEEDS

EC/List number	CAS number	Substance name; acronyms	Chemical structures	Registration type (full/OSII/TII/NONS), highest tonnage band among all the registrations (t/y) ¹
939-549-4	-	Reaction mass of 1-Hexanol, 2-ethyl-, reaction products with 1,6-diisocyanatohexane and Hexane, 1,6-diisocyanato-, homopolymer		Full 100-1000 tpa
939-657-1	-	HDI oligomers, allophanate		Full 100-1000 tpa
943-686-5	-	Reaction mass of 1,3,5-tris(5-isocyanatopentyl)-1,3,5-triazinane-2,4,6-trione and 1,1'-pentane-1,5-diylbis[3,5-bis(5-isocyanatopentyl)-1,3,5-triazinane-2,4,6-trione]		Full 1-10 tpa
943-687-0	-	Reaction mass of 1,3,5-tris(5-isocyanatopentyl)-1,3,5-triazinane-2,4,6-trione and isobutyl (5-isocyanatopentyl)[(5-isocyanatopentyl)carbamoyl]carbamate		Full 1-10 tpa

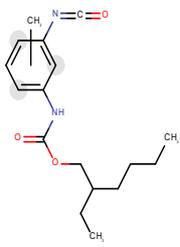
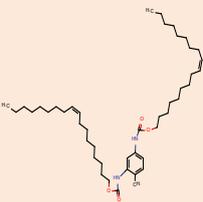
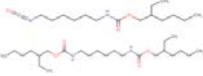
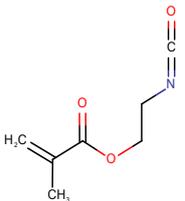
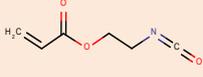
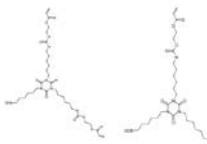
ASSESSMENT OF REGULATORY NEEDS

EC/List number	CAS number	Substance name; acronyms	Chemical structures	Registration type (full/OSII/TII/NONS), highest tonnage band among all the registrations (t/y) ¹
SUBGROUP 4				
Di-isocyanate reaction products with alcohols				
259-265-8	54634-94-5	2-ethylhexyl (3-isocyanatomethylphenyl)-carbamate		OSII or TII
273-133-7	68938-61-4	2-ethylhexyl (5-isocyanato-2-methylphenyl)-carbamate		OSII or TII
440-930-8	330198-48-6	Carbamic acid, [5-isocyanato-2(or 4)-methylphenyl]-, C10-14-alkyl esters		OSII or TII
611-014-7	53564-52-6	Carbamic acid, (3-isocyanatomethylphenyl)-, isotridecyl ester		OSII or TII
700-343-2	1163775-81-2	Reaction products of 2-[2-(2-butoxyethoxy)ethoxy]ethanol and 2-{2-[2-(2-butoxyethoxy)ethoxy]ethoxy}ethanol with 2,4-diisocyanato-1-methylbenzene and 1,3-diisocyanato-2-methylbenzene		OSII or TII

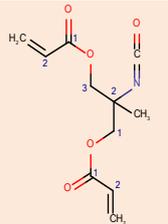
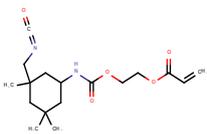
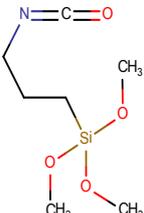
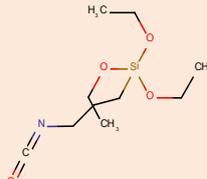
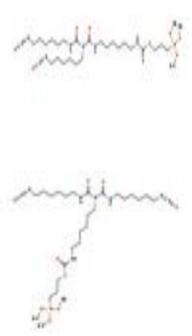
ASSESSMENT OF REGULATORY NEEDS

EC/List number	CAS number	Substance name; acronyms	Chemical structures	Registration type (full/OSII/TII/NONS), highest tonnage band among all the registrations (t/y) ¹
700-674-2		Reaction products of [formaldehyde, oligomeric reaction products with aniline and phosgene] and 2-ethylhexan-1-ol		Full 100-1000 tpa
917-282-4		Toluene diisocyanate reaction product with Triethylene glycol monobutyl and ether Tetraoxahexadecan-1-ol		OSII or TII
937-955-6		Reaction mass of Carbamic acid, N-(3-isocyanato-2-methylphenyl)-, 2-ethylhexyl ester and Carbamic acid, N-(3-isocyanato-4-methylphenyl)-, 2-ethylhexyl ester and N,N'-(4-Methyl-1,3-phenylene)bis(carbamic acid) C,C'-bis(2-ethylhexyl) ester		OSII or TII
946-063-6		Reaction mass of 3,5,5-trimethylhexyl (3-isocyanato-4-methylphenyl)carbamate and 3,5,5-trimethylhexyl (5-isocyanato-2-methylphenyl)carbamate		OSII or TII
946-190-7		Reaction mass of 3,5,5-trimethylhexyl (3-isocyanato-2-methylphenyl)carbamate and 3,5,5-trimethylhexyl (3-isocyanato-4-methylphenyl)carbamate and 3,5,5-trimethylhexyl (5-isocyanato-2-methylphenyl)carbamate		OSII or TII

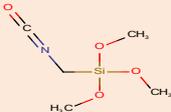
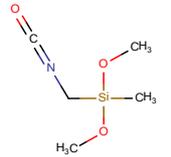
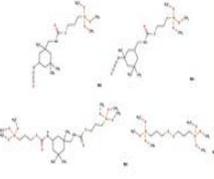
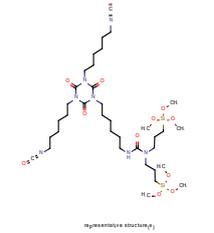
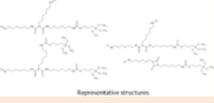
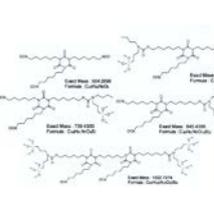
ASSESSMENT OF REGULATORY NEEDS

EC/List number	CAS number	Substance name; acronyms	Chemical structures	Registration type (full/OSII/TII/NONS), highest tonnage band among all the registrations (t/y) ¹
946-383-6		Reaction mass of 2-ethylhexyl (3-isocyanato-2-methylphenyl)carbamate and 2-ethylhexyl (3-isocyanato-4-methylphenyl)carbamate and 2-ethylhexyl (5-isocyanato-2-methylphenyl)carbamate		Full 10-100 tpa
946-534-6		Reaction products of (Z)-octadec-9-enol and m-tolylidene diisocyanate		OSII or TII
947-942-7		Reaction mass of 2-ethylhexyl (6-isocyanatohexyl)-carbamate and bis(2-ethylhexyl) 1,6-hexan-1,6-diylbiscarbamate		Full 10-100 tpa
SUBGROUP 5 Acrylate-functionalised mono-isocyanates				
250-284-7	30674-80-7	2-isocyanatoethyl methacrylate		Full 100-1000 tpa
482-140-6	13641-96-8	2-Propenoic acid, 2-isocyanatomethyl ester		Full 1-10 tpa
677-640-8	264888-31-5	Acrylated urethane resin based on HDI ~		Full 1-10 tpa

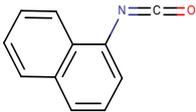
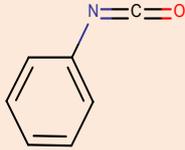
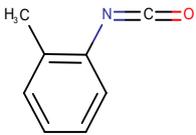
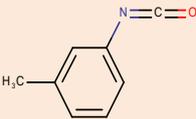
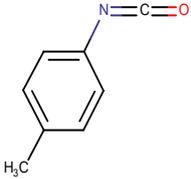
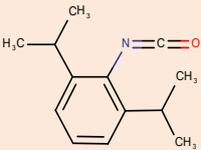
ASSESSMENT OF REGULATORY NEEDS

EC/List number	CAS number	Substance name; acronyms	Chemical structures	Registration type (full/OSII/TII/NONS), highest tonnage band among all the registrations (t/y) ¹
680-798-0	886577-76-0	2-isocyanato-2-methylpropane-1,3-diyl bisacrylate		Full 1-10 tpa
815-462-6	124451-79-2	2-([3-(isocyanatomethyl)-3,5,5-trimethylcyclohexyl]carbamoyl)oxyethyl acrylate		Full 1-10 tpa
SUBGROUP 6 Siloxane-functionalised isocyanates				
239-415-9	15396-00-6	3-(trimethoxysilyl)propyl isocyanate		Full 100-1000 tpa
246-467-6	24801-88-5	triethoxy(3-isocyanatopropyl)silane		Full 100-1000 tpa
402-290-8	85702-90-5	A mixture of: S-(3-trimethoxysilyl)propyl 19-isocyanato-11-(6-isocyanatohexyl)-10,12-dioxo-2,9,11,13-tetraazanadecanethioate ; S-(3-(trimethoxysilyl)propyl 17-isocyanato-9-(isocyanatohexyl-aminocarbonyl)-10-oxo-2,9,11-triazaheptadecanethioate		Full 1-10 tpa Revoked

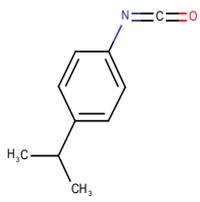
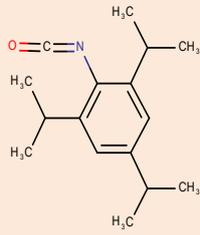
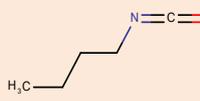
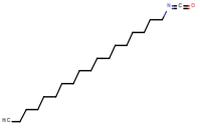
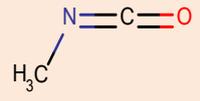
ASSESSMENT OF REGULATORY NEEDS

EC/List number	CAS number	Substance name; acronyms	Chemical structures	Registration type (full/OSII/TII/NONS), highest tonnage band among all the registrations (t/y) ¹
425-390-3	-	ADHESION PROMOTER PK-2247	Not (publicly) available	NONS Ceased manufacture
453-220-8	-	Not (publicly) available	Not (publicly) available	NONS 1-10 tpa
620-692-3	78450-75-6	(Isocyanatomethyl)(trimethoxy) silane		C&L notification
453-230-2 (678-644-2)	- 406679-89-8	Silane, (isocyanatomethyl)dimethoxymethyl- (Isocyanatomethyl)(dimethoxy)methylsilane		NONS 1-10 tpa
700-534-0	117172-56-2	Reaction products of 3-(trimethoxysilyl)propane-1-thiol and 5-isocyanato-1-(isocyanatomethyl)-1,3,3-trimethylcyclohexane (1:1)		Full 1-10 tpa
918-105-3		Hexamethylene diisocyanate, oligomers, reaction products with Bis-(Trimethoxysilylpropyl)amine		Full 10-100 tpa
924-669-1		Reaction product of Hexamethylene diisocyanate, oligomers with Mercaptopropyltrimethoxysilane		Full 10-100 tpa
926-191-9		Hexamethylene diisocyanate, oligomers, reaction products with N-(3-(3-trimethoxysilyl)propyl)butylamine and Bis-(Trimethoxysilylpropyl)amine		Full 100-1000 tpa
SUBGROUP 7 Aromatic mono-isocyanates				

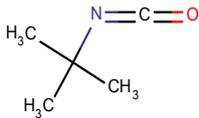
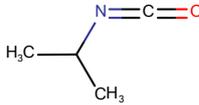
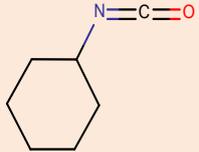
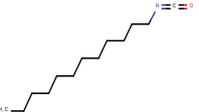
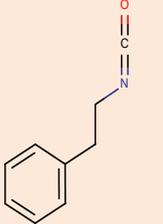
ASSESSMENT OF REGULATORY NEEDS

EC/List number	CAS number	Substance name; acronyms	Chemical structures	Registration type (full/OSII/TII/NONS), highest tonnage band among all the registrations (t/y) ¹
201-703-7	86-84-0	1-naphthyl isocyanate		OSII or TII
203-137-6	103-71-9	phenyl isocyanate		OSII or TII
210-389-0	614-68-6	o-tolyl isocyanate		C&L notification
210-676-0	621-29-4	m-tolyl isocyanate		OSII or TII
210-743-4	622-58-2	p-tolyl isocyanate		OSII or TII
248-885-4	28178-42-9	2,6-diisopropylphenyl isocyanate		OSII or TII

ASSESSMENT OF REGULATORY NEEDS

EC/List number	CAS number	Substance name; acronyms	Chemical structures	Registration type (full/OSII/TII/NONS), highest tonnage band among all the registrations (t/y) ¹
250-439-9	31027-31-3	p-isopropylphenyl isocyanate		OSII or TII
801-619-6	401515-81-9	2-isocyanato-1,3,5-triisopropylbenzene		OSII or TII
SUBGROUP 8 Aliphatic mono-isocyanates				
203-862-8	111-36-4	butyl isocyanate		OSII or TII
204-019-7	112-96-9	octadecyl isocyanate		OSII or TII
210-866-3	624-83-9	methyl isocyanate		C&L notification

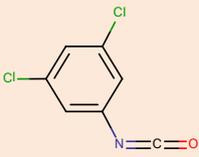
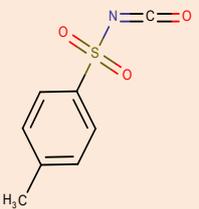
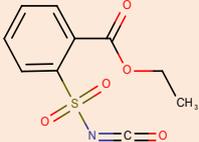
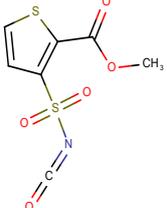
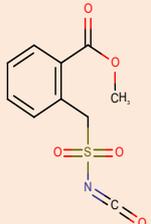
ASSESSMENT OF REGULATORY NEEDS

EC/List number	CAS number	Substance name; acronyms	Chemical structures	Registration type (full/OSII/TII/NONS), highest tonnage band among all the registrations (t/y) ¹
216-544-9	1609-86-5	tert-butyl isocyanate		OSII or TII
217-736-5	1943-84-6	Hexadecyl isocyanate		OSII or TII
217-276-5	1795-48-8	isopropyl isocyanate		OSII or TII
221-639-3	3173-53-3	cyclohexyl isocyanate		OSII or TII
224-111-0	4202-38-4	dodecyl isocyanate		OSII or TII
413-080-0	1943-82-4	2-phenylethylisocyanate		NONS 1-10 tpa
608-715-5	32175-00-1	trans-1-isocyanato-4-methylcyclohexane		OSII or TII

ASSESSMENT OF REGULATORY NEEDS

EC/List number	CAS number	Substance name; acronyms	Chemical structures	Registration type (full/OSII/TII/NONS), highest tonnage band among all the registrations (t/y) ¹
907-349-6		Reaction mass of hexadecyl isocyanate and octadecyl isocyanate		OSII or TII
SUBGROUP 9				
Chlorinated aromatic mono-isocyanates				
203-026-2	102-36-3	3,4-dichlorophenyl isocyanate		Full 1-10 tpa
203-176-9	104-12-1	4-chlorophenyl isocyanate		Full >1000 tpa
220-040-4	2612-57-9	2,4-dichlorophenyl isocyanate		OSII or TII
220-822-5	2909-38-8	3-chlorophenyl isocyanate		OSII or TII
222-023-7	3320-83-0	2-chlorophenyl isocyanate		OSII or TII
249-050-7	28479-22-3	3-chloro-p-tolyl isocyanate		OSII or TII

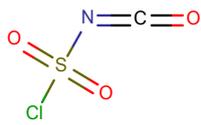
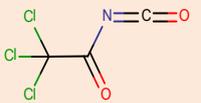
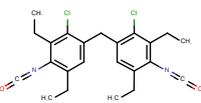
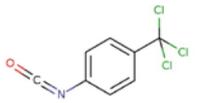
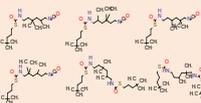
ASSESSMENT OF REGULATORY NEEDS

EC/List number	CAS number	Substance name; acronyms	Chemical structures	Registration type (full/OSII/TII/NONS), highest tonnage band among all the registrations (t/y) ¹
252-276-9	34893-92-0	1,3-dichloro-5-isocyanatobenzene		OSII or TII
SUBGROUP 10 Sulfo mono-isocyanates				
223-810-8	4083-64-1	p-toluenesulphonyl isocyanate		Full 100-1000 tpa
410-200-3	-	CPSI	Not (publically) available	NONS
410-220-2	77375-79-2	ethyl 2-(isocyanatosulfonyl)benzoate		NONS 1-10 tpa
410-550-7	79277-18-2	methyl 3-isocyanatosulfonyl-2-thiophenecarboxylate		NONS 10-100 tpa
410-900-9	83056-32-0	2-(isocyanatosulfonylmethyl) benzoic acid methyl ester		NONS 100-1000 tpa

ASSESSMENT OF REGULATORY NEEDS

EC/List number	CAS number	Substance name; acronyms	Chemical structures	Registration type (full/OSII/TII/NONS), highest tonnage band among all the registrations (t/y) ¹
618-297-6	897671-34-0	Methyl 5-methyl-4-[(oxomethylene)sulfamoyl]thiophene-3-carboxylate		OSII or TII
SUBGROUP 11 Miscellaneous mono- and di-isocyanates				
Subgroup 11.1: Functionalised aromatic mono-isocyanates				
402-440-2	2094-99-7	1-(1-isocyanato-1-methylethyl)-3-(1-methylethenyl)benzene		NONS 10-100 tpa
626-058-2	28479-19-8	1-isocyanato-3-(methylsulfanyl)benzene		OSII or TII
695-953-8	204918-22-9	1-(allyloxy)-2-methyl-1-oxopropan-2-yl 2-chloro-5-isocyanatobenzoate		OSII or TII
824-760-5	1472650-02-4	1-isocyanato-2-(methoxymethyl)-3-methylbenzene		OSII or TII
Subgroup 11.2: Various other functionalised mono-and di-isocyanates				

ASSESSMENT OF REGULATORY NEEDS

EC/List number	CAS number	Substance name; acronyms	Chemical structures	Registration type (full/OSII/TII/NONS), highest tonnage band among all the registrations (t/y) ¹
214-715-2	1189-71-5	chlorosulphonyl isocyanate		OSII or TII
221-165-7	3019-71-4	trichloroacetyl isocyanate		OSII or TII
420-530-1		4,4-methylene bis(3-chloro-2,6-diethylphenylisocyanate)		NONS 1-10 tpa
461-690-0	709-66-0	Benzene, 1-isocyanato-4-(trichloromethyl)-		NONS Ceased manufacture
926-601-6		3-Isocyanatomethyl-3,5,5-trimethylcyclohexyl isocyanate, oligomers reaction product with 3-(cyclohexylamino)propane-1-sulfonic acid and N,N-dimethylcyclohexanamine		Full 1-10 tpa
947-972-0		Reaction products of 2,2,4-trimethylhexa-1,6-diyl diisocyanate and 2,4,4-trimethylhexa-1,6-diyl diisocyanate with 3-trimethoxysilylpropane-1-thiol		Full 1-10 tpa ²

² The manufacture of the substance has ceased during the development of this ARN report.

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DISCLAIMER

The author does not accept any liability with regard to the use that may be made of the information contained in this document. Usage of the information remains under the sole responsibility of the user. Statements made or information contained in the document are without prejudice to any further regulatory work that ECHA, the Member States or other regulatory agencies may initiate at a later stage. Assessment of regulatory needs and their conclusions are compiled on the basis of available information and may change in light of newly available information or further assessment.

Foreword

The purpose of the assessment of regulatory needs of a group of substances is to help authorities conclude on the most appropriate way to address the identified concerns for a group of substances or a single substance, i.e. the combination of the regulatory risk management instruments to be used and any intermediate steps, such as data generation, needed to initiate and introduce these regulatory measures.

An assessment of regulatory needs can conclude that regulatory risk management at EU level is required for a (group of) substance(s) (e.g. harmonised classification and labelling, Candidate List inclusion, restriction, other EU legislation) or that no regulatory action is required at EU level. While the assessment is done for a group of substances, the (no) need for regulatory action can be identified for the whole group, a subgroup or for single substance(s).

The assessment of regulatory needs is an important step under ECHA's Integrated Regulatory Strategy. However, it is not part of the formal processes defined in the legislation but aims to support them.

The assessment of regulatory needs can be applied to any group of substances or single substance, i.e., any type of hazards or uses and regardless of the previous regulatory history or lack of such. It can be done based on a different level of information. A Member State or ECHA can carry out this case-by-case analysis. The starting point is available information in the REACH registrations and any other REACH and CLP information. However, a more extensive set of information can be available, e.g. assessment done under REACH/CLP or other EU legislation, or can be generated in some cases (e.g. further hazard information under dossier evaluation). Uncertainties associated to the level of information used should be reflected in the documentation. It will be revisited when necessary. For example, after further information is generated and the hazard has been clarified or when new insights on uses are available. It can be revisited by the same or another authority.

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

For more information on Assessment of regulatory needs please consult ECHA website³.

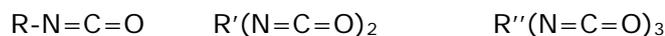
³ <https://echa.europa.eu/understanding-assessment-regulatory-needs>

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 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 the isocyanate, diisocyanate or triisocyanate moieties shown in the figure below:



where R, R' and R'' represent either (an) aliphatic chain(s), (a) cyclic or (an) aromatic group(s) or combinations of them as well as their oligomers.

The group is divided into 11 subgroups based on the identity of the isocyanates and introduced chemical functionalities (e.g. urethdione, biuret, allophanate, isocyanurate, oxadiazinetrione) in the oligomers and reaction products. They cover:

1. Aromatic polyisocyanates and their oligomers,
2. MDI polyurethanes⁴,
3. Aliphatic polyisocyanates and their oligomers,
4. Di-isocyanate reaction products with alcohols,
5. Acrylate-functionalised mono-isocyanates,
6. Siloxane-functionalised mono- and di-isocyanates,
7. Aromatic mono-isocyanates
8. Aliphatic mono-isocyanates,
9. Chlorinated aromatic mono-isocyanates,
10. Sulfo mono-isocyanates,
11. Miscellaneous mono- and di-isocyanates

Perfluorinated mono-isocyanates (Subgroup 12) were excluded from the group as they meet the OECD definition of being PFAS (Per- and Poly Fluoro Alkyl Substances)⁵ and may thereby also be in scope of the universal PFAS restriction that is currently under development.

The group contains 136 substances of which 63 are full registrations.

Isocyanates are in general very reactive compounds. The carbon atom of the isocyanate group is electrophilic and can react with nucleophiles, even water. This is an important property which determines the fate and behaviour of these substances in the environment as well as for the interpretation of results of ecotoxicity tests.

Under environmentally relevant conditions, substances which contain at least two -NCO groups per molecule (poly-isocyanates) will tend to spontaneously polymerise into polyureas and react with organic matter to form a number of polyurea derivatives of various size.

For mono-isocyanates (only one -NCO group per molecule), the transformations are more limited as they cannot polymerise into polyureas. The formation of respective mono-ureas, mono-amines, and reactions with the organic matter are expected.

⁴ Methylenediphenyl diisocyanate (MDI) is used in the production of polyurethanes for many applications. Polyurethanes contain urethane groups -NH-(C=O)-O-.

⁵ Reconciling Terminology of the Universe of Per- and Polyfluoroalkyl Substances: Recommendations and Practical Guidance; Series on Risk Management No.61. ENV/CBC/MONO(2021)25
[https://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=ENV/CBC/MONO\(2021\)25&docLangu age=En](https://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=ENV/CBC/MONO(2021)25&docLangu age=En)

Mono-isocyanates (subgroups 5-11) are mainly used in the manufacturing of pharmaceuticals and pesticides. Most of the mono-isocyanates are registered as intermediates and stated to be used under strictly controlled conditions. However, there are two mono-isocyanates which have full registrations with other than intermediate uses such as in coatings and adhesives and present high potential for dermal and inhalation exposure for industrial and professional workers (EC 223-810-8 (Subgroup 10) and EC 947-972-0⁶ (Subgroup 11)). Consumer uses for mono-isocyanates are only reported for EC 223-810-8 (Subgroup 10).

Diisocyanates and their oligomers (subgroups 1-4, 6 and 11) are mainly used in the polyurethane industry to produce polyurethane products including foams, insulation panels, paints, lacquers, coatings and glues. The polyurethane products are used in various industrial sectors, e.g. automotive, casting, building and construction, electricity, paints, plastics, printing, furniture, textiles, etc.

Aromatic diisocyanates and their oligomers are important ingredients to produce rigid and flexible foams, elastomers, adhesives, coatings and sealants, and others. MDI (Methylenediphenyl diisocyanate) and TDI (Tolylidene diisocyanate) are the most common diisocyanates used in Europe. The main use for MDI is in the manufacture of polyurethane rigid foam for thermal insulation in the construction industry and TDI is primarily used in flexible foam production for mattresses, upholstery and transport seats. Both MDI and TDI are used in C.A.S.E. (Coatings, Adhesives, Sealants, Elastomers) applications.

Aliphatic diisocyanates are used to produce highly resistant polyurethane materials which display higher UV stability and durability as well as chemical and mechanical resistance compared to polyurethanes based on aromatic diisocyanates. Their primary use is in coatings with a high degree of resistance to chemicals, abrasion and weather, but they are also used to make adhesives, sealants and for the production of polyurethane elastomers. Additionally, aliphatic diisocyanates are used in special applications such as leather refinishing formulations, textile and fibre treatments, inks and thermoplastic polyurethane sheets. The most relevant aliphatic diisocyanates are HDI (1,6-hexamethylene diisocyanate), IPDI (isophorone diisocyanate) and HMDI (4,4'-dicyclohexylmethane diisocyanate). Due to the hazard profile and the high volatility of HDI, most products do not use the monomers as such but polyisocyanates, typically made from HDI or IPDI. Such polyisocyanates usually still contain residual diisocyanate monomers with significant potential for exposure.

The production volumes are high for diisocyanates and there is high inhalation and dermal exposure potential for industrial and professional workers and in many cases also for consumers. Especially MDI and its oligomers and polyurethanes are used in consumer products.

Regarding triisocyanates, two aromatic triisocyanates (EC 219-351-8 and 223-981-9) have been identified (Subgroup 1.2). The substances are used in polymer production and to produce adhesives, sealants, fillers and putties with high inhalation and dermal exposure potential for industrial and professional workers. No consumer uses have been identified for these two substances.

Article service life is reported only for polymer products manufactured from diisocyanate and tri-isocyanate substances. Exposure to isocyanates from the final cured articles e.g. flexible and rigid PUs and elastomers during their normal application is unlikely. No occupational or consumer exposure is expected from

⁶ The manufacture of the substance has ceased during the development of this ARN report.

cured articles produced from isocyanates. However, the curing process is an integral part for instance in case of coatings, paints, adhesives and sealants and therefore exposure to isocyanates is likely during and for some time following their use until fully cured.

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 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 – review of the current restrictions entry 56 and 74 and OEL proposal to broaden their scope to all isocyanates in the group, i.e. subgroups 1-11, based on their skin and respiratory sensitising properties.

The potential inclusion of perfluorinated mono-isocyanates (Subgroup 12 outside the scope of this report, see section 1) within the scope of restrictions entry 56 and 74 and the OEL proposal might also be considered should the risks resulting from consumer and worker exposure to the substances not be addressed by the universal PFAS restriction that is currently under development.

Harmonised classification for respiratory sensitisation is in place for several substances (mainly MDI- or TDI-types) or CLH preparations are ongoing. Registrants for some other isocyanates have also self-classified as respiratory sensitiser although no substance-specific data may be available (see Annex 1 for the details). Epidemiological data and human case reports showing respiratory sensitisation among workers for in particular TDI, MDI and HDI have been compiled

by ECHA (2020)⁷, DECOS (2018)⁸, ATSDR (2018)⁹ and others. There are currently no validated in vivo or in vitro test guidelines for respiratory sensitisation. For isocyanates, there are, however, several scientific papers presenting animal study results indicating effects that can be linked to respiratory sensitisation. Such data have been published on diisocyanates (mainly TDI, MDI and HDI), but also on other isocyanates, and were mainly conducted by Pauluhn et al. (references summarised, e.g., in ECHA, 2020)¹⁰.

There is a suspected concern for sensitisation for all isocyanates, based on the following four aspects:

- 1) The available evidence from human studies (epidemiological observational studies and challenge studies) shows that diisocyanate exposure leads to respiratory effects including specific sensitisation, asthma, as well as accelerated lung function decline.
- 2) Sensitisation is assumed to be linked to the NCO group binding to proteins, which is considered to be the molecular initiating event of sensitisation induced by low molecular weight substances. This is partly supported by data indicating immunological cross-reactivity between diisocyanates in humans. All isocyanates contain the NCO group and may cause sensitisation. Differences in molecular structures and weight could influence the potency, but currently there is not enough data to assess differences in potency.
- 3) The animal testing protocol developed by Pauluhn et al. is based on initial systemic sensitisation achieved by dermal application of the substance isocyanate, followed by recurrent inhalation exposure. Clear induction in markers indicating respiratory sensitisation has been observed in animal tests conducted with MDI, TDI and HDI. The most potent respiratory sensitisers were substances which had positive results in skin sensitisation tests. All substances in the group which are skin sensitisers may have the potential to induce respiratory sensitisation.
- 4) Positive skin sensitisation study results have been obtained in tests conducted with the majority of the substances, with the exception of three substances, EC 223-981-9, EC 223-810-8 and EC 926-601-6 which present reliable negative skin sensitisation results. Out of these three substances, EC 223-810-8 has a harmonised classification for respiratory sensitisation, and EC 223-981-9 is notified as respiratory sensitiser. EC 926-601-6 is therefore the only substance in the group which presents negative skin sensitisation results and is not classified/notified as a respiratory sensitiser. Nevertheless, lack of skin sensitising potential does not exclude a possibility to cause respiratory sensitisation, and from a structural point of view there is no obvious reason why the NCO-group in EC 926-601-6 could not induce sensitisation.

At present, harmonised classification and labelling of isocyanates is not proposed taking into account that there are no validated test guidelines for respiratory

⁷ <https://echa.europa.eu/documents/10162/b74681f6-b553-56de-68bb-7b329cb03b2b>

⁸ <https://www.healthcouncil.nl/documents/advisory-reports/2018/11/28/di--and-triisocyanates>

⁹ <https://www.atsdr.cdc.gov/ToxProfiles/tp206.pdf>

¹⁰ <https://echa.europa.eu/documents/10162/b74681f6-b553-56de-68bb-7b329cb03b2b>

sensitisation and most of the substances have already a harmonised classification or are self-classified by registrants (see Annex 1). The broadening of the scope of the present restrictions and OEL proposal for isocyanates could address the risks to workers, including the self-employed workers and the consumers in a more effective way in terms of time and resources. Nevertheless, should the harmonised classification and labelling of substances trigger additional risk management measures in future to protect workers and consumers, this regulatory measure could be further considered for the isocyanate substances as a group.

Industrial and professional uses

The use of aromatic and aliphatic diisocyanates (Subgroups 1.1 and 3.1) by industrial and professional workers¹¹ are subject to restriction entry 74 under REACH (Annex 3 reproduces the legal text for convenience). The restriction defines the information and training requirements to minimise the risks resulting from the use of diisocyanates as substances on their own and in mixtures with conc. \geq 0.1% by weight and from the handling of warmed/uncured articles containing diisocyanates. Articles once fully cured contain no free diisocyanates and do not result in workers or consumer exposure according to the background document to the restriction.

It is to be noted that both aromatic and aliphatic diisocyanates (Subgroups 1.1 and 3.1) are within the scope of restriction entry 74 but their oligomers (Subgroups 1.3, 1.4, 2, 3.2, 3.3, 3.4 and 4) are not included unless they contain free diisocyanates with a conc. \geq 0.1% by weight. Triisocyanates (Subgroup 1.2) are also not addressed by restriction entry 74. High worker exposure potential is expected for all diisocyanate and triisocyanate substances, including their oligomers with active registrations (Subgroups 1,2,3,4,6 and 11) based on their use profile (adhesives, coatings, etc), high tonnage volumes and industrial and professional uses. Generally, a potential for substitution between the substances in these groups is expected based on structural similarity and similar use information.

Mono-isocyanates are also outside the scope of restriction for diisocyanates in entry 74. According to the background document of the restriction¹²: "Data on specific risks of uses of monoisocyanates are not available to the Dossier Submitter. If new data would give rise to a concern in this area, this should be dealt with in a separate process." RAC concluded in their opinion on the restriction proposal for diisocyanates¹³ that "regarding other types of isocyanates, namely polyisocyanates (diisocyanate-free) and monoisocyanates, which are not in the scope of this restriction proposal, RAC considers that although there is no direct evidence for respiratory sensitisation in human population, indirect evidence from humans and animals stated above indicates that the risk of respiratory sensitisation in humans cannot be excluded."

Monoisocyanates are used mainly as intermediates at industrial sites. Aromatic and aliphatic monoisocyanates (Subgroups 7 and 8) are registered as TII/OSII, other monoisocyanates are used as intermediates but most of them with full registrations in the range of 1 to 10 tonnes/y. Notable exceptions are EC 250-284-7 (Subgroup 5) used as intermediate and registered in the range of 100 to 1000 tonnes/y and

¹¹ Industrial and professional users mean any worker or self-employed worker handling diisocyanates on their own, as a constituent in other substances or in mixtures for industrial and professional use(s) or supervising these tasks

¹² [2452ec92-628c-42c2-b4d4-9ccdffe3773a \(europa.eu\)](https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:2452ec92-628c-42c2-b4d4-9ccdffe3773a)

¹³ [d6794aa4-8e3a-6780-d079-77237244f5f9 \(europa.eu\)](https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:d6794aa4-8e3a-6780-d079-77237244f5f9)

EC 246-467-1 (Subgroup 6) with industrial uses similar to those of diisocyanates (adhesives, coatings, etc) also registered in the 100 to 1000 tonnes/y. Professional uses of e.g. adhesives and sealants are identified for EC 223-810-8 (Subgroup 10) and EC 947-972-0¹⁴ (Subgroup 11). Low exposure potential can be expected from intermediate uses, especially if under strictly controlled conditions. However, the widespread uses identified for some of the substances show that mono-isocyanates may trigger similar level of concern as diisocyanates if used in similar applications. Substitution between different mono-isocyanates from the same group and even between groups for specific applications cannot be ruled out.

Therefore, taking into account the concern for respiratory and skin sensitisation for all substances in the group and the potential substitution among different substances with different regulatory obligations, **it is proposed that the scope of restriction entry 74 is broadened to all isocyanates (Subgroups 1, 2, 3, 4, 5, 6, 7, 8, 9, 10 and 11) to address the risks to industrial and professional workers resulting from the use of the substances as such or as constituent of mixtures.**

It is to be noted that EC 926-601-6, with no identified skin or respiratory sensitising properties so far, is already within the scope of restriction entry 74. Additionally, it could be considered whether the use of isocyanates manufactured and used under strictly controlled conditions, e.g. aliphatic and aromatic mono-isocyanates (Subgroups 6 and 7), could be exempted from the conditions of the restriction.

In addition to restriction entry 74, there is a RAC opinion on an OEL proposal for all diisocyanates in the OEL process (see Annex 3 for further details). The OEL report proposes a common approach for all diisocyanates taking into account that the substances share a common mechanism of inducing hypersensitivity reactions and there is not enough data to assess differences in potency for different diisocyanates. The scope of the OEL covers Subgroups 1 (except 1.2), 2, 3, 4, 6 (diisocyanates) and 11 (EC 926-601-6)). Subgroup 1.2 (aromatic triisocyanates) as well as all monoisocyanates (Subgroups 6, 7, 8, 9, 10, 11) would fall outside the scope of the OEL. Taking into consideration that all isocyanates are considered to have a similar mechanism to elicit sensitivity (see section 2.1) and in order to ensure occupational exposures are controlled and prevent regrettable substitutions to avoid compliance with regulatory obligations, it is proposed that the **scope of the OEL proposal would be broadened to cover all isocyanates (Subgroups 1, 2, 3, 4, 5, 6, 7, 8, 9, 10 and 11).**

Consumer use

Four diisocyanates, EC number 247-714-0, 202-966-0, 227-534-9, 219-799-4 (MDI and three isomers), are included in restriction entry 56 which defines the conditions to control the risks (gloves included in packaging, warnings against allergic reactions and instructions regarding ventilation and RPE) resulting from the use of the substances as constituent in mixtures with concentration equal or greater than 0.1% by weight of MDI by consumers (Annex 3 reproduces the legal text for convenience).

According to the registration dossiers, consumer uses of diisocyanate substances are reported for a number of aromatic diisocyanates and their oligomers included in Subgroup 1 (EC 247-722-4, EC 500-040-3, EC 500-297-1, EC 905-806-4) and Subgroup 6 (EC 924-669-1) with skin and respiratory sensitising properties. In addition, consumer uses are identified for the mono-isocyanate EC 223-810-8

¹⁴ The manufacture of the substance has ceased during the development of this ARN report.

(Group 10). All consumer uses are related to the use of adhesives, sealants, coatings and paints containing isocyanates as hardener or binders and resulting in a high potential for inhalation and dermal exposure.

Taking into account the similarity of applications for all isocyanates related to consumer uses, it is expected that isocyanate substances not identified above may be used for similar applications based on the presence of the NCO group. A restriction limited to the substances identified with consumer uses at present would not prevent the use of other isocyanates for consumer uses with similar sensitising properties as the ones already identified. Therefore, based on the potential interchangeability of different isocyanate substances for different uses, **it is proposed that the scope of restriction entry 56 is broadened to all isocyanates (Subgroups 1, 2, 3, 4, 5, 6, 7, 8, 9, 10 and 11) to address the risks to consumer from the use of the substances as constituent of mixtures. At the same time, it should be considered whether the conditions of the restriction entry 56 should be stricter to ensure it is effective in reducing risks for consumers and the general population (currently a derogation to the restriction is in place when the packaging contains protective gloves).**

It could be considered whether Subgroups 6 and 7, which present only uses registered under strictly controlled conditions could be exempted from the restriction.

Non-aromatic substances in the group (Subgroups 3, 4, 5, 6, 8, 10, 11) are unlikely to cause carcinogenicity. No data indicating such effects are available for these substances. However, aromatic monomeric isocyanates (Subgroups 1 and 2, e.g., MDI, TDI) are potential carcinogens. One postulated mode of action is through (bio)transformation to aromatic amines, which are known carcinogens. Many of these substances have harmonised classification or are self-classified as carcinogenic category 2, based on studies with selected category/group members. Data generation (evaluation of testing proposals and CCH; repeated dose toxicity and genotoxicity studies) on other aromatic monomeric isocyanates will be conducted to confirm absence of genotoxic potential.

It is expected that restrictions entry 74 and 56 proposed to address the respiratory and skin sensitisation properties of the isocyanates should be protective enough to address the risks to workers and consumers from the carcinogenicity properties (Carc 2) of the substances.

The substances in Subgroups 7 (Aromatic mono-isocyanates) and 9 (Chlorinated aromatic mono-isocyanates) could theoretically follow the same hazard pattern as other aromatic monomeric isocyanates ((bio)transformation to aromatic amines) but there is only limited toxicological data on these substances. Since Subgroups 7 and 9 consist only of Annex VII substances and transported isolated intermediates, further data generation is currently not possible under compliance check. Substance evaluation is not considered a priority for these low-tonnage substances, considering also the proposed extensions of restrictions entry 74 and 56 are suggested to apply.

Based on the currently available data, all substances in the group are unlikely to have the following human health hazards: mutagenicity, toxicity to reproduction/development, and endocrine disruption. Data generation via evaluation of already submitted testing proposals and via CCH of a representative number of substances will provide more information on mutagenicity and toxicity

to reproduction/development.

The need for further EU regulatory risk management of this group is not anticipated for the protection of the environment.

The substances in the group, or rather some of their transformation products, are potentially toxic to the aquatic environment. They are regarded as unlikely PBT/vPvB. Isocyanates are rapidly transformed in the environment, so they are not regarded as persistent. The transformation products are potentially P/vP but unlikely to be bioaccumulative. Neither the parent substances nor their transformation products are expected to be mobile in the environment. The parent substances or their transformation products are not expected to meet the T criterion, but classification for aquatic toxicity may be warranted.

The carbon atom of the isocyanate group easily reacts with nucleophiles. It can thus react with a lot of different molecules present in the surrounding environment (water, organic matter). Many different transformation products could be formed, which nature and amounts could be very variable and dependent on the other chemicals present and on the surrounding conditions.

In particular, the isocyanate group can react with water to produce carbon dioxide and an amino group. The amino group being more nucleophilic than water, a free isocyanate group will preferably react with amino groups than with water. Therefore, provided that the local concentration of the substance is high enough for the reaction to occur, an isocyanate group from one molecule can react rapidly with the previously formed -amino group from another molecule to form an urea.

If the number of isocyanate groups within the molecule is ≥ 2 (polyisocyanates), then the previous reaction can repeat within the molecules, and polyureas can be formed. Polyureas are solid insoluble substances and are generally regarded as inert.

As mentioned above, the latter reactions can occur only if the local concentration of the substance is high enough: even if the reaction between isocyanates and amines is much faster than between isocyanates and water, one isocyanate group from one molecule would still need to meet the amino group from another molecule rather than a new water molecule. This can be the case under heterogeneous conditions, e.g. when droplets of undissolved substance are formed. Insoluble and solid polyureas will tend to form at the water/substance interface, and the unreacted substance will stay encapsulated within the droplet.

On the contrary, if the concentrations are low and the formation of a homogeneous aqueous solution is favoured (e.g. vigorous mixing/stirring/sonification, co-solvent (not nucleophilic), low organic carbon content), then the remaining isocyanate groups cannot react with the amino groups and will react instead with water. Under those conditions, amines will tend to form instead of the ureas.

In the environment, conditions are heterogeneous. Therefore, under environmental conditions, poly-isocyanates are expected to form mainly polyureas (and derivatives, depending on the other molecules present in the medium).

Polyureas are considered to be very persistent, but at the same time not bioavailable. They are expected to be neither bioaccumulative nor toxic. They are not expected to be mobile either.

Mono-isocyanates could lead to the formation of amines and mono-ureas under environmental, heterogeneous, conditions.

Under homogeneous conditions, which are typically the conditions recommended when performing aquatic toxicity tests, the formation of amines will prevail for both poly- and mono-isocyanates.

A number of these amines are not readily biodegradable, i.e. screen for being P/vP, and pose some toxicity to aquatic organisms (leading to classification into one of hazard categories for hazardous to the aquatic environment, but not yet meeting criteria for T). Amines are less hydrophobic than their respective parent compounds, so less likely to be bioaccumulative. However, as they might be present in ionized forms at environmental pHs, bioaccumulation cannot be based on low log Kow alone. If persistence is confirmed, further bioaccumulation assessment of those amines could be necessary, taking into account the information potentially available and analysed in the group assessments of amines. Due to their potential to form covalent bonds and to bind to anions (e.g. to humic substances) present in environmental matrices, amines are probably not mobile in most soils or sediments.

Some data generation is proposed for both, mono- and poly-isocyanates to confirm the above hypotheses. Furthermore, for some of the group members, the generation of aquatic toxicity data is proposed to ensure compliance with standard information requirements of the REACH Regulation. Considering that isocyanates are very reactive, they can hardly be tested as such. Under the (homogenous) conditions of the standard test guidelines, amines will preferably be formed. This is regarded as a conservative approach for assessing the aquatic toxicity of this group.

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 ¹⁵	Relevant use(s) & exposure potential	Last foreseen action	Action
Subgroup 1 Aromatic polyisocyanates and their oligomers, including: Subgroup 1.1. Aromatic di-isocyanates Subgroup 1.2 Aromatic tri-isocyanates	Known or potential hazard for skin sensitisation, and respiratory sensitisation Known or potential hazard for carcinogenicity	Known or potential hazard for aquatic toxicity (transformation products) PBT/vPvB unlikely	Industrial, professional and consumer uses in polymers, coatings, paints, adhesives, and sealants; additionally industrial and professional uses in washing and cleaning products; main use is in polyurethane industry; used as monomer, intermediate, binding agent, hardener; high volumes and high potential for inhalation and dermal exposure in	Need for EU RRM: Restriction A review of the present restrictions (restrictions entry 74 and 56) is proposed to broaden their scope and include all substances in the isocyanate groups (subgroups 1, 2, 3, 4, 5, 6, 7, 8, 9, 10 and 11). The reviewed restrictions would address the risks to industrial and professional workers and to consumers resulting from the respiratory and skin sensitisation properties of the substances. Potential for substitution between all substances in the group is expected based on structural similarity. The	Restriction entry 74 to be reviewed to cover all substances in Subgroups 1.2, 1.3, 1.4 and 2 (substances in Subgroup 1.1. are already covered by restriction entry 74). Restriction entry 56 to be reviewed to cover all substances in Subgroups 1 and 2 (4 substances in subgroup 1.1, i.e. EC number 247-714-0, 202-966-0, 227-534-9, 219-799-4, are already covered by restriction entry 56).

¹⁵ In this column, the reported hazard or absence of hazard for the aquatic environment reflects the available classification for aquatic toxicity or available results from ecotoxicity tests. However, as explained above, the test results and the classification heavily depend on the test conditions and the potential subsequent formation of hazardous transformation products. Under homogeneous conditions (low concentrations, good mixing, low DOC content), recommended in standard laboratory tests, isocyanates can form hazardous amines. Under heterogeneous conditions, polyisocyanates will tend to form inert, non hazardous, transformation products.

ASSESSMENT OF REGULATORY NEEDS

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard ¹⁵	Relevant use(s) & exposure potential	Last foreseen action	Action
<p>Subgroup 1.3 MDI oligomers</p> <p>Subgroup 1.4 TDI oligomers</p> <p>Subgroup 2 MDI polyurethanes</p>			industrial, professional and consumer uses	<p>reviewed restrictions should address the risks to workers and consumers from the carcinogenicity properties (Carc 2) of the substances of subgroups 1, 2, 7 and 9. (To be noted that restriction entry 74 already addresses the risk to industrial and professional workers resulting from the respiratory and skin sensitisation properties of the substances in subgroups 1.1. and 3.1. Additionally, restriction entry 56 defines the conditions to control the risks to consumers resulting from the skin and respiratory sensitising properties of EC 247-714-0, EC-202-966-0, EC 227-534-9 and EC 219-799-4.)</p> <p>Need for EU RRM: OEL</p> <p>A review of the OEL proposal is recommended to broaden the scope and include all substances in the isocyanates group (subgroups 1, 2, 3, 4, 5, 6, 7, 8, 9, 10 and 11). The proposed OEL would define an exposure limit to isocyanates for workers. (To be noted</p>	<p>OEL proposal to be reviewed to cover all substances in Subgroup 1.2 (substances in Subgroups 1.1, 1.3, 1.4 and 2 are already covered by the OEL proposal).</p> <p>Data generation to confirm no hazard for mutagenicity, reproductive toxicity, ED, STOT RE, PBT/vPvB and to assess the aquatic toxicity of the transformation products formed under homogeneous conditions:</p> <p>TPE for EC: 500-079-6 227-534-9 202-966-0 CCH for EC: 247-722-4 209-544-5 202-039-0 813-050-0 218-485-4 221-641-4 203-207-6 202-112-7 247-953-0</p>

ASSESSMENT OF REGULATORY NEEDS

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard ¹⁵	Relevant use(s) & exposure potential	Last foreseen action	Action
				that there is a RAC opinion on an OEL proposal for all diisocyanates in the OEL process. The scope of the OEL proposal covers subgroups 1 (except 1.2), 2, 3, 4, 6 (diisocyanates) and 11 (EC 926-601-6)).	938-708-5 701-017-2 219-351-8 : TPE for EC 701-041-3
<p>Subgroup 3 Aliphatic polyisocyanates and their oligomers, including:</p> <p>Subgroup 3.1. Aliphatic diisocyanates</p> <p>Subgroup 3.2 Aliphatic diisocyanates oligomers</p> <p>Subgroup 3.4 Allophanates</p>	Known or potential hazard for skin sensitisation and respiratory sensitisation	Known or potential hazard for aquatic toxicity (transformation products) PBT/vPvB unlikely	Industrial and professional uses in polymers, coatings, paints, adhesives and sealants; main use is in polyurethane industry; used as monomer, intermediate, binding agent, hardener; high potential for worker exposure. No consumer uses identified	As above	<p>Restriction entry 74 to be reviewed to cover all substances in Subgroups 3.2, 3.3., 3.4 and 4. (substances in Subgroup 3.1 are already covered by restriction entry 74).</p> <p>Restriction entry 56 to be reviewed to cover all substances in Subgroups 3 and 4.</p> <p>(Note: The OEL proposal already covers substances in Subgroup 3 and 4).</p> <p>Data generation to confirm no hazard for mutagenicity, reproductive toxicity, ED, STOT RE, PBT/vPvB and to assess the aquatic toxicity of the transformation products</p>

ASSESSMENT OF REGULATORY NEEDS

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard ¹⁵	Relevant use(s) & exposure potential	Last foreseen action	Action
<p>Subgroup 4</p> <p>Di-isocyanate reaction products with alcohols</p>					<p>formed under homogeneous conditions</p> <p>CCH for EC: 212-485-8 807-040-5 223-242-0 943-686-5 931-274-8 931-288-4 931-297-3 931-312-3 939-340-8 939-549-4 939-657-1</p> <p>700-674-2</p>
<p>Subgroup 5</p> <p>Acrylate-functionalised mono-isocyanates,</p>	<p>Known or potential hazard for skin sensitisation and respiratory sensitisation</p>	<p>Known or potential hazard for aquatic toxicity (transformation products)</p> <p>PBT/vPvB unlikely</p>	<p>Mainly intermediate and industrial uses. For one substance also article service life identified. High exposure potential for workers. No consumer uses identified</p>	<p>As above</p>	<p>Restriction entry 74 to be reviewed to cover all substances in Subgroup 5.</p> <p>Restriction entry 56 to be reviewed to cover all substances in Subgroup 5.</p> <p>OEL proposal to be reviewed to cover all substances in Subgroup 5.</p>

ASSESSMENT OF REGULATORY NEEDS

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard ¹⁵	Relevant use(s) & exposure potential	Last foreseen action	Action
					<p>Data generation to confirm no hazard for mutagenicity, reproductive toxicity, ED, STOT RE, PBT/vPvB and to assess the aquatic toxicity of the transformation products formed under homogeneous conditions</p> <p style="text-align: right;">:</p> <p>CCH for EC: 250-284-7 677-640-8</p>
<p>Subgroup 6</p> <p>Siloxane-functionalised mono and di-isocyanates</p>	<p>Known or potential hazard for skin sensitisation and respiratory sensitisation</p>	<p>Known or potential hazard for aquatic toxicity (transformation products)</p> <p>PBT/vPvB unlikely</p>	<p>Main use is in polymer preparations, adhesives and sealants, fillers, coatings and paints. Three substances have professional uses (EC 918-105-3, EC 924-669-1, EC 926-191-9) and one substance (EC 924-669-1) also consumer uses. Others only industrial uses. High exposure potential for workers and consumers.</p>	<p>As above</p>	<p>Restriction entry 74 to be reviewed to cover all substances in Subgroup 6</p> <p>Restriction entry 56 to be reviewed to cover all substances in Subgroup 6.</p> <p>OEL proposal to be reviewed to cover all substances in Subgroup 6 (Siloxane functionalised di-isocyanates oligomers, i.e. EC 918-105-3, EC 924-669-1, EC 926-191-9 are already covered by the OEL proposal.</p>

ASSESSMENT OF REGULATORY NEEDS

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard ¹⁵	Relevant use(s) & exposure potential	Last foreseen action	Action
					<p>Data generation to confirm no hazard for mutagenicity, reproductive toxicity, ED, STOT RE, PBT/vPvB and to assess the aquatic toxicity of the transformation products formed under homogeneous conditions</p> <p>CCH for EC: 239-415-9 246-467-6 918-105-3 924-669-1 926-191-9</p>
<p>Subgroup 7 Aromatic mono-isocyanates</p> <p>Subgroup 8 Aliphatic mono-isocyanates</p>	<p>Known or potential hazard for skin sensitisation and respiratory sensitisation</p> <p>Inconclusive hazard For carcinogenicity (Subgroup 7)</p>	<p>Known or potential hazard for aquatic toxicity (transformation products)</p> <p>PBT/vPvB unlikely</p>	<p>Only intermediate registrations (TII/OSII < 1000 t/y) - low exposure potential</p>	<p>As above</p>	<p>Restriction entry 74 to be reviewed to cover all substances in Subgroups 7 and 8.</p> <p>Restriction entry 56 to be reviewed to cover all substances in Subgroups 7 and 8.</p> <p>OEL proposal to be reviewed to cover all substances in Subgroups 7 and 8.</p>

ASSESSMENT OF REGULATORY NEEDS

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard ¹⁵	Relevant use(s) & exposure potential	Last foreseen action	Action
<p>Subgroup 9</p> <p>Chlorinated aromatic mono-isocyanates,</p>	<p>Known or potential hazard for skin sensitisation and respiratory sensitisation</p> <p>Inconclusive hazard For carcinogenicity</p>	<p>Known or potential hazard for aquatic toxicity (transformation products)</p> <p>PBT/vPvB unlikely</p>	<p>Mainly industrial intermediate uses – low exposure potential</p>	<p>As above</p>	<p>Restriction entry 74 to be reviewed to cover all substances in Subgroup 9.</p> <p>Restriction entry 56 to be reviewed to cover all substances in Subgroup 9.</p> <p>OEL proposal to be reviewed to cover all substances in Subgroup 9.</p>
<p>Subgroup 10</p> <p>Sulfo mono-isocyanates</p>	<p>Known or potential hazard for skin sensitisation and respiratory sensitisation</p>	<p>Known or potential hazard for aquatic toxicity (transformation products)</p> <p>PBT/vPvB unlikely</p>	<p>Intermediate use only for EC 618-297-6 – low exposure potential; EC 223-810-8 used in polymers, adhesives & coatings – high exposure potential due to the wide dispersive uses (professional and consumer uses)</p>	<p>As above</p>	<p>Restriction entry 74 to be reviewed to cover all substances in Subgroup 10.</p> <p>Restriction entry 56 to be reviewed to cover all substances in Subgroup 10.</p> <p>OEL proposal to be reviewed to cover all substances in Subgroup 10.</p> <p>Data generation to confirm no hazard for mutagenicity, reproductive toxicity, ED, STOT RE, PBT/vPvB and to assess the aquatic toxicity of the transformation products formed under homogeneous conditions</p>

ASSESSMENT OF REGULATORY NEEDS

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard ¹⁵	Relevant use(s) & exposure potential	Last foreseen action	Action
					CCH for EC 223-810-8
Subgroup 11 Stand-alone substances	Known or potential hazard for skin sensitisation and respiratory sensitisation (EC 947-972-0, EC 402-440-2, EC 606-676-9) Hazards unlikely for 926-601-6	Known or potential hazard for aquatic toxicity (transformation products) PBT/vPvB unlikely	Mainly intermediate uses, polymer preparations, adhesives & sealants. Two substances (EC-926-601-6, EC 947-972-0 ¹⁶) have industrial and professional uses (one of them, EC-947-972-0, with skin and respiratory sensitising properties) resulting in high exposure potential for workers, other substances have low exposure potential.	As above	Restriction entry 74 to be reviewed to cover all substances in Subgroup 11. Restriction entry 56 to be reviewed to cover all substances in Subgroup 11. OEL proposal to be reviewed to cover all substances in Subgroup 11 (1 Substance: EC 926-601-6 already covered by the OEL proposal).

¹⁶ Cease of manufacture during the development of the ARN report

Annex 1: Overview of classifications

Data extracted on 18 January 2022

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations ¹⁷
SUB-GROUP 1				
227- 534-9	5873- 54-1	o-(p- isocyanatobenzyl)phenyl isocyanate	Category: Eye Irrit. 2 Class: Serious eye damage/irritation Statement: H319: C>=5% Additional Info: C, 2; Category: Resp. Sens. 1 Class: Respiratory sensitizers Statement: H334: C>=0.1% Additional Info: C, 2; Category: Skin Irrit. 2 Class: Skin Corrosion/Irritation Statement: H315: C>=5% Additional Info: C, 2; Category: STOT SE 3 Class: Specific Target Organ Toxicity - Single Exposure Statement: H335: C>=5% Additional Info: C, 2 Index number: 615-005- 00-9 Hazard Category: Skin Irrit. 2 Hazard Statement: H315 Notes: C, 2 STOT RE 2 Hazard Statement: H373 Notes: C, 2 (Minimum classification; No information to prove exclusion of certain routes of exposure) Hazard Category: Eye Irrit. 2 Hazard Statement: H319 Notes: C, 2 STOT SE 3 Hazard Statement: H335 Notes: C, 2 Carc. 2 Hazard Statement: H351 Notes: C, 2 Acute Tox. 4 Hazard	Carc. 2 H351 Acute Tox. 4 H332 Skin Irrit. 2 H315, specific concentration: >=5 Eye Irrit. 2 H319, specific concentration: >=5 Resp. Sens. 1 H334, specific concentration: >=.1 Skin Sens. 1 H317 STOT Rep. Exp. 2 H373, affected organs: respiratory system STOT Single Exp. 3 H335, affected organs: respiratory system, specific concentration: >=5

¹⁷ The column gives the classifications in registrations received under REACH. Additional classifications in intermediate and in inactive registrations (if any) are annotated and displayed last. For each classification the table includes information on the hazard category, the hazard statement and any available information on specific effects (relevant for reproductive toxicity), specific concentration limits, M-Factors and affected organs. Two classifications differing in any of these aspects are considered different and are repeated in the table. The columns "Classifications in registrations" and "Classifications in C&L notifications" are empty if there are no Registrations/C&L notifications (hazard is unknown). The value '-' is displayed on the same columns when there are (relevant) submissions but they do not contain self-classifications (substance is not hazardous).

ASSESSMENT OF REGULATORY NEEDS

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations ¹⁷
			Statement: H332 Notes: C, 2 (Minimum classification) Resp. Sens. 1 Statement: H334 Additional Info: C, 2 Skin Sens. 1 Statement: H317 Additional Info: C, 2	
247- 722-4	26471 -62-5	m-tolylidene diisocyanate	Index number: 615-006- 00-4 Hazard Category: Skin Irrit. 2 Hazard Statement: H315 Notes: C Hazard Category: Eye Irrit. 2 Hazard Statement: H319 Notes: C STOT SE 3 Hazard Statement: H335 Notes: C Carc. 2 Hazard Statement: H351 Notes: C Acute Tox. 2 Hazard Statement: H330 Notes: C (Minimum classification) Aquatic Chronic 3 Statement: H412 Additional Info: C Resp. Sens. 1 Statement: H334 Additional Info: C Skin Sens. 1 Statement: H317 Additional Info: C Category: Resp. Sens. 1 Class: Respiratory sensitizers Statement: H334: C>=0.1% Additional Info: C	Carc. 2 H351 Acute Tox. 1 H330 Skin Irrit. 2 H315 Eye Irrit. 2A H319 Resp. Sens. 1 H334, specific concentration: >=.1 Skin Sens. 1 H317 STOT Single Exp. 3 H335, affected organs: Lung Aquatic Chronic 3 H412 Resp. Sens. 1 H334 [intermediate (inactive)] Eye Irrit. 2 H319 [intermediate (inactive)] STOT Single Exp. 3 H335, affected organs: respiratory tract [intermediate (inactive)] Acute Tox. 2 H330 [intermediate (inactive)]
209- 544-5	584- 84-9	4-methyl-m- phenylene diisocyanate; 2,4-TDI	Index number: 615-006- 00-4 Hazard Category: Skin Irrit. 2 Hazard Statement: H315 Notes: C Hazard Category: Eye Irrit. 2 Hazard Statement: H319 Notes: C STOT SE 3 Hazard Statement: H335 Notes: C Carc. 2 Hazard Statement: H351 Notes: C Acute Tox. 2 Hazard Statement: H330 Notes: C (Minimum classification)	Carc. 2 H351 Acute Tox. 1 H330 Skin Irrit. 2 H315 Eye Irrit. 2A H319 Resp. Sens. 1 H334, specific concentration: >=.1 Skin Sens. 1 H317 STOT Single Exp. 3 H335, affected organs: Respiratory tract Aquatic Chronic 3 H412 Acute Tox. 2 H330

ASSESSMENT OF REGULATORY NEEDS

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations ¹⁷
			Aquatic Chronic 3 Statement: H412 Additional Info: C Resp. Sens. 1 Statement: H334 Additional Info: C Skin Sens. 1 Statement: H317 Additional Info: C Category: Resp. Sens. 1 Class: Respiratory sensitizers Statement: H334: C>=0.1% Additional Info: C	[intermediate (inactive)] Eye Irrit. 2 H319 [intermediate (inactive)] STOT Single Exp. 3 H335, affected organs: respiratory system [intermediate (inactive)] Resp. Sens. 1 H334 [intermediate (inactive)]
905- 806-4	-	Reaction mass of 4,4'- methylenediphen- yl diisocyanate and o-(p- isocyanatobenzyl)phenyl isocyanate		Carc. 2 H351 Acute Tox. 4 H332 Skin Irrit. 2 H315, specific concentration: >=5 Eye Irrit. 2 H319, specific concentration: >=5 Resp. Sens. 1 H334, specific concentration: >=.1 Skin Sens. 1 H317 STOT Rep. Exp. 2 H373, affected organs: respiratory system STOT Single Exp. 3 H335, affected organs: respiratory system, specific concentration: >=5
618- 498-9	9016- 87-9	Isocyanic acid, polymethylenepol- yphenylene ester		
223- 981-9	4151- 51-3	tris(p- isocyanatophenyl) thiophosphate		Acute Tox. 4 H302
247- 714-0	26447 -40-5	methylenediphen- yl diisocyanate	Category: Eye Irrit. 2 Class: Serious eye damage/irritation Statement: H319: C>=5% Additional Info: C, 2; Category: Resp. Sens. 1 Class: Respiratory sensitizers Statement: H334: C>=0.1% Additional Info: C, 2; Category: Skin Irrit. 2 Class: Skin Corrosion/Irritation Statement: H315: C>=5% Additional Info: C, 2; Category: STOT SE 3 Class: Specific Target Organ Toxicity - Single Exposure Statement: H335: C>=5% Additional Info: C, 2 Index number: 615-005- 00-9	Carc. 2 H351 [intermediate (inactive)] STOT Rep. Exp. 2 H373 [intermediate (inactive)] Skin Irrit. 2 H315 [intermediate (inactive)] Eye Irrit. 2 H319 [intermediate (inactive)] STOT Single Exp. 3 H335, affected organs: respiratory tract [intermediate (inactive)] Acute Tox. 4 H332 [intermediate (inactive)] Resp. Sens. 1 H334 [intermediate (inactive)] Skin Sens. 1 H317 [intermediate (inactive)]

ASSESSMENT OF REGULATORY NEEDS

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations ¹⁷
			<p>Hazard Category: Skin Irrit. 2 Hazard Statement: H315 Notes: C, 2 STOT RE 2 Hazard Statement: H373 Notes: C, 2 (Minimum classification; No information to prove exclusion of certain routes of exposure)</p> <p>Hazard Category: Eye Irrit. 2 Hazard Statement: H319 Notes: C, 2 STOT SE 3 Hazard Statement: H335 Notes: C, 2</p> <p>Carc. 2 Hazard Statement: H351 Notes: C, 2 Acute Tox. 4 Hazard Statement: H332 Notes: C, 2 (Minimum classification)</p> <p>Resp. Sens. 1 Statement: H334 Additional Info: C, 2 Skin Sens. 1 Statement: H317 Additional Info: C, 2</p>	
218-485-4	2162-73-4	2,4,6-triisopropyl-m-phenylene diisocyanate		<p>Carc. 2 H351 Acute Tox. 1 H330 Skin Irrit. 2 H315 Resp. Sens. 1 H334, specific concentration: >=.1 Skin Sens. 1 H317 STOT Single Exp. 3 H335, affected organs: respiratory tract</p>
247-953-0	26747-90-0	2,4-dioxo-1,3-diazetidone-1,3-bis(methyl-m-phenylene) diisocyanate		<p>Skin Sens. 1A H317 STOT Single Exp. 3 H335, affected organs: lungs</p>
500-040-3	25686-28-6	4,4'-Methylenediphenyl diisocyanate, oligomers		<p>Carc. 2 H351 Acute Tox. 4 H332 Skin Irrit. 2 H315, specific concentration: >=5 Eye Irrit. 2 H319, specific concentration: >=5 Resp. Sens. 1 H334, specific concentration: >=.1 Skin Sens. 1 H317 STOT Rep. Exp. 2 H373, affected organs: other: respiratory system STOT Single Exp. 3 H335, affected organs: other: respiratory system, specific concentration: >=5</p>

ASSESSMENT OF REGULATORY NEEDS

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations ¹⁷
202-112-7	91-97-4	3,3'-dimethylbiphenyl-4,4'-diyl diisocyanate		Acute Tox. 4 H332 Resp. Sens. 1 H334 Skin Sens. 1A H317 Aquatic Acute 1 H400 Aquatic Chronic 1 H410
701-017-2	-	Toluene-2,4(6)-diisocyanates and oligomeric reaction products of toluene-2,4(6)-diisocyanates and toluene-2,4(6)-diamines, containing biuret derivatives		Carc. 2 H351 Acute Tox. 1 H330 Skin Irrit. 2 H315 Eye Damage 1 H318 Resp. Sens. 1 H334, specific concentration: \geq .1 Skin Sens. 1 H317 STOT Single Exp. 3 H335, affected organs: lung Aquatic Chronic 3 H412
500-297-1	10933-1-54-6	4,4'-Methylenediphenyl diisocyanate, oligomeric reaction products with 2,4'-diisocyanatodiphenylmethane		Carc. 2 H351 Acute Tox. 4 H332 Skin Irrit. 2 H315 Eye Irrit. 2 H319 Resp. Sens. 1 H334 Skin Sens. 1 H317 STOT Rep. Exp. 2 H373, affected organs: Respiratory system STOT Single Exp. 3 H335, affected organs: Respiratory system
219-351-8	2422-91-5	methylidynetri-phenylene triisocyanate		Acute Tox. 4 H302 Acute Tox. 2 H330 Skin Irrit. 2 H315 Eye Irrit. 2 H319 Resp. Sens. 1 H334 Skin Sens. 1B H317 STOT Single Exp. 3 H335, affected organs: respiratory tract
500-079-6	32055-14-4	Formaldehyde, oligomeric reaction products with aniline and phosgene		Carc. 2 H351 Acute Tox. 4 H332 Skin Irrit. 2 H315, specific concentration: \geq 5 Eye Irrit. 2 H319, specific concentration: \geq 5 Resp. Sens. 1 H334, specific concentration: \geq .1 Skin Sens. 1 H317 STOT Rep. Exp. 2 H373, affected organs: respiratory system STOT Single Exp. 3 H335, affected organs: respiratory

ASSESSMENT OF REGULATORY NEEDS

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations ¹⁷
				system, specific concentration: >=5
813-050-0	2162-70-1	1,3-diethyl-2,4-diisocyanato-5-methylbenzene		Resp. Sens. 1 H334 Skin Sens. 1 H317 Aquatic Chronic 4 H413
203-207-6	104-49-4	p-phenylene diisocyanate		Acute Tox. 2 H330 Skin Irrit. 2 H315 Eye Irrit. 2A H319 Resp. Sens. 1 H334 Skin Sens. 1 H317 STOT Single Exp. 3 H335, affected organs: lungs Aquatic Chronic 2 H411
219-799-4	2536-05-2	2,2'-methylenediphenyl diisocyanate	Category: Eye Irrit. 2 Class: Serious eye damage/irritation Statement: H319: C>=5% Additional Info: C, 2; Category: Resp. Sens. 1 Class: Respiratory sensitizers Statement: H334: C>=0.1% Additional Info: C, 2; Category: Skin Irrit. 2 Class: Skin Corrosion/Irritation Statement: H315: C>=5% Additional Info: C, 2; Category: STOT SE 3 Class: Specific Target Organ Toxicity - Single Exposure Statement: H335: C>=5% Additional Info: C, 2 Index number: 615-005-00-9 Hazard Category: Skin Irrit. 2 Hazard Statement: H315 Notes: C, 2 STOT RE 2 Hazard Statement: H373 Notes: C, 2 (Minimum classification; No information to prove exclusion of certain routes of exposure) Hazard Category: Eye Irrit. 2 Hazard Statement: H319	Resp. Sens. 1 H334 [intermediate (inactive)] STOT Single Exp. 3 H335, affected organs: respiratory tract [intermediate (inactive)] Skin Irrit. 2 H315 [intermediate (inactive)] Eye Irrit. 2 H319 [intermediate (inactive)] STOT Rep. Exp. 2 H373 [intermediate (inactive)] Carc. 2 H351 Acute Tox. 4 H332 Skin Irrit. 2 H315, specific concentration: >=5 Eye Irrit. 2 H319, specific concentration: >=5 Resp. Sens. 1 H334, specific concentration: >=.1 Skin Sens. 1 H317 STOT Rep. Exp. 2 H373, affected organs: respiratory system STOT Single Exp. 3 H335, affected organs: respiratory system, specific concentration: >=5

ASSESSMENT OF REGULATORY NEEDS

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations ¹⁷
			Notes: C, 2 STOT SE 3 Hazard Statement: H335 Notes: C, 2 Carc. 2 Hazard Statement: H351 Notes: C, 2 Acute Tox. 4 Hazard Statement: H332 Notes: C, 2 (Minimum classification) Resp. Sens. 1 Statement: H334 Additional Info: C, 2 Skin Sens. 1 Statement: H317 Additional Info: C, 2	
202- 039-0	91-08- 7	2-methyl-m- phenylene diisocyanate	Index number: 615-006- 00-4 Hazard Category: Skin Irrit. 2 Hazard Statement: H315 Notes: C Hazard Category: Eye Irrit. 2 Hazard Statement: H319 Notes: C STOT SE 3 Hazard Statement: H335 Notes: C Carc. 2 Hazard Statement: H351 Notes: C Acute Tox. 2 Hazard Statement: H330 Notes: C (Minimum classification) Aquatic Chronic 3 Statement: H412 Additional Info: C Resp. Sens. 1 Statement: H334 Additional Info: C Skin Sens. 1 Statement: H317 Additional Info: C Category: Resp. Sens. 1 Class: Respiratory sensitizers Statement: H334: C>=0.1% Additional Info: C	STOT Single Exp. 3 H335, affected organs: respiratory system [intermediate (inactive)] Carc. 2 H351 Acute Tox. 2 H330 Skin Irrit. 2 H315 Eye Irrit. 2 H319 Resp. Sens. 1 H334 Skin Sens. 1 H317 STOT Single Exp. 3 H335, affected organs: Respiratory system Aquatic Chronic 3 H412

ASSESSMENT OF REGULATORY NEEDS

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations ¹⁷
202-966-0	101-68-8	4,4'-methylenediphenyl diisocyanate	<p>Category: Eye Irrit. 2 Class: Serious eye damage/irritation Statement: H319: C>=5% Additional Info: C, 2; Category: Resp. Sens. 1 Class: Respiratory sensitizers Statement: H334: C>=0.1% Additional Info: C, 2; Category: Skin Irrit. 2 Class: Skin Corrosion/Irritation Statement: H315: C>=5% Additional Info: C, 2; Category: STOT SE 3 Class: Specific Target Organ Toxicity - Single Exposure Statement: H335: C>=5% Additional Info: C, 2 Index number: 615-005-00-9 Hazard Category: Skin Irrit. 2 Hazard Statement: H315 Notes: C, 2 STOT RE 2 Hazard Statement: H373 Notes: C, 2 (Minimum classification; No information to prove exclusion of certain routes of exposure) Hazard Category: Eye Irrit. 2 Hazard Statement: H319 Notes: C, 2 STOT SE 3 Hazard Statement: H335 Notes: C, 2 Carc. 2 Hazard Statement: H351 Notes: C, 2 Acute Tox. 4 Hazard Statement: H332 Notes: C, 2 (Minimum classification) Resp. Sens. 1 Statement: H334 Additional Info: C, 2 Skin Sens. 1 Statement: H317 Additional Info: C, 2</p>	<p>Eye Irrit. 2 H319 [intermediate (inactive)] Resp. Sens. 1 H334 [intermediate (inactive)] Skin Irrit. 2 H315 [intermediate (inactive)] STOT Single Exp. 3 H335, affected organs: respiratory system [intermediate (inactive)] Carc. 2 H351 Acute Tox. 4 H332 Skin Irrit. 2 H315, specific concentration: >=5 Eye Irrit. 2 H319, specific concentration: >=5 Resp. Sens. 1 H334, specific concentration: >=.1 Skin Sens. 1 H317 STOT Rep. Exp. 2 H373, affected organs: respiratory system STOT Single Exp. 3 H335, affected organs: respiratory system, specific concentration: >=5</p>
938-708-5	-	m-TDI oligomers, isocyanurate		<p>Carc. 2 H351 Acute Tox. 4 H332 Acute Tox. 3 H331 Acute Tox. 2 H330 Resp. Sens. 1 H334 Skin Sens. 1B H317</p>

ASSESSMENT OF REGULATORY NEEDS

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations ¹⁷
<i>SUB-GROUP 2</i>				
701-276-1	-	4,4'-methylenebis(4-isocyanatobenzene) and 2,4'-diisocyanatodiphenylmethane and their oligomerisation reaction products with 2,2'-oxydiethanol, propane-1,2-diol and butane-1,3-diol		Eye Irrit. 2 H319, specific concentration: ≥ 5 [Article 10 (inactive)] Skin Sens. 1B H317 [Article 10 (inactive)] Acute Tox. 4 H332 [Article 10 (inactive)] Carc. 2 H351 [Article 10 (inactive)] Skin Irrit. 2 H315, specific concentration: ≥ 5 [Article 10 (inactive)] STOT Single Exp. 3 H335, affected organs: respiratory tract, specific concentration: ≥ 5 [Article 10 (inactive)] Resp. Sens. 1 H334, specific concentration: $\geq .1$ [Article 10 (inactive)] STOT Rep. Exp. 2 H373, affected organs: respiratory system [Article 10 (inactive)]
701-124-4	-	1,1'-Methylenebis(4-isocyanatobenzene) and its oligomeric reaction products with [(methylethylene)bis(oxy)]dipropylol		Carc. 2 H351 Acute Tox. 4 H332 Skin Irrit. 2 H315, specific concentration: ≥ 5 Eye Irrit. 2 H319, specific concentration: ≥ 5 Resp. Sens. 1 H334, specific concentration: $\geq .1$ Skin Sens. 1 H317 STOT Rep. Exp. 2 H373, affected organs: respiratory system STOT Single Exp. 3 H335, affected organs: respiratory system, specific concentration: ≥ 5
701-040-8	-	1,1'-Methylenebis(4-isocyanatobenzene) and oligomeric reaction products of 1,1'-methylenebis(4-isocyanatobenzene) and oxydipropylol		Carc. 2 H351 Acute Tox. 4 H332 Skin Irrit. 2 H315, specific concentration: ≥ 5 Eye Irrit. 2 H319, specific concentration: ≥ 5 Resp. Sens. 1 H334, specific concentration: $\geq .1$ Skin Sens. 1 H317 STOT Rep. Exp. 2 H373, affected organs: respiratory system STOT Single Exp. 3 H335, affected organs: respiratory system, specific concentration: ≥ 5

ASSESSMENT OF REGULATORY NEEDS

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations ¹⁷
701-072-2	-	4,4'-methylenediphenyl diisocyanate and its oligomeric reaction products with oxydipropanol and [(methylethylene)bis(oxy)]dipropanol		Carc. 2 H351 Acute Tox. 4 H332 Skin Irrit. 2 H315, specific concentration: >=5 Eye Irrit. 2 H319, specific concentration: >=5 Resp. Sens. 1 H334, specific concentration: >=.1 Skin Sens. 1 H317 STOT Rep. Exp. 2 H373, affected organs: respiratory system STOT Single Exp. 3 H335, affected organs: respiratory system, specific concentration: >=5
701-041-3	-	1,1'-Methylenebis(4-isocyanatobenzene) and oligomeric reaction products of 1,1'-methylenebis(4-isocyanatobenzene) and oxydipropanol and oligomerization reaction products of oxydipropanol		Carc. 2 H351 Acute Tox. 4 H332 Skin Irrit. 2 H315, specific concentration: >=5 Eye Irrit. 2 H319, specific concentration: >=5 Resp. Sens. 1 H334, specific concentration: >=.1 Skin Sens. 1 H317 STOT Rep. Exp. 2 H373, affected organs: respiratory system STOT Single Exp. 3 H335, affected organs: respiratory system, specific concentration: >=5
500-142-8	59952-43-1	4,4'-Methylenediphenyl diisocyanate, oligomeric reaction products with oxydipropanol		-

ASSESSMENT OF REGULATORY NEEDS

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations ¹⁷
500-313-7	-	4,4'-Methylenediphenyl diisocyanate, oligomeric reaction products with butane-1,3-diol, 2,4'-diisocyanatodiphenylmethane, 1,1'-methylenebis(4-isocyanatobenzene) homopolymer, [(methylethylene)bis(oxy)]dipropyl and propane-1,2-diol		-
686-803-2	68092-58-0	686-803-2		-
500-270-4	88288-99-7	4,4'-Methylenediphenyl diisocyanate, oligomeric reaction products with 2,4'-diisocyanatodiphenylmethane and oxydipropyl		-

ASSESSMENT OF REGULATORY NEEDS

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations ¹⁷
701- 173-1	-	1,1'- methylenebis(4- isocyanatobenzen e) and its oligomeric reaction products with butane-1,3- diol, 2,2'- oxydiethanol and propane-1,2-diol		Carc. 2 H351 Acute Tox. 4 H332 Skin Irrit. 2 H315, specific concentration: >=5 Eye Irrit. 2 H319, specific concentration: >=5 Resp. Sens. 1 H334, specific concentration: >=.1 Skin Sens. 1 H317 STOT Rep. Exp. 2 H373, affected organs: respiratory system STOT Single Exp. 3 H335, affected organs: respiratory system, specific concentration: >=5
500- 119-2	52747 -01-0	4,4'- Methylenediphen yl diisocyanate, oligomeric reaction products with [(methylethylene)bis (oxy)]dipropanol		-
701- 393-8	-	1,1'- Methylenebis(4- isocyanatobenzen e) and 1,1'- methylenebis(4- isocyanatobenzen e) homopolymer and their reaction products with [(methylethylene)bis(oxy)]dipropanol and butane- 1,3-diol and propane-1,2-diol		Carc. 2 H351 Acute Tox. 4 H332 Skin Irrit. 2 H315, specific concentration: >=5 Eye Irrit. 2 H319, specific concentration: >=5 Resp. Sens. 1 H334, specific concentration: >=.1 Skin Sens. 1 H317 STOT Rep. Exp. 2 H373, affected organs: respiratory system STOT Single Exp. 3 H335, affected organs: respiratory system, specific concentration: >=5

ASSESSMENT OF REGULATORY NEEDS

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations ¹⁷
500- 262-0	75880 -28-3	4,4'- Methylenediphen yl diisocyanate, oligomeric reaction products with 2,4'- diisocyanatodiphe nylmethane and [(methylethylene)bis(oxy)]dipropa nol		-
941- 496-7	-	Reaction products of 1,1'- methylenebis(4- isocyanatobenzen e) with 2,2'- [(methylethylene)bis(oxy)]di(meth ylethanol), butane-1,3-diol and propane-1,2- diol		Carc. 2 H351 Acute Tox. 4 H332 Skin Irrit. 2 H315, specific concentration: >=5 Eye Irrit. 2 H319, specific concentration: >=5 Resp. Sens. 1 H334, specific concentration: >=.1 Skin Sens. 1 H317 STOT Rep. Exp. 2 H373, affected organs: respiratory system STOT Single Exp. 3 H335, affected organs: respiratory system, specific concentration: >=5
500- 312-1	12371 4-19-2	4,4'- Methylenediphen yl diisocyanate, oligomeric reaction products with butane-1,3- diol, 2,4'- diisocyanatodiphe nylmethane, [(methylethylene)bis(oxy)]dipropa nol and propane- 1,2-diol		-

ASSESSMENT OF REGULATORY NEEDS

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations ¹⁷
701- 029-8	-	1-isocyanato- 2(or 4)-(4- isocyanatobenzyl)benzene and their reaction products with [(methylethylene)bis(oxy)]dipropa nol and butane- 1,3-diol and propylene glycol		Carc. 2 H351 Acute Tox. 4 H332 Skin Irrit. 2 H315, specific concentration: >=5 Eye Irrit. 2 H319, specific concentration: >=5 Resp. Sens. 1 H334, specific concentration: >=.1 Skin Sens. 1 H317 STOT Rep. Exp. 2 H373, affected organs: respiratory system STOT Single Exp. 3 H335, affected organs: respiratory system, specific concentration: >=5
500- 439-2	15916 8-82-8	4,4'- Methylenediphen yl diisocyanate, oligomeric reaction products with 2,4'- diisocyanatodiphe nylmethane, [(methylethylene)bis(oxy)]dipropa nol and oxydipropanol		-

ASSESSMENT OF REGULATORY NEEDS

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations ¹⁷
500-415-1	15888 5-29-1	4,4'-Methylenediphenyl diisocyanate, oligomeric reaction products with butane-1,3-diol, 2,4'-diisocyanatodiphenylmethane, 2,2'-oxydiethanol and propane-1,2-diol		-
SUB-GROUP 3				
931-297-3	-	HDI oligomers, iminooxadiazindione		Acute Tox. 4 H332 Skin Sens. 1 H317 STOT Single Exp. 3 H335, affected organs: respiratory tract
223-242-0	3779-63-3	(2,4,6-trioxotriazine-1,3,5(2H,4H,6H)-triy) tris(hexamethylene) isocyanate		Acute Tox. 4 H332 Skin Sens. 1 H317 STOT Single Exp. 3 H335, affected organs: respiratory tract
411-280-2	74091-64-8	2,5-bis-isocyanatomethyl - bicyclo[2.2.1]heptane		Acute Tox. 4 H302 Acute Tox. 2 H330 Skin Corr. 1B H314 Eye Damage 1 H318 Resp. Sens. 1 H334 Skin Sens. 1A H317 STOT Rep. Exp. 1 H372, affected organs: Respiratory tract Aquatic Chronic 3 H412
931-288-4	-	HDI oligomers, uretdione		Acute Tox. 3 H331 Skin Sens. 1 H317 STOT Single Exp. 3 H335, affected organs: respiratory tract
938-351-5	-	3-Isocyanatomethyl -3,5,5-trimethylcyclohexyl isocyanate homopolymer, uretdione type		Resp. Sens. 1 H334 [intermediate (active)] Acute Tox. 4 H332 [intermediate (active)] Skin Irrit. 2 H315 [intermediate (active)] Skin Sens. 1 H317 [intermediate (active)]

ASSESSMENT OF REGULATORY NEEDS

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations ¹⁷
931-312-3	-	3-Isocyanatomethyl-3,5,5-trimethylcyclohexyl isocyanate homopolymer, isocyanurate type		Skin Sens. 1B H317 STOT Single Exp. 3 H335, affected organs: respiratory tract
691-431-9	32052-51-0	2,2(4),4-Trimethylhexane-1,6-diisocyanate		-
249-151-6	28679-16-5	trimethylhexa-1,6-diyl diisocyanate		-
609-567-4	38661-72-2	1,3-bis(isocyanatomethyl)cyclohexane		Acute Tox. 4 H302 Acute Tox. 2 H330 Skin Corr. 1C H314 Eye Damage 1 H318 Resp. Sens. 1 H334 Skin Sens. 1A H317 Aquatic Chronic 4 H413
939-549-4	-	Reaction mass of 1-Hexanol, 2-ethyl-, reaction products with 1,6-diisocyanatohexane and Hexane, 1,6-diisocyanato-, homopolymer		Acute Tox. 4 H332 Skin Irrit. 2 H315 Skin Sens. 1B H317 STOT Single Exp. 3 H335, affected organs: respiratory tract
939-657-1	-	HDI oligomers, allophanate		Acute Tox. 4 H332 Skin Irrit. 2 H315 Skin Sens. 1 H317 STOT Single Exp. 3 H335, affected organs: respiratory tract
931-274-8	-	Oligomerisation products of 1,6-diisocyanatohexane, isocyanurate type		Acute Tox. 4 H332 Skin Sens. 1 H317 STOT Single Exp. 3 H335, affected organs: respiratory tract
223-861-6	4098-71-9	3-isocyanatomethyl-3,5,5-trimethylcyclohexyl isocyanate	Index number: 615-008-00-5 Hazard Category: Skin Irrit. 2 Hazard Statement: H315 Notes: 2 Hazard Category: Eye Irrit. 2 Hazard Statement: H319 Notes: 2 STOT SE 3 Hazard Statement: H335 Notes: 2 Acute Tox. 3 Hazard Statement: H331 Notes: 2	Acute Tox. 3 H331 Acute Tox. 1 H330 Skin Corr. 1B H314 Skin Irrit. 2 H315 Eye Irrit. 2 H319 Eye Damage 1 H318 Resp. Sens. 1 H334, specific concentration: >=.5 Skin Sens. 1 H317, specific concentration: >=.5 STOT Single Exp. 3 H335, affected organs: respiratory

ASSESSMENT OF REGULATORY NEEDS

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations ¹⁷
			(Minimum classification) Aquatic Chronic 2 Statement: H411 Additional Info: 2 Resp. Sens. 1 Statement: H334 Additional Info: 2 Skin Sens. 1 Statement: H317 Additional Info: 2 Category: Resp. Sens. 1 Class: Respiratory sensitizers Statement: H334: C>=0.5% Additional Info: 2; Category: Skin Sens. 1 Class: Skin sensitizers Statement: H317: C>=0.5% Additional Info: 2	tract STOT Single Exp. 3 H335, affected organs: Respiratory tract Aquatic Chronic 2 H411
222- 852-4	3634- 83-1	1,3- bis(isocyanatome thyl)benzene		Acute Tox. 2 H330 Skin Irrit. 2 H315 Eye Damage 1 H318 Resp. Sens. 1 H334 Skin Sens. 1A H317 STOT Rep. Exp. 1 H372, affected organs: Respiratory tract STOT Single Exp. 1 H370, affected organs: Respiratory tract Aquatic Chronic 3 H412
233- 757-2	10347 -54-3	1,4- bis(isocyanatome thyl)cyclohexane	-	
942- 994-7	-	HDI oligomers, oxadiazintrione		Acute Tox. 3 H331 Skin Sens. 1 H317 STOT Single Exp. 3 H335, affected organs: respiratory tract
943- 687-0	-	Reaction mass of 1,3,5-tris(5- isocyanatopentyl) -1,3,5-triazinane- 2,4,6-trione and isobutyl (5- isocyanatopentyl) [(5- isocyanatopentyl) carbamoyl]carba mate		Skin Mild Irrit. 3 H316 Skin Sens. 1 H317

ASSESSMENT OF REGULATORY NEEDS

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations ¹⁷
933-047-9	-	Oligomerisation products of 3-isocyanatomethyl-3,5,5-trimethylcyclohexyl isocyanate and butan-1-ol and pentan-1-ol and 2-ethylhexan-1-ol, allophanate type		Acute Tox. 4 H332 Skin Sens. 1B H317 STOT Single Exp. 3 H335, affected organs: Respiratory tract
255-693-4	42170-25-2	bis(isocyanatomethyl)cyclohexane		
915-277-1	-	2,2(4),4-Trimethylhexane-1,6-diisocyanate		Acute Tox. 1 H330 Skin Corr. 1C H314 Eye Damage 1 H318 Resp. Sens. 1 H334 Skin Sens. 1A H317 Aquatic Chronic 3 H412
500-060-2	28182-81-2	Hexamethylene diisocyanate, oligomers		

ASSESSMENT OF REGULATORY NEEDS

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations ¹⁷
225- 863-2	5124- 30-1	4,4'- methylenedicyclo hexyl diisocyanate	<p>Category: Resp. Sens. 1 Class: Respiratory sensitizers Statement: H334: C>=0.5% Additional Info: 2; Category: Skin Sens. 1 Class: Skin sensitizers Statement: H317: C>=0.5% Additional Info: 2</p> <p>Index number: 615-009-00-0 Hazard Category: Skin Irrit. 2 Hazard Statement: H315 Notes: 2 Hazard Category: Eye Irrit. 2 Hazard Statement: H319 Notes: 2 STOT SE 3 Hazard Statement: H335 Notes: 2 Acute Tox. 3 Hazard Statement: H331 Notes: 2 (Minimum classification) Resp. Sens. 1 Statement: H334 Additional Info: 2 Skin Sens. 1 Statement: H317 Additional Info: 2</p>	<p>Acute Tox. 2 H330 Skin Irrit. 2 H315 Eye Irrit. 2 H319 Resp. Sens. 1 H334, specific concentration: >=.5 Skin Sens. 1 H317, specific concentration: >=.5 STOT Single Exp. 3 H335, affected organs: Respiratory tract</p>
212- 485-8	822- 06-0	hexamethylene diisocyanate		<p>Resp. Sens. 1 H334 [intermediate (inactive)] Skin Sens. 1 H317 [intermediate (inactive)] Acute Tox. 4 H302 Acute Tox. 1 H330 Acute Tox. 3 H331 Skin Corr. 1C H314 Skin Irrit. 2 H315 Eye Irrit. 2 H319 Eye Damage 1 H318 Resp. Sens. 1 H334, specific concentration: >=.5 Skin Sens. 1 H317, specific concentration: >=.5 STOT Single Exp. 3 H335, affected organs: respiratory tract STOT Single Exp. 3 H335, affected organs: respiratory tract</p>

ASSESSMENT OF REGULATORY NEEDS

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations ¹⁷
500- 125-5	53880 -05-0	3- Isocyanatomethyl -3,5,5- trimethylcyclohex yl isocyanate, oligomers		-
939- 340-8	-	Oligomerisation products of 1,6- diisocyanatohexa ne, biuret type		Acute Tox. 4 H332 Skin Sens. 1 H317 STOT Single Exp. 3 H335, affected organs: lung
807- 040-5	4538- 42-5	807-040-5		Acute Tox. 3 H301 Acute Tox. 1 H330 Skin Corr. 1C H314 Eye Damage 1 H318 Resp. Sens. 1 H334 Skin Sens. 1 H317 STOT Single Exp. 3 H335, affected organs: Respiratory tract
825- 609-6	98458 -83-4	825-609-6		Acute Tox. 4 H302 Acute Tox. 2 H330 Skin Corr. 1C H314 Eye Damage 1 H318 Resp. Sens. 1 H334 Skin Sens. 1A H317 Aquatic Chronic 4 H413
943- 686-5	-	Reaction mass of 1,3,5-tris(5- isocyanatopentyl) -1,3,5-triazinane- 2,4,6-trione and 1,1'-pentane-1,5- diylbis[3,5-bis(5- isocyanatopentyl) -1,3,5-triazinane- 2,4,6-trione]		Skin Sens. 1 H317

ASSESSMENT OF REGULATORY NEEDS

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations ¹⁷
220- 474-4	2778- 42-9	1,3-bis(1- isocyanato-1- methylethyl)benz ene		Acute Tox. 1 H330 Skin Irrit. 2 H315 Eye Irrit. 2 H319 Resp. Sens. 1 H334 Skin Sens. 1A H317 STOT Rep. Exp. 1 H372, affected organs: Respiratory system Aquatic Acute 1 H400 Aquatic Chronic 1 H410
<i>SUB-GROUP 4</i>				
700- 674-2	-	Reaction products of [formaldehyde, oligomeric reaction products with aniline and phosgene] and 2- ethylhexan-1-ol		Carc. 2 H351 Acute Tox. 4 H332 Resp. Sens. 1 H334 Skin Sens. 1 H317 STOT Rep. Exp. 2 H373, affected organs: Respiratory system STOT Single Exp. 3 H335, affected organs: Respiratory system Aquatic Chronic 2 H411
917- 282-4	-	Toluene diisocyanate reaction product with Triethylene glycol monobutyl and ether Tetraoxahexadec an-1-ol		Resp. Sens. 1 H334 [intermediate (active)]

ASSESSMENT OF REGULATORY NEEDS

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations ¹⁷
700-343-2	-	Reaction products of 2-[2-(2-butoxyethoxy)ethoxy]ethanol and 2-{2-[2-(2-butoxyethoxy)ethoxy]ethoxy}ethanol with 2,4-diisocyanato-1-methylbenzene and 1,3-diisocyanato-2-methylbenzene		Acute Tox. 1 H330 [intermediate (active)] Resp. Sens. 1 H334, specific concentration: >.1 [intermediate (active)] Eye Irrit. 2 H319 [intermediate (active)] Skin Sens. 1 H317 [intermediate (active)] Aquatic Chronic 3 H412 [intermediate (active)] Carc. 2 H351 [intermediate (active)] STOT Single Exp. 3 H335, affected organs: respiratory system [intermediate (active)] Skin Irrit. 2 H315 [intermediate (active)]
947-942-7	-	Reaction mass of 2-ethylhexyl (6-isocyanatohexyl)-carbamate and bis(2-ethylhexyl) 1,6-hexan-1,6-diylbiscarbamate		Acute Tox. 3 H331 Skin Sens. 1A H317 STOT Single Exp. 3 H335, affected organs: respiratory tract Aquatic Chronic 3 H412
946-383-6	-	Reaction mass of 2-ethylhexyl (3-isocyanato-2-methylphenyl)carbamate and 2-ethylhexyl (3-isocyanato-4-methylphenyl)carbamate and 2-ethylhexyl (5-isocyanato-2-methylphenyl)carbamate		Repr. 2 H361, specific effect: Spermatid retention Eye Irrit. 2 H319 Skin Sens. 1B H317 Aquatic Chronic 4 H413

ASSESSMENT OF REGULATORY NEEDS

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations ¹⁷
937- 955-6	-	Reaction mass of Carbamic acid, N-(3-isocyanato-2-methylphenyl)-, 2-ethylhexyl ester and Carbamic acid, N-(3-isocyanato-4-methylphenyl)-, 2-ethylhexyl ester and N,N'-(4-Methyl-1,3-phenylene)bis(carbamic acid) C,C'-bis(2-ethylhexyl) ester		Skin Sens. 1 H317 [intermediate (active)] Acute Tox. 4 H332 [intermediate (active)] Carc. 2 H351 [intermediate (active)] Skin Irrit. 2 H315 [intermediate (active)] STOT Single Exp. 3 H335, affected organs: respiratory tract [intermediate (active)] Resp. Sens. 1 H334 [intermediate (active)] Eye Irrit. 2 H319 [intermediate (active)]
946- 534-6	-	Reaction products of (Z)-octadec-9-enol and m-tolylidene diisocyanate		Acute Tox. 4 H302 [intermediate (active)] Aquatic Chronic 4 H413 [intermediate (active)] Skin Sens. 1 H317 [intermediate (active)] Resp. Sens. 1 H334 [intermediate (active)] Acute Tox. 4 H332 [intermediate (active)]
946- 190-7	-	Reaction mass of 3,5,5-trimethylhexyl (3-isocyanato-2-methylphenyl)carbamate and 3,5,5-trimethylhexyl (3-isocyanato-4-methylphenyl)carbamate and 3,5,5-trimethylhexyl (5-isocyanato-2-methylphenyl)carbamate		Skin Sens. 1 H317 [intermediate (active)] Resp. Sens. 1 H334 [intermediate (active)] Acute Tox. 4 H332 [intermediate (active)] Acute Tox. 4 H302 [intermediate (active)] Aquatic Chronic 4 H413 [intermediate (active)]

ASSESSMENT OF REGULATORY NEEDS

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations ¹⁷
440- 930-8	33019 8-48-6	Carbamic acid, [5-isocyanato- 2(or 4)- methylphenyl]-, C10-14-alkyl esters		Aquatic Chronic 4 H413 [intermediate (active)] Acute Tox. 4 H332 [intermediate (active)] Acute Tox. 4 H302 [intermediate (active)] Resp. Sens. 1 H334 [intermediate (active)] Skin Sens. 1 H317 [intermediate (active)]
611- 014-7	53564 -52-6	Carbamic acid, (3- isocyanatomethyl phenyl)-, isotridecyl ester		Aquatic Chronic 3 H412 [intermediate (active)] Eye Irrit. 2 H319 [intermediate (active)] Skin Irrit. 2 H315 [intermediate (active)] Carc. 2 H351 [intermediate (active)] STOT Single Exp. 3 H335, affected organs: lung [intermediate (active)] Skin Sens. 1 H317 [intermediate (active)] Resp. Sens. 1 H334, specific concentration: >=.1 [intermediate (active)] Acute Tox. 1 H330 [intermediate (active)]
946- 063-6	-	Reaction mass of 3,5,5- Trimethylhexan- 1-yl 3- isocyanato-4- methylphenylcarb amate and 3,5,5- trimethylhexan- 1-yl 5- isocyanato-2- methylphenylcarb amate		Skin Sens. 1 H317 [intermediate (active)] Aquatic Chronic 4 H413 [intermediate (active)] Acute Tox. 4 H302 [intermediate (active)] Acute Tox. 4 H332 [intermediate (active)] Resp. Sens. 1 H334 [intermediate (active)]
273- 133-7	68938 -61-4	2-ethylhexyl (5- isocyanato-2- methylphenyl)- carbamate		Acute Tox. 4 H332 [intermediate (active)] Resp. Sens. 1B H334 [intermediate (active)]
259- 265-8	54634 -94-5	2-ethylhexyl (3- isocyanatomethyl phenyl)- carbamate		Aquatic Chronic 4 H413 [intermediate (active)] Acute Tox. 4 H332 [intermediate (active)] Resp. Sens. 1 H334 [intermediate (active)]

ASSESSMENT OF REGULATORY NEEDS

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations ¹⁷
<i>SUB-GROUP 5</i>				
680- 798-0	88657 7-76-0	2-isocyanato-2- methylpropane- 1,3-diyl bisacrylate		Acute Tox. 4 H302 Skin Irrit. 2 H315 Eye Irrit. 2 H319 Skin Sens. 1 H317 Aquatic Chronic 2 H411
250- 284-7	30674 -80-7	2-isocyanatoethyl methacrylate		Acute Tox. 4 H302 Acute Tox. 1 H330 Skin Irrit. 2 H315 Eye Damage 1 H318 Resp. Sens. 1 H334 Skin Sens. 1A H317
482- 140-6	-	2-Propenoic acid, 2-isocyanatoethyl ester		Carc. 1B H350 Muta. 2 H341 Acute Tox. 3 H301 Acute Tox. 3 H331 Skin Corr. 1C H314 Eye Damage 1 H318 Resp. Sens. 1 H334 Skin Sens. 1 H317 Aquatic Chronic 2 H411
815- 462-6	12445 1-79-2	2-({[3- (isocyanatomethy l)-3,5,5- trimethylcyclohex yl]carbamoyl}oxy ethyl acrylate		Acute Tox. 4 H332 Skin Irrit. 2 H315 Resp. Sens. 1 H334 Skin Sens. 1 H317
677- 640-8	26488 8-31-5	677-640-8		Skin Sens. 1B H317 Aquatic Chronic 3 H412
<i>SUB-GROUP 6</i>				

ASSESSMENT OF REGULATORY NEEDS

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations ¹⁷
239- 415-9	15396 -00-6	3- (trimethoxysilyl)propyl isocyanate		Acute Tox. 4 H302 Acute Tox. 4 H312 Acute Tox. 1 H330 Skin Corr. 1B H314 Resp. Sens. 1 H334 Skin Sens. 1 H317
918- 105-3	-	Hexamethylene diisocyanate, oligomers, reaction products with Bis-(Trimethoxysilylpropyl)amine		Skin Sens. 1B H317
453- 230-2	-	Silane, (isocyanatomethyl)dimethoxymethyl-		Acute Tox. 3 H301 Acute Tox. 1 H330 Eye Damage 1 H318 Resp. Sens. 1 H334 Skin Sens. 1 H317 STOT Rep. Exp. 1 H372, affected organs: Lung
924- 669-1	-	Reaction product of Hexamethylene diisocyanate, oligomers with Mercaptopropyltrimethoxysilane		Skin Sens. 1A H317
926- 191-9	-	Hexamethylene diisocyanate, oligomers, reaction products with N-(3-trimethoxysilyl)propylbutylamine and Bis-(Trimethoxysilylpropyl)amine		Skin Sens. 1B H317
678- 644-2	40667 9-89-8	678-644-2		-

ASSESSMENT OF REGULATORY NEEDS

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations ¹⁷
246- 467-6	24801 -88-5	triethoxy(3- isocyanatopropyl) silane		Acute Tox. 4 H302 Acute Tox. 4 H312 Acute Tox. 1 H330 Skin Corr. 1B H314 Resp. Sens. 1 H334 Skin Sens. 1 H317
700- 534-0	11717 2-56-2	Reaction products of 3- (trimethoxysilyl)p ropane-1-thiol and 5- isocyanato-1- (isocyanatometh yl)-1,3,3- trimethylcyclohex ane (1:1)		Acute Tox. 4 H332 Resp. Sens. 1 H334 Skin Sens. 1 H317
620- 692-3	78450 -75-6	(Isocyanatometh yl)(trimethoxy) silane		-
<i>SUB-GROUP 7</i>				
250- 439-9	31027 -31-3	p-isopropylphenyl isocyanate		STOT Single Exp. 3 H335, affected organs: lung [intermediate (active)] Aquatic Acute 1 H400 [intermediate (active)] Skin Corr. 1C H314 [intermediate (active)] Acute Tox. 1 H330 [intermediate (active)] Eye Damage 1 H318 [intermediate (active)] Aquatic Chronic 1 H410 [intermediate (active)] Skin Sens. 1A H317 [intermediate (active)]
248- 885-4	28178 -42-9	2,6- diisopropylphenyl isocyanate		Resp. Sens. 1 H334 [intermediate (active)] Acute Tox. 4 H302 [intermediate (active)] Acute Tox. 1 H330 [intermediate (active)] Skin Corr. 1B H314 [intermediate (active)] STOT Single Exp. 3 H335, affected organs: respiratory system [intermediate (active)]

ASSESSMENT OF REGULATORY NEEDS

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations ¹⁷
201- 703-7	86-84- 0	1-naphthyl isocyanate		Skin Irrit. 2 H315 [intermediate (active)] Resp. Sens. 1 H334 [intermediate (active)] STOT Single Exp. 3 H335, affected organs: respiratory system [intermediate (active)] Acute Tox. 4 H332 [intermediate (active)] Eye Damage 1 H318 [intermediate (active)]
203- 137-6	103- 71-9	phenyl isocyanate		Aquatic Acute 1 H400 [intermediate (active)] STOT Single Exp. 3 H335, affected organs: lung [intermediate (active)] Skin Corr. 1C H314 [intermediate (active)] Aquatic Chronic 1 H410 [intermediate (active)] Acute Tox. 4 H302 [intermediate (active)] Flam. Liquid 3 H226 [intermediate (active)] Skin Corr. 1B H314 [intermediate (active)] Skin Sens. 1A H317 [intermediate (active)] Acute Tox. 1 H330 [intermediate (active)] Resp. Sens. 1 H334 [intermediate (active)] Eye Damage 1 H318 [intermediate (active)]
210- 389-0	614- 68-6	o-tolyl isocyanate		-
801- 619-6	40151 5-81-9	801-619-6		Acute Tox. 1 H330 [intermediate (active)] Skin Corr. 1B H314 [intermediate (active)] Resp. Sens. 1 H334 [intermediate (active)] STOT Single Exp. 3 H335, affected organs: respiratory track [intermediate (active)] Acute Tox. 4 H302 [intermediate (active)]
SUB-GROUP 8				
210- 866-3	624- 83-9	methyl isocyanate		-

ASSESSMENT OF REGULATORY NEEDS

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations ¹⁷
907-349-6	-	Reaction mass of hexadecyl isocyanate and octadecyl isocyanate		-
216-544-9	1609-86-5	tert-butyl isocyanate		Skin Corr. 1C H314 [intermediate (active)] Acute Tox. 3 H301 [intermediate (active)] STOT Single Exp. 3 H335, affected organs: lung [intermediate (active)] Flam. Liquid 2 H225 [intermediate (active)] Acute Tox. 2 H330 [intermediate (active)] Skin Sens. 1 H317 [intermediate (active)] Eye Damage 1 H318 [intermediate (active)]
221-639-3	3173-53-3	cyclohexyl isocyanate		Flam. Liquid 3 H226 [intermediate (active)] Acute Tox. 3 H311 [intermediate (active)] Resp. Sens. 1 H334 [intermediate (active)] STOT Single Exp. 3 H335, affected organs: respiratory system [intermediate (active)] Eye Irrit. 2 H319 [intermediate (active)] Skin Irrit. 2 H315 [intermediate (active)] Acute Tox. 3 H301 [intermediate (active)] Acute Tox. 2 H330 [intermediate (active)]
217-276-5	1795-48-8	isopropyl isocyanate		Eye Irrit. 2 H319 [intermediate (active)] Acute Tox. 4 H302 [intermediate (active)] Skin Irrit. 2 H315 [intermediate (active)] Skin Sens. 1 H317 [intermediate (active)] Acute Tox. 2 H330 [intermediate (active)] Resp. Sens. 1 H334 [intermediate (active)] Flam. Liquid 2 H225 [intermediate (active)] STOT Single Exp. 3 H335,

ASSESSMENT OF REGULATORY NEEDS

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations ¹⁷
				affected organs: respiratory tract [intermediate (active)]
224-111-0	4202-38-4	dodecyl isocyanate		Acute Tox. 4 H332 [intermediate (active)] Acute Tox. 4 H312 [intermediate (active)] Eye Damage 1 H318 [intermediate (active)] Skin Irrit. 2 H315 [intermediate (active)] Acute Tox. 4 H302 [intermediate (active)] STOT Single Exp. 3 H335, affected organs: respiratory [intermediate (active)]
413-080-0	-	2-phenylethylisocyanate		Skin Sens. 1 H317 [intermediate (active)] Skin Corr. 1A H314 [intermediate (active)] Resp. Sens. 1 H334 [intermediate (active)] Aquatic Acute 2 [intermediate (active)] Acute Tox. 3 H331 [intermediate (active)] Acute Tox. 4 H302 [intermediate (active)]
203-862-8	111-36-4	butyl isocyanate		STOT Single Exp. 3 H335, affected organs: lung [intermediate (inactive); intermediate (active)] Eye Damage 1 H318 [intermediate (inactive); intermediate (active)] Skin Sens. 1 H317 [intermediate (active)] Skin Sens. 1A H317 [intermediate (inactive); intermediate (active)] Skin Corr. 1B H314 [intermediate (inactive); intermediate (active)] Aquatic Chronic 3 H412 [intermediate (active); intermediate (inactive)]

ASSESSMENT OF REGULATORY NEEDS

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations ¹⁷
				Acute Tox. 1 H330 [intermediate (inactive); intermediate (active)] Flam. Liquid 2 H225 [intermediate (inactive); intermediate (active)] Acute Tox. 4 H302 [intermediate (active); intermediate (inactive)]
608- 715-5	32175 -00-1	trans-1- isocyanato-4- methylcyclohexa ne		Skin Corr. 1B H314 [intermediate (active)] Acute Tox. 2 H330 [intermediate (active)] Acute Tox. 4 H302 [intermediate (active)] Skin Sens. 1 H317 [intermediate (active)] Resp. Sens. 1 H334 [intermediate (active)] Flam. Liquid 3 H226 [intermediate (active)] Aquatic Chronic 2 H411 [intermediate (active)]
204- 019-7	112- 96-9	octadecyl isocyanate		STOT Single Exp. 3 H335, affected organs: Respiratory tract [intermediate (active)] Acute Tox. 3 H331 [intermediate (active)] Acute Tox. 3 H301 [intermediate (active)] Resp. Sens. 1 H334 [intermediate (active)] Skin Sens. 1 H317 [intermediate (active)] Skin Irrit. 2 H315 [intermediate (active)] Eye Irrit. 2 H319 [intermediate (active)] STOT Single Exp. 3 H335, affected organs: Lung [intermediate (active)]
217- 736-5	1943- 84-6	hexadecyl isocyanate		Skin Irrit. 2 H315 [intermediate (active)] Eye Irrit. 2 H319 [intermediate (active)] STOT Single Exp. 3 H335, affected organs: Respiratory tract [intermediate (active)] Acute Tox. 3 H301 [intermediate (active)]

ASSESSMENT OF REGULATORY NEEDS

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations ¹⁷
<i>SUB-GROUP 9</i>				
203-176-9	104-12-1	4-chlorophenyl isocyanate		<p>Aquatic Acute 1 H400, M-factor: 10.00 [intermediate (active)]</p> <p>STOT Single Exp. 3 H335, affected organs: dark hemorrhagic lungs [intermediate (active)]</p> <p>Acute Tox. 2 H330 [intermediate (active)]</p> <p>Acute Tox. 4 H302 [intermediate (active)]</p> <p>Resp. Sens. 1 H334 [intermediate (active)]</p> <p>STOT Single Exp. 3 H335, affected organs: respiratory system [intermediate (active)]</p> <p>Eye Damage 1 H318 [intermediate (active)]</p> <p>Aquatic Chronic 1 H410 [intermediate (active)]</p> <p>Skin Irrit. 2 H315 [intermediate (active)]</p> <p>Acute Tox. 3 H301 [intermediate (active)]</p> <p>Acute Tox. 1 H330 [intermediate (active)]</p>
220-040-4	2612-57-9	2,4-dichlorophenyl isocyanate		<p>Eye Damage 1 H318 [intermediate (inactive)]</p> <p>Aquatic Acute 1 H400 [intermediate (inactive)]</p> <p>Acute Tox. 1 H330 [intermediate (inactive)]</p> <p>Aquatic Chronic 1 H410 [intermediate (inactive)]</p> <p>Skin Corr. 1C H314 [intermediate (inactive)]</p> <p>Skin Sens. 1A H317 [intermediate (inactive)]</p>
220-822-5	2909-38-8	3-chlorophenyl isocyanate		<p>Aquatic Chronic 1 H410 [intermediate (inactive)]</p> <p>Skin Sens. 1A H317 [intermediate (inactive)]</p> <p>Aquatic Acute 1 H400 [intermediate (inactive)]</p> <p>Skin Corr. 1C H314 [intermediate (inactive)]</p> <p>Acute Tox. 1 H330 [intermediate (inactive)]</p> <p>Eye Damage 1 H318 [intermediate (inactive)]</p>

ASSESSMENT OF REGULATORY NEEDS

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations ¹⁷
249- 050-7	28479 -22-3	3-chloro-p-tolyl isocyanate		Skin Corr. 1B H314 [intermediate (active)] Acute Tox. 2 H330 [intermediate (active)] Skin Sens. 1A H317 [intermediate (active)] Eye Damage 1 H318 [intermediate (active)] Aquatic Acute 1 H400 [intermediate (active)] Aquatic Chronic 1 H410 [intermediate (active)] STOT Single Exp. 3 H335, affected organs: lung [intermediate (active)]
252- 276-9	34893 -92-0	1,3-dichloro-5- isocyanatobenzene		Skin Sens. 1A H317 [intermediate (active)] Aquatic Chronic 2 H411 [intermediate (active)] Acute Tox. 1 H330 [intermediate (active)] STOT Single Exp. 3 H335, affected organs: lung [intermediate (active)]
203- 026-2	102- 36-3	3,4- dichlorophenyl isocyanate		Acute Tox. 3 H301 Acute Tox. 2 H330 Eye Damage 1 H318 Resp. Sens. 1 H334 Skin Sens. 1A H317 Aquatic Acute 1 H400 STOT Single Exp. 3 H335, affected organs: resp. tract Aquatic Chronic 1 H410, M- factor: 10.00 Acute Tox. 2 H331 [intermediate (active)] STOT Single Exp. 3 H335, affected organs: lung [intermediate (active)]
222- 023-7	3320- 83-0	2-chlorophenyl isocyanate		Aquatic Chronic 1 H410 [intermediate (active)] Aquatic Acute 1 H400 [intermediate (active)] Skin Corr. 1C H314 [intermediate (active)] Skin Sens. 1A H317 [intermediate (active)] Acute Tox. 1 H330 [intermediate (active)] Eye Damage 1 H318 [intermediate (active)]
SUB-GROUP 10				

ASSESSMENT OF REGULATORY NEEDS

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations ¹⁷
410-550-7	79277-18-2	methyl 3-isocyanatosulfonyl-2-thiophenecarboxylate	Index number: 615-022-00-1 STOT RE 2 Hazard Statement: H373 (Minimum classification; No information to prove exclusion of certain routes of exposure) Resp. Sens. 1 Statement: H334 Skin Sens. 1 Statement: H317	-
410-900-9	83056-32-0	2-(isocyanatosulfonylmethyl)benzoic acid methyl ester	Index number: 615-023-00-7 Flam. Liq. 3 Hazard Statement: H226 STOT RE 2 Hazard Statement: H373 (Minimum classification; No information to prove exclusion of certain routes of exposure) Hazard Category: Eye Dam. 1 Hazard Statement: H318 Muta. 2 Hazard Statement: H341 Acute Tox. 4 Hazard Statement: H332 (Minimum classification) Resp. Sens. 1 Statement: H334	-
223-810-8	4083-64-1	p-toluenesulphonyl isocyanate		Skin Irrit. 2 H315, specific concentration: >=5 Eye Irrit. 2 H319, specific concentration: >=5 Resp. Sens. 1 H334 STOT Single Exp. 3 H335, affected organs: Respiratory tract, specific concentration: >=5

ASSESSMENT OF REGULATORY NEEDS

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations ¹⁷
618- 297-6	897671 -34-0	Methyl 5-methyl- 4- [(oxomethylene)s ulfamoyl]thiophen e-3-carboxylate		Acute Tox. 3 H331 [intermediate (active)] Resp. Sens. 1 H334 [intermediate (active)] Eye Irrit. 2 H319 [intermediate (active)] Skin Sens. 1 H317 [intermediate (active)] Aquatic Chronic 3 H412 [intermediate (active)]
410- 220-2	77375- 79-2	ethyl 2- (isocyanatosulfony l)benzoate	Index number: 615-028- 00-4 Acute Tox. 4 Hazard Statement: H302 (Minimum classification) STOT RE 2 Hazard Statement: H373 (Minimum classification; No information to prove exclusion of certain routes of exposure) Hazard Category: Eye Dam. 1 Hazard Statement: H318 Resp. Sens. 1 Statement: H334 Skin Sens. 1 Statement: H317	-
SUB-GROUP 11				
402- 440-2	2094- 99-7	1-(1-isocyanato- 1-methylethyl)- 3-(1- methylethenyl)be nzene	Index number: 006-074- 00-0 Hazard Category: Skin Corr. 1B Hazard Statement: H314 STOT RE 2 Hazard Statement: H373 (Minimum classification; No information to prove exclusion of certain routes of exposure) Acute Tox. 2 Hazard Statement: H330 (Minimum classification) Aquatic Acute 1 Statement: H400 Aquatic Chronic 1 Statement: H410 Resp. Sens. 1 Statement: H334 Skin Sens. 1 Statement: H317	Acute Tox. 2 H330 Skin Corr. 1B H314 Eye Damage 1 H318 Resp. Sens. 1 H334 Skin Sens. 1 H317 STOT Rep. Exp. 2 H373, affected organs: lungs Aquatic Acute 1 H400 Aquatic Chronic 1 H410

ASSESSMENT OF REGULATORY NEEDS

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations ¹⁷
221- 165-7	3019- 71-4	trichloroacetyl isocyanate		-
926- 601-6	-	3- Isocyanatomethyl -3,5,5- trimethylcyclohex yl isocyanate, oligomers reaction product with 3- (cyclohexylamino)propane-1- sulfonic acid and N,N- dimethylcyclohex anamine		-
947- 972-0	-	Reaction products of 2,2,4- trimethylhexa- 1,6-diyl diisocyanate and 2,4,4- trimethylhexa- 1,6-diyl diisocyanate with 3- trimethoxysilylpr opane-1-thiol		Acute Tox. 3 H331 Resp. Sens. 1B H334 Skin Sens. 1A H317

ASSESSMENT OF REGULATORY NEEDS

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations ¹⁷
695- 953-8	20491 8-22-9	1-(allyloxy)-2- methyl-1- oxopropan-2-yl 2-chloro-5- isocyanatobenzoa te		-
214- 715-2	1189- 71-5	chlorosulphonyl isocyanate		Acute Tox. 4 H302 [intermediate (active)] Skin Corr. 1B H314 [intermediate (active)]
824- 760-5	14726 50-02- 4	1-isocyanato-2- (methoxymethyl) -3- methylbenzene		-
461- 690-0	-	Benzene, 1- isocyanato-4- (trichloromethyl)-		STOT Single Exp. 3 H335, affected organs: breath way organs [intermediate (inactive)] Acute Tox. 2 H330 [intermediate (inactive)] Eye Damage 1 H318 [intermediate (inactive)] Resp. Sens. 1 H334 [intermediate (inactive)] Skin Sens. 1 H317 [intermediate (inactive)] Skin Irrit. 2 H315 [intermediate (inactive)]
626- 058-2	28479 -19-8	626-058-2		Flam. Liquid 3 H226 [intermediate (active)] Acute Tox. 1 H330 [intermediate (active)] Skin Corr. 1B H314 [intermediate (active)] Skin Sens. 1 H317 [intermediate (active)] STOT Single Exp. 3 H335, affected organs: respiratoty tract [intermediate (active)] Acute Tox. 4 H302 [intermediate (active)] Eye Damage 1 H318 [intermediate (active)] Resp. Sens. 1 H334 [intermediate (active)]

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

Data extracted on 12/01/2022-17/03/2022

Subgroup*	1	2	3	4	5	6	7	8	9	10	11
Main types of applications structured by product or article types/Registration type	VII-X (20 subst) OSII/OSII OR TII (1 subst)	IX-X (9 subst)	VII-X (20 subst) OSII/OSII OR TII (1 subst)	VIII-IX (2 subst) OSII/OSII I OR TII (10 subst)	VII-IX (5 subst)	VII-IX (7 subst)	OSII/ OSII OR TII (7 subst)	OSII/OSI I OR TII (10 subst)	VII (4 subst) OSII/OSII OR TII (3 subst)	IX (1 subst) OSII/OSII OR TII (1 subst)	VII-VIII (2 subst) OSII/OSII OR TII (4 subst)
PC 1: Adhesives and sealants	F, I, P, C	I, P, C	F, I, P		I	F, I, P, C				F, I, P, C	F, I, P
PC 9a: Coatings, paints etc	F, I, P, C	I, P, C	F, I, P	F, P	F, I	F, I, P, C				F, I, P, C	F, I, P
PC 9b: Fillers etc.	F, I, P		F, I, P	F, P		F, I, P, C					
PC 18: Ink and toners	F, I, P		F, I, P		F, I	F, I					
PC 19: Intermediate	F, I, P		I	I	I	I	I	I	F, I	I	I
PC 21: Laboratory	I		F, I, P		I	I					
PC 32: Polymer preparations	F, I, P, C, A	I, P, C	F, I, P, A?	F, I, P		F, I, P, C		I		F, I, P	I
PC 35: Wash and clean	F, I, P	I, P	F, I, P	F, P		I					
PC 39: Cosmetics	F		F, P								
PC 13: Fuels	I, P		P	P							

* The substances included in each subgroup are identified at the beginning of this report

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 30/07/2021-19/08/2021.

EC numbers	RMOA	Authorisation		Restriction	CLH	Actions not under REACH/ CLP
		Candidate List	Annex XIV	Annex XVII	Annex VI (CLP)	
202-039-0	YES			YES		
202-112-7	YES*			YES	YES	
202-966-0	YES*			YES		
209-544-5	YES			YES		
212-485-8	YES			YES		
218-485-4	YES			YES	YES	
219-799-4	YES			YES		
220-474-4	YES			YES	YES	
221-641-4	YES			YES	YES	
222-852-4				YES	YES	
223-861-6	YES					
225-863-2	YES			YES		
227-534-9	YES*			YES		
247-714-0	YES					
247-722-4	YES*			YES		
247-953-0	YES*			YES		
500-040-3	YES					

*PBT assessment

Entry 56 of Annex XVII:

The legal text is reproduced below:

"Methylenediphenyl diisocyanate (MDI) CAS No 26447-40-5 EC No 247-714-0 including the following specific isomers: (a) 4,4'-Methylenediphenyl diisocyanate: CAS No 101-68-8 EC No 202-966-0; (b) 2,4'-Methylenediphenyl diisocyanate: CAS No 5873-54-1 EC No 227-534-9; (c) 2,2'-Methylenediphenyl diisocyanate: CAS No 2536-05-2 EC No 219-799-4

1. Shall not be placed on the market after 27 December 2010, as a constituent of mixtures in concentrations equal to or greater than 0,1 % by weight of methylenediphenyl diisocyanate (MDI) for supply to the general public, unless suppliers shall ensure before the placing on the market that the packaging:

(a) Contains protective gloves which comply with the requirements of Council Directive 89/686/EEC (*);

(b) Is marked visibly, legibly and indelibly as follows, and without prejudice to other Community legislation concerning the classification, packaging and labelling of substances and mixtures: — Persons already sensitised to diisocyanates may develop allergic reactions when using this product. — Persons suffering from asthma, eczema or skin problems should avoid

contact, including dermal contact, with this product. — This product should not be used under conditions of poor ventilation unless a protective mask with an appropriate gas filter (i.e. type A1 according to standard EN 14387) is used.

2. By way of derogation, paragraph 1(a) shall not apply to hot melt adhesives.”

Entry 74 of Annex XVII for diisocyanates

The legal text is reproduced below:

“Diisocyanates, $O = C=N-R-N = C=O$, with R an aliphatic or aromatic hydrocarbon unit of unspecified length

1. Shall not be used as substances on their own, as a constituent in other substances or in mixtures for industrial and professional use(s) after 24 August 2023, unless:

(a) the concentration of diisocyanates individually and in combination is less than 0,1 % by weight, or

(b) the employer or self-employed ensures that industrial or professional user(s) have successfully completed training on the safe use of diisocyanates prior to the use of the substance(s) or mixture(s).

2. Shall not be placed on the market as substances on their own, as a constituent in other substances or in mixtures for industrial and professional use(s) after 24 February 2022, unless:

(a) the concentration of diisocyanates individually and in combination is less than 0,1 % by weight, or

(b) the supplier ensures that the recipient of the substance(s) or mixture(s) is provided with information on the requirements referred to in point (b) of paragraph 1 and the following statement is placed on the packaging, in a manner that is visibly distinct from the rest of the label information: “As from 24 August 2023 adequate training is required before industrial or professional use”.

3. For the purpose of this entry “industrial and professional user(s)” means any worker or self-employed worker handling diisocyanates on their own, as a constituent in other substances or in mixtures for industrial and professional use(s) or supervising these tasks.

4. The training referred to in point (b) of paragraph 1 shall include the instructions for the control of dermal and inhalation exposure to diisocyanates at the workplace without prejudice to any national occupational exposure limit value or other appropriate risk management measures at national level. Such training shall be conducted by an expert on occupational safety and health with competence acquired by relevant vocational training.

6. The training shall comply with the provisions set by the Member State in which the industrial or professional user(s) operate. Member States may implement or continue to apply their own national requirements for the use of the substance(s) or mixture(s), as long as the minimum requirements set out in paragraphs 4 and 5 are met.

7. The supplier referred to in point (b) of paragraph 2 shall ensure that the recipient is provided with training material and courses pursuant to paragraphs 4 and 5 in the official language(s) of the Member State(s) where the substance(s) or mixture(s) are supplied. The training shall take into consideration the specificity of the products supplied, including composition, packaging, and design. 8. The employer or self-employed shall document the successful completion of the training referred to in paragraphs 4 and 5. The training shall be renewed at least every five years.

9. Member States shall include in their reports pursuant to Article 117(1) the following information: (a) any established training requirements and other risk management measures related to the industrial and professional uses of diisocyanates foreseen in national law; (b) the number of cases of reported and recognised occupational asthma and occupational respiratory and dermal diseases in relation to diisocyanates; (c) national exposure limits for diisocyanates, if there are any;

10. This restriction shall apply without prejudice to other Union legislation on the protection of safety and health of workers at the workplace."

RAC Opinion on the scientific evaluation of occupational exposure limits for diisocyanates¹⁸

A NCO group (R-N=C=O) approach for all diisocyanates is proposed, since diisocyanates share a common mechanism of inducing hypersensitivity reactions and there is not enough data to assess differences in potency for different diisocyanates.

Isocyanates are organic compounds that contain one or more functional groups with the molecular formula -N=C=O. The term polyisocyanate is commonly used when referring to an isocyanate containing multiple isocyanate functional groups. The isocyanates considered in this report have two isocyanate functional groups and are referred to as diisocyanates. Diisocyanates are the most common group of isocyanates used at the workplace. They are highly reactive compounds and undergo rapid exothermic reactions with all kinds of nucleophiles. In the reactive group (R-N=C=O) R can be aliphatic, cycloaliphatic or an aromatic group. Aromatic isocyanates are more reactive than aliphatic isocyanates. The diisocyanates considered in this proposal are those for which safety data are available, for which use at higher tonnages is known and which data could be extracted from registration dossiers. In total there are 28 diisocyanates either registered or with harmonised classification and 11 registered diisocyanates, which are individually registered for at least 1 000 t/a, account for > 99.9 % of the registered tonnage.

The table below presents the outcome of the RAC evaluation to derive limit values for diisocyanates.

Derived Limit Values

¹⁸ RAC Opinion on the scientific evaluation of occupational exposure limits for diisocyanates, link to the document at: [4ea3b5ee-141b-63c9-8ffd-1c268dda95e9 \(europa.eu\)](https://europea.europa.eu/4ea3b5ee-141b-63c9-8ffd-1c268dda95e9); Annex 1 in support of the Committee for Risk Assessment (RAC) for evaluation of limit values for diisocyanates at the workplace; ECHA/RAC/A77-O-0000006826-64-01/F; 11 June 2020; link to the document at: [b74681f6-b553-56de-68bb-7b329cb03b2b \(europa.eu\)](https://europea.europa.eu/b74681f6-b553-56de-68bb-7b329cb03b2b)

OEL as 8-hour time weighted average (TWA) exposure:	A threshold for bronchial hyper-responsiveness or for the development of asthma, could not be observed.	
	However, an OEL defined as an 8-hour time weighted average (TWA) exposure based on the 'NCO group' can be obtained from the exposure - excess risk relationships for hyperresponsiveness or diisocyanate asthma as derived below.	
	Excess risk over a working life period	Exposure - response relations derived from Pronk et al. (2009), and Collins et al. (2017), in $\mu\text{g}/\text{m}^3$ NCO in air
	0.1%	<0.025
	0.5%	0.027-0.040
	1%	0.055-0.070
	2%	0.12-0.19
	3%	0.22-0.33
4%	0.40-0.48	
5%	>0.67	
STEL:	A 15-minutes Short Term Exposure Limit (STEL) value which is maximally a factor 2 higher than a derived OEL based on the exposure - excess risk relation. This STEL value should not exceed $6 \mu\text{g}/\text{m}^3$ NCO.	
BLV:	No BLV	
BGV:	Set at the limits of quantification (LOQs) for relevant diisocyanate metabolites (diamines) in urine	

Notations

Notations:	skin sensitisation, respiratory sensitisation, 'skin'
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Plastics Regulation (EC) 10/2011

Annex I of Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food as regards information in the supply chain lists the following diisocyanates: mixture of (40 % w/w) 2,2,4-trimethylhexane-1,6-diisocyanate and (60 % w/w) 2,4,4-trimethylhexane-1,6-diisocyanate; 2,6-toluene diisocyanate; diphenylmethane-4,4'-diisocyanate; 2,4-toluene diisocyanate; hexamethylene diisocyanate; 1,5-naphthalene diisocyanate; diphenylether-4,4'-diisocyanate; dicyclohexylmethane-4,4'-diisocyanate; diphenylmethane-2,4'-diisocyanate and 2,4-toluene diisocyanate dimer. For these substances it is required that isocyanate migration from plastic packaging should not be analytically detectable in the food, and that the content of isocyanates in the food plastic material must not exceed 1 mg/kg in the final product expressed as isocyanate moiety.

Cosmetic Products Regulation (EC) 1223/2009

Toluene 2,6-diisocyanate, toluene 2,4-diisocyanate and toluene diisocyanate are included in the list of substances prohibited in cosmetic products (Annex II) of the Commission Regulation 1223/2009 on cosmetic products.