

COLLECTION OF PHRASES FOR REGISTRATION DOSSIERS

Update: July 2010

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When models are referred to in the waiving statement, the following should be stated:

- the substance falls within the applicability domain of the model
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IUCLID5 Section (including sub-section)	IUCLID5 Section (description)	Phrase	Comments/remarks
1.4	1.4 Analytical information	This test technique is not applicable for analysis because it will require sophisticated, advanced and non-routine handling of test samples. Furthermore for flammable gases it could arise in hazardous testing conditions.	Gases (LC), UV, IR and NMR
1.4	1.4 Analytical information	This test technique has not been applied, because it will not provide additional information beyond the other testing method(s) which will have been utilised. Detailed compositional analysis can be obtained by GC and/or GC/MS. Further evidence for functional groups and for obtaining average composition can be obtained by utilising NMR. The test methods used for each of the types of Substances will define and describe the desired conditions of the test conditions itself. The test methodology applied will allow sufficient identification of the molecular nature of the Substance	Volatile Liquids (LC), UV, and IR
1.4	1.4 Analytical information	Only if additional proof of structure is required, for functional group identification or average molecular structure.	Volatile Liquids (NMR)
1.4	1.4 Analytical information	This test technique has not been applied, because it will not provide additional information beyond the other testing method(s) which will have been utilised. Detailed compositional analysis can be obtained by GC and/or GC/MS. Further evidence for functional groups and for obtaining average composition can be obtained by utilising NMR. The test methods used for each of the types of Substances will define and describe the desired conditions of the test conditions itself. The test methodology applied will allow sufficient identification of the molecular nature of the Substance	Solids (UV) and IR
1.4	1.4 Analytical information	Only if additional proof of structure is required, for functional group identification or average molecular structure.	Solids (NMR)
1.4	1.4 Analytical information	Substance name, CAS-No. XX-YY-Z. EC-No. XXX-YYY-Z is exclusively registered under Article 17 (and/or 18) of Regulation (EC) 1907/2006 (REACH) as an on-site isolated (and/or transported isolated intermediate. Spectral and chromatographic data are therefore not required for this substance.	Field "Analytical methods and spectral data" In case that the substance is exclusively registered as an intermediate according to Art. 17 or 18 of the REACH regulation
1.4	1.4 Analytical information	From the structure of the substance it can be concluded that the substance is not optically active or Not relevant (UVCB substance)	Field "Optical activity"
4.10	4.10 Surface tension	In accordance with Column 2 of Annex VII Section 7.6 of the REACH regulation the study does not need to be conducted if the water solubility is below 1mg/L at 20 deg C.	
4.10	4.10 Surface tension	In accordance with Column 2 adaptation statement of REACH Annex VII, information requirement section 7.6, this study does not need to be conducted if (the water solubility is < 1 mg/L @ 20°C or based on structure, surface activity is not expected and no surface-active properties would be predicted for this compound. Surface activity is not a desired property of the material.)	Note, where there is blue text or multiple statements, choose correct option.
4.10	4.10 Surface tension	In accordance with column 2 of REACH Annex VII, this study does not need to be conducted as, based on structure, surface activity is not expected.	
4.11	4.11 Flash point	Flash point is a property relevant to liquids and low melting point solids and so is waived in accordance with Section 2 of annex XI of the REACH regulation.	
4.11	4.11 Flash point	In accordance with Column 2 adaptation statement of REACH Annex VII, information requirement section 7.9, this study is not required for (inorganic substances, substances with only volatile organic components with flash points >100°C for aqueous solutions, the estimated flash point is >200°C).	Note, where there are multiple statements, choose correct option.
4.11	4.11 Flash point	In accordance with Section 2 of REACH Annex XI, information requirement section 7.9, this study does not need to be conducted based on the physical state of the substance. According to ECHA guidance, flash point is only relevant to substances that are liquid at room temperature.	IUC5 Data Waiving: Study technically not feasible
4.12	4.12 Auto flammability	In accordance with Column 2 of Annex VII Section 7.12 and Section 2 of annex XI of the REACH regulation the study is not required for liquids that have a flash point of > 200 Deg C.	
4.12	4.12 Auto flammability	In accordance with Column 2 adaptation statement of REACH Annex VII, information requirement section 7.12, this study does not need to be conducted (for explosive or pyrophoric substances, liquids with flash point > 200oC, non flammable gases or solids with melting points < 160oC)	Note, where there are multiple statements, choose correct option.
4.13	4.13 Flammability	In accordance with REACH Annex XI this study is scientifically unjustified. The flammability of liquids is determined on basis of their flashpoint (in combination with their boiling point), their ability to emit flammable gases upon contact with water and their pyrophoricity. The molecular structure of xxxxxx does not contain groups that indicate potential reactivity with water or pyrophoric properties and handling of the substance indicates that this is the case.	
4.13	4.13 Flammability	- study scientifically unjustified: In accordance with section 1.5 of REACH Annex XI, the study does not need to be performed as based on chemical structure pyrophoric properties are not to be expected.	
4.13	4.13 Flammability	- study scientifically unjustified: In accordance with section 1.5 of REACH Annex XI, the study does not need to be performed as based on chemical structure water reactivity is not to be expected.	
4.13	4.13 Flammability	For liquids the primary value for ease of ignition is the flash point conducted using Method A9 'Flash Point Method' of Council Regulation (EC) No 440/2008. The result of the Flash Point test is used to allocate a liquid substance into the appropriate flammability class. Other measures of flammability include pyrophoricity and flammability on contact with water. These can be considered not a concern for the substance and testing waived if consideration of the structure and experience in handling and use show that no effects are envisaged. Such a screening procedure represents an intelligent testing strategy for flammability. If applied correctly then only liquid substances for which it is suspected will give a positive result in either the pyrophoric properties or flammability on contact with water tests need to be tested. A review of the structure suggests that there are no chemical groups present that would imply pyrophoric properties or flammability on contact with water. A	Relevant to fulfill section 4.13 of IUCLID to justify omission of Annex VII point 7.10 where a flash point has been carried out.

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IUCLID5 Section (including sub-section)	IUCLID5 Section (description)	Phrase	Comments/remarks
4.13	4.13 Flammability	In accordance with section 1 of REACH Annex XI testing does not appear scientifically necessary. The flammability of liquids is determined on basis of their flashpoint (in combination with their boiling point), their ability to emit flammable gases upon contact with water and their pyrophoricity. The molecular structure of XXXX does not contain groups that indicate potential reactivity with water or pyrophoric properties. The flashpoint is already reported, indicating that XXXX is a highly flammable liquid.	
4.13	4.13 Flammability	In accordance with Column 2 adaptation statement of REACH Annex VII, information requirement section 7.10, this study does not need to be conducted based on a structural assessment of the substance. OR this study is not required for explosive or pyrophoric solids, or for substances that ignite on contact with air.	Note, where there is blue text or multiple statements, choose correct option.
4.14	4.14 Explosiveness	In accordance with column 2 of REACH annex VII the explosivity test does not have to be conducted as xxxxxx contains no chemical groups associated with explosivity	
4.14	4.14 Explosiveness	- study scientifically unjustified: In accordance with section 1 of REACH Annex XI, the explosiveness does not need to be performed as the substance is a gas.	
4.14	4.14 Explosiveness	In accordance with Column 2 of section 7.11 of REACH Annex VII, the full study has not been conducted as there are no chemical groups associated with explosive properties present in the substance.	
4.14	4.14 Explosiveness	In accordance with column 2 of REACH Annex VII, the study does not need to be conducted. Potential explosive properties are indicated by the presence of certain reactive groups in the molecule and/or by the oxygen balance. Since XXXX is an ether, the molecular structure shows potential reactivity. However, the oxygen balance of XXXX is -272, where only an oxygen balance higher than -200 indicates the potential presence of explosive properties. Therefore, explosive properties are not expected.	
4.14	4.14 Explosiveness	In accordance with Column 2 adaptation statement of REACH Annex VII, information requirement section 7.11, this study does not need to be conducted based on a structural assessment of the substance. Examination of the structure indicates that there are no groups associated with explosive properties.	
4.14	4.14 Explosiveness	In accordance with Section 2 of REACH Annex XI, information requirement section 7.11, this study does not need to be conducted based on the physical state of the molecule. According to ECHA guidance, measurement of explosivity is not required for gases.	IUC5 Data Waiving: Study technically not feasible
4.14	4.14 Explosiveness.	If the substance does not contain any groups associated with explosivity then a negative result is likely. For many substances, the absence of structural alerts will mean that testing is not necessary. This would form the basis of a suitable justification for non-testing. Proposed waiver sentence: According to Reach Annex VII end point 7.11, the study does not need to be conducted if there are no chemical groups associated with explosive properties present in the molecule. This is the case for this substance. Alternative waiving statements (a) In accordance with column 2 of REACH Annex VII, the study does not need to be conducted because on the basis of its chemical structures, there are no chemical groups in the product associated with explosive properties. (b) The material does not contain any functional groups quoted in 'Manual of Tests and Criteria' (fourth revised edition, appendix 6, table A 6.1) or Bretherick's – Handbook (6th Edition, Volume 2, p 128 ff) which may indicate explosive properties. Therefore, it can be concluded by expert judgement that this substance is not explosive. The determination according to EC Guideline A 14 is not necessary	
4.15	4.15 Oxidising properties	Proposed waiver sentence: In accordance with column 2 of REACH Annex VII, the oxidising properties study does not need to be conducted as the substance is incapable of reacting exothermically with combustible materials on the basis of its chemical structure.	
4.15	4.15 Oxidising properties	(a) In accordance with column 2 of REACH Annex VII, the study does not need to be conducted because on the basis of its chemical structure, the substance is incapable of reacting exothermically with combustible materials.	
4.15	4.15 Oxidising properties	(b) The material does not contain any functional groups quoted in 'Manual of Tests and Criteria' (fourth revised edition, appendix 6, chapter 6) which may indicate oxidizing properties. Therefore, it can be concluded by expert judgement that this substance has no oxidizing properties in the sense of EC Guideline A 21. The determination according to EC Guideline A 21 is not necessary.	
4.15	4.15 Oxidising properties	In accordance with column 2 of REACH Annex VII, this study does not need to be conducted as this substance is incapable of reacting exothermically with combustible materials on the basis of its chemical structure.	
4.15	4.15 Oxidising properties	In accordance with Column 2 of REACH Annex VII (7.13), the full study has not been conducted as the substance is incapable of reacting exothermically with combustible materials on the basis of chemical structure.	
4.15	4.15 Oxidising properties	In accordance with column 2 of REACH Annex VII, the study does not need to be conducted as the substance does not contain oxygen or halogen atoms chemically bonded to nitrogen or oxygen. Furthermore, in accordance with column 2 of REACH Annex VII, the study does not need to be conducted as the substance is highly flammable.	
4.15	4.15 Oxidising properties	In accordance with Column 2 adaptation statement of REACH Annex VII, information requirement 7.13, this study does not need to be conducted based on structural assessment of the substance. The substance contains no oxidising groups and all (oxygen, halogen) atoms are bonded directly to	Note, where there is blue text or multiple statements, choose correct option.
4.17	4.17 Stability in organic solvents.	According to Reach Annex IX, column 1 of end point 7.15, this study is only required if stability of the substance is considered to be critical. Stability in solvents is not critical for this substance.	

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4.17	4.17 Stability in organic solvents.	In accordance with column 1 of REACH Annex IX, the study is only required if stability of the substance is considered to be critical.	
4.17	4.17 Stability in organic solvents and identity of relevant degradation products	In accordance with column 2 of REACH annex IX, it is not expected that the stability of xxxxx in organic solvents is critical.	
4.17	4.17 Stability in organic solvents and identity of relevant degradation products	The substance is inorganic and so the study has been omitted in accordance with Column 2 of Annex IX Section 7.16 of the REACH regulation.	
4.17	4.17 Stability in organic solvents and identity of relevant degradation products	In accordance with section 1 of REACH Annex XI testing does not appear scientifically necessary as XXXX is a stable chemical and is not expected to show instability when mixed with typical organic solvents.	
4.17	organic solvents and identity of relevant degra	In accordance with Column 2 adaptation statement of REACH Annex IX, information requirement section 7.15, this study does not need to be conducted since the stability in organic solvents is not considered critical. This would be assessed in individual studies where organic solvents are used.	
4.2	4.2 Melting point/freezing point	In accordance with Column 2 adaptation statement of REACH Annex VII, Information requirement section 7.2, this study does not need to be conducted below a lower limit of -20 °C.	
4.21	4.21 Dissociation constant	In accordance with REACH Annex XI this study is not scientifically relevant: due to the chemical structure, no dissociation is to be expected under naturally relevant pH conditions.	
4.21	4.21 Dissociation constant	- study scientifically unjustified: In accordance with section 1 of REACH Annex XI, the dissociation constant study does not need to be performed because the substance does not contain any ionic structure.	
4.21	4.21 Dissociation constant	- study scientifically unjustified: In accordance with section 1 of REACH Annex XI, the dissociation constant study does not need to be performed as the substance is not soluble in water.	
4.21	4.21 Dissociation constant	- study scientifically unjustified: In accordance with section 1 of REACH Annex XI, the dissociation constant study does not need to be performed as the substance is a salt. Salts are reaction products of acids and bases that retain their ionic character.	
4.21	4.21 Dissociation constant	In accordance with REACH Annex IX column 2, the study does not need to be conducted if the substance is hydrolytically unstable. In the present case the hydrolysis half-life of the test substance is < 12 hours and hence the study is not required.	
4.21	4.21 Dissociation constant	In accordance with REACH Annex IX column 2, the study does not need to be conducted if it is scientifically not possible to perform testing because analytical methods are not sensitive enough.	
4.21	4.21 Dissociation constant	In accordance with Column 2 adaptation statement of REACH Annex IX, information	Note, where there is blue text or multiple statements, choose correct option.
4.21	4.21 Dissociation constant	In accordance with Section 2 of REACH Annex XI, information requirement section 7.16, this study does not need to be conducted as the test substance has no dissociable groups. According to ECHA Chapter 7, pKa is irrelevant.	IUC5 Data Waiving: Study technically not feasible
4.21	4.21 Dissociation constant.	In accordance with REACH Chapter R.7A Endpoint Specific Guidance, specifically R.7.1.17.1 Information Requirements on Dissociation Constant, if the substance cannot dissociate due to a lack of relevant functional groups, the dissociation constant is irrelevant. does not contain functional groups subject to dissociation, consequently a study is not justified.	
4.21	4.21 Dissociation constant.	In accordance with column 2 of REACH Annex IX, this study does not need to be conducted because on the basis of its chemical structure the product does not include any ionisable atoms or functional groups.	
4.22	4.22 Viscosity	- study technically not feasible: In accordance with section 2 of REACH Annex XI, the viscosity does not need to be performed as the substance is a solid.	
4.22	4.22 Viscosity	SOLIDS: Viscosity is a property relevant only to liquids.	
4.22	4.22 Viscosity	In accordance with Section 2 of REACH Annex XI, information requirement section 7.17, this study cannot be conducted on solid materials or gases. According to ECHA Chapter 7 guidance, viscosity measurement is only relevant to liquids.	IUC5 Data Waiving: Study technically not feasible
4.3	4.3 Boiling point	The study is not needed for solids which melt above 300 DegC or decompose before boiling and has been omitted in accordance with Column 2 of Annex VII Section 7.3 of the REACH regulation.	
4.3	4.3 Boiling point	In accordance with Column 2 adaptation statement of REACH Annex VII, information	Note, where there is blue text or multiple statements, choose correct option.
4.4	4.4 Density	The study is not required as the substance is only stable in [solvent] and the solution density is similar to that of [solvent]. The solution density is [higher][lower] than the solvent density. The study is omitted in accordance with Column 2 of Annex VII Section 7.4 and Section 2 of annex XI of the REACH regulation.	
4.4	4.4 Density	In accordance with Column 2 adaptation statement of REACH Annex VII, information requirement section 7.4, this study does not need to be conducted since the substance is a gas. The value can be calculated based on molecular weight and Ideal Gas Law	
4.5	4.5 Particle size distribution (Granulometry)	In accordance with Reach Annex XI section 1 this study is not scientifically justified: xxxxxx is a solidified liquid at room temperature, forming a ductile mass. Smaller particles are not formed when handling the ductile mass. Therefore a particle size distribution is not necessary because not relevant for the marketed substance.	
4.5	4.5 Particle size distribution (Granulometry)	- other justification: In accordance with column 2 of REACH Annex VII, the study does not need to be conducted as the substance is marketed or used in a non solid or granular form. It is a solid which is produced and formulated only in wet processes.	
4.5	4.5 Particle size distribution (Granulometry)	The substance is a viscous liquid at room temperature and as such this study is not technically feasible and has been omitted in accordance with Column 2 of Annex VII Section 7.14 and Section 2 of annex XI of the REACH regulation.	
4.5	4.5 Particle size distribution (Granulometry)	The substance is marketed in a non-solid form and as such this study is not required and has been omitted in accordance with Column 2 of Annex VII Section 7.14.	
4.5	4.5 Particle size distribution (Granulometry)	In accordance with column 2 of REACH Annex VII, a granulometry study does not need to be conducted as XXXX is manufactured and used in a non solid (liquid) form.	
4.5	4.5 Particle size distribution (Granulometry)	In accordance with Column 2 adaptation statement of REACH Annex VII, information	Note, where there is blue text or multiple statements, choose correct option.

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4.5	4.5 Particle size distribution.	In accordance with REACH Chapter R.7A Endpoint Specific Guidance, specifically R.7.1.14.1 Information requirements on granulometry, the granulometry study does not need to be conducted as the substance is marketed or used in a non solid or granular form.	
4.5	4.5 Particle size distribution.	Alternative waiving statement In accordance with column 2 of REACH Annex VII, the particle size distribution study (granulometry) does not need to be conducted because the substance is not marketed or used in any solid or granular form	
4.6	4.6 Vapour pressure	- study scientifically unjustified: In accordance with section 1 of REACH Annex XI, vapour pressure testing is not required for chemicals with a standard boiling point of < 30 °C, as these substances will have vapour pressures above the limit of measurement.	
4.6	4.6 Vapour pressure	Study not needed. The melting point is above 300 Deg C and hence the study has been omitted in accordance with Column 2 of Annex VII Section 7.5.	
4.6	4.6 Vapour pressure	In accordance with Column 2 adaptation statement of REACH Annex VII, information requirement section 7.5, this study does not need to be conducted if the melting point is >300 C.	
4.6	4.6 Vapour pressure	In accordance with Section 2 of REACH Annex XI, information requirement section 7.5, this study does not need to be conducted as the boiling point is less than 30 C. According to ECHA guidance, it is not possible to conduct the study.	IUC5 Data Waiving: Study technically not feasible
4.7	4.7 Partition coefficient	The substance is inorganic and so the study has been omitted in accordance with Column 2 of Annex VII Section 7.8 and Section 2 of annex XI of the REACH regulation.	
4.7	4.7 Partition coefficient	In accordance with Column 2 of Annex VII Section 7.8 and Section 2 of annex XI of the REACH regulation the test cannot be performed as the substance [decomposes] [has a high surface activity] [reacts violently during the performance of the test] [does not dissolve in water or in octanol].	in these cases Column 2 of Annex VII also states that a calculated value for log P as well as details of the calculation method shall be provided
4.7	4.7 Partition coefficient	In accordance with Column 2 adaptation statement of REACH Annex VII, information requirement section 7.8, this study is not needed for inorganic substances.	
4.8	4.8 Water solubility	In accordance with Section 2 of REACH Annex XI, information requirement section 7.8, this study does not need to be conducted as the test substance is hydrolytically unstable at pH 4, 7 and 9 (t _{1/2} < 12 hr)	IUC5 Data Waiving: Study technically not feasible
4.7	4.7 Partition coefficient	Substance is a hydrocarbon UVCB. Standard tests for this endpoint are intended for single substances and are not appropriate for this complex substance. However, this endpoint is characterized for representative hydrocarbon structures that comprise the hydrocarbon blocks used to assess the environmental risk of this substance with the PETRORISK model	
4.8	4.8 Water solubility	The study does not need to be conducted as the substance is [hydrolytically unstable at pH 4, 7 and 9 (half-life < 12 hours)] [readily oxidisable in water]. This is in accordance with Column 2 of Annex VII Section 7.7 and Section 2 of annex XI of the REACH regulation.	
4.8	4.8 Water solubility	In accordance with Column 2 adaptation statement of REACH Annex VII, information	Note, where there is blue text or multiple statements, choose correct option.
4.8	4.8 Water solubility	Substance is a hydrocarbon UVCB. Standard tests for this endpoint are intended for single substances and are not appropriate for this complex substance. However, this endpoint is characterized for representative hydrocarbon structures that comprise the hydrocarbon blocks used to assess the environmental risk of this substance with the PETRORISK model	
5.1.2	5.1.2 Hydrolysis	In accordance with REACH Annex VIII column 2, the study does not need to be conducted if the substance is readily biodegradable or highly insoluble in water.	
5.1.3	5.1.3 Phototransformation in water	Direct photolysis will not be an important removal process since this class of substances does not absorb light at wavelengths >290 nm. The UV-spectrum (max at 289 nm) indicates that direct photolysis in water will not occur.	
5.2.2	5.2.2 Biodegradation in water and sediment: simulation tests	In accordance with column 2 of REACH annex IX, further degradation testing does not need to be conducted as the chemical safety assessment does not indicate a need for further investigation.	
5.2.2	Biodegradation in water and sediment: simulation tests	In accordance with Section 3 of REACH Annex XI, Substance-tailored exposure driven testing; simulation testing on ultimate degradation in surface water, information requirement 9.2.1.2 in Annex IX, may be omitted based on the exposure scenarios developed in the Chemical Safety Report. Justification and documentation are provided in Chapter 9 based on a thorough and rigorous exposure assessment in accordance with section 5 of Annex I.	IUC5 Data Waiving: Exposure considerations
5.2.2	Biodegradation in water and sediment: simulation tests	In accordance with Column 2 adaptation statement of REACH Annex IX, sediment simulation testing, information requirement 9.2.1.4 does not need to be conducted as direct and indirect exposure to sediment is unlikely. The test substance entering the water is not likely to sorb onto suspended solids and sediment based upon the calculated Kow (CSR section 1.3 Physico-Chemical Properties), mitigating exposure to sediment. See supporting sorption data (CSR section 4.2.1 Adsorption/desorption) and exposure assessment information (CSR Chapter 9).	IUC5 Data Waiving: other justification
5.2.2	Biodegradation in water and sediment: simulation tests	In accordance with Section 3 of REACH Annex XI, Substance-tailored exposure driven testing, Confirmatory testing on biodegradation rates (aerobic and/or anaerobic), information requirement 9.2.1 in Annex X, may be omitted, based on the exposure scenario(s) developed in the Chemical Safety Report. Justification and documentation are provided in CSR Chapter 9 based on a thorough and rigorous exposure assessment in accordance with section 5 of Annex I.	IUC5 Data Waiving: Exposure considerations
5.2.3	5.2.3 Biodegradation in soil	In accordance with column 2 of REACH annex IX, further degradation testing does not need to be conducted as the chemical safety assessment does not indicate a need for further investigation.	
5.2.3	5.2.3 Biodegradation in soil	In accordance with Column 2 adaptation statement of REACH Annex IX, information requirement 9.2.1.3, soil simulation testing does not need to be conducted as there is no direct or indirect exposure to soil for this test substance. See supporting exposure assessment information (CSR Chapter 9).	IUC5 Data Waiving: other justification
5.2.3	5.2.3 Biodegradation in soil	In accordance with Section 3 of REACH Annex XI, Substance-tailored exposure driven testing, Confirmatory testing on biodegradation rates (aerobic and/or anaerobic), information requirement 9.2.1 in Annex X, may be omitted, based on the exposure scenario(s) developed in the Chemical Safety Report. Justification and documentation are provided in CSR Chapter 9 based on a thorough and rigorous exposure assessment in accordance with section 5 of Annex I.	IUC5 Data Waiving: Exposure considerations

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5.2.3	5.2.3 Biodegradation in soil	Substance is a hydrocarbon UVCB. Standard tests for this endpoint are intended for single substances and are not appropriate for this complex substance. However, this endpoint is characterized using quantitative structure property relationships for representative hydrocarbon structures that comprise the hydrocarbon blocks used to assess the environmental risk of this substance with the PETRORISK model	Used QSARs should be applicable and justified for UVCB substance (compounds of it).
5.3.1	5.3.1 Bioaccumulation: aquatic / sediment	In accordance with column 2 of REACH Annex IX, the bioaccumulation in aquatic species study does not need to be conducted as the substance has a low potential for bioaccumulation (the substance has a log octanol water partition coefficient less than 3).	
5.4.1	5.4.1 Adsorption / desorption	In accordance with column 2 of REACH annex VIII, the adsorption/desorption screening test does not have to be conducted as xxxxxx has a low octanol water partition coefficient	
5.4.1	5.4.1 Adsorption / desorption	In accordance with Column 2 adaptation statement of REACH Annex VIII and IX, adsorption/desorption screening and further studies on adsorption/desorption, information requirements 9.3.1 and 9.3.3, may be omitted since the log Kow value for the test substance is <3.0 (CSR sections 1.3 and 4.2.1) and has low potential for adsorption.	IUC5 Data Waiving: other justification
5.4.1	5.4.1 Adsorption/desorption screening study (HPLC method)	Substance is a hydrocarbon UVCB. Standard tests for this endpoint are intended for single substances and are not appropriate for this complex substance. However, this endpoint is characterized using quantitative structure property relationships for representative hydrocarbon structures that comprise the hydrocarbon blocks used to assess the environmental risk of this substance with the PETRORISK model	Used QSARs should be applicable and justified for UVCB substance (compounds of it).
5.6	Additional information on environmental fate and behavior	In accordance with Section 3 of REACH Annex XI, Substance-tailored exposure driven testing; further environmental studies on the substance and/or degradation products, information requirement 9.3.4 in Annex X, may be omitted based on the exposure scenarios developed in the Chemical Safety Report. Justification and documentation are provided in Chapter 9 based on a thorough and rigorous exposure assessment in accordance with section 5 of Annex I.	IUC5 Data Waiving: Exposure considerations
6.1	6.1 Aquatic toxicity	B. READ ACROSS (DAPHNIA to FISH long term)	
6.1	6.1 Aquatic toxicity	In Annex IX of Regulation (EC) No 1907/2006, it is laid down that long-term toxicity testing shall be proposed by the registrant if the chemical safety assessment indicates the need to investigate further the effects on aquatic organisms.	
6.1.2.	6.1.2 Long-term toxicity to fish	C. No data available aquatic endpoints: PETROTOX	
6.1.3.	6.1.3 Short-term toxicity to aquatic invertebrates	B.1. Between species	
6.1.4	6.1.4 Long-term toxicity to aquatic invertebrates	In accordance with column 2 of REACH annex IX, further degradation testing does not need to be conducted as the chemical safety assessment does not indicate a need for further investigation.	
6.1.5.	6.1.5 Toxicity to aquatic algae and cyanobacteria	Read across has been applied for this endpoint. Toxic effects of hydrocarbons are primarily caused by narcosis, and occur in a narrow range of molar concentrations across aquatic taxa; hence, read across between species is justified (justification provided in CSR).	
6.1.7.	6.1.7 Toxicity to microorganisms	Read across to results from a different product has been applied for this endpoint. Data for [substance name] represent a worse case assessment of the toxic effects of this substance.	
6.1.7	6.1.7 Toxicity to microorganisms	In accordance with column 2 of REACH Annex VIII, the activated sludge respiration inhibition test does not need to be conducted as this substance was found to be readily biodegradable and the applied test concentrations are in the range of concentrations that can be expected in the influent of a sewage treatment plant.	
6.1.7	6.1.7 Toxicity to microorganisms	In accordance with Column 2 adaptation statement of REACH Annex VIII, activated sludge respiration inhibition testing, information requirement 9.1.4, study does not need to be conducted if there is no emission to a sewage treatment plant. See supporting information in CSR Chapter 9 exposure assessment.	IUC5 Data Waiving: other justification
6.2	6.2 Sediment toxicity	In accordance with column 2 of REACH annex X, further degradation testing does not need to be conducted as the chemical safety assessment does not indicate a need for further investigation.	
6.2	6.2 Sediment toxicity	For substances being considered as 'readily', it can be assumed that they will be completely biologically degraded within the STP process. Furthermore, for substances not passing the STP-process but being readily, it can be assumed that they will be also biological degraded in the surface water within a short time. Therefore tests on sediment organisms are not provided.	
6.2	6.2 Sediment toxicity	In accordance with column 2 of REACH Annex X, the study on sediment organisms does not need to be conducted as direct and indirect exposure of the sediment compartment is unlikely, which was demonstrated in the EU RAR.	
6.2	6.2 Sediment toxicity	Substance is a hydrocarbon UVCB. Standard tests for this endpoint are intended for single substances and are not appropriate for this complex substance. However, this endpoint is characterized for representative hydrocarbon structures that comprise the hydrocarbon blocks used to assess the environmental risk of this substance with the	DATA WAIVING 9.5.1
6.3	6.3 Terrestrial toxicity	The test substance is not supposed to be directly applied to soil and an indirect exposure to soil via sewage sludge transfer is unlikely since the substance is readily biodegradable. For a substance being considered as 'readily biodegradable', it can be assumed that it will be biodegraded within the STP process and as a consequence a transfer to the soil compartment is not expected. Therefore, no tests on terrestrial organisms are provided. [Additionally: Thus, risk assessment will be based on EPM]	
6.3	6.3 Terrestrial toxicity	Since the physicochemical data indicate that the substance is not adsorptive (log Koc = xxx) or bioaccumulative (log Kow = xxx), a significant distribution into the soil compartment and a significant exposure of terrestrial organisms is not expected. Hence, information about effects on terrestrial organisms is not required and the equilibrium partitioning method has been used for assessing the hazard to terrestrial organisms.	

COLLECTION OF PHRASES FOR REGISTRATION DOSSIERS

Update: July 2010

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When models are referred to in the waiving statement, the following should be stated:

- *the substance falls within the applicability domain of the model*
- *the results provided are adequate for the purpose of C&L/Risk Assessment*
- *background documentation of the applied model*

When tests are waived because they are scientifically not justifiable, the waivers need to be evaluated case-by-case. A justification should be available in the dossier'

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IUCLID5 Section (including sub-section)	IUCLID5 Section (description)	Phrase	Comments/remarks
6.3.1	6.3.1 Toxicity to soil macroorganisms except arthropods	In accordance with column 2 of REACH Annex X, the long term toxicity testing on invertebrates study does not need to be conducted as direct and indirect exposure of the soil compartment is unlikely. The substance shows a low adsorptive (log Koc = xxx) as well as a bioaccumulative (log Kow = xxx) potential. Hence, a relevant distribution into soil and a considerable exposure of soil macroorganisms is not expected.	
6.3.2	6.3.2 Toxicity to terrestrial arthropods	In accordance with column 2 of REACH Annex X, the long term toxicity testing on invertebrates study does not need to be conducted as direct and indirect exposure of the soil compartment is unlikely. The substance shows a low adsorptive (log Koc = xxx) as well as a bioaccumulative (log Kow = xxx) potential. Hence, a relevant distribution into soil and a considerable exposure of terrestrial arthropods is not expected.	
6.3.3	6.3.3 Toxicity to terrestrial plants	In accordance with column 2 of REACH Annex IX, the short term toxicity to plants study does not need to be conducted as direct and indirect exposure of the soil compartment is unlikely. The substance shows a low adsorptive (log Koc = xxx) as well as a bioaccumulative (log Kow ≤ xxx) potential. Hence, a relevant distribution into soil and a considerable exposure of terrestrial plants is not expected.	
6.3.3	6.3.3 Toxicity to terrestrial plants	The substance has no potential for adsorption to soils, is not bioaccumulative and readily biodegradable in both aerobic and anaerobic environments. Furthermore, results of aquatic studies clearly indicate no harmful effects. Therefore, the equilibrium partitioning method has been used to assess the hazard potential to soil organisms.	
6.3.4	6.3.4 Toxicity to soil microorganisms	In accordance with column 2 of REACH Annex IX, the effects on soil microorganisms study does not need to be conducted as direct and indirect exposure of the soil compartment is unlikely. The substance shows a low adsorptive (log Koc = xxx) as well as a bioaccumulative (log Kow ≤ xxx) potential. Hence, a relevant distribution into soil and a considerable exposure of soil microorganisms is not expected.	
7	7 Toxicological information	If "study technically not feasible" is chosen from the data waiving drop down menu: "In	Example: In accordance with section 2 of Annex XI, the acute dermal toxicity study is not feasible to conduct as the substance is a gas at room temperature.
7	7 Toxicological information	If "study scientifically unjustified" is chosen from the data waiving drop down menu: "In accordance with section 1 of REACH Annex XI, testing is not scientifically necessary based on sufficient weight of evidence. insert adequate justification based on the property of the substance that inhibits testing." "In accordance with section 1 of REACH Annex XI, testing is not scientifically necessary based on use of existing data. (insert adequate justification based on reasons outlined in section 1.1.1-1.1.3 in Annex XI)." "In accordance with section 1 of REACH Annex XI, testing is not scientifically necessary based on use of qualitative or quantitative structure-activity relationship (Q(Q)SAR). (insert brief results of Q(Q)SAR)."	
7	7 Toxicological information	If "exposure considerations" is chosen from the data waiving drop down menu: "In accordance with column 2 of REACH Annex (insert Annex#)section 2, the (insert study type) study does not need to be conducted as relevant human exposure is excluded in accordance with Annex XI section 3. (insert brief, yet adequate justification based on exposure assessment)."	#####
7	7 Toxicological information	If "other justification" is chosen from the drop down menu, the specific reason in column 2 of REACH Annex (insert Annex#) section 2, the (insert study type) study does not need to be conducted as relevant human exposure is excluded in accordance with Annex XI section 3. (insert brief, yet adequate justification based on exposure assessment)."	Example: In accordance with column of REACH Annex VIII, the in-vivo skin irritation study does not need to be conducted as the substance is a strong acid (pH<2).
7.2.1	7.2.1 Acute toxicity: oral	Waiving was done according to ANNEX VII column 2 of the REACH regulation: the available information regarding skin irritation indicates that the criteria for classification as corrosive for the skin is met.	column 2 waiving justification due to corrosive properties
7.2.2	7.2.2 Acute toxicity: inhalation	The test substance has very low vapor pressure and high melting point, so the potential for the generation of inhalable forms is low, also the use of this substance will not result in aerosols, particles or droplets of an inhalable size, so exposure to humans via the inhalatory route will be unlikely to occur, and no acute inhalation test was performed.	
7.3.2	7.3.2 Eye irritation	Waiving was done according to ANNEX VII column 2 of the REACH regulation: the available information regarding skin irritation indicates that the criteria for classification as corrosive for the skin is met.	column 2 waiving justification due to corrosive properties
7.5.1	7.5.1 Repeated dose toxicity: oral	The lead registration dossier is for a substance manufactured or imported at > 100 t/a and therefore we include a testing proposal for a 90-day repeated dose toxicity study in accordance with Section 8.6.2 of column 1, Annex IX rather than the results of a 28-day repeated dose toxicity study that is required by Annex VIII Section 8.6.1. Registrants note that Annex I, 0.5 last paragraph applies.	
7.5.1	7.5.1 Repeated dose toxicity: oral	The lead registration dossier is for a substance manufactured or imported at > 100 t/a. However, the conditions of Annex XI.3 are fulfilled by each registrant who requires repeat dose toxicity testing and hence the dossier contains a testing proposal for a 28-day repeated dose toxicity study in accordance with Section 8.6.1 of column 1, Annex IX.	
7.5.2	7.5.2 Repeated dose toxicity: dermal	The substance is unlikely to be inhaled, skin contact is unlikely and the physicochemical and toxicological properties suggest low potential for significant rate of absorption through the skin. Furthermore the results of laboratory animal studies show low acute dermal toxicity. In the 28 - days repeated dose study via oral gavage administration does not exacerbate systemic toxicity effects which suggest bioavailability is low, thereby there is low toxicity potential. This intrinsic property/toxicity potential can be extrapolated to repeated dermal route administration.	
7.5.3	7.5.3 Repeated dose toxicity: inhalation	The test substance has very low vapor pressure (include value) and high melting point (include value), so the potential for the generation of inhalable forms is low, also the use of this substance will not result in aerosols, particles or droplets of an inhalable size, so exposure to humans via the inhalatory route will be unlikely to occur. Furthermore the results of laboratory animal studies show low acute dermal toxicity. In the 28 - days repeated dose study via oral gavage administration does not exacerbate systemic toxicity effects which suggest bioavailability is low, thereby there is low toxicity potential. This intrinsic property/toxicity potential can be extrapolated to repeated inhalation route administration.	

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- background documentation of the applied model

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IUCLID5 Section (including sub-section)	IUCLID5 Section (description)	Phrase	Comments/remarks
7.8.1	7.8.1 Toxicity to reproduction	The lead registration dossier is for a substance manufactured or imported at > 100 t/a and therefore we include a testing proposal for a prenatal developmental toxicity study and a testing proposal for a 2-generation reproductive toxicity study rather than the screening for reproductive/deveopmental toxicty study required by Annex VIII section 8.7.1. Registrants note that Annex I, 0.5 last paragraph applies.	

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The content of this document is intended for guidance only and whilst the information is provided in utmost good faith and has been based on the best information currently available, is to be relied upon at the user's own risk.

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IUCLID5 Section (including sub-section)	Phrase	Comments
	Guideline study	Klimisch 1 justification
	Comparable to guideline study	Klimisch 1 justification
	Test procedure in accordance with national standard methods	Klimisch 1 justification
	Test procedure in accordance with generally accepted scientific standards and described in sufficient detail	Klimisch 1 justification
	Guideline study without detailed documentation	Klimisch 2 justification
	Guideline study with acceptable restrictions	Klimisch 2 justification
	Comparable to guideline study with acceptable restrictions	Klimisch 2 justification
	Test procedure in accordance with national standard methods with acceptable restrictions	Klimisch 2 justification
	Study well documented, meets generally accepted scientific principles, acceptable for assessment	Klimisch 2 justification
	Accepted calculation method	Klimisch 2 justification
	Data from handbook or collection of data	Klimisch 2 justification
	Documentation insufficient for assessment	Klimisch 3 justification
	Significant methodological deficiencies	Klimisch 3 justification
	Unsuitable test system	Klimisch 3 justification
	Abstract	Klimisch 4 justification
	Secondary literature	Klimisch 4 justification
	Documentation insufficient for assessment	Klimisch 4 justification
1.4 Analytical information	<ul style="list-style-type: none"> - UV/Vis spectrum - IR spectrum - 1H-NMR spectrum - 13C-NMR spectrum - MS spectrum - HPLC chromatogram - GC chromatogram - Certificate of analysis - Karl Fischer (water) - Sulphated ash - Elemental analysis (C, H, N, S) 	Field "Analytical methods and spectral data"
1.4 Analytical information	Specific rotation $[\alpha]_{D20} = + X.X$ to $+ X.X^\circ$ or The substance is not optically active	Field "Optical activity" (Add value range instead of X.X)