# The EU REACH Regulatory System: Pre-Registration Evaluation of OECD SIDS-Approved Chemicals – LAB and LAS as Case Studies*

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**Summary: The new REACH regulatory system for registration, evaluation and authorization of chemicals will be implemented in the European Union beginning next year. This far-ranging program requires the preparation and submission of registration dossiers for most chemicals that are manufactured or imported in Europe. Following the initial registration submission, some chemicals may also have to undergo further evaluation to determine potential hazard and risk; and a smaller set of chemicals may also have to undergo an authorization procedure in which uses of the chemicals might be severely restricted or banned. While all chemicals meeting the volume thresholds will have to be registered, some chemicals have already been extensively reviewed and assessed under the existing Organization for Economic Cooperation and Development (OECD) Screening Information Data Set (SIDS) assessment program. This paper presents case studies using linear alkylbenzene (LAB) and linear alkylbenzene sulfonate (LAS) to address the process for pre-registration evaluation of chemicals that already have previously approved OECD SIDS assessments. The evaluation demonstrates the use of "equivalent data" from published literature, weight of evidence, structure-activity relationships, read-across within chemical categories, and use and exposure information. For LAB and LAS, the evaluation indicates sufficient data are already available for the registration phase and neither LAB nor LAS meet the criteria for the evaluation and authorization phases of REACH given the extensive data available, including OECD SIDS assessments.**

## INTRODUCTION

The Registration, Evaluation, Authorization of Chemicals (REACH) program will impact all companies manufacturing, importing, and using chemicals in the EU and beyond. REACH is expected to enter into force in the spring of 2007. Prior to submitting a registration, manufacturers and importers for existing chemicals should conduct a "Pre-Registration" evaluation and submission that will qualify the chemicals for Phase-In status and a rolling timetable based on production volume triggers.

CLER and ECOSOL, the US and European associations most responsible for research on LAS and LAB, have conducted a pre-registration evaluation to determine how to make maximum use of the extensive existing data reviews already conducted on these two important surfactant chemicals. This evaluation followed a step-wise process to determine the regulatory status within REACH and what data requirements would be applicable to LAS and LAB. The steps included:

Step 1. Identify the chemical,

Step 2. Determine if any exemptions apply,

Step 3. Compile basic chemical and registrant information (described in REACH Annex IV),

Step 4. Determine data requirements

Step 5. Identify the existing data (based on data requirements described in REACH Annex V-VIII), and evaluate any data gaps.

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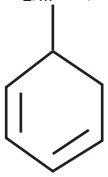
## STEP 1. IDENTIFY THE CHEMICAL

| LAS | LAB |
|---|---|
| OECD SIDS: Linear Alkylbenzene Sulfonate (LAS) is a mixture of chemicals represented by the following CAS numbers in Europe:<br><br>25155-30-0 Dodecylbenzene sulfonic acid, sodium salt<br>68081-81-2 $C_{10-16}$ Monoalkylbenzene sulfonic acid, sodium salt<br>68411-30-3 $C_{10-13}$ Alkylbenzene sulfonic acid, sodium salt<br>85117-50-6 $C_{10-14}$ Monoalkylbenzene sulfonic acid, sodium salt<br>90194-45-9 $C_{10-13}$ Alkyl deriv benzene sulfonic acid, sodium salt<br>127184-52-5 4-$C_{10-13}$-sec Alkyl deriv benzene sulfonic acid, sodium salt<br><br>The linear alkyl carbon chain typically has 10 to 14 carbon atoms, with the approximate mole ratio of 11.7 in Europe. The alkyl chains are >95% linear. The structure of $C_{12}$-LAS, representative of the category, is shown in the figure.<br><br>$CH_3(CH_2)_5CH(CH_2)_4CH_3$<br>  <br>$SO_3^-Na^+$ | EU Risk Assessment: Linear Alkylbenzene (LAB) is a mixture of chemicals represented in Europe by CAS number 67774-74-7 (EINECS number 267-051-0).<br><br>Various isomers are possible as the benzene ring may be positioned at all carbons of the alkyl chain except the terminal carbon. The alkyl carbon chain typically has 10 to 13 carbon atoms. The general structure of LAB in Europe is:<br><br>$CH_3(CH_2)_mCH(CH_2)_nCH_3$<br>  <br>where m + n = 7 – 10<br><br>Greater than 98% of all LAB is used as an intermediate in the production of LAS. |

**LAS and LAB are adequately identified. Continue to Step 2.**

## STEP 2. DETERMINE IF ANY EXEMPTIONS APPLY

**Some chemicals are excluded or exempted from REACH. The exemptions are limited to the specified uses, so even exempted chemicals can be covered by REACH if >1 ton/year is manufactured/imported for other uses. In addition to the exemptions, Biocides, Plant Protection Products, and other Notified Substances are "deemed to be registered" already.**

| Exclusions | LAS | LAB |
|---|---|---|
| Radioactive substances | No | No |
| Substances under customs supervision | No | No |
| Non-isolated intermediates | No | No |
| Waste | No | No |
| **Exemptions** | | |
| Biocides or Plant Protection Products | No | No |
| Substances <1 ton/year | No | No |
| Substances exported & reimported | No | No |
| Polymers | No | No |
| Already regulated substances | No | No |
| Annex II exemptions<br>- Listed low risk substances<br>- Generally food and food-related materials and common gases | No | No |
| Annex III exemptions<br>- Incidental substances<br>- By-products<br>- Hydrates of registered substances<br>- Most naturally-occurring substances not chemically modified<br>- Natural gas, crude oil, coal | No | No |

**Neither LAS nor LAB are exempted. Continue to Step 3.**

## STEP 3. COMPILE BASIC CHEMICAL AND REGISTRANT INFORMATION (DESCRIBED IN REACH ANNEX IV)

| LAS | LAB |
|---|---|
| General Registrant Information | |
| An existing data dossier and assessment was compiled by the Industry Coalition for the SIDS Assessment of LAS and accepted by OECD in 2005. LAS was concluded to be a low priority for further work. A Health and Environmental Risk Assessment of LAS use in household cleaning products was conducted and an updated assessment provided in 2002 (HERAproject.com). | An existing data dossier and assessment was compiled by CLER and accepted by OECD in 1995. LAB was concluded to be a low priority for further work. The LAB assessment was updated in 2002. ECOSOL conducted a risk assessment of LAB that was accepted by the EU in 1997. ECOSOL further updated the data dossier in 2001. |
| Identification of the Substance | |
| Step 1 provides a basic identification of the chemical substances. Additional characterization is included in the existing SIARs and will be included in the REACH dossier submission. | |
| Information on Manufacture and Use of the Substance | |
| LAS is manufactured from linear alkylbenzene (LAB) in self-contained, enclosed systems. The LAB is sulfonated, which in turn is then neutralized to sodium salts of LAS. The pure substance is a solid. | Greater than 98% of all LAB is used as an intermediate in the production of LAS. LAB is produced by reacting olefins or chloro-paraffins with benzene using a catalyst and isolating the LAB by distillation. The pure substance is a liquid. |
| Classification and Labelling | |
| None designated | None designated |
| Guidance on Safe use | |
| Safety Data Sheets are available | Safety Data Sheets are available |

**LAS/LAB: All data requirements specified in Annex IV have been adequately reported in the existing OECD assessments and risk assessments for LAS and LAB.**

**Continue to Step 4.**

## STEP 4. DETERMINE DATA REQUIREMENTS

**1. Determine deadlines for submission:**

| | European Commission Proposal | European Parliament and Council Proposals |
|---|---|---|
| Phase 1: 3 years | Carcinogen, Mutagen or Reproductive toxicant (CMR) class 1 and 2, or >1000 tons/year | Same as Commission, plus R50/53 environmental labelled substances at >100 tons/year |
| Phase 2: 6 years | >100 tons/year | Same as Commission, plus R50/53 substances at >1 ton/year (EP only) |
| Phase 3: 11 years | >1 ton | Same as Commission |

**LAS/LAB: Both >1000 tons/year, therefore deadline = 3 years to submit registration.**

**2. Assess which annexes apply based on tonnage:**

| | |
|---|---|
| >1 ton/year | Annex V |
| >10 ton/year | As above + Annex VI |
| >100 ton/year | As above + Annex VII |
| >1000 ton/year | As above + Annex VIII |

**LAS/LAB: Both >1000 tons/year, therefore Annexes V through VIII.**

3. **Identify applicable studies using Column 1 of Annexes V-VIII (See Tables below)**
4. **Use rules in Column 2 of each Annex to assess whether standard data requirement can be omitted, replaced with other information, provided at a different stage of the analysis, or otherwise adapted.**
5. **Use general rules in Annex IX to further adapt data requirements based on:**
   - **testing is not scientifically necessary**
   - **testing is not technically possible**
   - **testing may be omitted based on low exposure potential**
6. **Compile all relevant data**

Continue to Step 5.

## STEP 5. IDENTIFY APPLICABLE STUDIES (BASED ON DATA REQUIREMENTS DESCRIBED IN REACH ANNEXES V-VIII) AND EVALUATE ANY DATA GAPS

Each of the data requirements specified in Column 1 of the Annexes was adapted in accordance with Column 2 of each Annex and the general principles in REACH Annex IX. Data were then extracted from the existing LAS and LAB documents and assessed for acceptability for REACH. The results of this process are summarized in the following tables for LAS.

### Table 1. LAS Data Requirements (REACH Annex V)

| Data Requirement (from Column 1) | Applicable for LAS? | Data Available in Existing OECD SIDS? | Data Acceptable for REACH? | Additional Testing Proposed? | Comments |
|---|---|---|---|---|---|
| State of substance | Y | Y | Y | N | |
| Melting point | Y | Y | Y | N | Experimental ($C_{12}$) and calculated values |
| Boiling point | Y | Y | Y | N | Experimental ($C_{12}$) and calculated values; decomposes |
| Relative density | Y | Y | Y | N | Experimental data on $C_{11.6}$ |
| Vapour pressure | Y | Y | Y | N | Calculated values |
| Surface tension | Y | Y | Y | N | Surface tension data available |
| Water solubility | Y | Y | Y | N | Water solubility and critical micelle concentration discussed |
| Octanol/water partition coefficient | Y | Y | Y | N | Calculated using a surfactant-specific method |
| Flash-point | N | - | - | N | Not applicable for solid substance |
| Flammability | N | - | - | N | Not applicable for solid substance |
| Explosive properties | N | - | - | N | No chemical groups associated with explosive properties present |
| Self-ignition temperature | N | - | - | N | Not applicable for solid substance |
| Oxidising properties | N | - | - | N | Not applicable for solid substance |
| Granulometry | N | - | - | N | Not applicable for water soluble substances |
| Skin irritation | Y | Y | Y | N | Several animal studies available |
| Eye irritation | Y | Y | Y | N | Several animal studies available |
| Skin sensitisation | Y | Y | Y | N | Several animal studies available |
| Ames test | Y | Y | Y | N | Several studies available; all negative |
| Acute oral toxicity | Y | Y | Y | N | Nine acute studies available |
| Daphnia acute test | Y | Y | Y | N | Extensive database discussed in SIDS assessment |
| Algae inhibition test | Y | Y | Y | N | Extensive database discussed in SIDS assessment |
| Ready biodegradability | Y | Y | Y | N | Several studies available; all indicate ready biodegradability |

## Table 2. LAS Data Requirements (REACH Annex VI)

| Data Requirement (from Column 1) | Applicable for LAS? | Data Available in Existing OECD SIDS? | Data Acceptable for REACH? | Additional Testing Proposed? | Comments |
|---|---|---|---|---|---|
| In vivo skin irritation | Y | Y | Y | N | Several animal tests available |
| In vivo eye irritation | Y | Y | Y | N | Several animal tests available |
| Cytogenicity in mammalian cells | Y | Y | Y | N | Syrian hamster embryo study available |
| Gene mutation in mammalian cells | Y | Y | Y | N | Reliable in vivo data are available |
| Acute inhalation toxicity | Y | Y | Y | N | Acute inhalation study is available |
| Acute dermal toxicity | Y | Y | Y | N | Several studies available |
| 28-day repeated dose toxicity (appropriate routes) | N | Y | Y | N | Not required if 90-day available. Multiple sub-chronic and chronic repeated dose studies are available |
| Reproductive toxicity | Y | Y | Y | N | Three reproductive toxicity studies available; all show no effects |
| Reproductive/Develop-mental screening toxicity | N | Y | Y | N | Many developmental studies available |
| Toxicokinetics | Y | Y | Y | N | Several studies available |
| Acute fish toxicity | Y | Y | Y | N | Extensive database discussed in SIDS assessment |
| Activated sludge respiration inhibition | Y | Y | Y | N | Several microbial inhibition tests are available |
| Hydrolysis | N | - | - | N | Not required if readily biodegradable |
| Adsorption/Desorption screening | N | Y | Y | N | Not required if readily biodegradable. Data are available |

## Table 3. LAS Data Requirements (REACH Annex VII)

| Data Requirement (from Column 1) | Applicable for LAS? | Data Available in Existing OECD SIDS? | Data Acceptable for REACH? | Additional Testing Proposed? | Comments |
|---|---|---|---|---|---|
| Stability in organic solvents/Identity of degradation products | N | - | - | N | Not required if stability in organic solvents not a critical parameter; Degradation products are characterized in SIDS assessment |
| Dissociation constant | Y | Y | Y | N | Available in SIDS assessment for benzosulfonic acid |
| Viscosity | N | - | - | N | Not applicable for solid substance or solution/suspension of water soluble substance |
| 28-day repeated dose toxicity | Y | Y | Y | N | Many repeated dose toxicity studies are available |
| 90-day repeated dose toxicity | Y | Y | Y | N | Many repeated dose toxicity studies are available |
| Reproductive toxicity | Y | Y | Y | N | Many reproductive toxicity studies are available |
| Pre-natal developmental toxicity | Y | Y | Y | N | Many developmental toxicity studies are available |
| 2-generation reproductive toxicity | N | Y | Y | N | Only required if 28/90-day studies indicate severe adverse effects. However, data from 3-generation study are available |
| Chronic Daphnia | Y | Y | Y | N | Extensive database discussed in SIDS assessment |
| Long-term fish | Y | Y | Y | N | Extensive database discussed in SIDS assessment |
| Further biotic degradation | N | Y | Y | N | Not required if readily biodegradable. Additional data are available |
| Identification of degradation products | N | - | - | N | Not required if readily biodegradable. However, biodegradation intermediates for LAS have been identified and found to be orders of magnitude less toxic. |
| Bioaccumulation in fish | Y | Y | Y | N | Data are discussed in SIDS assessment |
| Terrestrial toxicity | Y | Y | Y | N | Several studies covering all relevant endpoints |

**Table 4. LAS Data Requirements (REACH Annex VIII)**

| Data Requirement (from Column 1) | Applicable for LAS? | Data Available in Existing OECD SIDS? | Data Acceptable for REACH? | Additional Testing Proposed? | Comments |
|---|---|---|---|---|---|
| In vivo genotoxicity | N | Y | Y | N | Only required if positive in vitro test result |
| Long-term repeated dose toxicity (>12 mo) | N | Y | Y | N | Only required if severe effects in 28/90-d tests; However, data for 2 year studies are available |
| Developmental toxicity | N | Y | Y | N | Not required unless classified Category 1 or 2; However, data are available |
| 2-generation reproductive toxicity | N | Y | Y | N | Data already provided under Annex VII (Table 3 above) |
| Carcinogenicity | Y | Y | Y | N | Several studies are available |
| Further biotic degradation | N | - | - | N | No additional biotic degradation studies required |
| Further environmental fate | N | - | - | N | No additional environmental fate studies required |
| Terrestrial organism toxicity | N | Y | Y | N | Only required if specific concern identified; However, data are available |
| Long-term invertebrate toxicity | N | Y | Y | N | Only required if specific concern identified; However, data are available |
| Long-term plant toxicity | N | Y | Y | N | Only required if specific concern identified; However, data are available |
| Long-term toxicity to sediment organisms | N | Y | Y | N | Only required if specific concern identified; However, data are available |
| Reproductive toxicity in birds | N | Y | Y | N | Only required if specific concern identified; However, data are available |

## LAB – DATA REQUIREMENTS

- LAB is an intermediate and thus the exposure potential is very limited
- Review of the available OECD SIDS assessment and EU risk assessment data (Appendix) confirms that, like LAS, sufficient data exist to meet all applicable REACH requirements
- In fact, considerably more data are available than is required under REACH

## CONCLUSIONS

1. **Based on the work of the industry to date, and through CLER and ECOSOL efforts, LAS and LAB are well positioned for REACH when it comes into effect.**
2. For LAS and LAB, sufficient data are already available for the Registration phase of REACH.
    a. Extensive data are available and have already been evaluated in published SIDS assessment approved by OECD. A Health and Environmental Risk Assessment (HERA) is also available for LAS and an EU risk assessment available for LAB.
    b. Data from these existing assessments can be transferred into the new IUCLID5 database for use in the European Chemical Agency's (ECA) REACH-IT data management system.

c. Data summaries available in the LAB SIDS assessment (1995, updated 2002) and EU risk assessment (1997, data dossier updated 2001) are less robust and detailed than those in the LAS SIDS assessment (2005). Also, no Klimisch-type reliability scores are given in the LAB SIDS assessment or EU risk assessment dossier. Therefore, there is a greater potential for the ECA to request additional information regarding the data available on LAB.

d. Due to widespread use in consumer products and subsequent "down-the-drain" disposal, the human and environmental exposure scenarios for LAS must be comprehensively examined in the registration dossier. The available monitoring data and all relevant routes of human and environmental exposure have already been addressed in the LAS SIDS assessment in an extensive exposure annex.

e. The use of LAB largely as an intermediate will enable a more limited exposure evaluation in the registration dossier. An exposure assessment for LAB is included in the EU risk assessment.

3. Neither LAS nor LAB need to be included in the Evaluation phase of REACH because sufficient data evaluation has already been completed in the OECD-approved SIDS assessments and the risk assessments.

4. Neither LAS nor LAB need to be addressed in the Authorization phase of REACH because neither meet the criteria for Persistent Bioaccumulative Toxicant (PBT), very Persistent, very Bioaccumulative substance (vPvB), Carcinogen, Mutagen or Reproductive toxicant (CMR), or equivalent toxicity criteria.

5. This assessment suggests that REACH poses substantial challenges for chemicals that have NOT been recently evaluated in the OECD SIDS program or the HERA or EU risk assessment.

## APPENDIX: LAB DATA TABLES

### Table 5. LAB Data Requirements (REACH Annex V)

| Data Requirement (from Column 1) | Applicable for LAS? | Data Available in Existing OECD SIDS?[a] | Data Acceptable for REACH? | Additional Testing Proposed? | Comments |
|---|---|---|---|---|---|
| State of substance | Y | Y | Y | N | |
| Melting point | Y | Y | Y | N | Value is < -20°C |
| Boiling point | Y | Y | Y | N | Several studies available |
| Relative density | Y | Y | Y | N | Data available in 2001 EU dossier |
| Vapour pressure | Y | Y | Y | N | Two measured values reported |
| Surface tension | N | - | - | N | Not applicable - not a surfactant; water solubility is too low |
| Water solubility | Y | Y | Y | N | Data available |
| Octanol/water partition coefficient | Y | Y | Y | N | Calculated values available |
| Flash-point | Y | Y | Y | N | Several values available |
| Flammability | Y | Y | Y | N | Flammable limits in air listed in 1997 EU RA |
| Explosive properties | Y | Y | Y | N | Data available in 1997 EU RA and 2001 dossier |
| Self-ignition temperature | N | Y | Y | N | Not required for solids if melting point <160°C; but data available in 2001 dossier |
| Oxidising properties | N | - | - | N | Not applicable for solid substance without reactive groups |
| Granulometry | N | - | - | N | Not applicable for liquid |
| Skin irritation | Y | Y | Y | N | Several animal studies available |
| Eye irritation | Y | Y | Y | N | Several animal studies available |
| Skin sensitisation | Y | Y | Y | N | Animal and human studies available |
| Ames test | Y | Y | Y | N | Several studies available; all negative |
| Acute oral toxicity | Y | Y | Y | N | Several acute studies available |
| Daphnia acute test | Y | Y | Y | N | Several studies available |
| Algae inhibition test | Y | Y | Y | N | Several studies available |
| Ready biodegradability | Y | Y | Y | N | Several studies available; most indicate ready biodegradability |

[a] Or in EU Risk Assessment (RA) Report 1997 or updated 2001 dossier

## Table 6. LAB Data Requirements (REACH Annex VI)

| Data Requirement (from Column 1) | Applicable for LAS? | Data Available in Existing OECD SIDS?[a] | Data Acceptable for REACH? | Additional Testing Proposed? | Comments |
|---|---|---|---|---|---|
| In vivo skin irritation | Y | Y | Y | N | Several animal tests available |
| In vivo eye irritation | Y | Y | Y | N | Several animal tests available |
| Cytogenicity in mammalian cells | Y | Y | Y | N | Several Chinese hamster ovary studies available |
| Gene mutation in mammalian cells | Y | Y | Y | N | Reliable in vivo data are available |
| Acute inhalation toxicity | Y | Y | Y | N | Acute inhalation studies are available |
| Acute dermal toxicity | Y | Y | Y | N | Acute dermal study available |
| 28-day repeated dose toxicity (appropriate routes) | N | Y | Y | N | Not required if 90-day available. Multiple sub-chronic and chronic repeated dose studies are available |
| Reproductive toxicity | Y | Y | Y | N | Reproductive toxicity studies are available |
| Reproductive/ Developmental screening toxicity | N | Y | Y | N | Several developmental studies available |
| Toxicokinetics | Y | Y | Y | N | A toxicokinetics study is available |
| Acute fish toxicity | Y | Y | Y | N | Many fish studies available |
| Activated sludge respiration inhibition | Y | Y | Y | N | Pseudomonas studies available in 2001 dossier |
| Hydrolysis | N | - | - | N | Not required if readily biodegradable |
| Adsorption/ Desorption screening | N | Y | Y | N | Not required if readily biodegradable. Data are available |

[a] Or in EU Risk Assessment (RA) Report 1997 or updated 2001 dossier

## Table 7. LAB Data Requirements (REACH Annex VII)

| Data Requirement (from Column 1) | Applicable for LAS? | Data Available in Existing OECD SIDS?[a] | Data Acceptable for REACH? | Additional Testing Proposed? | Comments |
|---|---|---|---|---|---|
| Stability in organic solvents/Identity of degradation products | N | - | - | N | Not required if stability in organic solvents not a critical parameter |
| Dissociation constant | N | - | - | N | Not applicable for non-ionic substance |
| Viscosity | N | Y | Y | N | Data available in 2001 dossier |
| 28-day repeated dose toxicity | Y | Y | Y | N | Several repeated dose toxicity studies are available |
| 90-day repeated dose toxicity | Y | Y | Y | N | Several repeated dose toxicity studies are available |
| Reproductive toxicity | Y | Y | Y | N | A 2-generation reproductive toxicity study is available |
| Pre-natal developmental toxicity | Y | Y | Y | N | A developmental toxicity study is available |
| 2-generation reproductive toxicity | N | Y | Y | N | Only required if 28/90-day studies indicate severe adverse effects. However, data from a 2-generation study is available |
| Chronic Daphnia | Y | Y | Y | N | Chronic Daphnia studies are available |
| Long-term fish | N | N | N | N | Chronic fish not required since no effects are observed at the water solubility limit |
| Further biotic degradation | N | Y | Y | N | Not required if readily biodegradable |
| Identification of degradation products | N | - | - | N | Not required if readily biodegradable. |
| Bioaccumulation in fish | Y | Y | Y | N | Data are available in the SIDS |
| Terrestrial toxicity | N | - | - | N | No terrestrial exposure likely |

[a] Or in EU Risk Assessment (RA) Report 1997 or updated 2001 dossier

## Table 8. LAB Data Requirements (REACH Annex VIII)

| Data Requirement (from Column 1) | Applicable for LAS? | Data Available in Existing OECD SIDS?[a] | Data Acceptable for REACH? | Additional Testing Proposed? | Comments |
|---|---|---|---|---|---|
| In vivo genotoxicity | N | Y | Y | N | Only required if positive in vitro test result |
| Long-term repeated dose toxicity (>12 months) | N | Y | Y | N | Only required if severe effects in 28/90-d tests; However, data for a 2 year study is available |
| Developmental toxicity | N | Y | Y | N | Not required unless classified Category 1 or 2; However, data are available |
| 2-generation reproductive toxicity | N | Y | Y | N | Data already provided under Annex VII |
| Carcinogenicity | Y | Y | Y | N | Studies are available |
| Further biotic degradation | N | - | - | N | No additional biotic degradation studies required |
| Further environmental fate | N | - | - | N | No additional environmental fate studies required |
| Terrestrial organism toxicity | N | - | - | N | Only required if specific concern identified |
| Long-term invertebrate toxicity | N | - | - | N | Only required if specific concern identified |
| Long-term plant toxicity | N | - | - | N | Only required if specific concern identified |
| Long-term toxicity to sediment organisms | N | - | - | N | Only required if specific concern identified |
| Reproductive toxicity in birds | N | - | - | N | Only required if specific concern identified |

[a] Or in EU Risk Assessment (RA) Report 1997 or updated 2001 dossier