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New and amended completeness check rules as of 1st of June 2023

IUCLID section	Rule description	Relevance
Business rules		
1.1 – Identification, 1.2 – Composition	If the substance is defined as mono-constituent, the first composition in section 1.2 indicated as 'boundary composition of the substance' must have a matching substance identity when compared with the reference substance in section 1.1.	Lead registration dossiers
1.1 – Identification, 1.2 – Composition	If the substance is defined as multi-constituent, the first composition in section 1.2 indicated as 'boundary composition of the substance' cannot contain constituents identical to the reference substance in section 1.1.	Lead registration dossiers
1.2 – Composition General information	For compositions indicated as 'boundary composition of the substance', 'State/form' of a composition must be specified by selecting the appropriate value in the picklist.	Lead registration dossiers
Technical completeness check rules		
1.2 – Composition Constituents	For compositions indicated as 'boundary composition of the substance', the constituent reference substances in section 1.2 must contain molecular and structural information. For a mono-constituent substance, or a multi-constituent substance, the molecular formula, molecular weight and structural formula of the reference substance must be indicated in the designated fields. For a UVCB substance, the molecular formula and molecular weight of the reference substance must be indicated in the designated fields, or a justification for not providing this information must be given in the related 'Remarks' field.	Lead registration dossiers
1.2 – Composition, Constituents, mono-constituent substance	For a mono-constituent substance, each composition indicated as 'boundary composition of the substance' is expected to contain only one constituent. When deviating from this rule, a justification must be given in the 'Justification for deviations' field.	Lead registration dossiers
1.2 – Composition, Constituents, multi-constituent substance	For a multi-constituent substance, each composition indicated as 'boundary composition of the substance' is expected to contain at least two constituents. When deviating from this rule, a justification must be given in the 'Justification for deviations' field.	Lead registration dossiers
1.2 – Composition, Constituents, UVCB substance	For a UVCB substance, each composition indicated as 'boundary composition of the substance' is expected to contain more than one constituent. When deviating from this rule, a justification must be given in the 'Justification for deviations' field.	Lead registration dossiers

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1.2 – Composition Additives	For compositions indicated as 'boundary composition of the substance', the molecular formula, molecular weight and structural formula of each additive reference substance must be indicated in the designated fields, or a justification for not providing this information must be given in the related 'Remarks' field.	Lead registration dossiers
1.2 – Composition Additives	For compositions indicated as 'boundary composition of the substance', for each additive, the stabilising function must be confirmed by selecting the relevant value starting with 'stabiliser' in the picklist 'Function'. Further details on the mechanism of stabilisation can be provided under 'Details of function in composition'.	Lead registration dossiers
3.5.3 – Uses at industrial sites	For each record created in section 3.5.3 'Uses at industrial sites', the field 'Product category used' must be filled in. If 'other:' is selected, then the below field must be filled in. Note that a product category is not required for uses registered as intermediates. When reporting that type of a use in section 3.5.3, it should be indicated in the field 'Registration/Notification status for the use'.	Lead, member, and individual registration dossiers
3.5.4 – Widespread uses by professional workers	For each record created in sections 3.5.3 'Uses at industrial sites' and 3.5.4 'Widespread uses by professional workers', the field 'Product category used' must be filled in. If 'other:' is selected, then the below field must be filled in.	Lead, member, and individual registration dossiers
3.5.6 – Service life	If any use record in sections 3.5.1, 3.5.2, 3.5.3, 3.5.4 or 3.5.5 contains a contributing activity/technique for the environment which is described with the environmental release categories 5, 8c, or 8f (ERC 5, 8c, 8f), at least one record must be created in section 3.5.6 'Service life'.	Lead, member, and individual registration dossiers
4.8 – Water solubility	If the water solubility study in section 4.8 is waived based on the fact that the substance is a metal or a sparingly soluble metal compound, you must also include in section 4.8 at least one endpoint study record indicated as 'key study' or 'weight of evidence' with the endpoint selection 'transformation / dissolution of metals and inorganic metal compounds'.	Lead and individual registration dossiers
5.2.2 – Biodegradation in water and sediment: simulation tests (surface water and sediment) **5.2.3 – Biodegradation in soil**	A data-waiving justification based on the Chemical Safety Assessment (CSA) outcome is no longer accepted for these endpoints. The decision of ECHA`s Board of Appeal in the case A-005-2021 clarified the meaning of Column 2 of Section 9.2. of Annex IX. The CSA results do not allow the omission of information required under column 1. Instead, further data must be generated **beyond** the standard information requirement if the CSA indicates such a need.	Lead and individual registration dossiers
6.1.2 – Long-term toxicity to fish **6.1.4 – Long-term toxicity to aquatic invertebrates**	A data-waiving justification that is based on the Chemical Safety Assessment (CSA) outcome is no longer accepted for these endpoints. The decision of ECHA`s Board of Appeal in the case A-011-2018 clarified the meaning of Column 2 of Section 9.1. of Annex IX. The CSA results do not allow the omission of information required under column 1. Instead, further data must be generated **beyond** the standard information requirement if the CSA indicates such a need.	Lead and individual registration dossiers

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7.6.1 – Genetic toxicity in vitro	**In-vitro gene mutation study in bacteria with positive/ambiguous results** If a positive and/or ambiguous result is reported in section 7.6.1 *in vitro gene mutation study in bacteria*, the following is required: - In section 7.6.1, at least one endpoint study record indicated as key study, weight of evidence, or data waiving must be provided for an *in vitro chromosome aberration study in mammalian cells* or *in vitro micronucleus study in mammalian cells*; **and** - In section 7.6.2, at least one endpoint study record indicated as a key study, weight of evidence, data waiving or testing proposal must be provided for *an in vivo mammalian somatic cell study* endpoint.	Lead and individual registration dossiers
7.6.1 – Genetic toxicity in vitro	**In-vitro gene mutation study in bacteria not applicable** If the *in vitro gene mutation study in bacteria* in section 7.6.1 is waived based on the fact that the study is not applicable to your substance, you are required to provide a justification in the field 'Justification for type of information'. In addition to the data waiving record, you must include in section 7.6.1 at least one endpoint study record indicated as a key study, weight of evidence or data waiving for an *in vitro gene mutation study in mammalian cells*.	Lead and individual registration dossiers
7.6.1 – Genetic toxicity in vitro	**In-vitro gene mutation study in mammalian cells with positive/ambiguous results** If a positive and/or ambiguous result is reported in section 7.6.1 *in vitro gene mutation study in mammalian cells*, the following is required: - In section 7.6.1, at least one endpoint study record indicated as key study, weight of evidence, or data waiving must be provided for an *in vitro chromosome aberration study in mammalian cells* or *in vitro micronucleus study in mammalian cells*; **and** - In section 7.6.2, at least one endpoint study record indicated as a key study, weight of evidence, data waiving or testing proposal must be provided for an *in vivo mammalian somatic cell study* endpoint.	Lead and individual registration dossiers
7.6.1 – Genetic toxicity in vitro	**In-vitro gene mutation study in mammalian cells not applicable** If the *in vitro gene mutation study in mammalian cells* in section 7.6.1 is waived based on the fact that the study is not applicable to your substance, you are required to provide a justification in the field 'Justification for type of information'. In addition to the data waiving record in section 7.6.1, you must include in section 7.6.2 at least one endpoint study record indicated as a key study, weight of evidence, data waiving or testing proposal for an *in vivo mammalian somatic cell study* endpoint.	Lead and individual registration dossiers
7.6.1 – Genetic toxicity in vitro	**In vitro chromosome aberration study in mammalian cells or in vitro micronucleus study not applicable** If *the in vitro chromosome aberration study in mammalian cells* or *in vitro micronucleus study* in section 7.6.1 is waived based on the fact that the study is not applicable to your substance,	Lead and individual registration dossiers

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	you are required to provide a justification in the field 'Justification for type of information'. In addition to the data waiving record in section 7.6.1, you must include in section 7.6.2 at least one endpoint study record indicated as a key study, weight of evidence, data waiving or testing proposal for an *in vivo mammalian somatic cell study* endpoint.	
7.6.1 – Genetic toxicity in vitro **7.6.2 – Genetic toxicity in vivo**	If an *in vitro and/or in vivo mutagenicity study* is waived based on the fact that the substance is known to be germ cell mutagenic category 1A, 1B or 2, and carcinogenic category 1A or 1B, **or** germ cell mutagenic category 1A or 1B, then in addition to the data waiving record in section 7.6.1 and/or 7.6.2, you must include in section 2.1 at least one record where you provide the appropriate classification for the corresponding hazard class(es).	Lead and individual registration dossiers
7.6.2 – Genetic toxicity in vivo	If any in vivo mammalian genotoxicity study in section 7.6.2 is waived based on no positive result in any in vitro genotoxicity studies, none of the studies reported in section 7.6.1 can have positive results.	Lead and individual registration dossiers
7.8.1 -Toxicity to reproduction **7.8.2 - Developmental toxicity / teratogenicity** (updated on 12 April 2023)	If a reproductive and/or developmental toxicity study is waived based on the fact that the substance is known to be germ cell mutagenic category 1A, 1B or 2, and carcinogenic category 1A or 1B, **or** germ cell mutagenic category 1A or 1B, then in addition to the data waiving record in section 7.8.1 and/or 7.8.2, you must include in section 2.1 at least one record where you provide the appropriate classification for the corresponding hazard class(es).	Lead and individual registration dossiers
4 – 7, Weight of evidence justification/conclusion	All records with the adequacy of study set to 'weight of evidence', created and added to the dossier as of 1st of May 2023, must be accompanied by one endpoint study record (per weight of evidence approach) with the type of information set to 'weight of evidence justification/conclusion'.	Lead and individual registration dossiers
4 – 7, Weight of evidence justification/conclusion	All records with the type of information set to 'weight of evidence justification/conclusion' must contain the following: - A justification in the field 'Justification for type of information'. It includes a template to support you in building the justification. - Weight of evidence source documents linked in the 'Cross-reference' table. - Information in the 'Results and discussion' table.	Lead and individual registration dossiers