



Standard data requirements for the inclusion of an adjuvant on the Official List

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You should perform any studies relating to the safety areas of the risk assessment to Good Laboratory Practice (GLP). This supports the principle of mutual acceptance of data for the evaluation of chemical products so that tests, particularly those involving animals, do not have to be repeated because of differences in laboratory practice from one country to another.

a) A technical specification for the Effective Adjuvant Component (EAC) detailing the minimum content (% w/w or g/kg) of pure EAC (excluding inactive isomers) and maximum levels (% w/w or g/kg) of impurities in the manufactured material used for production of the formulated product. The minimum purity of the EAC and sum of maximum amounts of impurities must be $\geq 100\%$.

It must be stated whether any impurities of toxicological, ecotoxicological or environmental significance are present. If present, the maximum level of these impurities in the manufactured material will need to be provided.

The technical specification must use chemical names as given in [UK REACH](#) or in accordance with IUPAC and/or CAS nomenclature. The information submitted must be sufficient to chemically characterise that component, e.g. for polyethoxylated components the information should include the degree of ethoxylation and the number of moles of ethylene oxide. In addition, where a component is itself a mixture, full details of the mixture (including ratios of sub-components, if appropriate) must be submitted.

Other specific information on the EAC must also be presented in a separate form and submitted together with the application form.

Information required includes:

- CAS/EC (ELINCS/EINECS) number(s) should be given where available.
- A description of the chemical composition must be included to supplement the chemical name e.g. 'PO-EO block co-polymers with approximate chain lengths and molar masses'.
- If trade names are included in the technical specification, these must be in addition to, and not instead of, the full chemical names; alternative trade names may only be listed if they are of the same chemical composition.

b) A method of manufacture of the EAC to include the minimum purity of the effective component produced as a result of the manufacturing process.

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c) Full formulation details are required as detailed below:

- The nominal amount of EAC in the formulation must be specified in units of % w/w, g/kg, or g/l, as appropriate.
- For co-formulants the following information should be specified:
 - Chemical name as given in [UK REACH](#) or in accordance with IUPAC and/or CAS nomenclature.
 - The information submitted for each co-formulant must be sufficient to chemically characterise that component e.g. for polyethoxylated components the information should include the degree of ethoxylation and the number of moles of ethylene oxide. In addition, where a component is itself a mixture, full details of the mixture (including ratios of sub-components, if appropriate) must be submitted.
 - Function of co-formulant e.g. emulsifier.
 - The nominal amount of each co-formulant present in the product must be given in units of %w/w, g/kg, or g/l as appropriate.
 - A description of the chemical composition must be included to supplement the chemical name e.g. xanthan gum, heteropolysaccharide molar mass 2 to 15 x 10⁶ g/mol.
 - Trade names where possible should be stated, including alternatives if required. Where alternative trade names are listed, the components must be identical in chemical composition. Where the alternatives are not chemically identical then a reasoned scientific case must be submitted showing why the change will not adversely affect the physical or chemical properties of the formulation.
 - CAS/EC (ELINCS/EINECS) number(s) should be given where available.
 - Colour index number for dyes.

d) A method of analysis for determining the EAC in the adjuvant formulation.

e) Such basic physico-chemical properties of the EAC as water solubility, octanol-water partition co-efficient, melting point and boiling point. Where certain properties are not relevant to a proposed adjuvant product, HSE encourages applicants to generate some basic physical and chemical properties data that are appropriate. The following tests could be considered appropriate: hydrophile-lipophile balance (HLB), pH, viscosity, surface tension, appearance, odour and density. (It would be preferable if these studies were conducted to GLP but this is not a requirement).

It should be noted that whilst some physico-chemical properties are available on Safety Data Sheets, all the relevant properties may not be reported, especially the octanol-water partition coefficient. (It is recognised that for adjuvants with surface acting properties (e.g. surfactants) meaningful measurements of octanol-water partition coefficients are not possible and therefore not relevant).

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- f) A signed compatibility assurance statement (see “The Applicant Guide: Tank-mix recommendations on product labels: Convenience tank mixes” on the HSE Website).
- g) Any other data deemed necessary based on the above.

If you have access to a previously submitted full data package on an EAC used to support a previously considered List Entry, it is likely that you will not need to address all of the above data requirements unless the technical specification for the EAC, the formulation recipe or the recommended uses differ to those covered by a previous List Entry. In such cases, certain new data may be required to support the List Entry.

Further information

For information about health and safety, or to report inconsistencies or inaccuracies in this guidance, visit www.hse.gov.uk/. You can view HSE guidance online and order priced publications from the website. HSE priced publications are also available from bookshops.

This guidance is issued by the Health and Safety Executive. Following the guidance is not compulsory, unless specifically stated, and you are free to take other action. But if you do follow the guidance you will normally be doing enough to comply with the law. Health and safety inspectors seek to secure compliance with the law and may refer to this guidance.

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Published by the Health and Safety Executive 01/21