Data requirements for biocidal product authorisation

By Joanna Sackey

Your active(s) have been approved and the clock is ticking to start preparing the data package for your biocidal product authorisation dossier. Wondering where to start and what is required? There are many prerequisites to be fulfilled to ensure your dossier is complete and ready to submit.

Read on to find out more and how Eurofins can help lead you to that successful authorisation!

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Letter of access and technical equivalence:

The product dossier requires the support of data on the active substance. If you are not the data owner of the active dataset, you will need to obtain a letter of access (LoA) to this data and if more than one active is contained in your biocidal product, then you will need to own or obtain access to data on each of these. If you require a LoA(s), this should be negotiated with your supplier and it is advisable to start these negotiations early on to avoid any delays.

Is the supplier of your active substance different from the reference source of the approved active substance? Then a positive decision on the **technical equivalence (TE)** of the active substance issued by ECHA is also a required element in the application for a product authorisation. The manufacturer or supplier of the active is not legally obliged to prove TE; therefore it is important to establish early on whether TE has already been proved or an application has been submitted to ECHA. If this is not the case then an application must be submitted (for example by the formulator) in order to support your product authorisation.

Efficacy:

The efficacy of your product is of paramount importance. It must be demonstrated that the product works against the claimed target organisms **in accordance with the use instructions, contact time and application rate stated on your product label**. ECHA has published specific guidance on the required efficacy testing for biocidal products and ideally efficacy should be performed in accordance with these guidelines. Efficacy testing can include laboratory tests and/or in some cases field studies. An application for a product authorisation must include a draft copy of the product label containing the claims for the product.

You should also be wary that if your product contains a co-formulant which is an active in the existing review programme or previously listed as an identified active then testing may be required to prove it is not contributing significantly to the efficacy of your product!

Storage stability and shelf life:

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Storage stability at **ambient temperature** must be performed in accordance with the claimed shelf life of the product. During the storage stability study parameters such as the concentration of the active, and appearance of the product and packaging are assessed. Where several packaging forms are available the 'worst case' commercial packaging should be selected for the study. Accelerated storage stability at elevated temperature should also be considered if the product is likely to be stored at higher temperatures. Accelerated storage stability can also be used to demonstrate if the product is likely to be stable for at least 2 years at ambient temperature and can therefore be used to support an authorisation whilst the ambient storage is ongoing. In some cases a cold storage stability study is required if the product is to be stored at temperatures ≤0°C.

Analytical methods:

Analytical methods are necessary and must be suitable to accurately determine the content of the active substance in the biocidal product(s). Validation parameters such as linearity, specificity, recovery and repeatability should also be addressed and must be met to demonstrate that the method of analysis is suitable for the intended purpose.

Phys-chem properties and technical characteristics:

Relevant physico-chemical (phys-chem) and technical characteristics of the product must also be determined. Which properties need to be tested? Standard phys-chem tests include appearance, acidity/alkalinity, and relative density. However, other properties are also required and are specifically selected based on the formulation type and proposed uses. For example if your product is a liquid formulation used as a trigger spray then properties such as the spray pattern, spray rate and valve clogging of the trigger should be determined. In contrast if the product is a bait formulation then properties such as particle size, dust content and caking should be investigated.

Ecotoxicity/toxicity/e-fate:

Generally, ecotoxicology or toxicology tests are covered by the LoA to the active substance dossier. However, studies for relevant components of the product or the product itself may be required if data on the active cannot give sufficient information and if there are indications of risk due to the specific properties of the product.

Dermal absorption:

A value for dermal absorption **must be stated in the dossier** and is required for the risk assessment. This is determined using a stepwise approach. In the case where no study is available on the formulation itself, a default value may be selected as a 'worst case exposure' or data can be extrapolated from the active substance providing that the biocidal product has a *similar* composition to the test formulation. If however, an unacceptable risk is identified by using such values than a study may be required in order to refine the exposure estimate.

Substance of concern:

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Any **'substances of concern' (SoC)** contained in the product must be addressed in the dossier. A SoC is normally a substance that triggers a hazardous classification in the product OR meets the criteria for being a persistent organic pollutant (POP), persistent, bio-accumulative and toxic (PBT) or very persistent and very bio-accumulative (vPvB). However there may also be the basis for substances meeting the criteria based on '*other grounds for concern'*.

The European Commission has published very clear guidance on SoC for human health and how these should be addressed in the dossier. It is therefore important to identify these early on to determine if any additional data is required. In some cases an assessment of the exposure and risk is necessary and applicants will need to obtain the appropriate data for the SoC in question. This may require requesting a LoA from the data owner to any proprietary data needed for risk assessment, thus resulting in further data negotiations and costs. Don't get caught out – the co-formulants of your product may also play an important role in your authorisation!

Take home messages:

- Be prepared – It is reasonable to start collecting data ~2 years before the submission date to avoid any surprises and unexpected costs!
- Check if your active substance supplier has proof of TE if different from the reference source of the active.
- Identify the tests required by performing a data gap analysis on your product and also identify any potential substances of concern.
- Don't leave testing too late and run the risk of unexpected or unfavourable results.
- A complete dossier fulfilling all the requirements will avoid delays/issues with your authorisation.

Eurofins support:

Eurofins Regulatory team are able to provide support on all aspects of the product authorisation process including:

- Identification of the tests required by means of a data gap analysis
- Identification of SoC(s)
    - Preliminary risk assessments
- Product testing including efficacy, phys-chem and storage stability
- Preparation and submission of the dossier including post submission support.

For further information please contact: Owenpryce@eurofins.com

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