

# Guidelines for Registration of Lubricants to H1, H2 or H3

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This provides detailed guidelines on how to register a product for InS H1, H2 or H3 approval

InS Services (UK) Ltd, 4 St Johns Close, Rugeley, Staffordshire, WS15 2TG. UK website: www.insservices.eu email: registration@insservices.eu

Our sheet 4S1 outlines the 4 simple steps to successful registration. This sheet explains in greater detail how to complete the required documentation.

### **BASIC REQUIREMENTS**

- All companies submitting an application must be registered with InS. This can be done at the same time as first product registration.
- All Product submissions must include full formulation details.
- Only ingredients listed in 21 CFR 178.3570 or associated approved standards will be acceptable.
- The reference standard by which the ingredient is approved must be indicated (eg 21 CFR 178.3570 or GRAS).
- Ingredients must always add up to 100%.
- Range additions must contain the same ingredients as the primary product but in varying proportions and within allowable limits.
- Any additional ingredients constitute a new product.
- Any product formulation change will invalidate a product approval.

### **FORMULATIONS**

InS has to know all the ingredients of a product so we can verify that they comply with 21 CFR 178.3570 or other applicable regulation. We have a confidentiality agreement available to safeguard your formulations.

The following details are required for each ingredient:

- Chemical name.
- Supplier (this may or may not be the manufacturer).
- Supplier's product Trade Name.
- CAS (Chemical Abstract Service registry) number or EINECS (European INventory of Existing Commercial chemical Substances) number.
- The reference standard by which the ingredient has been approved (eg 21 CFR 178.3570 or GRAS). Written evidence may be requested to support this.
- Percent by weight. All ingredients must total 100%.

### **SAMPLES**

Product samples are not normally required but InS reserves the right to request these in specific cases.

# **LABELS**

Label artwork is not required.

#### **REGISTRATION MARKS**

Registration marks appropriate to the products registered will be made available in electronic form. Their use is not compulsory but if wished they may be used on labels and literature for promotional purposes.





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### THE Ins REGISTER

All registered companies and products will be listed online at the InS website: www.insservices.eu. Here searches can be made by company, product, registration category or registration number. Company contact details will be available against each product and registration certificates can be viewed, printed or downloaded.

# **REGISTRATION CERTIFICATES**

A certificate will be made available via the online InS Register for each product registered. A sample is shown on the right.

#### **TERMINATION OF REGISTRATION**

InS may terminate the registration of a company or product for reasons including but not limited to:

- Incorrect formulation details
- Any change in formulation
- Non payment of invoices

# **DISCLAIMER**

In registering a product, InS Services accepts no responsibility or liability for the use of that product in any situation or for any consequential loss or damage either direct or indirect resulting from the use of that product.



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