

Application – Authorisation of adjuvants

### **Applicant**

Current or future authorisation holder, i.e. the party **responsible** for initial placing of the plant protection product on the Norwegian market

| **No** | **Information** |
| --- | --- |
| 1 | Company name      | Organisation number      |
| Address      | Postal code and town      |
| Contact person       | E-mail address      | Telephone no. (incl. country code)      |

### **Product information**

| **No** | **Information** |
| --- | --- |
| 2 | Name of the product (incl. trade name)      | Product code      |
| 3 | Type of adjuvant and intended use      | Other type (if applicable):      |
| 4 | Packaging size      | Packaging material      |
| 5 | Physical state of the product       |
| 6 | Complete composition of the product. State unambiguous chemical name for each co-formulant, in accordance with IUPAC (or CAS and CAS- no.). If the quantity of an ingredient varies from one batch to another, limits for the variation shall be given. The quantity of each active ingredient shall be given in g/L or g/kg.Please fill in the table in appendix 1 and submit it to the Norwegian Food Safety Authority as a separate sheet |

**Send application form to:**
Norwegian Food Safety Authority, Regional Office Stor-Oslo, P.O. Box 383, N –2381 Brumunddal, Norway
Or e-mail: postmottak@mattilsynet.no

**Send two full sets of documentation to:**

Norwegian Food Safety Authority, National Registration Department, Regional Office Stor -Oslo, Glynitveien 30, N-1400 Ski, Norway

The application form should be submitted as signed original. All other documents, including the copy of the application form,
must be delivered on CD or in another digital form.Application must be written in compliance with national guidance for approval of adjuvants and the Northern zone guidance document.

### **Temporary** representative [[1]](#footnote-1) (if applicable)

Representing the authorisation holder ( i.e. the applicant in point 10 ) **only during the application procedure**

| **No** | **Information** |
| --- | --- |
| 7 | Company name      | Organisation number      |
| Address      | Postal code and town      |
| Contact person       | E-mail address      | Telephone no. (incl. country code)      |
| 8 | A representative should prove the appointed level of representation with **a letter of appointment** by the applicant in original. [ ]  Letter of appointment as temporary representative is attached |

### **Permanent** representative (if applicable)

Representing the future authorisation holder (i.e. the applicant in point 10) **during the authorisation period**

| **No** | **Information** |
| --- | --- |
| 9 | Company name      | Organisation number      |
| Address      | Postal code and town      |
| Contact person       | E-mail address      | Telephone no. (incl. country code)      |

### **Invoicing address for application fee**

| **No.** | **Information** |
| --- | --- |
| 10 | Application fee will be paid by[ ]  Authorisation holder[ ]  Temporary representative[ ]  Permanent representative |
| Invoicing address      | Contact person      |
| Postal code and town      | E-mail address      |
|  | Country      | Telephone no. (incl. country code)      |

### **Signature [[2]](#footnote-2)**

|  |  |  |
| --- | --- | --- |
| 11 | Applying company       | Date (dd.mm.yyyy)      |
| Signature | Name      |

### **Completeness check for annexes**

Data requirements. If not added, a justification shall be made.

| No | Issue | Comments(e.g. confidential data claim) | Attached? | Annex No |
| --- | --- | --- | --- | --- |
| Yes | No |
| 12 | A declaration confirming that the product do not have any harmful effects on health and environment when used properly and for their intended use.      |       | [ ]  | [ ]  |       |
| 13 | Documentation on efficacy and phytotoxicity according to «Guidance on requirements for efficacy data for zonal evaluation of a plant protection product in the Northern Zone». |       | [ ]  | [ ]  |       |
| 14 | Documentation of physical and chemical compatibility on proposed mixes of adjuvant and plant protection products. |       | [ ]  | [ ]  |       |
| 15 | Safety data sheet for each formulant in the product (in Norwegian or English).  |       | [ ]  | [ ]  |       |
| 16 | Safety data sheet for the product (in Norwegian). |       | [ ]  | [ ]  |       |
| 17 | Complete composition of the product(see appendix 1). |       | [ ]  | [ ]  |       |
| 18 | Letter of Access (if the product data are not owned by the applicant). |       | [ ]  | [ ]  |       |
| 19 | Data sharing agreement/task force (if the product data are not owned by the applicant). |       | [ ]  | [ ]  |       |
| 20   | Proposed label (in Norwegian) according to the requirements.  |       | [ ]  | [ ]  |       |
| 21 | Letter of appointment. |       | [ ]  | [ ]  |       |
|  |       |       | [ ]  | [ ]  |       |
|  |       |       | [ ]  | [ ]  |       |
|  |       |       | [ ]  | [ ]  |       |
|  |       |       | [ ]  | [ ]  |       |
|  |       |       | [ ]  | [ ]  |       |
|  |       |       | [ ]  | [ ]  |       |

### **Appendix 1**

Complete composition of the formulation

| **Information** |
| --- |
| Name of the product (incl. trade name)      | Product code      |
| Company name      | Organisation number      |

|  |  |  |  |
| --- | --- | --- | --- |
| **Formulant (trade name)** | **CAS no** | **Content (g/L or g/kg)** | **SDS no.[[3]](#footnote-3)** |
|       |       |       |       |
|       |       |       |       |
|       |       |       |       |
|       |       |       |       |
|       |       |       |       |
|       |       |       |       |
|       |       |       |       |

 Extend the table if necessary

**Note:**

Safety Data Sheets will only be accepted in Norwegian or English. Purity of the formulants and the majority of the remaining components of the composition must be provided.

If the applicant does not own the product data, supplier of the different products can send this data directly to the Norwegian Food Safety Authority. The information will be treated as strictly confidential.

### **Signature**

|  |  |  |
| --- | --- | --- |
|  | Applying company       | Date (dd.mm.yyyy)      |
| Signature | Name      |

1. The applicant is fully responsible for the placing of a plant protection product on the Norwegian market. The representative cannot hold an authorisation [↑](#footnote-ref-1)
2. If the signature is done by someone other than the applying company, a power of attorney confirming the right to sign the application on behalf of the applicant should be submitted. [↑](#footnote-ref-2)
3. Safety Data Sheet, annex number. [↑](#footnote-ref-3)