Adjuvants

Definition

Adjuvants are defined in Commission Regulation (EC) No. 1107/2009 Article 2 (3) d, as substances or preparations which includes co-formulants or preparations with one or more co-formulant(s), and in the form in which they are delivered to the user and placed on the market with the purpose of being mixed by the user with a plant protection product in order to increase its impact or other pesticidal properties. Its impact is not to be interpreted in the sense of that of a safener/synergist. Adjuvants are products which are applied as a tank mix with plant protection products and which improve, for example, wetting or the adhesion of plant protection products, or which prevent foaming.

Provisions concerning the placing on the market of adjuvants

Adjuvants may only be placed on the market if they fulfil the following requirements:

- They must be approved by the Norwegian Food Safety Authority according to the specified national documentation requirements[1] and other Union legislation ((EC) No. 1107/2009 Article 58 (1)).
- They must not have any harmful effects on health and environment when used correctly and for their intended purpose.
- It must be documented that the adjuvant increase the effect of the plant protection product, and is only to be used as an adjuvant and not just alone.
- The adjuvant must be properly labelled with:
    - name of the additive,
    - name and address of the person who is responsible for packing the additive for delivery to the user,
    - the use of the product,
    - identification of the additive according to the nature and quantity,
    - proposed CLP classification according to Commission Regulation (EC) 1272/2008,
    - the expiration date.
- Where recommendations is proposed on the label for the use of the adjuvant product with other plant protection products, the performance of the mixture and physical/chemical compatibility of the different products must been determined/examinated.

[1] Until requirements for approval of adjuvants has been made on EU level, national requirements settled in this document are valid according to EC no. 1107/2009 Article 58.3.

The approval procedure for adjuvants

Applications for the approval of adjuvants according to specified requirements must be submitted to the Norwegian Food Safety Authority (in electronic form on a data CD). The authorities check to see whether it can be assumed for definite that the adjuvant will fulfil all the requirements to be placed on the marked.

Applicants must provide the following documents

- A completed application form.
- A declaration confirming that the product do not have any harmful effects on health and environment when used properly and for their intended use nor as a consequence of its application.
- Complete composition of the product (the content of all co-formulants (trade names) in the product must be listed in g/kg or g/L). All formulants in the product shall be identified in compliance with the requirements in Table 1.
- Safety data sheet (SDS) for the product (in Norwegian).
- Safety data sheet for all formulants (in Norwegian or English).
- Proposed label (in Norwegian).
- Documentation of physical and chemical compatibility on proposed mixes of adjuvant and plant protection products.
- 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».

Processing time for the application will be estimated to the applicant when application is received. If the Norwegian Food Safety Authority demands further documentation and samples in order to pursue any doubts, processing time will be extended.

Authorisation holder has the responsibility that safety data sheets are made pursuant to Article 31 of Commission Regulation (EC) no 1907/2006 and CLP. If the submitted information and documentation give rise to doubt, the Norwegian Food Safety Authority can demand further documentation and/or samples.

Table 1: *Requirements for identification of formulants.*

Identity, purity and composition	Formulants/adjuvants shall, where possible, be identified both by their chemical name as given in Part 3 of Annex VI to Commission Regulation (EC) No 1272/2008, if not included in that Regulation, in accordance IUPAC and CA nomenclature. For each component present in the adjuvant the relevant trade name, CAS and EC number, purity, and structural formula, where they exist, shall be provided. Where the information provided does not fully identify the formulants, an appropriate specification must be provided. For co-formulants, which are mixtures, the detailed complete composition shall be provided. If applicant do not have access to proprietary data of suppliers of the co-formulants, please ask supplier to submit the data the Norwegian Food Safety Authority.[2] The information will be treated as strictly confidential.

Application fee

The Norwegian Food Safety Authority charges fees for processing applications according to regulation *"Forskrift om gebyrer til Mattilsynet"* and *"Nasjonal godkjenning av klebemiddel",* FOR-2004-02-13-406.

[2] P.O. Box 3, 1431 Ås. Norway.