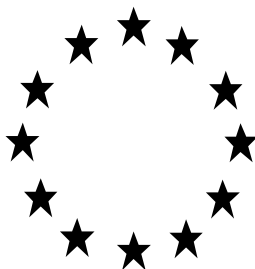


Draft Renewal Assessment Report
under Regulation (EC) 1107/2009



FORAMSULFURON

Volume 3 – B.3 (AS)

Rapporteur Member State: Finland
Co-Rapporteur Member State: Slovakia

March 2015

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List of Endpoints

Version History

When	What
2015/March	First draft RAR

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B.3. DATA ON APPLICATION

In accordance with the guidance document (SANCO/12592/2012) on the ‘Template Assessment Report’ only limited information for efficacy will be provided to address the requirements of Article 4(3) of Regulation (EC) No 1107/2009. Detailed consideration of efficacy will occur in the subsequent product authorisation process at Member State level when a full biological assessment dossier will be provided. Therefore only limited efficacy information is required for foramsulfuron and has been provided under the appropriate headings in line with the guidance for renewals - Guidance Document on the renewal of approval of active substances to be assessed in compliance with Regulation (EU) No 844/2012 Appendix II (SANCO/2012/11251).

B.3.1. USE OF THE ACTIVE SUBSTANCE

Active substance foramsulfuron belong to group of sulfonylurea family.

The application rate of Equip OD is either one application at 2.6L/ha (equivalent to 60g foramsulfuron) or a split application (two applications) at 1.3L/ha (30g foramsulfuron). The water volume used for the application varies from 150 to 400 L/ha.

B.3.2. FUNCTION

Foramsulfuron acts as a selective post-emergent herbicide in maize.

B.3.3. EFFECTS ON HARMFUL ORGANISMS

The visible symptoms of herbicidal action after post-emergence application are almost immediate arrestation of growth followed by leaf yellowing, inhibition of anthocyanin production and finally progressive shoot necrosis. Depending on plant susceptibility and environmental conditions, plants will be completely destroyed between 1 and 3 weeks after application.

At dose rates of 45 to 60 g per hectare, foramsulfuron is effective in controlling annual and perennial grasses occurring in maize, especially *Agropyron repens*, *Echinochloa crus-galli*, *Setaria viridis*, *Poa annua*, *Panicum* spp., *Lolium* spp., *Sorghum* spp. Efficacies of the indicated species were equal or surpassed a reference substance. Foramsulfuron was found to poorly control *Digitaria* spp.

At dose rates of 45 to 60 g per hectare, foramsulfuron is also controlling a broad spectrum of broad-leaved weeds:

Control of *Chenopodium album*, *Galinsoga parviflora*, *Mercurialis annua*, *Stellaria media*, *Solanum nigrum* and *Viola* spp. (average efficacy ca. 94 %) surpassed the standard reference substance.

Cruciferous weeds such as *Brassica napus napus*, *Capsella bursa-pastoris*, *Myagrurn perfoliatum*, *Raphanus raphanistrum*, *Sinapis arvensis* and *Thlaspi arvense* were controlled by 98-100 % on average.

Control of *Amaranthus retroflexus*, *Anagallis arvensis*, *Abutilon theophrasti*, *Galium aparine*, *Lamium* spp., *Matricaria* spp. and *Portulaca oleracea* was equivalent to the standard reference substance.

The main gap in efficacy of foramsulfuron was found with *Polygonum* species, mainly with *P. convolvulus* and *P. aviculare* and to a lesser extent also with *P. lapathifolium* and *P. persicaria*.

B.3.4. FIELD OF USE ENVISAGED

Foramsulfuron was developed for agricultural use. The use evaluated for the first EU approval was the use as a post-emergence herbicide for the control of broadleaved weeds and grasses in maize (*Zea mays*). The same use pattern is submitted for the renewal process.

B.3.5. HARMFUL ORGANISMS CONTROLLED AND CROPS OR PRODUCTS PROTECTED OR TREATED

Foramsulfuron is effective in controlling most annual and perennial grasses occurring in maize, such as *Echinochloa crus-galli*, *Setaria* spp., *Panicum* spp., *Poa annua*, *Lolium* spp., *Sorghum* spp. and *Agropyron repens*. It also controls a broad spectrum of broad-leaved weeds, including *Amaranthus retroflexus*, *Solanum nigrum*, *Stellaria media*, *Mercurialis annua*, *Abutilon theophrasti*, and most agriculturally important crucifers.

B.3.6. MODE OF ACTION

As with other herbicides of the sulfonylurea family, the primary biochemical target site of foramsulfuron is the enzyme acetohydroxyacid synthase (AHAS) in the aliphatic amino acid pathway. Selectivity of foramsulfuron is due to a combination of factors. Maize plants take up significantly less material than susceptible target plants, translocation to other parts is less pronounced in maize and degradation is much faster.

The only compound accountable for the herbicidal action is the parent substance, foramsulfuron. No herbicidal active metabolite is formed in plants or in soil. Consequently, foramsulfuron does not release active metabolites or degradation products after agricultural use as a herbicide.

Summary information on foramsulfuron

A.I.

IUPAC name:

Foramsulfuron

1-(4,6-dimethoxypyrimidin-2-yl)-3-[2-(dimethylcarbamoyl)-5-formamidophenylsulfonyl]urea

Chemical group:

Sulfonylurea

Mode of action:

ALS inhibition

Plant translocation:

Foliar systemic translocation

Biological action:

Foliar uptake by target weeds, followed by stopping of growth, yellowing chlorosis, necrosis and destruction of the plant between 1 and 3 weeks after application

Harmful organism, plant growth regulator, etc..

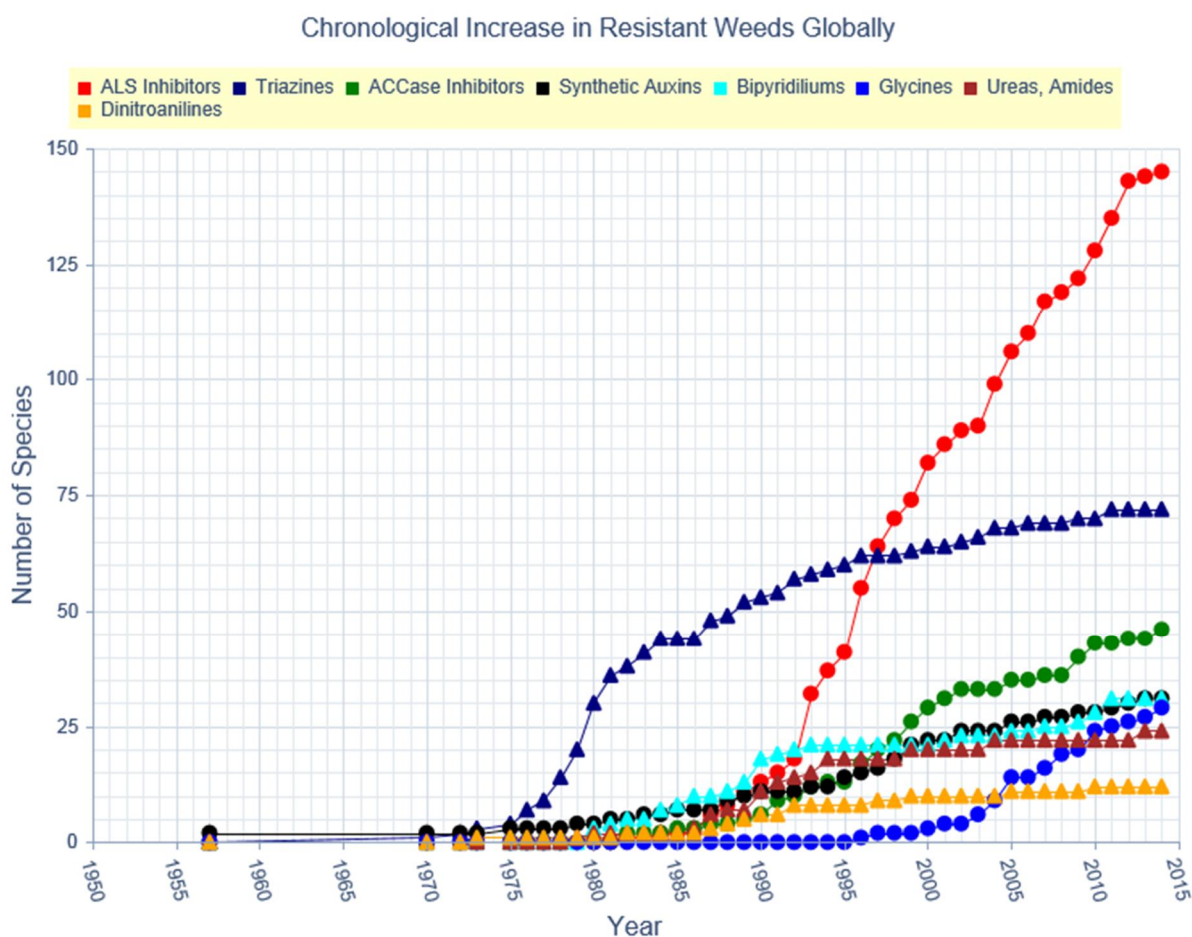
Foliar uptake and systemic translocation. Root uptake only to a very limited degree

Root-uptake, foliar-uptake, systemic etc..

B.3.7. INFORMATION ON THE OCCURRENCE OR POSSIBLE OF THE DEVELOPMENT OF RESISTANCE AND APPROPRIATE MANAGEMENT STRATEGIES

As with other herbicides of the sulfonylurea family, primary biochemical target site of foramsulfuron is the enzyme acetolactate synthase (ALS) in the aliphatic amino acid pathway. Hence the substance belongs to the mode of action group B according to the HRAC (Herbicide Resistance Action Committee) classification.

It has been shown that populations of the indicated weeds exhibit resistance to ALS-inhibiting substances (<http://weedsience.org/Resistance>). These species are known to easily evolve resistance due to their high inherent intraspecific variability and their high fecundity. 37 % of the resistant weeds worldwide exhibit resistance to ALS-inhibitors. None of the various mode of actions groups is provoking higher numbers of resistant biotypes every year than ALS-inhibitors. For some cases, especially *Lolium perenne*, even cross resistance to alternate mode of action groups has been reported.



The risk of weeds developing resistance to foramsulfuron is increased by the fact, that maize is a widely grown crop in certain areas, with short rotations, sometimes even monocropped. Selection pressure is augmented by the temporary necessity of two foramsulfuron applications in order to obtain satisfactory control of certain weeds. This applies particularly to weeds, that are characterised by

continuous emergence, hence requesting a first application shortly after emergence (BBCH 12-13) and the second within the forthcoming 7 to 14 days.

Altogether, the inherent and agronomic risk factors mentioned lead to the overall assessment of a potentially high risk of resistance to foramsulfuron.

The notifier himself assesses the resistance risk as to be “moderate to high”, stating that the risk is reduced mainly by the facts, that (i) ALS-inhibiting herbicides have not been used in maize for a long time and (ii) as in maize a great number of products acting differently in the target plants than ALS-inhibitors is available, farmers have not necessarily to rely on ALS-inhibitor herbicides for weed control. The alternative herbicides belong to the mode of action groups C1 (inhibition of Photosynthesis II), C3 (C1 (inhibition of Photosynthesis II), F2 (4-hydroxyphenyl-pyruvate-dioxygenase -inhibition), K1 (microtubule assembly inhibition), K3 (inhibition of cell division) and O (action like indole acetic acid).

B.3.8. REFERENCES RELIED ON

Literature search:

The literature search carried out by the applicant was summarised in Document MCA section 9. The RMS considers the literature search provided as acceptable.

Databases: STN, a scientific information platform hosted by CAS, itself a division of the American Chemical Society, was selected as the preferred provider. Following data bases were used for the literature search: Agricola, Biosis, CABA, Chemical Abstracts, Derwent Drug File (DRUGU), EMBASE, Esbiobase, IPA, Medline, Pascal, PQSciTech, Registry, Scisearch, Toxcenter, Ulidat and FSTA.

Time window: January 1st 2004 – August 2nd 2013 for the parent compound and metabolites.

Input parameters: IUPAC name, CAS number, common name, code and abbreviation, molecular structure, molecular formula, molar mass and/or other names/codes, as far as available.

Results: A total of 430 identified and evaluated for potential relevance for foramsulfuron and its metabolites. Of these, 384 summary records were excluded after a rapid assessment of relevance, and 46 full-text documents were assessed in detail.

As a summary 45 studies were excluded from the risk assessment because the publications did not meet the relevance criteria for the detailed assessment. Moreover, one study was unclear of relevance and only one study from the whole literature search was revealed for further examination (KCA 8.6.2).

A reference list containing these 46 documents were included in Doc MCA section 9.

There were no articles with relevance for this section.

Data Point	Author(s)	Year	Title Compagny Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation