



## HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

### 1. **BESLUIT**

Op 27 juni 2012 is van

Du Pont de Nemours (Nederland) B.V.  
Baanhoekweg 22  
3313 LA DORDRECHT

een aanvraag tot Vrijwillig Zonale Herregistratie van de toelating van een gewasbeschermingsmiddel met Nederland als betrokken lidstaat ontvangen als bedoeld in artikel 33 Verordening (EG) 1107/2009 (verder te noemen: de Verordening) voor het gewasbeschermingsmiddel

### **SAFARI**

op basis van de werkzame stof triflusulfuron-methyl. Nederland is in deze een betrokken lidstaat, als bedoeld in artikel 36, tweede lid; de beoordelend lidstaat is Duitsland.

**HET COLLEGE BESLUIT** tot toelating van bovenstaand middel.

Alle bijlagen, waaronder registratierapport deel A en deel B, vormen een onlosmakelijk onderdeel van dit besluit.

#### **1.1 Samenstelling, vorm en verpakking**

De toelating geldt uitsluitend voor het middel in de samenstelling, vorm en de verpakking als waarvoor de toelating is verleend.

#### **1.2 Gebruik**

Het middel mag slechts worden gebruikt volgens het wettelijk gebruiksvoorschrift, letterlijk en zonder enige aanvulling, zoals opgenomen in deel A van het registratierapport, Appendix I.

#### **1.3 Classificatie en etikettering**

Mede gelet op de onder "wettelijke grondslag" vermelde wetsartikelen, dienen alle volgende aanduidingen en vermeldingen conform de geldende regelgeving op of bij de verpakking te worden vermeld:

- De aanduidingen, letterlijk en zonder enige aanvulling, zoals vermeld onder "verpakkingsinformatie" in bijlage I.
- Het wettelijk gebruiksvoorschrift, letterlijk en zonder enige aanvulling, zoals opgenomen in deel A van het registratierapport, Appendix I.
- Overige bij wettelijk voorschrift voorgeschreven aanduidingen en vermeldingen.

- De classificatie die overeenkomstig het toelatingsbesluit is vastgesteld, moet volgens de voorschriften op de verpakking worden vermeld, zoals beschreven in bijlage II en in paragraaf 2.2 van deel A van het registratierapport.

#### 1.4 Aflever- en opgebruiktermijn (respijtperiode)

Bij de herregistratie wordt het etiket uitgebreid. Rode biet wordt toegelaten als nieuwe toepassing en de restricties met het verbod op vervoeding van het loof aan vee en gebruik van maximaal 120 g product per hectare in 1 jaar binnen een cyclus van 3 jaar vervallen.

Daarnaast wordt het etiket uitgebreid met de eis dat bij toepassing van SAFARI op percelen die grenzen aan oppervlaktewater 75% driftreducerende technieken worden gebruikt.

Het volgnummer van het etiket wordt bij deze herregistratie daarom opgehoogd van W.5 naar W.6. Vanwege de inperking worden de respijttermijnen voor afleveren en opgebruik van verpakkingen met volgnummer W.5 en ouder beperkt.

Het nieuwe gebruiksvoorschrift en de nieuwe etikettering dienen bij de eerstvolgende aanmaak op de verpakking te worden aangebracht. De te hanteren w-coderingen en aflever- en opgebruiktermijnen voor oude verpakkingen staan vermeld onder "toelatingsinformatie" in bijlage I.

## 2. WETTELIJKE GRONDSLAG

Besluit	Artikel 80, vijfde lid juncto artikel 128 Wgb (oud)
Classificatie en etikettering	artikel 31 en artikel 65 van de Verordening (EG) 1107/2009
Gebruikt toetsingskader	Rgb d.d. 13 juni 2011 en Evaluation Manual 1.1

## 3. BEOORDELINGEN

### 3.1 Fysische en chemische eigenschappen

De aard en de hoeveelheid van de werkzame stoffen en de in humaan-toxicologisch en ecotoxicologisch opzicht belangrijke onzuiverheden in de werkzame stof en de hulpstoffen zijn bepaald. De identiteit van het middel is vastgesteld. De fysische en chemische eigenschappen van het middel zijn vastgesteld en voor juist gebruik en adequate opslag van het middel aanvaardbaar geacht.

### 3.2 Analysemethoden

De geleverde analysemethoden voldoen aan de vereisten om de residuen te kunnen bepalen die vanuit humaan-toxicologisch en ecotoxicologisch oogpunt van belang zijn, volgend uit geoorloofd gebruik.

### 3.3 Risico voor de mens

Van het middel wordt voor de toegelaten toepassingen volgens de voorschriften geen onaanvaardbaar risico voor de mens verwacht.

### 3.4 Risico voor het milieu

Van het middel wordt voor de toegelaten toepassingen volgens de voorschriften geen onaanvaardbaar risico voor het milieu verwacht.

### 3.5 Werkzaamheid

Van het middel wordt voor de toegelaten toepassingen volgens de voorschriften verwacht dat het werkzaam is.

11754 N

Voor nadere onderbouwing van de beoordelingen verwijzen wij u naar deel A en B van het Registration Report als toegevoegd aan de bijlagen van dit besluit overeenkomstig Besluit beleidsregel bekendmaken delen A en B van het Registration Report.

**Bezwaarmogelijkheid**

*Degene wiens belang rechtstreeks bij dit besluit is betrokken kan gelet op artikel 4 van Bijlage 2 bij de Algemene wet bestuursrecht en artikel 7:1, eerste lid, van de Algemene wet bestuursrecht, binnen zes weken na de dag waarop dit besluit bekend is gemaakt een bezwaarschrift indienen bij: het College voor de toelating van gewasbeschermingsmiddelen en biociden (Ctgb), Postbus 8030, 6710 AA, EDE. Het Ctgb heeft niet de mogelijkheid van het elektronisch indienen van een bezwaarschrift opengesteld.*

Ede, 13 mei 2016

HET COLLEGE VOOR DE TOELATING VAN  
GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN,

Ir. J.F. de Leeuw  
Voorzitter

11754 N

## BIJLAGE I DETAILS VAN DE AANVRAAG EN TOELATING

### 2.1 Aanvraaginformatie

*Aanvraagnummer:* 20120802 NLTHG  
*Type aanvraag:* Vrijwillig zonale aanvraag tot herregistratie van gewasbeschermingsmiddeltoelating met Nederland als betrokken lidstaat  
*Middelnaam:* SAFARI  
*Verzenddatum aanvraag:* 20 juni 2012  
*Formele registratiedatum: \** 27 juni 2012  
*Datum in behandeling name:*  
*Datum compliance check:* 27 augustus 2010

\* Datum waarop zowel de aanvraag is ontvangen als de aanvraagkosten zijn voldaan.

### 2.2 Stofinformatie

Werkzame stof	Gehalte
triflusulfuron-methyl	50%

- De stof is per 1 januari 2010 geplaatst op Annex I van Richtlijn 91/414/EEG (Dir 2009/77/EC d.d. 1 juli 2009) en vervolgens bij Uitvoeringsverordening (EU) [540/2011](#) d.d. 25 mei 2011 goedgekeurd) voor alleen gebruik in bieten en met restricties op vervoeding en met een maximale dosering per hectare eens per 3 jaar. Bij EC Richtlijn 287/2012 d.d. 30 maart 2012 zijn de voorwaarden voor goedkeuring aangepast en mag de stof ook in andere gewassen worden toegepast. Bovendien vervallen hierbij de restricties op vervoeding en de maximale dosering eens per 3 jaar. De goedkeuring van deze werkzame stof expireert op 31 december 2019.

### 2.3 Toelatingsinformatie

*Toelatingsnummer:* 11754 N  
*Expiratiedatum:* 1 april 2026  
*Afgeleide parallel of origineel:* origineel  
*Biocide, gewasbeschermingsmiddel of toevoegingsstof:* Gewasbeschermingsmiddel  
*Gebruikers:* Professioneel

W-coderingen en aflever- en opgebruiktermijnen:

- W-codering professioneel gebruik: 6
- Vorige w-codering professioneel gebruik: 5 en ouder
- Aflevertermijn professioneel gebruik: Tot 1 september 2016
- Opgebruiktermijn professioneel gebruik: Tot 1 juni 2017

### 2.4 Verpakkingsinformatie

*Aard van het preparaat:* Water dispergeerbaar granulaat

## BIJLAGE II Etikettering van het middel SAFARI

Professioneel gebruik

de identiteit van alle stoffen in het mengsel die bijdragen tot de indeling van het mengsel:

triflusulfuron-methyl

Pictogram	GHS08 GHS09
Signaalwoord	WAARSCHUWING
Gevarenaanduidingen	H351 Verdacht van het veroorzaken van kanker. H410 Zeer giftig voor in het water levende organismen, met langdurige gevolgen.
Voorzorgsmaatregelen	P201 Alvorens te gebruiken de speciale aanwijzingen raadplegen. P202 Pas gebruiken nadat u alle veiligheidsvoorschriften gelezen en begrepen heeft. P280 Beschermende handschoenen/beschermende kleding/oogbescherming/gelaatsbescherming dragen. P308 + P313 Na (mogelijke) blootstelling: een arts raadplegen. P391 Gelekte/gemorste stof opruimen. P501 Inhoud/verpakking afvoeren naar .... SP 1 Zorg ervoor dat u met het product of zijn verpakking geen water verontreinigt.
Aanvullende etiketelementen	EUH401 Volg de gebruiksaanwijzing om gevaar voor de menselijke gezondheid en het milieu te voorkomen.
Kinderveilige sluiting verplicht	Nee
Voelbare gevaarsaanduiding verplicht	Nee

**REGISTRATION REPORT  
Part A**

**Risk Management**

**Product name: SAFARI**

**Product code: triflusulfuron-methyl 50 WG**

**Active Substance: triflusulfuron-methyl 500 g/kg**

**Central Zone**

**Zonal Rapporteur Member State: Germany**

**NATIONAL ASSESSMENT: The Netherlands**

**Applicant:**

**DuPont de Nemours**

**Date: April 2016**

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## **PART A – Risk Management**

This document describes the acceptable use conditions required for the re-registration of SAFARI containing triflusaluron-methyl in The Netherlands. This evaluation is required subsequent to the inclusion of triflusaluron on Annex 1.

The risk assessment conclusions are based on the information, data and assessments provided in Registration Report, Part B Sections 1-7 and Part C and where appropriate the addendum for The Netherlands. The information, data and assessments provided in Registration Report, Parts B includes assessment of further data or information as required at national re-registration/registration by the EU review. It also includes assessment of data and information relating to SAFARI where that data has not been considered in the EU review. Otherwise assessments for the safe use of SAFARI have been made using endpoints agreed in the EU review of triflusaluron.

This document describes the specific conditions of use and labelling required for The Netherlands for the re-registration of SAFARI.

Appendix 1: The submitted draft product label has been checked by the competent authority. The applicant is requested to amend the product label in accordance with the decisions made by the competent authority. The final version of the label has to fulfil the requirements according to Article 16 of Directive 91/414/EEC.

Appendix 2: No letters of access to the protected data are needed for evaluation of this formulation.

Appendix 3: provides a list of data submitted in support of this evaluation.

### **1 Details of the application**

#### **1.1 Application background**

This application was submitted by DuPont de Nemours (Nederland) B.V. on 27 June 2012. It concerns a re-registration of the plant protection product SAFARI, a water dispersible granule containing 500 g/kg triflusaluron-methyl for use as a herbicide against broad leaf weeds and various annual grasses on sugar and fodder beets and in the minor uses of chicory and red beets. The minor use in red beets concerns an extension of the existing label.

#### **1.2 Annex I inclusion**

Triflusaluron-methyl was included on Annex I of Directive 91/414/EEC on 01 January 2010 under Commission Directive 2009/77/EC for uses as a herbicide in application on sugar and fodder beet at a maximum application rate of 60 g/ha only every third year on the same field. That inclusion was further restricted by a prohibition to feed foliage of treated crops to livestock.

Since the replacement of Directive 91/414/EEC by Regulation (EC) No 1107/2009, this substance is deemed to have been approved under that Regulation and is listed in Part A of the Annex to Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011, implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances.

On 25 June 2010 the notifier submitted an application for an amendment to the conditions of approval of triflusaluron. It requested the removal of the restrictions on use as a herbicide and of the limit on the

content of the impurity. That application was accompanied by additional information. It was submitted to France which had been designated rapporteur Member. The rapporteur Member State assessed the additional information submitted by the applicant.

By Commission Implementing Regulation (EU) No 287/2012 of 30 March 2012 amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance triflusaluron Part A of the Annex is amended as follows:

(1) the column purity is replaced by the following: '≥ 960 g/kg';

(2) in the column 'Specific provisions' Part A is replaced by the following: 'Only uses as a herbicide may be authorised.'

For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on triflusaluron, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 26 February 2009 shall be taken into account. In this overall assessment

Member States must pay particular attention to the:

dietary exposure of consumers to residues of metabolites IN-M7222 and IN- E7710 in succeeding rotational crops and in products of animal origin,

protection of aquatic organisms and aquatic plants from the risk arising from triflusaluron and the metabolite IN-66036 and ensure that conditions of authorisation include risk mitigation measures such as buffer zones, where appropriate,

potential for ground water contamination by the degradation products IN- M7222 and IN-W6725 when the active substance is applied in regions with vulnerable soil and/or climatic conditions. Conditions of authorisation must include risk mitigation measures, where appropriate.

Specific Conditions: If triflusaluron is classified as carcinogenic category 2 in accordance with Regulation (EC) No 1272/2008, the Member States concerned shall request the submission of further information on the relevance of the metabolites IN-M7222, IN-D8526 and IN-E7710 with respect to cancer. They shall ensure that the notifier provides that information to the Commission within six months from the notification of the classification decision concerning that substance.

These concerns were all addressed.

Expiration of approval: 31/12/2019

### **1.3 Regulatory approach**

To obtain re-approval the product SAFARI must meet the conditions of Annex I inclusion and be supported by dossiers satisfying the requirements of Annex II and Annex III, with an assessment to Uniform Principles, using Annex I agreed end-points.

This application was submitted in order to allow the re-registration of an already approved product in The Netherlands in accordance with the above.

#### 1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of SAFARI it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B, sections 1, 5, 6 and 7 and Part C.

#### 1.5 Letters of Access

Letter of Access is not necessary as the applicant is owner of the EU data package for the active substance.

### 2 Details of the authorisation

#### 2.1 Product identity

Product name:	SAFARI
Authorization number (for re-registration):	11754 N
Function:	herbicide
Applicant:	DuPont de Nemours (Nederland) B.V.
Composition:	500 g/kg triflusulfuron-methyl
Formulation type:	WG
Packaging:	120g (210mL) or 600g (1100mL) HDPE jars

#### 2.2 Classification and labelling

##### 2.2.1 Classification and labelling under Regulation (EC) No 1272/2008

The identity of all substances in the mixture that contribute to the classification of the mixture \*:

Triflusulfuron-methyl

Pictogram:	GHS08 GHS09	Signal word:	Warning
H-statements:	H351 H410	Suspected of causing cancer. Very toxic to aquatic life with long lasting effects.	
P-statements:	P201 P202 P280 P308+P313	Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Wear protective gloves/protective clothing/eye protection/face protection. IF exposed or concerned: Get medical advice/attention.	

	P391	Collect spillage.	
	P501	Dispose of contents/container to ....	
Supplemental Hazard information:	EUH401	To avoid risks to human health and the environment, comply with the instructions for use.	
	SP1	Do not contaminate water with the product or its container.	
Child-resistant fastening obligatory?			Not applicable
Tactile warning of danger obligatory?			Not applicable

## 2.2.2 Specific restrictions linked to the intended uses

### The following restriction and warning sentences need to be included in the Legal Instructions for Use:

*Om in het water levende organismen te beschermen is toepassing uitsluitend toegestaan wanneer in perceelstroken die grenzen aan oppervlaktewater in de eerste 14 m vanaf de insteek van de sloot gebruik wordt gemaakt van minimaal 75% driftreducerende spuitdoppen.*

*Om niet tot de doelsoorten behorende planten te beschermen is toepassing uitsluitend toegestaan wanneer in perceelstroken die niet grenzen aan oppervlaktewater in de eerste 14 m van het gewas, gemeten vanaf het midden van de laatste gewasrij of de laatste plant in de rij, gebruik wordt gemaakt van minimaal 50% drift reducerende spuitdoppen in combinatie met een kantdop.*

*Na toepassing in bieten kunnen onder stresscondities enkele dagen na toepassing gele vlekjes op het blad verschijnen welke echter weer snel verdwijnen"*

#### Resistentiemanagement

*Dit middel bevat de werkzame stof triflusulfuron-methyl. Triflusulfuron-methyl behoort tot de sulfonylureumverbindingen. De HRAC code is B. Bij dit product bestaat er kans op resistentieontwikkeling. In het kader van resistentiemanagement dient u de adviezen die gegeven worden in de voorlichtingsboodschappen op te volgen.*

### 2.3 Product uses

Table 2.3: Authorized uses = uses applied for: SAFARI; triflusulfuron-methyl 500 g/kg

1	2	3	4	5	6	7	8	10	11	12	13	14
Use- No.	Member state(s)	Crop and/ or situation	F G or I	Pests or Group of pests controlled	Application			Application rate per treatment			PHI (days)	Remarks: a) max. no. of applications per crop and season b) Maximum product rate per season c) additional remarks
					Method / Kind	Timing / Growth stage of crop & season	Number / (min. Interval between applications)	kg product / ha	g as/ha	Water L/ha  min / max		
Existing use												
1	NL	Sugar and fodder beet	F	Broad leaf weeds	Medium-low volume spraying, broadcast or band application	BBCH 10-39 (april-july)	4 / 7	0.03	15	150-400	None <sup>1</sup>	60 g a.s. maximum per season <sup>2</sup>
Minor use												
2	NL	Red beet	F	Broad leaf weeds	Medium-low volume spraying, broadcast or band application	BBCH 10-39 (april-july)	4 / 7	0.01- 0.03	15	150-400	None <sup>1</sup>	30 g a.s. maximum per season <sup>2</sup>
3	NL	Chicory (NL: witlof) pennenteelt en zaadteelt	F	Broad leaf weeds	Medium-low volume spraying, broadcast or band application	BBCH 10-39 (april-july)	4 / 7	0.01- 0.03	15	150-400	None <sup>1</sup>	30 g a.s. maximum per season <sup>2</sup>
4	NL	Chicory (NL: cichorei)	F	Broad leaf weeds	Medium-low volume spraying, broadcast or band application	BBCH 10-39 (april-july)	4 / 7	0.03	15	150-400	None <sup>1</sup>	60 g a.s. maximum per season <sup>2</sup>

<sup>1</sup> PHI is covered by conditions of use and/or growing period between application and harvest.

<sup>2</sup> All applications may include the use of an adjuvant

### **3 Risk management**

#### **3.1 Reasoned statement of the overall conclusions taken in accordance with the Uniform Principles**

##### **3.1.1 Physical and chemical properties (Part B, Section 1, Points 2 and 4)**

###### **Overall Summary:**

SAFARI was the representative formulation during the EU review process. The water dispersible granules should be used together with an adjuvant.

All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is that of a brown granular with a mild lignin odour. It is not explosive, has no oxidising properties and is not highly flammable. In aqueous solution, it has a pH value around 8. The stability data indicate a shelf life of at least 2 years at ambient temperature in HDPE. Its technical characteristics are acceptable for a water dispersible granule.

**Implications for labelling:** None

###### **Compliance with FAO specifications:**

The product SAFARI complies with FAO specifications.

###### **Compliance with FAO guidelines:**

The product SAFARI complies with FAO guidelines, as far as could be assessed.

###### **Compatibility of mixtures:**

Tank mixes with Betanal Quattro, Centium, Ethosat 500, Fasnet, Venzar and Venzar SC were tested. For all combinations constant agitation was necessary, but they were all physical compatible. Studies were provided in Section 7 (efficacy).

###### **Nature and characteristics of the packaging:**

Information with regard to type, dimensions, capacity, size of opening, type of closure, strength, leakproofness, resistance to normal transport and handling, resistance to and compatibility with the contents of the packaging, have been submitted, evaluated and is considered to be acceptable.

###### **Nature and characteristics of the protective clothing and equipment:**

Information regarding the required protective clothing and equipment for the safe handling of SAFARI has been provided and is considered to be acceptable.

##### **3.1.2 Methods of analysis (Part B, Section 2, Point 5)**

###### **3.1.2.1 Analytical method for the formulation (Part B, Section 2, Point 5.2)**

The active substance of SAFARI can be quantified using an analytical HPLC method. The active substance is dissolved in acetonitrile / borat buffer, and analysed on a HPLC reversed phase system with UV-detection and internal calibration. The method can be used in water dispersible granules (WG).

Triflurosulfuron does not contain any impurity of toxicological or ecotoxicological concern.

### **3.1.2.2 Analytical methods for residues (Part B, Section 2, Points 5.3 – 5.8)**

Adequate analytical methods are available to monitor all compounds given in the respective residue definition of food of plant origin, soil, water and air. Residues of triflurosulfuron-methyl can be determined in food of plant origin, soil and water by LC-MS/MS. Methods for animal matrices are not required, because no MRLs have been set. An HPLC-UV method exists for the determination of triflurosulfuron-methyl in air. Methods for body fluids and tissues are not required since triflurosulfuron-methyl is not considered to be toxic or very toxic (T / T+).

The Dutch national requirement regarding the residue analytical method for surface water is met. The LOQ for the method for surface water is 0.1µg/L.

### **3.1.3 Mammalian Toxicology (Part B, Section 3, Point 7)**

#### **3.1.3.1 Acute Toxicity (Part B, Section 3, Point 7.1)**

SAFARI was the representative formulation in the EU review of triflurosulfuron-methyl. The acute toxicity studies for SAFARI were evaluated during the EU review. All data are considered adequate.

SAFARI containing 500 g/kg triflurosulfuron-methyl, has a low toxicity in respect to acute oral and dermal toxicity and is not irritating to the rabbit eye and skin. It has been found to be not a skin sensitiser to the guinea pig.

#### **3.1.3.2 Operator Exposure (Part B, Section 3, Point 7.3)**

The operator exposure estimations carried out with NL model for mixing and loading and EUROPOEM I indicated that the acceptable operator exposure level (AOEL) will not be exceeded under conditions of intended uses without the use of PPE (20% of the AOEL).

#### **3.1.3.3 Bystander Exposure (Part B, Section 3, Point 7.4)**

The bystander and/or resident exposure estimations carried out with EUROPOEM II and the UK and DE models indicated that the acceptable operator exposure level (AOEL) for triflurosulfuron-methyl will not be exceeded under conditions of intended uses (max 1.45% of the AOEL).

#### **3.1.3.4 Worker Exposure (Part B, Section 3, Point 7.5)**

The worker exposure estimations carried out with EUROPOEM II indicated that the acceptable operator exposure level (AOEL) will not be exceeded under conditions of intended uses without the use of PPE (4% of the AOEL).

### **3.1.4 Residues and Consumer Exposure (Part B, Section 4, Point 8)**

#### **3.1.4.1 Residues (Part B, Section 4, Points 8.3 and 8.7)**

Subsequent to the EU review of triflurosulfuron-methyl an evaluation of all uses has been made to establish EU MRLs (Reg. (EC) No 839/2008). This evaluation reviewed all the data relevant to establishing MRLs for all supported uses and considered the dietary risk assessments appropriate for all EU member states utilising the EFSA model. The MRLs for triflurosulfuron-methyl are published in Annex III of Regulation (EC) No 396/2005.

The proposed uses of SAFARI concern sugar and fodder beet, red beet and chicory root (NL cichorei) and chicory witloof. The risk assessment conclusions are based on the information, data and assessments

provided in Registration Report, Part B Sections 4 prepared for the product DEBUT by ZRMS Germany. The data available is considered sufficient for risk assessment of the use of triflurosulfuron-methyl on red beets, witloof chicory and sugar and fodder beets.

A new study demonstrating storage stability was provided.

Six supervised residue trials on sugar beets were available. The available data has been previously evaluated at EU level and is described in detail in the DAR and in EFSA's conclusion regarding the peer review of the pesticide risk assessment of the active substance triflurosulfuron. Although in Part B Sections 4 prepared by ZRMS Germany the critical GAP indicates three applications, the trials were performed with four applications and with application rates according to the critical GAP. However, since a higher number of treatments represent a more critical situation, these trials were used by ZRMS Germany for risk assessment of sugar and fodder beets. Furthermore these trials can be used for the evaluation of the intended use on red beets and chicory roots (extrapolation guideline SANCO7525/VI/95 – rev.9, March 2011).

Residues of triflurosulfuron methyl and its metabolites IN-E7710 and IN-M7222 were all below the LOQ of 0.01 mg/kg in sugar beet roots at harvest (PHI: 90 d). In sugar beet leaves (PHI: 28 d) triflurosulfuron methyl residues between <0.01 and 0.015 mg/kg were detected while residues of IN-E7710 and IN-M7222 were all below the LOQ of 0.01 mg/kg. An exceedance of the current MRL of 0.02\* mg/kg for triflurosulfuron in beetroot, sugar beet root and chicory roots as laid down in Reg. (EU) 396/2005 is not expected.

For the evaluation of the intended use on witloof, three residue trials were available all performed with four applications with application rates threefold the intended rate. However, in spite of exaggerated dose rates at harvest neither residues of triflurosulfuron methyl nor of its metabolites IN-E7710 and IN-M7222 above the LOQ of 0.01 mg/kg were detected in shoots.

An exceedance of the current MRL of 0.02\* mg/kg for triflurosulfuron in witloof as laid down in Reg. (EU) 396/2005 is not expected.

According to Regulation (EU) No 540/2011, Member States must pay particular attention to the dietary exposure of consumers to residues of metabolites IN-M7222 and IN-E7710 in succeeding rotational crops and in products of animal origin. A field crop rotation study with triflurosulfuron methyl was conducted during the growing seasons of 2009 and 2010 investigating residues in rotational crops planted after treatment of sugar beet with triflurosulfuron methyl. In succeeding crops, no residues of triflurosulfuron methyl or metabolites IN-M7222 or IN-E7710 were present at significant levels (max 0.037 mg/kg of IN-M7222 in rotated straw). This gives indication that the possible presence of residual compounds in rotational crops resulting from the use of triflurosulfuron methyl is limited to low amounts and that the resulting dietary burden for human and livestock can be considered as minor, taking into account the ADI value established for those metabolites. Thus, it is concluded that there is no need for a plant-back restriction or the setting of MRLs of IN M7222 in rotational crops.

#### **3.1.4.2 Consumer exposure (Part B, Section 4, Point 8.10)**

Long term exposure:

The chronic consumer risk assessment was carried out using the EFSA PRIMo model (TMDI calculation) and the German NVS II – model (NTMDI calculation).

Triflurosulfuron-methyl:

The TMDI was found to utilise the ADI of 0.003 mg/kg bw/day by 29 % based on UK toddlers.



As no acute reference (ARfD) has been set for triflurosulfuron-methyl, there is no need to evaluate the acute risk for this active substance.

Based on these assessments to estimate the risk for consumer through diet and other means it can be concluded that the use of product SAFARI does not lead to unacceptable risk for consumer when applied according to the recommendations.

### **3.1.5 Environmental fate and behaviour (Part B, Section 5, Point 9)**

The following chapters summarise specific exposure assessment for soil and surface water and the specific risk assessment for groundwater for the authorization of SAFARI in The Netherlands according to its intended uses in sugar beets, red beet and chicory.

No new study on the fate and behaviour of triflurosulfuron-methyl or SAFARI has been performed. Hence no potentially new metabolites need to be considered for environmental risk assessment.

For the metabolites IN-W6725, IN-D8526, IN-E7710 and IN-M7222 concentrations of  $\geq 0.1 \mu\text{g/L}$  in groundwater cannot be excluded in most FOCUS groundwater scenarios in the intended uses. An assessment of metabolites regarding their relevance for groundwater has been conducted during the EU evaluation process of active substance triflurosulfuron-methyl (see part B Section 8). The relevance of IN-W6725 was evaluated during the EU review (EFSA Scientific Report, 2008) and it was considered a non-relevant metabolite in accordance with the European Commission guidance document on the assessment of relevant metabolites in groundwater (SANCO/221/2000-rev.10, 25 February 2003). The Addendum to the DAR (August 2010) that was issued after submission of confirmatory data post Annex I inclusion states that the newly submitted information demonstrates that the metabolites IN-M7222, IN-D8526 and IN-E7710 are not relevant.

#### **3.1.5.1 Predicted Environmental Concentration in Soil (PECsoil) (Part B, Section 5, Points 9.4 and 9.5)**

For the intended use of the plant protection product SAFARI in sugar beets, red beet and chicory PECsoil was calculated for the active substance triflurosulfuron-methyl considering a soil depth of 5 cm, an SFO DT50 of 15 days, 2 applications of 30 g a.s./ha and an interception appropriate to the crop stage of 20%. The initial PEC relevant for risk assessment is 0.0552 mg/kg. Due to the fast degradation of triflurosulfuron-methyl in soil (DT90 < 365 d, SFO, field data) the accumulation potential of triflurosulfuron-methyl does not need to be considered.

For the metabolites no soil concentrations are calculated in the core assessment since they have been regarded as ecotoxicologically not relevant in the EU review of Triflurosulfuron-methyl.

The results for PEC soil for the active substance and its metabolites were used for the ecotoxicological risk assessment.

### 3.1.5.2 Predicted Environmental Concentration in Ground Water (PECGW) (Part B , Section 5, , Point 9.6)

Results of modelling with FOCUS-PELMO 5.5.3 in the core assessment show that the active substance triflurosulfuron-methyl is not expected to penetrate into groundwater at concentrations of  $\geq 0.1\mu\text{g/L}$  in the intended for uses in sugar beets.

For the metabolites IN-W6725, IN-D8526 and IN-M7222 concentrations of  $\geq 0.1\mu\text{g/L}$  in groundwater cannot be excluded. However, the metabolites IN-W6725, IN-D8526 and IN-M7222 are classified as not relevant for groundwater (SANCO/4439/09 – final rev.). As two metabolites (IN-D8526 and IN-M7222) show pH dependent degradation and this was not fully addressed by the calculations in the core assessment, Ctgb performed an additional assessment using the first tier model with worst-case input values related to the pH dependent degradation, in line with recent assessments of SAFARI.

This also addresses the Dutch requirement to use the FOCUS-PEARL model as opposed to the model used in the core.

As a result a higher leaching potential than assessed in the core was observed for all metabolites (IN-W6725, IN-D8526, IN-M7222 and IN-E7710), however it was checked that this was still covered by the non-relevance assessment presented in the EU dossier of triflurosulfuron-methyl (Addendum December 2010).

Hence the risk for leaching of the a.s. and metabolites is acceptable.

#### ***Monitoring data groundwater***

There are no data available regarding the presence of the substance triflurosulfuron-methyl in groundwater.

Regarding the presence of metabolites IN-W6725, IN-D8526, IN-E7710 and IN-M7222 no monitoring data are available.

### 3.1.5.3 Predicted Environmental Concentration in Surface Water (PECSW) (Part B , Section 5, Point 9.7 and 9.8)

For the intended use of the plant protection product SAFARI in sugar beets, red beet and chicory PEC<sub>sw</sub> was calculated for the active substance triflurosulfuron considering spray drift entry according to the Dutch model TOXSWA 1.2 and using the latest guidance documents on PEC<sub>sw</sub> calculations in the national registration procedure for pesticides in The Netherlands.

In compliance with Dutch guidelines, a standard drift rate of 1% was used for application to sugar beets/fodder beets. In addition the use of 75% drift reducing nozzles (corresponding to 0.5% drift) was assessed. The Dutch standard spring scenario was used in all simulation runs. Results are shown in the tables below.

**Predicted environmental concentrations of triflurosulfuron methyl and its metabolites in water and sediment for the edge-of-field ditch, 1.0% drift (corresponding to the obligatory use of 50% drift reducing nozzles)**

	Triflurosulfuron methyl	IN-D8526	IN-W6725	IN-E7710	IN-JK555
Initial PEC <sub>sw</sub> (µg/L)	0.2669	0.0522	0.0541	0.0183	0.1213
TWA PEC <sub>sw</sub> 21d (µg/L)	0.2243	0.0437	0.0457	0.0153	0.1023
TWA PEC <sub>sw</sub> 28 d (µg/L)	0.2072	0.0404	0.0422	0.0142	0.0945

**Predicted environmental concentrations of triflurosulfuron methyl and its metabolites in water and sediment for the edge-of-field ditch, 0.5% drift (corresponding to the use of 75% drift reducing nozzles)**

	Triflurosulfuron methyl	IN-D8526	IN-W6725	IN-E7710	IN-JK555
Initial PEC <sub>sw</sub> (µg/L)	0.1333	0.0261	0.0271	0.0091	0.0606
TWA PEC <sub>sw</sub> 21d (µg/L)	0.1121	0.0218	0.0229	0.0076	0.0511
TWA PEC <sub>sw</sub> 28 d (µg/L)	0.1035	0.0202	0.0212	0.0070	0.0473

The results for PEC surface water for the active substance and its metabolites were used for the ecotoxicological risk assessment.

**Monitoring data surface water**

Data from the Pesticide Atlas are used to evaluate potential exceedances of the authorisation threshold and environmental quality standards (MKN in Dutch, data source <http://www.rivm.nl/rvs/Normen>). These environmental quality standards consist either of the harmonised WFD thresholds derived according to the Fraunhofer methodology<sup>1</sup> (AA-EQS and MAC-EQS) or of an MPC value (which is usually derived on the basis of outdated guidance). When EQS values according to the Water Framework Directive are available, the MPC value is not used further in the analysis of monitoring data for the purpose of the registration.

The active substance triflurosulfuron-methyl was observed in the surface water (most recent data from 2013). The authorisation threshold equals 0.22 µg/L (30/11/2007, consisting of first or higher tier acute or chronic ecotoxicological threshold value, including relevant safety factors, which is used for risk assessment, in this case 0.1\*EC50 *Lemna*). The relevant EQS for this substance are the WFD thresholds and equal 0.13 µg/L for the AA-EQS and 0.28 µg/L for the MAC-EQS.

Several locations show an exceedance of the authorisation threshold, AA-EQS, and MAC-EQS. Therefore it is assessed whether there is a correlation between the observed exceedances and land use types. The observed exceedance of the water quality standard authorisation threshold is significantly correlated to the use in grassland, but not to the currently assessed uses. For the other water quality thresholds AA-EQS and MAC-EQS no correlation analysis is presented in the Pesticide Atlas. Therefore, no consequences can be drawn from the observed exceedance.

<sup>1</sup> P.L.A. van Vlaardingen and E.M.J. Verbruggen, Guidance for the derivation of environmental risk limits within the framework of 'International and national environmental quality standards for substances in the Netherlands' (INS). Revision 2007'. RIVM report 601782001.

**Drinking water criterion**

Triflurosulfuron-methyl has been on the Dutch market for > 3 years (authorised since authorised since 04-10-1996). This period is sufficiently large to consider the market share to be established. From the general scientific knowledge collected by the Ctgb about the product and its active substance, the Ctgb concludes that there are in this case no concrete indications for concern about the consequences of this product for surface water from which drinking water is produced, when used in compliance with the directions for use. The Ctgb does under this approach expect no exceeding of the drinking water criterion. The standards for surface water destined for the production of drinking water are met.

**3.1.5.4 Predicted Environmental Concentration in Air (PECAir) (Part B, Section 5, Point 9.9)**

Triflurosulfuron-methyl has a vapour pressure of  $6 \times 10^{-10}$  Pa at 20 °C. From calculations according to the Atkinson method, atmospheric half-life for triflurosulfuron-methyl was estimated to be 33.1 hours. Volatilisation from soil and plant surfaces is low showing 6.4 % and 0.8 %, resp., within 24 h. Therefore long-range transport is considered as negligible.

**3.1.6 Ecotoxicology (Part B, Section 6, Point 10)****3.1.6.1 Effects on Terrestrial Vertebrates Part B, Section 6, Points 10.1 and 10.3)**

The risk assessment for effects on birds and other terrestrial vertebrates was carried out according to the European Food Safety Authority Guidance Document on Risk Assessment for Birds and Mammals on request from EFSA (EFSA Journal 2009; 7(12): 1438).

Based on the presumptions of the screening step, the calculated TER values for the acute and long-term risk resulting from an exposure of birds and mammals to the active substance triflurosulfuron-methyl according to the GAP of the formulation SAFARI achieves the acceptability criteria  $TER \geq 10$  and  $TER \geq 5$ , respectively, according to commission implementing regulation (EU) No 546/2011, Annex, Part I C, 2. Specific principles point 2.5.2. The results of the assessment indicate an acceptable risk for birds and mammals due to the intended use of SAFARI in sugar beet red beet and chicory.

**3.1.6.2 Effects on Aquatic Species (Part B, Section 6, Point 10.2)**

Environmental concentrations of triflurosulfuron methyl were estimated in surface waters to support the ecological risk assessment for Triflurosulfuron methyl 50WG in The Netherlands using the latest guidance documents on  $PEC_{sw}$  calculations in the national registration procedure for pesticides in The Netherlands. The entry of triflurosulfuron methyl and its aquatic metabolites into a standard surface water body (edge-of-field ditch) was assessed by means of simulations conducted using TOXSWA (ver. 1.2) model. The route of entry is a spray drift event that results in a standardized loss *via* spray drift. In compliance with Dutch guidelines, a 75% reduced drift rate was used for application to sugar beets/fodder beets. The Dutch standard spring scenario was used in all simulation runs.

Aquatic risk assessment for triflurosulfuron methyl and its major aquatic metabolites are based on guidance from the Evaluation Manual for the Authorisation of Plant protection products and Biocides, NL Plant protection products, Chapter 7, Ecotoxicology; aquatic, Version 1.0; January 2010.

The acute and chronic risk for aquatic organisms following treatment with SAFARI + IN-KG691surfactant in accordance with the worst-case use patterns (1% drift) is low and acceptable, except for *Lemna gibba*. When 75% drift reducing nozzles are used, the risk for *Lemna gibba* is acceptable. Therefore the risk for aquatic organisms is acceptable, provided the following restriction are taken and placed on the label:

*Om in het water levende organismen te beschermen is toepassing uitsluitend toegestaan wanneer in percelen die grenzen aan oppervlaktewater wordt gespoten met minimaal 75% driftreducerende spuitdoppen.*

### **3.1.6.3 Effects on Bees and Other Arthropod Species (Part B, Section 6, Points 10.4 and 10.5)**

#### **Bees**

Due to the results of laboratory tests triflusulfuron-methyl 50WG + IN-KG691 is considered to be practically non-toxic to bees in the oral route and low-toxic in the contact route. All hazard quotients are clearly below the trigger of 50, indicating that the intended use poses a low risk to bees in the field. Bee brood testing is not required since the test item is not an IGR and exposure is considered negligible.

It is concluded that triflusulfuron-methyl 50WG + IN-KG691 will not adversely affect bees or bee colonies when used as recommended.

#### **Other non-target arthropods**

Risk assessments were conducted based on the current Guidance Document on Terrestrial Ecotoxicology (SANCO/10329/2002). When only taken into account the formulation SAFARI both in-field and off-field HQ were below the trigger and the risk for non-target arthropods was acceptable.

However, in the core dossier of Germany toxicity data for of SAFARI+ DuPont TREND are available. Since SAFARI is recommended to be used in a LDS with an adjuvant, Ctgb is of the opinion that these data should be taken into account.

For both in-field and off-field a high risk was found for *A. rhopalosiphi*. The applicant was requested to demonstrate a safe use of SAFARI + an adjuvant based on the Dutch GAP. The applicant responded to this request with the submission of an aged residue study with Triflusulfuron methyl 50WG (=SAFARI®) plus DPX-KG691 Surfactant (=TREND® 90) for parasitoids (*A. rhopalosiphi*).

Ctgb agrees with the applicant that the extended laboratory study with *Aphidius rhopalosiphi* shows that it can be expected that populations of this species are able to recover within a year.

The in-field and off-field risks for non-target arthropods are therefore considered acceptable.

### **3.1.6.4 Effects on Earthworms and Other Soil Organisms**

Based on the predicted concentrations of triflusulfuron-methyl/SAFARI in soils, the TER values describing the acute and longterm risk for earthworms and other non-target soil organisms following exposure to triflusulfuron-methyl / SAFARI / SAFARI + DuPont TREND according to the GAP of the formulation SAFARI achieve the acceptability criteria  $TER \geq 10$  resp.  $TER \geq 5$  according to commission implementing regulation (EU) No 546/2011, Annex, Part I C, 2. Specific principles point 2.5.2.

The results of the assessment indicate an acceptable risk for soil organisms due to the intended use of SAFARI in a tank mix with the surfactant DuPont TREND in sugar beet, red beet and chicory according to the label. The average field DT90 of triflusulfuron-methyl is below 100 days and other non-target macro-organisms are not expected to be at risk from exposure to residues of triflusulfuron-methyl. Evidence from earthworm and beneficial arthropod toxicity tests suggest low toxicity of triflusulfuron-methyl to non-target invertebrate fauna.

### 3.1.6.5 Effects on organic matter breakdown (Part B, Section 6, Point 10.6)

Since the  $DT_{90f}$  of the active substance is <365d and no risk was identified for soil fauna, soil micro-organisms and non-target arthropods from the use of SAFARI + DuPont TREND in sugar beet, red beet and chicory, data on the effects on organic matter breakdown (litterbag) is not required.

### 3.1.6.6 Effects on Soil Non-target Micro-organisms (Part B, Section 6, Point 10.7)

For the active ingredient of SAFARI, triflurosulfuron-methyl, the soil concentrations which caused no deviations greater than  $\pm 25\%$  in the activity of the soil microorganisms in a test with SAFARI + surfactant DuPont TREND are 5.4-times higher than the corresponding maximum PEC in soil. Hence, a low risk to soil microflora is concluded.

### 3.1.6.7 Assessment of Potential for Effects on Other Non-target Organisms (Flora and Fauna) (Part B, Section 6, Point 10.8)

#### Terrestrial plants

Based on the predicted rates of triflurosulfuron-methyl / SAFARI in off-field areas, the TER values describing the risk for non-target plants following exposure to SAFARI according to the GAP of the formulation are below the trigger of 5 for the formulation + X-77 or + IN-KG691. When using at least 50% drift reducing measures + end nozzle, the risk becomes acceptable.

Therefore the risk to non-target plants is acceptable, provided at least 50% drift reducing measures are taken and the following restriction is placed on the label:

*Om niet tot de doelsoorten behorende planten te beschermen is toepassing uitsluitend toegestaan indien gebruik wordt gemaakt van minimaal 50% drift reducerende spuitdoppen combinatie met een kantdop.*

#### 3.1.6.8 Restriction sentences ecotoxicology

The proposed use of SAFARI is found to be acceptable with the 2 following restrictions:

*Om in het water levende organismen te beschermen is toepassing uitsluitend toegestaan wanneer in percelen die grenzen aan oppervlaktewater wordt gespoten met minimaal 75% driftreducerende spuitdoppen.*

*Om niet tot de doelsoorten behorende planten te beschermen is toepassing uitsluitend toegestaan indien gebruik wordt gemaakt van minimaal 50% drift reducerende spuitdoppen combinatie met een kantdop.*

However, as the two different drift reduction classes may cause confusion when combined in one label, the restrictions will be stated as follows:

*Om in het water levende organismen te beschermen is toepassing uitsluitend toegestaan wanneer in perceelstroken die grenzen aan oppervlaktewater in de eerste 14 m vanaf de insteek van de sloot gebruik wordt gemaakt van minimaal 75% driftreducerende spuitdoppen.*

*Om niet tot de doelsoorten behorende planten te beschermen is toepassing uitsluitend toegestaan wanneer in perceelstroken die niet grenzen aan oppervlaktewater in de eerste 14 m van het gewas,*

*gemeten vanaf het midden van de laatste gewasrij of de laatste plant in de rij, gebruik wordt gemaakt van minimaal 50% drift reducerende spuitdoppen in combinatie met een kantdop.*

### **3.1.7 Efficacy (Part B, Section 7, Point 8)**

SAFARI is a herbicide for the control of dicotyledonous weeds in the major crops sugar and fodder beet, and the minor crops red beet and chicory. It concerns a re-registration for sugar and fodder beet and chicory. Red beet is claimed as an extension. For minor uses, effectiveness and crop safety are not assessed. As a consequence, efficacy evaluation for those minor uses (chicory and red beet) has not been carried out.

Sufficient trials were carried out to assess the efficacy of SAFARI in beets. Based on the provided data and long-term experience SAFARI can be considered as sufficiently effective against many relevant weed species.

Sufficient selectivity trials were carried out in beets. In several trials phytotoxic symptoms were observed. However, these effects did not result in yield reduction. The warning sentence "*Na toepassing in bieten kunnen onder stresscondities enkele dagen na toepassing gele vlekjes op het blad verschijnen welke echter weer snel verdwijnen*" remains on the label.

As a consequence of the short soil persistence of SAFARI and the high EC<sub>10</sub> values on tested indicative crop species, it is not proposed to include any label restrictions concerning succeeding crops.

As a consequence, the sentence that is now present on the Dutch label (*Volg- en vervanggewassen Gezien de aard van het middel kan niet uitgesloten worden dat er negatieve effecten op bepaalde volg- en vervanggewassen op kunnen treden*) may be removed from the label.

Triflusaluron methyl, the active ingredient in this product, is a Group B herbicide based on the mode of action classification system of the Herbicide Resistance Action Committee. Any weed population may contain plants more tolerant or naturally resistant to Group B herbicides.

Triflusaluron methyl 50WG is an herbicide for control of various species of broadleaved weeds in beet crops and chicory. The spectrum of activity of Triflusaluron methyl 50WG is wide, and literature suggests that certain broadleaved weeds are the most likely to develop resistance. As a result of the risk assessment, the conclusion drawn is that Triflusaluron methyl 50WG poses an unacceptable risk from unmodified use of the product. Cropping systems and the availability and use of alternative modes of action within The Netherlands may already impose modifiers on the products' unrestricted use. In order to responsibly manage and maintain the activity of this group of compounds, resistance management strategies have to be implemented. Confidence in the strategies is supported by the fact that these strategies have been in place since the introduction of sulfonyleureas into Europe over 25 years ago. Since their launch there have been only a restricted number of cases of sulfonyleurea resistance in dicotyledonous weeds and in no case has resistance led to withdrawal of a product due to a loss of efficacy.

The following resistance sentence remains on the label:

#### Resistentiemanagement

*Dit middel bevat de werkzame stof triflusaluron-methyl. Triflusaluron-methyl behoort tot de sulfonyleureumverbindingen. De HRAC code is B. Bij dit product bestaat er kans op resistentieontwikkeling. In het kader van resistentiemanagement dient u de adviezen die gegeven worden in de voorlichtingsboodschappen op te volgen.*

### **3.2 Conclusions**

Regarding identity, physical, chemical and technical properties as well as analytical methods for the formulation an authorisation can be granted.

With respect to analytical methods for residues an authorisation can be granted.

If used properly and according to the intended conditions of use, adverse health effects for operators, workers, bystanders and residents are not expected.

The intended uses in sugar and fodder beets, witloof, and beetroot will not result in residues of triflurosulfuron-methyl above the MRL of 0.02 mg/kg (LOQ) set in Regulation (EC) No 396/2005. A risk for consumers through the consumption of food containing residues of triflurosulfuron-methyl below LOQ is not expected. There is no special risk mitigation necessary which deviate from the existing registration. As far as consumer health protection is concerned, an authorization can be granted..

Considering an application in accordance with the evaluated use pattern and good agricultural practice as well as strict observance of the conditions of use no harmful effects on groundwater nor adverse effects on the ecosystem are to be expected.

An authorization can be granted for efficacy in sugar and fodder beet. For the minor uses in red beet, chicory (witloof) and chicory effectiveness and phytotoxicity were not assessed, which will be stated on the label with a disclaimer.

The assessment conducted for SAFARI was in accordance with Uniform Principles and demonstrates an acceptable risk to human health and all aspects of the environment.

### **3.3 Substances of concern for national monitoring**

None.

### **3.4 Further information to permit a decision to be made or to support a review of the conditions and restrictions associated with the authorisation**

No further information is required.



## Appendix 1 – Copy of the product label

### Wettelijk Gebruiksvoorschrift

Het middel is uitsluitend toegelaten als onkruidbestrijdingsmiddel voor het professionele gebruik door middel van een na opkomst toepassing in de volgende toepassingsgebieden (volgens Definitielijst toepassingsgebieden versie 2.0, Ctgb juni 2011) onder de hierna vermelde toepassingsvoorwaarden.

Toepassings-gebied	Werkzaamheid getoetst op	Dosering* middel per toepassing	Maximaal aantal toepassingen per teeltcyclus	Maximaal aantal kg middel per ha per teeltcyclus	Minimum interval tussen toepassingen in dagen
Bieten	breedbladige onkruiden	30 g/ha**	4	0,12 kg/ha	7

\*Verlaging van de dosering is toegestaan, maar van het maximaal aantal toepassingen en de andere toepassingsvoorwaarden mag niet worden afgeweken. Werkzaamheid is bij lagere dosering niet beoordeeld.

\*\*In LDS-systeem in combinatie met toegelaten middelen.

Het gebruik in de teelt van witlof, cichorei en rode biet is beoordeeld conform artikel 51 EG 1107/2009. Er zijn voor deze toepassingen geen werkzaamheids- en fytoxiciteitonderzoek uitgevoerd. Er wordt daarom aangeraden een proefbespuiting uit te voeren, voordat het middel gebruikt wordt. Het risico voor het gewas bij gebruik van dit middel in deze toepassingsgebieden valt onder verantwoordelijkheid van de gebruiker.

Toepassings-gebied	Werkzaamheid aannemelijk tegen	Dosering* middel per toepassing	Maximaal aantal toepassingen per teeltcyclus	Maximaal aantal kg middel per ha per teeltcyclus	Minimum interval tussen toepassingen in dagen
Witlof (pennenteelt en zaadteelt)	breedbladige onkruiden	10-30 g/ha**	4	0,06 kg/ha	7
Cichorei	breedbladige onkruiden	30 g/ha**	4	0,12 kg/ha	7
Rode biet	breedbladige onkruiden	10-30 g/ha**	4	0,06 kg/ha	7

\*Verlaging van de dosering is toegestaan, maar van het maximaal aantal toepassingen en de andere toepassingsvoorwaarden mag niet worden afgeweken. Werkzaamheid is bij lagere dosering niet beoordeeld.

\*\*In LDS-systeem in combinatie met toegelaten middelen.

### Overige toepassingsvoorwaarden

Het middel toepassen in 150-400 liter water per ha.

Om in het water levende organismen te beschermen is toepassing uitsluitend toegestaan wanneer in perceelstroken die grenzen aan oppervlaktewater in de eerste 14 m vanaf de insteek van de sloot gebruik wordt gemaakt van minimaal 75% driftreducerende spuitdoppen.

Om niet tot de doelsoorten behorende planten te beschermen is toepassing uitsluitend toegestaan wanneer in perceelstroken die niet grenzen aan oppervlaktewater in de eerste 14 m van het gewas, gemeten vanaf het midden van de laatste gewasrij of de laatste plant in de rij, gebruik wordt gemaakt van minimaal 50% drift reducerende spuitdoppen in combinatie met een kantdop.

Na toepassing in bieten kunnen onder stresscondities enkele dagen na toepassing gele vlekjes op het blad verschijnen welke echter weer snel verdwijnen

#### Resistentiemanagement

Dit middel bevat de werkzame stof triflusaluron-methyl. Triflusaluron-methyl behoort tot de sulfonyleureumverbindingen. De HRAC code is B. Bij dit product bestaat er kans op resistentieontwikkeling. In het kader van resistentiemanagement dient u de adviezen die gegeven worden in de voorlichtingsboodschappen op te volgen.

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**Appendix 2 – Letter of Access**

No letters of access to the protected data are needed for evaluation of this formulation.

## Appendix 3 – References relied on

Annex point/ reference No	Year	Title Source (where different from company) Report-No. GLP or GEP status (where relevant), Published or not	Data protectio n claimed	Data protectio n granted yes/no	Relied on Yes/no	Owner
KIIIA1 2.1, KIIIA1 2.4.2, KIIIA1 2.6.2, KIIIA1 2.7.2, KIIIA1 2.7.3, KIIIA1 2.8.1, KIIIA1 2.8.2, KIIIA1 2.8.3.1, KIIIA1 2.8.3.2, KIIIA1 2.8.5.1, KIIIA1 2.8.5.2, KIIIA1 2.8.6.2, KIIIA1 2.8.6.3, KIIIA1 2.8.6.5, KIIIA1 2.8.8.1	2011a	Triflusulfuron-methyl 50WG (DPX-66037) water- dispersible granule formulation: Laboratory study of physical and chemical properties, 31086, GLP, unpublished	Y	Y	Y	DuPont
KIIIA1 2.1/02, KIIIA1 2.4.2, KIIIA1 2.7.2, KIIIA1 2.7.3, KIIIA1 2.8.1, KIIIA1 2.8.2, KIIIA1 2.8.3.1, KIIIA1 2.8.3.2, KIIIA1 2.8.5.2, KIIIA1 2.8.6.2, KIIIA1 2.8.6.3, KIIIA1 2.8.6.5, KIIIA1 2.8.8.1,	2011b	Triflusulfuron-methyl 50WG (DPX-66037) water- dispersible granule formulation with spray tank adjuvant: Laboratory study of physical and chemical properties, 31088, GLP, unpublished	Y	Y	Y	DuPont
KIIIA1 2.1/03, KIIIA1 2.4.2, KIIIA1 2.7.2, KIIIA1 2.7.3, KIIIA1 2.8.1, KIIIA1 2.8.2, KIIIA1 2.8.3.1, KIIIA1 2.8.3.2, KIIIA1 2.8.5.2, KIIIA1 2.15.1	2011c	Triflusulfuron-methyl 50WG (DPX-66037) water- dispersible granule formulation in a water soluble bag: Laboratory study of physical and chemical properties, 31087, RV 1, GLP, unpublished	Y	Y	Y	DuPont

<b>Annex point/ reference No</b>	<b>Year</b>	<b>Title Source (where different from company) Report-No. GLP or GEP status (where relevant), Published or not</b>	<b>Data protectio n claimed</b>	<b>Data protectio n granted yes/no</b>	<b>Relied on Yes/no</b>	<b>Owner</b>
KIIIA1 2.1, KIIIA1 2.4.2, KIIIA1 2.7.5, KIIIA1 2.8.1, KIIIA1 2.8.2, KIIIA1 2.8.3.1, KIIIA1 2.8.3.2, KIIIA1 2.8.5.2,	2013	Triflusulfuron-methyl 50WG (DPX-66037) waterdispersible granule formulation with spray tank adjuvant: laboratory study of shelf-life stability, 31176, GLP, unpublished	Y	Y	Y	DuPont
KIIIA1 2.1, KIIIA1 2.4.2, KIIIA1 2.7.5, KIIIA1 2.8.1, KIIIA1 2.8.2, KIIIA1 2.8.3.1, KIIIA1 2.8.3.2, KIIIA1 2.8.5.2, KIIIA1 2.8.6.3, KIIIA1 2.8.6.5,	2013	Triflusulfuron-methyl 50WG (DPX-66037) waterdispersiblen granule formulation: laboratory study of shelf-life stability, 31177, GLP, unpublished	Y	Y	Y	DuPont
KIIIA1 2.1, KIIIA1 2.4.2, KIIIA1 2.7.5, KIIIA1 2.8.1, KIIIA1 2.8.2, KIIIA1 2.8.3.1, KIIIA1 2.8.3.2, KIIIA1 2.8.5.2, KIIIA1 2.15.1	2013	Triflusulfuron-methyl 50WG (DPX-66037) waterdispersible granule formulation in a water soluble bag: laboratory study of shelf-life stability, 31178, GLP, unpublished	Y	Y	Y	DuPont
KIIIA1 4.2.2	2013	Triflusulfuron-methyl 50WG: Laboratory Study of Spray Tank Cleanout, 37972, GLP, unpuböished	Y	Y	Y	DuPont

<b>Annex point/ reference No</b>	<b>Year</b>	<b>Title Source (where different from company) Report-No. GLP or GEP status (where relevant), Published or not Authority registration No</b>	<b>Data protectio n claimed</b>	<b>Data protectio n granted Yes/No</b>	<b>Relied on Yes/no</b>	<b>Owner</b>
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Annex point/ reference No	Year	Title Source (where different from company) Report-No. GLP or GEP status (where relevant), Published or not Authority registration No	Data protectio n claimed	Data protectio n granted Yes/No	Relied on Yes/no	Owner
KIIIA1 5.2.1	2012	Validation of an analytical method for determination of triflurosulfuron-methyl (DPX-66037) in SAFARI (DPX- 66037 50 WG) formulated product, 31089, Revision 1, GLP, unpublished	Y	Y	Y	DuPont
OECD: KIIA 4.3, OECD: KIIIA1 5.3.1	2006	Independent laboratory method validation of a multi- residue method for the analysis of Sulfonyurea herbicides in crops, DuPont- 13412 Revision 1 - Revision Number 1 (Revision report dated 09.03.2006) DuPont-17207 BVL-2094639, BVL-2313668, BVL-2323616, ASB2009- 11839	Y	Y	Y	DuPont

## Mammalian Toxicology

Annex point / Reference No.	Year	Title Source (where different from company) Report No. GLP or GEP Status (where relevant) Published or not	Data Protection Claimed (Y/N)	Data protection granted Y/N	Studies relied on Y/N	Owner
KIIIA, 7.6.2/01	2008	Triflusulfuron methyl (DPX-66037) 50WG: <i>In vitro</i> kinetics in human skin in the presence and absence of the adjuvant, Actirob B DuPont-20077, Revision No. 1 GLP: Yes Published: No	Y	Y	Y	DuPont
OECD: KIIIA1 7.1.1	1991 a	Acute oral toxicity study with DPX-66037-29 (50 DF) in male and female rats MR 4581-898 ! HLR 392-91 BVL-2323795, <a href="#">Z49804</a>	-	N	Y	DuPont
OECD: KIIIA1 7.1.2	1991 b	Acute dermal toxicity study of DPX-66037-29 (50 DF) in rabbits (Revision 1) MR 4581-898 ! HLR 572-91 BVL-2325107, <a href="#">ASB2011-9503</a>	-	N	Y	DuPont
OECD: KIIIA1 7.1.3	1992	Acute inhalation toxicity study with DPX-66037-67 (50 DF) in rats MR 9581-017 ! 428-92 BVL-2325145, <a href="#">Z49809</a>	-	N	Y	DuPont
OECD: KIIIA1 7.1.4	1991 c	Primary dermal irritation study with DPX-66037-29 (50 DF) in rabbits MR 4581-898 ! HLR 510-91 BVL-2325150, <a href="#">Z49807</a>	-	N	Y	DuPont
OECD: KIIIA1 7.1.5	1991 d	Primary eye irritation study with DPX-66037-29 (milled) in rabbits MR 4581-898 ! HLR 339-91 BVL-2325169, <a href="#">Z49813</a>	-	N	Y	DuPont
OECD: KIIIA1 7.1.6	1991	Closed-patch repeated insult dermal sensitization study (maximization method) with DPX-66037-29 (50 DF) in guinea pigs PH423-DU-003-91 ! HLO 729-91 ! MR 4581-898 BVL-2325173, <a href="#">Z49811</a>	-	N	Y	DuPont

**Residues**

<b>Annex point/ reference No</b>	<b>Year</b>	<b>Title Report-No. Authority registration No</b>	<b>Data protection claimed</b>	<b>Owner</b>	<b>Studies relied on Y/N</b>	<b>Data protection granted Y/N</b>
OECD: KIIA 6.1.1	2012	Storage stability of triflusulfuron methyl (DPX-66037), IN-M7222 and IN E7710 in representative crops stored frozen Vyzkumny ustav organickych syntez a.s. (VUOS) DuPont-28236 GLP: Yes Published: No	Y	DuPont	Y	Y
OECD: KIIA 6.3	2011	Determination of magnitude of residues of triflusulfuron methyl after application of Triflusulfuron methyl 50WG on chicory - Europe - 2010 Charles River Laboratories DuPont-30032 GLP: Yes Published: No	Y	DuPont	Y	Y
OECD: KIIA 6.6	2012	Field crop rotation study with triflusulfuron methyl (DPX-66037) 50WG - Europe 2009/2010 Charles River Laboratories DuPont-27587 GLP: Yes Published: No	Y	DuPont	Y	Y



## Fate and behaviour

Annex No., OECD Data Requirement No., Reference No.	Year	Title Source Company Report No. GLP or GEP Status (where relevant) Published or not	National Data Protection Claimed (Y/N)	Owner	Data protection granted Y/N	Study relied on Y/N
KIIIA, 9.7/02	2012	Predicted concentrations of triflurosulfuron methyl (DPX-66037) and its metabolites in surface water and sediment in The Netherlands - a modeling study conducted with TOXSWA and DROPLET Simulogic Environmental Consulting Pvt. Ltd. DuPont-25494 NL GLP: No Published: No	Y	DuPont	N	Y

## Ecotoxicology

Annex point	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Data protection granted y/n	Studies relied on y/n	Owner
10.5.2	2015	Trisulfuron methyl (DPX-66037) 50 WG plus isodecylalcohol ethoxylated (DPX-KG691) surfactant: an extended laboratory test to study the effects on the aphid parasitoid, <i>Aphidius rhopalosiphi</i> de Stefani Perez (Hymenoptera, Braconidae) on aged spray deposits DuPont de Nemours, report no Dupont-44449 GLP Unpublished	Y	Y	Y	DuPont de Nemours

Annex point	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Data protection granted y/n	Studies relied on y/n	Owner
KIIIA, 10.2.2.1/01	2002	Triflusulfuron methyl (DPX-66037) 50WG plus isodecylalcohol ethoxylated (IN-KG691) surfactant: Static, acute, 96-hour LC <sub>50</sub> to rainbow trout, <i>Oncorhynchus mykiss</i> DuPont-10698 GLP: Yes Published: No	Y	Y	Y	DuPont
KIIIA, 10.2.2.2/01	2002	Triflusulfuron methyl (DPX-66037) 50WG plus isodecylalcohol ethoxylated (IN-KG691) surfactant: Static, acute, 48-hour EC <sub>50</sub> to <i>Daphnia magna</i> DuPont Haskell Laboratory DuPont-10697 GLP: Yes Published: No	Y	Y	Y	DuPont
KIIIA, 10.2.2.3/01	2002	Triflusulfuron methyl (DPX-66037) 50WG plus isodecylalcohol ethoxylated (IN-KG691) surfactant: Influence on growth and growth rate of the green alga <i>Selenastrum capricornutum</i> DuPont Haskell Laboratory DuPont-11494 GLP: Yes Published: No	Y	Y	Y	DuPont
KIIIA, 10.4.2.1/01	2002	Triflusulfuron methyl (DPX-66037) 50 WG plus isodecylalcohol ethoxylated (IN-KG691) surfactant: Acute oral and contact toxicity to the honey bee, <i>Apis mellifera</i> L. GAB Biotechnologie GmbH and IFU Umweltanalytik GmbH DuPont-11055 GLP: Yes Published: No	Y	Y	Y	DuPont

Annex point	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Data protection granted y/n	Studies relied on y/n	Owner
KIIIA, 10.4.2.2/01	2002	Triflusulfuron methyl (DPX-66037) 50 WG plus isodecylalcohol ethoxylated (IN-KG691) surfactant: Acute oral and contact toxicity to the honey bee, <i>Apis mellifera</i> L. GAB Biotechnologie GmbH and IFU Umweltanalytik GmbH DuPont-11055 GLP: Yes Published: No	Y	Y	Y	DuPont
KIIIA, 10.5.1/01	2003a	Triflusulfuron methyl (DPX-66037) 50WG plus isodecylalcohol ethoxylated (IN-KG691) surfactant: A laboratory rate response test to evaluate the effects on the predatory mite <i>Typhlodromus pyri</i> Scheuten (Acari, phytoseiidae) GAB Biotechnologie GmbH and IFU Umweltanalytik GmbH DuPont-10079 GLP: Yes Published: No	Y	Y	Y	DuPont
KIIIA, 10.5.1/02	2003b	Triflusulfuron methyl (DPX-66037) 50WG plus isodecylalcohol ethoxylated (IN-KG691) surfactant: A laboratory rate response test to study the effects on the parasitoid <i>Aphidius rhopalosiphi</i> (Hymenoptera, braconidae) GAB Biotechnologie GmbH and IFU Umweltanalytik GmbH DuPont-10080, Amendment No. 1 GLP: Yes Published: No	Y	Y	Y	DuPont

Annex point	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Data protection granted y/n	Studies relied on y/n	Owner
KIIIA, 10.5.2/01	2003	Triflusulfuron methyl (DPX-66037) 50WG plus isodecylalcohol ethoxylated (IN-KG691) surfactant: An extended laboratory rate response test to study the effects on the predatory mite <i>Typhlodromus pyri</i> Scheuten (Acari, Phytoseiidae) GAB Biotechnologie GmbH and IFU Umweltanalytik GmbH DuPont-12893 GLP: Yes Published: No	Y	Y	Y	DuPont
KIIIA, 10.5.2/02	2003	Triflusulfuron methyl (DPX-66037) 50WG plus Isodecylalcohol ethoxylated (IN-KG691) surfactant: An extended laboratory rate response test to study the Effects on the green lacewing <i>Chrysoperla carnea</i> Steph. (Neuroptera, Chrysopidae) GAB Biotechnologie GmbH and IFU Umweltanalytik GmbH DuPont-12891 GLP: Yes Published: No	Y	Y	Y	DuPont
KIIIA, 10.5.2/03	2003	Triflusulfuron methyl (DPX-66037) 50WG plus isodecylalcohol ethoxylated (IN-KG691) surfactant: An extended laboratory rate response test to study the effects on the <i>Aphidius rhopalosiphi</i> (Hymenoptera, Braconidae) GAB Biotechnologie GmbH and IFU Umweltanalytik GmbH DuPont-12892 GLP: Yes Published: No	Y	Y	Y	DuPont
KIIIA, 10.6.2/01	2003	Triflusulfuron methyl (DPX-66037) 50WG plus isodecylalcohol ethoxylated (IN-KG691) surfactant: Acute toxicity to the earthworm, <i>Eisenia fetida</i> in artificial soil IBACON GmbH DuPont-13233 GLP: Yes Published: No	Y	Y	Y	DuPont

Annex point	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Data protection granted y/n	Studies relied on y/n	Owner
KIIIA, 10.6.3/01	2003	Triflusulfuron methyl (DPX-66037) 50WG plus isodecylalcohol ethoxylated (IN-KG691) surfactant: Effects on reproduction and growth of the earthworm, <i>Eisenia fetida</i> , in artificial soil IBACON GmbH DuPont-13234 GLP: Yes Published: No	Y	Y	Y	DuPont
KIIIA, 10.8.2.1/02	2002	Triflusulfuron methyl (DPX-66037) 50WG plus isodecylalcohol ethoxylated (IN-KG691) surfactant: Influence on growth and reproduction of <i>Lemna gibba</i> G3 DuPont Haskell Laboratory DuPont-11495 GLP: Yes Published: No	Y	Y	Y	DuPont
KIIIA, 10.10.1/01	2006	Triflusulfuron methyl (DPX-66037) technical: 21-day non-reproduction fish screening assay for potential endocrine effects using the fathead minnow ( <i>Pimephales promelas</i> ) DuPont-20614 GLP: Yes Published: No	Y	Y	Y	DuPont