# Art. 51
# Extension of authorisation for minor uses

## REGISTRATION REPORT
## Part A

## Risk Management

**Product code: Basagran**

**Active Substance:**

**Bentazon 480 g/l (524 g/l Sodium-Salt)**

**COUNTRY: Germany**

**Central Zone**

**Zonal Rapporteur Member State: Germany**

**NATIONAL ASSESSMENT**

**Applicant: BASF SE E-APE/DT, Li 556**

**Date: 01/07/2014**

# Table of Contents

## PART A – Risk Management

This document describes the acceptable use conditions required for extension of the registration of Basagran containing bentazone in Germany.

The risk assessment conclusions are based on the already existing registration of the PPP. The following sections of Registration Report, Part B were prepared on basis of new data:

- Section 4.

Assessments for the safe use of Basagran have been made using endpoints agreed in the EU reviews of bentazone.

Appendix 1 of this document provides a copy of the final product authorisation in Germany.
See below

Appendix 2 – Copy of the product label
No product label available. Not mandatory according to Article 51 (5)

Appendix 3 – Letter of Access
No letter of access necessary. The applicant is owner of the new studies submitted. The authorisation holder is the applicant of this extension of the authorisation.

## 1 Details of the application

Application to extend the authorisation of a plant protection product (PPP) already authorised in Germany to minor uses not yet covered by that authorisation.
The application is intended for use in Germany only.

### 1.1 Application background

**Details on applicant and application**

| | |
|---|---|
| Plant protection product | **Basagran** |
| Type of application | Zonal application according to Article 51, ZRMS=DE, first application (GV1) |
| Registration number | 052506-00/04 |
| Applicant | BASF SE E-APE/DT, Li 556 , Speyerer Straße 2, 67117 Limburgerhof, Deutschland |
| Authorisation holder | BASF SE E-APE/DT, Li 556 , Speyerer Straße 2, 67117 Limburgerhof, Deutschland |
| Function | Herbicide |
| Type of formulation | Water soluble concentrate |
| Expiration of authorisation | 2016-12-31 |

## 1.2 Annex I inclusion

The active substances included in the plant protection product are approved according Regulation (EC) No 1107/2009. The present application is in line with the provisions of the approvals.

| | |
|---|---|
| Active substance (BVL Number) | |
| Bentazon (335) | |
| Content in PPP | 480 g/l (524 g/l Sodium-Salt) |
| Approval status | Approved according to Regulation (EC) No 1107/2009 |
| Approval | Regulation (EC) No 540/2011 |
| Expiration of approval | 31/12/2015 |

## 1.3 Regulatory approach

The PPP is already registered in Germany according to Directive 91/414/EEC taking into account the uniform principles of Annex VI. Therefore the evaluation of the current application is limited to the points not covered by the existing registration.

### 1.3.1 Uses applied for and registration decision

| Number of use | Plant/commodity/object | Harmful organism/purpose | decision |
|---|---|---|---|
| 001 | Majoram, oregano | annual dicotyledonous weeds | Authorise |
| 002 | sage, common | annual dicotyledonous weeds | Authorise |
| 003 | thyme, garden | annual dicotyledonous weeds | Authorise |

### 1.3.2 Public interest and minor use

According to Article 51 (2) a and c of the Regulation (EC) No 1107/2009 extensions of authorisation are only possible if the intended use applied for is minor in nature and in public interest.
In Germany the cultivated area of Majoram, oregano is about 60 ha, of which approx. 48 ha need to be controlled, the cultivated area of sage, common is about 35 ha, of which approx. 28 ha need to be controlled, the cultivated area of thyme, garden is about 200 ha, of which approx. 160 ha need to be controlled Calculation shows that authorisation holder will not profit from an authorisation of the requested uses.
Upon this calculation and the examination of available alternative measures for the applied uses it can be stated that the applied uses is minor in nature and the authorisation is in the public interest.

## 1.4 Data protection claims

The applicant is owner of the new studies submitted and claims data protection.

## 1.5 Letters of Access

The applicant is owner of the new studies submitted.
The authorisation holder is the applicant of this extension of the authorisation.

# 2 Details of the authorisation

## 2.1 Product identity

| | |
|---|---|
| Product name | Basagran |
| Authorisation number | 052506-00 |
| Composition | Bentazone 480 g/l (524 g/l Sodium-Salt) |
| Type of formulation | Water soluble concentrate |
| Function | Herbicide |
| Authorisation holder | BASF SE E-APE/DT, Li 556 , Speyerer Straße 2, 67117 Limburgerhof, Deutschland |

## 2.2 Classification and labelling

### 2.2.1 Classification and labelling under Directive 99/45/EC

| | |
|---|---|
| Xn | Harmful |
| R 52/53 | Hazardous to aquatic organisms, may cause long-term adverse effects in the aquatic environment |
| R 22 | Harmful if swallowed |
| R 43 | May cause sensitisation by skin contact |
| S 2 | Keep out of the reach of children |
| S 13 | Keep away from food, drink and animal feeding stuffs. |
| S 24 | Avoid contact with skin. |
| S 35 | This material and its container must be disposed of in a safe way. |
| S 36 | Irritating to eyes |
| S 37 | Irritating to respiratory system |
| S 46 | If swallowed, seek medical advice immediately and show this container or label. |
| SP001 | To avoid riks to man and the environment, comply with the instructions for use. |

### 2.2.2 R and S phrases under Regulation (EC) No 547/2011

None.

### 2.2.3 Other phrases

#### 2.2.3.1 Restrictions linked to the PPP

The authorization of the PPP is linked to the following conditions (mandatory labelling):

**Operator protection**

SB001 Avoid any unnecessary contact with the product. Misuse can lead to health damage.

SE110 Wear standard protective gloves (plant protection) when handling the undiluted product.

SS110 Wear standard protective gloves (plant protection) when handling the undiluted product.

SS2101 Wear a protective suit against pesticides and sturdy shoes (e.g. rubber boots) when handling the undiluted product.

SS610 Wear a rubber apron when handling the undiluted product.

**Ecosystem protection**

NG315 Not to be used before 15 April in each calendar year

NG407 Not to be used on the following soils: pure sand, slightly silty sand and slightly clayey sand.

NG413 Not to be used on soils with an organic carbon content under 1 %.

NW466 The product and its remains and empty containers and packaging must not be dumped in water

NW711 Between treated areas and surface waters - including periodically but excluding occasionally water-bearing surface waters - there must be a buffer zone under complete plant cover. The buffer zone's protective function must not be impaired by the use of implements. It must be at least 5 m wide. This buffer zone is not necessary if: -sufficient catching systems are available for the water and soil transported by run-off, which do not flow into surface water or are not connected with the urban drainage system or -the product is used for conservation or no-tillage methods.

**Honeybee**

**Integrated Pest Management (IPM)**

Mode of action (FRAC/HRAC/IRAC-Group): C3

**Active substance**

None.

The authorization of the PPP is linked to the following conditions (voluntary labelling):

**Honeybee**

NB6641 The product is classified as non-hazardous to bees, even when the maximum application rate, or concentration if no application rate is stipulated, as stated for authorisation is applied. (B4)

**Integrated Pest Management (IPM)**

NN160 The product is classified as harmless for populations of the species Aleochara bilineata (staphylinid beetle).

NN165 The product is classified as harmless for populations of the species Poecilus cupreus (ground beetle).

### 2.2.3.2 Specific restrictions linked to the intended uses

Some of the authorized uses are linked to the following conditions (mandatory labelling):
See 2.3 (Product uses)

**Ecosystem protection**

NW642-1 The product may not be applied in or in the immediate vicinity of surface or coastal waters.

Irrespective of this, the minimum buffer zone from surface waters stipulated by state law must be observed. Violations may be punished by fines of up to 50 000 EUR

## 2.3 Product uses

**PPP (product name/code)** **Basagran (052506-00)**
**active substance** **Bentazon**

**Formulation type:** **Water soluble concentrate**
**Conc. of as:** **480 g/L**

**safener** -
**synergist** -

**Conc. of safener:** -
**Conc. of synergist:** -

**Applicant:** **BASF SE E-APE/DT, Li 556**
**Zone(s):** **central EU**

**professional use** ☒
**non professional use** ☐

**Verified by MS: y**

| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 10 | 11 | 12 | 13 | 14 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Use-No.** | **Member state(s)** | **Crop and/ or situation**<br>**(crop destination / purpose of crop)** | **F G or I** | **Pests or Group of pests controlled**<br>(additionally: developmental stages of the pest or pest group) | **Application** | | | **Application rate** | | | **PHI** (days) | **Remarks:**<br>e.g. safener/synergist per ha<br>e.g. recommended or mandatory tank mixtures |
| | | | | | Method / Kind | Timing / Growth stage of crop & season | Max. number (min. interval between applications)<br>a) per use<br>b) per crop/ season | kg, L product / ha<br>a) max. rate per appl.<br>b) max. total rate per crop/season | g, kg as/ha<br>a) max. rate per appl.<br>b) max. total rate per crop/season | Water L/ha<br>min / max | | |
| 001 | DE | Majoram (ORISS), oregano (ORIVU) | F | annual dicotyledonous weeds (TTTDS) | spraying | From BBCH 41<br>after planting, after the sprouting | a) 1 (8 to 14 days)<br>b) 2 | a) 1 L/ha<br>b) 2 L/ha | a) 0.48 kg as/ha<br>b) 0,96 kg/ha | 200 - 400 | 28 | Restrictions (see 2.2.3.2)<br>NW 642-1<br>splitting (2 applications)<br>utilization as fresh herb |
| 002 | DE | sage, common (SALOF) | F | annual dicotyledonous weeds (TTTDS) | spraying | From BBCH 41<br>after planting, after the sprouting | a) 1 (8 to 14 days)<br>b) 2 | a) 1 L/ha<br>b) 2 L/ha | a) 0.48 kg as/ha<br>b) 0,96 kg/ha | 200 - 400 | 28 | splitting (2 applications)<br>NW 642-1<br>utilization as fresh herb |
| 003 | DE | thyme, garden (THYVU) | F | annual dicotyledonous weeds (TTTDS) | spraying | From BBCH 41<br>from 2nd year after planting, | a) 1 (8 to 14 days)<br>b) 2 | a) 1 L/ha<br>b) 2 L/ha | a) 0.48 kg as/ha | 200 - 400 | 28 | splitting (2 applications)<br>NW 642-1 |

| | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | after the sprouting | | | b) 0,96 kg/ha | | | utilization as fresh herb |

# 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

Not relevant for extension of authorisation according article 51.

### 3.1.2 Methods of analysis

#### 3.1.2.1 Analytical method for the formulation

Not relevant for extension of authorisation according article 51.

#### 3.1.2.2 Analytical methods for residues

Oregano, sage and thyme belong to the group of high water content commodities. According to the residue definition, acceptable analytical methods are available for enforcing bentazone in these fresh herbs.

### 3.1.3 Mammalian Toxicology

The PPP is already registered in Germany according to Directive 91/414/EEC.
If used properly and according to the intended conditions of use, adverse health effects for operators, workers, bystanders and residents will not be expected.

### 3.1.4 Residues and Consumer Exposure

The residue behaviour of the active substance bentazone has been evaluated within the EU review process. Information about metabolism is sufficient to evaluate the intended use in fresh herbs.

#### 3.1.4.1 Residues

The available residue information is sufficient to perform an adequate assessment. Residues that are expected from the intended use of the plant protection product will not exceed the MRL of 15 mg/kg set in Regulation (EC) No 396/2005 for bentazone in fresh herbs.

#### 3.1.4.2 Consumer exposure

Long-term exposure:
The assessment of uptake of bentazone residues by consumers (TMDI calculation, EFSA PRIMo and NTMDI calculation, German NVS II) results in the following maximum ADI (0.1 mg/kg bw/d) consumptions:
TMDI = 5 % (UK toddler)
NTMDI = 7.7 % (DE child)
Long-term dietary intake of residues of bentazone is unlikely to present a public health concern for European consumers.
Short-term exposure:
The assessment of uptake of bentazone residues by consumers (IESTI calculation, EFSA PRIMo and NESTI calculation, German NVS II) results in the following maximum ARfD (0.25 mg/kg bw) consumptions:
IESTI = 2.3 % (DE child; thyme, oregano, marjoram)

NESTI = <0.1 % (DE child; oregano, marjoram, sage, thyme)
No acute risk is expected from the consumption of fresh herbs treated according to the intended use.

### 3.1.5 Environmental fate and behaviour

No new studies are presented; all data were reviewed within the EU review and approval of the national authorisation 052506-00 /00 according the uniform principles of directive 91/414/EEC.

The specific German assessment scheme for groundwater contamination considers the entry paths direct leaching and bank filtration from adjacent ditches after surface run-off and drainage.
The active substance bentazon has a high potential for direct leaching due to its inherent properties. This is proven by lysimeter studies and modelling results which also show the dependence of groundwater concentrations on the date of application. Shifting the application to later in the year will lower the concentration in groundwater. To reduce the entry of the active substance, the condition of use NG315 (Not to be used before 15 April in each calendar year) is assigned.
The active bentazon shows low $K_{oc}$-values and low sorption especially in pure sand, slightly silty sand and slightly clayey sand soils and with low organic carbon content. To reduce entry of the active substance into groundwater, the conditions of use NG407 (Not to be used on the following soils: pure sand, slightly silty sand and slightly clayey sand) and NG413 (Not to be used on soils with an organic carbon content under 1 %) are assigned.
Considering bank filtration to groundwater from adjacent ditches after surface run-off and drainage the calculated concentration in groundwater the trigger of 0,1 µg/L is not exceeded.

### 3.1.6 Ecotoxicology

No new studies are presented; all data were reviewed within the EU review and approval of the national authorisation 052506-00 /00 according the uniform principles of directive 91/414/EEC.

The PPP Basagran and the active substance bentazone are hazardous to the aquatic environment (Navicula pelliculosa: Preparation $EbC_{50}$ 0.4 mg/L; Bentazone $EbC_{50}$ 0.013 mg/L). Subsequently no additional entries as those according to the evaluated use pattern and good agricultural practise are acceptable. Therefore the condition of use NW466, NW711 is assigned, see also 2.2.
The PPP Basagran and the active substance bentazone are toxic to terrestrial non-target plants (Basagran: Beta vulgaris 130 g a.i./ha). Due to the vapour pressure of 1.7 x 10-4 Pa, also volitilisation and subsequent deposition have to be considered. The resulting TER value for the active substance bentazone are acceptable.

**Risk Assessment for Honeybees**

The honeybee risk assessment for the main application covers the use(s) in accordance with Article 51 of regulation (EC) No 1107/2009 (see also point 2.2).

### 3.1.7 Efficacy

Labelling in accordance with the requirements of ANNEX III General principles of integrated pest management under directive 2009/128/EC (see also point 2.2):

-The classification of effects on beneficial arthropods for the main application covers the use(s) applied for under the terms of Article 51 of regulation (EC) No 1107/2009.

-The categories and labelling for mode of action for the main application cover the use(s) applied for under the terms of Article 51 of regulation (EC) No 1107/2009.

According to Article 51 of the regulation (EC) No 1107/2009 the requirements for approval concerning the sufficient effect and any unacceptable effects on plants and plant products not need to be checked.

## 3.2 Conclusions

PPP Basagran is already registered in Germany according to Directive 91/414/EEC taking into account the uniform principles of Annex VI.
The intended use is minor in nature and the extension of authorisation is in public interest. Effects on bees and other beneficials were evaluated in the frame of the already authorised uses. No additional effects are anticipated because of the extension of uses.
The indended use in fresh herbs will not result in residues above the MRL of 15 mg/kg set for bentazone in Regulation (EC) No 396/2005. A risk for consumers through the consumption of food with these residues is not expected. There is no special risk mitigation necessary which deviate from the existing registration.
Considering an application in accordance with the evaluated use pattern and good agricultural practise as well as strict observance of the conditions of use no harmful effects on groundwater or adverse effects on the ecosystem are to be apprehended.

**An authorisation can be granted.**

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

None

## Appendix 1 – Copy of the product authorisation

See below

## Appendix 2 – Copy of the product label

No product label available. Not mandatory according to Article 51 (5)

## Appendix 3 – Letter of Access

No letter of access necessary. The applicant is owner of the new studies submitted. The authorisation holder is the applicant of this extension of the authorisation.

Bundesamt für
Verbraucherschutz und
Lebensmittelsicherheit

Bundesamt für Verbraucherschutz und Lebensmittelsicherheit
Dienstsitz Braunschweig • Postfach 15 64 • 38005 Braunschweig

BASF SE
E-APE/DT, Li 556
Speyerer Straße 2
67117 Limburgerhof

**Kristina Schuierer**
Referentin

TELEFON +49 (0)531 299-3571
TELEFAX +49 (0)531 299-3002
E-MAIL kristina.schuierer@bvl.bund.de

IHR ZEICHEN
IHRE NACHRICHT VOM

AKTENZEICHEN 200.22200.052506-00/04.81358
(bitte bei Antwort angeben)

DATUM 10. Juli 2014

**GV1 052506-00/04**

**Basagran**

**Verfahren zur Erweiterung einer Zulassung nach Artikel 51 Abs. 1 der Verordnung (EG) Nr. 1107/2009**

Bescheid

Die Zulassung des oben genannten Pflanzenschutzmittels

| | | |
|---|---|---|
| mit dem Wirkstoff: | 480 g/l | Bentazon (als Natrium-Salz 524 g/l) |
| Zulassungsnummer: | 052506-00 | |
| Versuchsbezeichnung: | BAS-35180-H-0-SL | |
| Antrag vom: | 5. April 2013 | |

wird wie in Anlage 1 beschrieben auf der Grundlage von Art. 51 der Verordnung (EG) Nr. 1107/2009 des Europäischen Parlaments und des Rates vom 21. Oktober 2009 über das Inverkehrbringen von Pflanzenschutzmitteln und zur Aufhebung der Richtlinien 79/117/EWG und 91/414/EWG des Rates (Abl. L 309 vom 24.11.2009, S. 1) um folgende Anwendungsgebiete bzw. Anwendungen erweitert:

| Anwendungs-nummer | Schadorganismus/ Zweckbestimmung | Pflanzen/-erzeugnisse/ Objekte | Verwendungszweck |
|---|---|---|---|
| 052506-00/04-001 | Einjährige zweikeim-blättrige Unkräuter | Oregano, Dost | |
| 052506-00/04-002 | Einjährige zweikeim-blättrige Unkräuter | Salbei | |
| 052506-00/04-003 | Einjährige zweikeim-blättrige Unkräuter | Thymian | |

## Festgesetzte Anwendungsbestimmungen

Es werden folgende Anwendungsbestimmungen gemäß § 36 Abs. 1 S. 1 des Gesetzes zum Schutz der Kulturpflanzen (Pflanzenschutzgesetz - PflSchG) vom 6. Februar 2012 (BGBl. I S. 148, 1281), zuletzt geändert durch Artikel 4 Absatz 87 des Gesetzes vom 7. August 2013 (BGBl. I S. 3154) festgesetzt:

Siehe anwendungsbezogene Anwendungsbestimmungen in Anlage 1, jeweils unter Nr. 3.

## Auflagen

Die Zulassung wird mit folgenden Auflagen gemäß § 36 Abs. 3 S. 1 PflSchG verbunden:

Siehe Anlage 1, jeweils unter Nr. 2.

## Vorbehalt

Dieser Bescheid wird mit dem Vorbehalt der nachträglichen Aufnahme, Änderung oder Ergänzung von Anwendungsbestimmungen und Auflagen verbunden.

## Abgelehnte Anwendungsgebiete bzw. Anwendungen

Für folgende Anwendungsgebiete bzw. Anwendungen lehne ich Ihren Antrag ab (siehe Anlage 2):

- keine -

## Rechtsbehelfsbelehrung

Gegen diesen Bescheid kann innerhalb eines Monats nach Bekanntgabe Widerspruch erhoben werden. Der Widerspruch ist bei dem Bundesamt für Verbraucherschutz und Lebensmittelsicherheit, Messeweg 11/12, 38104 Braunschweig, schriftlich oder zur Niederschrift einzulegen.

Mit freundlichen Grüßen
im Auftrag

gez. Dr. Hans-Gerd Nolting
Abteilungsleiter

Dieses Schreiben wurde maschinell erstellt und ist daher ohne Unterschrift gültig.

**Anlage**

# Anlage 1 zugelassene Anwendung: 052506-00/04-001

## 1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Einjährige zweikeimblättrige Unkräuter

Pflanzen/-erzeugnisse/Objekte: Oregano, Dost

Verwendungszweck:

## 2 Kennzeichnungsauflagen

### 2.1 Angaben zur sachgerechten Anwendung

| | |
|---|---|
| Einsatzgebiet: | Gemüsebau |
| Anwendungsbereich: | Freiland |
| Anwendung im Haus- und Kleingartenbereich: | Nein |
| Stadium des Schadorganismus: | 11 bis 14 |
| Erläuterung zur Kultur: | Nutzung als frisches Kraut |
| Stadium der Kultur: | ab 41 |
| Anwendungszeitpunkt: | Nach dem Pflanzen, nach dem Austrieb |
| Maximale Zahl der Behandlungen | |
| - in dieser Anwendung: | 2 |
| - für die Kultur bzw. je Jahr: | 2 |
| - Abstand: | 8 bis 14 Tage |
| Anwendungstechnik: | spritzen |
| - Erläuterungen: | im Splittingverfahren (2 Behandlungen) |
| Aufwand: | |
| - Zeitpunkt 1: | 1 l/ha in 200 bis 400 l Wasser/ha |
| - Zeitpunkt 2: | 1 l/ha |

### 2.2 Sonstige Kennzeichnungsauflagen

(NW642-1)
Die Anwendung des Mittels in oder unmittelbar an oberirdischen Gewässern oder Küstengewässern ist nicht zulässig. Unabhängig davon ist der gemäß Länderrecht verbindlich vorgegebene Mindestabstand zu Oberflächengewässern einzuhalten. Zuwiderhandlungen können mit einem Bußgeld bis zu einer Höhe von 50.000 Euro geahndet werden.

### 2.3 Wartezeiten

| | |
|---|---|
| 28 Tage | Freiland: Oregano |
| 28 Tage | Freiland: Dost |

## 3 Anwendungsbezogene Anwendungsbestimmungen

- keine -

# Anlage 1 zugelassene Anwendung: 052506-00/04-002

## 1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Einjährige zweikeimblättrige Unkräuter

Pflanzen/-erzeugnisse/Objekte: Salbei

Verwendungszweck:

## 2 Kennzeichnungsauflagen

### 2.1 Angaben zur sachgerechten Anwendung

| | |
|---|---|
| Einsatzgebiet: | Gemüsebau |
| Anwendungsbereich: | Freiland |
| Anwendung im Haus- und Kleingartenbereich: | Nein |
| Stadium des Schadorganismus: | 11 bis 14 |
| Erläuterung zur Kultur: | Nutzung als frisches Kraut |
| Stadium der Kultur: | ab 41 |
| Anwendungszeitpunkt: | Nach dem Pflanzen, nach dem Austrieb |
| Maximale Zahl der Behandlungen | |
| - in dieser Anwendung: | 2 |
| - für die Kultur bzw. je Jahr: | 2 |
| - Abstand: | 8 bis 14 Tage |
| Anwendungstechnik: | spritzen |
| - Erläuterungen: | im Splittingverfahren (2 Behandlungen) |
| Aufwand: | |
| - Zeitpunkt 1: | 1 l/ha in 200 bis 400 l Wasser/ha |
| - Zeitpunkt 2: | 1 l/ha |

### 2.2 Sonstige Kennzeichnungsauflagen

(NW642-1)
Die Anwendung des Mittels in oder unmittelbar an oberirdischen Gewässern oder Küstengewässern ist nicht zulässig. Unabhängig davon ist der gemäß Länderrecht verbindlich vorgegebene Mindestabstand zu Oberflächengewässern einzuhalten. Zuwiderhandlungen können mit einem Bußgeld bis zu einer Höhe von 50.000 Euro geahndet werden.

### 2.3 Wartezeiten

| | |
|---|---|
| 28 Tage | Freiland: Salbei |

## 3 Anwendungsbezogene Anwendungsbestimmungen

- keine -

# Anlage 1 zugelassene Anwendung: 052506-00/04-003

## 1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Einjährige zweikeimblättrige Unkräuter

Pflanzen/-erzeugnisse/Objekte: Thymian

Verwendungszweck:

## 2 Kennzeichnungsauflagen

### 2.1 Angaben zur sachgerechten Anwendung

| | |
|---|---|
| Einsatzgebiet: | Gemüsebau |
| Anwendungsbereich: | Freiland |
| Anwendung im Haus- und Kleingartenbereich: | Nein |
| Stadium des Schadorganismus: | 11 bis 14 |
| Erläuterung zur Kultur: | Nutzung als frisches Kraut |
| Stadium der Kultur: | ab 41 |
| Anwendungszeitpunkt: | Ab 2. Standjahr, nach dem Austrieb |
| Maximale Zahl der Behandlungen | |
| - in dieser Anwendung: | 2 |
| - für die Kultur bzw. je Jahr: | 2 |
| - Abstand: | 8 bis 14 Tage |
| Anwendungstechnik: | spritzen |
| - Erläuterungen: | im Splittingverfahren (2 Behandlungen) |
| Aufwand: | |
| - Zeitpunkt 1: | 1 l/ha in 200 bis 400 l Wasser/ha |
| - Zeitpunkt 2: | 1 l/ha |

### 2.2 Sonstige Kennzeichnungsauflagen

(NW642-1)
Die Anwendung des Mittels in oder unmittelbar an oberirdischen Gewässern oder Küstengewässern ist nicht zulässig. Unabhängig davon ist der gemäß Länderrecht verbindlich vorgegebene Mindestabstand zu Oberflächengewässern einzuhalten. Zuwiderhandlungen können mit einem Bußgeld bis zu einer Höhe von 50.000 Euro geahndet werden.

### 2.3 Wartezeiten

| | |
|---|---|
| 28 Tage | Freiland: Thymian |

## 3 Anwendungsbezogene Anwendungsbestimmungen

- keine -

# REGISTRATION REPORT
# Part B

## Section 4: Metabolism and Residues

### Detailed summary of the risk assessment

---

**Product code: Basagran**

**Active Substance: 480 g/L Bentazone**

---

**Central Zone**
**Zonal Rapporteur Member State: Germany**

---

## CORE ASSESSMENT

---

**Applicant: BASF SE**

**Date: February 2014**

# Table of Contents

# 4 METABOLISM AND RESIDUES DATA

## 4.1 Evaluation of the active substances

Not detailed in the context of this assessment. Data on bentazone has been previously evaluated at EU level and is described in detail in the DAR (Germany, 1996: ASB2010-10277; renewal Assessment Report 2013; ASB2014-1524) and the Reasoned Opinion of EFSA on the review of the existing MRLs for bentazone (EFSA Journal 2012; 10(7):2822, ASB2012-2360).

## 4.2 Evaluation of the intended use(s)

### 4.2.1 Selection of critical use and justification

The critical GAP used for consumer intake and risk assessment is presented in Table 4.2-1.

## Table 4.2-1: Critical Use (worst case) used for consumer intake and risk assessment

| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Use-No.** | **Member state(s)** | **Crop and/ or situation**<br><br>**(crop destination / purpose of crop)**<br><br>**(a)** | **F G or I**<br><br>**(b)** | **Pests or Group of pests controlled**<br><br>**(additionally: developmental stages of the pest or pest group)**<br><br>**(c)** | **Application** | | | **Application rate** | | | **PHI (days) (i)** | **Remarks:**<br><br>**e.g. safener/synergist per ha**<br><br>**e.g. recommended or mandatory tank mixtures**<br><br>**(j)** |
| | | | | | **Method / Kind**<br><br>**(d-f)** | **Timing / Growth stage of crop & season**<br><br>**(g)** | **Max. number (min. interval between applications)**<br>**a) per use**<br>**b) per crop/ season**<br>**(h)** | **L product / ha**<br>**a) max. rate per appl.**<br>**b) max. total rate per crop/season** | **kg as/ha**<br><br>**a) max. rate per appl.**<br>**b) max. total rate per crop/season** | **Water L/ha**<br><br>**min / max** | | |
| 001 | DE | Oregano, Marjoram | F | Annual dicotyledonous weeds (BBCH 11 – 14) | spraying | BBCH 41;<br>After planting, after the sprouting | a) 2<br>b) 2<br>(8 to 14 days) | a) 1<br>b) 1 | a) 0.48<br>b) 0.48 | 200 - 400 | 28 | utilization as fresh herb |
| 002 | DE | Sage | F | Annual dicotyledonous weeds (BBCH 11 – 14) | spraying | BBCH 41;<br>After planting, after the sprouting | a) 2<br>b) 2<br>(8 to 14 days) | a) 1<br>b) 1 | a) 0.48<br>b) 0.48 | 200 - 400 | 28 | utilization as fresh herb |
| 001 | DE | Thyme | F | Annual dicotyledonous weeds (BBCH 11 – 14) | spraying | BBCH 41;<br>From 2nd year after planting, after the sprouting | a) 2<br>b) 2<br>(8 to 14 days) | a) 1<br>b) 1 | a) 0.48<br>b) 0.48 | 200 - 400 | 28 | utilization as fresh herb |

Remarks:
(a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (*e.g.* fumigation of a structure)
(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(c) e.g. biting and suckling insects, soil born insects, foliar fungi, weeds
(d) All abbreviations used must be explained
(e) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
(f) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
(g) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(h) The minimum and maximum number of application possible under practical conditions of use must be provided
(i) PHI - minimum pre-harvest interval
(j) Remarks may include: Extent of use/economic importance/restrictions

## 4.2.2 Oregano, sage and thyme

### *4.2.2.1 Residues in primary crops*

The following table gives a brief overview of the supervised residue trials selected for the assessment of bentazone in fresh herbs. For the detailed evaluation of the residue trials it is referred to Appendix 2.

**Table 4.2-2: Overview of the selected supervised residue trials for bentazone in fresh herbs**

| Commodity | Region [(a)] | Outdoor/ Indoor | Individual trial results (mg/kg) | | STMR (mg/kg) [(b)] | HR (mg/kg) [(c)] | Median CF [(d)] |
|---|---|---|---|---|---|---|---|
| | | | Enforcement (sum of bentazone and the conjugates of 6-OH and 8-OH bentazone, expressed as bentazone) | Risk assessment (sum of bentazone and the conjugates of 6-OH and 8-OH bentazone, expressed as bentazone) | | | |
| Fresh herbs (oregano, sage, thyme) | NEU | Outdoor | 2 x <0.03; 0.15; 0.40; 1.35 | 2 x <0.03; 0.15; 0.40; 1.4 | 0.15 | 1.4 | 1 |

(a): NEU, SEU, EU or Import (country code).
(b): Median value of the individual trial results according to the risk assessment residue definition.
(c): Highest value of the individual trial results according to the risk assessment residue definition.
(d): The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors for each residues trial.

Five residue trials on oregano, sage and thyme conducted in Germany were submitted. Trials were carried out in compliance with the intended GAP, using two applications at BBCH 32-49 at rates of 0.45 to 0.48 kg as/ha. Samples were collected 27 or 28 days after the last application and analysed for bentazone and its hydroxy metabolites. The analytical method includes a hydrolysis step and is therefore assumed to consider conjugates. Bentazone residues were in the range of 0.03 to 1.4 mg/kg.

Analytical methods for commodities of high water content such as fresh herbs are available and acceptable for enforcing all compounds given in the residue definition.

### *4.2.2.2 Distribution of the residue in peel/pulp*

Not relevant.

### *4.2.2.3 Residues in processed commodities*

Such studies are not considered necessary taking into account the low dietary intake of the crops under consideration.

### *4.2.2.4 Proposed pre-harvest intervals, withholding periods*

The proposed PHI of 28 days is considered acceptable.

## 4.3 Consumer intake and risk assessment

The consumer intake and risk assessment is based on the appropriate input values given in Table 4.3-1 and the toxicological reference values stated in Table 4.3-2. For the detailed calculation results it is referred to Appendix 3.

**Table 4.3-1: Residue input values for the consumer risk assessment**

| Commodity | Chronic risk assessment | | Acute risk assessment | |
|---|---|---|---|---|
| | **Input value (mg/kg)** | **Comment** | **Input value (mg/kg)** | **Comment** |
| Oregano, majoram, thyme, sage | 15 | MRL | 1.4 | HR |
| Others | various | MRL (Reg 270/2012) | not performed in the framework of the application for authorizations under consideration | |

**Table 4.3-2: Consumer risk assessment (Annex IIA, point 6.9, Annex IIIA, point 8.8)**

| | |
|---|---|
| ADI | 0.1 mg/kg bw |
| TMDI (% ADI) according to EFSA PRIMo | 5.0 % (based on UK toddler, 14.5 kg mean body weight) |
| NTMDI (% ADI) according to German NVS II | 7.7 % (based on DE children, aged 2 to 4 years, individual consumption/ body weight ratio) |
| IEDI (EFSA PRIMo) (% ADI) | Not necessary |
| NEDI (DE NVS II) (% ADI) | Not necessary |
| Factors included in IEDI and NEDI | Not applicable |
| ARfD | 0.25 mg/kg bw |
| IESTI (EFSA PRIMo) (% ARfD) | Thyme (incl. oregano and majoram): 2.3 % (based on 2-4 years old DE children)<br>Sage: <1.0 % (based on 2-4 years old DE children)<br><br>Data are based on mean body weight. |
| NESTI (DE NVS II) (% ARfD) | Oregano: <1.0 % (based on 2-4 years old DE children)<br>Majoram: <1.0 % (based on 2-4 years old DE children)<br>Thyme: <1.0 % (based on 2-4 years old DE children)<br>Sage: <1.0 % (based on 2-4 years old DE children)<br><br>Data are based on individual consumption/body weight ratios. |
| Factors included in IESTI and NESTI | see Table 4.3-3: |

## 4.4 Proposed maximum residue levels (MRLs)

No new MRLs are required.

## 4.5 Conclusion

The data available are considered sufficient for risk assessment. An exceedance of the current MRL of 15 mg/kg bentazone for oregano, majoram, sage and thyme as laid down in Reg. (EU) 396/2005 is not expected.

The chronic and the short-term intake of bentazone residues are unlikely to present a public health concern.
As far as consumer health protection is concerned, the BfR/Germany agrees with the authorization of the intended uses.

# Appendix 1 List of data submitted in support of the evaluation

**Table A 1: List of data submitted in support of the evaluation**

| Annex point/ reference No | Author(s) | Year | Title<br>Report-No.<br>Authority registration No | Data protection claimed | Owner | How considered in dRR * |
|---|---|---|---|---|---|---|
| All | EFSA | 2012 | Reasoned opinion on the review of the existing maximum residue levels (MRLs) for Bentazone according to Article 12 of Regulation (EC) No 396/2005<br>EFSA Journal 2012;10(7):2822 ! EFSA-Q-2008-495<br>ASB2012-2360 | | | Add |
| All | Germany | 1996 | bentazone (Monograph)<br>17 September 1996<br>GLP: Open Published: Yes<br>ASB2010-10277 | Open | | Add |
| All | The Netherlands; Co-RMS Germany | 2013 | Bentazon: Renewal Assessment Report; Volume 1-3<br><br>ASB2014-1524 | | | Add |
| OECD KII 6.3 | Anon. | 2013 | Residue summary from supervised field trials Bentazone ( Basagran 480 SL) in sage / fresh herbs<br><br>GLP: No Published: No<br>BVL-2434314, ASB2013-6869 | Yes | BAS | Y |
| OECD KII 6.3 | Anon. | 2013 | Residue summary from supervised field trials Bentazone ( Basagran 480 SL) in thyme / fresh herbs<br><br>GLP: No Published: No<br>BVL-2434315, ASB2013-6870 | Yes | BAS | Y |
| OECD KII 6.3 | Anon. | 2013 | Residue summary from supervised field trials Bentazone ( Basagran 480 SL) in oregano / fresh herbs<br><br>GLP: No Published: No<br>BVL-2434316, ASB2013-6871 | Yes | BAS | Y |
| OECD KII 6.3 | Anon. | 2013 | Residue behaviour of Bentazone in/on oregano, sage and thyme, outdoor, after application of Basagran (SL, 480 g/l) in Germany, 2010 and 2011<br>2012/1167621<br>GLP: Yes Published: No<br>BVL-2434313, ASB2013-6868 | Yes | BAS | Y |

* Y yes, relied on
N no, not relied on
Add Relied on, study not submitted by applicant but necessary for evaluation

# Appendix 2 Detailed evaluation of the additional studies relied upon

## A 2.1 Storage stability

No further study on storage stability submitted/needed.

## A 2.2 Residues in primary crops

### A 2.2.1 Nature of residues

No further study on nature of residues submitted/needed.

## A 2.2.2 Magnitude of residues in oregano

| | |
|---|---|
| Reference: | OECD KIIA 6.3 |
| Report | Anonym, Residue behaviour of Bentazone in/on oregano, sage and thyme, outdoor, after application of Basagran (SL, 480 g/l) in Germany, 2010 and 2011, 2012/1167621, ASB2013-6868<br>Anonym, Residue summary from supervised field trials Bentazone (Basagran 480 SL) in oregano/fresh herbs , ASB2013-6871 |
| Guideline(s): | BBA-Richtlinie Teil IV, 3-1; IVA-Richtlinie Rückstandsversuche |
| Deviations: | No |
| GLP: | Yes |
| Acceptability: | Yes |

**Table A 2: Residues of bentazone in oregano**

**RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)**
(Application on agricultural and horticultural crops)

Federal Institute for Risk Assessment, Berlin
Federal Republic of Germany

| | | | |
|---|---|---|---|
| Content of a.i. | (g/kg or g/l) | : | 480 g/L (524 g/L bentazone sodium) |
| Formulation | (e.g. WP) | : | SL (Soluble concentrate) |
| Commercial product | (name) | : | Basagran |
| Applicant | | : | BASF SE |

| | | |
|---|---|---|
| Active ingredient | : | Bentazone |
| Crop / crop group | : | Oregano |
| Crop Code | : | ORIVU |
| Submission date | : | 2013-05-24 |
| Indoors / Outdoors | : | Outdoors (European North) |
| Other a.i. in formulation (content and common name) | : | |
| Residues calculated as | : | 8.1 bentazone<br>8.2 6-OH-bentazone, calculated as bentazone<br>8.3 8-OH-bentazone, calculated as bentazone |

| 1 | 2 | 3 | 4 | | | 5 | 6 | 7 | 8.1 | 8.2 | 8.3 | 9 | 10 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Report-No. Location incl. Postal code and date | Commodity/ Variety | Date of 1) Sowing or planting 2) Flowering 3) Harvest | Application rate per treatment | | | Dates of treatments or no. of treatments and last date | Growth stage at last treatment or date | Portion analysed | Residues (mg/kg) | Residues (mg/kg) | Residues (mg/kg) | PHI (days) | Remarks |
| | | | kg a.i./ha | Water l/ha | kg a.i./hl | | | | | | | | |
| | (a) | (b) | | | | (c) | | (a) | | | | (d) | (e) |
| 2012/1167621, 1LHSOR0111/02<br><br>Germany (DE) 06406 Bermburg<br><br>2013-03-15 | Vulkan | 1) 2010-04-26 (planting)<br>2) 2011-07-07<br>3) 2011-07-15 | 0.48<br>0.45 | 400<br>380 | 0.12<br>0.12 | 2011-05-30[4)]<br>2011-06-07[4)] | BBCH 45-47 | leaf with stem, fresh | **0.010**<br><0.010 | **0.38**<br>0.18 | **<0.010**<br><0.010 | 27<br>38 | 4) spraying<br>analytical method: BASF L0044/02 (438/2) (LC-MS/MS), LOQ: 0.01 mg/kg, max. sample storage time in months: 9<br><br>ASB2013-6868<br>ASB2013-6871 |

Remarks: (a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

| Comments of zRMS: | Acceptable. |
|---|---|

## A 2.2.3 Magnitude of residues in sage

| | |
|---|---|
| Reference: | OECD KIIA 6.3 |
| Report | Anonym, Residue behaviour of Bentazone in/on oregano, sage and thyme, outdoor, after application of Basagran (SL, 480 g/l) in Germany, 2010 and 2011, 2012/1167621, ASB2013-6868<br>Anonym, Residue summary from supervised field trials Bentazone (Basagran 480 SL) in sage/fresh herbs, ASB2013-6869 |
| Guideline(s): | BBA-Richtlinie Teil IV, 3-1; IVA-Richtlinie Rückstandsversuche |
| Deviations: | No |
| GLP: | Yes |
| Acceptability: | Yes |

**Table A 3: Residues of bentazone in sage**

**RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)**
(Application on agricultural and horticultural crops)

Federal Institute for Risk Assessment, Berlin
Federal Republic of Germany

| | | | |
|---|---|---|---|
| Content of a.i. | (g/kg or g/l) | : | 480 g/L (524 g/L bentazone sodium) |
| Formulation | (e.g. WP) | : | SL (Soluble concentrate) |
| Commercial product | (name) | : | Basagran |
| Applicant | | : | BASF SE |

| | | |
|---|---|---|
| Active ingredient | : | Bentazone |
| Crop / crop group | : | Sage |
| Crop Code | : | SALOF |
| Submission date | : | 2013-05-24 |
| Indoors / Outdoors | : | Outdoors (European North) |
| Other a.i. in formulation (content and common name) | : | |
| Residues calculated as | : | 8.1 bentazone<br>8.2 6-OH-bentazone, calculated as bentazone<br>8.3 8-OH-bentazone, calculated as bentazone |

| 1 | 2 | 3 | 4 | | | 5 | 6 | 7 | 8.1 | 8.2 | 8.3 | 9 | 10 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Report-No. Location incl. Postal code and date | Commodity/ Variety | Date of 1) Sowing or planting 2) Flowering 3) Harvest | Application rate per treatment | | | Dates of treatments or no. of treatments and last date | Growth stage at last treatment or date | Portion analysed | Residues (mg/kg) | Residues (mg/kg) | Residues (mg/kg) | PHI (days) | Remarks |
| | | | kg a.i./ha | Water l/ha | kg a.i./hl | | | | | | | | |
| | (a) | (b) | | | | (c) | | (a) | | | | (d) | (e) |
| 2012/1167621, LR-K-11-TK-H-05 SN 01<br><br>Germany (DE) 01326 Dresden-Pillnitz<br><br>2013-03-15 | no data | 1) 2011-06-23 (planting)<br>2)<br>3) 2011-09-02 | 0.48<br>0.48 | 400<br>400 | 0.12<br>0.12 | 2011-07-26[4)]<br>2011-08-05[4)] | BBCH 45-49 | leaf, fresh | **<0.010**<br><0.010 | **<0.010**<br><0.010 | **<0.010**<br><0.010 | 28<br>40 | 4) spraying<br>analytical method: BASF L0044/02 (438/2) (LC-MS/MS), LOQ: 0.01 mg/kg, max. sample storage time 7 months<br><br>ASB2013-6868<br>ASB2013-6869 |
| 2012/1167621, LR-K-11-TK-H-05 AHR 01<br><br>Germany (DE) 53359 Rheinbach<br><br>2013-03-15 | Extracta | 1) 2007-04-03 (sowing)<br>2)<br>3) 2001-05-26 - 2001-06-07 | 0.48<br>0.48 | 400<br>400 | 0.12<br>0.12 | 2011-04-20[4)]<br>2011-04-28[4)] | BBCH 32-36 | leaf, fresh | **0.010**<br><0.010 | **0.13**<br>0.010 | **<0.010**<br><0.010 | 28<br>40 | 4) spraying<br>analytical method: BASF L0044/02 (438/2) (LC-MS/MS), LOQ: 0.01 mg/kg, max. sample storage time: 11 months<br><br>ASB2013-6868<br>ASB2013-6869 |
| 2012/1167621, R-H-K-0510/1/1AHR<br><br>Germany (DE) 53359 Rheinbach<br><br>2013-03-15 | Extracta | 1) 2007-04-03 (sowing)<br>2)<br>3) 2010-06-01 - 2010-06-14 | 0.48<br>0.48 | 400<br>400 | 0.12<br>0.12 | 2010-04-26[4)]<br>2010-05-04[4)] | BBCH 32-36 | leaf, fresh | **<0.010**<br><0.010 | **<0.010**<br><0.010 | **<0.010**<br><0.010 | 28<br>41 | 4) spraying<br>analytical method: BASF L0044/02 (438/2) (LC-MS/MS), LOQ: 0.01 mg/kg, max. sample storage time 22 months<br><br>ASB2013-6868<br>ASB2013-6869 |

Remarks: (a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

| Comments of zRMS: | Acceptable. |
|---|---|

## A 2.2.4 Magnitude of residues in thyme

| | |
|---|---|
| Reference: | OECD KIIA 6.3 |
| Report | Anonym, Residue behaviour of Bentazone in/on oregano, sage and thyme, outdoor, after application of Basagran (SL, 480 g/l) in Germany, 2010 and 2011, 2012/1167621, ASB2013-6868<br>Anonym, Residue summary from supervised field trials Bentazone (Basagran 480 SL) in thyme/fresh herbs, ASB2013-6870 |
| Guideline(s): | BBA-Richtlinie Teil IV, 3-1; IVA-Richtlinie Rückstandsversuche |
| Deviations: | No |
| GLP: | Yes |
| Acceptability: | Yes |

**Table A 4: Residues of bentazone in thyme**

**RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)**
(Application on agricultural and horticultural crops)

Federal Institute for Risk Assessment, Berlin
Federal Republic of Germany

| | | | |
|---|---|---|---|
| Content of a.i. | (g/kg or g/l) | : | 480 g/L (524 g/L bentazone sodium) |
| Formulation | (e.g. WP) | : | SL (Soluble concentrate) |
| Commercial product | (name) | : | Basagran |
| Applicant | | : | BASF SE |

| | | |
|---|---|---|
| Active ingredient | : | Bentazone |
| Crop / crop group | : | Thyme |
| Crop Code | : | THYVU |
| Submission date | : | 2013-05-24 |
| Indoors / Outdoors | : | Outdoors (European North) |
| Other a.i. in formulation (content and common name) | : | |
| Residues calculated as | : | 8.1 bentazone<br>8.2 6-OH-bentazone, calculated as bentazone<br>8.3 8-OH-bentazone, calculated as bentazone |

| 1 | 2 | 3 | 4 | | | 5 | 6 | 7 | 8.1 | 8.2 | 8.3 | 9 | 10 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Report-No. Location incl. Postal code and date | Commodity/ Variety | Date of 1) Sowing or planting 2) Flowering 3) Harvest | Application rate per treatment | | | Dates of treatments or no. of treatments and last date | Growth stage at last treatment or date | Portion analysed | Residues (mg/kg) | Residues (mg/kg) | Residues (mg/kg) | PHI (days) | Remarks |
| | | | kg a.i./ha | Water l/ha | kg a.i./hl | | | | | | | | |
| | (a) | (b) | | | | (c) | | (a) | | | | (d) | (e) |
| 2012/1167621, 1<br>LHSTH0211/02<br><br>Germany (DE)<br>06406<br>Bernburg<br><br>2013-03-15 | Deutscher Winter (established) | 1) 2010-04-08 (sowing)<br>2) 2011-05-06 - 2011-06-15<br>3) 2011-06-16 | 0.48<br>0.48 | 400<br>400 | 0.12<br>0.12 | 2011-04-26[4)]<br>2011-05-06[4)] | BBCH 45-55 | leaf, fresh | 0.050<br>**0.040**<br>0.010 | 1.1<br>**1.3**<br>0.56 | <0.010<br>**<0.010**<br><0.010 | 19<br>28<br>40 | 4) spraying<br>analytical method: BASF L0044/02 (438/2) (LC-MS/MS), LOQ: 0.01 mg/kg, max. sample storage time in months: 11<br><br>ASB2013-6868<br>ASB2013-6870 |

Remarks: (a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

| Comments of zRMS: | Acceptable. |
|---|---|

## A 2.3 Residues in processed commodities

No new study on residues in processed commodities has been submitted and none is needed due to low residues at harvest.

## A 2.4 Residues in rotational crops

No new study on residues in rotational crops has been submitted.

## A 2.5 Residues in livestock

No new study on residues in livestock has been submitted.

## A 2.6 Other studies/information

None

# Appendix 3 Pesticide Residue Intake Model (PRIMo)

## of 6-OH and 8-OH bentazone expressed as bentazone) (R)

| | | | |
|---|---|---|---|
| Status of the active substance: | | Code no. | |
| LOQ (mg/kg bw): | | proposed LOQ: | |
| **Toxicological end points** | | | |
| ADI (mg/kg bw/day): | **0,1** | ARfD (mg/kg bw): | **0,25** |
| Source of ADI: | **COM** | Source of ARfD: | **COM** |
| Year of evaluation: | **2000** | Year of evaluation: | **2010** |

Explain choice of toxicological reference values.
The risk assessment has been performed on the basis of the MRLs collected from Member States in April 2006. For each pesticide/commodity the highest national MRL was identified (proposed temporary MRL = pTMRL).
The pTMRLs have been submitted to EFSA in September 2006.

## Chronic risk assessment

TMDI (range) in % of ADI
minimum - maximum
1 5

**No of diets exceeding ADI:** ---

| Highest calculated TMDI values in % of ADI | MS Diet | Highest contributor to MS diet (in % of ADI) | Commodity / group of commodities | 2nd contributor to MS diet (in % of ADI) | Commodity / group of commodities | 3rd contributor to MS diet (in % of ADI) | Commodity / group of commodities | pTMRLs at LOQ (in % of ADI) |
|---|---|---|---|---|---|---|---|---|
| 5,0 | UK Toddler | 2,3 | SUGAR PLANTS | 0,6 | FRUIT (FRESH OR FROZEN) | 0,5 | CEREALS | |
| 5,0 | WHO Cluster diet B | 1,2 | CEREALS | 0,7 | FRUIT (FRESH OR FROZEN) | 0,7 | Herbs | |
| 4,7 | DE child | 2,3 | FRUIT (FRESH OR FROZEN) | 0,7 | Herbs | 0,6 | CEREALS | |
| 4,2 | NL child | 1,5 | FRUIT (FRESH OR FROZEN) | 0,7 | Root and tuber vegetables | 0,6 | Milk and cream, | |
| 4,1 | FR toddler | 1,2 | FRUIT (FRESH OR FROZEN) | 0,8 | Root and tuber vegetables | 0,8 | Milk and cream, | |
| 3,9 | UK Infant | 1,0 | SUGAR PLANTS | 0,8 | Milk and cream, | 0,6 | FRUIT (FRESH OR FROZEN) | |
| 3,8 | IE adult | 1,1 | FRUIT (FRESH OR FROZEN) | 0,7 | CEREALS | 0,7 | Herbs | |
| 3,5 | FR infant | 1,5 | FRUIT (FRESH OR FROZEN) | 0,7 | Root and tuber vegetables | 0,5 | Milk and cream, | |
| 3,5 | WHO cluster diet E | 0,8 | Herbs | 0,6 | CEREALS | 0,6 | FRUIT (FRESH OR FROZEN) | |
| 3,4 | WHO cluster diet D | 1,0 | Herbs | 0,8 | CEREALS | 0,4 | Root and tuber vegetables | |
| 2,9 | SE general population 90th percentile | 0,6 | FRUIT (FRESH OR FROZEN) | 0,6 | Root and tuber vegetables | 0,5 | CEREALS | |
| 2,8 | DK child | 1,0 | CEREALS | 0,5 | FRUIT (FRESH OR FROZEN) | 0,4 | Root and tuber vegetables | |
| 2,8 | WHO regional European diet | 0,5 | Herbs | 0,5 | Root and tuber vegetables | 0,4 | CEREALS | |
| 2,3 | ES child | 0,6 | FRUIT (FRESH OR FROZEN) | 0,5 | CEREALS | 0,3 | Milk and cream, | |
| 2,1 | WHO Cluster diet F | 0,5 | CEREALS | 0,4 | Root and tuber vegetables | 0,4 | FRUIT (FRESH OR FROZEN) | |
| 2,0 | IT kids/toddler | 0,8 | CEREALS | 0,4 | FRUIT (FRESH OR FROZEN) | 0,3 | Herbs | |
| 1,9 | PT General population | 0,6 | FRUIT (FRESH OR FROZEN) | 0,5 | CEREALS | 0,3 | Brassica vegetables | |
| 1,8 | UK vegetarian | 0,4 | SUGAR PLANTS | 0,3 | FRUIT (FRESH OR FROZEN) | 0,3 | CEREALS | |
| 1,7 | NL general | 0,5 | FRUIT (FRESH OR FROZEN) | 0,3 | Root and tuber vegetables | 0,3 | CEREALS | |
| 1,6 | IT adult | 0,5 | CEREALS | 0,4 | Herbs | 0,3 | FRUIT (FRESH OR FROZEN) | |
| 1,6 | FR all population | 0,6 | FRUIT (FRESH OR FROZEN) | 0,3 | CEREALS | 0,2 | Root and tuber vegetables | |
| 1,5 | UK Adult | 0,4 | SUGAR PLANTS | 0,3 | FRUIT (FRESH OR FROZEN) | 0,2 | CEREALS | |
| 1,5 | ES adult | 0,4 | FRUIT (FRESH OR FROZEN) | 0,3 | CEREALS | 0,1 | Meat, preparations of meat, offals, | |
| 1,2 | DK adult | 0,3 | FRUIT (FRESH OR FROZEN) | 0,3 | CEREALS | 0,2 | Root and tuber vegetables | |
| 1,2 | LT adult | 0,3 | Root and tuber vegetables | 0,3 | CEREALS | 0,2 | FRUIT (FRESH OR FROZEN) | |
| 1,1 | PL general population | 0,4 | Root and tuber vegetables | 0,3 | FRUIT (FRESH OR FROZEN) | 0,2 | Herbs | |
| 0,9 | FI adult | 0,3 | FRUIT (FRESH OR FROZEN) | 0,2 | CEREALS | 0,1 | Root and tuber vegetables | |

**Conclusion:**
The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.
A long-term intake of residues of Bentazone (sum of bentazone and the conjugates of 6-OH and 8-OH bentazone expressed as bentazone) (R) is unlikely to present a public health concern.