

**FAO SPECIFICATIONS AND EVALUATIONS
FOR PLANT PROTECTION PRODUCTS**

BENTAZONE

(3-isopropyl-1H-2,1,3-benzothiadiazin-4(3H)-one 2,2-dioxide)

1999



FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

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Disclaimer¹

FAO specifications are developed with the basic objective of ensuring that pesticides complying with them are satisfactory for the purpose for which they are intended so that they may serve as an international point of reference. The specifications do not constitute an endorsement or warranty of the use of a particular pesticide for a particular purpose. Neither do they constitute a warranty that pesticides complying with these specifications are suitable for the control of any given pest, or for use in a particular area. Owing to the complexity of the problems involved, the suitability of pesticides for a particular application must be decided at the national or provincial level.

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INTRODUCTION

FAO establishes and publishes specifications* for technical pesticides and related formulations of plant protection products, with the objective that these specifications may be used to provide an international point of reference against which products can be judged either for regulatory purposes or in commercial dealings.

Since 1999 the development of FAO specifications has followed the **New Procedure**, described in the 5th edition of the “Manual on the development and use of FAO specifications for plant protection products” (FAO Plant Production and Protection Page No. 149). This **New Procedure** follows a formal and transparent evaluation process. It describes the minimum data package required for evaluation, the procedures to be applied in the evaluation process by FAO and the Experts of the “FAO Panel of Experts on Pesticide Specifications, Registration Requirements, Application Standards and Prior Informed Consent.”

FAO Specifications now only apply to the products of manufacturers whose data have been evaluated as satisfactory and to whose products the specifications are thus known to be appropriate. Consequently from the year 2000 onwards the publication of FAO specifications under the **New Procedure** has changed. Every specification document consists now of two parts, namely the specifications and the evaluation report(s):

Part One: The Specifications of the technical material and the related formulations of the plant protection product, in accordance with the requirements of chapters 4, 5 and 6 of the 5th edition of the “Manual on the development and use of FAO specifications for plant protection products”.

Part Two: The Evaluation Report(s) of the plant protection product, reflecting the evaluation of the data package carried out by FAO and the Panel of Experts, and providing the justification for any deviation in the specifications from requirements of the 5th edition of the Manual. The data have been provided by the manufacturer(s) according to the requirements of Appendix A, Annex 1, of the 5th edition of the “Manual on the development and use of FAO specifications for plant protection products”. The Evaluation Report includes the name(s) of the manufacturer(s) whose technical pesticide has been evaluated.

FAO Specifications under the **New Procedure** do not necessarily apply to nominally similar products of other manufacturer(s), nor to those where the active ingredient is produced by other methods of synthesis. FAO may extend the scope of the specifications to notionally similar products, if the Panel of Experts has been satisfied that the additional products are equivalent to those which formed the basis of the reference specification.

* Footnote: The publications are available on the Internet under (<http://www.fao.org/waicent/faoinfo/agricult/agp/>) or as hardcopy from the Plant Protection Information Officer.

FAO SPECIFICATIONS AND EVALUATIONS FOR PLANT PROTECTION
PRODUCTS

BENTAZONE

INFORMATION

ISO common name

bentazone (BSI, E-ISO, F-ISO, JMAF)

Synonyms

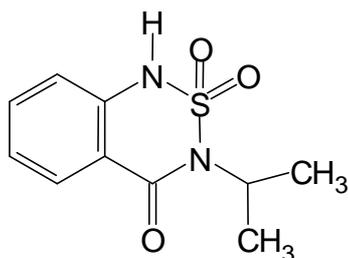
bentazon (ANSI, Canada, WSSA)

Chemical names

IUPAC 3-isopropyl-1H-2,1,3-benzothiadiazin-4(3H)-one 2,2-dioxide

CA 3-(1-methylethyl)-1H-2,1,3-benzothiadiazin-4(3H)-one 2,2-dioxide

Structural formula



Molecular formula

$C_{10}H_{12}N_2O_3S$

Relative molecular mass

240.3

CAS Registry number

25057-89-0

CIPAC number

366

EEC number

613-012-00-1

BENTAZONE TECHNICAL

366/TC (1999)

This specification, which is PART ONE of this publication, is based on an evaluation of data submitted by the manufacturer whose name is listed in the evaluation report (366/1999). It should be applicable to relevant products of this manufacturer but it is not an endorsement of those products, nor a guarantee that they comply with the specifications. The specification may not be appropriate for the products of other manufacturers. The evaluation report (366/1999) as PART TWO forms an integral part of this publication.

1 Description

The material shall consist of bentazone together with related manufacturing impurities and shall be an ochre-yellow solid, free from visible extraneous matter and added modifying agents.

2 Active ingredient

2.1 Identity tests (366/TC/(M)/2, CIPAC 1C, p. 1974) (Note 1)

The active ingredient shall comply with an identity test and, where the identity remains in doubt, shall comply with at least one additional test.

2.2 Bentazone content [366/TC/(M)/3, CIPAC 1C, p. 1974]

The bentazone content shall be declared (not less than 960 g/kg) and, when determined, the mean measured content shall not be lower than the declared minimum content.

Note 1 In addition to retention time in HPLC, given as an identity test in the CIPAC method, the following may also be used.

- (i) the infra-red spectrum produced from the sample shall be consistent with that produced from an authentic standard of bentazone;
- (ii) the major component in the sample thin-layer chromatogram shall have the same R_f value as that of an authentic standard of bentazone;
- (iii) after methylation, the major component in the sample gas chromatogram shall have the same retention time as that of an authentic standard of bentazone derivatized and chromatographed under identical conditions.

Further details are available from the Plant Protection Officer, FAO Plant Production and Protection Division, or from BASF AG, Germany.

BENTAZONE SALT TECHNICAL CONCENTRATES

366/TK (1999)

This specification, which is PART ONE of this publication, is based on an evaluation of data submitted by the manufacturer whose name is listed in the evaluation report (366/1999). It should be applicable to relevant products of this manufacturer but it is not an endorsement of those products, nor a guarantee that they comply with the specifications. The specification may not be appropriate for the products of other manufacturers. The evaluation report (366/1999) as PART TWO forms an integral part of this publication.

1 Description

The material shall consist of bentazone together with related manufacturing impurities (complying with the requirements of FAO Specification 366/TC) in the form of a bentazone salt dissolved in water, and shall be a clear or opalescent liquid, yellow to dark brown in colour. The solution shall be free from more than a trace of visible suspended matter or sediment.

2 Active ingredient

2.1 Salt

The name of the bentazone salt present shall be stated.

2.2 Identity tests (366/SL/(M)/2, CIPAC 1C, p. 1976)

The active ingredient shall comply with an identity test and, where the identity remains in doubt, shall comply with at least one additional test.

2.3 Bentazone content (366/SL/(M)/3, CIPAC 1C, p. 1976)

The bentazone content shall be declared (g/l at $20 \pm 2^\circ\text{C}$ or g/kg: Note 1) and, when determined, the mean measured content shall not differ from that declared by more than the following tolerance:

Declared content in g/kg or g/l at $20 \pm 2^\circ\text{C}$	Tolerance
above 500 g/kg or g/l	+/- 25 g/kg or g/l

3 Impurities

3.1 Water insolubles (MT 10.3, CIPAC F, p. 28)

The product shall pass through a 150 μm test sieve leaving not more than 1g/kg on the sieve.

4 **Physical properties**

4.1 **pH range** (MT 75.1, CIPAC F, p. 205)

pH range: 6.5 to 9.5

Note 1 If the buyer requires both g/l at 20°C and g/kg, then in case of dispute the analytical results shall be calculated as g/kg.

BENTAZONE WETTABLE POWDERS

366/WP (1999)

This specification, which is PART ONE of this publication, is based on an evaluation of data submitted by the manufacturer whose name is listed in the evaluation report (366/1999). It should be applicable to relevant products of this manufacturer but it is not an endorsement of those products, nor a guarantee that they comply with the specifications. The specification may not be appropriate for the products of other manufacturers. The evaluation report (366/1999) as PART TWO forms an integral part of this publication.

1 Description

The material shall consist of an homogeneous mixture of technical bentazone, complying with the requirements of FAO specification 366/TC, together with filler(s) and any other necessary formulants. It shall be in the form of a fine powder, free from visible extraneous matter and hard lumps.

2 Active ingredient

2.1 Identity tests (366/TC/(M)/2, CIPAC 1C, p. 1974)

The active ingredient shall comply with an identity test and, where the identity remains in doubt, shall comply with at least one additional test.

2.2 Bentazone content (366/SL/(M)/3, CIPAC 1C, p. 1976) (Note 1)

The bentazone content shall be declared (g/kg) and, when determined, the mean measured content shall not differ from that declared by more than the following tolerance:

Declared content in g/kg	Tolerance
above 250 up to 500 g/kg	+/- 5% of declared content
above 500 g/kg	+/- 25 g/kg
Note: In each range the upper limit is included	

3 Physical properties

3.1 pH range (MT 75.2, CIPAC F, p. 206)

pH range: 2.0 to 4.0.

3.2 Wet sieve test (MT 59.3, CIPAC F, p. 179)

Maximum: 0.5 % retained on a 75 µm test sieve.

3.3 Suspensibility (MT 15.1, CIPAC F, p. 45) (Note 2)

A minimum of 75 % of the bentazone content found under .2.2 shall be in suspension after 30 minutes in CIPAC Standard Water D at 30 ± 2°C (Notes 3, 4 and 5).

3.4 Persistent Foam (MT 47, CIPAC F, p. 152) (Note 6)

Maximum: 10 ml after 1 min.

3.5 Wettability (MT 53.3.1 CIPAC F, p. 165)

The product shall be completely wetted in 2 min without swirling.

4 Storage stability

4.1 Stability at elevated temperature (MT 46.1.1 CIPAC F, p. 149)

After storage at $54 \pm 2^{\circ}\text{C}$ for 14 days, the determined average active ingredient content must not be lower than 97 % relative to the determined average content found before storage (Note 7) and the product shall continue to comply with clauses for pH range (3.1), wet sieve test (3.2), suspensibility (3.3) and wettability (3.5), as required.

Note 1 For analysis, suspend the product containing approximately 0.1 M bentazone in 90 ml 1 N NaOH. Add 1 N NaOH until the pH 7.5 - 8.5 is reached. Isolate the solution by filtration. Suspend the undissolved residue in 50 ml fully de-ionized water. Filter and add the filtrate to the filtered solution of active ingredient. Dilute the combined solutions to 200 ml. Continue as for 366/SL/(M)/3, CIPAC 1C, p. 1976.

Note 2 This test will normally only be carried out after the heat stability test 5.1.

Note 3 Chemical assay is the only fully reliable method to measure the mass of active ingredient still in suspension. However, simpler methods such as gravimetric and solvent extraction determination may be used on a routine basis provided that these methods have been shown to give results equal to those of chemical assay. In case of dispute, chemical assay shall be the "referee method".

For the chemical assay, adjust the pH of the 25 ml bottom sediment to 7.5 - 8.5 by adding 0.1 N NaOH solution. Add fully deionized water to obtain a volume of 50 ml. Remove insoluble matter by filtration or centrifugation and determine the amount of active ingredient on the clear solution according to the method 366/SL/(M)/3, CIPAC 1C, p. 1976.

Note 4 Unless different temperatures, times and/or different CIPAC Standard Waters are specified when ordering.

Note 5 The formulation should be tested at the highest and lowest rates of use recommended by the supplier, provided this does not exceed the conditions given in method MT 15.1, CIPAC F, p. 45.

Note 6 The concentration of sample to be used in the test should be specified at the highest rate of use recommended by the supplier.

Note 7 Samples of the product taken before and after the storage stability test should be analyzed concurrently after the test in order to reduce the analytical error.

BENTAZONE SALT SOLUBLE CONCENTRATES

366/SL (1999)

This specification, which is PART ONE of this publication, is based on an evaluation of data submitted by the manufacturer whose name is listed in the evaluation report (366/1999). It should be applicable to relevant products of this manufacturer but it is not an endorsement of those products, nor a guarantee that they comply with the specifications. The specification may not be appropriate for the products of other manufacturers. The evaluation report (366/1999) as PART TWO forms an integral part of this publication.

1 Description

The material shall consist of a salt of technical bentazone, complying with the requirements of FAO specification 366/TK, in the form of a bentazone salt dissolved in water, together with any other necessary formulants. It shall be in the form of a clear or opalescent aqueous liquid, to be applied as a true solution of the active ingredient in water. The material shall be of yellow to dark brown colour. The solution shall be free from more than a trace of visible suspended matter or sediment.

2 Active ingredient

2.1 Salt

The name of the bentazone salt present shall be stated.

2.2 Identity tests (366/SL/(M)/2, CIPAC 1C, p. 1976)

The active ingredient shall comply with an identity test and, where the identity remains in doubt, shall comply with at least one additional test.

2.3 Bentazone content (366/SL/(M)/3, CIPAC 1C, p. 1976)

The nominal bentazone content (g/kg or g/l at $20 \pm 2^\circ\text{C}$: Note 1) shall be declared and, when determined, the mean measured content shall not differ from that declared by more than the following tolerances:

Declared content in g/kg or g/l at $20 \pm 2^\circ\text{C}$	Tolerance
250 to 500	$\pm 5\%$ of declared content
above 500	± 25 g/kg or g/l
Note: In each range the upper limit is included	

3 Impurities

3.1 Water insolubles (MT 10.3, CIPAC F, p. 28)

The product shall pass through a $150 \mu\text{m}$ test sieve leaving not more than 1g/kg on the sieve.

4 Physical properties

4.1 pH Range (MT 75.1, CIPAC F, p. 205)

pH range: 6.5 to 9.5

4.2 Solution stability (MT 41, CIPAC F, p. 131)

The formulation shall give after dilution with CIPAC Standard Water D and standing for 18h at $30 \pm 2^\circ\text{C}$ (Notes 2 and 3) a clear or opalescent solution, free from more than a trace of sediment and/or visible solid particles. Any visible sediment or particles generated shall pass through a $45 \mu\text{m}$ test sieve.

4.3 Persistent foam (MT 47.2, CIPAC F, p. 152) (Note 4)

Maximum 25 ml after 1 min.

5 Storage stability

5.1 Stability at 0°C (MT 39.3)

After storage at $0 \pm 2^\circ\text{C}$ for 7 days, the volume of solid and/or liquid which separates shall not be more than 0.3 ml.

5.2 Stability at elevated temperature (MT 46.1.3, CIPAC F, p. 150)

After storage at $54 \pm 2^\circ\text{C}$ for 14 days, the determined average active ingredient content must not be lower than 97% relative to the determined average content found before storage (Note 4) and the product shall continue to comply with clauses for water insolubles (3.1), pH range (4.1) and solution stability (4.2).

Note 1 If the buyer requires both g/l at 20°C and g/kg, then in case of dispute the analytical results shall be calculated as g/kg.

Note 2 Unless other temperatures, times and/or CIPAC Standard Waters are specified for particular products.

Note 3 The concentration used for the test should not be higher than the highest concentration recommended in the instructions for use.

Note 4 Samples of the product taken before and after storage stability test should be analyzed concurrently after the test in order to reduce the analytical error.

FAO SPECIFICATIONS AND EVALUATIONS FOR PLANT PROTECTION PRODUCTS

BENTAZONE

EVALUATION REPORT 366/1999

Explanation

Bentazone was scheduled as an existing FAO specification to be reviewed in 1999 under the procedure introduced in 1998 (FAO Panel, 1998).

FAO had existing specifications for bentazone technical (FAO Specification 366/TC/S/F (1992)), technical concentrates (TK), wettable powders (WP) and bentazone salt aqueous solutions (SL).

Bentazone was considered for the first time by FAO/WHO JMPR for toxicology in 1991 (WHO, 1992) and an acceptable daily intake (ADI) of 0-0.1 mg/kg bw was allocated. The ADI was unchanged after the JMPR toxicology review in 1998.

Bentazone was also evaluated for the first time by JMPR for residues and environmental fate in 1991 (FAO, 1991). The JMPR concluded that bentazone and its metabolite 2-amino-*N*-isopropylbenzamide (the only degradation product detected in soil) are readily leached in light sandy soils. The JMPR has not reviewed the ecotoxicology of bentazone.

The Proposer for bentazone specifications was BASF AG. Data were provided in 1999.

Uses

Bentazone formulations are used as post-emergence herbicides for the control of broad-leaved weeds and *Cyperaceae* in a range of crops, including dicotyledonous (broad-leaved) and non-edible agricultural crops, and in other situations such as lawns and pastures. Bentazone has a contact action on the leaves and to a lesser extent an action via the soil. The active ingredient is principally absorbed by the green parts of plants and acts as a photosynthesis inhibitor (FAO, 1991).

Identity

ISO common name

bentazone (BSI, E-ISO, F-ISO, JMAF)

Synonyms

bentazon (ANSI, Canada, WSSA)

Chemical names

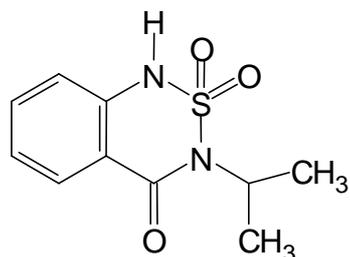
IUPAC

3-isopropyl-1H-2,1,3-benzothiadiazin-4(3H)-one 2,2-dioxide

CA

3-(1-methylethyl)-1*H*-2,1,3-benzothiadiazin-4(3*H*)-one 2,2-dioxide

Structural formula



Molecular formula

C₁₀H₁₂N₂O₃S

Relative molecular mass

240.3

CAS Registry number

25057-89-0

CIPAC number

366

EEC number

613-012-00-1

Identity tests

The test relies on the HPLC method for bentazone analysis. The retention time of bentazone in the sample solution should not deviate by more than 1% from that of authentic bentazone in the calibration solution. [CIPAC 1C, p. 1974]. IR, TLC and gas chromatography (after methylation) form additional identity tests.

Physical and chemical properties of pure active ingredient

Vapour pressure	5.4×10 ⁻⁶ Pa at 20°C (99.9% purity, bentazone) Method: evaporation rate determination (Gückel <i>et al</i> , 1995)
Melting point	139.4-141.0°C (99.8% purity, bentazone) Method: CIPAC MT2, CIPAC F, p. . 5
Temperature of decomposition	210°C, with gas evolution (99.8% purity, bentazone) Method: CIPAC MT2, CIPAC F, p. 5
Solubility in water	490 mg/l water (pH 3, 20°C) (99.9% purity, bentazone) Method: CIPAC MT157, CIPAC F, p. 384
	>1000 g/l water (pH ≥ 7, at 20°C) (bentazone sodium salt)
Octanol/water partition coefficient	log P _{OW} = 0.77 (pH 5 buffer) log P _{OW} = -0.46 (pH 7 buffer) log P _{OW} = -0.55 (pH 9 buffer) Method: EEC A 8.1.4, flask shaking method
Hydrolysis	Solutions of [¹⁴ C]bentazone were stable to hydrolysis in the dark at pH 5, 7 and 9 at 25°C for 30 days Bentazone was not degraded after 120 days in either distilled water or WHO Standard Hard Water in the dark at pH levels of 5, 7 or 9 (FAO, 1991)
Photolysis	The half-lives and the major photo-decomposition products were a function of solution pH The half-life decreased from 122 to 93 to 14 hours as the pH increased from 5 to 7 to 9 in a photolysis study of aqueous solutions exposed to simulated sunlight at 25°C
Dissociation constant	pK _a = 3.28 at 24°C (99.5% purity) Method: OECD 112, titration method

Chemical composition and properties of the technical material (TC and TK)

The Meeting was provided with commercially confidential information on the manufacturing process and batch analysis data on impurities present at or above 1 g/kg in free bentazone and bentazone sodium salt.

Data were provided on the identified impurities present at or above 1 g/kg in 5 batches of bentazone TK 600 g/l (sodium salt). Mass balances for the 5 batches were in the range 98.4% to 99.6%. Total impurities accounted for 1.1-1.3%, expressed on a whole TK basis.

Data were also provided on the identified impurities in 5 batches of bentazone TC. The 5 TC batches were derived from the 5 TK batches previously mentioned. Mass balances for the 5 TC batches were in the range 98.7% to 99.3%. Total impurities accounted for 0.67% to 0.93%. The production of the TC material acted as a purification step for those impurities which tended to remain in solution rather than to precipitate with the bentazone, e.g. levels of compounds containing a sulphamic acid group were much lower in the TC material. For this reason, the TC and TK impurity profiles are quite different for a few impurities but similar for the majority.

The 1991 JMPR reported that the content of impurities ranged between 0.1 and 0.7 % w/w and consisted mainly of benzothiadiazines or benzamides related to the parent compound (FAO, 1991).

The list of impurities and their maximum limits were identical to the impurity profile delivered to the German authorities for review under the European Union procedure.

Declared minimum bentazone content in the TC

960 g/kg (maximum 10 g/kg water content).

Declared minimum of bentazone (present as sodium salt) in the TK

600 g/l.

Relevant impurities and maximum limits for them

none of the impurities was considered relevant.

Hazard summary

The 1991 JMPR reported that bentazone has a relatively low acute toxicity in rats, guinea pigs and rabbits (WHO, 1992). WHO has classified bentazone as slightly hazardous. Acute oral toxicity results are summarized in Table 1; other acute exposure tests are summarized in Table 2.

Table 1. Acute oral toxicity of bentazone¹ and bentazone sodium salt¹ (WHO, 1992)

Compound	Species	Sex	LD ₅₀ mg/kg bw	Source ²
Bentazone	rat	m f	1220 (1056-1409)	BASF
Bentazone	rat	m f	1780, 1470	BASF
Bentazone	rat	m f	2340, 2470	BASF
Bentazone	rabbit	m f	750 ³	BASF
Bentazone	cat	m f	ca. 500 ³	BASF
Bentazone	dog	m f	>100 ³	BASF
Bentazone	guinea pig	m f	ca. 1100 ³	BASF
Bentazone sodium salt	rat	m f	1480, 1336	BASF
Bentazone sodium salt	guinea pig	m f	1100, 1000 (as acid)	BASF

JMPR reported that most ¹⁴C was still on the skin 10 and 72 hours after treatment in a rat dermal absorption study with [¹⁴C]bentazone sodium. The amount absorbed was no more than 1.2-2.9% of applied dose (WHO, 1992).

Table 2. Acute dermal and inhalation toxicity, skin and eye irritation and skin sensitization testing of bentazone (WHO, 1992)

Test substance	Purity	Species	Sex	Test	Test result	Source ⁴

¹ Purity of test materials not reported.

² Source of data submitted to WHO.

³ Approximate median lethal dose (ALD₅₀)

Test substance	Purity	Species	Sex	Test	Test result	Source ⁴
Bentazone	not stated	rat	m f	dermal toxicity	> 2500 mg/kg bw	BASF
Bentazone	not stated	rat		acute inhalation, bentazone volatiles at 1.2 mg/l at 20°C	no mortality for 8 hours exposure	BASF
Bentazone	97.8%	rat	m f	dust inhalation, at 5.1 mg/l	body weight gain slightly retarded, signs of toxicity, noisy respiration, no deaths	BASF
Bentazone 50% formulation	not stated	rabbit	m f	application for 24 hours to intact and abraded skin at 0.5 g/dose	irritation index 1, slight erythema, clearing by day 8 post dosing	BASF
Bentazone	not stated	rabbit	m f	eye irritation, 0.1 ml (ca. 33 mg bentazone)	irritation index 35 (moderately irritating)	BASF
Bentazone	not stated	guinea pig		open epicutaneous test	bentazone has sensitizing potential	BASF

⁴ Source of data submitted to FAO.

Table 3. Short-term and chronic toxicity of bentazone (WHO, 1992)

Compound	Purity	Species	Duration or test	Route	Sex	NOAEL	Source ⁵
Bentazone	97.8%	rat	13 weeks	oral	m f	400 ppm (25.3, 28.9 mg/kg bw/day)	BASF
Bentazone	technical	rat	90 days	oral	m f	800 ppm (40 mg/kg bw/day)	?
Bentazone	97.8%	rabbit	21 days (6 hours/day)	derma l	m f	500 mg/kg bw/day	BASF
Bentazone	not stated	dog	13 weeks	oral	m f	300 ppm (12 mg/kg bw/day)	BASF
Bentazone	97.8%	dog	52 weeks	oral	m f	400 ppm (13.07 mg/kg bw/day)	BASF
Bentazone	93.9%	mouse	24 months	oral	m f	100 ppm (12 mg/kg bw/day)	BASF
Bentazone	93.9%	rat	2 years	oral	m f	200 ppm (9, 11 mg/kg bw/day)	BASF
Bentazone	not stated	rat	multi-generation	oral	m f	180 ppm (14 mg/kg bw/day)	BASF
Bentazone	technical	rat	two-generation	oral	m f	200 ppm (15 mg/kg bw/day)	?
Bentazone	97.8%	rat	embryo/fetotoxicity	oral	f	100 mg/kg bw/day - no evidence of teratogenic activity even at the highest dose	BASF
Bentazone	93.9%	rat	embryo/fetotoxicity	oral	f	2000 ppm - no evidence of teratogenic activity even at the highest dose	BASF
Bentazone	92.5%	rat	embryo/fetotoxicity	oral	f	>200 mg/kg bw/day - no evidence of teratogenic activity at the highest dose	BASF
Bentazone	97.8%	rabbit	embryo/fetotoxicity	oral	f	150 mg/kg bw/day - no evidence of teratogenic activity at the highest dose	BASF
Bentazone	92.5%	rabbit	embryo/fetotoxicity	oral	f	50 mg/kg bw/day - no evidence of teratogenic activity at the highest dose	BASF

⁵ Source of data submitted to FAO.

The 1991 JMPR concluded that there was no evidence of genotoxicity for bentazone (WHO, 1992).

FAO (1991) reported that bentazone is not considered to be hazardous to aquatic organisms under normal conditions of use and is only slightly toxic to wildfowl, as represented by bobwhite quail and mallard ducks. Results of ecotoxicity tests are summarized in Table 4.

Table 4. Bentazone toxicity to aquatic organisms and birds (FAO, 1991)

Test substance	Purity	Species	Test	Test result	Source ⁶
Bentazone	not stated	trout	LC50 (96 h)	> 100 mg/l	BASF
Bentazone formulation (480 g/l)	not stated	trout	LC50 (96 h)	> 100 mg/l	BASF
Bentazone	not stated	bluegill	LC50 (96 h)	> 100 mg/l	BASF
Bentazone formulation (480 g/l)	not stated	bluegill	LC50 (96 h)	> 100 mg/l	BASF
Bentazone	not stated	<i>Daphnia</i>	EC50 (48 h)	125 mg/l	BASF
Bentazone formulation (480 g/l)	not stated	<i>Daphnia</i>	EC50 (48 h)	>500 mg/l	BASF
Bentazone	not stated	algae	EC50 (96h)	47 mg/l	BASF
Bentazone formulation (480 g/l)	not stated	algae	EC50 (96h)	30 mg/l	BASF
Bentazone	not stated	Bobwhite quail	LD50	1140 mg/kg	BASF
Bentazone	not stated	Bobwhite quail	LC50	>5000 mg/l	BASF
Bentazone	not stated	mallard duck	LC50	>5000 mg/l	BASF

The effects of Basagran (BAS 351 32 H) and bentazone (salt or acid) on non-target organisms were studied in birds, laboratory mammals, aquatic organisms, bees and other arthropods, earthworms and soil micro-organisms.

Single-dose and short-term feeding studies showed a low toxicity of bentazone to birds :

- single-dose LD50 (bobwhite quail) = 1140 mg/kg body weight;
- dietary LC50 (bobwhite quail and mallard duck > 5000 mg/kg feed).

A hazard assessment based on short-term exposure of birds to dietary residues of bentazone revealed no practical hazard.

Single-dose and feeding studies in mammals showed that bentazone was equally non-toxic:

- single dose LD50 (rats) = 1470 mg/kg body weight;
- 4 weeks feeding NOEL (rats) = 1800 mg/kg feed.

The hazard assessment based on exposure of free-living mammals to residues of bentazone did not indicate adverse effects.

Acute and chronic exposure of fish, daphnids, green algae and duckweed to bentazone or Basagran confirmed the low environmental toxicity of these compounds :

⁶ Source of data submitted to FAO.

- LC50 (96 hours) in fish > 100 mg/l;
- EC 50 (48 hours) in daphnids = 125 mg/l;
- EC50 (72 hours) in green algae = 60-70 mg/l;
- EC50 (14 days) in duckweed = 5.3 mg/l;
- NOEC (28 days) in trout = 48 mg/l;
- NOEC (21 days) in daphnids = 125 mg/l.

A hazard assessment based on predicted environmental concentrations of bentazone and Basagran in surface waters including the negligible bioaccumulation potential of bentazone revealed no practical hazard to aquatic organisms.

Exposure of honeybees and beneficial arthropods to field rates of bentazone or Basagran relevant to the practical use led to the following classifications:

- non-toxic to honeybees;
- harmless to the ground beetles *Aleochara*, *Bembidion* and *Poecilus*;
- harmless to the aphid predator *Chrysopa*;

The toxicity of bentazone and Basagran to earthworms is equally low:

- LC50 (14 days) > 1000 mg/kg soil.

The hazard assessment demonstrated that earthworm populations will not be affected adversely by exposure to concentrations of bentazone resulting from practical application of Basagran.

Laboratory trials with biologically active soils showed that the exposure of soil micro-organisms to field rates of bentazone or Basagran will result in negligible effects.

Bentazone or Basagran will not impair the function of sewage treatment plants.

Formulations

Main formulation types available in the market

Bentazone is usually formulated as soluble concentrates (SL) and the most commonly used trade name is Basagran; a less common formulation is a wettable powder (WP). Bentazone or its sodium salt may be formulated in mixtures with other herbicides.

Main countries where bentazone is registered and sold

Bentazone is registered and sold in about 80 countries.

Methods of analysis and testing

Chemical analysis methods for active ingredient

Bentazone in technical materials is separated by HPLC on a reversed-phase column (C₁₈, methanol/acetate buffer) and quantitatively determined by UV detection with external standardization (366/TC/(M)/3, CIPAC 1C, p. 1974).

Bentazone in soluble concentrates is determined by method 366/TC/(M)/3 following sample dilution (366/SL/(M)/3, CIPAC 1C, p. 1976).

Bentazone in wettable powders is determined by a modification of method 366/SL/(M)/3, which is described in Note 1 of the specification. The

formulation is suspended in 1 M NaOH and the pH adjusted to 7.5 - 8.5 with additional NaOH solution. The solution is filtered, the undissolved residue is rinsed with de-ionized water, filtered again and the filtrates are combined. After making to volume, the determination is continued as for 366/SL/(M)/3, CIPAC 1C, p. 1976.

Analytical methods for relevant impurities

Water insolubles are the only relevant impurities identified and, in both cases, the method used is MT 10.3 CIPAC F, p 28.

Analytical methods used for other impurities

Organic impurities in bentazone TC and bentazone-sodium TK (batch analyses) were determined by an HPLC method with UV detection. The method was proven acceptable in terms of recoveries and repeatability.

Physical testing methods

Bentazone TK	pH range, MT 75.1 CIPAC F, p 205.
Bentazone WP	pH range, MT 75.2 CIPAC F, p 206. Wet sieve test, MT 59.3 CIPAC F, p 179. Suspensibility, MT15.1 CIPAC F, p 45. Persistent foam, MT 47 CIPAC F, p 152. Wetting of the product, MT 53.3.3.1 CIPAC F, p 165. Stability at elevated temperature, MT 46.1.1 CIPAC F, p 149.
Bentazone SL	pH range. MT 75.1 CIPAC F, p 205. Stability on dilution, MT 41 CIPAC F, p 131. Persistent foam. MT 47.2 CIPAC F, p 152. Stability at 0°C. MT 39.3 CIPAC, 4043/m, Menschel, G). Stability at elevated temperature. MT 46.1.3 CIPAC F, p 150.

Physical properties

The Proposer has declared that bentazone produced and commercialized by BASF complies with the proposed FAO specifications (1999).

Containers and packaging

No requirements specific to bentazone call for specifications.

Expression of active ingredient

The concentration in formulations is expressed as g bentazone per kg (or alternatively for liquid formulations, g/l at 20°C) of formulation. Where applicable, the name of the bentazone salt present is stated.

Appraisal

The previous FAO specifications for bentazone were published in 1992. The Proposer for revised bentazone specifications was BASF AG.

Bentazone itself has sparing solubility in water but, at pH above 7, the bentazone sodium salt is highly water-soluble (>1000 g/l). Bentazone is stable to hydrolysis

at pH 5, 7 and 9 but it is subject to photolytic breakdown in sunlight, particularly at high pH.

The Meeting was provided with information on the manufacturing process and the nature of the impurities exceeding 0.1% and their maximum limits (0.1-1.5%) in TC and TK materials. The list of impurities and their maximum limits were identical to the bentazone impurity profile presented to the German authorities for review under the European Union procedure. Analyses for impurities in 5 batches of TK and the 5 corresponding batches of TC bentazone were provided. Material balances were high.

The production of the TC material acted as a purification step for those impurities which tended to remain in solution rather than to precipitate with the bentazone, e.g. levels of compounds containing a sulphamic acid group were much lower in the TC material. For this reason, the TC impurity profile is quite different for a few impurities from the TK impurity profile, but is similar for the majority. The Meeting noted the differences and recommended that the appropriate profile be used if equivalence of TC or TK materials is to be determined.

None of the impurities was considered to be relevant, except for water insolubles in TK and SL products.

Bentazone has a relatively low acute toxicity in rats, guinea pigs and rabbits. WHO has allocated an ADI of 0-0.1 mg/kg bw for bentazone based on a full package of toxicology data including short-term and chronic testing on rats, rabbits, dogs and mice. The purity of the test substance was not stated in some studies, but in others the stated purity ranged from 92.5% to 97.8%.

WHO has classified bentazone as slightly hazardous.

FAO reported that bentazone is considered not to be hazardous to aquatic organisms under normal conditions of use and is only slightly toxic to wildfowl. Data submitted indicated that it is non-toxic to honeybees and that it is harmless to beneficial arthropods and soil microorganisms.

The Proposer declared that bentazone produced and commercialized by BASF complies with the FAO specifications (1999).

The primary test of identity is HPLC retention time matching (CIPAC 1C, p. 1974). IR, TLC and GLC (after methylation) were proposed as additional identity tests.

A confidential document of the bentazone reference profile is held by FAO. It contains summary information on: bentazone synthesis; bentazone impurity profile; bentazone TK and TC batch analyses profiles; bentazone toxicological profile; bentazone ecotoxicological profile.

Recommendations

IR, TLC and gas chromatography (after methylation) were proposed for additional identity tests. The Meeting recommended that details of the tests should be provided to FAO by the Proposer.

The Meeting recommended that extension of the CIPAC analytical method to WP should be validated, using the AOAC, CIPAC or equivalent approaches.

The Meeting recommended adoption of the specifications for TC, TK and SL. The Meeting recommended adoption of the specification for WP upon satisfactory validation of the extension of analytical method for bentazone.

References

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