WHO SPECIFICATIONS AND EVALUATIONS FOR PUBLIC HEALTH PESTICIDES

BENDIOCARB

2,2-dimethyl-1,3-benzodioxol-4-yl methylcarbamate
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## PART ONE

SPECIFICATIONS FOR BENDIOCARB

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Disclaimer

WHO specifications are developed with the basic objective of promoting, as far as practicable, the manufacture, distribution and use of pesticides that meet basic quality requirements.

Compliance with the specifications does not constitute an endorsement or warranty of the fitness of a particular pesticide for a particular purpose, including its suitability for the control of any given pest, or its suitability for use in a particular area. Owing to the complexity of the problems involved, the suitability of pesticides for a particular purpose and the content of the labelling instructions must be decided at the national or provincial level.

Furthermore, pesticides which are manufactured to comply with these specifications are not exempted from any safety regulation or other legal or administrative provision applicable to their manufacture, sale, transportation, storage, handling, preparation and/or use.

WHO disclaims any and all liability for any injury, death, loss, damage or other prejudice of any kind that may be arise as a result of, or in connection with, the manufacture, sale, transportation, storage, handling, preparation and/or use of pesticides which are found, or are claimed, to have been manufactured to comply with these specifications.

Additionally, WHO wishes to alert users to the fact that improper storage, handling, preparation and/or use of pesticides can result in either a lowering or complete loss of safety and/or efficacy.

WHO is not responsible, and does not accept any liability, for the testing of pesticides for compliance with the specifications, nor for any methods recommended and/or used for testing compliance. As a result, WHO does not in any way warrant or represent that any pesticide claimed to comply with a WHO specification actually does so.

1 This disclaimer applies to all specifications published by WHO.
INTRODUCTION

WHO establishes and publishes specifications* for technical material and related formulations of public health pesticides 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.

From 2002, the development of WHO specifications follows the New Procedure, described in the Manual for Development and Use of FAO and WHO Specifications for Pesticides. This New Procedure follows a formal and transparent evaluation process. It describes the minimum data package, the procedure and evaluation applied by WHO and the experts of the “FAO/WHO Joint Meeting on Pesticide Specifications” (JMPS).

WHO specifications now only apply to products for which the technical materials have been evaluated. Consequently, from the year 2002 onwards the publication of WHO specifications under the New Procedure has changed. Every specification consists now of two parts, namely the specifications and the evaluation report(s):

**Part One:** The Specification of the technical material and the related formulations of the pesticide in accordance with chapters 4 to 9 of the above-mentioned manual.

**Part Two:** The Evaluation Report(s) of the pesticide, reflecting the evaluation of the data package carried out by WHO and the JMPS. The data are provided by the manufacturer(s) according to the requirements of chapter 3 of the above-mentioned manual and supported by other information sources. The Evaluation Report includes the name(s) of the manufacturer(s) whose technical material has been evaluated. Evaluation reports on specifications developed subsequently to the original set of specifications are added in a chronological order to this report.

WHO 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 routes of manufacture. WHO has the possibility to extend the scope of the specifications to similar products but only when the JMPS has been satisfied that the additional products are equivalent to that which formed the basis of the reference specification.

Specifications bear the date (month and year) of publication of the current version. Evaluations bear the date (year) of the meeting at which the recommendations were made by the JMPS.

* Footnote: The publications are available on the Internet under (http://www.who.int/whopes/quality/en/).
PART ONE

SPECIFICATIONS

BENDIOCARB

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WHO SPECIFICATIONS FOR PUBLIC HEALTH PESTICIDES

BENDIOCARB

INFORMATION

ISO common name
Bendiocarb (E-ISO, BSI, ANSI, ESA), bendiocarbe ((m) F-ISO)

Synonyms
None

Chemical names
IUPAC: 2,2-dimethyl-1,3-benzodioxol-4-yl methylcarbamate
        2,3-isopropylidenedioxyphenyl methylcarbamate
CA: 2,2-dimethyl-1,3-benzodioxol-4-yl methylcarbamate

Structural formula

Empirical formula
C_{11}H_{13}NO_{4}

Relative molecular mass
223.2

CAS Registry number
22781-23-3

CIPAC number
232

Identity tests
HPLC retention time, \(^1\)H NMR spectrum
WHO SPECIFICATIONS FOR PUBLIC HEALTH PESTICIDES

BENDIOCARB TECHNICAL MATERIAL
WHO specification 232/TC (December 2008”)

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 (232/2008). It should be applicable to TC produced by this manufacturer but it is not an endorsement of those products, nor a guarantee that they comply with the specification. The specification may not be appropriate for TC produced by other manufacturers. The evaluation report (232/2008), as PART TWO, forms an integral part of this publication.

1 Description

The material shall consist of bendiocarb together with related manufacturing impurities and shall be a beige crystalline powder, free from visible extraneous matter and added modifying agents.

2 Active ingredient

2.1 Identity tests (232/TC/(M)/2, CIPAC Handbook D, p.10, 1988)

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 Bendiocarb content (232/TC/(M)/3, CIPAC Handbook D, p.11, 1988)

The bendiocarb content shall be declared (not less than 970 g/kg) and, when determined, the average measured content shall not be lower than the declared minimum content.

3 Relevant impurities (Note 1)

Note 1 There are no relevant impurities to be controlled in products of the manufacturer identified in evaluation report 232/2008. However, methyl isocyanate and/or toluene can occur as a result of certain manufacturing processes. If methyl isocyanate (≥1 g/kg) or toluene (≥10 g/kg) would occur in the bendiocarb TC of other manufacturers it may be designated as a relevant impurity and a specification clause may be required to limit its concentration.

* Specifications may be revised and/or additional evaluations may be undertaken. Ensure the use of current versions by checking at: http://www.who.int/whopes/quality/en/.
WHO SPECIFICATIONS FOR PUBLIC HEALTH PESTICIDES

BENDIOCARB WETTABLE POWDER

WHO specification 232/WP (June 2014*)

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 reports (232/2008, 232/2013). It should be applicable to relevant products of this manufacturer, and those of any other formulators who use only TC from the evaluated source. The specification is not an endorsement of those products, nor a guarantee that they comply with the specification. The specification may not be appropriate for the products of other manufacturers who use TC from other sources. The evaluation reports (232/2008, 232/2013), as PART TWO, form an integral part of this publication.

1 Description

The material shall consist of a homogeneous mixture of technical bendiocarb, complying with the requirements of WHO specification 232/TC (December 2008), 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 (232/WP/(M)/2, CIPAC Handbook D, p.12, 1988)

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 Bendiocarb content (232/WP/(M)/3, CIPAC Handbook D, p.12, 1988)

The bendiocarb content shall be declared (800 g/kg) and, when determined, the average measured content shall not differ from that declared by more than ±25 g/kg.

3 Relevant impurities (Note 1)

4 Physical properties


Maximum: 1% retained on a 75 µm test sieve.

4.2 Suspensibility (MT 184, CIPAC Handbook K, p.142, 2003) (Notes 2, 3 & 4)

A minimum of 70% of the bendiocarb content found under 2.2 shall be in suspension after 30 min in CIPAC Standard Water D at 30 ± 2 °C.

* Specifications may be revised and/or additional evaluations may be undertaken. Ensure the use of current versions by checking at: http://www.who.int/whopes/quality/en/.
4.3 **Persistent foam** (MT 47.3, Notes 5 & 6)  
Maximum: 50 ml after 1 min.

4.4 **Wettability** (MT 53.3.1, CIPAC Handbook F, p.165, 1995)  
The formulation shall be completely wetted in 1 min without swirling.

5 **Storage stability**

5.1 **Stability at elevated temperature** (MT 46.3, CIPAC Handbook J, p.128, 2000)  
After storage at 54 ± 2°C for 14 days, the determined average active ingredient content must not be lower than 95% relative to the determined mean content found before storage (Note 7) and the formulation shall continue to comply with the clauses for:
- wet sieve test (4.1);
- suspensibility (4.2);
- wettability (4.4).

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**Note 1** There are no relevant impurities to be controlled in products of the manufacturer identified in evaluation report 232/2008. However, methyl isocyanate and/or toluene can occur as a result of certain manufacturing processes. If methyl isocyanate (≥1 g/kg) or toluene (≥10 g/kg) would occur in the formulations of other manufacturers it may be designated as a relevant impurity and a specification clause may be required to limit its concentration.

**Note 2** 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 184.

**Note 3** This test will normally only be carried out after the heat stability test (5.1).

**Note 4** Chemical assay is the only fully reliable method to measure the mass of active ingredient still in suspension. However, the 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 equal results to those of chemical assay. In case of dispute, chemical assay shall be the "referee method".

**Note 5** The CIPAC method MT 47.2 published in Handbook F for determination of persistent foam created when formulations are added to water before use was updated to MT 47.3. This new method was accepted as a full CIPAC method in 2013. Prior to the publication in a Handbook, copies of the method may be obtained through the CIPAC website, http://www.cipac.org/cipacpub.htm

**Note 6** The mass of sample to be used in the test should correspond to the highest rate of use recommended by the supplier. The test is to be conducted in CIPAC standard water D.

**Note 7** Samples of the formulation taken before and after the storage stability test should be analyzed concurrently after the test in order to reduce the analytical error.
WHO SPECIFICATIONS FOR PUBLIC HEALTH PESTICIDES

BENDIOCARB WETTABLE POWDER IN SEALED WATER SOLUBLE BAG

WHO specification 232/WP-SB (November 2015*)

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 reports (232/2013, 232/2015). It should be applicable to relevant products of this manufacturer, and those of any other formulators who use only TC from the evaluated source. The specification is not an endorsement of those products, nor a guarantee that they comply with the specification. The specification may not be appropriate for the products of other manufacturers who use TC from other sources. The evaluation reports (232/2013, 232/2015), as PART TWO, form an integral part of this publication.

1 Description

The material shall consist of a defined quantity of a homogeneous mixture of technical bendiocarb, complying with the requirements of WHO specification 232/TC (December 2008), 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, contained in a sealed water soluble bag.

2 Active ingredient

2.1 Identity tests (232/WP/(M)/2, CIPAC Handbook D, p.12, 1988)

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 Bendiocarb content (232/WP/(M)/3, CIPAC Handbook D, p.12, 1988)

The bendiocarb content shall be declared (400 or 800 g/kg) and, when determined, the average measured content shall not differ from that declared by more than the following tolerances:

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<th>Declared content in g/kg</th>
<th>Tolerance</th>
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<td>above 250 up to 500</td>
<td>± 5% of the declared content</td>
</tr>
<tr>
<td>above 500</td>
<td>± 25 g/kg</td>
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</table>

Note: in each range the upper limit is included

3 Relevant impurities (Note 1)

* Specifications may be revised and/or additional evaluations may be undertaken. Ensure the use of current versions by checking at: http://www.who.int/whopes/quality/en/.

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4 **Physical properties** (Note 2)


Maximum: 1% retained on a 75 µm test sieve.

4.2 **Suspensibility** (MT 184, CIPAC Handbook K, p.142, 2003) (Notes 2, 3, 4, 5 & 6)

The suspensibility shall be tested on a suspension containing the WP and the bag material in the actual ratio of application, prepared according to the procedure described in Note 6.

A minimum of 70% shall be in suspension after 30 minutes in CIPAC Standard Water D at 30 ± 2°C.

4.3 **Persistent foam** (MT 47.3, Notes 2, 6, 7 & 8)

The persistent foam shall be tested on a suspension containing the WP and the bag material in the actual ratio of application, prepared according to the procedure described in Note 6.

Maximum: 50 ml after 12 min.

4.4 **Wettability** (MT 53.3.1, CIPAC Handbook F, p.165, 1995)

The formulation shall be completely wetted in 4 min without swirling.

4.5 **Dissolution of the bag** (MT 176, CIPAC Handbook F, p. 440, 1995) (Notes 2 & 9)

The dissolution of the bag shall be tested on a sample of the emptied and cleaned bag taken according to the procedure described in Note 9.

Flow time of the suspension: maximum 30 sec.

5 **Storage stability**

5.1 **Stability at elevated temperature** (MT 46.3, CIPAC Handbook J, p.128, 2000)

The package should be enclosed in a watertight sachet, box or any other container at 54°C for 14 days. The determined average active ingredient content must not be lower than 95% relative to the determined average content found before storage (Note 10) and the formulation shall continue to comply with the clauses for:

- wet sieve test (4.1);
- suspensibility (4.2);
- persistent foam (4.3);
- wettability (4.4);
- dissolution of the bag (4.5)

None of the bags tested should show signs of leakage or rupture during normal handling, before and after storage.
Note 1 There are no relevant impurities to be controlled in products of the manufacturer identified in evaluation report 232/2008. However, methyl isocyanate and/or toluene can occur as a result of certain manufacturing processes. If methyl isocyanate (≥1 g/kg) or toluene (≥10 g/kg) would occur in the formulations of other manufacturers it may be designated as a relevant impurity and a specification clause may be required to limit its concentration.

Note 2 Sub-sampling.
Lay the bag on a bench and carefully open one side of the bag with a cutter, taking care not to damage the seals. Transfer the contents of the bag into a suitable flask. This material shall be used to carry out the tests for:
- active ingredient identity (2.1)
- active ingredient content (2.2)
- wet sieve test (4.1)
- suspensibility (4.2)
- persistent foam (4.3)
- wettability (4.4)
- dissolution of the bag (4.5)

The bag is then opened on three sides, completely cleaned from adhering powder by brushing or suction and weighed to the nearest 0.01 g. It shall be used to carry out the dissolution test (4.5). Aliquots of an aqueous solution of the bag material shall be used in the suspensibility (4.2) and persistent foam (4.3) tests.

In the case of delay of the above tests, the bag shall be stored in a watertight container (glass bottle or equivalent) to avoid any change in its properties.

Note 3 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 184.

Note 4 This test will normally only be carried out after the heat stability test (5.1).

Note 5 Chemical assay is the only fully reliable method to measure the mass of active ingredient still in suspension. However, the 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 equal results to those of chemical assay. In case of dispute, chemical assay shall be the "referee method".

Note 6 The procedure for adding the bag material to the solution for the suspensibility and the persistent foam tests should be as follows:
Prepare a stock solution of the bag material (1 mg/ml) by weighing approximately a sample (n mg) of the bag (excluding sealed parts) to the nearest mg. Dissolve this sample by stirring in the standard water used for the tests to give a final volume of n ml. Store the stock solution in a stoppered bottle before use.

Calculate the volume (V ml) of the stock solution of the bag to be added to the test suspension of the wettable powder according to the following equation:

$$V(\text{ml}) = \frac{X}{W} \times \frac{1000B}{1000}$$

Where:
- B (g) = weight of the emptied and cleaned bag
- W (g) = nominal weight of the WP contained in the bag
- X (g) = weight of the WP sample used in the test

Note 7 The CIPAC method MT 47.2 published in Handbook F for determination of persistent foam created when formulations are added to water before use was updated to MT 47.3. This new method was accepted as a full CIPAC method in 2013. Prior to the publication in a Handbook, copies of the method may be obtained through the CIPAC website, http://www.cipac.org/cipacpub.htm

Note 8 The mass of sample to be used in the test should correspond to the highest rate of use recommended by the supplier. The test is to be conducted in CIPAC standard water D.
Note 9  The sampling of the bag for the dissolution test should be as follows:

Lay the empty cleaned bag in its original configuration (double layer). Delineate and then cut up a test sample including part of the upper seal (5 cm) and symmetrically including the vertical seal (10 cm). If the size of the bag is less than this dimension, use the whole bag.

Carry out the dissolution test immediately to avoid any modification of the sample.

Note 10  Samples of the formulation taken before and after the storage stability test should be analyzed concurrently after the test in order to reduce the analytical error.
## PART TWO

### EVALUATION REPORTS

**BENDIOCARB**

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Recommendations
The Meeting recommended that:

(i) The specification for bendiocarb 400 g/kg WP-SB, proposed by Bayer CropScience, as amended, should be adopted by WHO.

(ii) The specification for the product containing 400 g/kg should be merged with that for 800 g/kg bendiocarb.

Appraisal
A draft specification for bendiocarb 400 g/kg WP-SB, provided by Bayer CropScience, was received in 2015 and considered by the JMPS for development of a new WHO specification. A data package on physical-chemical properties of the formulation in the water soluble bag was also received (Mo5227, 2015) and supported the clauses and the proposed limits.

Bendiocarb has been developed as mosquito adulticide for indoor residual spraying (IRS) by the company and the specification is therefore limited to WHO. The product was successfully evaluated by WHOPES and has a recommendation for IRS. The product is intended to complement the existing WHO specification for bendiocarb WP-SB containing 800 g/kg active ingredient. As content and physical-chemical properties do slightly differ, the published WHO specification for 800 g/kg with its limits had to be somewhat extended to accommodate the product with 400 g/kg (with respect to the limits for persistent foam and wettability).

The proposed specification for bendiocarb WP-SB was broadly in agreement with the guidelines given in the Manual (FAO/WHO 2010).

Formulation type, description, active ingredient content and analytical method
Bendiocarb is formulated as a wettable powder packed in a water soluble bag. Up to now, a bendiocarb WP-SB with 800 g/kg was available (WHO, June 2014). The product is intended to complement the existing WHO specification for bendiocarb WP-SB containing 800 g/kg active ingredient. As content and physical-chemical properties do slightly differ, the content clause with its tolerance was amended.

Description clause
The formulation is intended for IRS with a target dose of 0.1 to 0.4 g bendiocarb per m². A certain defined amount of bendiocarb WP with a declared content of 400 g/kg is packed in a water soluble sachet so that dosing in a standard compression sprayer is facilitated without direct contact of the operator with the powder.
**Physical-chemical properties**

In certain tests to be carried out to assess the physical-chemical parameters of the WB-SB, the neat formulation is used (e.g. in the wet sieve test and wettability). Whereas bendiocarb as WP formulation is fairly stable at 54°C for two weeks, the water soluble polymer material used for the bag may deteriorate and have an impact on the limits of certain clauses like dissolution of the bag and wettability. The test results of samples before and after storage at 54°C for two weeks showed that the majority of physical-chemical parameters were not adversely affected after storage at 54°C. The most significant effect was on the wettability that increased to around 200 seconds. The Meeting also noted that both the fresh and aged product showed the development of a significant amount of foam (typically 80 to 100 mL after 1 min, at concentrations of 2.5 and 5 % w/v, respectively).

However, in practice, the apparent ageing of the product that occurs under the rather harsh conditions of the accelerated storage at 54°C for two weeks in original packaging is not expected to have such an impact on the two physical-chemical parameters when stored under moderate conditions for longer time. The company explained, that under practical conditions the product rapidly mixes with water in the pressurized sprayer for IRS and the foam that is formed is decaying readily. For these reasons, the use of the product will not lead to a higher risk for the spray personnel and environment.

The Meeting accepted these explanations. As the new persistent foam method, MT 47.3, allows for two observation times - 1 and 12 min - the longer time and a limit of 50 mL was chosen. A significant increase in foam volume was observed with higher concentrations (5 %). Apparently - and not surprising - the dissolved bag material seems to contribute to the occurrence of foam in the persistent foam test.

**Storage stability**

The clauses and limits in the physical-chemical subsection were broadly in agreement with the requirement of the Manual. In addition to standard clauses for a WP-SB formulation, the persistent foam after storage was included, in agreement with the latest amendments of the Manual. After accelerated storage at 54°C for 2 weeks, the products still complies with the clauses for wet sieve test, dissolution of the bag, suspensibility, wettability and persistent foam.
## ANNEX 1: REFERENCES

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<th>Author(s)</th>
<th>Year</th>
<th>Study title. Study identification number. Report identification number. GLP [if GLP]. Company conducting the study</th>
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<td>Mo5227</td>
<td>Brux A.</td>
<td>2015</td>
<td>Determination of physico-chemical properties and storage stability of bendiocarb BND WP-SB 40. GLP. BioGenius, Germany.</td>
</tr>
</tbody>
</table>
Recommendations
The Meeting recommended that the specification for bendiocarb wettable powder in sealed water soluble bag (WP-SB), proposed by Bayer CropScience, as amended, should be adopted by WHO.

Appraisal
A draft specification for bendiocarb WP-SB, provided by Bayer CropScience, was received in 2013 and considered by the JMPS for development of a new WHO specification. A data package on physical-chemical properties of the formulation in the water soluble bag was also received (Brux A. 2013) and supported the clauses and the proposed limits. Bendiocarb has been developed as mosquito adulticide for indoor residual spraying (IRS) by the company and the specification therefore is limited to WHO. The product was successfully evaluated by WHOPES and has a recommendation for IRS.

The proposed specification for bendiocarb WP-SB was broadly in agreement with the guidelines given in the Manual (FAO/WHO 2010).

Formulation type, description, content of active ingredient and analytical method
Bendiocarb is formulated as a wettable powder packed in a water soluble bag. Up to now, a neat bendiocarb WP specification (WHO, December 2008) was available. Therefore, the clauses dealing with the formulation itself are expected to remain the same, but some clauses – especially those referring to the description and to the physical-chemical properties where the soluble bag as a part of the formulation is tested with the WP – do change. This reflects the advantages of the soluble bag that helps to minimize operator exposure. The Meeting concluded that bendiocarb WP and bendiocarb WP-SB should be standalone specifications.

Description clause
The formulation is intended for IRS with a target dose of 0.1 to 0.4 g bendiocarb per m$^2$. A certain defined amount of bendiocarb WP with a declared content of 800 g/kg is packed in a water soluble sachet so that dosing in a certain amount of water is facilitated without direct contact of the operator with the powder.

Physical-chemical properties
The clauses and limits in the physical-chemical subsection were essentially in agreement with the requirement of the Manual. In certain tests to be carried out to assess the physical-chemical parameters of the WB-SB, the neat formulation is used (e.g. in wet sieve test and wettability). Suspensibility and persistent foam tests have to be carried out on the neat formulation with the bag material in the actual ratio of application.
Storage stability

The Meeting questioned some parameters and limits, e.g. the temperature used in the accelerated storage test. Whereas bendiocarb as WP formulation is fairly stable at 54°C for two weeks, the water soluble polymer material used for the bag may deteriorate, and have an impact on the limits of certain clauses like dissolution of the bag and wet sieve test. The company responded that both bag material and formulation are stable under these conditions and that the limits proposed are well supported by the studies submitted.

In addition to standard clauses for a WP-SB formulation, the persistent foam after storage was included, in agreement with the latest amendments of the Manual. After accelerated storage at 54°C for 2 weeks, the product still complies with the clauses for wet sieve test, suspensibility, persistent foam, wettability and dissolution of the bag.

The Meeting agreed also to update in the specification for bendiocarb WP the CIPAC method for persistent foam (MT 47.3 instead of MT 47.2) to be in line with the current CIPAC method.
### ANNEX 1: REFERENCES

<table>
<thead>
<tr>
<th>Study number</th>
<th>Author(s)</th>
<th>Year</th>
<th>Study title. Study identification number. Report identification number. GLP [if GLP]. Company conducting the study</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mo4640</td>
<td>Biogenius</td>
<td>2013</td>
<td>Determination of physico-chemical properties and storage stability of bendiocarb WP-SB 80. GLP. BioGenius, Germany.</td>
</tr>
</tbody>
</table>
Recommendations

The Meeting recommended that:

(i) the specifications for bendiocarb TC and WP, proposed by Bayer CropScience and as amended, should be adopted by WHO; and

(ii) the existing WHO specifications for bendiocarb TC, WP, DP and UL should be withdrawn.

Appraisal

The Meeting considered data and draft specifications (TC and WP only) for bendiocarb, submitted by Bayer CropScience in support of a review of existing WHO specifications for bendiocarb (TC, WP, DP, UL, all published in 1999). Existing specifications for bendiocarb DP and UL were not supported by the proposer.

Bendiocarb is a crystalline solid of low solubility in highly polar solvents (including water), and in solvents of low polarity, but is very soluble in various organic solvents of intermediate polarity. Bendiocarb is rapidly hydrolysed under moderately alkaline conditions but only slowly hydrolysed under moderately acidic conditions. Although it is subject to photolysis, degradation by this route does not occur very readily. It has no measurable acidic or basic properties.

The Meeting was provided with commercially confidential information on the manufacturing process and 5-batch analysis data on purity and all impurities ≥1 g/kg. These data were confirmed as identical to those submitted to the Health and Safety Executive (HSE) for registration in the U.K. Mass balances in the batch analytical data were good (98.7-99.7%) and the bendiocarb was of high purity (982-991 g/kg).

The Meeting and proposer considered in detail whether or not methyl isocyanate and toluene should be designated relevant impurities, for the purposes of WHO specifications, on the basis of their hazard characteristics.

The Meeting noted that the hazards associated with both impurities differ from those of bendiocarb but that their hazards have been well-characterized in the scientific literature. The Meeting also noted that both impurities are very volatile, in contrast with the low volatility of bendiocarb. In consequence, the patterns and routes of user and environmental exposure to the active ingredient and the two impurities were considered likely to be very different. Thus the simple “concentration and relative toxicity” approach, used by JMPS to determine the relevance of impurities having characteristics similar to those of the active ingredient, was not entirely appropriate in this case.

Methyl isocyanate. WHO/PCS advised the Meeting that methyl isocyanate is an eye and skin irritant and perhaps a respiratory sensitizer. However, in the proposer’s bendiocarb TC, it was not detectable at or above 1 g/kg, the manufacturing limit
below which all impurities (other than those associated with exceptional hazards) are considered to become non-relevant. The Meeting therefore agreed that it was not necessary to designate methyl isocyanate as a relevant impurity in the proposer’s TC, nor in WP prepared using TC from that source. The extent to which this volatile impurity would be likely to persist in (crystalline) bendiocarb TC or WP was unknown but the Meeting agreed that, although a specification clause is unnecessary in this case, a cautionary note should be appended to the specifications, alerting users to the possibility that the impurity may occur at ≥1 g/kg (and thus require control) in the bendiocarb products of other manufacturers.

**Toluene.** The large body of information available on the hazards involved in exposures to toluene would have been ignored by the default approach of JMPS to the determination of the relevance of impurities which have a hazard profile different from that of the active ingredient (i.e., the application of the GHS labelling limits for mixtures). Therefore, WHO/PCS proposed that a more refined approach should be adopted.

WHO/PCS advised that the assessment of toluene toxicity and classification by the European Union (EU 2003) is based on its toxicity arising from inhalation exposure, making it pertinent to the JMPS assessment of toluene in bendiocarb. The key end points that determine whether or not toluene should be designated as a relevant impurity in FAO/WHO specifications are related to its reproductive toxicity.

WHO/PCS advised that, with respect to reproductive toxicity, there are no data to indicate that toluene affects fertility or that it is teratogenic. However, it has been associated with developmental neurotoxicity in experimental animals and spontaneous abortions in humans. As there is uncertainty in the interpretation of these studies, the European union has classified toluene in reproductive toxicity category 3, corresponding to the GHS category 2. In addition, case reports have been published of “fetal alcohol syndrome” among toluene sniffers, with no information on exposure, although high levels almost certainly would have been involved. No information is available to show whether bendiocarb could produce similar effects but, to determine whether or not toluene levels should be controlled in bendiocarb, it was therefore conservatively assumed that the effects would be produced only by the toluene.

In the most informative study (Hass et al. 1999), adverse neuro-developmental effects were observed in rats exposed to air containing 4500 mg toluene/m$^3$ for 6 h/d from pregnancy day 7 to post-natal day 18. These effects have not been studied at lower concentrations, so a no-observed-adverse-effect-concentration (NOAEC) is not available and the test level was considered to be the lowest-observed-adverse-effect-concentration (LOAEC).

Two studies in humans have indicated a possible increase of spontaneous abortions among women exposed to toluene, either alone (Ng et al. 1992) or in combination with other solvents (Taskinen et al. 1994). In the study involving exposure only to toluene, in which limited quantitative exposure data were available, an elevated incidence of spontaneous abortions was observed among

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1 The effects were not observed in animals exposed only during the pre-natal period.
women exposed to an average concentration of 330 mg toluene/m$^3$ air in the workplace.

The default uncertainty factor used by the JMPR to derive acute reference doses (ARfD) and acceptable daily intakes (ADIs) from no-observable-adverse-effect-levels (NOAELs) is 100 (10 for inter-species extrapolation, 10 for inter-individual variation). When the NOAEL is not available to the JMPR, the use of the lowest-observed-adverse-effect-level (LOAEL) is usually compensated by incorporating an additional uncertainty factor of 3-10 (IPCS 1994, 1999; JMPR 2002; Solecki et al. 2005). WHO/PCS proposed that, for the hazard characterization of toluene in bendiocarb, the tolerable inhaled concentration (TIC), conceptually similar to the ARfD and ADI$^1$, should be used. The TIC represents a range$^2$ of concentrations of a chemical in air that may be inhaled without health consequences over a day (TIC for acute effects) or over long periods of time (TIC for chronic effects). Calculated TIC maximum values, equivalent to JMPR ARfD maximum values (developmental effects being considered acute effects), for an 8-h daily airborne exposure of humans$^3$ to toluene would be:

\[
\frac{(6/8 \times 4500)}{(10 \times 10 \times [3 to 10])} = 3.4 \text{ to } 11 \text{ mg/m}^3,
\]
derived from data on adverse neuro-developmental effects in the study of reproductive toxicity in rats; and

\[
\frac{(330 \times 10 \times [3 to 10])} = 3.3 \text{ to } 11 \text{ mg/m}^3,
\]
derived from data on spontaneous abortions in the human study.

The estimated maximum values for the TIC thus converge toward a geometric mean of 6 mg/m$^3$.

In most circumstances when solid bendiocarb TC or WP is exposed to air, any volatilized toluene impurity would be diluted by the environmental air. However, if bendiocarb becomes airborne as a dust$^4$ the toluene impurity concentration in air is maximized, as is the potential inhalation exposure to toluene. In such conditions, the toluene concentration in bendiocarb, the concentration of bendiocarb in air, and the toluene concentration in the air are related by the formula:

\[
a = \frac{b \times c}{1000}
\]

where:
- $a =$ toluene-in-air (mg/m$^3$);
- $b =$ bendiocarb-in-air (mg/m$^3$);
- $c =$ toluene-in-bendiocarb (g/kg).

So, for example, a toluene-in-air concentration of 6 mg/m$^3$ (the estimated TIC maximum) would be reached at a toluene-in-bendiocarb concentration of 11 g/kg and a corresponding a bendiocarb-in-air concentration of 550 mg/m$^3$. The corresponding bendiocarb-in-air concentration equals the 4-h inhalation toxicity LC$_{50}$ (rat) for bendiocarb. Therefore, at a toluene-in-bendiocarb concentration of 11 g/kg, the risk associated with the acute inhalation hazard of the bendiocarb active ingredient greatly overshadows the risk associated with the reproductive

---

$^1$ “Dose” being considered to be the amount inhaled at the TIC concentration over a working day.

$^2$ The minimum of the range being zero.

$^3$ The rats were exposed for 6 h/d.

$^4$ For example, during pouring or other transfer operations.
hazards of the toluene impurity and thus the contribution of toluene impurity to the overall hazard of the bendiocarb product is negligible. WHO/PCS therefore concluded that, at concentrations less than 10 g/kg of bendiocarb, toluene is a non-relevant impurity.

WHO/PCS also advised that the minimum toluene concentration for ignition in air is about 1% v/v and thus, as an impurity in bendiocarb, the toluene would present no fire/explosion risk at or about the proposed cut-off value of 10 g/kg.

The manufacturing limit for toluene in the proposer’s bendiocarb was well below 10 g/kg and the Meeting agreed that it was not necessary to designate it as a relevant impurity in the proposer’s TC, nor in WP prepared using TC from that source.

As in the case of methyl isocyanate, the extent to which (volatile) toluene would be likely to persist in (crystalline) bendiocarb TC or WP was unknown but, again, the Meeting agreed that, although a specification clause is unnecessary in this case, a cautionary note should be appended to the specifications, alerting users to the possibility that the impurity may occur at ≥10 g/kg (and require control) in the products of other manufacturers.

The Meeting agreed that none of the other impurities should be designated as relevant.

The analytical method for determination of the active ingredient (including identity tests) is a full CIPAC method, validated for analysis of TC and WP. Bendiocarb is determined by reversed-phase HPLC, using UV detection at 254 nm and internal standardization with propiophenone.

Test methods for determination of physico-chemical properties of the technical active ingredient were OECD, EPA or EC, while those for the WP formulation were CIPAC, as indicated in the specification. The Meeting questioned the melting point quoted for TC, as it was the same as that for the pure active ingredient. The proposer stated the similarity is a reflection of the generally very high purity of the TC in current production.

Noting that the existing WHO specifications for bendiocarb DP and UL were not supported by the proposer, the Meeting considered the following issues arising from the proposed specifications for TC and WP, which were otherwise in accordance with the requirements of the manual (FAO/WHO 2006).

TC. The Meeting welcomed the proposed increase in purity of bendiocarb (940 g/kg in the existing WHO specification) to 970 g/kg.

The existing clause for water content had been deleted. Although bendiocarb is subject to rapid hydrolysis under alkaline conditions, this does not occur in the crystalline solid TC and water is not considered to be a quality criterion for a TC used in the preparation of WP formulations.

WP. The Meeting noted that the existing WHO specification encompassed bendiocarb contents in the ranges 250-500 and >500 g/kg but was informed that only the 800 g/kg WP had been evaluated for efficacy by WHOPES. The Meeting therefore agreed that the new specification should be restricted to 800 g/kg products.
The Meeting questioned whether the existing specification limits for certain physical properties remained appropriate for the new specification, as they represented values at or about the limit of acceptability. After checking current product performance, the proposer revised the specification limits for wet sieve test (from 2% to 1% of the formulation retained on a 75 µm sieve); suspensibility (from 50% to 70% in suspension after 30 min in hard water); persistent foam (from 60 ml to 50 ml); and wettability (from 2 min to 1 min for complete wetting without swirling). These improvements were welcomed by the Meeting.

The Meeting questioned the need for a proposed clause to limit the pH range, as this was not included in the existing specification. Although bendiocarb is unstable in alkaline solution, the manufacturer agreed that significant degradation is unlikely in the storage and use of the WP and the proposed clause was withdrawn.
Uses

Bendiocarb is a cholinesterase-inhibitor \( N \)-methyl carbamate insecticide. It is mainly used in public health, industrial and storage applications, having low odour and no corrosive or staining properties.

Identity

ISO common names
Bendiocarb (E-ISO, BSI, ANSI, ESA), bendiocarbe (fr F-ISO)

Synonyms None

Chemical names
IUPAC: 2,2-dimethyl-1,3-benzodioxol-4-yl methylcarbamate
2,3-isopropylidenedioxyphenyl methylcarbamate
CA: 2,2-dimethyl-1,3-benzodioxol-4-yl methylcarbamate

Structural formula

Empirical formula
\( \text{C}_{11}\text{H}_{13}\text{NO}_4 \)

Relative molecular mass
223.2

CAS Registry number
22781-23-3

CIPAC number
232

Identity tests
HPLC retention time, \(^1\text{H}\) NMR spectrum.
Physico-chemical properties of bendiocarb

Table 1. Physico-chemical properties of pure bendiocarb

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value(s) and conditions</th>
<th>Purity %</th>
<th>Method</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vapour pressure</td>
<td>4.6 x 10^{-3} Pa at 25 °C (extrapolated)</td>
<td>99.8</td>
<td>gas saturation</td>
<td>M-166699-01-1</td>
</tr>
<tr>
<td>Melting point</td>
<td>129 °C</td>
<td>98.5</td>
<td>OECD 102</td>
<td>M-248943-01-1</td>
</tr>
<tr>
<td>Boiling point</td>
<td>decomposed with boiling at about 264 °C</td>
<td>98.5</td>
<td>OECD 103</td>
<td>M-248943-01-1</td>
</tr>
<tr>
<td>Temperature of decomposition</td>
<td>≥240 °C</td>
<td>98.5</td>
<td>OECD 103</td>
<td>M-248943-01-1</td>
</tr>
<tr>
<td>Solubility in water at 20 °C</td>
<td>0.31 g/l at pH 3-5 0.28 g/l at pH 7 0.03 g/l at pH 9-11 with significant hydrolysis</td>
<td>99.3</td>
<td>84/449/EEC A6</td>
<td>M-166763-01-1</td>
</tr>
<tr>
<td>Octanol/water partition coefficient</td>
<td>K_{ow} log P = 1.7 at 25 °C at pH 6.9</td>
<td>99.0</td>
<td>84/449/EEC A8</td>
<td>M-166668-01-1</td>
</tr>
<tr>
<td>Hydrolysis characteristics, half-life at 25 °C</td>
<td>46.5 d at pH 5 48.1 h at pH 7 43.8 min at pH 9</td>
<td>99.0</td>
<td>OECD 111</td>
<td>M-166890-01-1</td>
</tr>
<tr>
<td>Photolysis characteristics</td>
<td>Half-life = 37.3 d (corrected for dark reaction); 187 d (extrapolated to natural sunlight 40° north, midday, summer); 1070-20000 days (using the quantum yield)</td>
<td>99.0</td>
<td>US EPA NTIS PB83-153973 (1982)</td>
<td>M-166721-01-1 M-166722-01-1</td>
</tr>
<tr>
<td>Dissociation characteristics</td>
<td>Not measurable due to rapid hydrolysis in alkaline solution. Not protonated under acidic conditions. The “parent phenol” of bendiocarb (NC7312) has pKa = 8.8 at 20°C</td>
<td>99.0</td>
<td>US EPA OPPTS 830.6310, UV spectrophotometric method</td>
<td>M-166694-01-1</td>
</tr>
</tbody>
</table>

Table 2. Chemical composition and properties of technical bendiocarb (TC)

<table>
<thead>
<tr>
<th>Manufacturing process, maximum limits for impurities ≥ 1 g/kg, 5 batch analysis data</th>
<th>Confidential information supplied and held on file by WHO. Mass balances were 98.7-99.7% and no unidentified impurities were reported.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Declared minimum bendiocarb content</td>
<td>970 g/kg</td>
</tr>
<tr>
<td>Relevant impurities ≥ 1 g/kg and maximum limits for them</td>
<td>None</td>
</tr>
<tr>
<td>Relevant impurities &lt; 1 g/kg and maximum limits for them</td>
<td>None</td>
</tr>
<tr>
<td>Stabilisers or other additives and maximum limits for them</td>
<td>None</td>
</tr>
<tr>
<td>Melting temperature of the TC</td>
<td>129 °C</td>
</tr>
</tbody>
</table>

* Data from a laboratory study at pH 5 (to minimize hydrolysis) under artificial light conditions (light source: Hg-arc TQ 150, light intensity corresponding to about 2.5x natural sunlight at 290-320 nm, being the region in which bendiocarb absorbs sunlight).
Hazard summary

Bendiocarb was evaluated by the FAO/WHO JMPR in 1982 and 1984. In 1984, the JMPR set an ADI for bendiocarb of 0-0.004 mg/kg bw.

The WHO hazard classification of bendiocarb is: moderately hazardous, class II (WHO 2002).

Within the EU, according to the 19th adaptation to technical progress of Council Directive 67/548/EEC, bendiocarb is classified as: “toxic by inhalation and if swallowed (T, R23/25)”; “harmful in contact with skin (Xn, R21)”; and “very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment (N, R50/53)”.

In May 2005, as part of a review of anticholinesterase compounds, the UK Health & Safety Executive classified bendiocarb as: “toxic by inhalation and if swallowed (T, R23/25)” and “harmful in contact with skin (Xn, R21)”.

Formulations

The main formulation type available for public health is a wettable powder (WP), which is registered and/or sold in many countries throughout the world.

Bendiocarb is not usually co-formulated with other pesticides.

Methods of analysis and testing

The analytical method for the active ingredient (including identity tests) is a full CIPAC method, in which bendiocarb is determined by reversed-phase HPLC, using UV detection at 254 nm and internal standardization with propiophenone (CIPAC Handbook D). It was validated for analysis of the TC and WP formulation.

Test methods for determination of physico-chemical properties of the technical active ingredient were OECD, EPA or EC, while those for the formulation were EC or CIPAC, as indicated in the specifications.

Physical properties

The physical properties, the methods for testing them and the limits proposed for the WP formulation, comply with the requirements of the manual (FAO/WHO 2006).

Containers and packaging

No special requirements for containers and packaging have been identified.

Expression of the active ingredient

The active ingredient is expressed as bendiocarb.
ANNEX 1

HAZARD SUMMARY PROVIDED BY THE PROPOSER

Note: Bayer CropScience provided written confirmation that the toxicological and ecotoxicological data included in the following summary were derived from bendiocarb having impurity profiles similar to those referred to in Table 2, above.
Table A. Toxicology profile of bendiocarb technical material, based on acute toxicity, irritation and sensitization

<table>
<thead>
<tr>
<th>Species</th>
<th>Test</th>
<th>Purity</th>
<th>Duration and conditions or guideline adopted</th>
<th>Result</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat, Sprague Dawley (m)*</td>
<td>Oral</td>
<td>91-98.9</td>
<td>Single dose by gavage, in 0.5% w/v aqueous gum tragacanth, to groups of 6 m. Observed 7 d.</td>
<td>$LD_{50} = 71.9-155.9$ mg/kg bw (m)</td>
<td>M-167182-01-1</td>
</tr>
<tr>
<td>Rat, Sprague Dawley (m,f)*</td>
<td>Oral</td>
<td>98.8</td>
<td>Single dose by gavage, in corn oil, to 4 groups of 6 m and 6 f. Observed 14 d.</td>
<td>$LD_{50} = 25$ mg/kg bw (m) 27.3 mg/kg bw (f)</td>
<td>M-167235-01-1</td>
</tr>
<tr>
<td>Rat, Wistar (m,f)*</td>
<td>Oral</td>
<td>“pure”</td>
<td>Single dose by gavage, in glycerol formal, to 6 groups of 2-10 m and 8 groups of 2-6 f. Observed 24 h.</td>
<td>$LD_{50} = 45-48$ mg/kg bw (m) 34-40 mg/kg bw (f)</td>
<td>M-167655-01-1</td>
</tr>
<tr>
<td>Rat, strain not specified (m)*</td>
<td>Oral</td>
<td>not known</td>
<td>Single dose by gavage, in glycerol formal, to 10 groups of 4 m. Observation period not specified.</td>
<td>$LD_{50} = 40-64$ mg/kg bw (m)</td>
<td>M-167657-01-1</td>
</tr>
<tr>
<td>Mouse, CFW (f)*</td>
<td>Oral</td>
<td>“pure”</td>
<td>Single dose by gavage, in glycerol formal, to 3 groups of 2-4 f. Observed 24 h.</td>
<td>$LD_{50} = 45$ mg/kg bw (f)</td>
<td>M-167655-01-1</td>
</tr>
<tr>
<td>Mouse, CD-1 (m,f)*</td>
<td>Oral</td>
<td>91.8</td>
<td>Single dose by gavage, in 0.5% w/v aqueous gum tragacanth, to 9 groups of 6 m and 6 f. Observed 14 d.</td>
<td>$LD_{50} = 28.3$ mg/kg bw (m) 28.2 mg/kg bw (f)</td>
<td>M-167195-01-1</td>
</tr>
<tr>
<td>Guinea pig, strain not specified (f)*</td>
<td>Oral</td>
<td>“pure”</td>
<td>Single dose by gavage, in glycerol formal, to 2 groups of 2 f. Observed 24 h.</td>
<td>$LD_{50} = 35$ mg/kg bw (f)</td>
<td>M-167655-01-1</td>
</tr>
<tr>
<td>Hamster, Syrian (f)*</td>
<td>Oral</td>
<td>not known</td>
<td>Single dose by gavage, in water, to 5 groups of 4 f. Observed 7 d.</td>
<td>$LD_{50} = 141$ mg/kg bw (f)</td>
<td>M-167102-01-1</td>
</tr>
<tr>
<td>Rabbit, strain not specified (m,f)*</td>
<td>Oral</td>
<td>“pure”</td>
<td>Single dose by gavage, in glycerol formal, to 3 groups of 2 m and 2 groups of 2 f. Observed 24 h.</td>
<td>$LD_{50} = 35$ mg/kg bw (f) 40 mg/kg bw (m)</td>
<td>M-167655-01-1</td>
</tr>
</tbody>
</table>

* Studies performed prior to introduction of testing guidelines and GLP regulations but conducted according to good scientific practice.
Table A. Toxicology profile of bendiocarb technical material, based on acute toxicity, irritation and sensitization

<table>
<thead>
<tr>
<th>Species</th>
<th>Test</th>
<th>Purity %</th>
<th>Duration and conditions or guideline adopted</th>
<th>Result</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat, Wistar (m,f)*</td>
<td>Dermal</td>
<td>not known</td>
<td>In glycerol, applied to skin of 4 m and 4 f, 400, 800 mg/kg bw, held in contact by occlusive patch 24 h. Observed 7 d.</td>
<td>$LD_{50} = 566$ mg/kg bw (m,f)</td>
<td>M-167065-01-1</td>
</tr>
<tr>
<td>Rat, Wistar (f)*</td>
<td>Dermal</td>
<td>“pure”</td>
<td>In glycerol formal, applied to skin of 2 m and 2 f, 400, 800 mg/kg bw, held in contact by occlusive patch 24 h. Observed 7 d.</td>
<td>$LD_{50} = 800$ mg/kg bw (f)</td>
<td>M-167655-01-1</td>
</tr>
<tr>
<td>Rat, Sprague Dawley (m,f)</td>
<td>Inhalation</td>
<td>97.9</td>
<td>OECD 403, US EPA guideline 81-3 (GLP). Groups of 5 m and 5 f exposed whole body, 4 h, to 248, 377, 512, 701 mg/m$^3$ bendiocarb by dust generator at 25 l/min. Observed 14 d.</td>
<td>$LC_{50} = 550$ mg/m$^3$ (0.55 mg/l of air) (m,f)</td>
<td>M-167335-01-1</td>
</tr>
<tr>
<td>Rabbit, New Zealand White (m,f)**</td>
<td>Skin irritation</td>
<td>not known</td>
<td>US EPA guideline 40 CFR 162</td>
<td>Not a skin irritant</td>
<td>M-167702-01-1</td>
</tr>
<tr>
<td>Rabbit, New Zealand White (m,f)**</td>
<td>Eye irritation</td>
<td>99.2</td>
<td>US EPA guideline 40 CFR 162.</td>
<td>Not an eye irritant</td>
<td>M-167153-01-1</td>
</tr>
<tr>
<td>Guinea pig, Dunkin/Hartley albino (f)</td>
<td>Skin sensitization</td>
<td>97.5</td>
<td>OECD guideline 406 (Buehler test - GLP).</td>
<td>Not a sensitizer</td>
<td>M-167357-01-1</td>
</tr>
</tbody>
</table>

* Studies performed prior to introduction of testing guidelines and GLP regulations but conducted according to good scientific practice.

** Study conducted prior to introduction of GLP regulations.
## Table B. Toxicology profile of bendiocarb technical material, based on repeated administration (sub-acute to chronic)

<table>
<thead>
<tr>
<th>Species</th>
<th>Test</th>
<th>Purity</th>
<th>Duration and conditions or guideline adopted</th>
<th>Result</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat, Sprague Dawley (m,f)*</td>
<td>Oral (dietary), sub-chronic</td>
<td>92.7-98</td>
<td>Administered to groups of 10 m and 10 f in diet for 13 weeks at 0, 2, 10, 50, 250 ppm (equivalent to 0, 0.13, 0.65, 3.45, 17.3 mg/kg bw/d).</td>
<td>NOAEL = 0.65 mg/kg bw/d based on inhibition of whole blood cholinesterase activity (up to 20%) at 3.45 mg/kg bw/d dose. LOAEL = 3.45 mg/kg bw/d</td>
<td>M-167672-01-1</td>
</tr>
<tr>
<td>Dog, beagle (m,f)*</td>
<td>Oral (dietary), sub-chronic</td>
<td>96-97</td>
<td>Administered to groups of 4 m and 4 f in diet for 16 weeks at 0, 20, 100, 500-1000 ppm (1000 ppm for the last 4 weeks of the study) (equivalent to 0, 0.2, 1.0, 6.25 mg/kg bw/d).</td>
<td>NOAEL = 1.0 mg/kg bw/d based on inhibition of whole blood (43-46%) and brain (28-42%) cholinesterase activity at 6.25 mg/kg bw/d. LOAEL = 6.25 mg/kg bw/d</td>
<td>M-167076-01-1</td>
</tr>
<tr>
<td>Rat, Sprague Dawley (m,f)</td>
<td>Inhalation, sub-chronic</td>
<td>97.2-97.6</td>
<td>US EPA guideline 82.4 (GLP). Groups of 10 m and 10 f exposed snout-only 6 h/d to particulate aerosol at 0, 0.18, 1.97, 19.3 mg/m³ of bendiocarb. Exposure 5 d/week for 13 weeks.</td>
<td>NOAEL = 0.9 mg/m³ = 0.24 mg/kg bw/d based on slight inhibition of whole blood cholinesterase activity at week 6 at 2 mg/m³. LOAEL = 2 mg/m³ = 0.54 mg/kg bw/d</td>
<td>M-266196-01-1</td>
</tr>
<tr>
<td>Rat, Wistar (m)*</td>
<td>Dermal, repeated dose toxicity</td>
<td>80% WP</td>
<td>Doses 50, 100, 200, 400 or 800 mg bendiocarb/kg bw/d, aqueous suspension, to skin of 5 groups of 6 m under occlusive dressing for 6 h/d, 5 d/week for 3 weeks.</td>
<td>NOAEL = 50 mg/kg bw/d based on dose-related decrease in whole blood cholinesterase activity from 100 to 800 mg/kg bw/d. LOAEL = 100 mg/kg bw/d</td>
<td>M-167061-01-1</td>
</tr>
<tr>
<td>Rabbit, New Zealand White (m,f)</td>
<td>Dermal, repeated dose toxicity</td>
<td>31% WP**</td>
<td>US EPA guideline 82.2 and Japan 59 NohSan No. 4200 (1985) (GLP). Administered daily to intact skin of 5 m and 5 f at 1.67, 5, 15 mg bendiocarb/kg bw/d for 21 consecutive days.</td>
<td>NOAEL = 5 mg/kg bw/d based on reduction in erythrocyte and plasma cholinesterase levels at 15 mg/kg bw/d. LOAEL = 15 mg/kg bw/d</td>
<td>M-167323-01-1</td>
</tr>
</tbody>
</table>

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** Ficam Plus wettable powder formulation, nominally containing 31% bendiocarb, 3.0% natural pyrethrins and 7% piperonyl butoxide.
Table B. Toxicology profile of bendiocarb technical material, based on repeated administration (sub-acute to chronic)

<table>
<thead>
<tr>
<th>Species</th>
<th>Test</th>
<th>Purity %</th>
<th>Duration and conditions or guideline adopted</th>
<th>Result</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dog, beagle (m,f)</td>
<td>Oral, chronic</td>
<td>98.1-99</td>
<td>Groups of 8 m and 8 f dosed in diet for 104 weeks at 0, 20, 100, 500 ppm (equivalent to 0, 0.65, 3.12, 16.24 mg/kg bw/d).</td>
<td>NOAEL = 0.65 mg/kg bw/d based on inhibition of brain cholinesterase activity (20%) at 3.12 mg/kg bw/d. LOAEL = 3.12 mg/kg bw/d</td>
<td>M-167690-01-1</td>
</tr>
<tr>
<td>Rat, Sprague Dawley (m,f)**</td>
<td>Oral, long-term dietary &amp; carcinogenicity</td>
<td>96.5</td>
<td>OECD guideline 453. 50 m and 50 f weanlings (100 animals/sex in control) from F1 litters of fertility study given 0, 10, 20, 200 ppm in diet for 104 weeks (equivalent to approx. 0, 0.4, 0.8, 8 (m) and 0, 0.5, 1, 10 (f) mg/kg bw/d)</td>
<td>NOAEL = 0.8/1 mg/kg bw/d (m/f) based on whole blood and brain cholinesterase inhibition at 8/10 mg/kg bw/d. No evidence of carcinogenicity. LOAEL = 8/10 mg/kg bw/d (m/f)</td>
<td>M-265313-01-1, M-265496-01-1</td>
</tr>
<tr>
<td>Mouse, CD-1 (m,f)**</td>
<td>Oral, long-term dietary &amp; carcinogenicity</td>
<td>92.7</td>
<td>OECD guideline 453. 50 m and 50 f (100 animals/sex in control group) administered 0, 50, 250, 1250 ppm in diet for 104 weeks (equivalent to approx. 0, 8.06, 42.4, 211 (m) and 0, 10.7, 56.8, 286 (f) mg/kg bw/d).</td>
<td>NOAEL = 211/286 mg/kg bw/d (m/f). No evidence of carcinogenicity.</td>
<td>M-167163-01-1</td>
</tr>
<tr>
<td>Rat, Sprague Dawley (m,f)**</td>
<td>Oral (dietary), 3-generation</td>
<td>97.0-99.3</td>
<td>OECD 2-generation reproduction toxicity study guideline. Groups of 30 m and 30 f (F0) fed continuously at 0, 10, 50, 250 ppm in diet (equivalent to approx. 0, 1, 4, 18 mg/kg bw/d) for 90 d prior to pairing, and during mating (max. 21 d), gestation and lactation of 2 litters, F1A and F1B. Repeated for 2 litters of 2d (F2) and 3d (F3) generations.</td>
<td>Parental and offspring toxicity NOAEL = 18 mg/kg bw/d (250 ppm) No effect upon fertility, no significant parental toxicity.</td>
<td>M-167165-01-1</td>
</tr>
</tbody>
</table>

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<table>
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<tr>
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</tr>
</thead>
<tbody>
<tr>
<td>Rat, Sprague Dawley (f)</td>
<td>Teratogenicity</td>
<td>97.2</td>
<td>US EPA guideline 83.3 (GLP). Groups of 25-30 pregnant f dosed by oral gavage 0, 0.4, 2, 10 mg/kg bw/d in 1% methylcellulose on 6-15 d gestation (sacrifice 20 d gestation).</td>
<td>NOAEL developmental and maternal toxicity = 2 mg/kg bw/d. No teratogenic effect.</td>
<td>M-167345-01-1</td>
</tr>
<tr>
<td>Rabbit, New Zealand White (f)**</td>
<td>Teratogenicity</td>
<td>97.7-98.5</td>
<td>OECD guideline. Groups of 27-29 pregnant (artificially inseminated) f dosed by oral gavage 0, 1, 2.5, 5 mg/kg/d in 0.5% w/v aqueous gum tragacanth on d 6-28 of gestation (sacrifice on 29 d gestation).</td>
<td>NOAEL developmental toxicity = 2.5 mg/kg bw/d based on increased incidence of foetuses with incomplete ossification of cranial bones at highest dose. NOAEL maternal toxicity &lt;1 mg/kg bw/d based on whole blood cholinesterase inhibition in dams at 1 mg/kg bw/d. No teratogenic effect.</td>
<td>M-167160-01-1</td>
</tr>
<tr>
<td>Hen, domestic (f)**</td>
<td>Acute delayed neurotoxicity</td>
<td>not known</td>
<td>US EPA guideline 162, 81-8. 4 groups of 10 hens dosed at 20% concentration in corn oil (doses 0, 189, 378, 757 mg/kg), birds protected by atropine intramuscular injection at 1% concentration in sterile water at 10 mg/kg bw. Observed 21 days.</td>
<td>No signs of delayed neurotoxicity at levels up to and including 757 mg/kg.</td>
<td>M-167141-01-1</td>
</tr>
</tbody>
</table>

** Study conducted prior to introduction of GLP regulations.
Table C. Mutagenicity profile of bendiocarb technical material based on *in vitro* and *in vivo* tests

<table>
<thead>
<tr>
<th>Species</th>
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<th>Purity %</th>
<th>Conditions and doses</th>
<th>Result</th>
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</tr>
</thead>
<tbody>
<tr>
<td><em>S. typhimurium</em></td>
<td>Ames test, <em>in vitro</em></td>
<td>100</td>
<td>GLP study, ± S9 metabolic activation. 15, 50, 150, 500, 1500 µg/plate.</td>
<td>Negative</td>
<td>M-167333-01-1</td>
</tr>
<tr>
<td>(TA98, 100, 1535, 1537, 1538)</td>
<td></td>
<td></td>
<td>Japanese guideline for Ames test. ± S9 metabolic activation. 5, 10, 50, 100, 500, 1000, 5000 µg/plate.</td>
<td>Negative</td>
<td>M-167201-01-1</td>
</tr>
<tr>
<td><em>S. typhimurium</em></td>
<td>Ames test, <em>in vitro</em></td>
<td>98.8</td>
<td>± S9 metabolic activation. 5, 10, 50, 100, 500, 1000, 5000 µg/plate.</td>
<td>Negative</td>
<td>M-167217-01-1</td>
</tr>
<tr>
<td>(TA98, 100, 1535, 1537, 1538) and <em>E. coli</em> (WP2) **</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>S. cerevisiae</em> (D7) *</td>
<td>Conversion and mitotic recombination, <em>in vitro</em></td>
<td>98.5</td>
<td>500, 1000, 2000, 4000, 6000 µg/plate ± S9 and 375, 750, 1500, 3000, 6000 µg/plate +S9.</td>
<td>Negative</td>
<td>M-167217-01-1</td>
</tr>
<tr>
<td>Human lymphocytes</td>
<td>Chromosome aberration, <em>in vitro</em></td>
<td>97.6</td>
<td>US EPA guideline 84-2; OECD guideline 473 (GLP). 17, 85, 170 µg/ml -S9 and 14.3, 71.5, 143 µg/ml -S9 and 30, 150, 225, 300 µg/ml +S9.</td>
<td>Positive (+S9)</td>
<td>M-167334-01-1</td>
</tr>
<tr>
<td>Human epithelioid (HeLa) cells</td>
<td>Unscheduled DNA synthesis, <em>in vitro</em></td>
<td>96.4</td>
<td>US EPA guideline 84-2; EPA TSCA 560/6-83-001; OECD guideline 482 (GLP). ± S9 metabolic activation. 1.25 to 2560 µg/ml.</td>
<td>Negative</td>
<td>M-167336-01-1</td>
</tr>
<tr>
<td>Mouse lymphoma L5178Y cells*</td>
<td>Gene mutation, <em>in vitro</em></td>
<td>98.5</td>
<td>± S9 metabolic activation. 0.2 to 25 µg/ml.</td>
<td>Negative</td>
<td>M-167209-01-1</td>
</tr>
<tr>
<td>Rat, Sprague Dawley (m,f) bone marrow</td>
<td>Clastogenicity (metaphase analysis), <em>in vivo</em></td>
<td>96.4</td>
<td>US EPA guideline 84-2; EPA TSCA 560/6-83-001; OECD guideline 475 (GLP). Single dose of 1% w/v in methylcellulose by oral gavage to groups of 5 m and 5 f at 2.6, 13, 26 mg/kg bw. 5 m and 5 f each group sacrificed 6, 24, 48 h after dosing</td>
<td>Negative</td>
<td>M-167338-01-1</td>
</tr>
<tr>
<td>Mouse, Charles River CD-1 (m) bone marrow *</td>
<td>Clastogenicity (micronucleus), <em>in vivo</em></td>
<td>97.9</td>
<td>2 intra-peritoneal injection in propylene glycol 24 h apart to groups of 5 m at 0.625, 1.25, 2.5 mg/kg bw. Femoral bone marrow cells harvested 6 h after 2nd dose</td>
<td>Negative</td>
<td>M-167214-01-1</td>
</tr>
</tbody>
</table>

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Table C. Mutagenicity profile of bendiocarb technical material based on *in vitro* and *in vivo* tests

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<th>Purity %</th>
<th>Conditions and doses</th>
<th>Result</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat, Sprague Dawley (m,f)*</td>
<td>Dominant lethal mutations, <em>in vivo</em></td>
<td>99</td>
<td>Administered in diet to groups of 20 m at 10, 50 or 250 ppm for 13 weeks. Treated m mated with untreated, mature virgin f for 7 d. Pregnant and non-pregnant f sacrificed 14 d post-mating and examined for numbers of <em>corpora lutea</em>, implantation sites, live and dead foetuses and early and late resorptions. Males subjected to gross pathological examination, those with abnormal gonads also examined histopathologically.</td>
<td>Negative</td>
<td>M-167098-01-1</td>
</tr>
</tbody>
</table>

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### Table D. Ecotoxicology profile of bendiocarb technical material

<table>
<thead>
<tr>
<th>Species</th>
<th>Test</th>
<th>Purity %</th>
<th>Duration and conditions</th>
<th>Results</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Daphnia magna</em> (water flea)</td>
<td>Acute toxicity</td>
<td>97.62</td>
<td>OECD guideline 202, EEC C2 and US EPA guideline 72.2 (GLP). 48-h flow-through. 0.015, 0.029, 0.050, 0.11, 0.16 mg/l.</td>
<td>EC₅₀ (48 h) = 0.0377 mg/l</td>
<td>M-259123-01-1</td>
</tr>
<tr>
<td><em>Cyprinodon variegatus</em> (sheephead minnow)</td>
<td>Acute toxicity</td>
<td>98.0</td>
<td>US EPA guideline 72.3 (GLP). 96-h flow-through. 2.6, 1.9, 1.0, 0.64, 0.45 mg/l.</td>
<td>LC₅₀ (96 h) = 0.86 mg/l</td>
<td>M-167340-01-1</td>
</tr>
<tr>
<td><em>Pseudokirchneriella subcapitata</em> (green alga)</td>
<td>Acute/chronic toxicity</td>
<td>97.62</td>
<td>OECD guideline 201 (GLP). 72-h, flasks. 0.015, 0.035, 0.087, 0.17, 0.54 mg/l.</td>
<td>ErC₅₀ (0-48 h) = 0.408 mg/l NOEC (0-48h, growth rate) =0.087 mg/l</td>
<td>M-259108-01-1</td>
</tr>
<tr>
<td><em>Eisenia fetida andrei</em> (earthworm)</td>
<td>Acute toxicity</td>
<td>97.62</td>
<td>OECD guideline 207 (GLP). 14-d. 0.1, 0.18, 0.32, 0.56, 1.0, 3.2, 10, 100, 178, 316, 562, 1000 mg/kg dry soil.</td>
<td>LC₅₀ (14 d) = 188 mg/kg dry soil</td>
<td>M-253937-03-1</td>
</tr>
<tr>
<td><em>Colinus virginianus</em> (bobwhite quail)</td>
<td>Acute toxicity</td>
<td>97.5</td>
<td>EPA guideline 71-1 (GLP). Doses 20, 33, 54, 90, 148 mg/kg bw.</td>
<td>LD₅₀ = 26 mg/kg bw</td>
<td>M-167304-01-1</td>
</tr>
<tr>
<td><em>Anas platyrhynchos</em> (mallard duck)</td>
<td>Acute toxicity</td>
<td>97.5</td>
<td>EPA guideline 71-1 (GLP). Doses levels of 2, 4, 8, 16, 32 mg/kg bw.</td>
<td>LD₅₀ = 8.7 mg/kg bw</td>
<td>M-167302-01-1</td>
</tr>
<tr>
<td><em>Colinus virginianus</em> (bobwhite quail) **</td>
<td>Short-term toxicity</td>
<td>not known</td>
<td>US EPA guideline 162 70-4. Groups of 10 birds exposed 5 d to diet containing 10.0, 21.5, 46.4, 100.0, 215.0, 464.0, 1000.0, 2150.0, 2750.0, 3500.0, 4500.0 ppm. Observed 3 days.</td>
<td>LC₅₀ = 1770 ppm</td>
<td>M-167138-01-1</td>
</tr>
</tbody>
</table>

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<tr>
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<th>Results</th>
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</tr>
</thead>
<tbody>
<tr>
<td><em>Anas platyrhynchos</em></td>
<td>Short term toxicity</td>
<td>not known</td>
<td>US EPA guideline 162 70-4. Groups of 10 birds exposed 5 d to diet containing 50, 100, 200, 400, 800, 1600, 2400, 3200, 4000 ppm. Observed 3 days.</td>
<td>$\text{LC}_{50} = 477$ ppm</td>
<td>M-167665-01-1</td>
</tr>
</tbody>
</table>
ANNEX 2. REFERENCES

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Year and title of report or publication details

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1978. The subacute dietary LC50 of NC 6897 technical, CR 4799/4 to the bobwhite quail.

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1981. NC 6897 Toxicity and Tumorigenicity to Rats in Long-Term Dietary Administration (Final Report – Reproductive Phase and Main Phase) Main Phase = 104 weeks.
<table>
<thead>
<tr>
<th>Document Number</th>
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<tbody>
<tr>
<td>M-167195-01-1</td>
<td>1981. The Acute Oral Toxicity of Unformulated Bendiocarb (NC 6897, CR 4799/10) to the Male and Female Mouse.</td>
</tr>
<tr>
<td>M-167302-01-1</td>
<td>1984. The acute oral toxicity (LD50) of technical bendiocarb and technical FBC 34570 to the mallard duck.</td>
</tr>
<tr>
<td>M-167304-01-1</td>
<td>1984. The acute oral toxicity (LD50) of technical bendiocarb and technical FBC 34570 to the bobwhite quail.</td>
</tr>
<tr>
<td>M-167338-01-1</td>
<td>1989. Technical Bendiocarb: Analysis of Metaphase Chromosomes from Rat Bone Marrow.</td>
</tr>
<tr>
<td>M-167357-01-1</td>
<td>1992. Technical Bendiocarb Guinea Pig Skin Sensitisation Study (Buehler Test).</td>
</tr>
<tr>
<td>M-167657-01-1</td>
<td>1970. The Toxicology of NC 6897: Acute Toxicity To The Rat of Technical Grade NC 6897.</td>
</tr>
<tr>
<td>M-167665-01-1</td>
<td>1978. Subacute dietary toxicity (LC50) of NC 6897 technical CR 4799/6 to the mallard duck.</td>
</tr>
<tr>
<td>M-167672-01-1</td>
<td>1979. NC 6897 Technical (CR 4799/3) toxicity to Rats when Administered in the Diet for 13 Weeks (Final Report).</td>
</tr>
<tr>
<td>M-248943-01-1</td>
<td>2005. Bendiocarb; Substance pure AE B052020 00 1B99 0005 – Melting point; Boiling point; Thermal stability.</td>
</tr>
<tr>
<td>M-253937-03-1</td>
<td>2007. 2d amendment to study report: Bendiocarb (tech): Acute Toxicity to Earthworms (Eisenia fetida) tested in Artificial Soil.</td>
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</tbody>
</table>
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