



Document Title

**Fenhexamid**

List of additional safety relevant documents  
which led to European approval under Council Directive 91/414/EEC  
and Regulation 1107/2009/EC



M-623825-01-1

*This document is the property of Bayer AG and/or any of its affiliates. Property and/or rights such as intellectual property and copy rights of the owner and third parties may fall under a regulatory data protection regime. Furthermore, this document may be subject to rights of the owner and third parties. Distribution, reproduction and/or publishing and any commercial exploitation, reproduction and use of this document or its contents without the permission of the owner may therefore be prohibited and violate the rights of its owner.*

Date

**2018-05-15**

**Bayer Crop Science Division**



## OWNERSHIP STATEMENT

This document, the data contained in it and copyright therein are owned by Bayer and/or affiliated entities.

No part of the document or any information contained therein may be disclosed to any third party without the prior written authorisation of Bayer and/or affiliated entities.

This document is the property of Bayer AG and/or any of its affiliates. It may be subject to rights such as intellectual property and copyright. Furthermore, this document may fall under a regulatory data protection regime. Consequently, any publication, distribution, reproduction or publishing and any commercial exploitation, distribution, reproduction or publishing and without the permission of the owner and third parties may therefore be prohibited and violate the rights of its owner.



Year	Title Source (where different from company) Company name, Report No., Date
1997	Predicted environmental concentration of KBR 2738 in ground water recharge based on the calculation with PELMO [REDACTED] Report No.: MR-69/97 Edition Number: <a href="#">M-003786-01-1</a> Date: 1997-02-03
1997	Predicted environmental concentration of KBR 2738 in soil based on the calculation with PELMO [REDACTED] Report No.: MR-77/97 Edition Number: <a href="#">M-003784-01-1</a> Date: 1997-02-03
1996	Calculation of the chemical lifetime of KBR 2738 in the troposphere [REDACTED] Report No.: MR-948/96 Edition Number: <a href="#">M-003783-01-1</a> Date: 1996-12-13
1996	Photolysis of KBR 2738 on soil surfaces [REDACTED] Report No.: PF4160 Edition Number: <a href="#">M-002407-01-1</a> Date: 1996-09-26
1996	Adsorption/desorption of KBR 2738 on different soils [REDACTED] Report No.: PF4136 Edition Number: <a href="#">M-003777-01-1</a> Date: 1996-05-22
1997	Determination of the quantum yield and assessment of the environmental half-life of the direct photodegradation of KBR 2738 in water [REDACTED] Report No.: PF4201 Edition Number: <a href="#">M-003778-01-1</a> Date: 1997-02-28
1996	Photolysis of KBR 2738 in aqueous solutions [REDACTED] Report No.: PF4194 Edition Number: <a href="#">M-003780-01-1</a> Date: 1996-12-19



Year	Title Source (where different from company) Company name, Report No., Date
1996	Metabolism of KBR 2738 in apples [REDACTED] Report No.: PF4183 Edition Number: <a href="#">M-003793-01-1</a> MRID#: 44346759 Date: 1996-11-15
1996	Metabolism of KBR 2738 in tomatoes [REDACTED] Report No.: PF4163 Edition Number: <a href="#">M-003797-02-1</a> MRID#: 44346758 Date: 1996-09-13
1996	[Phenyl-UL-14C]KBR 2738: Investigation of the kinetic behaviour and the metabolism in the rat [REDACTED] Report No.: PF4149 Edition Number: <a href="#">M-003789-01-1</a> Date: 1996-06-24
1996	Metabolism of KBR 2738 in grapes [REDACTED] Report No.: PF4077 Edition Number: <a href="#">M-003798-01-1</a> MRID#: 44346757 Date: 1996-02-20
1995	Hydrolysis of KBR 2738 in sterile aqueous buffer solutions [REDACTED] Report No.: PF4098 Edition Number: <a href="#">M-003772-01-1</a> Date: 1995-10-30
2003	Determination of residues of KBR 2738 (50 WG) in tomato in the Federal Republic of Germany, Italy, Belgium and Greece [REDACTED] Report No.: RA-2035/96 Edition Number: <a href="#">M-004940-02-1</a> Date: 1996-11-26
2003	Determination of residues of KBR 2738 50WG in/on plum in the Federal Republic of Germany



Year	Title Source (where different from company) Company name, Report No., Date
	<p>[REDACTED]</p> <p>Report No.: RA-2047/95 Edition Number: <a href="#">M-004226-02-1</a> Date: 1996-07-24</p>
2002	<p>Determination of residues of KBR 2738 50 WG on plum following spray application in Italy and France</p> <p>[REDACTED]</p> <p>Report No.: RA-2048/95 Edition Number: <a href="#">M-004225-02-1</a> Date: 1996-07-24</p>
2001	<p>Determination of residues of KBR 2738 50 WG on grape and table grape in France, Spain and Italy</p> <p>[REDACTED]</p> <p>Report No.: RA-2045/94 Edition Number: <a href="#">M-004223-02-1</a> Date: 1996-05-07</p>
1997	<p>Determination of residues of KBR 2738 (50WG) in black currant in Great Britain and the Federal Republic of Germany</p> <p>[REDACTED]</p> <p>Report No.: RA-2032/96 Edition Number: <a href="#">M-004183-01-1</a> Date: 1997-01-30</p>
1997	<p>Determination of residues of KBR 2738 (50 WG) on tomato in France, Italy and Spain</p> <p>[REDACTED]</p> <p>Report No.: RA-2034/96 Edition Number: <a href="#">M-004938-01-1</a> Date: 1997-01-17</p>
1997	<p>Determination of residues of KBR 2738 (50 WG) on sweet cherry in Italy</p> <p>[REDACTED]</p> <p>Report No.: RA-2050/96 Edition Number: <a href="#">M-004208-01-1</a> Date: 1997-01-17</p>
1997	<p>Determination of residues of KBR 2738 (50WG) on strawberry in France</p> <p>[REDACTED]</p> <p>Report No.: RA-2037/96 Edition Number: <a href="#">M-004202-01-1</a> Date: 1997-01-17</p>



Year	Title Source (where different from company) Company name, Report No., Date
1997	Determination of residues of KBR 2738 (50 WG) in plum in France, Great Britain, Netherlands and the Federal Republic of Germany [REDACTED] Report No.: RA-2036/96 Edition Number: <a href="#">M-004224-01-1</a> Date: 1997-01-16
1996	Determination of residues of KBR 2738 (50 WG) on sweet cherry and sour cherry in the Federal Republic of Germany and France [REDACTED] Report No.: RA-2030/96 Edition Number: <a href="#">M-004209-01-1</a> Date: 1996-11-28
1996	Determination of residues of KBR 2738 (50 WG) on strawberry in Spain, France and Italy [REDACTED] Report No.: RA-2033/96 Edition Number: <a href="#">M-004204-01-1</a> Date: 1996-11-28 GLP/GSP: Yes, unpublished ... also filed KDA 6.3.0.06
1996	Determination of residues of KBR 2738 (50 WG) in raspberry in the Federal Republic of Germany and Great Britain [REDACTED] Report No.: RA-2031/96 Edition Number: <a href="#">M-004179-01-1</a> Date: 1996-11-18
1996	Aqueous hydrolysis of KBR 2738 under conditions of processing studies [REDACTED] Report No.: PF4166 Edition Number: <a href="#">M-004165-01-1</a> Date: 1996-09-16
1996	Determination of residues of KBR 2738 (50 WG) on grape in Spain, Portugal and Italy [REDACTED] Report No.: RA-2057/95 Edition Number: <a href="#">M-004251-01-1</a> Date: 1996-08-23
1996	Determination of residues of KBR 2738 (50 WG) on grape in the Federal Republic of Germany



Year	Title Source (where different from company) Company name, Report No., Date
	<p>[Redacted]</p> <p>Report No.: RA-2056/95 Edition Number: <a href="#">M-004249-01-1</a> Date: 1996-08-21</p>
1996	<p>Determination of the storage stability of KBR 2738 residues in fortified analytical samples of grape, processed commodities of grape, peach, tomato and strawberry.</p> <p>[Redacted]</p> <p>Report No.: MR-603/96 Edition Number: <a href="#">M-003949-01-1</a> Date: 1996-08-13</p>
1996	<p>Determination of residues of KBR 2738 50 WG on tomato in France and Italy</p> <p>[Redacted]</p> <p>Report No.: RA-2066/95 Edition Number: <a href="#">M-004947-01-1</a> Date: 1996-08-06</p>
1996	<p>Determination of residues of KBR 2738 50 WG on tomato in Portugal and France</p> <p>[Redacted]</p> <p>Report No.: RA-2059/95 Edition Number: <a href="#">M-004947-01-1</a> Date: 1996-08-02</p>
1996	<p>Determination of residues of KBR 2738 50WG on raspberry in Great Britain</p> <p>[Redacted]</p> <p>Report No.: RA-2055/95 Edition Number: <a href="#">M-004181-01-1</a> Date: 1996-07-31</p>
1996	<p>Determination of residues of KBR 2738 50WG on strawberry in Italy and France</p> <p>[Redacted]</p> <p>Report No.: RA-2053/95 Edition Number: <a href="#">M-004188-01-1</a> Date: 1996-07-30</p>
1996	<p>Determination of residues of KBR 2738 50WG on strawberry in Spain</p> <p>[Redacted]</p> <p>Report No.: RA-2054/95 Edition Number: <a href="#">M-004187-01-1</a> Date: 1996-07-30</p>



Year	Title Source (where different from company) Company name, Report No., Date
1996	Determination of residues of KBR 2738 50WG on strawberry in the Federal Republic of Germany and France [REDACTED] Report No.: RA-2052/95 Edition Number: <a href="#">M-004191-01-1</a> Date: 1996-07-26
1996	Determination of residues of KBR 2738 50 WG on nectarine and peach in Italy and Spain [REDACTED] Report No.: RA-2046/95 Edition Number: <a href="#">M-004234-01-1</a> Date: 1996-07-25
1996	Determination of residues of KBR 2738 50WG on plum following spray application in Italy [REDACTED] Report No.: RA-3048/95 Edition Number: <a href="#">M-004168-01-1</a> Date: 1996-07-24
1996	Determination of residues of KBR 2738 50 WG on kiwi in Italy [REDACTED] Report No.: RA-2045/95 Edition Number: <a href="#">M-004215-01-1</a> Date: 1996-07-08
1996	Determination of residues of KBR 2738 50WG on plum and sour cherry in the Federal Republic of Germany and Great Britain [REDACTED] Report No.: RA-2092/95 Edition Number: <a href="#">M-004210-01-1</a> Date: 1996-07-05
1996	Determination of residues of KBR 2738 50WG on sweet cherry in Italy [REDACTED] Report No.: RA-2050/95 Edition Number: <a href="#">M-004211-01-1</a> Date: 1996-06-28
1996	Determination of residues of KBR 2738 50 WG on peach in Spain and Italy [REDACTED] Report No.: RA-2116/94 Edition Number: <a href="#">M-004232-01-1</a>





Year	Title Source (where different from company) Company name, Report No., Date
	Date: 1996-05-10
1996	Determination of residues of KBR 2738 50 WG in/on grape in the Federal Republic of Germany [REDACTED] Report No.: RA-2118/94 Edition Number: <a href="#">M-004254-01-1</a> Date: 1996-04-24
1995	Determination of residues of KBR 2738 50WG in/on strawberry in Great Britain and the Federal Republic of Germany [REDACTED] Report No.: RA-2042/94 Edition Number: <a href="#">M-004192-01-1</a> Date: 1995-12-13
1995	Determination of residues of KBR 2738 50WG in/on strawberry in Spain and Italy [REDACTED] Report No.: RA-2118/94 Edition Number: <a href="#">M-004194-01-1</a> Date: 1995-11-17
1995	Determination of residues of KBR 2738 50WG in/on cherry and plum in Italy [REDACTED] Report No.: RA-2082/94 Edition Number: <a href="#">M-004213-01-1</a> Date: 1995-10-19
1995	Determination of residues of KBR 2738 50WG on black currant in Great Britain [REDACTED] Report No.: RA-2051/94 Edition Number: <a href="#">M-004184-01-1</a> Date: 1995-07-10
2009	Effects of fenhexamid WG 50 W (acute contact and oral) on honey bees ( <i>Apis mellifera</i> L.) in the laboratory [REDACTED] Report No.: 52241035 Edition Number: <a href="#">M-360877-01-2</a> Date: 2009-12-16
2013	[biscarboxamide-14C]BCS-CQ88719: Adsorption on four European soils - Final report - Amendment No. 2 Report No.: EnSa-13-0440



Year	Title Source (where different from company) Company name, Report No., Date
	Edition Number: <a href="#">M-460032-03-1</a> Date: 2013-07-19
2013	Fenhexamid (FHM) and metabolite: PEC <sub>gw</sub> FOCUS PEARL, PELMO EUR, Use in vines, strawberries and tomatoes in Europe Report No.: EnSa-13-0778 Edition Number: <a href="#">M-467566-01-1</a> Date: 2013-10-18
2012	Fenhexamid (FHM) and metabolites: PEC <sub>sw,seed</sub> FOCUS EUR, Use in vines, strawberries, and tomatoes in the EU Report No.: MEF-11/917 Edition Number: <a href="#">M-422697-03-1</a> Date: 2012-01-20
1997	Calculation of DT-50 values of metabolites of KBR 2738 formed by photolysis in water [REDACTED] Report No.: MR-96/97 Edition Number: <a href="#">M-004948-01-1</a> Date: 1997-02-14
2013	Determination of the residues of fenhexamid in/on grass after spraying of fenhexamid WG 50 in the field in France (North), Italy, Spain and United Kingdom Report No.: 09-2041 Edition Number: <a href="#">M-384914-02-1</a> Date: 2010-06-25 ... amended: 2013-06-03
2010	Determination of residues of KBR 2738 (50 WG) in processed commodities of tomato [REDACTED] Report No.: RA-3035/06 Edition Number: <a href="#">M-004173-02-1</a> Date: 1996-11-26
2010	Determination of residues of KBR 2738 50WG on grape and grape processing products in France [REDACTED] Report No.: RA-3045/04 Edition Number: <a href="#">M-004171-03-1</a> Date: 1996-05-07
2010	Determination of residues of KBR 2738 (50 WG) in/on grape and grape processed products from the Federal Republic of Germany [REDACTED]



Year	Title Source (where different from company) Company name, Report No., Date
	Report No.: RA-3056/95 Edition Number: <a href="#">M-004170-02-1</a> Date: 1996-08-21
2010	Determination of residues of KBR 2738 (50 WG) on grape in Spain [Redacted] Report No.: RA-3057/95 Edition Number: <a href="#">M-004169-02-1</a> Date: 1996-08-23
2010	Determination of residues of KBR 2738 50 WG on processed commodities from sweet cherry [Redacted] Report No.: RA-3050/95 Edition Number: <a href="#">M-004167-02-1</a> Date: 1996-06-28
2010	Determination of residues of KBR 2738 50 WG in/on grape and processing products from grape in the Federal Republic of Germany [Redacted] Report No.: RA-2118/94 Edition Number: <a href="#">M-004172-02-1</a> Date: 1996-04-24
1998	Determination of residues of KBR 2738 50 WG following spray application in the field on grape in France, Italy, Spain and Portugal [Redacted] Report No.: RA-2183/98 Edition Number: <a href="#">M-005134-01-1</a> Date: 1998-12-15
1998	Determination of residues of KBR 2738 50 WG following spray application in the field on grape in France and Germany [Redacted] Report No.: RA-2182/98 Edition Number: <a href="#">M-005126-01-1</a> Date: 1998-12-15
1997	Determination of residues of KBR 2738 & tolylfluanid 50 WG on strawberry in Italy, France and Spain [Redacted] Report No.: RA-2052/96 Edition Number: <a href="#">M-004943-01-1</a> Date: 1997-01-20



Year	Title Source (where different from company) Company name, Report No., Date
1996	Determination of residues of KBR 2738 & tolylfluanid (50 WG) in Strawberry in the Federal Republik of Germany, Great Britain and France [REDACTED] Report No.: RA-2051/96 Edition Number: <a href="#">M-004944-01-1</a> Date: 1996-11-28
2013	KBR 2738 - Study for subchronic oral toxicity in mice (feeding study over 13 weeks) [REDACTED] Report No.: 28580 Edition Number: <a href="#">M-009771-02-1</a> Date: 1999-03-19
1998	KBR 2738 (Fenhexamid) - Study on subacute inhalation toxicity in rats exposure: 5x6 hrs/week for 4 weeks) according to OECD protocol 412 [REDACTED] Report No.: 25489 Edition Number: <a href="#">M-010326-02-1</a> Date: 1996-09-30
1997	KBR 2738 - Chronic toxicity study in Beagle dogs (52 week feeding study) [REDACTED] Report No.: 25618 Edition Number: <a href="#">M-010293-02-1</a> Date: 1996-11-12
1997	KBR 2738 - Subchronic toxicity study in Beagle dogs (13 week feeding study) [REDACTED] Report No.: 23959 Edition Number: <a href="#">M-010238-03-1</a> Date: 1995-05-05
1997	KBR 2738 - Studies for the skin sensitization effect in guinea pigs (Guinea pig maximization tests according Magnusson and Stigman) [REDACTED] Report No.: 25638 Edition Number: <a href="#">M-010316-02-1</a> Date: 1996-10-16
1997	KBR 2738 - Investigations of subchronic toxicity in Wistar rats (feeding study over 13 weeks with a subsequent recovery period over 4 weeks)



Year	Title Source (where different from company) Company name, Report No., Date
	[REDACTED] Report No.: 23579 Edition Number: <a href="#">M-010131-02-1</a> Date: 1994-12-28
1996	KBR 2738 - Preliminary investigations for a subacute inhalation toxicity study in the rat (x 6h exposures) [REDACTED] Report No.: 20224 Edition Number: <a href="#">M-010326-03-1</a> Date: 1991-05-10
1996	KBR 2738 - Studies of the acute inhalation toxicity in rats [REDACTED] Report No.: 20369 Edition Number: <a href="#">M-010261-03-1</a> Date: 1991-06-21
1996	KBR 2738 - Developmental toxicity study in rabbits after oral administration [REDACTED] Report No.: 20733 Edition Number: <a href="#">M-010151-02-1</a> MRID#: 44346801 Date: 1995-02-10
1996	KBR 2738 - Oncogenicity study in B6C3F1 mice (administration in diet over 2 years) [REDACTED] Report No.: 23523 Edition Number: <a href="#">M-010370-01-1</a> MRID#: 44346895 Date: 1996-10-14
1996	KBR 2738 - Study on chronic toxicity and carcinogenicity in Wistar rats (administration in the diet over 2 years) [REDACTED] Report No.: 25520 Edition Number: <a href="#">M-010347-02-1</a> MRID#: 44346806 Date: 1996-10-14
1996	KBR 2738 - Study for skin and eye irritation/corrosion in rabbits [REDACTED]



Year	Title Source (where different from company) Company name, Report No., Date
	Report No.: 19884 Edition Number: <a href="#">M-010406-02-1</a> Date: 1991-01-17
1996	KBR 2738 - Subacute oral toxicity study on Wistar rats (administration per gavage over 28 days) [Redacted] Report No.: 23160 Edition Number: <a href="#">M-010100-02-1</a> Date: 1994-07-07
1996	KBR 2738 - Studies on skin sensitizing effect on guinea pigs (Buehler Test) [Redacted] Report No.: 20973 Edition Number: <a href="#">M-010386-02-1</a> Date: 1992-01-16
1996	KBR 2738 - Acute oral neurotoxicity screening study in Wistar rats [Redacted] Report No.: 24745 Edition Number: <a href="#">M-010207-01-1</a> Date: 1996-02-22
1995	KBR 2738 - In vitro mammalian chromosome aberration test with Chinese hamster ovary (CHO) cells [Redacted] Report No.: 24405 Edition Number: <a href="#">M-010307-01-1</a> Date: 1995-10-24
1995	KBR 2738 - Subacute dermal toxicity study on rabbits Bayer AG, Wuppertal, Germany Report No.: 23715 Edition Number: <a href="#">M-010293-01-1</a> MRID# 44346780 Date: 1995-02-06
1994	KBR 2738 - Determination of the test substance in plasma and urine after subchronic feeding to Wistar rats over 8 weeks [Redacted] Report No.: 23678 Edition Number: <a href="#">M-004998-01-1</a> Date: 1994-12-28



Year	Title Source (where different from company) Company name, Report No., Date
1994	KBR 2738 - Mutagenicity study for the detection of induced forward mutations in the V79-HGPRT assay in vitro [REDACTED] Report No.: 23529 Edition Number: <a href="#">M-005000-01-1</a> Date: 1994-12-07
1993	KBR 2738 - Micronucleus test on the mouse [REDACTED] Report No.: 22625 Edition Number: <a href="#">M-010301-01-1</a> Date: 1993-10-21
1993	KBR 2738 - Range-finding subchronic toxicological investigation for a 2-year feeding study with B6C3F1 mice (administered in feed over approx. 14 weeks) [REDACTED] Report No.: 22332 Edition Number: <a href="#">M-010281-01-1</a> MRID#: 44946778 Date: 1993-06-22
1992	KBR 2738 - Mutagenicity test on unscheduled DNA synthesis in rat liver primary cell cultures in vitro [REDACTED] Report No.: 21312 Edition Number: <a href="#">M-010253-01-1</a> Date: 1992-04-29
1991	KBR 2738 - Study for acute dermal toxicity in rats [REDACTED] Report No.: 20639 Edition Number: <a href="#">M-010360-01-1</a> Date: 1991-09-20
1991	KBR 2738 - Study for acute oral toxicity in mice [REDACTED] Report No.: 20638 Edition Number: <a href="#">M-010359-01-1</a> Date: 1991-09-20
1991	Safety evaluation of KBR 2738: Four-week dietary toxicity study in dogs [REDACTED]



Year	Title Source (where different from company) Company name, Report No., Date
	Report No.: R5319 Edition Number: <a href="#">M-010455-01-1</a> Date: 1991-06-14
1991	KBR 2738 - Salmonella/microsome test [REDACTED] Report No.: 20307 Edition Number: <a href="#">M-010410-01-1</a> Date: 1991-05-29

This document is the property of Bayer AG and/or any of its affiliates. It may be subject to rights such as intellectual property and/or publishing and/or protection regime. Furthermore, this document may fall under a regulatory data protection regime. Consequently, any publication, distribution, reproduction and/or publishing and/or commercial exploitation, use of this document or its contents without the permission of the owner may therefore be prohibited and violate the rights of its owner.