Review of the existing maximum residue levels for bromadiolone according to Article 12 of Regulation (EC) No 396/2005

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Abstract
According to Article 12 of Regulation (EC) No 396/2005, EFSA has reviewed the maximum residue levels (MRLs) currently established at European level for the pesticide active substance bromadiolone. Considering that this active substance is not authorised for use on edible crops within the EU, that no MRLs are established by the Codex Alimentarius Commission (codex maximum residue limits) and that no import tolerances were notified to EFSA, residues of bromadiolone are not expected to occur in any plant or animal commodity. Even though information on the limit of quantification (LOQ) of bromadiolone was provided by the European Union Reference Laboratories for Pesticide Residues, the available data were not sufficient to derive a residue definition for enforcement against potential illegal uses.

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Keywords: bromadiolone, MRL review, Regulation (EC) No 396/2005, consumer risk assessment, long-acting anticoagulant, rodenticide

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Summary

Bromadiolone was included in Annex I to Directive 91/414/EEC on 1 June 2011 by Commission Implementing Directive 2011/48/EU, and has been deemed to be approved under Regulation (EC) No 1107/2009, in accordance with Commission Implementing Regulation (EU) No 540/2011, as amended by Commission Implementing Regulation (EU) No 541/2011. As bromadiolone was approved after the entry into force of Regulation (EC) No 396/2005 on 2 September 2008, the European Food Safety Authority (EFSA) is required to provide a reasoned opinion on the review of the existing maximum residue levels (MRLs) for that active substance in compliance with Article 12(1) of the aforementioned regulation. To collect the relevant pesticide residues data, EFSA asked Sweden, the designated rapporteur Member State (RMS), to complete the Pesticide Residues Overview File (PROFile) and to prepare a supporting evaluation report. The evaluation report provided by the RMS was made available to the Member States. The need for preparation of a PROFile was not considered necessary in view of the specific provisions of Commission Implementing Directive 2011/48/EU. A request for additional information was addressed to the Member States in the framework of a completeness check period, which was initiated by EFSA on 21 October 2016 and finalised on 21 December 2016. After having considered the information provided, EFSA prepared a completeness check report which was made available to Member States on 20 January 2017.

Based on the conclusions derived by EFSA in the framework of Directive 91/414/EEC and the additional information provided by the European Union Reference Laboratories for Pesticide Residues (EURLs), EFSA prepared in February 2017 a draft reasoned opinion, which was circulated to Member States for consultation via a written procedure. Comments received by 22 March 2017 were considered during the finalisation of this reasoned opinion. The following conclusions are derived.

Residues of bromadiolone are not expected to occur in any plant or animal commodities because its use as a pesticide is not intended for direct application on any food or feed crop. Codex maximum residue limits (CXLs) are not available for bromadiolone and no uses authorised in third countries were notified to the RMS. A consumer risk assessment is therefore in principle not required. However, to assist risk managers in applying the most appropriate enforcement measures against illegal uses, EFSA assessed the available data with particular attention to the analytical methods, the toxicological reference values and the possibility and nature of residues in plant and livestock.

Due to a lack of data regarding plant and livestock metabolism, EFSA is not in a position to derive any residue definition. According to the information provided by the EURLs, bromadiolone can be enforced at a limit of quantification (LOQ) of 0.1 mg/kg in dry and high oil commodities, and of 0.01 mg/kg in high water and high acid commodities. However, since toxicological reference values for dietary exposure were not allocated to bromadiolone, it is not possible to verify whether these LOQs provide sufficient consumer protection.

As sufficient information was available to demonstrate that bromadiolone is highly toxic to mammals on ingestion, it is in any case not recommended for inclusion into Annex IV of Regulation (EC) No 396/2005. EFSA also recommends that adequate restrictions are being imposed on the authorised products by Member States to avoid contamination of stored food and feed crops.
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Background

Regulation (EC) No 396/2005\(^1\) (hereinafter referred to as ‘the Regulation’) establishes the rules governing the setting and the review of pesticide maximum residue levels (MRLs) at European level. Article 12(1) of that Regulation stipulates that the European Food Safety Authority (EFSA) shall provide within 12 months from the date of the inclusion or non-inclusion of an active substance in Annex I to Directive 91/414/EEC\(^2\) a reasoned opinion on the review of the existing MRLs for that active substance. As bromadiolone was included in Annex I to Council Directive 91/414/EEC on 1 June 2011 by means of Commission Implementing Directive 2011/48/EU\(^3\), and has been deemed to be approved under Regulation (EC) No 1107/2009\(^4\), in accordance with Commission Implementing Regulation (EU) No 540/2011\(^5\), as amended by Commission Implementing Regulation (EU) No 541/2011\(^6\), EFSA initiated the review of all existing MRLs for that active substance.

According to the legal provisions, EFSA shall base its reasoned opinion in particular on the relevant assessment report prepared under Directive 91/414/EEC. It should be noted, however, that, in the framework of Directive 91/414/EEC, only a few representative uses are evaluated, whereas MRLs set out in Regulation (EC) No 396/2005 should accommodate all uses authorised within the European Union (EU), and uses authorised in third countries that have a significant impact on international trade. The information included in the assessment report prepared under Directive 91/414/EEC is therefore insufficient for the assessment of all existing MRLs for a given active substance.

To gain an overview of the pesticide residues data that have been considered for the setting of the existing MRLs, EFSA developed the Pesticide Residues Overview File (PROFile). The PROFile is an inventory of all pesticide residues data relevant to the risk assessment and MRL setting for a given active substance. This includes data on:

- the nature and magnitude of residues in primary crops;
- the nature and magnitude of residues in processed commodities;
- the nature and magnitude of residues in rotational crops;
- the nature and magnitude of residues in livestock commodities;
- the analytical methods for enforcement of the proposed MRLs.

Sweden, the designated rapporteur Member State (RMS) in the framework of Directive 91/414/EEC, was asked to complete the PROFile for bromadiolone and to prepare a supporting evaluation report (Sweden, 2011). The supporting evaluation report was submitted to EFSA on 29 August 2011 and made available to Member States. The need for preparation of a PROFile was not considered necessary in view of the specific provisions of Commission Implementing Directive 2011/48/EU. A request for additional information was addressed to the Member States in the framework of a completeness check period which was initiated by EFSA on 21 October 2016 and finalised on 21 December 2016. No additional evaluation reports were provided by Member States as no uses with direct application on any food or feed crops were reported for this active substance. An evaluation report on analytical methods has been submitted by the European Union Reference Laboratories for Pesticide Residues (EURL, 2016). After having considered this information, EFSA prepared a completeness check report which was made available to all Member States on 20 January 2017. No further clarifications were sought from Member States.

Based on the conclusions derived by EFSA in the framework of Directive 91/414/EEC and the additional information provided by the EURLs, EFSA prepared in February 2017 a draft reasoned

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\(^1\) Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. OJ L 70, 16.3.2005, p. 1–16.

\(^2\) Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.8.1991, p. 1–32. Repealed by Regulation (EC) No 1107/2009.

\(^3\) Commission Implementing Directive 2011/48/EU of 15 April 2011 amending Council Directive 91/414/EEC to include bromadiolone as active substance and amending Commission Decision 2008/941/EC. OJ L 102, 16.4.2011, p. 28–31.

\(^4\) Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309, 24.11.2009, p. 1–50.

\(^5\) Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances. OJ L 153, 11.6.2011, p. 1–186.

\(^6\) Commission Implementing Regulation (EU) No 541/2011 of 1 June 2011 amending Implementing Regulation (EU) No 540/2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances. OJ L 153, 11.6.2011, p. 187–188.
opinion, which was submitted to Member States for commenting via a written procedure. All comments received by 22 March 2017 were evaluated by EFSA.

The evaluation report submitted by the RMS (Sweden, 2011) and the evaluation report submitted by the EURL (2016) are considered as supporting documents to this reasoned opinion and, thus, are made publicly available.

In addition, key supporting documents to this reasoned opinion are the completeness check report (EFSA, 2017a) and the Member States consultation report (EFSA, 2017b). These reports are developed to address all issues raised in the course of the review, from the initial completeness check to the reasoned opinion and are made publicly available. Bromadiolone residues are not expected to occur on edible crops and no toxicological reference values for dietary exposure were derived. Therefore, chronic and acute dietary exposure calculations using the EFSA Pesticide Residues Intake Model (PRIMo) could not be performed and a PROFile was not considered necessary in the framework of this review.

**Terms of Reference**

According to Article 12 of Regulation (EC) No 396/2005, EFSA shall provide a reasoned opinion on:

- the inclusion of the active substance in Annex IV to the Regulation, when appropriate;
- the necessity of setting new MRLs for the active substance or deleting/modifying existing MRLs set out in Annex II or III of the Regulation;
- the inclusion of the recommended MRLs in Annex II or III to the Regulation;
- the setting of specific processing factors as referred to in Article 20(2) of the Regulation.

**The active substance and its use pattern**

Bromadiolone is the ISO common name for 3-[(1RS,3RS;1RS,3SR)-3-(4'-bromobiphenyl-4-yl)-3-hydroxy-1-phenylpropyl]-4-hydroxycoumarin (IUPAC).

Bromadiolone belongs to the second generation of long-acting anticoagulant rodenticides. The mode of action is common to the family of antivitamin K (AVK) rodenticides, i.e. interfering with prothrombin synthesis by blocking the regeneration of vitamin K in the liver, disrupting the clotting mechanisms and increasing the tendency to haemorrhages. This results in decrease of prothrombin time, internal haemorrhages and subsequent death.

The chemical structure of bromadiolone is reported in Appendix D.

Bromadiolone was evaluated in the framework of Directive 91/414/EEC with Sweden designated as RMS. The representative use supported for the peer review process comprised placement of baits in rodent tunnels in non-crop areas to control rodents which may damage agricultural crops. Following the peer review, which was carried out by EFSA in accordance with Commission Regulation (EC) No 33/2008, a decision on inclusion of the active substance in Annex I to Directive 91/414/EEC was published by means of Commission Implementing Directive 2011/48/EU, which entered into force on 1 June 2011. According to Regulation (EU) No 540/2011, bromadiolone is deemed to have been approved under Regulation (EC) No 1107/2009. This approval is restricted only to uses as a rodenticide in the form of preprepared baits placed into the rodent tunnels, with the nominal concentration of the active substance in the plant protection products not exceeding 50 mg/kg. In addition, authorisations may be granted for uses by professional users only.

The EU MRLs for bromadiolone are set to default (0.01 mg/kg) according to Article 18(1)(b) of Regulation (EC) No 396/2005 and codex maximum residue limits (CXLs) are not available.

For the purpose of this MRL review, no uses authorised within the EU with direct application on any food or feed crops were reported for this active substance. The details of the authorised Good Agricultural Practices (GAPs) for bromadiolone are given in Appendix A. The RMS did not report any uses authorised in third countries that might have a significant impact on international trade.

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7 Commission Regulation (EC) No 33/2008 of 17 January 2008 laying down detailed rules for the application of Council Directive 91/414/EEC as regards a regular and an accelerated procedure for the assessment of active substances which were part of the programme of work referred to in Article 8(2) of that Directive but have not been included into its Annex I. OJ L 15, 18.1.2008, p. 5–12.
Assessment

European consumers are not expected to be exposed to residues of bromadiolone and a consumer risk assessment is, in principle, not required considering that the use of bromadiolone is only authorised within the EU on forestry, amenity, in and around buildings, sewage systems and waste dumps (non-crop areas) and on products for storage (where no direct contact with food or feed is expected), that no CXLs are available for bromadiolone and that no uses authorised in third countries were notified to the RMS.

Risk managers might have an interest, however, to apply enforcement measures against potential illegal uses of bromadiolone within the EU, such as the presence of illegitimate residue levels in imported products. To assist risk managers in applying the most appropriate enforcement measures, EFSA assessed the available information with particular attention to the analytical methods and the toxicological reference values. The possibility and nature of residues in plant and livestock was also considered.

The assessment of EFSA is mainly based on the draft assessment report (DAR) (Sweden, 2007), the additional report prepared under Commission Regulation (EC) No 33/2008 (Sweden, 2009), as well as on the review report on bromadiolone (European Commission, 2011) and the EFSA conclusion on the peer review (EFSA, 2010). The evaluation report submitted by the RMS in the framework of this MRL review (Sweden, 2011) was considered as additional information.

The toxicological assessment of bromadiolone was peer reviewed under Commission Regulation (EC) No 33/2008; however, an allocation of toxicological reference values for dietary exposure was not considered necessary because a direct application of bromadiolone on edible crops is not intended. Nevertheless, during the peer review, values for an acute and subchronic/chronic acute reference dose (AOEL) of $0.0023 \text{ \mu g/kg bodyweight (bw)}$ and of $0.0012 \text{ \mu g/kg bw per day}$, respectively were set (EFSA, 2010; European Commission, 2011).

Due to the lack of data regarding the plant and livestock metabolism, EFSA is not in a position to derive any residue definition. According to the information provided by the EURLs, bromadiolone can be enforced at a LOQ of $0.1 \text{ mg/kg}$ for dry and high oil commodities, and of $0.01 \text{ mg/kg}$ in high water and high acid commodities (EURL, 2016). However, since toxicological reference values for dietary exposure were not allocated to bromadiolone, it was not possible to verify whether these LOQs were sufficient to protect consumers.

More detailed information on the available data and on the conclusions derived by EFSA can be retrieved from the list of end points reported in Appendix B.

Conclusions and Recommendations

Residues of bromadiolone are not expected to occur in any plant or animal commodities because its use as a pesticide is not intended for direct application on any food or feed crop. CXLs are not available for bromadiolone and no uses authorised in third countries were notified to the RMS.

A consumer risk assessment is therefore in principle not required. However, to assist risk managers in applying the most appropriate enforcement measures against illegal uses, EFSA assessed the available data with particular attention to the analytical methods, the toxicological reference values and the possibility and nature of residues in plant and livestock.

Due to a lack of data regarding plant and livestock metabolism, EFSA is not in a position to derive any residue definition. According to the information provided by the EURLs, bromadiolone can be enforced at a LOQ of $0.1 \text{ mg/kg}$ for dry and high oil commodities, and of $0.01 \text{ mg/kg}$ in high water and high acid commodities. However, since toxicological reference values for dietary exposure were not allocated to bromadiolone, it is not possible to verify whether these LOQs provide sufficient consumer protection.

As sufficient information was available to demonstrate that bromadiolone is highly toxic to mammals on ingestion, it is in any case not recommended for inclusion into Annex IV of Regulation (EC) No 396/2005. EFSA also recommends that adequate restrictions are being imposed on the authorised products by Member States to avoid contamination of stored food and feed crops.
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Abbreviations

a.s. active substance
AOEL acceptable operator exposure level
AVK antivitamin K rodenticides
bw body weight
CXL codex maximum residue limit
DAR draft assessment report
EURLs EU Reference Laboratories for Pesticide Residues (former CRLs)
GAP Good Agricultural Practice
ISO International Organisation for Standardization
IUPAC International Union of Pure and Applied Chemistry
LC–MS/MS liquid chromatography with tandem mass spectrometry
LOQ limit of quantification
MRL maximum residue level
MS Member States
MS mass spectrometry detector
MS/MS tandem mass spectrometry detector
NEU northern European Union
PHI preharvest interval
PRIMo (EFSA) Pesticide Residues Intake Model
PROFile (EFSA) Pesticide Residues Overview File
RA risk assessment
RMS rapporteur Member State
SEU southern European Union
SMILES simplified molecular-input line-entry system
## Appendix A – Summary of authorised uses considered for the review of MRLs

| Crop and/or situation                        | NEU, SEU, MS or country | F G or I(3) | Pests or group of pests controlled                                      | Preparation | Application | Application rate per treatment | PHI (days)(d) | Remarks |
|---------------------------------------------|-------------------------|-------------|-------------------------------------------------|-------------|-------------|-------------------------------|----------------|---------|
| All cultures                                | BE                      | –           | –                                               | CB**        | 10 g/l      | –                             | –              | –       |
| –                                           | BG                      | –           | Field voles                                     | –           | 0.005%      | –                             | 7 g/ha         | –       |
| Non-crop areas, Forest tree nursery, forest plantations | CZ F                    | Microtus arvalis, Microtus agrestis, Clethrionomys glareolus, Arvicol a terrestreis, Apodemus | GB**        | 0.005%      | –           | –                             | 10 kg product/ha (0.50 g a.s./ha) | 3 days for entry  |
| Non crop areas, products for storage        | DE                      | RD*         | Common and brown rat                             | RB**        | 0.05 g/kg   | –                             | –              | –       |
|                                            | RX*                     | Common and brown rat, house mice                 | RB**        | 0.05 g/kg   | –           | –                             | –              | –       |
|                                            | HB*                     | Common and brown rat                             | RB**        | 0.05 g/kg   | –           | –                             | –              | –       |
|                                            | HR*                     | Common/brown rat, house mice                     | RB**        | 0.05 g/kg   | –           | –                             | –              | –       |
| Farmland, turfs                             | IT                      | F           | Target pest, underground and meadow voles       | RB**        | 5 mg/100 g  | –                             | –              | mg a.s./hole (min/max): 0.75–1.5 |
|                                            |                         |             | Moles                                           | RB**        | 5 mg a.s./100 g | –                             | 7 days          | –       |

Preparation: CB**: 10 g/l; GB**: 0.005%; RB**: 0.05 g/kg; RX**: 0.05 g/kg; HB**: 0.05 g/kg; HR**: 0.05 g/kg

Application: CB**: Product applied on carrot pieces of 1.5 cubic cm, put in 15 cm deep galleries

Remarks: Max rate per seed/plant or area: 1 L/50 kg baits; 25 kg baits/ha = 10 kg per 1,000 m galleries

Interval between application: Depending on the infestation

Range of growth stages & season: 1–2

Number min-max: 7 days

Water L/ha min-max: mg a.s./hole (min/max): 0.75–1.5

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| Crop and/or situation | NEU, SEU, MS or country | Pest or group of pests controlled | Preparation Type\(^{(b)}\) | Conc. a.s. | Method kind | Application Range of growth stages & season\(^{(c)}\) | Number min-max | Interval between application (min) | Application rate per treatment g a.s./ha min-max | Water L/ha min-max | g a.s./ha min-max | PHI (days)\(^{(d)}\) | Remarks |
|-----------------------|-------------------------|-----------------------------------|-----------------|----------|-------------|------------------|--------------|-----------------------------|---------------------|-----------------|----------------|-------------|---------|
| -                     | PT                      | Rodents                           | AB**            | 0.01%    |             | –                | –             | –                           | –                   | –               | –               | –          | –       |
|                       |                         |                                   | BB**            | 0.005%   |             | –                | –             | –                           | –                   | –               | –               | –          | –       |
|                       |                         |                                   | RB**            | 0.005%   |             | –                | –             | –                           | –                   | –               | –               | –          | –       |
|                       |                         |                                   | In baits        |           |             | –                | –             | –                           | –                   | –               | –               | –          | –       |
|                       |                         |                                   | 0.005%          |           |             | –                | –             | –                           | –                   | –               | –               | –          | –       |
|                       |                         |                                   | See crop and/or situation |           |             | –                | –             | –                           | –                   | –               | –               | –          | –       |
| In/around buildings, waste dumps (baits in secure stations), sewage systems | SE | Rats and mice | RB** | 0.005% | See crop and/or situation | – | – | – | – | – | – | – | – |
|                       |                         |                                   | PA**/BB**       | 0.005%   |             | –                | –             | –                           | –                   | –               | –               | –          | –       |

NEU: northern European Union; SEU: southern European Union; MS: Member State; a.s.: active substance.

*: HB: Amateur gardening, outside areas surrounding buildings; HR: Amateur gardening, rooms; RD: Around the outside of buildings; RX: In rooms.

**: AB: grain bait; BB: block bait; CB: bait concentrate; GB: granular bait; PA: paste; RB: bait, ready for use.

(a): Outdoor or field use (F), greenhouse application (G) or indoor application (I).

(b): CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide.

(c): Growth stage range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including, where relevant, information on season at time of application.

(d): PHI: minimum preharvest interval.
Appendix B – List of end points

B.1. Residues in plants

Not applicable for the authorised uses of bromadiolone.

| Question                                                                 | Answer          |
|-------------------------------------------------------------------------|-----------------|
| Can a general residue definition be proposed for primary crops?         | Not applicable  |
| Rotational crop and primary crop metabolism similar?                    | Not applicable  |
| Residue pattern in processed commodities similar to residue pattern in raw commodities? | Not applicable  |
| Plant residue definition for monitoring (RD-Mo)                         | Not applicable  |
| Plant residue definition for risk assessment (RD-RA)                    | Not applicable  |
| Conversion factor (monitoring to risk assessment)                       | Not applicable  |
| Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs) | High oil and dry commodities: |
|                                                                         | • LC-MS/MS, LOQ: 0.1 mg/kg for bromadiolone in almonds, wheat, rye, rice, barley (EUR, 2016) |
|                                                                         | High water and high acid commodities: |
|                                                                         | • LC-MS/MS, LOQ: 0.01 mg/kg for bromadiolone in cucumber and orange juice (EURL, 2016) |

B.2. Residues in livestock

Not expected for the authorised uses of bromadiolone.

B.3. Consumer risk assessment

Not needed for the authorised uses of bromadiolone.

B.4. Proposed MRLs

Not applicable for the authorised uses of bromadiolone.
Appendix C – Decision tree for deriving MRL recommendations (not applicable for bromadiolone)

Review of the existing MRLs for bromadiolone.

Evaluation of the GAPs and available residues data at EU level

Consumer risk assessment for GAPs evaluated at EU level - EU scenarios

Comparison with CXLs

Recommendations resulting from EU authorisations and import tolerances

Appendix C – Decision tree for deriving MRL recommendations (not applicable for bromadiolone)
Comparison of the EU recommendation with the existing CXL

- CXL available?
  - Yes: Continue
  - No: Continue

- RD comparable?
  - Yes: Continue
  - No: Continue

- CXL higher?
  - Yes: Continue
  - No: Continue

Consumer risk assessment with consideration of the existing CXL

- CXL supported by data?
  - Yes: Continue
  - No: Continue

- Risk identified?
  - Yes: Continue
  - No: Continue

Recommendations with consideration of the existing CXL

1. Maintain EU recommendation if no CXL is available.
2. Maintain EU recommendation indicating CXL is not compatible.
3. Maintain EU recommendation indicating CXL is not safe for consumers.
4. Maintain current CXL or EU recommendation.
5. Maintain EU recommendation indicating higher CXL is not safe for consumers.
6. Maintain EU recommendation; higher CXL is not safe for consumer.
7. CXL is recommended; EU recommendation is covered as well.
### Appendix D – Used compound codes

| Code/trivial name | Chemical name/SMILES notation | Structural formula |
|-------------------|--------------------------------|--------------------|
| Bromadiolone      | 3-[(1RS,3RS;1RS,3SR)-3-(4′-Bromobiphenyl-4-yl)-3-hydroxy-1-phenylpropyl]-4-hydroxycoumarin Brc1ccc(cc1)c2ccc(cc2)C(O)CC(C3=C(O) c4ccccc4OC3=C(O)c5ccccc5 | ![Structural formula graphic] |

SMILES: simplified molecular-input line-entry system.