

IV

(Informazzjoni)

INFORMAZZJONI MINN ISTITUZZJONIJIET, KORPI, UFFIĊĠI U AĠENZIJI
TAL-UNJONI EWROPEA

IL-KUMMISSJONI EWROPEA

Komunikazzjoni tal-Kummissjoni fil-qafas tal-implimentazzjoni tar-Regolament tal-Kummissjoni (UE) Nru 283/2013 tal-1 ta' Marzu 2013 li jistipula r-rekwiżiti tad-dejta ghas-sustanzi attivi, skont ir-Regolament (KE) Nru 1107/2009 tal-Parlament Ewropew u tal-Kunsill dwar it-tqeghid fis-suq ta' prodotti għall-protezzjoni tal-pjanti ⁽¹⁾

(Test b'relevanza għaż-ŻEE)

(2013/C 95/01)

Din il-Komunikazzjoni tal-Kummissjoni tissodisfa l-Punt 6 tal-Introduzzjoni tal-Anness tar-Regolament (UE) Nru 283/2013 li jipprovdli li għal finijiet ta' informazzjoni u armonizzazzjoni, il-lista tal-metodi ta' ttestjar u d-dokumenti ta' gwida relevanti għall-implimentazzjoni ta' dan ir-Regolament, għandhom jiġu ppubblikati f'Il-Ġurnal Uffiċjali tal-Unjoni Ewropea. It-tabella ta' hawn taht tirrappreżenta din il-lista u se tiġi aġġornata b'mod regolari.

| Referenza għal Parti A tal-Anness tar-Regolament (UE) Nru 283/2013 | Metodi ta' ttestjar ⁽¹⁾ | Dokumenti ta' gwida ⁽²⁾ |
|--|--|---|
| 1. IDENTITÀ TAS-SUSTANZA ATTIVA | — | WHO/FAO. 2002. Pesticide Specifications. Manual on development and use of FAO and WHO specifications for pesticides. Series FAO Plant Production and Protection Papers, Rome, 2002 ⁽³⁾ EU Guidance Document on the assessment of the equivalence of technical materials of substances regulated under Regulation (EC) No. 1107/2009 ⁽⁴⁾ (SANCO/10597/2003 rev. 10.1) |
| 2. KARATTERISTIĠI FIŻIĠI U KIMIĠI TAS-SUSTANZA ATTIVA | — | |
| 2.1. Il-punt ta' tidwib u ta' toghlija | Method A.1 Melting/Freezing temperature (Annex to Regulation (EC) No 440/2008). OECD Test Guideline 102: Melting Point/ Melting Range Method A.2 Boiling temperature (Annex to Regulation (EC) No 440/2008). OECD Test Guideline 103: Boiling point | — |

⁽¹⁾ ĠU L 93, 3.4.2013, p. 1.

| Referenza għal Parti A tal-Anness tar-Regolament (UE) Nru 283/2013 | Metodi ta' ttestjar ⁽¹⁾ | Dokumenti ta' gwida ⁽²⁾ |
|---|--|------------------------------------|
| 2.2. Il-pressjoni tal-fwar, volatilità | Method A.4 Vapour pressure (Annex to Regulation (EC) No 440/2008). OECD Test Guideline 104: Vapour Pressure | — |
| 2.3. Id-dehra (stat fiżiku, kulur) | — | — |
| 2.4. L-ispettri (UV/VIS, IR, NMR, MS), estinzjoni molari fil-frekwenzi rilevanti, purità ottika | OECD Test Guideline 101: UV-VIS Absorption Spectra | — |
| 2.5. Is-solubilità fl-ilma | Method A.6 Water solubility (Annex to Regulation (EC) No 440/2008). OECD Test Guideline 105: Water Solubility | — |
| 2.6. Is-solubilità f'solventi organiċi | CIPAC Method MT 181: Solubility in organic solvents | — |
| 2.7. Il-koeffiċjent tas-sehem ta' n-octanol/ilma | Method A.8 Partition coefficient (Annex to Regulation (EC) No 440/2008). OECD Test Guideline 107: Partition coefficient, shake-flask method <i>Jekk kompost ikun tensjoattiv (kif iddefinit mill-Metodu A.5 Tensjoni tal-wiċċ) il-metodu tat-thawwid tal-flask fil-metodu A.8 jista' jkun applikabbli jekk fir-rapport ikun ċar li ma nholqu l-ebda problemi (eż. is-separazzjonijiet f'fażijiet). Il-metodu HPLC deskritt fil-Metodu A.8 mhux applikabbli għall-komposti li huma attivi fil-wiċċ.</i> | — |
| 2.8. Id-dissocjazzjoni fl-ilma | OECD Test Guideline 112: Dissociation Constants in Water. | — |
| 2.9. Il-fjammabbiltà u l-awtotiżhin | <u>Fjammabbiltà:</u> Methods A.10 Flammability (solids), A.11 Flammability (gases), A.12 Flammability (contact with water) (Annex to Regulation (EC) No 440/2008), as appropriate; Test N.1: test method for readily combustible solids (UN RTDG Manual of Tests and Criteria ST/SG/AC.10/11/Rev. 5 – Part III, section 33.2.1.4) <u>Awtotiżhin:</u> Methods A.15 Auto-ignition temperature (liquids and gases), A16 Relative self-ignition temperature for solids, (Annex to Regulation (EC) No 440/2008), as appropriate. Test N.4: test method for self-heating substances (UN RTDG Manual of Tests and Criteria ST/SG/AC.10/11/Rev. 5 – Part III, section 33.3.1.6) | — |

| Referenza għal Parti A tal-Anness tar-Regolament (UE) Nru 283/2013 | Metodi ta' ttestjar ⁽¹⁾ | Dokumenti ta' gwida ⁽²⁾ |
|--|---|------------------------------------|
| 2.10. Il-punt ta' fjamabbiltà | <p>Method A.9 Flash-point (Annex to Regulation (EC) No 440/2008) - only closed cup methods should be used.</p> <p>Test methods according to table 2.6.3 of Annex I, Part 2 of Regulation (EC) No 1272/2008 ⁽³⁾ (liquids);</p> | — |
| 2.11. Karatteristiċi splussivi | <p>Method A.14 Explosive properties (Annex to Regulation (EC) No 440/2008)</p> <p>United Nations Recommendations on the Transport of Dangerous Goods (UN RTDG) Manual of Tests and Criteria ST/SG/AC.10/11/ Rev. 5 - Part I (Test series), section 11.</p> | — |
| 2.12. It-tensjoni tal-wiċċ | <p>Method A.5 Surface tension (Annex to Regulation (EC) No 440/2008).</p> <p>OECD Test Guideline 115: Surface tension of aqueous solutions</p> | — |
| 2.13. Il-karatteristiċi ossidanti | <p>Solidi: Method A.17 Oxidising properties (solids) (Annex to Regulation (EC) No 440/2008)</p> <p>Likwidi: Method A.21 Oxidising properties (liquids) (Annex to Regulation (EC) No 440/2008)</p> <p>United Nations Recommendations on the Transport of Dangerous Goods (UN RTDG) Manual of Tests and Criteria ST/SG/AC.10/11/Rev. 4 - Part I (Test series).</p> <p>Test O.1: Test for oxidizing solids (UN RTDG Manual of Tests and Criteria ST/SG/AC.10/11/Rev. 5 - Part III, section 34.4.1)</p> <p>Test O.2: Test for oxidizing liquids (UN RTDG Manual of Tests and Criteria ST/SG/AC.10/11/Rev. 5 - Part III, section 34.4.2)</p> | — |
| 2.14. Studji ohrajn | Metodi ta' ttestjar rrapportati fl-Anness I, il-Parti II tar-Regolament (KE) Nru 1272/2008 | — |
| 3. IKTAR INFORMAZZJONI DWAR IS-SUSTANZA ATTIVA | EPPO standard series PP1: Efficacy evaluation of plant protection products ⁽⁶⁾ | — |
| 3.1. L-użu tas-sustanza attiva | — | — |
| 3.2. Il-funzjoni | — | — |
| 3.3. L-effetti fuq organiżmi dannużi | — | — |
| 3.4. Il-firxa tal-użu mbassra | — | — |

| Referenza għal Parti A tal-Anness tar-Regolament (UE) Nru 283/2013 | Metodi ta' ttestjar ⁽¹⁾ | Dokumenti ta' gwida ⁽²⁾ |
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| 3.5. L-organizmi dannużi kkontrollati u l-ghelejjeġ jew il-prodotti protetti jew ittrattati | — | — |
| 3.6. Il-modalità tal-azzjoni | — | — |
| 3.7. Informazzjoni dwar l-okkorrenza jew l-okkorrenza possibbli tal-iżvilupp tar-reżistenza u strateġiji ta' ġestjoni xierqa | EPP0 standard PP 1/213: Resistance risk analysis | — |
| 3.8. Il-metodi u l-prekawzjonijiet rakkomandati li jikkoncernaw il-manipulazzjoni, il-ħżin, it-trasport jew in-nar | — | — |
| 3.9. Il-proċeduri għall-qerda jew id-dekontaminazzjoni | — | — |
| 3.10. Il-miżuri ta' emerġenza fil-każ ta' incident | — | — |
| 4. METODI ANALITIĊI | — | <p><u>Materjal tekniku u preparazzjonijiet:</u></p> <p>EU guidance document on analytical methods for the analysis of technical material and preparation (SANCO/3030/99 rev. 4)</p> <p><u>Residwi:</u></p> <p>EU guidance document on analytical methods for the determination of residues (Post-registration monitoring and control) (SANCO/825/00 rev. 8.1, 2010)</p> <p>EU guidance document for generating and reporting methods of analysis in support of pre-registration data requirements (SANCO/3029/99 rev. 4).</p> <p>OECD (2007). Guidance Document on Pesticide Residue Analytical Methods. Environment, Health and Safety Publications. Series on Testing and Assessment No. 72 and Series on Pesticides No. 39.</p> |
| 5. L-ISTUDJI TOSSIKOLOĠIĊI U TAL-METABOLIZMU | — | — |
| 5.1. Studji dwar l-assorbiment, id-distribuzzjoni, il-metabolizmu u t-tneħħija fil-mammiferi | — | <p>EU Working Document. Draft Guidance for the Setting and Application of Acceptable Operator Exposure Levels (AOEL's) (SANCO 7531 rev. 10, 10.07.2006)</p> <p>OECD (2010) Guidance for the Derivation of an Acute Reference Dose" OECD Series on testing and assessment, No. 124, 08-Jun-2010</p> |

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|---|--|------------------------------------|
| 5.1.1. L-assorbiment, id-distri-buzzjoni, il-metaboliżmu u t-tnehhija wara espożizzjoni mir-rotta orali | Method B.36 Toxicokinetics (Annex to Regulation (EC) No 440/2008). OECD Test Guideline 417: Toxicokinetics | — |
| 5.1.2. L-assorbiment, id-distri-buzzjoni, il-metaboliżmu u t-tnehhija wara espożizzjoni minn rotot oħra | Method B.36 Toxicokinetics (Annex to Regulation (EC) No 440/2008). OECD Test Guideline 417: Toxicokinetics | — |
| 5.2. Tossicità akuta | — | — |
| 5.2.1. Orali | Method B.1 bis Acute oral toxicity - fixed dose procedure (Annex to Regulation (EC) No 440/2008). Method B.1 tris Acute oral toxicity - Acute toxic class method (Annex to Regulation (EC) No 440/2008). OECD Test Guideline 420: Acute oral toxicity: fixed dose procedure OECD Test Guideline 423: Acute oral toxicity: acute toxic class method OECD Test Guideline 425: Acute oral toxicity: up-and-down procedure OECD Test Guideline No 401: Acute oral toxicity (only acceptable, if performed before December 2002) | — |
| 5.2.2. Dermal | Method B.3 Acute toxicity (dermal) (Annex to Regulation (EC) No 440/2008). OECD Test Guideline 402: Acute Dermal Toxicity | — |
| 5.2.3. Tehid man-nifs | Method B.2 Acute toxicity (inhalation) (Annex to Regulation (EC) No 440/2008). OECD Test Guideline 403: Acute Inhalation Toxicity OECD Test Guideline 436: Acute Inhalation Toxicity – Acute Toxic Class Method | — |
| 5.2.4. Irritazzjoni tal-ġilda | Method B.4 Acute toxicity: dermal irritation/corrosion (Annex to Regulation (EC) No 440/2008). Method B.40 <i>In vitro</i> skin corrosion: transcutaneous electrical resistance test (TER) (Annex to Regulation (EC) No 440/2008). Method B.40 bis <i>In vitro</i> skin corrosion: human skin model test (Annex to Regulation (EC) No 440/2008). OECD Test Guideline 404: Acute Dermal Irritation/Corrosion OECD Test Guideline 431: <i>In vitro</i> Skin Corrosion: Human Skin Model Test | — |

| Referenza għal Parti A tal-Anness tar-Regolament (UE) Nru 283/2013 | Metodi ta' ttestjar ⁽¹⁾ | Dokumenti ta' gwida ⁽²⁾ |
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| | <p>OECD Test Guideline 430: <i>In vitro</i> Skin Corrosion: Transcutaneous Electrical Resistance Test</p> <p>OECD Test Guideline 435: <i>In vitro</i> Membrane Barrier Test Method for Skin Corrosion</p> <p>OECD Test Guideline 439: <i>In vitro</i> Skin Irritation: Reconstructed Human Epidermis Test Method</p> <p>Method B.46 <i>In vitro</i> skin irritation: reconstructed human epidermis model test (Annex III of Regulation (EC) No 761/2009 ⁽⁷⁾).</p> | |
| 5.2.5. Irritazzjoni tal-ghajnejn | <p>Method B.5 Acute toxicity: eye irritation/corrosion (Annex to Regulation (EC) No 440/2008).</p> <p>OECD Test Guideline 405: Acute eye irritation/corrosion</p> <p>OECD Test Guideline 437: Bovine Corneal Opacity and Permeability Test Method for Identifying Ocular Corrosives and Severe Irritants</p> <p>OECD Test Guideline 438: Isolated Chicken Eye Test Method for Identifying Ocular Corrosives and Severe Irritants</p> <p>Method B.47 Bovine corneal opacity and permeability test method for identifying ocular corrosives and severe irritants (Annex of Regulation (EC) No 1152/2010 ⁽⁸⁾)</p> <p>Method B.48 Isolated chicken eye test method for identifying ocular corrosives and severe irritants (Annex of Regulation (EC) No 1152/2010)</p> | — |
| 5.2.6. Is-sensitizzazzjoni tal-ġilda | <p>Method B.42 Skin sensitisation: Local lymph node assay (Annex to Regulation (EC) No 440/2008).</p> <p>Method B.6 Skin sensitisation (Annex to Regulation (EC) No 440/2008).</p> <p>OECD Test Guideline 429: Skin Sensitisation – Local Lymph Node Assay</p> <p>OECD Test Guideline 406: Skin sensitisation</p> <p>OECD Test Guideline 442A: Skin Sensitisation – Local Lymph Node Assay: DA</p> <p>OECD Test Guideline 442B: Skin Sensitisation – Local Lymph Node Assay: BrdU-ELISA</p> | — |
| 5.2.7. Fototossicità | <p>Method B.41 <i>In vitro</i> 3T3 NRU phototoxicity test (Annex to Regulation (EC) No 440/2008).</p> | — |

| Referenza għal Parti A tal-Anness tar-Regolament (UE) Nru 283/2013 | Metodi ta' ttestjar ⁽¹⁾ | Dokumenti ta' gwida ⁽²⁾ |
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| | <p>OECD Test Guideline 432: <i>In vitro</i> 3T3 NRU Phototoxicity Test</p> <p>OECD Test Guideline 101: UV-VIS Absorption Spectra</p> | |
| 5.3. It-tossocità fuq perjodu qasir | — | — |
| 5.3.1. L-istudju orali ta' 28 ġurnata | <p>Method B.7 Repeated dose (28 days) toxicity (oral) (Annex to Regulation (EC) No 440/2008).</p> <p>OECD Test Guideline 407: Repeated dose 28-day oral toxicity study in rodents</p> | — |
| 5.3.2. L-istudju orali ta' 90 ġurnata | <p>Method B.26 Sub-chronic oral toxicity test. Repeated dose 90-day oral toxicity study in rodents (Annex to Regulation (EC) No 440/2008).</p> <p>Method B.27 Sub-chronic oral toxicity test. Repeated dose 90-day oral toxicity study in non-rodents (Annex to Regulation (EC) No 440/2008).</p> <p>OECD Test Guideline 408: Repeated dose 90-day oral toxicity study in rodents</p> <p>OECD Test Guideline 409: Repeated dose 90-day oral toxicity study in non-rodents</p> | — |
| 5.3.3. Rotot ohrajn | <p>Method B8 Repeated dose (28 days) toxicity (inhalation) (Annex to Regulation (EC) No 440/2008).</p> <p>Method B.9 Repeated dose (28 days) toxicity (dermal) (Annex to Regulation (EC) No 440/2008).</p> <p>Method B.28 Sub-chronic dermal toxicity test: 90-day repeated dermal dose study using rodent species (Annex to Regulation (EC) No 440/2008).</p> <p>Method B.29 Sub-chronic inhalation toxicity study 90-day repeated inhalation dose study using rodent species (Annex to Regulation (EC) No 440/2008).</p> <p>OECD Test Guideline 410: Repeated dose dermal toxicity: 21/28-day study.</p> <p>OECD Test Guideline 411: Subchronic dermal toxicity: 90-day study.</p> <p>OECD Test Guideline 412: Subacute inhalation toxicity: 28-day study.</p> <p>OECD Test Guideline 413: Subchronic inhalation toxicity: 90-day study.</p> | — |
| 5.4. Ittestjar tal-ġenotossicITÀ | — | — |

| Referenza għal Parti A tal-Anness tar-Regolament (UE) Nru 283/2013 | Metodi ta' ttestjar ⁽¹⁾ | Dokumenti ta' gwida ⁽²⁾ |
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| 5.4.1. Studji <i>in vitro</i> | <p>Method B.13/14 Mutagenicity - reverse mutation test using bacteria (Annex to Regulation (EC) No 440/2008).</p> <p>Method B.10 Mutagenicity - <i>In vitro</i> mammalian chromosome aberration test (Annex to Regulation (EC) No 440/2008).</p> <p>Method B.17 – Mutagenicity – <i>In vitro</i> mammalian cell gene mutation test (Annex to Regulation (EC) No 440/2008). - For this test mouse lymphoma assay is recommended.</p> <p>OECD Test Guideline 471: Bacterial Reverse Mutation Test</p> <p>OECD Test Guideline 473: <i>In vitro</i> Mammalian Chromosome Aberration Test</p> <p>OECD Test Guideline 476: <i>In vitro</i> Mammalian Cell Gene Mutation Test - For this test mouse lymphoma assay is recommended.</p> <p>OECD Test Guideline 487. <i>In vitro</i> Mammalian Cell Micronucleus Test.</p> <p><i>In vitro</i> Comet assay could be used when justified.</p> | — |
| 5.4.2. Studji <i>in vivo</i> f'ċelloli somatiċi | <p>Method B.12 - Mutagenicity - <i>In vivo</i> mammalian erythrocyte micronucleus test (Annex to Regulation (EC) No 440/2008).</p> <p>Method B.11 - Mutagenicity – <i>In vivo</i> mammalian bone-marrow chromosome aberration test (Annex to Regulation (EC) No 440/2008).</p> <p>OECD Test Guideline 474: Mammalian Erythrocyte Micronucleus Test</p> <p>OECD Test Guideline 475: Mammalian Bone Marrow Chromosome Aberration Test</p> <p>OECD Test Guideline 486: Unscheduled DNA synthesis (UDS) - Test with mammalian liver cells <i>in vivo</i>.</p> <p>OECD Test Guideline 488: Transgenic Rodent Somatic and Germ Cell Gene Mutation Assays</p> <p>Method B.39 Unscheduled DNA synthesis (UDS) - Test with mammalian liver cells <i>in vivo</i> (Annex to Regulation (EC) No 440/2008).</p> <p><i>In vivo</i> Comet assay could be used when justified and considering EFSA (2012). Minimum Criteria for the acceptance of <i>in vivo</i> alkaline Comet Assay Reports. EFSA Journal 2012;10(11):2977</p> | |

| Referenza għal Parti A tal-Anness tar-Regolament (UE) Nru 283/2013 | Metodi ta' ttestjar ⁽¹⁾ | Dokumenti ta' gwida ⁽²⁾ |
|--|--|------------------------------------|
| 5.4.3. Studji <i>in vivo</i> f'ċelloli ġerminali | <p>Method B.23 Mammalian spermatogonial chromosome aberration test (Annex to Regulation (EC) No 440/2008).</p> <p>OECD Test Guideline 483: Mammalian Spermatogonial Chromosome Aberration Test.</p> <p>OECD Test Guideline 488: Transgenic Rodent Somatic and Germ Cell Gene Mutation Assays.</p> | — |
| 5.5. It-tossicità fuq perjodu twil u l-karċinogenicità | <p>Method B.30 Chronic toxicity test (Annex to Regulation (EC) No 440/2008).</p> <p>Method B.32 Carcinogenicity test (Annex to Regulation (EC) No 440/2008).</p> <p>Method B.33 Combined chronic toxicity/carcinogenicity test (Annex to Regulation (EC) No 440/2008).</p> <p>OECD Test Guideline 451: Carcinogenicity Studies.</p> <p>OECD Test Guideline 452: Chronic Toxicity Studies.</p> <p>OECD Test Guideline 453: Combined Chronic Toxicity/Carcinogenicity Studies.</p> | — |
| 5.6. It-tossicità għar-riproduzzjoni | | — |
| 5.6.1. Studji fuq ħafna generazzjonijiet | <p>Method B.35 Two-generation reproduction toxicity study (Annex to Regulation (EC) No 440/2008).</p> <p>OECD Test Guideline 416: Two-Generation Reproduction Toxicity.</p> <p>OECD Test Guideline 443: Extended One-generation Reproduction Toxicity.</p> | — |
| 5.6.2. Studji tal-effett tossiku fuq l-iżvilupp | <p>Method B.31 Prenatal developmental toxicity study (Annex to Regulation (EC) No 440/2008).</p> <p>OECD Test Guideline 414: Prenatal developmental toxicity study.</p> <p>OECD Test Guideline 426: Developmental neurotoxicity study.</p> | — |
| 5.7. Studji tan-newrotossicità | | — |
| 5.7.1. Studji tan-newrotossicità f'annimali li jgerrmu | <p>Method B.43 Neurotoxicity study in rodents (Annex to Regulation (EC) No 440/2008).</p> <p>OECD Test Guideline 424: Neurotoxicity study in rodents.</p> | — |

| Referenza għal Parti A tal-Anness tar-Regolament (UE) Nru 283/2013 | Metodi ta' ttestjar ⁽¹⁾ | Dokumenti ta' gwida ⁽²⁾ |
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| 5.7.2. Studji tal-polinewropatija ttardjata | <p>Method B.37 Delayed neurotoxicity of organophosphorus substances after acute exposure (Annex to Regulation (EC) No 440/2008).</p> <p>Method B.38 Delayed neurotoxicity of organophosphorus substances 28-day repeated dose study (Annex to Regulation (EC) No 440/2008).</p> <p>OECD Test Guideline 418: Delayed Neurotoxicity of Organophosphorus Substances Following Acute Exposure.</p> <p>OECD Test Guideline 419: Delayed Neurotoxicity of Organophosphorus Substances: 28-day Repeated Dose Study.</p> | — |
| 5.8. Studji tossikoloġiċi oħrajn | — | — |
| 5.8.1. Studji tossikoloġiċi tal-metaboliti | | EU Guidance document on the assessment of the relevance of metabolites in groundwater of substances regulated under Council Directive 91/414/EEC (SANCO/221/2000 – rev.10. final) |
| 5.8.2. Studji addizzjonali dwar is-sustanza attiva | — | OECD (2010) Guidance for conducting a single exposure toxicity study. IN: OECD (2010) Guidance for the Derivation of an Acute Reference Dose" OECD Series on testing and assessment, No. 124, 08-Jun-2010 |
| 5.8.3. Karatteristiċi li jfixxlu l-endokrina | <p>OECD Test Guideline 456: H295R Steroidogenesis Assay</p> <p>OECD Test Guideline 441: Hershberger Bioassay in Rats, A Short-term Screening Assay for (Anti)Androgenic Properties</p> <p>OECD Test Guideline 455: Stably Transfected Human Estrogen Receptor-alpha Transcriptional Activation Assay for Detection of Estrogenic Agonist-Activity of Chemicals</p> <p>OECD Test Guideline 440: Uterotrophic Bioassay in Rodents A short-term screening test for oestrogenic properties</p> <p>OCSPP Guideline 890.1500: Pubertal Development and Thyroid Function in Intact Juvenile/Peripubertal Male Rats Assay</p> <p>OCSPP Guideline 890.1450: Pubertal Development and Thyroid Function in Intact Juvenile/Peripubertal Female Rats Assay</p> <p>U.S. Environmental Protection Agency (2007): 15-Day Intact Adult Male Rat Assay</p> | — |
| 5.9. Deġta medika | — | — |

| Referenza ghal Parti A tal-Anness tar-Regolament (UE) Nru 283/2013 | Metodi ta' ttestjar ⁽¹⁾ | Dokumenti ta' gwida ⁽²⁾ |
|---|---|---|
| 6. RESIDWI FIL- PRODOTTI, L-IKEL JEW L-GHALF ITTRATTATI JEW FUQHOM | | OECD (2009). Guidance Document on Overview of Residue Chemistry Studies (as revised in 2009). Environment, Health and Safety Publications. Series on Testing and Assessment No. 64 and Series on Pesticides No. 32. |
| 6.1 L-istabilità tar-residwi matul il-ħażna | OECD Test Guideline 506: Stability of pesticide residues in stored commodities | — |
| 6.2 Il-metaboliżmu, id-distri- buzzjoni u l-espressjoni tar-residwi | — | — |
| 6.2.1. Pjanti | OECD Test Guideline 501: Metabolism in crops | — |
| 6.2.2. Tjur | OECD Test Guideline 503: Metabolism in livestock | — |
| 6.2.3. Ruminanti li jaħilbu | OECD Test Guideline 503: Metabolism in livestock | — |
| 6.2.4. Hnieżer | OECD Test Guideline 503: Metabolism in livestock | — |
| 6.2.5. Hut | — | — |
| 6.3. Il-kobor tal-provi tar- residwi fil-pjanti | OECD Test Guideline 509: Crop field trials | OECD (2011) Guidance Document on Crop Field Trials (Series on Testing and Assessment No. 164 and Series on Pesticides No. 66) |
| 6.4. Studji dwar l-ġhalf | — | — |
| 6.4.1. Tjur | OECD Test Guideline 505: Residues in livestock. | — |
| 6.4.2. Ruminanti | OECD Test Guideline 505: Residues in livestock. | — |
| 6.4.3. Hnieżer | OECD Test Guideline 505: Residues in livestock. | — |
| 6.4.4. Hut | — | — |
| 6.5. L-effetti tal-ipproċessar | — | — |
| 6.5.1. In-natura tar-residwu | OECD Test Guideline 507: Nature of the pesticide residues in processed commodities – High temperature hydrolysis. | — |
| 6.5.2. Id-distribuzzjoni tar- residwu fil-qoxra u l-polpa mhux tal-ikel | OECD Test Guideline 508: Magnitude of the pesticide residues in processed commodities. OECD Test Guideline 509: Crop field trials. | — |
| 6.5.3. Il-kobor tar-residwi fi prodotti pproċessati | OECD Test Guideline 508: Magnitude of the pesticide residues in processed commodities. | OECD (2008). Guidance document on magnitude of pesticide residues in processed commodities. Environment, Health and Safety Publications. Series on Testing and Assessment No. 96. |
| 6.6. Ir-residwi fl-għelejjet ta' rotazzjoni | — | — |

| Referenza għal Parti A tal-Anness tar-Regolament (UE) Nru 283/2013 | Metodi ta' ttestjar ⁽¹⁾ | Dokumenti ta' gwida ⁽²⁾ |
|--|---|---|
| 6.6.1. Il-metaboliżmu fl-ghelejjet ta' rotazzjoni | OECD Test Guideline 502: Metabolism in rotational crops. | — |
| 6.6.2. Il-kobor tar-residwi fl-ghelejjet ta' rotazzjoni | OECD Test Guideline 504: Residues in rotational crops (limited field studies). OECD Test Guideline 509: Crop field trials. | — |
| 6.7. Id-definizzjonijiet proposti ta' residwu u l-livelli massimi ta' residwu | — | — |
| 6.7.1. Id-definizzjonijiet proposti ta' residwu | — | OECD (2009). Guidance Document on the Definition of Residues. Environment, Health and Safety Publications. Series on Testing and Assessment No. 63 and Series on Pesticides No. 31 |
| 6.7.2. Livelli massimi ta' residwu proposti (MRLs) u ġustifikazzjoni tal-aċċettabilità tal-livelli proposti | — | EU guidance document "Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs" (SANCO 7525/VI/95 rev. 9, March 2011). OECD MRL calculator (2011) |
| 6.7.3. Livelli massimi ta' residwu proposti (MRLs) u ġustifikazzjoni tal-aċċettabilità tal-livelli proposti għal prodotti importati (tolleranza tal-importazzjoni) | — | EU guidance document "Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs" (SANCO 7525/VI/95 rev. 9, March 2011). OECD MRL calculator (2011) |
| 6.8. Intervalli proposti tas-sigurtà | — | EU guidance document "Calculation of Maximum Residue Levels and Safety Intervals e.g. Pre-harvest Intervals" (SANCO 7039/VI/95, 22/7/1997) |
| 6.9. Stima tal-espożizzjoni potenzjali u reali permezz tad-dieta u sorsi oħra | — | EFSA calculation model Pesticide Residue Intake Model "PRIMO" - revision 2 ^(?) |
| 6.10. Studji oħrajn | — | — |
| 6.10.1. Il-livell ta' residwu fl-ghabra tad-dakra u l-prodotti tan-naħal | — | — |
| 7. DESTIN U MĠIBA FL-AMBJENT | — | — |
| 7.1. Destin u mġiba fil-hamrija | OECD Test Guideline 307: Aerobic and anaerobic transformation in soil. ISO 10381-6:2009 Soil quality. Sampling. Guidance on the collection, handling and storage of soil under aerobic conditions for the assessment of microbiological processes, biomass and diversity in the laboratory | — |
| 7.1.1. Ir-rotta tad-degradazzjoni fil-hamrija | — | — |

| Referenza għal Parti A tal-Anness tar-Regolament (UE) Nru 283/2013 | Metodi ta' ttestjar ⁽¹⁾ | Dokumenti ta' gwida ⁽²⁾ |
|--|--|---|
| 7.1.1.1. Id-degradazzjoni aerobika | OECD Test Guideline 307: Aerobic and anaerobic transformation in soil. | — |
| 7.1.1.2. Id-degradazzjoni anaerobika | OECD Test Guideline 307: Aerobic and anaerobic transformation in soil. | — |
| 7.1.1.3. Il-fotolizi tal-hamrija | — | SETAC 1995 – Procedures for assessing the environmental fate and ecotoxicity of pesticides |
| 7.1.2. Ir-rata ta' degradazzjoni fil-hamrija | — | EFSA (2010). EFSA Panel on Plant Protection Products; Guidance for evaluating laboratory and field dissipation studies to obtain DegT ₅₀ values of plant protection products in soil. EFSA Journal 2010;8(12):1936. |
| 7.1.2.1. Studji tal-laboratorji | OECD Test Guideline 307: Aerobic and anaerobic transformation in soil. | FOCUS Ground Water FOCUS Degradation Kinetics EFSA (2007). Scientific Opinion on a request from EFSA related to the default Q10 value used to describe the temperature effect on transformation rates of pesticides in soil. The EFSA Journal (2007) 622, 1-32. |
| 7.1.2.2. Studji fuq il-post | US EPA OCSPP 835.6100: Terrestrial field dissipation | FOCUS Ground Water FOCUS Degradation Kinetics FOCUS soil persistence models <u>Aspetti tekniċi li jghinu biex jiddeterminaw ir-rati ta' degradazzjoni fil-hamrija fl-istudji fuq il-post, jistgħu jiġu kkonsultati fi:</u> Regulatory Directive DIR2006-01: Harmonization of Guidance for Terrestrial Field Studies of Pesticide Dissipation under the North American Free Trade Agreement. Pest Management Regulatory Agency (PMRA). Health Canada ⁽¹⁰⁾ |
| 7.1.3. Assorbiment u dissorbiment fil-hamrija | — | — |
| 7.1.3.1. Assorbiment u dissorbiment | OECD Test Guideline 106: Adsorption - Desorption Using a Batch Equilibrium Method OECD Test Guideline 121: Estimation of the Adsorption Coefficient (K _{oc}) on Soil and on Sewage Sludge using High Performance Liquid Chromatography (HPLC) OECD Test Guideline 307: Aerobic and anaerobic transformation in soil. | FOCUS Ground Water European Commission. Scientific Committee on plants SCP/KOC/002-Final. Opinion of the Scientific Committee on Plants on methods for the determination of the organic carbon adsorption coefficient (K _{oc}) for a plant protection product active substance in the context of Council Directive 91/414/EEC (18 July 2002) ⁽¹¹⁾ |
| 7.1.3.2. Sorbiment li għadda ż-żmien fuq | — | FOCUS Ground Water |
| 7.1.4. Mobilità fil-hamrija | — | — |

| Referenza għal Parti A tal-Anness tar-Regolament (UE) Nru 283/2013 | Metodi ta' ttestjar ⁽¹⁾ | Dokumenti ta' gwida ⁽²⁾ |
|--|---|---|
| 7.1.4.1. Studji ta' lissija fuq kolonna | OECD Test Guideline 312: Leaching in Soil Columns | — |
| 7.1.4.2. Studji lisimetriċi | OECD Guidance Document 22: Guidance Document for the Performance Of Out-door Monolith Lysimeter Studies | FOCUS Ground Water |
| 7.1.4.3. Studji tal-lissija fil-post | — | FOCUS Ground Water |
| 7.2. Destin u mġiba fl-ilma u s-sediment | — | — |
| 7.2.1. Ir-rotta u r-rata ta' degradazzjoni fis-sistemi akkwatiċi (degradazzjoni kimika u fotokimika) | — | — |
| 7.2.1.1. Id-degradazzjoni idrolitika | OECD Test Guideline 111: Hydrolysis as a Function of pH | — |
| 7.2.1.2. Id-degradazzjoni fotokimika diretta | OECD Test Guideline 316: Phototransformation of Chemicals in Water - Direct Photolysis | — |
| 7.2.1.3. Id-degradazzjoni fotokimika indiretta | — | — |
| 7.2.2. Ir-rotta u r-rata ta' degradazzjoni bijoloġika fis-sistemi akkwatiċi | — | — |
| 7.2.2.1. "Bijodegradabilità immedjata" | Method C.4 Determination of "ready" biodegradability (Annex to Regulation (EC) No 440/2008). OECD Guideline Test 301: Ready Biodegradability (301 A - F) | — |
| 7.2.2.2. Mineralizzazzjoni aerobika fl-ilma tal-wiċċ | OECD Test Guideline 309: Aerobic Mineralisation in Surface Water - Simulation Biodegradation Test | ECHA Guidance on information requirements and chemical safety assessment Chapter R 11: PBT Assessment |
| 7.2.2.3. Studju tal-ilma/sediment | OECD Test Guideline 308: Aerobic and Anaerobic Transformation in Aquatic Sediment Systems | FOCUS Surface Water FOCUS Degradation Kinetics |
| 7.2.2.4. Studju tal-ilma/sediment irradjat | OECD Test Guideline 308: Aerobic and Anaerobic Transformation in Aquatic Sediment Systems | — |
| 7.2.3. Degradazzjoni fiż-żona ta' saturazzjoni | — | — |
| 7.3. Destin u mġiba fl-arja | — | FOCUS Air |
| 7.3.1. Ir-rotta u r-rata ta' degradazzjoni fl-arja | — | — |
| 7.3.2. Trasport bl-arja | — | — |
| 7.3.3. Effetti lokali u globali | — | — |

| Referenza għal Parti A tal-Anness tar-Regolament (UE) Nru 283/2013 | Metodi ta' ttestjar ⁽¹⁾ | Dokumenti ta' gwida ⁽²⁾ |
|---|---|--|
| 7.4. Definizzjoni tar-residwu | — | — |
| 7.4.1. Id-definizzjoni tar-residwu għall-valutazzjoni tar-riskju | — | — |
| 7.4.2. Id-definizzjoni tar-residwu għall-monitoraġġ | — | — |
| 7.5. Dejta dwar il-monitoraġġ | — | — |
| 8. STUDJI EKOTOSSIKO-LOGIĊI | — | OECD series of testing and assessment Number 54. "Current approaches in the statistical analysis of ecotoxicity data: a guidance to application" |
| 8.1. Effetti fuq l-ghasafar u vertebrati terrestri oħrajn | — | EFSA (2009) Guidance of EFSA - Risk assessment for birds and mammals. EFSA Journal 2009; 7(12):1438. |
| 8.1.1. Effetti fuq l-ghasafar | — | — |
| 8.1.1.1. Tossicità orali akuta għall-ghasafar | OECD Test Guideline No 223: Avian acute oral toxicity study jew US EPA OCSPP 850.2100: Avian oral toxicity test | — |
| 8.1.1.2. Tossicità dijetetika għall-ghasafar fuq perjodu qasir | OECD Test Guideline 205: Avian Dietary Toxicity Test jew US EPA OCSPP 850.2200: Avian dietary toxicity test. | — |
| 8.1.1.3. Tossicità subkronika u riproduttiva għall-ghasafar | OECD Test Guideline 206: Avian Reproduction Test jew US EPA OCSPP 850.2300: Avian Reproduction Test | — |
| 8.1.2. Effetti fuq vertebrati terrestri li mhumiex ghasafar | — | — |
| 8.1.2.1. Tossicità orali akuta għall-mammiferi | — | — |
| 8.1.2.2. Tossicità riproduttiva u fitul għall-mammiferi | — | — |
| 8.1.3. Bijokoncentrazzjoni tas-sustanza attiva fil-priża ta' ghasafar u mammiferi | — | — |
| 8.1.4. Effetti fuq l-annimali vertebrati terrestri (ghasafar, mammiferi, rettili u amfibji) | OECD Test Guideline 231: Amphibian Metamorphosis Assay | — |

| Referenza għal Parti A tal-Anness tar-Regolament (UE) Nru 283/2013 | Metodi ta' ttestjar ⁽¹⁾ | Dokumenti ta' gwida ⁽²⁾ |
|--|---|--|
| 8.1.5. Karatteristiċi li jfixxlu l-endokrina | — | Workshop report on OECD countries activities regarding testing, assessment and management of endocrine disrupters. Series on testing and assessment No 118. 18 January 2010. |
| 8.2. Effetti fuq organiżmi akkwatiċi | — | EU Guidance Document on Aquatic Ecotoxicology (SANCO/3268/2001 rev.4) OECD (2000). Guidance document on aquatic toxicity testing of difficult substances and mixtures. OECD series on testing and assessment Number 23. |
| 8.2.1. Tossicità akuta għall-ħut | OECD Test Guideline 203: Fish, Acute Toxicity Test ⁽¹²⁾ | OECD. Series on testing and assessment No 126. Short guidance on the threshold approach for acute fish toxicity. ENV/JM/MONO(2010)17 |
| 8.2.2. Tossicità kronika u fit-tul għall-ħut | — | — |
| 8.2.2.1. Test tat-tossicità fi stadju bikri tal-ħajja tal-ħut | OECD Test Guideline 210: Fish, Early-Life Stage Toxicity Test | — |
| 8.2.2.2. Test taċ-ċiklu shiħ tal-ħajja tal-ħut | US EPA protocol OCSPP 850.1500 Fish life cycle toxicity. | — |
| 8.2.2.3. Il-bijokonċentrazzjoni fil-ħut | — | — |
| 8.2.3. Karatteristiċi li jfixxlu l-endokrina | OECD Test Guideline 229: Fish Short Term Reproduction Assay OECD Test Guideline 230: 21-day Fish Assay: A Short-Term Screening for Oestrogenic and Androgenic Activity, and Aromatase Inhibition OECD Test Guideline 231: Amphibian Metamorphosis Assay OECD Test Guideline 234 Fish Sexual Development Test | Workshop report on OECD countries activities regarding testing, assessment and management of endocrine disrupters. Series on testing and assessment No 118. 18 January 2010. |
| 8.2.4. Tossicità akuta għall-invertebrati akkwatiċi | — | EU Guidance Document on Aquatic Ecotoxicology (SANCO/3268/2001 rev.4) |
| 8.2.4.1. Tossicità akuta għad- <i>Daphnia magna</i> | OECD Test Guideline 202: <i>Daphnia sp.</i> Acute Immobilisation Test | — |
| 8.2.4.2. Tossicità akuta għal speċi ta' invertebrat akkwatiku addizzjonali | US EPA OCSPP 850.1035 Mysid Acute Toxicity Test | — |
| 8.2.5. Tossicità kronika u fit-tul għall-invertebrati akkwatiċi | — | — |
| 8.2.5.1. Effett tossiku fuq ir-riproduzzjoni u l-iżvilupp għad- <i>Daphnia magna</i> | OECD Test Guideline 211: <i>Daphnia magna</i> Reproduction Test | — |

| Referenza għal Parti A tal-Anness tar-Regolament (UE) Nru 283/2013 | Metodi ta' ttestjar ⁽¹⁾ | Dokumenti ta' gwida ⁽²⁾ |
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| 8.2.5.2. Effett tossiku fuq ir-riproduzzjoni u l-iżvilupp għal speċi invertebrata akkwatika addizzjonali | US EPA OCSP 850.1350 Mysisid Chronic Toxicity Test | — |
| 8.2.5.3. L-iżvilupp u t-faċċar fi <i>Chironomus riparius</i> | OECD Test Guideline 219: Sediment-Water Chironomid Toxicity Using Spiked Water [B'mod ġenerali, sistema ta' sediment tal-ilma (jiġifieri OECD 219) tkopri aħjar ir-rotot ta' espożizzjoni li huma tipiċi għall-prodotti ta' protezzjoni tal-pjanti] | — |
| 8.2.5.4. Organizmi li jgħixu fis-sediment | OECD Test Guideline 218: Sediment-Water Chironomid Toxicity Using Spiked Sediment | — |
| 8.2.6. Effetti fuq it- <i>tkabbir tal-alga</i> | — | — |
| 8.2.6.1. Effetti fuq it- <i>tkabbir tal-alga ħadra</i> | OECD Test Guideline 201: Algae growth inhibition test | — |
| 8.2.6.2. Effetti fuq it- <i>tkabbir ta' speċi oħrajn ta' alga</i> | OECD Test Guideline 201: Algae growth inhibition test. | — |
| 8.2.7. Effetti fuq il- <i>makrofiti akkwatiċi</i> | <p>OECD Test Guideline 221: <i>Lemna sp.</i> Growth Inhibition Test</p> <p>ASTM E1913-04: Standard Guide for Conducting Static, Axenic, 14-Day Phytotoxicity Tests in Test Tubes with the Submersed Aquatic Macrophyte, <i>Myriophyllum sibiricum Komarov</i></p> <p>Development of a proposed test method for the rooted aquatic macrophyte <i>Myriophyllum sp.</i> In: Maltby L, Arnold D, Arts G, et al (2010). Aquatic Macrophyte Risk Assessment for pesticides (AMRAP). SETAC Press & CRC Press, Taylor & Francis Group, Boca Raton, London, New York, p. 46-56.</p> | |
| 8.2.8. Iktar ittestjar fuq <i>organizmi akkwatiċi</i> | — | EU Guidance Document on Aquatic Ecotoxicology (SANCO/3268/2001 rev.4) |
| 8.3. Effetti fuq l- <i>artropodi</i> | — | EU Guidance Document on Terrestrial Ecotoxicology (SANCO/10329/2002 rev 2) |
| 8.3.1. Effetti fuq in- <i>naħal</i> | — | EPPO Standard PP 3/10 (3) Environmental risk assessment scheme for plant protection products. Chapter 10: honeybees. |
| 8.3.1.1. Tossicità akuta għan- <i>naħal</i> | — | |
| 8.3.1.1.1. Tossicità orali akuta | <p>EPPO Standard PP1/170 (4): Test methods for evaluating the side-effects of plant protection products on honeybees.</p> <p>OECD Test Guideline 213: Honeybees, Acute Oral Toxicity Test</p> | |

| Referenza għal Parti A tal-Anness tar-Regolament (UE) Nru 283/2013 | Metodi ta' ttestjar ⁽¹⁾ | Dokumenti ta' gwida ⁽²⁾ |
|---|--|--|
| 8.3.1.1.2. Tossicità akuta minn kuntatt | EPPO Standard PP1/170 (4): Test methods for evaluating the side-effects of plant protection products on honeybees. OECD Test Guideline 214: Honeybees, Acute Contact Toxicity Test | |
| 8.3.1.2. Tossicità kronika għan-naħal | Aupinel et al (2007): A new larval in vitro rearing method to test effects of pesticides on honey bee brood. <i>Redia XC</i> : 87-90 Oomen PA, de Ruijter A and van der Steen J, 1992. Method for honeybee brood feeding tests with insect growth - regulating insecticides. Bulletin OEPP/EPPO Bulletin 22, 613-616. | |
| 8.3.1.3. Effetti fuq l-iżvilupp tan-naħal tal-għasel u stadji tal-hajja oħrajn tan-naħal tal-għasel | Aupinel et al (2007): A new larval in vitro rearing method to test effects of pesticides on honey bee brood. <i>Redia XC</i> : 87-90 | |
| 8.3.1.4. Effetti subletali | Oomen PA, de Ruijter A and van der Steen J, 1992. Method for honeybee brood feeding tests with insect growth - regulating insecticides. Bulletin OEPP/EPPO Bulletin 22, 613-616. | |
| 8.3.2. Effetti fuq antropodi mhux fil-mira għajr in-naħal | | Candolfi et al (2001). Guidance Document on Regulatory Testing and Risk Assessment Procedures for Plant Protection Products With Non-Target Arthropods: From the Escort 2 Workshop (European Standard Characteristics of Non-Target Arthropod Regulatory Testing). SETAC press, pp 46. ISBN 1-880611-52-x. |
| 8.3.2.1. Effetti fuq <i>Aphidius rhopalosiphii</i> | M.P. Candolfi, S. Blümel, R. Forster et al. (2000): Guidelines to evaluate side-effects of plant protection products to non-target arthropods. IOBC, BART and EPPO Joint Initiative. ISBN: 92-9067-129-7. | |
| 8.3.2.2. Effetti fuq <i>Typhlodromus pyri</i> | M.P. Candolfi, S. Blümel, R. Forster et al. (2000): Guidelines to evaluate side-effects of plant protection products to non-target arthropods. IOBC, BART and EPPO Joint Initiative. ISBN: 92-9067-129-7 | |
| 8.4. Effetti fuq mesofawna u makrofawna tal-hamrija li mhumiex fil-mira | — | EU Guidance Document on Terrestrial Ecotoxicology (SANCO/10329/2002 rev 2) |
| 8.4.1. Il-hanex – l-effetti subletali | OECD Test Guideline 222: Earthworm Reproduction Test (<i>Eisenia fetida</i> / <i>Eisenia andrei</i>) | |
| 8.4.2. Effetti fuq mesofawna u makrofawna tal-hamrija li mhumiex fil-mira (min-barra l-hniex) | — | |

| Referenza għal Parti A tal-Anness tar-Regolament (UE) Nru 283/2013 | Metodi ta' ttestjar ⁽¹⁾ | Dokumenti ta' gwida ⁽²⁾ |
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| 8.4.2.1. Ittestjar tal-livell tal-ispeċi | <u>Għall-Collembola:</u> OECD Test Guideline 232: Collembolan Reproduction Test in Soil <u>Għad-dud predatorju:</u> OECD Test Guideline 226: Predatory mite (<i>Hypoaspis (Geolaelaps) aculeifer</i>) reproduction test in soil | |
| 8.5. Effetti fuq it-trasformazzjoni tan-nitroġenu tal-ħamrija | OECD Test Guideline 216: Soil Microorganisms: Nitrogen Transformation Test | EU Guidance Document on Terrestrial Ecotoxicology (SANCO/10329/2002 rev 2) |
| 8.6. Effetti fuq pjanti terrestri oghla li mhumiex fil-mira | — | EU Guidance Document on Terrestrial Ecotoxicology (SANCO/10329/2002 rev 2) |
| 8.6.1. Sommarju tad-dejta ta' tgħarbil | — | — |
| 8.6.2. Ittestjar fuq pjanti mhux fil-mira | <u>Bidu u tkabbir ta' nebbieta:</u> OECD Test Guideline 208: Terrestrial Plant Test: Seedling Emergence and Seedling Growth Test <u>Ittestjar tal-vitalità veġetattiva tal-pjanti terrestri</u> OECD Test Guideline 227: Terrestrial Plant Test: Vegetative Vigour Test | — |
| 8.7. Effetti fuq organiżmi terrestri oħra (flora u fauna) | — | EU Guidance Document on Terrestrial Ecotoxicology (SANCO/10329/2002 rev 2) |
| 8.8. Effetti fuq metodi bijoloġiċi għat-trattament tad-drenaġġ | OECD Test Guideline 209: Activated Sludge, Respiration Inhibition Test | EU Guidance Document on Terrestrial Ecotoxicology (SANCO/10329/2002 rev 2) |
| 9. DEJTA MIL-LETTERATURA | | EFSA (2011). Guidance of EFSA - Submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) No 1107/2009. EFSA Journal 2011; 9(2):209 |
| 10. KLASSIFIKAZZJONI U TIKKETTAR | | ECHA Guidance on the application of the CLP criteria. Guidance to Regulation (EC) No 1272/2008 on classification, labelling and packaging (CLP) of substances and mixtures. |

(1) Bl-eċċezzjoni tal-metodi deskritti fir-Regolament (KE) Nru 440/2008 (ĠU L 142, 31.5.2008, p. 1), il-biċċa l-kbira tal-metodi ta' ttestjar imsemmija huma disponibbli biss bl-Ingliż (xi whud anke bil-Franċiż). Informazzjoni ddettaljata dwar il-metodi ta' ttestjar:

- CIPAC <http://www.cipac.org/>
- ASTM <http://www.astm.org/Standard/index.shtml>
- ISO http://www.iso.org/iso/home/store/catalogue_ics.htm
- OECD <http://www.oecd.org/env/chemicalsafetyandbiosafety/testingofchemicals/>
- Eppo <http://www.eppo.int/STANDARDS/standards.htm>
- US EPA OCSPP <http://www.epa.gov/ocspp/pubs/firs/home/testmeth.htm>

(2) Il-biċċa l-kbira tad-dokumenti ta' gwida msemmija huma disponibbli biss bl-Ingliż. Informazzjoni ddettaljata dwar id-dokumenti ta' gwida:

- Il-Kummissjoni Ewropea:
http://ec.europa.eu/food/plant/pesticides/approval_active_substances/guideline_documents_en.htm
http://ec.europa.eu/food/plant/pesticides/guidance_documents/mrls_en.htm
- OECD <http://www.oecd.org/env/chemicalsafetyandbiosafety/testingofchemicals/>
- Eppo: <http://www.eppo.int/STANDARDS/standards.htm>
- ECHA: <http://echa.europa.eu/support/guidance-on-reach-and-clp-implementation>
- EFSA: <http://www.efsa.europa.eu/en/publications.htm>
- FOCUS: <http://focus.jrc.ec.europa.eu/index.html>

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- (3) http://www.fao.org/fileadmin/templates/agphome/documents/Pests_Pesticides/PestSpecsManual2010.pdf
- (4) ĠU L 309, 24.11.2009, p. 1.
- (5) ĠU L 353, 31.12.2008, p. 1.
- (6) EPPO standards are available at <http://pp1.eppo.int/> - EPPO standards of series PP1 describe how to evaluate the efficacy of plant protection products. The series contain general standards and specific standards. Specific standards should be used together with relevant general standards and vice versa.
- (7) ĠU L 220, 24.8.2009, p. 1.
- (8) ĠU L 324, 9.12.2010, p. 13.
- (9) <http://www.efsa.europa.eu/en/mrls/mrlteam.htm>
- (10) http://www.hc-sc.gc.ca/cps-spc/pubs/pest/_pol-guide/dir2006-01/index-eng.php
- (11) http://ec.europa.eu/food/fs/sc/scp/outcome_ppp_en.html
- (12) Prior to the adoption of the revised guideline, efforts to reduce the number of animals in the limit and main tests should be made as far as possible.
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