European Commission

Renewal Assessment Report of the Inclusion of the Active Substance in Annex I of the Regulation (EC) 1107/2009

Oxamyl

Volume 3 (CA)
ANNEX B.1 Identity

Rapporteur Member State: Italy
Co-Rapporteur Member State: France

January 2018

VERSION HISTORY

Date	Data points containing amendments or additions	Document identifier or version number

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B.1 IDENTITY

B.1.1 Identity of the active substance

B.1.1.1 Applicant

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Primary contact:
Address:
Telephone:
Email:
Alternate contact:
Address:
Telephone:
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B.1.1.2 Producer

DuPont International Operations Sàrl

Contact:
Address:
Telephone:
Email:
Location of Plant(s): Confidential Information, data are provided in the Oxamyl EU Renewal Dossier, Document J, Part 1, DuPont-40926 EU

B.1.1.3 Common name proposed or ISO-accepted and synonyms

Oxamyl

B.1.1.4 Chemical name (IUPAC and CA nomenclature)

IUPAC: N,N-dimethyl-2-methylcarbamoyloxyimino-2-(methylthio) acetamide

CA: Methyl 2-(dimethylamino)-N-[[(methylamino) carbonyl]oxy]-2-oxoethanimidothioate

B.1.1.5 Producer's development codes numbers

DPX-D1410

B.1.1.6 CAS, EC, and CIPAC numbers

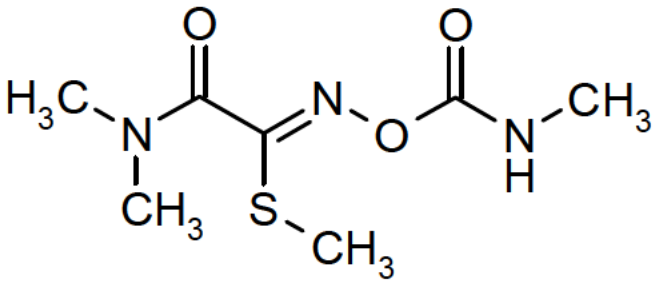
CAS number: 23135-22-0
CIPAC number: 342
EEC number: 245-445-3

B.1.1.7 Molecular and structural formula, molar mass

Active substance

Molecular Formula: $C_7H_{13}O_3N_3S$
Molecular Mass: 219.3 g/mol

Figure 1 Structural formula of active substance



B.1.1.8 Method of manufacture (synthesis pathway) of the active substance

Confidential information, data are provided in the Volume 4

B.1.1.9 Specification of purity of the active substance in g/kg

Minimum purity is 926 g/kg (based on precipitated material).

Specifications are confidential information and are provided in the Volume 4

Oxamyl EU Renewal Dossier, Document J, Part 1, DuPont-40926 EU.

Identity content and structural formula of additives (such as stabilisers) and impurities

B.1.1.9.1 Additives

Specifications are confidential information and are provided in the Volume 4.

B.1.1.9.2 Significant Impurities

Specifications are confidential information and are provided in the Volume 4.

B.1.1.9.3 Relevant impurities

Specifications are confidential information and are provided in the Volume 4.

B.1.1.9.4 Analytical profile of batches

Specifications are confidential information and are provided in the Volume 4.

B.1.1.9.5 References relied on

Unless otherwise specified data submitted with this dossier are necessary for the renewal of the approval of oxamyl because they address standard data requirements or reflect changes in scientific and/or technical knowledge or changes in uses since the first inclusion of the active substance. The reasons why individual studies are necessary are specified in a separate column below. The corresponding studies were conducted according to GLP or GEP standards and did not benefit from a previous period of protection.

In line with Article 60(1) of Regulation (EC) No. 1107/2009, the Rapporteur Member State shall prepare a list of the test and study reports necessary for the renewal of the approval of oxamyl and the reference list below can be used as a basis.

DuPont will make final claims of data protection for these necessary active substance and plant protection product data at application for authorisation or renewal of authorisation of our plant protection products after the approval renewal of oxamyl in line with the provisions set in Articles 33.4 and 59 of Regulation (EC) No. 1107/2009.

List of information, tests and studies which are considered as relied upon by the RMS for the evaluation with a view to the approval of the active substance.