

Material group	642 (50002136)	Page 1 of 18
Product name	Cloquintocet-mexyl 28% w/w MC	Revision: March 2021
Safety data sheet according to EU Reg. 1907/2006 as amended		Supersedes September 2020

SAFETY DATA SHEET

Cloquintocet-mexyl 28% w/w MC

Revision: Sections containing a revision or new information are marked with a ♣.

♣ SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

- 1.1. **Product identifier** **Cloquintocet-mexyl 28% w/w MC**
Contains cloquintocet-mexyl and hydrocarbons, C10-C13, aromatics, < 1% naphthalene
- 1.2. **Relevant identified uses of the substance or mixture and uses advised against**
 1) Formulation in closed system
 2) Safener in plant protection products
- 1.3. **Details of the supplier of the safety data sheet** **FCM Agricultural Solutions A/S**
 Thyborønvej 78
 DK-7673 Harbøre
 Denmark
SDS.Ronland@fmc.com
- 1.4. **Emergency telephone number**
Medical emergencies:
- | | |
|-------------------------------------|---|
| Austria: +43 1 406 43 43 | Malta: 112 |
| Belgium: +32 70 245 245 | Netherlands: +31 30 274 88 88 |
| Bulgaria: +359 2 9154 409 | Norway: +47 22 591300 |
| Cyprus: 1401 | Poland: +48 22 619 66 54 |
| Czech Republic: +420 224 919 293 | +48 22 619 08 97 |
| +420 224 915 402 | Portugal: 800 250 250 (in Portugal only) |
| Denmark: +45 82 12 12 12 | +351 21 330 3284 |
| England and Wales: 111 | Romania: +40 21318 3606 |
| Estonia: +372 7943500 | Scotland: +8454 24 24 24 |
| Finland: +358 9 471 977 | Slovakia: +421 2 54 77 4 166 |
| France: +33 (0) 1 45 42 59 59 | Slovenia: +386 41 650 500 |
| Greece: 30 210 77 93 777 | South Africa: +27 83 123 3911 (Bateleur Emergency Response Co.) |
| Hungary: +36 80 20 11 99 | Spain: +34 91 562 04 20 |
| Ireland (Republic): +353 1 837 9964 | Sweden: +46 08-331231 |
| Italy: +39 02 6610 1029 | 112 |
| Latvia: +371 670 42 473 | Switzerland: 145 |
| 112 | Turkey: 114 |
| Lithuania: +370 523 62052 | U.S.A. & Canada: +1 800 331-3148 |
| +370 687 53378 | All other countries: +1 651 632-6793 (Collect) |
| Luxembourg: +352 8002 5500 | |

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For fire, leak, spill or other accident emergencies:

U.S.A.: +1 800 424-9300 (CHEMTREC – U.S.A.)
 All other countries: +1 703 741-5970 (CHEMTREC – International)

♣ SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

Sensitisation – skin: Category 1 (H317)
 Aspiration toxicity: Category 1 (H304)
 Hazards to the aquatic environment, acute: Category 1 (H400)
 chronic: Category 1 (H410)

Health hazards The product may cause allergic sensitisation.

Environmental hazards The product is very toxic to aquatic organisms.

2.2. Label elements

According to EU Reg. 1272/2008 as amended

Product identifier Cloquintocet-mexyl 28% w/w MC
 Contains cloquintocet-mexyl and hydrocarbons, C10-C13, aromatics,
 < 1% naphthalene

Hazard pictograms (GHS07, GHS08, GHS09)



Signal word Danger

Hazard statements

H304 May be fatal if swallowed and enters airways.
 H317 May cause an allergic skin reaction.
 H410 Very toxic to aquatic life with long lasting effects.

Supplementary hazard statements

EUH066 Repeated exposure may cause skin dryness and cracking.
 EUH401 To avoid risks to human health and the environment, comply with the instructions of use.

Precautionary statements

P261 Avoid breathing vapours.
 P280 Wear protective gloves.
 P301+P310 IF SWALLOWED: Immediately call a POISON CENTER or physician.
 P302+P352 IF ON SKIN: Wash with plenty of soap and water.
 P331 Do NOT induce vomiting.
 P501 Dispose of contents and container as hazardous waste.

2.3. Other hazards None of the ingredients in the product meets the criteria for being PBT or vPvB.

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♣ SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. **Substances** The product is a mixture, not a substance.

3.2. **Mixtures** See section 16 for full text of hazard statements.

Active ingredient

Cloquintocet-mexyl Content: 28% by weight
 CAS name Acetic acid, [(5-chloro-8-quinolinyl)oxy]-, 1-methylhexyl ester
 CAS no. 99607-70-2
 IUPAC name 1-Methylhexyl (5-chloroquinolin-8-yloxy)acetate
 ISO name Cloquintocet-mexyl
 EC no. (EINECS no.) None
 EU index no. None
 EU registration no. 01-0000012013-89-0000
 Molecular weight 319.82
 Classification of the ingredient Acute oral toxicity: Category 4 (H302)
 Sensitisation – skin: Category 1B (H317)
 Hazards to the aquatic environment,
 acute: Category 1 (H400), M-factor 1
 chronic: Category 1 (H410), M-factor 1
 EUH401

Reportable ingredient

	Content (% w/w)	CAS no.	EC no.	Classification
Hydrocarbons, C10-C13, aromatics, < 1% naphthalene Reg. no. 01-2119451097-39	72		922-153-0	Asp. Tox. 1 (H304) Aquatic Chronic 2 (H411) EUH066

SECTION 4: FIRST AID MEASURES

4.1. **Description of first aid measures**

Inhalation If experiencing any discomfort, immediately remove from exposure.
 Light cases: Keep person under surveillance. Get medical attention immediately if symptoms develop. Serious cases: Get medical attention immediately or call for an ambulance.

Skin contact Immediately remove contaminated clothing and footwear. Flush skin with water. Wash with water and soap. See physician if irritation develops.

Eye contact Immediately rinse eyes with much water or eyewash solution, occasionally opening eyelids, until no evidence of chemical remains. Remove contact lenses after a few minutes and rinse again. Get medical attention if irritation develops.

Ingestion Inducing vomiting is not recommended. Rinse mouth and drink water or milk. If vomiting does occur, rinse mouth and drink fluids again. Get medical attention immediately.

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- 4.2. **Most important symptoms and effects, both acute and delayed** Allergic reactions. In animal tests, non-specific signs of toxicity were seen after oral intake of cloquintocet-mexyl, such as difficulty breathing and sedation.
- 4.3. **Indication of any immediate medical attention and special treatment needed** Immediate medical attention is required in case of ingestion.
 It may be helpful to show this safety data sheet to physician.
- Notes to physician A specific antidote for exposure to this material is not known. Gastric lavage and/or administration of activated charcoal can be considered. After decontamination, treatment of exposure is as for a general chemical and should be directed at the control of symptoms and the clinical condition.
- The product contains petroleum distillates which may pose an inhalation pneumonia hazard.

SECTION 5: FIRE-FIGHTING MEASURES

- 5.1. **Extinguishing media** Dry chemical or carbon dioxide for small fires, water spray or foam for large fires. Avoid heavy hose streams.
- 5.2. **Special hazards arising from the substance or mixture** The essential breakdown products are volatile, toxic, irritant and inflammable compounds such as carbon monoxide, carbon dioxide, nitrogen oxides, hydrogen chloride and various organic chlorinated compounds.
- 5.3. **Advice for firefighters** Use water spray to keep fire-exposed containers cool. Approach fire from upwind to avoid hazardous vapours and toxic decomposition products. Fight fire from protected location or maximum possible distance. Dike area to prevent water runoff. Firemen should wear self-contained breathing apparatus and protective clothing.

SECTION 6: ACCIDENTAL RELEASE MEASURES

- 6.1. **Personal precautions, protective equipment and emergency procedures** It is recommended to have a predetermined plan for the handling of spills. Empty, sealable vessels for the collection of spills should be available.
- In case of large spill (involving 10 tonnes of the product or more):
 1. use personal protection equipment; see section 8
 2. call emergency telephone no.; see section 1
 3. alert authorities.
- Observe all safety precautions when cleaning up spills. Use personal protection equipment. Depending on the magnitude of the spill this may mean wearing respirator, face mask or eye protection, chemical resistant clothing, gloves and boots.

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Stop the source of the spill immediately if safe to do so. Keep unprotected persons away from the spill area. Remove sources of ignition. Avoid and reduce mist formation as much as possible.

6.2. Environmental precautions

Contain the spill to prevent any further contamination of surface, soil or water. Wash waters must be prevented from entering surface water drains. Uncontrolled discharge into water courses must be alerted to the appropriate regulatory body.

6.3. Methods and materials for containment and cleaning up

It is recommended to consider possibilities to prevent damaging effects of spills, such as bunding or capping. See GHS (Annex 4, Section 6).

If appropriate, surface water drains should be covered. Minor spills on the floor or other impervious surface should be absorbed onto an absorptive material such as universal binder, hydrated lime, Fuller's earth or other absorbent clays. Collect the contaminated absorbent in suitable containers. Clean area with soda lye and much water. Absorb wash liquid with absorbent and transfer to suitable containers. The used containers should be properly closed and labelled.

Large spills which soak into the ground should be dug up and transferred to suitable containers.

Spills in water should be contained as much as possible by isolation of the contaminated water. The contaminated water must be collected and removed for treatment or disposal.

6.4. Reference to other sections

See subsection 8.2. for personal protection.
 See section 13 for disposal.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

The product must always be handled in a closed system under strictly controlled conditions.

Spraying of formulated products must be done by tractor-mounted/trailed boom sprayer.

For its use as an adjuvant for pesticides, first look for precautions and personal protection measures on the officially approved label on the packaging or for other official guidance or policy in force. If these are lacking, see section 8.

Remove contaminated clothing immediately. Wash thoroughly after handling. Before removing gloves, wash them with water and soap. After work, take off all work clothes and footwear. Take a shower, using water and soap. Wear only clean clothes when leaving job. Wash protective clothing and protective equipment with water and soap after each use.

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Inhalation of vapours of the product can cause lowered consciousness, which increases the risks of operating machinery and driving.

Do not discharge to the environment. Do not contaminate water when disposing of equipment wash waters. Collect all waste material and remains from cleaning equipment, etc., and dispose of as hazardous waste. See section 13 for disposal.

7.2. Conditions for safe storage, including any incompatibilities

The product should be stored at temperatures between 10 and 35°C. Protect against strong heat from sunshine or other source, e.g. fire.

Store in closed, labelled containers. The storage room should be constructed of incombustible material, closed, dry, ventilated and with impermeable floor, without access of unauthorised persons or children. A warning sign reading "POISON" is recommended. The room should only be used for storage of chemicals. Food, drink, feed and seed should not be present. A hand wash station should be available.

7.3. Specific end use(s)

The product is meant for the production of registered pesticides which may only be used for the applications they are registered for, in accordance with a label approved by the regulatory authorities.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

Personal exposure limits To our knowledge, not established for cloquintocet-mexyl.

Aromatic hydrocarbons 100 ppm total hydrocarbon is recommended.

However, other personal exposure limits defined by local regulations may exist and must be observed.

Cloquintocet-mexyl

Permissible exposure levels The following exposure levels are derived from the exposure scenarios presented in the attachments. If these are not exceeded, no harmful effects to health or the environment are expected to occur.

Values for farm workers

DNEL, dermal 0.25 mg/cm² for acute local effects
 3.2 mg/kg bw/day for long-term effects
 DNEL, inhalation 0.05 mg/m³ for long-term effects

PNEC, aquatic environment 0.0024 mg/l in surface water
 0.203 mg/kg dry weight in sediment
 > 0.34 mg/kg dry weight in soil

Aromatic hydrocarbons

DNEL, dermal 12.5 mg/kg bw/day

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DNEL, inhalation 151 mg/m³
 PNEC, aquatic environment Not applicable

8.2. Exposure controls

Personal protection According to the attached exposure scenarios the following personal protection measures must be kept.

Industry (Exposure Scenario 1) When used in a closed system, personal protection equipment will not be required during normal work. When it is necessary to open the system, personal protection equipment must be used, depending on the work to be done. Consider the need to render equipment or piping systems non-hazardous before opening.

Farm (Exposure Scenario 2) Gloves must be used for mixing/loading. Other personal protection is not required.



Respiratory protection

In the event of an accidental discharge of the material which produces a heavy vapour or mist, workers must put on officially approved respiratory protection equipment with a universal filter type including particle filter.



Protective gloves

Wear chemical resistant gloves, such as barrier laminate, butyl rubber or nitrile rubber. The breakthrough times of these materials for the product are unknown, but it is expected that they will give adequate protection if the amount of work to be done manually is kept limited.

Work/hygienic practices The substance is allergenic. In case allergic reactions occur, other personal protection measures than those mentioned above may be required. It may be necessary to isolate the person from the substance.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Physical state	Liquid
Colour	Yellow
Odour	Of aromatic hydrocarbons
Melting point/freezing point	Not determined
Boiling point or initial boiling point and boiling range	Not determined
Flammability	Aromatic hydrocarbons : 200 - 310°C
Lower and upper explosive limit ..	Ignitable
Flash point	Aromatic hydrocarbons : 0.6 - 7.0 vol% (≈ 0.6 - 7.0 kPa)
Auto-ignition temperature	> 100°C (Pensky-Martens closed cup)
Decomposition temperature	Aromatic hydrocarbons : above 450°C
pH	Not determined
Kinematic viscosity	Not determined
Solubility	Not determined
	Solubility of cloquintocet-mexyl in:
	acetone > 250 g/l

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Partition coefficient n-octanol/water (log value)	n-heptane 8.95 g/l water 0.59 mg/l at 25°C Cloquintocet-mexyl : log K_{ow} = 5.03 at 25°C Aromatic hydrocarbons : some of the main components have log K_{ow} = 4.0 - 4.4 at 25°C by model calculation
Vapour pressure	Cloquintocet-mexyl : 5.3×10^{-6} Pa at 25°C Aromatic hydrocarbons : < 0.1 kPa at 25°C
Density and/or relative density	Not determined
Relative vapour density	(Air = 1) Aromatic hydrocarbons : > 1
Particle characteristics	Not applicable (liquid)
9.2. Other information	
Evaporation rate	(Butyl acetate = 1) Aromatic hydrocarbons : < 0.01

SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity	To our knowledge, the product has no special reactivities.
10.2. Chemical stability	The product is stable during normal handling and storage at ambient temperatures.
10.3. Possibility of hazardous reactions	None known.
10.4. Conditions to avoid	Heating of the product will produce harmful and irritant vapours.
10.5. Incompatible materials	Strong acids and alkalis.
10.6. Hazardous decomposition products	See subsection 5.2.

♣ SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008	* = Based on available data, the classification criteria are not met.	
<u>Product</u>		
Acute toxicity	The product is not considered harmful by ingestion, inhalation or dermal contact. * The acute toxicity of the product is estimated as:	
Route(s) of entry	- ingestion	LD ₅₀ , oral, rat: > 2000 mg/kg
	- skin	LD ₅₀ , dermal, rat: > 2000 mg/kg
	- inhalation	LC ₅₀ , inhalation, rat: > 5 mg/l/4 h
Skin corrosion/irritation	May be mildly irritating to skin. *	
Serious eye damage/irritation	May be mildly irritating to eyes. *	

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Respiratory or skin sensitisation ...	May cause skin sensitisation.
Germ cell mutagenicity	The product contains no ingredient known to be mutagenic. *
Carcinogenicity	The product contains no ingredient known to be carcinogenic. *
Reproductive toxicity	The product contains no ingredient found to have adverse effects on reproduction. *
STOT – single exposure	To our knowledge, no specific effects have been observed after single exposure. *
STOT – repeated exposure	The following is valid for cloquintocet-mexyl: NOEL: 1000 mg/kg bw/day in a 28-day dermal rat study (method OECD 410). *
Aspiration hazard	The product presents an aspiration pneumonia hazard.
<u><i>Cloquintocet-mexyl</i></u>	
Toxicokinetics, metabolism and distribution	Cloquintocet-mexyl is very rapidly absorbed and excreted after oral intake, within one day. It is mainly found in the gastrointestinal tract, where it is partially metabolised. There is no potential for accumulation.
Acute toxicity	The substance is harmful by ingestion. The acute toxicity is measured as:
Route(s) of entry	- ingestion LD ₅₀ , oral, rat: 1098 mg/kg (method OECD 425)
	- skin LD ₅₀ , dermal, rat: > 2000 mg/kg (method OECD 402) *
	- inhalation LC ₅₀ , inhalation, rat: > 5.05 mg/l (method OECD 403) *
Skin corrosion/irritation	Mildly irritating to skin (method OECD 404). *
Serious eye damage/irritation	Mildly irritating to eyes (method OECD 405). *
Respiratory or skin sensitisation ...	Skin sensitizer (method OECD 429).
<u><i>Hydrocarbons, C10-C13, aromatics, < 1% naphthalene</i></u>	
Acute toxicity	The substance is not considered as harmful by single exposure. *
Skin corrosion/irritation	Can cause skin dryness (measured on similar products; method OECD 404).
Serious eye damage/irritation	May cause mild, short-lasting discomfort to eyes (measured on similar products; method OECD 405). *
Respiratory or skin sensitisation ...	Not expected to cause respiratory or skin sensitisation (measured on similar products; method OECD 406). *
Aspiration hazard	Aromatic hydrocarbons present an aspiration hazard.

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11.2. **Information on other hazards** No more relevant information is available.

SECTION 12: ECOLOGICAL INFORMATION

12.1. **Toxicity** The product is very toxic to aquatic plants and harmful to fish. It is not considered as harmful to aquatic invertebrates, birds, soil micro- and macroorganisms and insects.

The ecotoxicity of cloquintocet-mexyl is measured as:

- Fish	Rainbow trout (<i>Salmo gairdneri</i>)	96-h LC ₅₀ : > 76 mg/l
	Catfish (<i>Ictalurus punctatus</i>)	96-h LC ₅₀ : 14 mg/l
- Invertebrates	Daphnids (<i>Daphnia magna</i>)	48-h LC ₅₀ : > 100 mg/l
- Algae	Green algae (<i>Scenedesmus subspicatus</i>)	96-h EC ₅₀ : 0.63 mg/l
- Birds	Bobwhite quail (<i>Colinus virginianus</i>)	LD ₅₀ : > 2000 mg/kg
	Mallard duck (<i>Anas platyrhynchos</i>)	LD ₅₀ : > 2000 mg/kg
- Insects	Honey bee (<i>Apis mellifera</i>)	48-h LD ₅₀ , oral: > 100 µg/bee 48-h LD ₅₀ , contact: > 100 µg/bee

12.2. **Persistence and degradability** **Cloquintocet-mexyl** is biodegradable, but does not meet the criteria for being readily biodegradable. Primary degradation half-lives are found to be less than 1 day in aerobic soil.

Aromatic hydrocarbons are readily biodegradable as measured according to OECD guidelines. However, they are not always rapidly degraded in the environment, but are expected to be degraded at a moderate rate, depending on circumstances.

12.3. **Bioaccumulative potential** See section 9 for octanol-water partition coefficients.

Due to rapid degradation, **cloquintocet-mexyl** does not bioaccumulate.

Aromatic hydrocarbons have a potential to bioaccumulate if continuous exposure is maintained. Most components can be metabolised by many organisms. Bioaccumulation factors (BCFs) of some of the main components are 1200 - 3200 by model calculation.

12.4. **Mobility in soil** **Cloquintocet-mexyl** is not mobile in the environment. It adsorbs strongly to soil.

Aromatic hydrocarbons are not mobile in the environment, but are volatile and will evaporate to the air if released onto water or on the surface of soil. They float and can migrate to sediment.

12.5. **Results of PBT and vPvB assessment** None of the ingredients meets the criteria for being PBT or vPvB.

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- 12.6. **Endocrine disrupting properties** None of the ingredients is known to have endocrine disrupting properties.
- 12.7. **Other adverse effects** Other relevant hazardous effects in the environment are not known.

SECTION 13: DISPOSAL CONSIDERATIONS

- 13.1. **Waste treatment methods** Remaining quantities of the material and empty but unclean packaging should be regarded as hazardous waste.
- Disposal of waste and packagings must always be in accordance with all applicable local regulations.
- Disposal of product According to the Waste Framework Directive (2008/98/EC), possibilities for reuse or reprocessing should first be considered. If this is not possible, the material can be disposed of by removal to a licensed chemical destruction plant or by controlled incineration with flue gas scrubbing.
- Disposal of packaging Do not contaminate water, foodstuffs, feed or seed by storage or disposal. Do not discharge to sewer systems.
- Disposal of packaging It is recommended to consider possible ways of disposal in the following order:
1. Reuse or recycling should first be considered. If offered for recycling, containers must be emptied and triply rinsed (or equivalent). Do not discharge rinsing water to sewer systems.
 2. Controlled incineration with flue gas scrubbing is possible for combustible packaging materials.
 3. Delivery of the packaging to a licensed service for disposal of hazardous waste.
 4. Disposal in a landfill or burning in open air should only occur as a last resort. For disposal in a landfill, containers should be emptied completely, rinsed and punctured to make them unusable for other purposes. If burned, stay out of smoke.

SECTION 14: TRANSPORT INFORMATION

ADR/RID/IMDG/IATA/ICAO classification

- 14.1. **UN number** 3082
- 14.2. **UN proper shipping name** Environmentally hazardous substance, liquid, n.o.s. (cloquintocet-mexyl and alkyl(C3-C6)benzenes)
- 14.3. **Transport hazard class(es)** 9
- 14.4. **Packing group** III

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- 14.5. **Environmental hazards** Marine pollutant
- 14.6. **Special precautions for user** Avoid any unnecessary contact with the product. Misuse can result in damage to health. Do not discharge to the environment.
- 14.7. **Maritime transport in bulk according to IMO instruments** .. The product is not transported in bulk by ship.

SECTION 15: REGULATORY INFORMATION

- 15.1. **Safety, health and environmental regulations/legislation specific for the substance or mixture**
- Seveso category (Dir. 2012/18/EU): dangerous for the environment
- Young people under the age of 18 are not allowed to work with the substance.
- All ingredients are covered by EU chemical legislation.
- 15.2. **Chemical safety assessment** A chemical safety assessment has been performed. The results are attached as Annex 1 and 2.

♣ SECTION 16: OTHER INFORMATION

Relevant changes in the safety data sheet	Product name change
List of abbreviations	Asp. Tox. Aspiration Toxicity CAS Chemical Abstracts Service Dir. Directive DNEL Derived No Effect Level EC European Community EC ₅₀ 50% Effect Concentration EINECS European INventory of Existing Commercial Chemical Substances GHS Globally Harmonized classification and labelling System Of chemicals, seventh revised edition 2017 IMO International Maritime Organisation ISO International Organisation for Standardization IUPAC International Union of Pure and Applied Chemistry LC ₅₀ 50% Lethal Concentration LD ₅₀ 50% Lethal Dose MC Manufacturing Concentrate M-factor Multiplication factor NOEL No Observed Effect Level n.o.s. Not otherwise specified OECD Organisation for Economic Cooperation and Development PBT Persistent, Bioaccumulative, Toxic PNEC Predicted No Effect Concentration Reg. Registration, or Regulation STOT Specific Target Organ Toxicity

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vPvB very Persistent, very Bioaccumulative
 WHO World Health Organisation

References Data on ingredients are available from published literature and can be found several places.

Method for classification Calculation method

Used hazard statements
 H302 Harmful if swallowed.
 H304 May be fatal if swallowed and enters airways.
 H317 May cause an allergic skin reaction.
 H400 Very toxic to aquatic life.
 H410 Very toxic to aquatic life with long lasting effects.
 H411 Toxic to aquatic life with long lasting effects.
 EUH066 Repeated exposure may cause skin dryness and cracking.
 EUH401 To avoid risks to human health and the environment, comply with the instructions of use.

Advice on training This material should only be used by persons who are made aware of its hazardous properties and have been instructed in the required safety precautions.

The information provided in this safety data sheet is believed to be accurate and reliable, but uses of the product vary and situations unforeseen by FMC Corporation may exist. The user has to check the validity of the information under local circumstances.

Prepared by FMC Agricultural Solutions A/S / GHB

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Annex 1. Exposure Scenario 1 (ES1): Formulation in closed system

1.1. Description of activities and processes covered in the Exposure Scenario

Exposure Scenario 1 covers the formulation of cloquintocet-mexyl into plant protection products; the substance is formulated on the same site responsible for manufacture. Products are formulated in bulk prior to transfer to containers (1 litre, 5 litre or 10 litres) for distribution to the users. The formulation of cloquintocet-mexyl takes place under closed conditions.

1.2. Risk management measures

Several measures are taken to ensure minimisation of emission and any resulting exposure. These include pre-cleansing by regeneration, basic hydrolysis, extraction and active carbon filter.

To ensure that requirements are met, measurements are made on the working environment. The environmental approval also includes spillage and waste reports and predetermined plans for handling of spills. Personal protection equipment (PPE) is available and there are directions when to use this.

These systems include keeping a log of attended courses and other training for each employee and providing the personnel with safety data sheets for each substance handled.

All of these measures ensure that the substance is rigorously contained during its whole lifecycle; emissions and any resulting exposure are minimised, both during the process and in case of accidents or waste generation; personnel are properly trained; special procedures are applied before opening systems; substance handling procedures are documented and supervised by the site operator.

Local exhaust ventilation (LEV) is used to reduce exposure to solvent. Exposure to cloquintocet-mexyl is not envisaged due to its low volatility. Workers are provided with PPE (helmet, protective goggles, PVC gloves and coveralls). However no exposure to cloquintocet-mexyl is predicted as it is formulated in a closed system.

Waste water is treated on-site. No cloquintocet-mexyl is released from the formulation site into waste water. Air from the plant is conducted through a scrubber and to air incineration (98.5 - 99.5% effectiveness).

Predicted operator and environmental exposure: none.

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Annex 2. Exposure scenario 2 (ES2): Safener in plant protection products

2.1. Description of activities and processes covered in the Exposure Scenario

The substance is used in formulated products. The products are supplied to professional users (farmers, spray contractors) only and applied to cereal crops.

Application to crops

The potential for exposure to cloquintocet-mexyl occurs during addition of the product from the container in which it is supplied to the spray tank and subsequent dilution with water ('mixing/loading'), and also during application of the product to the crop (spraying).

Secondary exposure

Cereal crops such as wheat and barley are exclusively harvested mechanically. Incidental exposure may arise should crop inspection be required following treatment. However, this type of activity is likely to be of short duration and will not result in intensive contact with the crop due to the low crop height at the time of application.

2.2. Operational conditions related to frequency, duration and amount of use

Plant protection products are formulations containing 1.5-3.35% w/w cloquintocet-mexyl. The products are used for application to cereals using a tractor-mounted/trailed boom sprayer with hydraulic nozzles. The use of products containing 3.35% cloquintocet-mexyl/ha represents the worst-case application.

The frequency of mixing/loading activities is determined by default assumptions of the level of application of cloquintocet-mexyl, the volume of application (water in the spray) and work rates (area of crops sprayed per day). The default assumptions vary between the exposure models used, but are generally conservative or worst-case assumptions. Both of the exposure models assume that the duration of spraying is 6 hours per day. The default assumption is that the products may be used daily during the season of use. The season of use is potentially a period of several weeks in every year, although any given area will only be treated once per season.

A work period of two hours is considered for re-entry worker exposure, using worst-case assumptions about the application rate of cloquintocet-mexyl to crops. Exposure is likely to be occasional, during the season of use.

When up to 112.5 l product per day (worst-case POEM assumption) at the higher concentration of 3.35% is used, the used amount of substance (as such or in preparation) per worker [workplace] is 3.76875 kg per day, equivalent to 938 kg per year if used daily.

2.3 Risk management measures

Tractors/sprayers most frequently have enclosed cabs. PPE (gloves) are specified during mixing and loading activities. No PPE is specified during spraying of the product. Spray buffer zones are specified on the product label to protect bodies of water

Spray applicators may have to be registered and/or undergo specific training under relevant national legislation. Unused product must undergo special treatment, e.g. at suitable disposal sites, to comply with local regulations. Contaminated packaging is disposed of as unused product.

2.4. Exposure estimation

Estimates of worker exposure were made using the two exposure models referenced below.

* Uniform Principles for Safeguarding the Health of Applicators of Plant Protection Products (Uniform Principles for Operator Protection); Mitteilungen aus der Biologischen Bundesanstalt für Land- und Forstwirtschaft, Berlin-Dahlem, no. 277, 1992 ('German model')

* Predictive Operator Exposure Model (POEM) 2007 ('UK model')

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2.4.1. Workers exposure

The predicted exposures shown below are for a representative (worst case) use of a liquid product containing 3.35% cloquintocet-mexyl to cereal crops using a tractor-mounted boom sprayer. The use of protective gloves is assumed during product mixing and loading, consistent with the classification of cloquintocet-mexyl as a skin sensitizer. No personal protective equipment is assumed during spray application.

German model:

Routes of exposure	Estimated Exposure		Explanation / source of measured data
	value	unit	
Dermal exposure	0.019872	mg/d	Predicted exposure during product mixing/loading
	1.3776264	mg/d	Predicted exposure during product application
Inhalation exposure	0.0004968	mg/d	Predicted exposure during product mixing/loading
	0.000828	mg/d	Predicted exposure during product application

UK model:

Routes of exposure	Estimated Exposure		Explanation / source of measured data
	value	unit	
Dermal exposure	0.39675	mg/d	Predicted dermal exposure during product mixing/loading
	1433	mg/d	Predicted dermal exposure during product application
Inhalation exposure	–	mg/d	No predicted inhalation exposure during product mixing/loading
	0.009315	mg/d	Predicted inhalation exposure during product application

Exposure values

The predicted short-term exposure values are shown below. Systemic exposure values are expressed as a sum of inhalation and dermal exposure resulting from mixing/loading and spray application activities and assuming 100% inhalation absorption, 7% dermal absorption (from the product concentrate during mixing/loading) and 19% dermal absorption (from the diluted product during spray application). The total systemic exposure to cloquintocet-mexyl is expressed in terms of mg/kg bw/d.

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Summary of acute exposure concentrations to workers:

Routes of exposure	Concentrations	Justification
Dermal local exposure (in mg/cm ²)	0.00003 - 0.0008	German model: local dermal (hand exposure) during mixing/loading can be estimated to be 0.00003 mg/cm ² based on the predicted dermal exposure to 1.9872 mg cloquintocet-mexyl, hand surface area of 500 cm ² and penetration of gloves of 1%. UK model: local dermal (hand exposure) during mixing/loading can be estimated to be 0.0008 mg/cm ² based on the predicted dermal exposure to 0.3 ml product containing 34.5 mg/ml cloquintocet-mexyl, hand surface area of 500 cm ² and penetration of gloves of 5%.
Dermal systemic exposure (in mg/kg bw/d)	0.0038 - 0.021	German model: predicted systemic exposure resulting from product mixing/loading and application by spraying: 0.0038 mg/kg bw/d. UK model: predicted systemic exposure resulting from product mixing/loading and application by spraying: 0.021 mg/kg bw/d.
Inhalation exposure (in mg/m ³ /8h working day)	0.00007 - 0.001	German model: mean inhalation exposure of 0.00007 mg/m ³ can be calculated from the total inhalation exposure of 0.0004968 mg/day (for a 6-hour working day) and assuming a breathing rate of 1.25 m ³ /h. UK model: mean inhalation exposure of 0.001 mg/m ³ can be calculated from the total inhalation exposure of 0.009315 mg/day (for a 6-hour working day) and assuming a breathing rate of 1.25 m ³ /h.

Exposure of re-entry workers

It is assumed that workers may enter the treated area two hours following spray application in order to carry out activities such as crop inspection.

The Uniform Principles were used to estimate theoretical worker exposures to cloquintocet-mexyl from application to cereal crops. Plant protection products containing cloquintocet-mexyl as a safener are used on cereal crops early in the season with only a single application being recommended. The initial DFR (Dislodgeable Foliar Residue) was estimated using the conservative default assumption that an application rate of 1 kg cloquintocet-mexyl/ha corresponds to an initial DFR of 3 µg/cm². In the absence of data, a conservative Transfer Coefficient of 5000 cm²/h has been used to cover all activities as a worst-case, assuming no protective clothing is worn.

Dermal absorption is assumed to be 17% and the daily dermal exposure (without PPE) to cloquintocet-mexyl for a 60 kg worker is estimated as shown in the following calculation:

$$[0.0414 \times 3 \text{ µg/cm}^2] \times 5000 \text{ cm}^2/\text{h} + 2 \text{ h/d} \times 100\% \text{ 60 kg} \times 1000 \text{ µg/mg} = 0.0207 \text{ mg/kg bw/d.}$$

2.4.2. Environmental exposure

Direct release to soil is 2.57 kg/d based on a total EU annual usage of 938 kg/year (2008). This corresponds to 41.4 g/ha according to the maximum application rate.

The mean adsorption coefficient (K_{oc}) for cloquintocet-mexyl is 12850 ml/g indicating cloquintocet-mexyl to be immobile in soil. There is no expectation that cloquintocet-mexyl will leach to groundwater in significant amounts.

The concentration in the environment resulting after application is calculated as:

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Concentration in soil: initial PECs (mg/kg)	0.055
Concentration in groundwater: PEC _{gw} (µg/l)	< 0.1

	Drift 1 m (2.77%)	Drift 5 m (0.57%)	Drift 10 m (0.29%)	Drift 20 m (0.15%)
Concentration in aquatic compartment: PEC _{sw} (µg/l)	0.38	0.08	0.04	0.02
Concentration in sediment: PEC _{sed} (µg/kg)	2.85	0.6	0.3	0.15