

Section 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product Identifier

Product Name: AFFILEX®
Product Code: 152-01
UFI Code: PNWS-5CKE-740E-4XYF

1.2 Relevant identified uses of the substance or mixture and uses advised against

Product Use: Fungicide

1.3 Details of the supplier of the safety data sheet

Company: Life Scientific Ltd,
Block 4,
Belfield Office Park,
Beech Hill Road,
Dublin 4
Ireland
Telephone: +353 (0) 1 2832024
Email: info@lifescientific.com
Web: www.lifescientific.com

1.4 Emergency contact information

In case of Emergency: Tel. NHS 111

Section 2. HAZARD IDENTIFICATION

2.1 Classification of the substance or mixture

Classification according to Regulation (EU) No. 1272/2008

Skin Sens.	Category 1	H317
Eye Dam./Irrit.	Category 2	H319
Acute Tox.	Category 4 (Inhalation – mist)	H332
Repr.	Category 2	H361d
Repr.	Additional category for effects on or via lactation	H362
Aquatic Acute	Category 1	H400
Aquatic Chronic	Category 1	H410

2.2 Label Elements

Labelling according to Regulation (EU) 1272/2008

Hazard components:

- Fluxapyroxad
- Metconazole
- Propanoic acid

Hazard Pictograms:



Signal Word:

Warning

Hazard Phrases:

H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H332	Harmful if inhaled.
H361d	Suspected of damaging the unborn child.
H362	May cause harm to breast-fed children.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.

Precautionary Phrases:

P102	Keep out of reach of children.
P264	Wash hands thoroughly after handling
P272	Contaminated work clothing should not be allowed out of the workplace
P280	Wear protective gloves / protective clothing / eye protection / face protection
P304 + P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do - continue rinsing
P405	Store locked up
P501	Dispose of contents/container to a licensed hazardous waste disposal contractor or collection site except for empty clean containers which can be disposed of as non-hazardous waste.

Other Phrases:

EUH208	Contains: propanoic acid, 2-hydroxy-, 2-ethylhexyl ester, (2S)-. May produce an allergic reaction.
EUH401	To avoid risks to human health and the environment, comply with the instructions for use.
SP 1	Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads).
SPe 3	To protect aquatic organisms respect an unsprayed buffer zone to surface water bodies in line with LERAP requirements.

2.3 Other Hazards

Substance does/does not meet the criteria for vPvB according to regulation (EC) No 1907/2006, Annex III.

The mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Section 3. COMPOSITION / INFORMATION ON INGREDIENTS

3.1 Substances

No substances fulfil the criteria set out in Annex II, Part A of the REACH Regulation (EC) No 1907/2006.

3.2 Mixtures

Chemical Name	CAS	EC	Classification (Regulation (EC) No 1272/2008)	Concentration (% w/w)
1H-Pyrazole-4-carboxamide, 3-(difluoromethyl)-1-methyl-N-(3',4',5'-trifluoro[1,1'-biphenyl]-2-yl)-; Fluxapyroxad	907204-31-3	620-041-3	Repr. Add. cat. lact.; H362 Aquatic Acute 1; H400 Aquatic Chronic 1; H410 M-factor acute: 1 M-factor chronic: 1	6.07%
(1RS, 5RS;1RS, 5SR)-5-(4-chlorobenzyl)-2,2-dimethyl-1-(1H-1,2,4-triazol-1-ylmethyl)cyclopentanol Metconazole	125116-23-6	603-031-3	Acute Tox. 4 (oral); H302 Repr. 2 (unborn child); H361d Aquatic Chronic 2; H411	4.37%
Propanoic acid, 2-hydroxy-, 2-ethylhexyl ester, (2S)-	186817-80-1	606-097-1	Skin Corr./Irrit. 2; H315 Skin Sens. 1B; H317 Eye Dam./Irrit. 2; H319	< 35%

Alcohols, C9-C11, ethoxylated, propoxylated	103818-93-5	-	Acute Tox. 4 (oral); H302 Eye Dam./Irrit. 2; H315	< 20%
Isotridecanoethoxylate	69011-36-5	-	Acute Tox. 4 (oral); H302 Eye Dam./Irrit. 1; H318	< 15%
Poly(oxy-1,2-ethanediyl), .alpha.-phenyl-.omega.-hydroxy- -, styrenated	104376-75-2	-	Aquatic Chronic 2; H411	< 5%
Poly(oxy-1,2-ethanediyl), .alpha.-[tris(1-phenylethyl)phenyl]-.omega.- hydroxy-	99734-09-5	-	Aquatic Chronic 3; H412	< 5%
Poly(oxy-1,2-ethanediyl), .alpha.-phosphono-.omega.- [2,4,6-tris(1-phenylethyl)phenoxy]-	114535-82-9		Eye Dam./Irrit. 2; H319	< 5 %

Section 4. FIRST AID MEASURES

4.1 Description of first aid measures

General information:	Have the product container, label or Safety Data Sheet with you when calling the emergency number, a Poison Control Centre or physician, or going for treatment.
Inhalation:	Move to fresh air. Keep patient warm and calm. Seek medical attention.
Ingestion:	If swallowed, immediately rinse mouth and then drink 200-300 mL of water. Seek medical advice.
Skin contact:	Wash off immediately with plenty of soap and water. Remove contaminated clothing.
Eye contact:	Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Consult an eye specialist.

4.2 Most important symptoms and effects, both acute and delayed

Symptoms:	None known.
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4.3 Indication of any immediate medical attention and special treatment needed

Notes to physicians:	There is no specific antidote available. Treat symptomatically.
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Section 5. FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media: water spray, carbon dioxide, foam, dry powder.

5.2 Special hazards arising from the substance or mixture

Endangering substances: carbon monoxide, carbon dioxide, hydrogen fluoride, hydrogen chloride, nitrogen oxides, phosphorus oxides, halogenated compounds, sulphur oxides.

Advice: The substances/groups of substances mentioned can be released in case of fire.

5.3 Advice for firefighters

Special protective equipment for fire fighters: Wear self-contained breathing apparatus and chemical -protective clothing.

Collect contaminated extinguishing water separately, do not allow to reach sewage or effluent systems. Dispose of fire debris and contaminated extinguishing water in accordance with official regulations. In case of fire and/or explosion do not breathe fumes. Keep containers cool by spraying with water if exposed to fire.

Section 6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Do not breathe vapour/spray. Use personal protective clothing. Avoid contact with the skin, eyes and clothing.

6.2 Environmental precautions

Do not discharge into the subsoil/soil. Do not discharge into drains/surface waters/groundwater.

Do not allow contamination of public drains or surface or ground waters. Inform local water plc if spillage enters drains and the Environment Agency (England & Wales), the Scottish Environmental Protection Agency (Scotland), or the Environment and Heritage Service (Northern Ireland) if it enters surface or ground waters. Keep people and animals away.

6.3 Methods and materials for containment and cleaning up

For small amounts: Pick up with suitable absorbent material (e.g. sand, sawdust, general-purpose binder, diatomaceous earth).

For large amounts: Dike spillage. Pump off product.
Collect waste in suitable containers, which can be labelled and sealed. Clean contaminated floors and objects thoroughly with water and detergents, observing environmental regulations. Dispose of absorbed material in accordance with regulations. Wear suitable protective equipment.

6.4 Reference to other sections

Information regarding exposure controls/personal protection and disposal considerations can be found in section 8 and 13.

Section 7. HANDLING AND STORAGE

7.1 Precautions for safe handling

No special measures necessary if stored and handled correctly. Ensure thorough ventilation of stores and work areas. When using do not eat, drink or smoke. Hands and/or face should be washed before breaks and at the end of the shift.

Protection against fire and explosion:
Vapours may form ignitable mixture with air. Prevent electrostatic charge - sources of ignition should be kept well clear - fire extinguishers should be kept handy.

7.2 Conditions for safe storage, including any incompatibilities

Segregate from foods and animal feeds. Keep away from heat. Protect from direct sunlight.

Protect from temperatures below: -10 °C
Changes in the properties of the product may occur if substance/product is stored below indicated temperature for extended periods of time.
Protect from temperatures above: 40 °C
Changes in the properties of the product may occur if substance/product is stored above indicated temperature for extended periods of time. If transport time lasts more than 4 days, the packed product must be protected against exceeding the indicated temperature.

7.3 Specific end use(s)

For the relevant identified use(s) listed in Section 1 the advice mentioned in this section 7 is to be observed.

Section 8. EXPOSURE CONTROL/PERSONAL PROTECTION

8.1 Control parameters

Refer to the current edition of HSE Guidance Note EH40 Occupational Exposure Limits (United Kingdom). For normal use and handling refer to the product label/leaflet.

8.2 Exposure controls

When using this product refer to the label for details. In all other cases, use the following Personal Protective Equipment:

Respiratory protection:	Suitable respiratory protection for higher concentrations or long-term effect: Combination filter for gases/vapours of organic, inorganic, acid inorganic and alkaline compounds (e.g. EN 14387 Type ABEK-P3).
Hand protection:	Suitable chemical resistant safety gloves (EN 374-1) also with prolonged, direct contact (Recommended: Protective index 6, corresponding > 480 minutes of permeation time according to EN 374): E.g. nitrile rubber (0.4 mm), chloroprene rubber (0.5 mm), butyl rubber (0.7 mm) etc.
Eye protection:	Safety glasses with side-shields (frame goggles) (e.g. EN 166).
Body protection:	Body protection must be chosen depending on activity and possible exposure, e.g. apron, protecting boots, chemical-protection suit (according to EN 14605 in case of splashes or EN ISO 13982 in case of dust).
General safety and hygiene measures:	The statements on personal protective equipment in the instructions for use apply when handling crop-protection agents in final-consumer packing. Wearing of closed work clothing is recommended. Keep away from food, drink and animal feeding stuffs. Store work clothing separately.

Section 9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Results based on a similar composition

Form:	Liquid.
Colour:	Colourless.
Odour:	Faintly aromatic.
Odour threshold:	Not determined since harmful by inhalation.
pH (at 20 °C):	approx. 3 – 5.
Melting Point:	< 20 °C
Flash Point:	Approx. 106 °C.
Boiling point (°C):	The product has not been tested.
Flammability:	Not applicable.
Lower/Upper explosion limit:	As a result of our experience with this product and our knowledge of its composition we do not expect any hazard as long as the product is used appropriately and in accordance with the intended use.
Vapour pressure:	The product has not been tested.
Relative vapour density (air):	Not applicable.
Density (at 20 °C):	Approx. 1.03 g/cm ³
Solubility in water:	Emulsifiable.
Partition coefficient (n-Octanol/water):	Not applicable.
Ignition temperature:	258 °C.
Viscosity, dynamic:	approx. 27 mPa.s (40 °C).
Explosive properties:	Not explosive.

9.2 Other Information

None.

Section 10. STABILITY AND REACTIVITY

10.1 Reactivity

No hazardous reactions if stored and handled as prescribed/indicated.

10.2 Chemical Stability

The product is stable if stored and handled as prescribed/indicated.

10.3 Possibility of hazardous reactions

No hazardous reactions if stored and handled as prescribed/indicated.

10.4 Conditions to avoid

See SDS section 7 - Handling and storage.

10.5 Incompatible material

Substances to avoid: strong acids, strong bases, strong oxidizing agents.

10.6 Hazardous decomposition products

No hazardous decomposition products if stored and handled as prescribed/indicated.

Section 11. TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Results based on a similar composition

Acute toxicity:

LD₅₀ oral rat: >2000mg/kg.
No mortality was observed. Virtually nontoxic after a single ingestion.

LD₅₀ dermal rat: >2000mg/kg.
No mortality was observed. Virtually nontoxic after single skin contact.

LC₅₀ inhalation rat (aerosol): 2.74 mg/L.

Irritation

Serious eye damage/irritation (rabbit): Irritant.
Skin corrosion/irritation (rabbit): Not Irritant.

Respiratory/Skin sensitisation

Mouse LLNA: Sensitizing. Sensitization after skin contact possible.

Mutagenicity

Product: The product has not been tested. The statement has been derived from the properties of the individual components. Mutagenicity tests revealed no genotoxic potential.

Carcinogenicity

Product: The product has not been tested. The statement has been derived from the properties of the individual components. Mutagenicity tests revealed no genotoxic potential.

Component (fluxapyroxad): Indication of possible carcinogenic effect in animal tests. The effect is caused by an animal specific mechanism that has no human counterpart.

Component (metconazole): In long-term studies in rodents exposed to high doses, a tumorigenic effect was found; however, these results are thought to be due to a rodent-specific liver effect that is not relevant to humans

Reproductive toxicity

Product: The product has not been tested. The statement has been derived from the properties of the individual components.

Component (fluxapyroxad): The results of animal studies gave no indication of a fertility impairing effect. May cause harm to children via breast-feeding.

Developmental Toxicity

Product: The product has not been tested. The statement has been derived from the properties of the individual components.

Component (metconazole): Indications of possible developmental toxicity/teratogenicity were seen in animal studies.

STOT (single exposure)

The product has not been tested. Based on the available information there is no specific target organ toxicity to be expected after a single exposure.

Repeated dose toxicity and STOT (repeated exposure)

Product: The product has not been tested. The statement has been derived from the properties of the individual components.

Components:

Fluxapyroxad: Adaptive effects were observed after repeated exposure in animal studies.

Metconazole: Adaptive effects were observed after repeated exposure in animal studies.

Propanoic acid, 2-hydroxy-, 2-ethylhexyl ester, (2S)-: After repeated exposure the prominent effect is local irritation.

Other relevant toxicity information: Misuse can be harmful to health.

11.2 Information on other hazards

Endocrine disrupting properties

Product:

The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Section 12. ECOLOGICAL INFORMATION

12.1 Toxicity

Results based on a similar composition

Product

LC₅₀ *Oncorhynchus mykiss* (96 h): 1.0 mg/L.
EC₅₀ *Daphnia magna* (48 h): 1.383 mg/L.
EC₅₀ *Pseudokirchneriella subcapitata* (72 h): >100 mg/L mg/L (growth rate).

Components

Fluxapyroxad:
NOEC *Pimephales promelas* (33 d): 0359 mg/L.
NOEC *Daphnia magna* (21 d): 0.5 mg/L.

Metconazole:
EC₁₀ *Oncorhynchus mykiss* (95 d): 0.00398 mg/L.
NOEC *Oncorhynchus mykiss* (95 d): 0.00291 mg/L.
NOEC *Daphnia magna* (21 d): 0.16 mg/L.

12.2 Persistence and degradability

Product: Not tested. The statement has been derived from the properties of the individual components.

Component (fluxapyroxad): Not readily biodegradable.
Component (metconazole): Not readily biodegradable.

12.3 Bioaccumulative potential

Product: Not tested.

Component (fluxapyroxad):
BCF *Lepomis macrochirus* (28 d): 36 – 37. Does not accumulate in organisms.

Component (metconazole):
BCF *Lepomis macrochirus*: 51 – 80. Does not accumulate in organisms.

12.4 Mobility in soil

Product: Not tested. The statement has been derived from the properties of the individual components.

Component (fluxapyroxad): Following exposure to soil, adsorption to solid soil particles is probable, therefore contamination of groundwater is not expected.

12.5 Results of PBT and vPvB assessment

The product does not contain a substance fulfilling the PBT (persistent/bioaccumulative/toxic) criteria or the vPvB (very persistent/very bioaccumulative) criteria.

12.6 Endocrine disrupting properties

Product:
Assessment: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

12.7 Other adverse effects

The product does not contain substances that are listed in Regulation (EC) 1005/2009 on substances that deplete the ozone layer.

Section 13. DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Waste disposal procedures: Must be disposed of or incinerated in accordance with local regulations. The UK Environmental Protection (Duty of Care) Regulations (EP) and amendments should be noted (United Kingdom). This product and any uncleaned containers must be disposed of as hazardous waste in accordance with the 2005 Hazardous Waste Regulations and amendments (United Kingdom).

Contaminated packaging: Contaminated packaging should be emptied as far as possible and disposed of in the same manner as the substance/product.

Section 14. TRANSPORT INFORMATION

Transport the product in accordance with the provisions of ADR for road, RID for rail, IMDG for the sea, and ICAO / IATA for air transport

14.1 UN Number

3082.

14.2 UN proper shipping name

ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S., (FLUXAPYROXAD, METCONAZOLE)

14.3 Transport hazard class(es)

9.

14.4 Packing group

III.

14.5 Environmental hazards

Yes

14.6 Special precautions for user

None known.

14.7 Transport in bulk according to Annex II of Marpol 73/78 and the IBC code

Maritime transport in bulk is not intended.

Section 15. REGULATORY INFORMATION

15.1 Safety, health and environmental regulation/legislation specific for the substance or mixture

Prohibitions, Restrictions and Authorizations

Annex XVII of Regulation (EC) No 1907/2006: Number on List: 3

Restrictions of Regulation (EC) No 1907/2006, Annex XVII, do not apply for the intended use(s) of the product given in this SDS.

Directive 2012/18/EU - Control of Major Accident Hazards involving dangerous substances (EU):

List entry in regulation: E1

List entry in regulation: E2

This product is classified under the European CLP Regulation.

The data should be considered when making any assessment under the Control of Substances Hazardous to Health Regulations (COSHH), and related guidance, for example, 'COSHH Essentials' (United Kingdom).

This product may be subject to the Control of Major Accident Hazards Regulations (COMAH), and amendments if specific threshold tonnages are exceeded (United Kingdom).

15.2 Chemical safety assessment

Advice on product handling can be found in sections 7 and 8 of this safety data sheet.

Section 16. OTHER INFORMATION

Full list of relevant hazard and precautionary statements that were not given in full in sections 2 and 3.

H302	Harmful if swallowed.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H332	Harmful if inhaled.
H361d	Suspected of damaging the unborn child.
H362	May cause harm to breast-fed children.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long-lasting effects.
H411	May cause harm to breast-fed children.
H412	Harmful to aquatic life with long lasting effects.
EUH208	Contains: propanoic acid, 2-hydroxy-, 2-ethylhexyl ester, (2S)-. May produce an allergic reaction.
EUH401	To avoid risks to human health and the environment, comply with the instructions for use.

The information presented in this document is accurate to the best of our knowledge at the date of its publication. However, the information given is designed only as a guide for the methods of handling, storage, use, transportation and disposal of the product and is not considered a warranty or quality specification. Life Scientific Limited cannot be held responsible for any loss or damage resulting from the handling, storage, use or disposal of the product. The information contained in this document relates only to this specific product.

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