LAXMI ORGANIC INDUSTRIES

Safety Data Sheet
According to 1907/2006/EC, Article 31

Revision: 28.03.2015

01 Identification of the Substance/mixture and of the Company/undertaking

Product details: Trade name: ethyl acetate Registration number: 01-2119475103-46-0012

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

Sector of Use

SU8 Manufacture of bulk, large scale chemicals (including petroleum products)

SU9 Manufacture of fine chemicals

Su10 Formulation [mixing] of preparations and/or re-packaging (excluding alloys)

Product category

PC1 Adhesives, sealants

PC9a Coatings and paints, thinners, paint removers

PC9b Fillers, putties, plasters, modeling clay

PC9c Finger paints

PC18 Ink and toners

PC27 Plant protection products

PC39 Cosmetics, personal care products

Process category

PROC1 Use in closed process, no likelihood of exposure

PROC2 Use in closed, continuous process with occasional controlled exposure

PROC3 Use in closed batch process (synthesis or formulation)

PROC4 Use in batch and other process (synthesis) where opportunity for exposure arises

PROC5 Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact)

PROC7 Industrial spraying

PROC8a Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non- dedicated facilities

PROC8b Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities

PROC9 Transfer of substance or preparation into small containers (dedicated filling line, including weighing)

PROC10 Roller application or brushing

PROC11 Non industrial spraying

PROC13 Treatment of articles by dipping and pouring

Manufacturer / Supplier
Laxmi Organic Industries Ltd.
Chandermukhi, 3rd Floor,
Nariman Point, Mumbai 400 021
Tel No. : +91 22 49104444
Fax No. : +91 22 22853752
Email : info@laxmiorganic.co.in

Contact details of European importer
Laxmi Organic Industries (Europe) B.V.
Burgemeester Feithplein 11, 2273 BZ
Voorburg, The Netherlands
Tel No. : +31(0)70 20 40 600
Fax No. : +31 (0)70 20 40 604
Email : marketing@laxmiorganic.eu

Emergency telephone numbers:
+31 646159978 (for EU)
+91 7738092735 (for other regions)
Other Comments (e.g. language(s) of the phone service): English

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

PROC14 Production of preparations or articles by tabletting, compression, extrusion, pelletisation

PROC15 Use as laboratory reagent

PROC17 Lubrication at high energy conditions and in partly open process

PROC18 Greasing at high energy conditions

PROC19 Hand-mixing with intimate contact and only PPE available

PROC20 Heat and pressure transfer fluids in dispersive, professional use but closed systems

Environmental release category

ERC1 Manufacture of substances

ERC2 Formulation of preparations

ERC4 Industrial use of processing aids in processes and products, not becoming part of articles

ERC7 Industrial use of substances in closed systems

ERC8a Wide dispersive indoor use of processing aids in open systems

ERC8d Wide dispersive outdoor use of processing aids in open systems

Application of the substance / the mixture

Industrial Manufacturing of Ethyl Acetate

Drumming and Distribution of Ethyl Acetate

Industrial Formulation of Ethyl Acetate and its Mixtures

Industrial use as an Extraction Solvent and/or Processing Aid

Industrial Application of Paints, Coatings and other Mixtures containing Ethyl Acetate by way of Spraying

Industrial Application of Paints and Coatings \(non-spray application)

Industrial and Professional (end) use of ethyl acetate as a laboratory reagent

Professional application of paints, coatings, adhesives and other mixtures/products containing ethyl acetate (indoors or outdoors, spray or non spray application)

Industrial and Professional (end) use of ethyl acetate as a laboratory reagent

Consumer use of Ethyl Acetate in Adhesives and Coatings

Consumer use of ethyl acetate in cosmetic products

02 Hazards Identification

Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008

Flame

Flam. Liq. 2 H225 Highly flammable liquid and vapour

Eye Irrit. 2 H319 Causes serious eye irritation.

STOT SE 3 H336 May cause drowsiness or dizziness

Classification according to Directive 67/548/EEC or Directive 1999/45/EC

Xi; Irritant

R36: Irritating to eyes

F; Highly flammable

R11: Highly flammable

R66-67: Repeated exposure may cause skin dryness or cracking. Vapours may cause drowsiness and dizziness.

Label elements

Labelling according to Regulation (EC) No 1272/2008

The substance is classified and labelled according to the CLP regulation

Hazard pictograms:

GHS02 GHS07

Signal Word Danger

Hazard statements

H225	Highly flammable liquid and vapour.
H319	Causes serious eye irritation.
H336	May cause drowsiness or dizziness

Precautionary statements

P210	Keep away from heat/sparks/open flames/hot surfaces. - No smoking.
P241	Use explosion-proof electrical/ventilating/ lighting/equipment.
P303+P361+ P353	IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.
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 off contents/container in accordance with local/regional/national/international regulations.

Additional information:

EUH066 Repeated exposure may cause skin dryness or cracking.

Other hazards

EMERGENCY OVERVIEW:

Highly flammable. Repeated exposure may cause skin dryness or cracking. Vapors may cause drowsiness and dizziness.

Results of PBT and vPvB assessment

PBT : Not applicable.

vPvB : Not applicable.

03 Composition/Information on Ingredients

Chemical characterization: Substances

CAS No.: 141-78-6 **Description:** ethyl acetate

Identification number(s)

EC number : 205-500-4

Index number : 607-022-00-5

Additional information:

Molecular Formula : C4H8O2

Molecular Weight : 88.11

Purity % : > 80

04 First Aid Measures

General information:

Immediately remove any clothing soiled by the product.

After inhalation:

If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention if symptoms appear. Do NOT use mouth-to-mouth resuscitation

After skin contact:

Wash with soap and water.

Cover the irritated skin with an emollient.

Get medical attention if irritation develops. Cold water may be used.

After swallowing:

Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an

unconscious person. Loosen tight clothing such as a collar, tie, belt or waistband. Get medical attention if symptoms appear.

Most important symptoms and effects, both acute and delayed

May affect gastrointestinal tract (nausea, vomiting).

May affect behavior/central nervous system (mild central nervous system depression - exhilaration, talkativeness, boastfulness, belligerancy, vertigo, diplopia, drowsiness, slurred speech, slowed reaction time, dizziness, lightheadedness, somnolence, ataxia, unconciousness, irritability, fatigue, sleep disturbances, reduced memory and concentration, stupor, coma), cardiovascular system (peripheral vascular collapse (shock) - rapid pulse, hypotension, cold pale skin, hypothermia). Other symptoms may include: flushing of face and sweating.

Indication of any immediate medical attention and special treatment needed

No further relevant information available.

05 Firefighting Measures

Extinguishing media

Suitable extinguishing agents:

For small fires, use water spray, dry chemical, carbon dioxide or chemical foam. Water may be ineffective. For large fires, use water spray, fog or alcohol-resistant foam. Do NOT use straight streams of water. Cool containers with flooding quantities of water until well after fire is out. DO NOT USE DRY CHEMICAL for fires involving nitromethane or nitroethanes.

For safety reasons unsuitable extinguishing agents:

Water with full jet

Special hazards arising from the substance or mixture

Fire Hazards in Presence of Various Substances:

Highly flammable in presence of open flames and sparks, of heat. Slightly flammable to flammable in presence of oxidizing materials, of acids, of alkalis. Non-flammable in presence of shocks.

Explosion Hazards in Presence of Various Substances:

Risks of explosion of the product in presence of static discharge. Slightly explosive in presence of heat. Nonexplosive in presence of shocks.

Advice for firefighters

Protective equipment: No special measures required.

06 Accidental Release Measures

Personal precautions, protective equipment and emergency procedures

Wear protective equipment. Keep unprotected persons away.

Environmental precautions: Do not allow to enter sewers/ surface or ground water.

Methods and material for containment and cleaning up:

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

Ensure adequate ventilation.

Reference to other sections

IN CASE OF LEAKS: Avoid runoff into storm sewers and ditches which lead to waterways. Clean up spills

immediately, observing precautions in the Protective Equipment section. Remove all sources of ignition. Absorb spill using an absorbent, non-combustible material such as earth, sand, or vermiculite. Do not use combustible materials such as saw dust. Provide ventilation.

SMALL SPILL: Dilute with water and mop up, or absorb with an inert dry material and place in an appropriate waste disposal container.

LARGE SPILL: Flammable liquid. Keep away from heat. Keep away from sources of ignition. Stop leak if without risk. Absorb with DRY earth, sand or other non- combustible material. Do not touch spilled material. Prevent entry into sewers, basements or confined areas; dike if needed. Be careful that the product is not present at a concentration level above TLV. Check TLV on the MSDS and with local authorities.

07 Handling and Storage

Handling

Precautions for safe handling

Wash thoroughly after handling. Use with adequate ventilation. Ground and bond containers when transferring material. Avoid contact with eyes, skin, and clothing.

Empty containers retain product residue, (liquid and/or vapor), and can be dangerous. Keep container tightly closed.

Avoid ingestion and inhalation. Do not pressurize, cut, weld, braze, solder, drill, grind, or expose empty containers to heat, sparks or open flames.

Information about fire - and explosion protection:

Keep ignition sources away - Do not smoke.

Protect against electrostatic charges.

Conditions for safe storage, including any incompatibilities

Storage

Requirements to be met by storerooms and receptacles:

Store in a cool location.

Information about storage in one common storage facility:

Store in a segregated and approved area. Keep container in a cool, well-ventilated area. Keep container tightly closed and sealed until ready for use. Avoid all possible sources of ignition (spark or flame). Moisture sensitive.

Further information about storage conditions:

Suitable material for packaging: stainless steel, carbon steel, iron, aluminum, copper, nickel, polypropylene, glass or tin. To be avoided: plastics.

Specific end use(s)

Industrial Manufacturing of Ethyl Acetate

Drumming and Distribution of Ethyl Acetate

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Industrial Application of Paints and Coatings \(non-spray application)

Industrial and Professional (end) use of ethyl acetate as a laboratory reagent

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Consumer use of Ethyl Acetate in Adhesives and Coatings

Consumer use of ethyl acetate in cosmetic products

08 Exposure Controls/ Personal Protection

Additional information about design of technical facilities:

Engineering Controls:

Provide exhaust ventilation or other engineering controls to keep the airborne concentrations of vapors below their respective threshold limit value. Ensure that eyewash stations and safety showers are proximal to the work- station location

Control parameters

Ingredients with limit values that require monitoring at the workplace: Not required.

DNELs

Acute - systemic effects
Inhalation
DNEL (Derived No Effect Level)
1468 mg/m³

Acute - local effects
Inhalation
DNEL (Derived No Effect Level)
1468 mg/m³

Long-term - systemic effects
Dermal
DNEL (Derived No Effect Level)
63 mg/kg bw/day

Long-term - systemic effects
Inhalation
DNEL (Derived No Effect Level)
734 mg/m³

Long-term - local effects
Inhalation
DNEL (Derived No Effect Level)
734 mg/m³

Acute - systemic effects
Inhalation
DNEL (Derived No Effect Level)
734 mg/m³

Acute - local effects
Inhalation
DNEL (Derived No Effect Level)
734 mg/m³
Long-term - systemic effects
Dermal
DNEL (Derived No Effect Level)
37 mg/kg bw/day

Long-term - systemic effects
Inhalation
DNEL (Derived No Effect Level)
367 mg/m³

Long-term - systemic effects
Oral
DNEL (Derived No Effect Level)
4.5 mg/kg bw/day

Long-term - local effects
Inhalation
DNEL (Derived No Effect Level)
367 mg/m³

PNECs

Freshwater
PNEC aqua (freshwater): 0.24 mg/L

Marine water
PNEC aqua (marine water): 0.024 mg/L

Intermittent releases to water
PNEC aqua (intermittent releases): 1.65 mg/L

PNEC sediment (freshwater):
1.15mg/kg sediment dw

PNEC sediment (marine water):
0.115 mg/kg sediment dw

PNEC soil: 0.148mg/kg soil dw

PNEC STP: 650 mg/L

08 Exposure Controls/ Personal Protection

Additional information about design of technical facilities:

Additional Occupational Exposure Limit Values for possible hazards during processing:

141-78-6 ethyl acetate

TWA	400 (ppm) from OSHA (PEL) [United States]
TWA	400 from ACGIH (TLV) [United States]
TWA	1400 (mg/m3) fromNIOSH [United States]
TWA	400 (ppm) from NIOSH [United States]
TWA	400 (ppm) [Canada]
TWA	1440 (mg/m3) [Canada]
TWA	1400 (mg/m3) from OSHA (PEL) [United States]
	Consult local authorities for acceptable exposure limits.

Additional information: The lists valid during the making were used as basis.

Exposure controls

Personal protective equipment:

General protective and hygienic measures:

Keep away from foodstuffs, beverages and feed.

Immediately remove all soiled and contaminated clothing

Wash hands before breaks and at the end of work.

Avoid contact with the eyes and skin.

Respiratory protection:

Follow the OSHA respirator regulations found in 29CFR 1910.134 or European Standard EN 149. Always use a NIOSH or European Standard EN 149 approved respirator when necessary.

Protection of hands

Protective gloves

Material of gloves

Material which give excellent resistance: polyethylene/ethylene vinyl alcohol. Give good resistance: PVA. Give less resistance: neoprene, natural rubber, nitrile rubber, polyethylene, PVC and Viton.

Penetration time of glove material

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

Eye Protection

Tightly sealed goggles

Eye protection:

Wear appropriate protective eyeglasses or chemical safety goggles as described by OSHA's eye and face protection regulations in 29 CFR 1910.133 or European Standard EN166.

Risk management measures

Please check Annex I for the Exposure Assessment pertaining to uses mentioned in section 1 of SDS

09 Physical and Chemical Properties

Information on basic physical and chemical properties

General Information	Physical State: Liquid
Appearance:	Clear, colorless
Form:	Fluid
Colour:	Colourless
Odour:	Sweet, fruity odour
Change in condition	
Melting point/Melting range:	-84.15 C (at 1013 hPa)
Boiling point/Boiling range:	76.85 C (at 1013 hPa)
Flash point:	-4.15 C (at 1013 hPa)
Flammability (solid, gaseous):	Highly flammable
Self-igniting:	426.85 C at 1013 hPa
Danger of explosion:	Product does not present an explosion hazard.
Explosion limits:	
Oxidizing properties	The criteria for adaptation from the testing requirements for this end point as listed in annex VII, paragraph 7.13 of the regulation clearly state that the study does not need to be conducted if the substance is highly flammable. This substance is highly flammable therefore a test for oxidising properties is not required. In addition, according to the guidance on information requirements and chemical safety assessment for this end point, the molecule contains no groups associated with oxidising properties (table 7.1-29) and also oxygen only bonded to carbon atoms within the molecular structure. These are both confirmative criteria confirming that testing does not need to be carried out for this end point
Vapour pressure at 21°C:	10.3 kPa
Density :	
Relative density at 20 °C	900.3 kg/m3
Solubility in / Miscibility with water at 25°C:	80000 mg/l
Partition coefficient (n-octanol/water) at 25°C:	0.68 log POW
Viscosity:	
Dynamic at 20°C:	0.45 mPas
Other information	Surface tension Reason: other justification Justification: According to column 2 of annex VII of the regulation, a study for surface tension need only be conducted if based on the structure, surface activity is expected or can be predicted. In the case of this substance, surface activity is neither expected nor predicted, therefore a study is not required. Explosive properties

09 Physical and Chemical Properties

Reason: other justification

Justification: There are no chemical groups associated with explosive properties present in the molecule. According to annex VII, paragraph 7.11 of the regulation and the criteria for adaptation, as study for this end point is not required.

Granulometry

Reason: other justification

Justification: Substance meets the rules specified in Annex VII column 2 for adaptation. A study does not need to be tested as the substance is a liquid under all conceivable environmental conditions (ie. it is not marketed or used in a solid or granular form.)

Dissociation constant

Reason: study scientifically unjustified

Justification: The substance structure contains no ionisable functionality. According to the integrated testing strategy for this end point (fig R.7.1.9) in the guidance on information requirements and chemical safety assessment, no test is required therefore for this end point.

10 Stability and reactivity

Reactivity

Chemical stability

Thermal decomposition / conditions to be avoided:

High temperatures, incompatible materials, ignition sources, excess heat.

Possibility of hazardous reactions

No dangerous reactions known.

Conditions to avoid

No further relevant information available.

Incompatible materials:

Chlorosulfonic acid, lithium aluminum hydride + 2-chloromethylfuran,lithium tetrahydroaluminate, oleum, potassium t-butoxide. Substance coming in contact with nitrates or strong acids/oxidizers/alkalies may cause fire

Hazardous decomposition products:

Carbon monoxide, irritating and toxic fumes and gases, carbon dioxide.

11 Toxicological information

Information on toxicological effects
Acute Toxicity

LD/ LC 50 values relevant for classification

Oral	LD 50	4934 mg/kg bw (male/female) (rabbit)
Dermal	LD 50	> 20000 mg/kg bw (male) (rabbit (New Zealand White))
Inhalative	LCL0 (6 hrs)	> 6000 ppm (rat(Sprague-Dawley)male/female)

Primary irritant effect:

on the skin:

1st study

rabbit (New Zealand White) Coverage: un-occlusive (shaved) Result: slightly irritating

Primary dermal irritation index (PDII): 1.7 of max. 8 (mean) (Time point: 24 h) (not fully reversible within: 7 days) (tested using membrane polymer formulation 1)

Primary dermal irritation index (PDII): 1.3 of max. 8 (mean) (Time point: calculated from 24, 48, 72 hour observations) (fully reversible within: 7 days) (tested using membrane polymer formulation 2)

Erythema score:

1.33 of max. 4 (mean) (Time point: average of 24, 48, 72 hour readings) (not fully reversible within: 7 days) (tested using membrane polymer formulation 1)

Edema score:

0.4 of max. 4 (mean) (Time point: average of 24, 48, 72 hour readings) (not fully reversible within: 7 days) (tested using membrane polymer formulation 1)

2nd Study

Species: Humans

Study type: study with volunteers

Subjects: - Number of subjects exposed: 118

Endpoint addressed: skin irritation / corrosion

Result: No reactions were observed in any of the subjects. The procedure was repeated after the subjects has used the product (no further details) for 4 weeks. Again no reactions were observed in the open patch test.

on the eye:

1st study

rabbit (New Zealand White) Result: not irritating

Overall irritation score: 15 of max. 110 (mean) (Time point: average at time points 24, 48, 72hrs) (not fully reversible within: 7 days) (See notes below)

Cornea score:

0.41 of max. 4 (mean) (Time point: average at time points 24, 48, 72hrs) (fully reversible within: 2 days)

0.5 of max. 4 (mean) (Time point: average at time points 24, 48, 72hrs) (fully reversible within: 2 days) (average of results for 2 worst affected animals.)

Iris score:

0.08 of max. 2 (mean) (Time point: average at time points 24, 48, 72hrs) (fully reversible within: 2 days)

0.17 of max. 2 (mean) (Time point: average at time points 24, 48, 72hrs) (fully reversible within: 2 days) (average of results for 2 worst affected animals.)

Conjunctivae score:

1.25 of max. 3 (mean) (Time point: average at time points 24, 48, 72hrs) (fully reversible within: 7 days)

11 Toxicological information

Information on toxicological effects
Acute Toxicity

1.33 of max. 3 (mean) (Time point: average at time points 24, 48, 72hrs) (fully reversible within: 2 days) (average of results for 2 worst affected animals.)

Chemosis score:

0.58 of max. 4 (mean) (Time point: average at time points 24, 48, 72hrs) (fully reversible within: 3 days)

0.67 of max. 4 (mean) (Time point: average at time points 24, 48, 72hrs) (fully reversible within: 2 days) (average of results for 2 worst affected animals.)

2nd study

Species: Humans

Study type: study with volunteers

Type of population: occupational

Subjects: - Number of subjects exposed: 9 volunteers

Endpoint addressed: respiratory irritation

Endpoint addressed: eye irritation

Result: Exposure to 200ppm was clearly without effect. Exposure to 400ppm for 4 hours produced marginal subjective sensations of mild to medium eye soreness in 2 out of 6 individuals. Exposure to high levels (600-

1000ppm) for short periods produced increasing subjective sensations, albeit only mild to medium in the eyes, nose and throat of some volunteers. No changes in eye redness were observed. There was a wide variation in blink rate between individuals and there was no correlation with exposure.

Sensitization:

guinea pig (Dunkin-Hartley) female

Guinea pig maximisation test Induction: intradermal Result: not sensitising

No. with positive reactions:

1st reading: 0 out of 20 (test group); 24 h after chall.; dose: 100%

2nd reading: 0 out of 10 (test group); 48 h after chall.; dose: 100%

1st reading: 0 out of 10 (negative control); 24 h after chall.; dose: 0%

2nd reading: 0 out of 10 (negative control); 48 h after chall.; dose: 0%

Other information (about experimental toxicology): Hazardous in case of ingestion, or inhalation.

Additional toxicological information:

Inhalation: May cause respiratory tract and mucous membrane irritation. May affect respiration and may cause acute pulmonary edema.

Prolonged inhalation may affect behavior/central nervous system (symptoms similar to those of acute inhalation), and cause liver, kidney, lung, and heart damage. It may also affect metabolism, and blood (anemia, leukocytosis).

Ingestion: Prolonged or repeated ingestion may affect the liver.

Toxicokinetics, metabolism and distribution

rat (Sprague-Dawley) male

intravenous and in vitro

Exposure regime: Intravenous studies: single bolus dose

11 Toxicological information

Information on toxicological effects
Acute Toxicity

In vitro studies: incubation for 120 minutes

Doses/conc.: Intravenous Blood Kinetic Studies: 100 or 10 mg/kg (3.75 ml/kg) Intravenous Brain Kinetic Study: 100 mg/kg (3.75 ml/kg)

In vitro Blood Study: the highest concentration (400 ug/g) seen in blood following the high dose (100 mg/kg) iv administration in vivo

The hydrolysis of ethyl acetate was monitored by following the decline in [14C] ethyl acetate and increase in [14C]ethanol and [14C]acetic acid concentrations in blood following an intravenous (iv) dose. Similarly for the brain kinetic studies, concentrations of [14C]ethyl acetate, [14C]ethanol, and [14C] acetic acid in brain tissue were also determined. In addition, the in vitro hydrolysis rate of ethyl acetate in whole blood was determined by measuring the decline in [14C] ethyl acetate concentrations in blood spiked with micromolar concentrations of [14C]ethyl acetate. Together, these studies provide kinetic information on the in vivo systemic hydrolysis and in vitro blood hydrolysis of ethyl acetate in the rat.

Result:

Toxicokinetic parameters:

Half-life 1st: Elimination half-lives of 33.4 s and 36.9 s were estimated for the 10 and 100 mg/kg doses, respectively. (Test No.: 1)

Metabolites identified: no

Evaluation of results: ethyl acetate is rapidly hydrolyzed in vivo

Repeated dose toxicity

Repeated dose toxicity: oral

Species: rat (Sprague-Dawley) male/female

Test Type: subchronic (oral: gavage)

Dose: 0, 300, 900 and 3600 mg/kg bw d (actual ingested) Exposure: 90 - 92 d (daily)

Result: NOAEL: 900 mg/kg bw/day (nominal) (male/female)

LOAEL: 3600 mg/kg bw/day (nominal) (male/female) (clinical signs, body weights, food consumption)

Repeated dose toxicity: inhalation

Species: rat (Crl:CD®BR) male/female

Test type: subchronic (inhalation) (whole body) Dose: 0, 350, 750, 1500 ppm

Vehicle: unchanged (no vehicle)

Exposure: 94 days (6 hours/day - 5 days/week (68 total exposures).)

Result: NOEC (systemic toxicity): 350 ppm (male/female) (all other acute effects, site of contact effects and systemic toxicity)

LOEC: 350 ppm (male/female) (nasal irritation.)

11 Toxicological information

Information on toxicological effects
Acute Toxicity

Repeated dose toxicity: dermal

Annex IX paragraph 8.6.2 of regulation 1907/2006 stated that a sub-chronic (repeat dose) testing is required by the most appropriate route of testing. For a volatile solvent such as ethyl acetate, the most relevant route is inhalation exposure. Reliable data by this route is available (see chapter 7.5.3 of this dossier.) Data is also available for the oral route as supporting information. Testing by the dermal route is not scientifically justified because the physicochemical properties do not suggest a significant rate of absorption through the skin (low rate of penetration predicted, see chapter 7.1.2 plus high rate of evaporation from skin expected), acute toxicity observed in the dermal toxicity test is not seen at lower doses that the oral toxicity test, there is no evidence of systemic toxicity in acute skin or eye irritancy tests and significant dermal toxicity is not seen with structurally related compounds (eg. other acetate esters.) Any prediction required for chronic toxicity by the dermal route can be obtained by route to route extrapolation using appropriately conservative assessment factors

CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)

Mutagenicity:

Test type: bacterial reverse mutation assay (e.g. Ames test) (gene mutation)

Species: S. typhimurium TA 1535, TA 1537, TA 98 and TA 100 (met. act.: with and without) S. typhimurium TA 97 (met. act.: with and without)

Doses: 0 ; 100 ; 333 ; 1000 ; 3333 ; 10000 µ g/plate. Doses were prepared using dimethyl sulphoxide as the solvent; a maximum of 0.5 ml solvent was added to each plate. Each dose was tested in triplicate without activation, and with 10% rat and hamster liver S-9.

Evaluation of results:

negative

Test results:

negative for S. typhimurium TA 1535, TA 1537, TA 98 and TA 100(all strains/cell types tested); met. act.: with and without; cytotoxicity: no (up to maximum dose tested (10000ug/ml))

negative for S. typhimurium TA 97(all strains/cell types tested); met. act.: with and without; cytotoxicity: no (up to maximum dose tested (10000ug/ml))

Carcinogenicity:

Species: mouse (A/He) male/female

Route: (intraperitoneal)

Dose: 150 mg/kg bw/injection (total dose: 3600 mg/kg bw) and 750 mg/kgbw/injection (total dose: 18000 mg/kg bw)

Exposure: 8 w (3 times/week)

Mouse Pulmonary Tumour Test according to method of Andervant and Shimkin

Result: Ethyl acetate did not produce an increase in mouse lung tumours compared with controls:

Toxicity for reproduction:

Species/Strain: mouse (CD-1) male/female

Study type: two-generation study

Route of administration: oral: drinking water

Dose: 5, 10 and 15% v/v in water (analytical conc.)

11 Toxicological information

Information on toxicological effects
Acute Toxicity

0.0 6900, 13800, and 20700 mg/kg/day. (actual ingested (based on water consumption values))

Exposure: Exposure period: 18 weeks

Premating exposure period (males): Parental 7 days; F1 74 days

Premating exposure period (females): Parental 7 days; F1 74 days (ad libitum)

NOAEL (P): 20700 mg/kg bw/day (actual dose received) (male/female) (No effects observed in parameters studied at all doses. Result for ethanol. Equivalent to 39600mg/kg/day for ethyl acetate on a molar basis.) NOAEL (F1): 13800 mg/kg bw/day (actual dose received) (male/female) (At the highest dose fewer pups per litter were observed and significant changes to sperm motility. Result for ethanol. Equivalent to 26400mg/kg/ day for ethyl acetate on a molar basis.)

no NOAEL identified (F2): < 20700 mg/kg bw/day (actual dose received) (male/female) (Lower live pup weight observed at the 15% dose studied. Lower doses not examined. Result for ethanol. Equivalent to 39600mg/kg/day for ethyl acetate on a molar basis.)

Developmental toxicity:

Species/Strain: rat (Sprague-Dawley)

Route of exposure: inhalation (whole body)

Dose: 10,000, 16,000 or 20,000 ppm (Doses are calculated to be equivalent to 17, 29 and 28 g/kg bodyweight.) (nominal conc.)

Exposure: 7 hours per day in exposure chamber on gestation days 1-19. Animals left in the chambers for degassing for approximately 1/2 hr after vapor generation terminated. (daily (7 days/week))

Result: NOAEL (maternal toxicity): 16000 ppm (Narcosis and reduced food consumption in highest dose group)

NOAEL (teratogenicity): ≥ 20000 ppm (Borderline significant on incidence of malformations at 20000ppm) LOAEL (maternal toxicity): 20000 ppm (Narcosis and reduced food consumption)

12 Ecological Information

Toxicity

Acquatic toxicity:

EC50 (24 hrs)	3090 mg/L (Daphnia magna)
LC50 (96 hrs)	230mg/L (Pimephales Promelas (Fathead Minnow))
NOEC (21 days)	2.4 mg/L (Daphnia magna)
NOEC (32 days)	< 9.65 mg/L (Pimephales Promelas (Fathead Minnow))
NOEC (72 hrs)	> 100 mg/L (Desmodesmus subspicatus)

Persistence and degradability

Biodegradation in water
Test type: ready biodegradability
sewage, domestic, non-adapted
Result: readily biodegradable
% Degradation of test substance:
ca. 62 after 5 d (O2 consumption)
ca. 62 after 10 d (O2 consumption)
ca. 69 after 15 d (O2 consumption)
ca. 69 after 20 d (O2 consumption)

Biodegradation in water and sediment activated sludge, domestic (adaptation not specified)
Continuous Flow Activated Sludge Reactor Test. Specific chemical compound analyses followed the instructions for gas chromatograph analyses given in the Federal Register. All other analyses were conducted according to EPA-approved procedures.
Result: % Degradation of test substance:
99.9 after 6 d (overall removal rate including volatile loss)
91 after 2 d (TOC removal) (same efficiency at days 4 and 6)
94 after 2 d (COD) (same efficiency at days 4 and 6)
99.4 after 2 d (BOD5) (same efficiency at days 4 and 6) Metabolites: not measured

Biodegradation in soil
According to the conditions for adaptation listed in column 2 in Annexes VIII and IX under section 9.2, further testing for degradation in water and sediment (simulation testing) is not required if the substance is readily biodegradable

Other information:
Hydrolysis
Half-life (DT50):
t1/2 (pH 5): 16 yr at 24.9 °C; Rate constant: 0.04 a-1; Type: (pseudo-)first order (= DT50) (Hydrolysis rate constant 1.36E-9 s-1)
t1/2 (pH 7): 24 mo at 24.9 °C; Rate constant: 0.35 a-1; Type: (pseudo-)first order (= DT50) (Hydrolysis rate constant 1.09E-8 s-1)
t1/2 (pH 9): 7.5 d at 24.9 °C; Rate constant: 0.09 d-1; Type: (pseudo-)first order (= DT50) (Hydrolysis rate constant 1.07E-6 s-1)

Transformation products: not measured

12 Ecological Information

Toxicity

Bioaccumulative potential
Chlorella fusca (var vaculolata)
aqueous (freshwater)
aerobic

Total uptake duration: 1 d
Details of method: For the determination of accumulation 10 ml samples are taken from the homogeneous test mixture and are centrifuged for 10 minutes at 2000 g. The algae-free supernatant is siphoned off and its l4C activity determined. After washing with water the algae are sucked dry on a membrane filter (3 micron pore size). Combustion of the algae (together with the filter) and 14C measurement are used to determine the concentration of the substances in the algae. If the accumulation is less than 2% or more than 98% the entire remainder of the preparation is used for determining a more accurate concentration in algae and water respectively. The accumulation factor f24 is obtained from the ratio of the concentration of the substance in the algae (ug/g D. S.) to the content in water (ug/ml) after the 24-hour duration of the test.
Bioaccumulation test using algae. Methods following Freitag (1982) and Korte (1978)
Result: BCF: 13500 (based on concentration in algae versus water at end of study)

Mobility in soil
Based on the physicochemical properties (low octanol water partition co-efficient, <3), the substance has a low potential for adsorption. According to the adaptation criteria of column 2 of annex VIII (paragraph 9.3.1) of the regulation, a study is not therefore required for this end point.

Additional ecological information:
General notes:
Water hazard class 1 (German Regulation) (Assessment by list): slightly hazardous for water
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

Results of PBT and vPvB assessment
Persistence Assessment
Substance does not meet screening criteria. Substance is readily biodegradable and is therefore neither P nor vP.
Bioaccumulation Assessment
Substance does not meet screening criteria. Substance logKow<4.5 and is therefore it is neither B nor vB.

Toxicity Assessment
Substance does not meet screening criteria. Acute aquatic toxicity (LC50 and EC50) >0.1mg/l. Substance is neither carcinogenic, mutagenic nor teratogenic. Substance is not T.
Summary and overall Conclusions on PBT or vPvB Properties
Substance does not meet the screening criteria for persistency nor toxicity so is neither PBT nor vPvB.

Emission Characterisation

Not required as substance is neither PBT nor vPvB.

PBT : Not applicable.

vPvB : Not applicable.

Other adverse effects : No further relevant information available

13 Disposal considerations

Waste treatment methods

Recommendation:

Waste must be disposed of in accordance with federal, state and local environmental control regulations.

Uncleaned packaging:

Recommendation: Disposal must be made according to official regulations.

14 Transport Information

UN-Number

ADR, IMDG, IATA 1173

UN proper shipping name

ADR 1173 ETHYL ACETATE

IMDG, IATA ETHYL ACETATE

Transport hazard class(es)

ADR

Class	3 Flammable liquids
Label	3

Packing group

ADR, IMDG, IATA	II

Environmental hazards:

Marine pollutant:	No
Special precautions for user	Warning: Flammable liquids
Danger code (Kemler):	33
EMS Number:	F-E,S-D
Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	Not applicable.

Transport/Additional information:

ADR

Limited quantities (LQ)	LQ4
Transport category	2
Tunnel restriction code	D/E
UN "Model Regulation":	UN1173, ETHYL ACETATE, 3, II

15 Regulatory Information

Labelling according to regulation (EC) No 1272/2008

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

Single word Danger

National regulations:

Other regulations, limitations and prohibitive regulations:

OSHA: Hazardous by definition of Hazard Communication Standard (29 CFR 1910.1200).

EINECS: This product is on the European Inventory of Existing Commercial Chemical Substances.

Substances of very high concern (SVHC) according to REACH, Article 57:

The substance is not listed as SVHC.

Chemical safety assessment:

A Chemical Safety Assessment has been carried out.

16 Other Information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

Abbreviations and acronyms

RID	:	Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)
ADR	:	Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
IMDG	:	International Maritime Code for Dangerous Goods
IATA	:	International Air Transport Association
GHS	:	Globally Harmonized System of Classification and Labelling of Chemicals
EINECS	:	European Inventory of Existing Commercial Chemical Substances
CAS	:	Chemical Abstracts Service (division of the American Chemical Society)
DNEL	:	Derived No-Effect Level (REACH)
PNEC	:	Predicted No-Effect Concentration (REACH)
LC50	:	Lethal concentration, 50 percent
LD50	:	Lethal dose, 50 percent
Flam. Liq. 2	:	Flammable liquids, Hazard Category 2
Eye Irrit. 2	:	Serious eye damage/eye irritation, Hazard Category 2
STOT SE 3	:	Specific target organ toxicity - Single exposure, Hazard Category 3

Sources

Data is from Chemical Safety Report (CSR) of CAS NO 141-78-6

***Data compared to the previous version altered.**

Section 4	:	First Aid Measures
Section 7	:	Handling And Storage
Section 8	:	Exposure Controls, Personal Protection
Section 9	:	Physical And Chemical Properties
Section 10	:	Stability And Reactivity
Section 11	:	Toxicological Information
Section 12	:	Ecological Information
Section 16	:	Additional Information