SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product name         Midazolam Maleate
Product code         04 0674 0

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

Use - pharmaceutical active substance (short-acting hypnotic)

1.3. Details of the supplier of the safety data sheet

Company information Enquiries: F. Hoffmann-La Roche AG
Local representation: Postfach
                      CH-4070 Basel
                      Switzerland

                      Phone         +41-61/688 54 80
                      Fax           +41-61/681 72 76
                      E-Mail        info.sds@roche.com

1.4. Emergency telephone number

Emergency telephone number Phone         +41-61/688 54 80
SECTION 2: Hazards identification

2.1. / 2.2. Classification of the substance or mixture / Label elements

GHS Classification

Health Hazards:
3.1 Acute toxicity (Category 4)
H302 Harmful if swallowed.

Environmental Hazards:
4.1 Hazardous to the aquatic environment (Category 2)
H411 Toxic to aquatic life with long lasting effects.

Signalword: Warning

Label:

Precautionary statements:
- P260 Do not breathe dust
- P273 Avoid release to the environment.
- P312 Call a POISON CENTER or doctor/physician if you feel unwell.

2.3. Other hazards

Note
- Benzodiazepines induce central nervous system depression and drowsiness. In addition, longer use may be habit forming. Hence, these compounds are also misused by addicts.
- may form explosible dust-air mixture if dispersed

SECTION 3: Composition/information on ingredients

Characterization
pharmaceutical active substance in the class of benzodiazepines

Chemical name
- 8-Chloro-6-(2-fluorophenyl)-1-methyl-4H-imidazo-[1,5a][1,4]benzodiazepine maleate

Synonyms
- DORMICUM substance (maleate)
- Dobralam
- Versed

CAS number 59467-94-6
EINECS number 261-775-0
UN number 3077
Roche number RO0213981-001
Empirical formula $C_{18}H_{13}ClFN_3 \cdot C_4H_4O_4$
Molecular mass 441.84 g/mol

SECTION 4: First aid measures

4.1. Description of first aid measures

Eye contact - rinse immediately with tap water for at least 20 minutes - open eyelids forcibly
- consult a physician

Skin contact - remove immediately contaminated clothes, wash affected skin with water and soap - do not use any solvents

Inhalation - remove the casualty to fresh air and keep him/her calm
- get medical treatment

4.2. Most important symptoms and effects, both acute and delayed

Note - no information available

4.3. Indication of any immediate medical attention and special treatment needed

Note to physician - treat symptomatically
- in cases of severe poisoning: Anexate i.v.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media - water spray jet, dry powder, foam, carbon dioxide

5.2. Special hazards arising from the substance or mixture

Specific hazards - formation of toxic and corrosive combustion gases (hydrogen chloride, hydrogen fluoride, nitrogen oxides) possible
- consider dust explosion hazard
- substance is hazardous for water: contain fire-fighting wastewater
### 5.3. Advice for firefighters

Protection of fire-fighters - precipitate gases/vapours/mists with water spray

### SECTION 6: Accidental release measures

#### 6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions - avoid exposure

#### 6.2. Environmental precautions

Environmental protection - do not allow to enter drains or waterways
- if the substance reaches waters or the sewer system, inform the competent authority

#### 6.3. Methods and material for containment and cleaning up

Methods for cleaning up - collect solids (avoid dust formation) and hand over to waste removal

### SECTION 7: Handling and storage

#### 7.1. Precautions for safe handling

Technical measures - processing in closed systems, if possible superposed by inert gas (e.g. nitrogen)
- local exhaust ventilation necessary
- take precautionary measures against electrostatic charging
- avoid dust formation; high dust explosion hazard

Suitable materials - stainless steel, aluminium, enamel, glass
- test plastics before use

#### 7.2. Conditions for safe storage, including any incompatibilities

Validity - 36 months, under nitrogen, at room temperature

Packaging materials - tightly closing; material: glass, steel (lined with polyethylene bag)

### SECTION 8: Exposure controls/personal protection

#### 8.1. Control parameters

Threshold value (Roche) air - IOEL (Internal Occupational Exposure Limit): 100 µg/m³ (defined as 8-hour time-weighted average)
- STEL: 400 µg/m³ (defined as 15-minutes time-weighted average)
8.2. Exposure controls

General protective and hygiene measures
- instruction of employees recommended

Respiratory protection
- in case of open handling or accidental release:
  particle mask or respirator with independent air supply

Hand protection
- protective gloves (neoprene, nitrile or butyl rubber)

Eye protection
- safety glasses

Body protection
- protective clothing

Analytics
- sampling on glass fibre filter and gravimetric or chemical determination

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Colour
- white to practically white

Form
- crystalline powder

Odour
- none to faint

Solubility
- ~ 40'000 mg/l, water (25 °C)
- ~ 100'000 mg/l, methanol (~ 20 °C)
- > 400'000 mg/l, DMSO (dimethyl sulfoxide) (~ 20 °C)
- ~ 14'000 mg/l, isopropanol (~ 20 °C)
- ~ 5'000 mg/l, n-octanol (~ 20 °C)

pH value
- 3.5 to 4.5 (1 % aqueous solution)

Melting temperature
- 111 to 117.5 °C

9.2. Other information

Dissociation constant
- $pK_1 \quad 6.0$

SECTION 10: Stability and reactivity

10.1. Reactivity

Note
- no information available

10.2. Chemical stability

Note
- no information available
10.3. Possibility of hazardous reactions

Note - no information available

10.4. Conditions to avoid

Conditions to avoid - humidity
- light

10.5. Incompatible materials

Materials to avoid - strong acids

10.6. Hazardous decomposition products

Note - no information available

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity
- LD₅₀ 825 mg/kg (oral, rat)
- LD₅₀ 760 mg/kg (oral, mouse)
- LD₅₀ 86 mg/kg (i.v., mouse)

Local effects
- eye: may be slightly irritating (rabbit)
- skin: slightly irritant (rabbit)

Sensitization - no information available

Mutagenicity - not mutagenic (various in vivo and in vitro test systems)

Carcinogenicity - not carcinogenic

Reproductive toxicity
- not embryotoxic (rabbit)
- not teratogenic (rabbit)
- not teratogenic (rat)

STOT-single exposure - no information available

STOT-repeated exposure - no information available

Aspiration hazard - no information available

Note
- dosage: 7.5 to 15 mg/d (adults)
- elimination half-life: 1.5 to 2.5 hours
- caution: alcohol potentiates the effect!
- after intake of substance within a short time (5 - 30 minutes, depending on the dose): tiredness and somnolence
SECTION 12: Ecological information

12.1. Toxicity

Ecotoxicity
- strongly toxic for algae (Scenedesmus (=Desmodesmus) subspicatus)
  EbC50 (72 h) 7.5 mg/l
  NOEbC (72 h) 1.2 mg/l
  (OECD No. 201)
- moderately toxic for planktonic crustaceans (Daphnia magna)
  NOEC (48 h) 9 mg/l
  EC50 (48 h) 16 mg/l
  EC100 (48 h) 25 mg/l
  (OECD No. 202)
- strongly toxic for fish (rainbow trout)
  NOEC (96 h) 4.8 mg/l
  LC50 (96 h) 10.7 mg/l
  LC100 (96 h) 14.8 mg/l
  (OECD No. 203)

12.2. Persistence and degradability

Inherent biodegradability - inherently biodegradable
  80 %, 14 days
  (Zahn-Wellens test, OECD No. 302 B)

12.3. Bioaccumulative potential

Note - no information available

12.4. Mobility in soil

Note - no information available

12.5. Results of PBT and vPvB assessment

Note - no information available

12.6. Other adverse effects

Air pollution - observe local/national regulations

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste from residues - incinerate in qualified installation with flue gas scrubbing
- observe local/national regulations regarding waste disposal
Midazolam Maleate

SECTION 14: Transport information

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Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.

Technical name: Midazolam maleate

SECTION 15: Regulatory information

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

Water hazard class (Germany): 2: hazardous for water (own classification according to directive VwVwS of 17.05.1999)

SECTION 16: Other information

Safety-lab number: BS-2160

Note: the antidote for an overdose of midazolam (or any other benzodiazepine) is flumazenil (Anexate®)

Edition documentation: changes from previous version in sections 8

The information in this safety data sheet is based on current scientific knowledge. It should not be taken as expressing or implying any warranty concerning product characteristics.