

Safety Data Sheet**Ibandronat III**

according to Regulation (EU) nr. 453/2010

SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1. Product identifier**

Product name Ibandronat III

Product code 04 7909 8

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

Use - intermediate

1.3. Details of the supplier of the safety data sheet

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

Physical Hazards:

- 2.6 Flammable liquids (Category 3)
- H226 Flammable liquid and vapour.

Health Hazards:

- 3.2 Skin corrosion/irritation (Category 2)
- H315 Causes skin irritation.
- 3.3 Serious eye damage/eye irritation (Category 1)
- H318 Causes serious eye damage.
- 3.4 Skin sensitization (Category 1)
- H317 May cause an allergic skin reaction.

Signalword: Danger

Label:



Precautionary statements:

- P210 Keep away from heat/sparks/open flames/hot surfaces. - No smoking.
- P261 Avoid breathing vapour
- P280 Wear protective gloves/ protective clothing / eye protection / face protection.
- P302 + P352 IF ON SKIN: Wash with plenty of soap and water.
- P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

2.3. Other hazards

Note

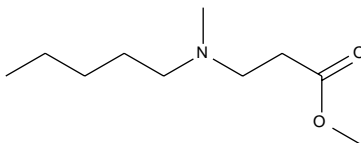
- no information available

SECTION 3: Composition/information on ingredients

Chemical name	- 3-(Methylpentylamino)propanoic acid methyl ester
Synonyms	- BM 91.0043 - N-Methyl-N-pentyl-β-alanine methyl ester - Ibandron acid step III
CAS number	744266-99-7
UN number	1993
Roche number	RO4982847-000
Empirical formula	C ₁₀ H ₂₁ NO ₂

Ibandronat III

Molecular mass 187.28 g/mol



SECTION 4: First aid measures

4.1. Description of first aid measures

- | | |
|--------------|--|
| Eye contact | - rinse immediately with tap water for 10 minutes - open eyelids forcibly |
| Skin contact | - remove immediately contaminated clothes, wash affected skin with water and soap - do not use any solvents
- consult a physician if skin irritation persists |
| 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

SECTION 5: Firefighting measures

5.1. Extinguishing media

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|--------------------------------|--|
| Suitable extinguishing media | - foam, powder, carbon dioxide |
| Unsuitable extinguishing media | - use water spray for cooling purposes only (fat explosion hazard) |

5.2. Special hazards arising from the substance or mixture

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|------------------|---|
| Specific hazards | - formation of toxic and corrosive combustion gases (nitrogen oxides (NOx)) possible
- heating of container(s) will cause pressure rise with risk of bursting and subsequent explosion
- may form potentially explosive mixtures with air
- Vapours may be invisible and they are heavier than air. They spread on the soil and could penetrate into the sewerage system and into cellars. |
|------------------|---|

5.3. Advice for firefighters

Protection of fire-fighters	<ul style="list-style-type: none">- precipitate gases/vapours/mists with water spray- chemical incident emergency response unit with full protective equipment
Special method of fire-fighting	<ul style="list-style-type: none">- cool endangered containers with water spray

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions	<ul style="list-style-type: none">- check the possibility of an explosive atmosphere- do not use tools which produce sparks, make use of explosion proof equipment- if this is not endangering the action force or other people, ventilate sewers and cellars
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6.2. Environmental precautions

Environmental protection	<ul style="list-style-type: none">- if possible close leaks- collect the leaked product by all means available- if the substance reaches waters or the sewer system, inform the competent authority
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6.3. Methods and material for containment and cleaning up

Methods for cleaning up	<ul style="list-style-type: none">- collect liquid by means of sand, earth or another suitable material or cover it with alcohol-resistant foam- during the pouring by a pump bear in mind adequate earthing- make use of explosion-proof pumps- collect the product spilled out into ventilated containers equipped with absorption filters
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SECTION 7: Handling and storage

7.1. Precautions for safe handling

Technical measures	<ul style="list-style-type: none">- processing in closed systems, superposed by inert gas (e.g. nitrogen)- local exhaust ventilation necessary- take precautionary measures against electrostatic charging
Suitable materials	<ul style="list-style-type: none">- aluminium, enamel, stainless steel

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions	<ul style="list-style-type: none">- dry, cool and ventilated place- secure container and keep tightly closed
Packaging materials	<ul style="list-style-type: none">- tightly closing; material: aluminium, stainless steel

SECTION 8: Exposure controls/personal protection**8.1. Control parameters**

Note - no information available

8.2. Exposure controls

- | | |
|---|---|
| General protective and hygiene measures | - cleanse skin thoroughly after work, apply skin cream |
| Respiratory protection | - in case of open handling or accidental release: protective mask with combination filter (e.g. ABEKP) or special filter (e.g. BEP) or respirator with independent air supply |
| Hand protection | - protective gloves (eg made of NBR Acrylnitril-Butadien-Rubber) |
| Eye protection | - safety glasses (i.e. in capsule-shaped frames) |
| Body protection | - disposable (eg TYVEK) or reusable protective clothing; the latter must be washed (decontaminated) after use |

SECTION 9: Physical and chemical properties**9.1. Information on basic physical and chemical properties**

Form	liquid
Solubility	4'900 mg/l, water
Partition coefficient	log P _{ow} 2.0 (octanol/water) (calculated)
Melting temperature	< -70.7 °C (OECD No. 102)
Boiling temperature	214.5 °C (99.3 kPa) (OECD No. 103)
Vapour pressure	1.6 Pa (25 °C) (OECD No. 104)
Flash point (liquid)	57.9 °C (DIN 51'755)
Ignition point (liquid)	240 °C

9.2. Other information

Surface tension	58.3 mN/m (20.5 °C) (OECD No. 115, "Surface Tension of Aqueous Solutions")
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Solubility properties

Hydrolysis	t _{1/2} = 25.4 h (pH 7.0, 22 °C) t _{1/2} = 4.1 h (pH 7.8, 22 °C) t _{1/2} = 0.5 h (pH 9.0, 22 °C)
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SECTION 10: Stability and reactivity

10.1. Reactivity

Note - no information available

10.2. Chemical stability

Stability - stable under the conditions mentioned in chapter 7

10.3. Possibility of hazardous reactions

Note - no information available

10.4. Conditions to avoid

Note - no information available

10.5. Incompatible materials

Note - no information available

10.6. Hazardous decomposition products

Note - hydrolyses

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity - LD₅₀ > 2'000 mg/kg (oral, rat)
(OECD No. 423 (Acute Toxic Class Method))

Local effects - skin: irritant (rabbit; OECD No. 404)
- eye: irritant; expert statement

Sensitization - sensitizing (mouse)
(OECD No. 429, LLNA (Local Lymph Node Assay))

Mutagenicity - not mutagenic (in vitro test system; OECD No. 471 (Salmonella typhimurium))

SECTION 12: Ecological information

12.1. Toxicity

Ecotoxicity - barely toxic for planktonic crustaceans (Daphnia magna)
EC₅₀ (48 h) > 100 mg/l
NOEC (48 h) ≥ 100 mg/l
(OECD No. 202)

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12.2. Persistence and degradability

Ready biodegradability - readily biodegradable
98 %, 14 d
(DOC Die-Away Test, OECD No. 301A)

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 - observe local/national regulations regarding waste disposal
- incinerate in qualified installation with flue gas scrubbing

SECTION 14: Transport information

IATA	Class	UN/ID	PG		PI	Label	Mark	
	3	1993	III		355/366	3		
IMDG	Class	UN	PG	EmS	PI	Label	Mark	
	3	1993	III	F-E S-E	P001/IBC03	3		
RID/ADR	Class	UN	PG	Haz.no	PI	Label	Mark	Classif. code
	3	1993	III	30	P001/IBC03	3		F1

Ibandronat III

Proper shipping name FLAMMABLE LIQUID, N.O.S.

Technical name 3-(Methylpentylamino)propanoic acid methyl ester

SECTION 15: Regulatory information

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

Water hazard class (Germany) 1: weakly hazardous for water (own classification according to directive VwVwS of 17.05.1999)

SECTION 16: Other information

Safety-lab number - BS-7969

Edition documentation - changes from previous version in sections 2

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.