

Invoice

Our Order Nr: 20250210 ZE
Invoice: 2500383 RL
Invoice Date: 25/03/25
Your Reference: PO1-005689 rel.1

Sold To: 26006
 A.MENARINI ASIA-PACIFIC HOLDINGS PTE.
 LTD
 30 PASIR PANJANG ROAD,
 #08-32 MAPLETREE BUSINESS CITY,
 SINGAPORE 117440
 Singapore

Delivery Terms: FCA - Transport by air FIS WAREHOUSE MONTECCHIO
 final destination Japan
 Incoterms ® 2020
Payment Method: DIRECT REMITTANCE **Payment Terms:** 30 DAYS INVOICE DATE

Marks:
 KYOWA PHARMACEUTICAL INDUSTRY
 HYOGO - JAPAN
 PO1-006617

Product Code	Description	UM	Quantity	Unit Price	Currency	Total Price	Tax Cd
0510	FLURAZEPAM MONOHYDROCHLORIDE EP Customs tariff 2933 9190	KG	14,990	1.150,0000	EUR	17.238,50	8B

.	TEMPTALE	PZ	2,000	30,0000	EUR	60,00	8B
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GOODS MANUFACTURED AND SUPPLIED BY F.I.S. - FABBRICA ITALIANA SINTETICI S.p.A. - ITALY
 EXPORT PERMIT No. 978 OF 18/03/2025 ISSUED BY MINISTRY OF HEALTH ROME Y/IMPORT 0221013
 Packaging: No. 1 DRUM 40x40x65 CM - GROSS WEIGHT: 18,64 KG

Tax Group Summary		
N.I. ART .8 1 C. LETT. B OPERAZIONE NON IMPONIBILE	EUR	17.298,50
Total Invoice:	EUR	17.298,50

The exporter of the products covered by this document (Exporter Reference n. ITREXIT01712670247) declares that, except where otherwise clearly indicated, these products are of European preferential origin
 Origin criteria used: C 3

Pag. 1 of 2

F.I.S. — Fabbrica Italiana Sintetici S.p.A.

With sole shareholder Molecule (BC) Bidco S.p.A., subject to the activity of direction and coordination by Molecule (BC) Holdco S.p.A.

Montecchio site & Headquarters
 Viale Milano, 26
 36075 Montecchio Maggiore (VI) — Italy
 Ph. +39 0444 708011
 Fax +39 0444 698094

Termoli site
 Via Massimo D'Antona, 13
 86039 Termoli (CB) — Italy
 Ph. +39 0875 75351
 Fax +39 0875 751827

Lonigo site
 Via Dovaro, snc
 36045 Lonigo (VI) — Italy
 Ph. +39 0444 433111
 Fax +39 0444 831192

Share Capital €10.000.000 i.v.
 R.I. - C.F. & VAT Nr. IT01712670247
 M/VIO02266
 R.E.A. Vicenza 179183
fisvi.com



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Singapore

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Payments

The following Banks are available for receiving payments. Please note: for payments in USD currency, kindly use INTESA SANPAOLO New York Branch Account

<p>UNICREDIT S.P.A. Viale Mazzini 77 36100 VICENZA</p> <p>Swift: UNCRITMMVIE IBAN IT11T 02008 05364 000004997331 C/c 000004997331 ABI 02008 CAB 05364</p>	<p>BANCO BPM Corso G.Mazzini 25 36071 ARZIGNANO (VI)</p> <p>Swift: BAPP IT 21 107 IBAN IT58O 05034 60120 000000006718 C/c 000000006718 ABI 05034 CAB 60120</p>
<p>BANCA DELLE TERRE VENETE CREDITO COOPERATIVO Viale Trieste 46 36075 MONTECCHIO MAGGIORE (VI)</p> <p>Swift: ICRAITRRB30 IBAN IT86C 08399 60531 000000118733 C/c 000000118733 ABI 08399 CAB 60531</p>	<p>BNL GRUPPO BNP PARIBAS Corso A. Palladio 45 36100 VICENZA</p> <p>Swift: BNLI IT RR IBAN IT64 M 010 05 11800 000000005165 C/c 000000005165 ABI 01005 CAB 11800</p>
<p>BANCA IFIS SPA FILIALE DI VICENZA – Via Ettore Gallo 10 36100 VICENZA (VI)</p> <p>Swift: IFISIT2VXXX IBAN IT31C 03205 11800 000002240030 C/c 000002240030 ABI 03205 CAB 11800</p>	<p>INTESA SANPAOLO Via IV Novembre 38 36075 MONTECCHIO MAGGIORE (VI)</p> <p>Swift: BCITITMM IBAN IT73F 03069 60538 100000001462 C/c 100000001462 ABI 03069 CAB 60538</p>
<p>(USD) INTESA SANPAOLO New York Branch One William Street New York NY 1004</p> <p>A/c 14831 162 0001 ABA#026-005-319 Swift: BCITUS33</p>	

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PERMESSO DI ESPORTAZIONE
di stupefacenti e sostanze psicotrope
(DPR n.309 del 09/10/1990)

PERMIT TO EXPORT
narcotics or psychotropic substances
(Presidential Decree n. 309 of 09/10/1990)

ESPORTATORE

Exporter

F.I.S. FABBRICA ITALIANA SINTETICI S.P.A.-F 5 - Viale Milano 26 - 36075 - Montecchio
Maggiore (VI)

PER CONTO DI

Account of

- -

IMPORTATORE

Importer

KYOWA PHARMACEUTICAL INDUSTRY CO., LTD. SANDA PLANT 11-1 TECHNO-PARK,
SANDA, HYOGO, 669-1339 JAPAN

PERMESSO DI IMPORTAZIONE N.

Import permit n.

0221013

DEL

21/02/2025

RILASCIATO DA

Issued by

MINISTRY OF HEALTH LABOUR AND WELFARE JAPAN

NOME E QUANTITA' DELLA SOSTANZA O PREPARAZIONE

Controlled substances and/or preparations, description and quantity

N. 1743 - FLURAZEPAM MONOHYDROCHLORIDE KG. 14.99

CONTENUTO DELLA SOSTANZA IN BASE ANIDRA

Anhydrous base content

FLURAZEPAM 13640.9 G;

DOGANA DI USCITA

Custom of EXIT

Vicenza - Ufficio delle Dogane di Vicenza;



MINISTERO DELLA SALUTE (Ministry of Health)
Direzione Generale dei Dispositivi Medici e del Servizio
Farmaceutico
Ufficio Centrale Stupefacenti
Viale Giorgio Ribotta, 5 - 00144 Roma

Ai sensi delle convenzioni internazionali e del DPR 309/1990 in materia di sostanze stupefacenti e psicotrope, si rilascia alla ditta suindicata il permesso di esportazione per le merci sopra specificate.

In conformity with international conventions and with Presidential Decree n. 309/90 concerning narcotics and psychotropic substances, the permit to export is issued to aforesaid Company for the goods referred to above.

PERMESSO DI ESPORTAZIONE N.

Permit to export

VALIDO FINO AL

Valid until

978

20/06/2025

Roma,
18/03/2025



Il Direttore dell'Ufficio Centrale Stupefacenti
THE CENTRAL OFFICE OF DRUGS DIRECTOR

*Dott.ssa Maria Grazia LEONE

Maria Grazia Leone

**Firma autografa elettronicamente riprodotta ai sensi del decreto ministeriale 31 marzo 2022*

*(*Electronic signature reproduced in accordance with the Decree of Ministry of Health 31 March 2022)*

Copia che scorta la merce fino al Paese di importazione

MONTECCHIO MAGGIORE, 25 March 2025

PACKING LIST

RE. YOUR ORDER NO. PO1-005689 rel.1

OUR REFERENCE ORDER NO. 20250210 / ZE
NO. 1 DRUM MARKED:

INVOICE N. 2500383 RL
KYOWA PHARMACEUTICAL INDUSTRY
HYOGO - JAPAN
PO1-006617

<u>PRODUCT NAME</u>	<u>QUANTITY</u>	<u>BATCH NUMBER</u>
FLURAZEPAM MONOHYDROCHLORIDE EP	KG. 14,990	202410150064

TOTAL GROSS WEIGHT **KG 18,640**
TOTAL NET WEIGHT **KG 14,990**

MEASUREMENTS: NO. DRUM 1 CM 40 X 40 X 65

F.I.S. - Fabbrica Italiana Sintetici S.p.A.

Page 1 of 1

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CERTIFICATE OF ANALYSIS

CoA # 61133

Product: FLURAZEPAM MONOHYDROCHLORIDE

Chemical Name (IUPAC): 7-chloro-1-[2-(diethylamino)ethyl]-5-(2-fluorophenyl)-3H-1,4-benzodiazepin-2-one hydrochloride

CAS NBR: 36105-20-1

Lot Number: 202410150064

Code: 0510

Manufacturing date: 11-May-2024

Retest Date : 10-May-2029

Test Item:

Test Results:

Specifications:

APPEARANCE (EP)	white crystalline powder	White or almost white crystalline powder
IDENTIFICATION BY IR SPECTROPHOTOMETRY	conform	Must be conform to EP-CRS spectrum
IDENTIFICATION BY CHLORIDES TEST	positive	Must be positive (EP)
LOSS ON DRYING (4 H AT 105°C) (EP)	0.0%	NMT 0.5%
RESIDUE ON IGNITION (EP)	0.0%	NMT 0.1%
FLUORIDES (EP)	less than 500 ppm	NMT 500 ppm
ASSAY (with HClO ₄ 0.1N) (calc. on dried substance)	100.2%	99.0% - 101.0%
ASSAY (with NaOH 0.1N) (calc. on dried substance) (EP)	100.8%	99.0% - 101.0%
pH VALUE (5% in H ₂ O) (EP)	5.1	5.0 - 6.0
EP RELATED SUBSTANCE A (HPLC, EP)	<0.05%	NMT 0.1%
EP RELATED SUBSTANCE B (HPLC, EP)	<0.05%	NMT 0.1%
ANY UNSPECIFIED IMPURITY (HPLC, EP)	<0.05%	NMT 0.10%
TOTAL IMPURITIES (HPLC, EP)	0.0%	NMT 0.3%
RESIDUAL METHANOL (GC-HS)	<90ppm	NMT 3000ppm



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CERTIFICATE OF ANALYSIS

CoA # 61133

Product: FLURAZEPAM MONOHYDROCHLORIDE

Chemical Name (IUPAC): 7-chloro-1-[2-(diethylamino)ethyl]-5-(2-fluorophenyl)-3H-1,4-benzodiazepin-2-one hydrochloride

CAS NBR: 36105-20-1

Lot Number: 202410150064

Code: 0510

Manufacturing date: 11-May-2024

Retest Date : 10-May-2029

Test Item:

Test Results:

Specifications:

RESIDUAL 2-PROPANOL (GC-HS)

<150ppm

NMT 5000ppm

RESIDUAL n-HEXANE (GC-HS)

233ppm

NMT 290ppm

RESIDUAL TOLUENE (GC-HS)

<53ppm

NMT 890ppm

The product complies with specifications of EP 11.0.

Lot Approval Date: 12-November-2024

Control and manufacturing records have been reviewed according to FIS internal SOP and found to be in accordance with cGMPs, applicable laws and with all current documentation submitted by FIS to regulatory authorities or to the customer.

QA release date: 19-November-2024

Certificate of Analysis was e-signed on 19-Nov-2024 14:34 by Federica Panarotto, Quality Control Manager

Certificate of Analysis was e-signed on 19-Nov-2024 15:59 by Alessandro Rottigni, Qualified Person

The information hereto reported is Confidential. Any disclosure to third parties should be approved by FIS.

Safety Data Sheet**FLURAZEPAM MONOCLORIDRATO_FLURAZEPAM HYDROCHLORIDE****Safety Data Sheet dated 18/11/2022, version 3.0****Regulation (EU) n. 2020/878****SECTION 1: Identification of the substance/mixture and of the company/undertaking**

1.1. Product identifier

Identification of the substance:

IUPAC name:

7-chloro-1-[2-(diethylamino)ethyl]-5-(2-fluorophenyl)-3H-1,4-benzodiazepin-2-one hydrochloride

Synonyms:

Dalmadorm; Flunox; Remdue

Trade name:

FLURAZEPAM MONOCLORIDRATO_FLURAZEPAM
HYDROCHLORIDE

CAS number:

36105-20-1

EC number:

252-867-1

Index number:

Not available

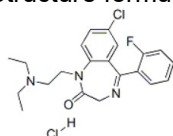
REACH number:

Not Applicable

Molecular formula:

C₂₁H₂₃ClFN₃O*ClH

Structure formula:



Molecular weight:

424.34

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

Recommended use:

Substance used in chemical-pharmaceutival industry for research & development activities, production, packaging or preparation of medicines.

Pharmaceutical active ingredient.

Benzodiazepin

Uses advised against:

All except those indicated in the previous point

1.3. Details of the supplier of the safety data sheet

Company:

F.I.S. FABBRICA ITALIANA SINTETICI SPA

Viale Milano, 26

36075 MONTECCHIO MAGGIORE (VI) – ITALY

+39 0444-708011 (office hours)

Competent person responsible for the safety data sheet:

hsdept@fisvi.com

1.4. Emergency telephone number

+39 0444-708011 (office hours)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

EC regulation criteria 1272/2008 (CLP)



Warning, Acute Tox. 4, Harmful if swallowed.



Warning, Repr. 2, Suspected of damaging fertility or the unborn child.

Safety Data Sheet

FLURAZEPAM MONOCLORIDRATO_FLURAZEPAM HYDROCHLORIDE



Warning, STOT SE 3, May cause drowsiness or dizziness.

Adverse physicochemical, human health and environmental effects:

No other hazards

2.2. Label elements

Hazard pictograms:



Warning

Hazard statements:

H302 Harmful if swallowed.

H361 Suspected of damaging fertility or the unborn child.

H336 May cause drowsiness or dizziness.

Precautionary statements:

P202 Do not handle until all safety precautions have been read and understood.

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

P264 Wash hands thoroughly after handling.

P270 Do not eat, drink or smoke when using this product.

P301+P312 IF SWALLOWED: Call a POISON CENTER if you feel unwell.

P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.

P308+P313 IF exposed or concerned: Get medical advice/attention.

P501 Dispose of contents/container in accordance with applicable regulations.

Special Provisions:

None

Special provisions according to Annex XVII of REACH and subsequent amendments:

None

2.3. Other hazards

This substance has no PBT, vPvB or endocrine disrupting properties

Other Hazards:

Airborne powders are sensitive to ignition and can give rise to explosive phenomena in the presence of electrostatic charges.

Avoid accumulating electrostatic charge.

May cause eye, skin and respiratory tract irritation.

All precautions for drugs and pharmaceuticals should thoroughly be observed

SECTION 3: Composition/information on ingredients

3.1. Substances

Identification of the substance:

Chemical characterization: FLURAZEPAM MONOCLORIDRATO_FLURAZEPAM
HYDROCHLORIDE

CAS number: 36105-20-1

EC number: 252-867-1

REACH number: Not Applicable

Concentration (%): >=99%

3.2. Mixtures

N.A.

Safety Data Sheet

FLURAZEPAM MONOCLORIDRATO_FLURAZEPAM HYDROCHLORIDE

SECTION 4: First aid measures

4.1. Description of first aid measures

Remove contaminated clothing. In case of loss of knowledge put the person in the safe position and transport the person to the fresh air. Rescuers have to worry primarily about their protection.

In case of skin contact:

Remove contaminated clothing and wash thoroughly with water. Consult a physician if symptoms appear.

In case of eyes contact:

Wash immediately with plenty of water for at least 15 minutes taking care to keep the eyelids separated the eye, contact lens should be removed only by experienced personnel. Consult a physician if symptoms appear.

In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

In case of Ingestion:

Do not induce vomiting unless on the advice of medical personnel, in case of vomiting tilt the patient forward or put it on the side with head facing down to keep the airways open and prevent aspiration. Don't give anything by mouth to people who give signs of drowsiness or numbness, or who are about to lose consciousness. Consult a physician if symptoms appear.

In case of Inhalation:

Move the affected person from the area and make it stretch; if breathing is difficult, give oxygen; if breathing is absent use mechanical ventilation. Consult a physician if symptoms appear.

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

The most common adverse effects reported with the clinical use:

Tolerance

Dependance

Withdrawal

Depression of blood pressure

Coma

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

In case of accident or unwellness, seek medical advice immediately (show directions for use or safety data sheet if possible).

Treatment:

Treat symptomatically and supportively

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media:

Water.

Carbon dioxide (CO₂).

Dry chemical extinguisher

In case of fire, use a foam fire extinguisher to extinguish.

Extinguishing media which must not be used for safety reasons:

None in particular.

5.2. Special hazards arising from the substance or mixture

When heated to decomposition or under fire conditions it could be emitted toxic fumes like carbon monoxide or other typical organic combustion products.

5.3. Advice for firefighters

Fire fighters should use self-contained breathing apparatus and protective clothing.

As the substance, when exposed to thermal irradiation or directly involved in a fire, may produce toxic fumes, if it is safe to do, remove the containers from the fire area or keep containers cool.

Safety Data Sheet

FLURAZEPAM MONOCLORIDRATO_FLURAZEPAM HYDROCHLORIDE

Extinguish flames at a safe distance from the containers, by using fire hoses or extinguishers automatic systems with nozzles positioned at the top of the containers.
Damaged containers must be handled only by authorized trained personnel.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

For non emergency personnel:

Evacuate from affected area the personnel not involved in emergency intervention.

Avoid breathing vapors, mist or gas.

For emergency responders:

Fist-gloves.

6.2. Environmental precautions

Do not allow to enter into soil/subsoil. Do not allow to enter into surface water or drains.

6.3. Methods and material for containment and cleaning up

For containment:

If possible to do it in safe conditions, stop the leakage of substance or limit the loss with inert material.

Remove any source of ignition, stop the source of the spillage, avoid contact with skin or inhalation, use PPE (see section 8)

In case of leakage, immediately report the incident and remove unnecessary personnel. Stop the source of leakage and isolate the spilled material.

Isolate sewers discharging to superficial waters and/or segregate any water runoff into collection basins or tanks to facilitate processing or disposal

Personnel involved in maintenance and cleaning operations must wear adequate personal protective equipment to minimize exposure.

Collect the spilled substance with non-sparking mechanical means, avoiding the formation of airborne dust and put in labeled containers to be sent for disposal in accordance with applicable laws.

Wash the residues with water, preventing them from entering the sewage system.

Immediately clean using absorbent materials.

Collected material should be placed in proper container, labeled and sent for disposal according to the procedures and regulations in force.

For cleaning up:

Immediately clean using absorbent materials.

6.4. Reference to other sections

See also section 8 and 13

SECTION 7: Handling and storage

7.1. Precautions for safe handling

The substance must be handled in ventilated environment or with the appropriate local air extraction.

Minimize dust formation and avoid accumulation on surfaces

Use antistatic equipment and clothing to avoid contact with any sources of ignition

Avoid contact with skin and eyes, inhalation of vapours and mists.

Exercise the greatest care when handling or opening the container.

Don't use empty container before they have been cleaned.

Before making transfer operations, assure that there aren't any incompatible material residuals in the containers.

See also section 8 for recommended protective equipment.

Advice on general occupational hygiene:

Contaminated clothing should be changed before entering eating areas.

Do not eat or drink while working.

Safety Data Sheet

FLURAZEPAM MONOCLORIDRATO_FLURAZEPAM HYDROCHLORIDE

7.2. Conditions for safe storage, including any incompatibilities

Use container tightly closed and resistant, away from moisture and sunlight. Avoid contact with air and light.

Properly label containers in case of pouring and store in cool area.

Clean external container surfaces with proper detergents and/or solvents.

Keep away from food, drink and feed.

Incompatible materials:

None in particular.

Instructions as regards storage premises:

Adequately ventilated premises.

7.3. Specific end use(s)

None in particular

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

FLURAZEPAM MONOCLORIDRATO_FLURAZEPAM HYDROCHLORIDE - CAS:

36105-20-1

- OEL Type: OEB 2, 10-500 µg/m³

- OEL Type: OEL, 50 µg/m³

DNEL Exposure Limit Values

N.A.

PNEC Exposure Limit Values

N.A.

Monitoring procedures: Environmental monitoring is in place using appropriate devices. For more information contact the supplier.

8.2. Exposure controls

Eye protection:

For dry products use safety glasses goggles. For the wet product use face shield or other fullface protection if it is required also airways protection. If you use semi-mask for respiratory protection. Use safety goggles for complete protection, as in the case of dry.

Protection for skin:

In production or packaging plants it is recommended full-body suite like Tyvek® type, protection against liquid aerosols Type 4 (EN 14605) resistant to penetration by solid particles sprayed Type 5 (EN 13982-2), low intensity sprays Type 6 (EN 13034 and EN 17491) and antistatic (EN 1149)

Protection for hands:

Use chemical resistant gloves (EN374) with material compatible with solvent in which the substance is dissolved; the actual permeation time through the gloves and their life can be affected by mode of use, temperature and substance quantities handled.

Respiratory protection:

Use protective mask with P2 or P3 type dust filter (EN 143). If the substance is dissolved in organic solvent and manipulated in an open environment in significant quantities use an appropriate filter for chemicals (A type for boiling temperature > 65°C or Ax type for boiling temperature < 65°C) or ABEK type if simultaneous presence of others substances (like inorganic vapors, ammonia, etc.).

Thermal Hazards:

None

Environmental exposure controls:

None

Appropriate engineering controls:

Safety Data Sheet

FLURAZEPAM MONOCLORIDRATO_FLURAZEPAM HYDROCHLORIDE

In Production or re-packaging plants: use general ventilation systems, or closed systems to ensure the isolation of the substance from the working personnel. Additional protective measures can be adopted according to specific "control band" and the specific Exposure Control Matrix established for the substance. In laboratories: it is always recommended to use fume cupboard or cabinet. Additional protection measures can be adopted according to specific "control band" and the specific Exposure Control Matrix.

Warning: Substance properties, local substance concentration, quantity handled and conditions of use (hierarchy of controls) determine the type of protective equipment needed.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Properties	Value	Method:	Notes
Physical state:	Solid	--	--
Colour:	White to off white	--	--
Odour:	---	--	--
Melting point/freezing point:	202-204°C	--	--
Boiling point or initial boiling point and boiling range:	Not available	--	--
Flammability:	Not available	--	--
Lower and upper explosion limit:	Not available	--	--
Flash point:	Not available	--	--
Auto-ignition temperature:	Not available	--	--
Decomposition temperature:	Not available	--	--
pH:	Not available	--	--
Kinematic viscosity:	N.A.	--	--
Solubility in water:	---	--	Very soluble (20°C)
Solubility in oil:	Not available	--	--
Partition coefficient n-octanol/water (log value):	Not available	--	--
Vapour pressure:	Not available	--	--
Density and/or relative density:	Not available	--	--
Relative vapour density:	Not available	--	--

Particle characteristics:

Particle size:	Not available	--	--
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9.2. Other information

Properties	Value	Method:	Notes
Evaporation rate:	1.90*10E-09	--	Estimated
Fat Solubility:	---	--	Very soluble in ethanol (20°C)

SECTION 10: Stability and reactivity

10.1. Reactivity

Stable and non-reactive under normal conditions of use, storage and transport

10.2. Chemical stability

Safety Data Sheet

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- In solution with acids and bases it undergoes hydrolysis to benzophenone
- 10.3. Possibility of hazardous reactions
As a precautionary measure, keep away from heat and electrostatic discharge.
- 10.4. Conditions to avoid
As a precautionary measure, keep away from heat and electrostatic discharge
- 10.5. Incompatible materials
As a precautionary measure, keep away from strong oxidizing agents.
- 10.6. Hazardous decomposition products
Thermal decomposition can produce toxic carbon dioxide vapors in case of partial combustion and other typical products of combustion of organic materials

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Toxicological information of the substance:

FLURAZEPAM MONOCLORIDRATO_FLURAZEPAM HYDROCHLORIDE - CAS:
36105-20-1

a) acute toxicity

The product is classified: Acute Tox. 4 H302

Test: LD50 - Route: Oral - Species: Rat = 978 mg/kg

Test: LD50 - Route: intraperitoneal - Species: Rat = 179 mg/kg

Test: LD50 - Route: Intravenous - Species: Rat = 40 mg/kg

Test: LD50 - Route: Oral - Species: Mouse 684 mg/kg

Test: LD50 - Route: intraperitoneal - Species: Mouse 205 mg/kg

Test: LD50 - Route: Intravenous - Species: Mouse 58 mg/kg

b) skin corrosion/irritation

Not classified

Slightly irritating

c) serious eye damage/irritation

Not classified

Slightly irritating

d) respiratory or skin sensitisation

Not classified

Not sensitizer

e) germ cell mutagenicity

Not classified

Insufficient data available

f) carcinogenicity

Not classified

Not listed in IARC, NTP, OSHA

g) reproductive toxicity

The product is classified: Repr. 2 H361

Test: TDLo - Route: Oral - Species: Rat = 330 mg/kg - Notes: 30 D pre mating

h) STOT-single exposure

The product is classified: STOT SE 3 H336

Benzodiazepin

i) STOT-repeated exposure

Not classified

No data available for the product

j) aspiration hazard

Not classified

No data available for the product

Adverse health effects

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Immediate, delayed and chronic effects: As in all cases of uncontrolled exposure to drugs, intoxication effects may occur.

Likely routes of exposure:

Ingestion: not probable in the workplace;

Inhalation: possible in the workplace without the use of personal protective equipment or in case of accidental release

Cutaneous exposure: possible in the workplace without the use of personal protective equipment or in case of accidental release

Contact with eyes: possible in the workplace without the use of personal protective equipment or in case of accidental release.

Symptoms related to exposure: not available; see section 4.2

Immediate, delayed and chronic effects: As in all cases of uncontrolled exposure to drugs, intoxication effects may occur.

Other information: not available

11.2. Information on other hazards

Endocrine disrupting properties:

Unknown

SECTION 12: Ecological information**12.1. Toxicity**

Adopt good working practices, so that the product is not released into the environment.

FLURAZEPAM MONOCLORIDRATO_FLURAZEPAM HYDROCHLORIDE - CAS: 36105-20-1

Not classified for environmental hazards

Aquatic acute toxicity:

No data available for the product

Aquatic chronic toxicity:

No data available for the product

12.2. Persistence and degradability

FLURAZEPAM MONOCLORIDRATO_FLURAZEPAM HYDROCHLORIDE - CAS:
36105-20-1

Biodegradability: Not available

12.3. Bioaccumulative potential

FLURAZEPAM MONOCLORIDRATO_FLURAZEPAM HYDROCHLORIDE - CAS:
36105-20-1

Not available

12.4. Mobility in soil

FLURAZEPAM MONOCLORIDRATO_FLURAZEPAM HYDROCHLORIDE - CAS:
36105-20-1

Not available

12.5. Results of PBT and vPvB assessment

vPvB Substances: None - PBT Substances: None

12.6. Endocrine disrupting properties

Unknown

12.7. Other adverse effects

None

SECTION 13: Disposal considerations

Safety Data Sheet**FLURAZEPAM MONOCLORIDRATO_FLURAZEPAM HYDROCHLORIDE****13.1. Waste treatment methods**

Send to a suitable authorized treatment facility. In any case, comply with the current regulations on the disposal and recovery of waste

SECTION 14: Transport information**14.1. UN number or ID number**

Not classified as dangerous in the meaning of transport regulations.

14.2. UN proper shipping name

N.A.

14.3. Transport hazard class(es)

N.A.

14.4. Packing group

N.A.

14.5. Environmental hazards

ADR-Environmental Pollutant: No

IMDG-Marine pollutant: No

14.6. Special precautions for user

N.A.

14.7. Maritime transport in bulk according to IMO instruments

N.A.

SECTION 15: Regulatory information**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture**

Dir. 98/24/EC (Risks related to chemical agents at work)

Dir. 2000/39/EC (Occupational exposure limit values)

Regulation (EC) n. 1907/2006 (REACH)

Regulation (EC) n. 1272/2008 (CLP)

Regulation (EC) n. 790/2009 (ATP 1 CLP) and (EU) n. 758/2013

Regulation (EU) n. 286/2011 (ATP 2 CLP)

Regulation (EU) n. 618/2012 (ATP 3 CLP)

Regulation (EU) n. 487/2013 (ATP 4 CLP)

Regulation (EU) n. 944/2013 (ATP 5 CLP)

Regulation (EU) n. 605/2014 (ATP 6 CLP)

Regulation (EU) n. 2015/1221 (ATP 7 CLP)

Regulation (EU) n. 2016/918 (ATP 8 CLP)

Regulation (EU) n. 2016/1179 (ATP 9 CLP)

Regulation (EU) n. 2017/776 (ATP 10 CLP)

Regulation (EU) n. 2018/669 (ATP 11 CLP)

Regulation (EU) n. 2018/1480 (ATP 13 CLP)

Regulation (EU) n. 2019/521 (ATP 12 CLP)

Regulation (EU) n. 2020/217 (ATP 14 CLP)

Regulation (EU) n. 2020/1182 (ATP 15 CLP)

Regulation (EU) n. 2021/643 (ATP 16 CLP)

Regulation (EU) n. 2021/849 (ATP 17 CLP)

Regulation (EU) n. 2022/692 (ATP 18 CLP)

Restrictions related to the product or the substances contained according to Annex XVII Regulation (EC) 1907/2006 (REACH) and subsequent modifications:

Restrictions related to the product:

No restriction.

Restrictions related to the substances contained:

No restriction.

Where applicable, refer to the following regulatory provisions :

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Directive 2012/18/EU (Seveso III)
Regulation (EC) nr 648/2004 (detergents).
Dir. 2004/42/EC (VOC directive)

Provisions related to directive EU 2012/18 (Seveso III):
N.A.

WGK Classification (Water hazard class - Verwaltungsvorschrift wassergefährdende Stoffe)
Not available

15.2. Chemical safety assessment
Not applicable

SECTION 16: Other information

Hazard class and hazard category	Code	Description
Acute Tox. 4	3.1/4/Oral	Acute toxicity (oral), Category 4
Repr. 2	3.7/2	Reproductive toxicity, Category 2
STOT SE 3	3.8/3	Specific target organ toxicity - single exposure, Category 3

This safety data sheet has been completely updated in compliance to Regulation 2020/878.

This document was prepared by a competent person who has received appropriate training.
Main bibliographic sources:

PDE determination Flurazepam-26/04/2016
OEB Desalkylflurazepam vs.01 - 19/10/2016
SDS FIS Flurazepam monohydrochloride ENG v.01 10/05/2012
RTECS DF0880000
<https://pubchem.ncbi.nlm.nih.gov/compound/37368>

Supersedes SDS date: 26/07/2019 ver. 2 (Italian, English)

The information contained herein is based on our state of knowledge at the above-specified date. It refers solely to the product indicated and constitutes no guarantee of particular quality.

It is the duty of the user to ensure that this information is appropriate and complete with respect to the specific use intended.

This MSDS cancels and replaces any preceding release.

ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road.
ATE: Acute Toxicity Estimate
ATEmix: Acute toxicity Estimate (Mixtures)
CAS: Chemical Abstracts Service (division of the American Chemical Society).
CLP: Classification, Labeling, Packaging.
DNEL: Derived No Effect Level.
EINECS: European Inventory of Existing Commercial Chemical Substances.
GefStoffVO: Ordinance on Hazardous Substances, Germany.
GHS: Globally Harmonized System of Classification and Labeling of Chemicals.
IATA: International Air Transport Association.
IATA-DGR: Dangerous Goods Regulation by the "International Air Transport

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	Association" (IATA).
ICAO:	International Civil Aviation Organization.
ICAO-TI:	Technical Instructions by the "International Civil Aviation Organization" (ICAO).
IMDG:	International Maritime Code for Dangerous Goods.
INCI:	International Nomenclature of Cosmetic Ingredients.
KSt:	Explosion coefficient.
LC50:	Lethal concentration, for 50 percent of test population.
LD50:	Lethal dose, for 50 percent of test population.
PNEC:	Predicted No Effect Concentration.
RID:	Regulation Concerning the International Transport of Dangerous Goods by Rail.
STEL:	Short Term Exposure limit.
STOT:	Specific Target Organ Toxicity.
TLV:	Threshold Limiting Value.
TWA:	Time-weighted average
WGK:	German Water Hazard Class.