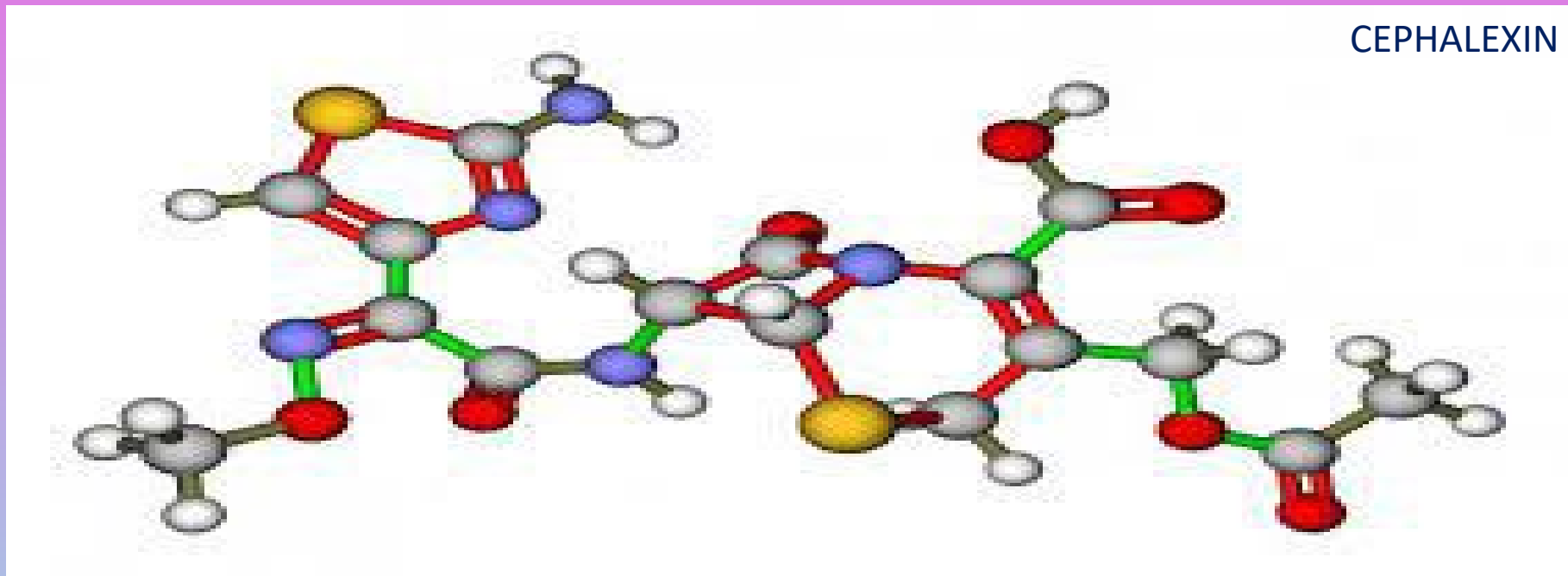


ACS DOBFAR ENVIRONMENTAL HEALTH & SAFETY



**ACS DOBFAR IS A PRIVATE PHARMACEUTICAL CHEMICAL COMPANY
THAT SUPPLIES ACTIVE INGREDIENTS TO MANY BIG PHARMA COMPANIES
WORLDWIDE.**



**ACS DOBFAR HAS BEGUN THIS ACTIVITY SINCE 1973 WITH THE OPENING OF ITS
FIRST MANUFACTURING PLANT IN VIMERCATE AND IT CONTINUES TODAY WITH
THE OPENING AND ACQUISITION OF ALSO OTHER FACILITIES.**

CLASSES OF ANTIBIOTICS WE MANUFACTURE

BETA LACTAMS (MAIN PRODUCTION)

- **CEPHALOSPORINS** (CEFEPIME , CEFTRIAZONE, CEFIXIME, CEFTOLOZANE ...)
- **CARBAPENEMS** (MEROPENEM FOR INJECTION, IMIPENEM & CILASTATIN FOR INJECTION...)
- **PENICILLINS** (AMOXICILLIN, AMPICILLIN ,CLOXACILLIN, NAFCILLIN, PIPERACILLIN...)

AMINOGLYCOSIDES

(AMIKACIN BASE, AMIKACIN SULPHATE...)

LINCOSAMIDES

(CLINDAMYCIN HCL & PHOSPHATE...)

ORAL FORMS

- CAPSULES
- FILM COATED AND UNCOATED TABLETS in bottles and blisters
- GRANULATES FOR ORAL SUSPENSION

STERILE FORMS

- VIALS FOR INJECTION



ACSD 1

Via Rossini

ACSD 2

Viale Addetta

ACSD 3

Via Paullo

ACSD 4

Vimercate

ACSD 5

Albano S. Alessandro

ACSD 8

Sesto Ulteriano

ACSD 12

Verona

ACSD 6

Anagni

ACSD 10

Pomezia

ACSD 11

Teramo



Health & Safety Activities

MAJOR ACCIDENT RISK COMPANY

- Under National **Seveso Law** (2012/18/UE, 4th July 2012)
- Safety Management System in place, active and kept up to date.
 - Policy & Policy Document
 - Corporate & Site Specific Safety Procedures & Operating Instructions
- **Certified UNI EN ISO 45001: 2018 (from 17/10/2019)**



Health & Safety Activities

POLICY (DECLARATION OF AUTHORITY)

- The company's progress, which is essential for the good performance of the Company, must always and only be achieved in respect with the Safety and Health of Workers, Citizens and the Environment by taking every necessary resource for the prevention and management of risks.
- In order to achieve these objectives and taking into account the context in which it operates and its changes, the ACSD group undertakes to make adequate resources available and to maintain an adequate organizational and management structure aimed at minimizing risks in its production sites.

POLICY DOCUMENT

- Is consistent with the principles and directives reported in the above mentioned declaration.
- Includes both General & Specific Objectives and principles of intervention regarding compliance with the hazards control of major accidents.

Health & Safety Activities

SAFETY PROCEDURES & OPERATING INSTRUCTIONS

ACTIVE ROLES OF:

WORKERS by applying procedures concerning them.

RSPP (Site Prevention and Protection Safety Responsible)

- Check workers on the correct application of the procedures
- Adverse events reporting
- Incidents & near misses reporting
- “Management of Change” procedure, that addresses the safety impact of proposed changes to hazardous processes.
- Documentation Update for Seveso Law and Fire Brigades related items.
-

Health & Safety Activities

SAFETY STAFF

- carries out Site Internal Audits and Self-Assessments to evaluate the effectiveness of the HS management programmes.
- prepares the “Annual State SGS Report”
- communicates HS performance and reports the activities done to employees and any other interested parties during the annual meetings

Health & Safety Activities

INTERNAL EMERGENCY PLAN

- The emergency situations are herein defined. The facility has identified potential accidents, emergency situations and other significant events that might plausibly occur and are incorporated into the Emergency Response Plan.
- The Emergency Teams are present at each site.
They are periodically trained: 4 times /year with two practical exercises.
They are fully equipped and they are always ready for an intervention in case of need.
- The Employees are expected to respond during the practical exercise (2 Drills/year);
They have been informed on how to respond.

FIRST AID ON SITE

- Infirmaries are present at each site. They are equipped with all the necessary things to help injured people. First-aid kit are also present in different points on the plant.

Health & Safety Activities

OTHER RISKS

- Under National Legislative Decree **N°81/2008** for “**Safety in the Workplaces**”.
- DVR “Risk Evaluation Document” in place, active and kept up to date with specific periodicity.

Main evaluated Risks :

- Safety and industrial hygiene (SOV, Dust)
- Noise
- Workplace Microclimate
- Biological
- ATEX
- Fire prevention
- Manual Handling of Loads
- Work at height
- Confined spaces
- Electrical
- Indoor Nitrogen
- Work station
- Stress Work related
- Asbestos
- Electromagnetic fields
- Carcinogenic and Mutagenic

Health & Safety Activities

OTHER RISKS

The management of risks that could come from the carrying out of different types of works within our sites is performed through the use of:

Permits of Work (PWTs)

In accordance with our internal procedure, both ACSD Personnel and Contractors are trained together for their correct use by Safety Department.

Technical Department has the task of enforcing the use of permits and does so by also carrying out a control activity.

Contractors then, are also informed on ACSD hazardous materials, productions, emergency plan and health matters.

Health & Safety Activities

SECURITY:

Management of antiintrusion systems.

-On the external perimeter of the factory there are burglar alarms and video surveillance.

-All the doors facing the outside are equipped with burglar alarms.

-access to the different rooms takes place through the use of personal badges (ACSD2, ACSD5.....)

At the entrance to the plants there are receptions where all visitors, workers of external companies and transporters are registered.

Eu Regulations:

Substance Safety Office for REACH (EC N.1907/2006) and CLP (EC N.1272/2008) regulations accomplishment. It is in charge for the REACH registration submissions and manages the drafting, updating and of internal diffusion of MSDS.

TRAINING:

Health & Safety Division closely cooperates with HR department in providing the permanent information-schooling and training programme of the company's workers, contractors' workers and visitors.

OTHER ACTIVITIES OF THE SITES

➤ Chemical R&D Laboratory:

It develops chemical synthesis methods and effective technologies for this manufacturing plant, with the aim of optimizing the scaling-up of the production processes.

➤ Synthesis Department:

Where Synthesis processes takes place. There is a Batch production method; Raw Materials are loaded into the reactor/s, then reactions take place and the products obtained, after being centrifuged, are then crystallized, filtered and dried, so as to obtain the Finished Products.

OTHER ACTIVITIES OF THE SITES

➤ Chemical Quality Control :

Our Finished Products and Raw Materials are analysed from a quality point of view.

➤ Warehouse:

Storage of Raw Materials and Finished Products.

- at room temperature;
- at controlled temperature: Cold store ($T = +5^{\circ}\text{C} - 20^{\circ}\text{C}$).

ENVIRONMENTAL ACTIVITIES

Environmental Management System

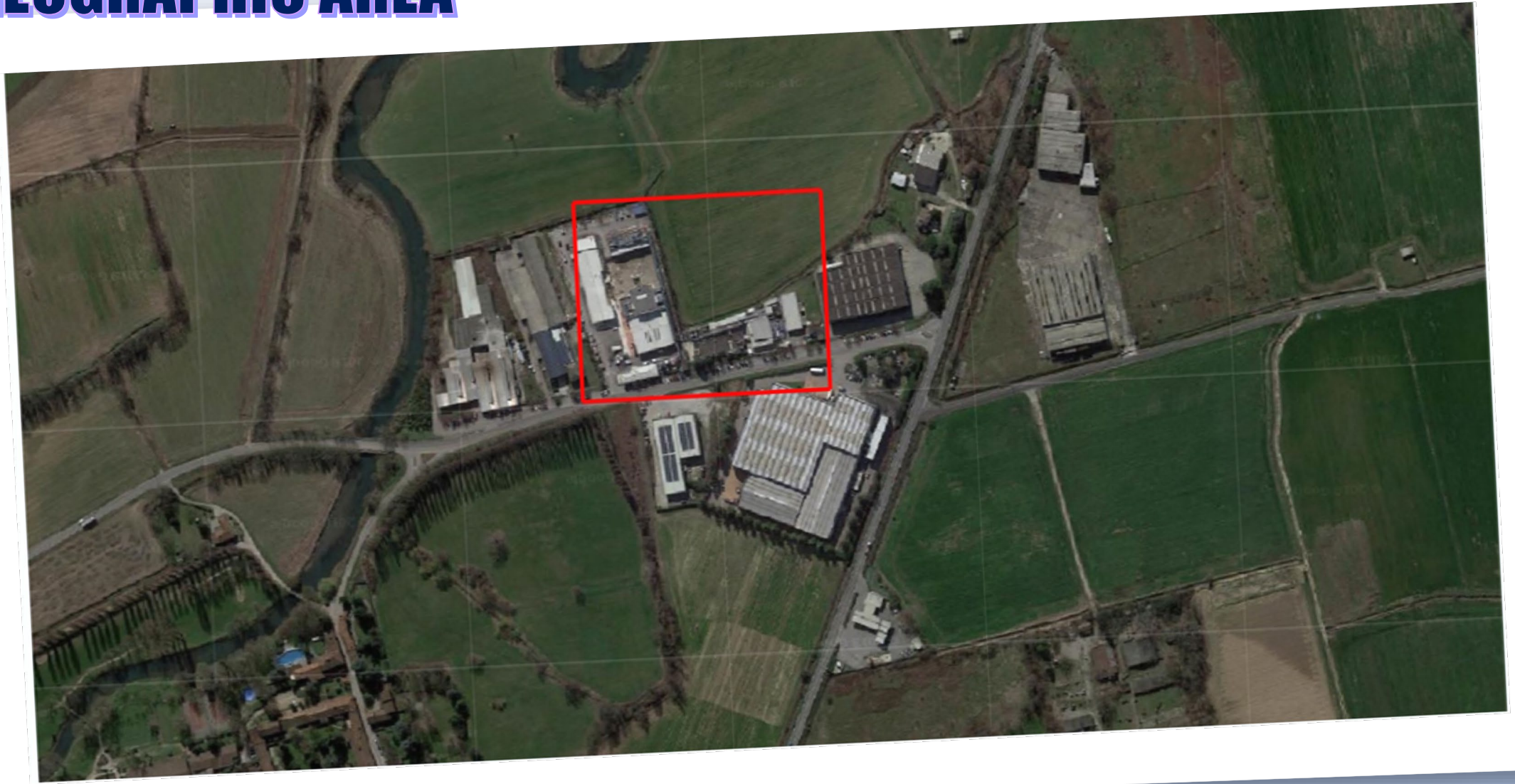
- Each plant is certified according to UNI EN ISO 14001:2015
- ACS Dobfar has a proper Environmental Policy
- Strong control and incidents report guaranteed by Internal Audits and Self Assessments conducted to evaluate the system application

Environmental Laboratory

- Environmental laboratory personnel conducts analysis on air emissions, wastewaters, solid and liquid wastes, exhausted solvents and soils
- The monitoring plan of each plant's permit gives the frequency of the analysis and the parameters to be determined

ACSD1 ROSSINI PLANT

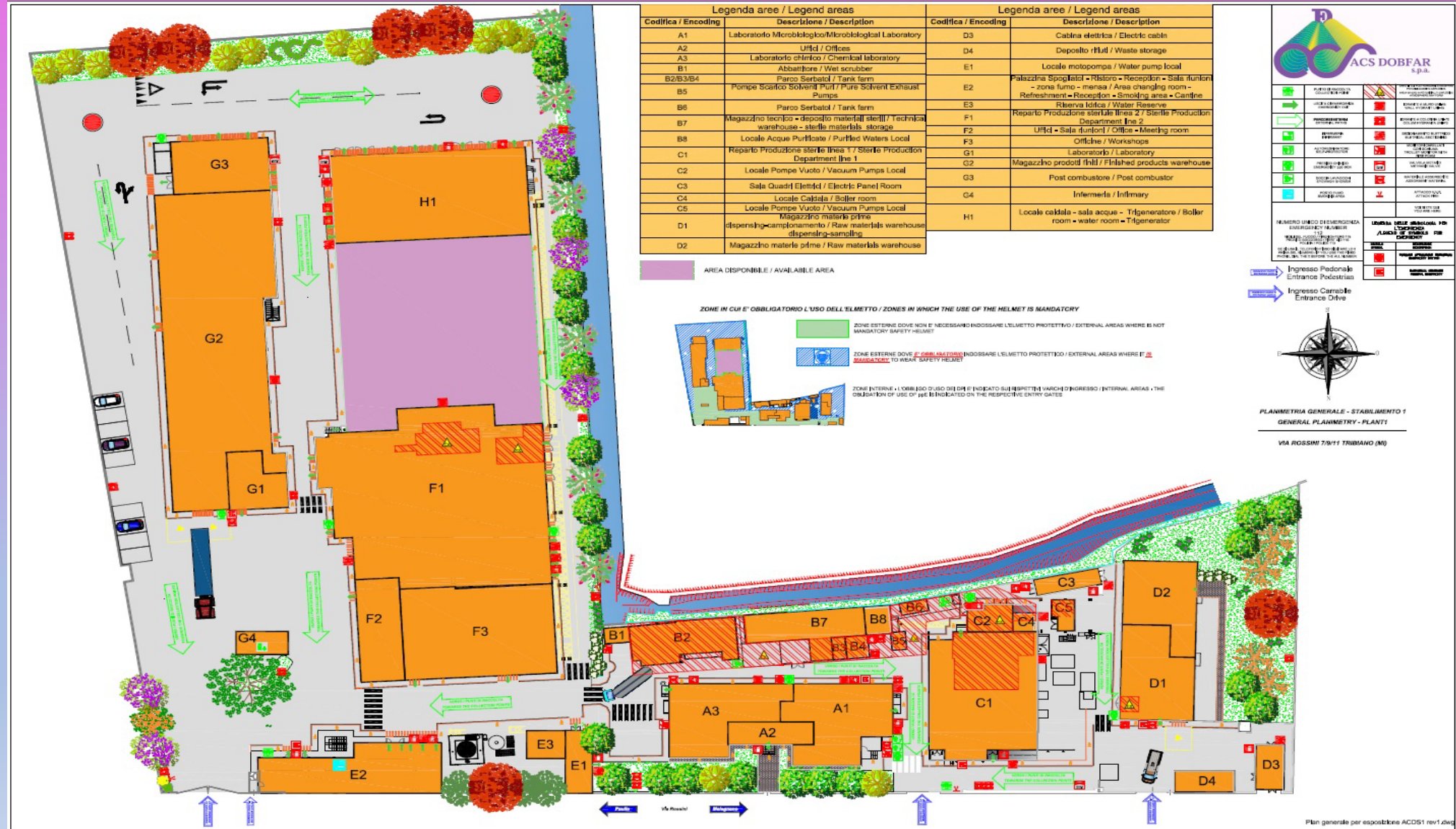
GEOGRAPHIC AREA



SITE MAP

Total Covered Area: 16600 m2

The plant is classified according to ATEX Standards



GEOGRAPHIC AREA

The productive site ACSD1 is located in Via Rossini, 7 and access to the plant takes place from this street.

Geographical coordinates:

Latitude: 45°25'07"N Longitude: 9°21'31" E

Gauss-Boaga Coordinates :

X(E)= 1528098.21 Y(N)= 5027712.19

The land, in the Southern part of Milan lowlands, is flat, slightly degrading towards the South.

The area is registered in the cadastral register of Tribiano (sheet 2 map 75-100).

Within a distance of 5 Km from the plant there are:

- towns of Tribiano, Paullo, Settala, Mediglia;
- roads: SP158, SP39, SS45;
- other chemical productive sites.

PLANT EQUIPMENT

Reactors:

7 reactors, both in steel and enamel –coated, are operated.

Capacity range: between 900 and 6000 litres.

The utilities supplied to reactors are:

cold and hot water, steam, brine, liquid nitrogen (only to some reactors), gas nitrogen.

Probes for the temperature, pressure and PH control are installed.

Some reactors operate at a temperature range between -90°C (liquid nitrogen) and 130°C (steam at 3 bar).

PLANT EQUIPMENT

Filter dryers:

Three filter dryers in steel are installed; they have the double function of filtering and drying.

Dissolving filters:

Three dissolving filters are installed; they have the double function of filtering and dissolving.

PLANT SAFETY EQUIPMENT

- Automatic extinguishing system with water supply is present.
Water Reserve for sprinkler system (100 m³)
The automatic system is actioned by : 2 Diesel motor pump and 1 electric pump
- 2 Sprinkler Systems (Raw Materials Warehouse, Sterile 2 emergency escape way)
- 13 Column hydrants (UNI 70)
- 35 Wall hydrants (UNI 45)
- 4 Wall hydrants (UNI 25)
- 3 Foam Monitors
- Smoke Detectors (Control Room, Electrical cabins, Thermal Power plant, Sterile 2, finished goods warehouse, Raw Materials Warehouse, Sterile 3, QC Lab.)
- Gas Detectors (Thermal Power plant, post-combustion plant)
- Hydrogen detector (QC Lab.)
- Extinguishers (n°115)

PLANT ENVIRONMENTAL EQUIPMENT

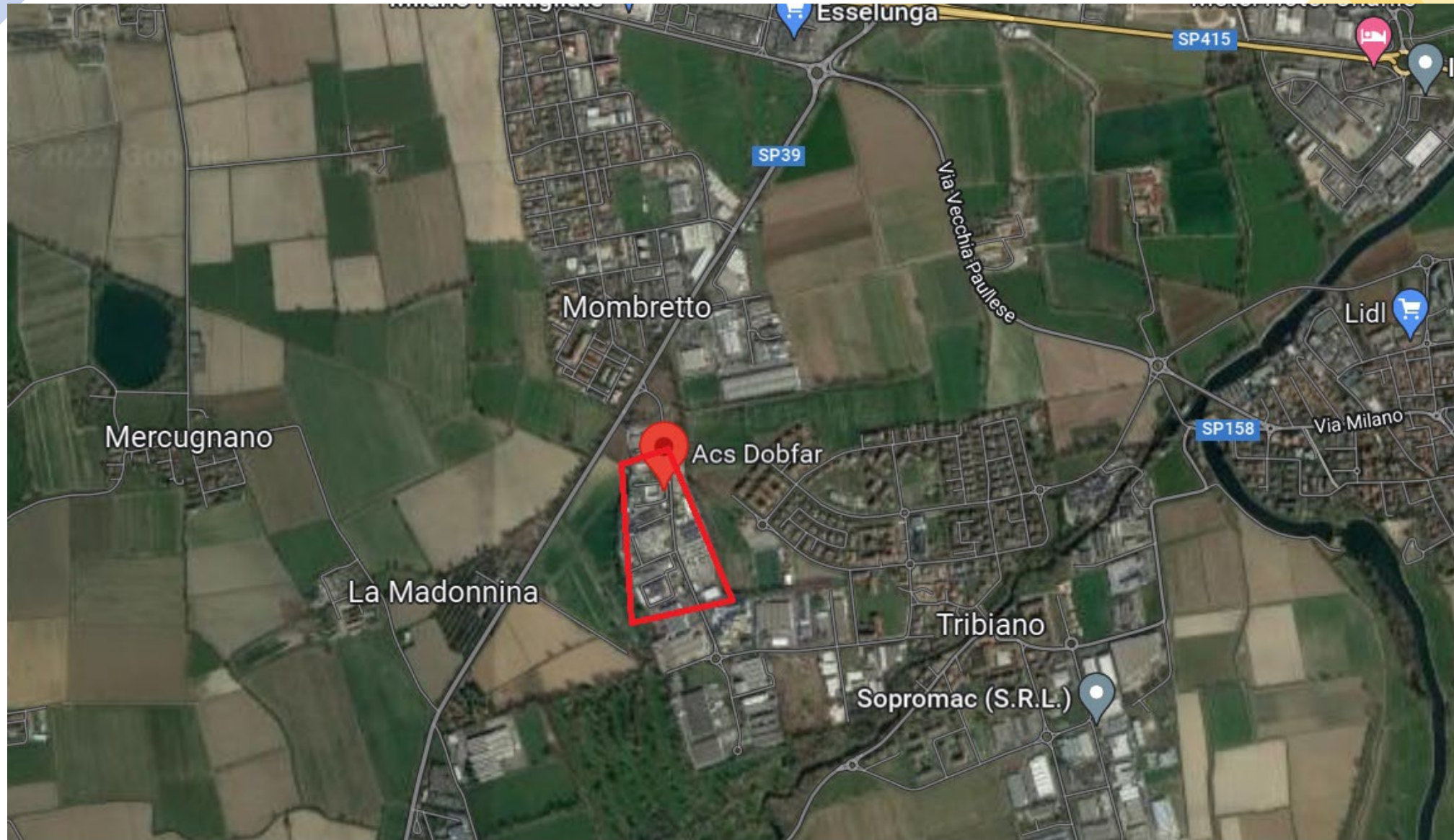
- POST-COMBUSTION PLANT FOR EMISSIONS TREATMENT
- TRIGENERATOR FOR ENERGY PRODUCTION
- SOLID WASTE ZONE
- TANK FARM
- COLLECTION PIPES AND TUBES FOR RAINWATER

ENVIRONMENTAL AUTHORIZATION

- AUA (AUTORIZZAZIONE UNICA AMBIENTALE) N° 7212 OBTAINED IN 2017
 - EMISSIONS IN ATMOSPHERE
 - PUBLIC SEWAGE SYSTEM DISCHARGES
 - SOIL DISCHARGES
- PERMIT N°02 FROM COMUNE OF TRIBIANO OBTAINED IN 2019
 - RIVER DISCHARGES

ACSD2 ADDETTA PLANT

GEOGRAPHIC AREA



The plant is classified according to ATEX Standards



PLANIMETRIA GENERALE - STABILIMENTO N.°2

VIALE ADDETTA, 3/9 TRIBIANO (MI)



LEGENDA DELLE SIMBOLICHE FUNZIONALI LUNGO	DESCRIZIONE
	USCITA DI EMERGENZA
	PERCORSO ESTERNO
	PIANTA DI RACCOLTA
	ALIMENTAZIONE
	PORTO FIAMMIFERO
	CONFINI A RISCOPO
	CONFINI A COLLEZIONE
	MECCANISMO ELETTRICO
	VALVOLA SFRIDATE
	ATTACCO VAPOR
	VALVOLA SFRIDATE

ZONE IN CUI E' OBBLIGATORIO L'USO DELL'ELMETTO /
ZONES IN WHICH THE USE OF THE HELMET IS COMPULSORY



- ZONE ESTERNE DOVE NON E' NECESSARIO INDOSSARE L'ELMETTO PROTETTIVO / EXTERNAL AREAS WHERE NO PROTECTIVE HELM IS NECESSARY
- ZONE ESTERNE DOVE E' OBBLIGATORIO INDOSSARE L'ELMETTO PROTETTIVO / EXTERNAL AREAS WHERE IT IS OBBLIGATORY TO WEAR THE PROTECTIVE HELMET
- ZONE INTERNE - L'OBLIGO D'USO DEI DPI E' INDICATO SUI RISPETTIVI VARCHI D'INGRESSO / INTERNAL AREAS - THE OBLIGATION OF USE OF PPE IS INDICATED ON THE RESPECTIVE ENTRY VIEWS

NUMERO UNICO DI EMERGENZA
112
VIGILI DEL FUOCO / FIRE DEPT 115
PRONTO SOCCORSO / FIRST AID 118
POLIZIA / POLICE 112
SE SI USA IL TELEFONO FISSO DIGITARE LO 0
PRIMA DEL NUMERO / IF YOU USE THE FIXED
PHONE, DIAL THE 0 BEFORE THE ALL NUMBER

Ingresso Pedonale
Entrance Pedestrian
Ingresso Carrabile
Entrance Drive

Legenda aree

Codifica	Descrizione
N1	Uffici
N2	Caldia - cabina elettrica
N3	Laboratorio Controllo Qualità Chimico
N4	Area stoccaggio materiali per reparti sterili
N5	Area Test Sterilità - Isolatori GB5 e GB7
N6	Deposito apparecchiature
N7	Deposito controcampioni
N8	Locali deposito - spogliatoi/ bagni
N9	Area stabilità
N10	Area raccolta rifiuti
P1	Uffici
P2	Laboratorio Validation Team
P3	Control Room
P4	Magazzino
P5	Archivio
P6	Box

GEOGRAPHIC AREA

The productive site ACSD2 is located in Viale Addetta n.4/12 in Tribiano

Geographical coordinates:

Latitude: 45°'410896'N Longitude: 9°'369856' E

Gauss-Boaga Coordinates:

X(E)= 1528772.16 Y(N)= 5029222.698

The ACSD2 area is assessed in the municipal land register of Tribiano and it is included in D1 productive/industrial area

Within a distance of 5 Km from factory there are:

- towns of Paullo, Pantigliate, Colturano, Dresano, Peschiera, Settala, Zelo Buonpersico;
- some provincial roads;
- other chemical productive sites.

PLANT EQUIPMENT

SYNTHESIS DEPARTMENT

Reactors:

- 28 reactors, steel and enameled
- minimum capacity: 3000 liters
- max capacity: 25000 liters

The reactors have the following services:

Warm and Cold water, vapor, Liquid nitrogen, liquids for cooling, nitrogen gas.

There are probes for the control of temperature, pressure and pH.

Some reactors can work in a range of temperatures between -60°C and +40°C.

PLANT EQUIPMENT

8 Centrifuges:

They are used to isolate the finish solid products.

They are steel centrifuges:

6 with vertical axis.

5 Dryers:

2 static rotating dryer

3 rotating dryer

PLANT EQUIPMENT

STERILE DEPARTMENT:

15 steel dissolutors

6 steel crystallizer

This equipment have the following services:

Warm and Cold water, vapor, liquids for cooling, nitrogen gas.

6 Filter Dryers

PLANT SAFETY EQUIPMENT

- Automatic extinguishing system with water supply is present.
- Water Reserve for sprinkler system (1800 m³)
- The automatic system is actioned by :
 - 2 Diesel motor pump with a capacity of 570 m³/h for each.
 - Sprinkler Systems:
 - 2 Dry systems (Cold Stores Raw Material & Finished Product Warehouses)
 - 3 Water deluge systems
 - (Two inside vapors abatement pipes on synthesis roof,
 - One runs along the outer perimeter of synthesis dep.)
 - 1 Foam deluge system (roof vacuum pumps)
 - 1 Foam system (Sterile 3 department)
 - 10 water systems (Thermal power plant, Synthesis dep., Raw Mat Warehouse, Finished product Warehouse, Ster.2 Drying Dep., Cri 1 Syntesis dep & Warehouse)
 - Fire Foam Pourer in Tank Farm containment basins

PLANT SAFETY EQUIPMENT

- 24 column hydrants (UNI 70)
- 76 wall hydrants (UNI 45)
- Smoke Detectors (Flammables Depository, Eletrical Cabins, QA Archive, Technical Warehouse, Raw Material & Finished Products Warehouses, Sterile 3 Dep., IT dep., Tools Rooms n° 1-5)
- Gas Detectors (Thermal Power plant, Canteen)
- Dedicated track with pump and equipment
- Extinguishers (n° 289)
- Fire Foam (2 Tanks of 2000Lt each, 1Tank of 3000Lt and other 2500 Lt)
- Generator
- Inergen System (Server Room – IT dep.)
- Central Control Room in Drying dep.

PLANT ENVIRONMENTAL EQUIPMENT

AIR EMISSIONS

- 2 WET SCRUBBERS
- CRYOGENIC SYSTEM
- COGENERATION PLANT

WASTEWATERS

- TANK FARM
- COLLECTION PIPES AND TANKS FOR RAINWATER

SOIL SPILL PREVENTION

- CONTAINMENT BASIN

SOLID WASTES

- WASTE COLLECTION ZONE

ACSD3 PAULLO PLANT

GEOGRAPHIC AREA



SITE MAP

Total Covered Area: 33200 m²

The plant is classified according to ATEX Standards

GEOGRAPHIC AREA

ACSD3 production plant is situated in Via Paullo n.9, also accessible from the entrance of Via Edison n. 9, in the town of Tribiano.

Geographical Coordinates:

Latitude: 45°24'58" N; Longitude: 09°23'06" E

Gauss-Boaga Coordinates :

X(E) = 1 530 030; Y(N) = 5 029 260

The land, in the Southern part of Milan lowlands, is flat, slightly degrading towards the South.

The area is registered in the cadastral register of Tribiano (sheet 2 map 75-100), included in the production area D1 suitable for building and to be completed (PRG roading zoning – Town of Tribano, January 2004).

Within a distance of 5 km from the plant:

- Towns: Tribiano, Paullo, Settala, Mediglia
- Roads: SP158, SP39, SS45
- Other production plants of chemical nature

PLANT EQUIPMENT

Reactors:

37 reactors, both in steel and enamel-coated, are operated. Their capacity range is between 150 and 17000 litres. The utilities supplied to reactors are: cold and hot water, steam, brine, liquid nitrogen (only to some reactors), gas nitrogen.

Probes for the temperature, pressure and pH control are installed.

Some reactors operate at a temperature range between -90°C (liquid nitrogen) and 130°C (steam at 3 bar).

Centrifugal spinners:

They are used to isolate finished solid products.

Centrifugal spinners are in steel: 4 with vertical axis and removable bag and 1 with vertical axis and pneumatic transport

PLANT EQUIPMENT

Filter dryers:

Three filter dryers in steel are installed; they have the double function of filtering and drying.

Dissolving filters:

Three dissolving filters are installed; they have the double function of filtering and dissolving.

Dryers:

One double-cone rotary dryer is installed to dry the solids.

PLANT SAFETY EQUIPMENT

- Automatic extinguishing system with water supply is present.
- Water Reserve for sprinkler system (562 m³)

The automatic system is actioned by 2 Diesel motor pump (in backup configuration) with a capacity of 680 m³/h.

- 5 Sprinkler System

(Flammable Depository, Synthesis Dep., Raw Material Warehouse, Thermal Power Plant)

- Foam Pourer System (manual valve) (Distillation Columns containment basin)
- Foam Pourer System (manual valve) (Solvent tank farm containment basin)
- Water Deluge System (Distillation Columns C01, C02, C03; Abatement systems)
- Foam sparger in containment basin of the solvent tank farm
- 3 Water wall (for solvent tank farm, distillation columns and warehouses protection)

PLANT SAFETY EQUIPMENT

- 15 Column hydrants (UNI 70)
- 30 Wall hydrants (UNI 45)
- 3 movable Foam Monitors
- 2 steady Water Monitors (solvent tank farm)
- Smoke Detectors

(Control Room, Electrical Cabins, Electrical panel rooms in the synthesis department)

- Methane Detectors (Steam generator)
- Hydrogen detector (QC Lab.)
- Extinguishers (n° 93)
- Fire Foam (1 Tank of 6000Lt (synthesis Plant, 1 Tank of 2500Lt (solvent tank farm and flammable warehouse and other 500Lt in drums for foam monitors)
- Electrical Generator

PLANT ENVIRONMENTAL EQUIPMENT

AIR EMISSIONS

- 4 WET SCRUBBERS
- CRYOGENIC SYSTEM
- COGENERATION PLANT

SOIL SPILL PREVENTION

- CONTAINMENT BASIN

SOLID WASTES

- WASTE COLLECTION ZONE

PLANT ENVIRONMENTAL EQUIPMENT

WASTEWATER

- WASTE WATER TREATMENT PLANT
 1. 2 OXYDATION TANKS (2720 m³)
 2. 1 CLARIFIER
 3. 2 WASTEWATER STORAGE TANKS
 4. 2 LIQUID OXYGEN STORAGE TANKS
- TANK FARM
- COLLECTION PIPES AND TANKS FOR RAINWATER

DISTILLATION PLANT

- 3 DISTILLATION TOWERS FOR SOLVENT RECOVERY

ACSD4 VIMERCATE PLANT

GEOGRAPHIC AREA



SITE MAP

Total Covered Area: 54350 m2

The plant is classified according to ATEX Standards

© RANDOLPH LEEU & PAUL SPOON[illegible][illegible]

GEOGRAPHIC AREA

ACSD4 production plant is located in Via Marzabotto 7/9 of Vimercate Town.

On this side there is the main entrance with the reception; a secondary access is also present on the opposite side of the main entrance in Via Trento.

Geographical Coordinates:

Latitude: 45°35'32" N; Longitude: 09°21'25" E

Gauss-Boaga Coordinates :

$X(E) = 1\,527\,970$; $Y(N) = 5\,049\,040$

The land in the Northern part of Milan , is initially flat and then going north becomes hilly.

Within a distance of 2,5 km from the plant:

- Towns: Vimercate, Agrate Brianza, Concorrezzo;
- Roads: A51 Est Highway;
- Other: Few little companies.

PLANT EQUIPMENT

Reactors:

- 36 reactors, steel and enameled
- minimum capacity: 3950 liters
- max capacity: 16000 liters

The reactors have the following services:

Warm and Cold water, vapor, Liquid nitrogen, liquids for cooling, (only for some reactors), nitrogen gas.

There are probes for the control of temperature, pressure and pH.

Some reactors can work in a range of temperatures between -60°C and $+40^{\circ}\text{C}$.

PLANT EQUIPMENT

10 Centrifuges:

They are used to isolate the finish solid products.

They are steel centrifuges:

8 with vertical axis and 2 with extractable bag.

4 Dryers :

One Comber dryer

One Filtromix dryer

One fluid flow dryer

One rotating dryer

PLANT SAFETY EQUIPMENT

- Automatic extinguishing system with water supply is present.
- Water Reserve for sprinkler system (400 m³)

The automatic system is actioned by :

1 Diesel motor pump with a capacity of 454 m³/h.

1 Electric pump with a capacity of 455 m³/h.

- 5 Sprinkler System (Synthesis Dep. Ext Area C; Synthesis Dep. Ceiling Area C; Azo Area B; Synthesis Dep. New part Area C; Cold Store Area A)
- Water Deluge system (Flammable Box Area E, Box HCL Area D)
- Foam Deluge system (Tank Farm Area E)
- Water Blade System (Warehouse Area A)
- 12 Wall Hydrants UNI 45

PLANT SAFETY EQUIPMENT

- 14 Column Hydrants UNI 70
- 1 Foam Monitor
- Smoke Detectors (Control Room, Elettrical Cabins, Thermal Power plant, QA Archive)
- 5 Smoke evacuators (Synthesis Dep., Raw Material Warehouse entrance)
- Gas Detectors – (HMDS, TMCS Flammable Deposit Area M, HCL)
- Gas Detectors – (Methane - Thermal Power plant Area H)
- Extinguishers (n°113)
- Fire Foam Drums (n° 11 - 200 Litres Drums)

PLANT ENVIRONMENTAL EQUIPMENT

AIR EMISSIONS

- 2 WET SCRUBBERS
- CRYOGENIC SYSTEM MADE OF:
 - 2 CRYOGENIC COLUMN UNITS
 - 2 CARBON UNITS
 - 2 WET SCRUBBERS
- 1 COGENERATION PLANT

PLANT ENVIRONMENTAL EQUIPMENT

COGENERATOR PLANT



PLANT ENVIRONMENTAL EQUIPMENT

WASTEWATERS

- WASTE WATER TREATMENT PLANT MADE OF:
1 BIOLOGICAL AEROBIC PLANT MADE.
- COLLECTION PIPES AND TANKS FOR WASTE WATER

SOLID WASTES

- WASTE COLLECTION ZONE

PLANT ENVIRONMENTAL EQUIPMENT

WASTE WATER TREATMENT PLANT



PLANT ENVIRONMENTAL EQUIPMENT

SOLID WASTE COLLECTION ZONE



ACSD5 ALBANO S' ALESSANDRO PLANT

GEOGRAPHIC AREA



S I T E M A P



GEOGRAPHIC AREA

The productive site ACSD5 is located in Via Tonale, 87 Albano Sant'Alessandro.

Geographical coordinates:

Latitude: 45°40'58" N; Longitude: 09°46'52" E

Gauss-Boaga:

X(E)= 1.560.910 ; Y(N)= 5.059.130

Within a distance of 2 Km from factory there are:

- towns of San Paolo d'Argon, Bagnatica, Brusaporto;
- some provincial roads;
- other chemical productive sites

PLANT EQUIPMENT

Reactors:

- 31 reactors, steel and enameled;
- minimum capacity: 1400 liters;
- max capacity: 18700 liters.

The reactors have the following services:

Warm and cold water, vapor, liquid nitrogen, liquids for cooling, nitrogen gas.

There are probes for the control of temperature, pressure and pH.

Some reactors operate at a temperature range between -60°C (liquid nitrogen) and 200°C (steam)

PLANT EQUIPMENT

Centrifuges:

They are used to isolate the finish solid products.

They are steel centrifuges:

3 with vertical axis.

Dryers:

2 Static dryer

1 Static filter-dryer

1 Rotating dryer

2 Rotating filter-dryer

PLANT SAFETY EQUIPMENT

- Automatic extinguishing system with water supply is present.
- Water Reserve for sprinkler system (350 m³)

The automatic system is actioned by :

- 2 Diesel motor pump with a capacity of 420 m³/h for each.

- Sprinkler Systems:
- 2 Dry systems (Raw Materials Tanks)
- 3 Water deluge systems with foam (Synthesis Department)

PLANT SAFETY EQUIPMENT

- 16 column hydrants (UNI 70)
- 10 wall hydrants (UNI 45)
- 7 fire-fighting nose with foaming bottle
- Smoke Detectors (Flammables Depository, Electrical Cabins, Steam Generator, Raw Material Warehouses, Fridge Container)
- Gas Detectors (Synthesis 1-2, Laboratories)
- Dedicated track with pump and equipment
- Extinguishers (n° 117)
- Fire Foam (1 Tanks of 5000Lt and other 2600 Lt)
- Central Control Room

PLANT ENVIRONMENTAL EQUIPMENT

AIR EMISSIONS

- 2 WET SCRUBBERS
- POST BURNER

WASTEWATERS

SOIL SPILL PREVENTION

- CONTAINMENT BASIN

SOLID WASTES

- WASTE COLLECTION ZONE

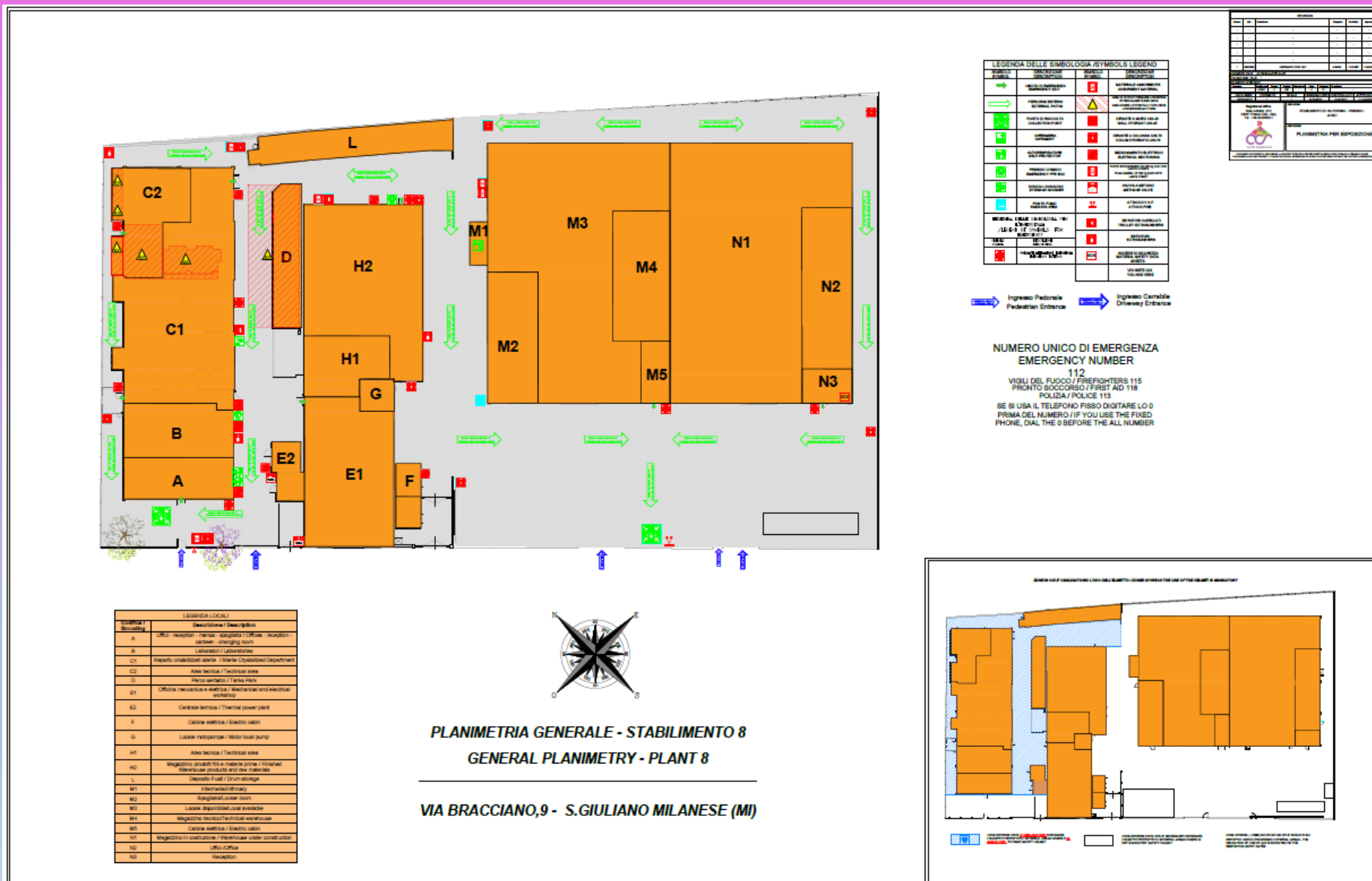
ACSD8 SESTO ULTERIANO PLANT

[illegible]

SITE MAP

Total Covered Area: 2805 m2

The plant is classified according to ATEX Standards



GEOGRAPHIC AREA

The productive site ACSD8 is located in Via Bracciano,9 and access to the plant takes place in this street.

Geographical coordinates:

Latitude: 45°24'07"N; Longitude: 9°14'52" E

Gauss-Boaga Coordinates :

X(E)= 1519434.41; Y(N)= 5027661.36

The land, in the Southern part of Milan lowlands, is flat, slightly degrading towards the South.

Within a distance of 5 Km from the plant there are:

- towns of San Donato, San Giuliano Milanese, Milano;
- roads: A1;ex SS415;SS9,A51;
- other chemical productive sites.

PLANT EQUIPMENT

Reactors:

Four reactors, both in steel and enamel-coated, are operated. Their capacity range is between 2300 and 4000 litres.

The utilities supplied to reactors are: cold and hot water, steam, brine, liquid nitrogen (only to some reactors), gas nitrogen.

Probes for the temperature, pressure and pH control are installed.

Some reactors operate at a temperature range between -90°C (liquid nitrogen) and 130°C (steam at 3 bar).

PLANT EQUIPMENT

Filter dryers:

Two filter dryers in steel are installed; they have the double function of filtering and drying.

PLANT SAFETY EQUIPMENT

➤ Automatic extinguishing system with water supply is present.

➤ Water Reserve for sprinkler system (144 m³)

The automatic system is actioned by :

1 Diesel motor pump

1 Electric pump

➤ 9 Column Hydrants UNI 70

➤ 11 Wall hydrants (UNI 45)

➤ Gas Detectors (Thermal Power Plant)

➤ Oxygen Detector (QC Lab. & Sterile)

➤ Hydrogen detector (QC Lab.)

➤ Extinguishers (n°82)

PLANT ENVIRONMENTAL EQUIPMENT

SOIL SPILL PREVENTION

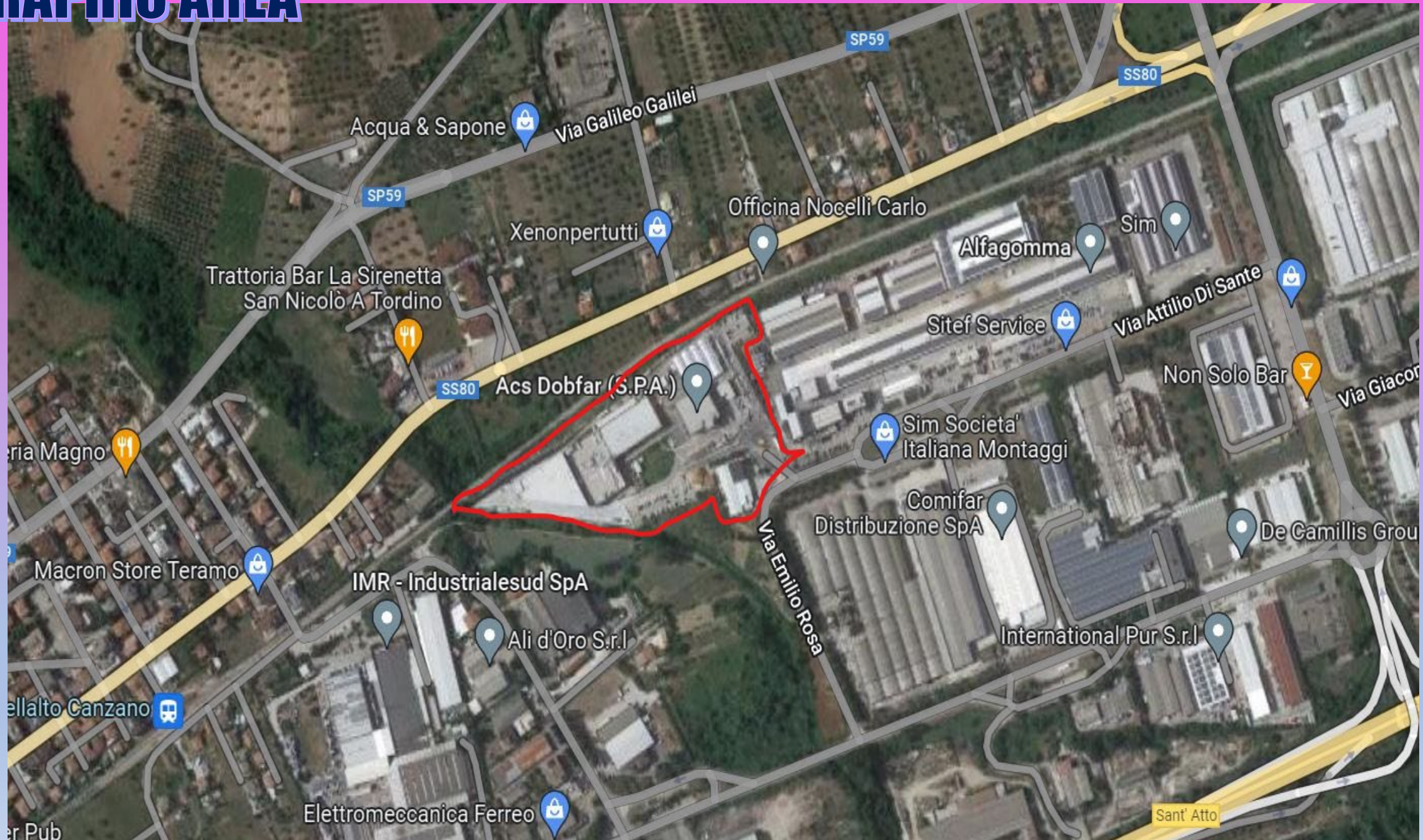
➤CONTAINMENT BASIN

SOLID WASTES

➤WASTE COLLECTION ZONE

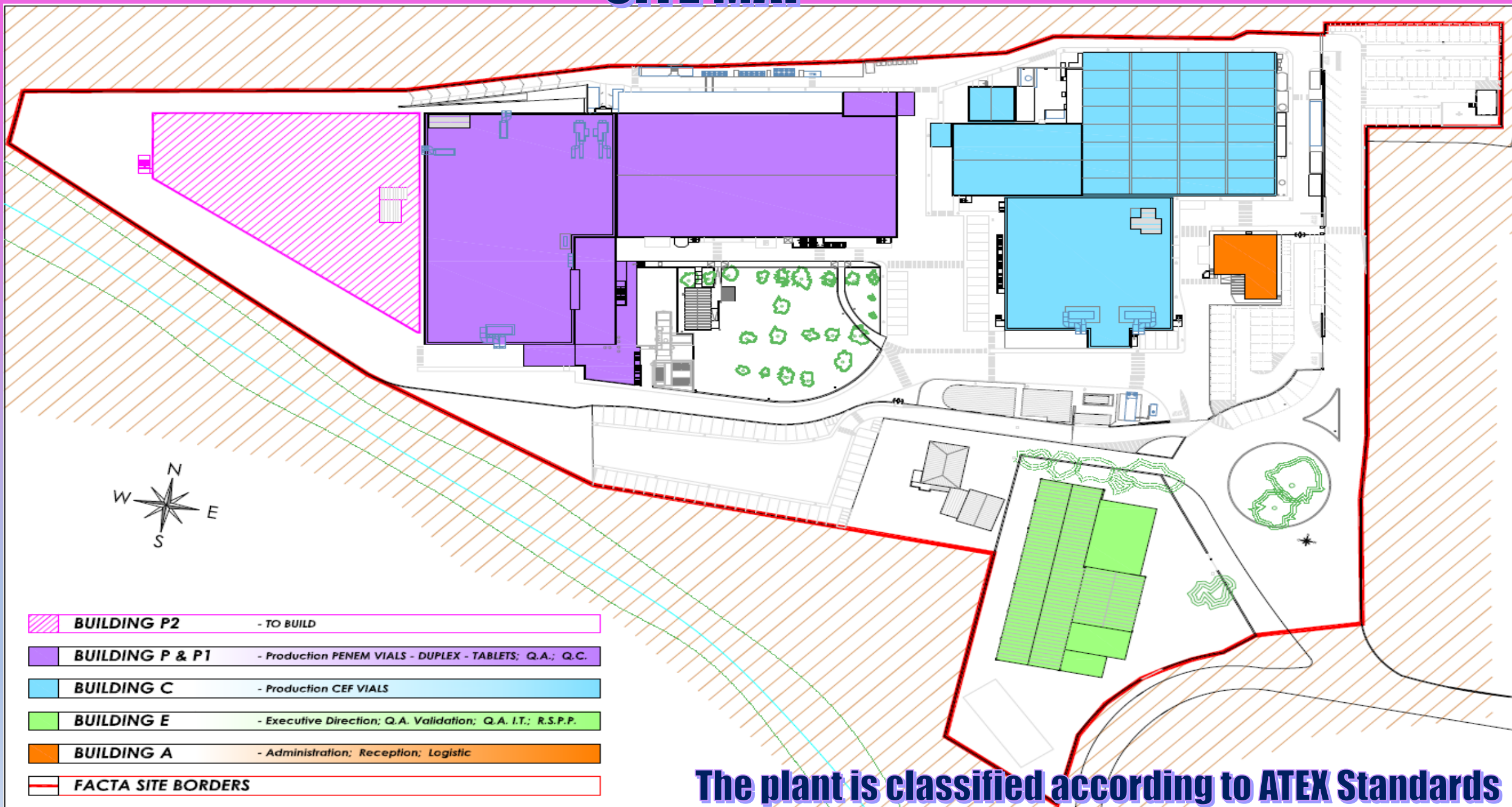
ACSD11 TERAMO PLANT

GEOGRAPHIC AREA



Total Covered Area:m2

SITE MAP



The plant is classified according to ATEX Standards

BUILDING
P2

BUILDING P1

-GROUND FLOOR:PRODUCTION TABLET
-FIRST FLOOR:QUALITY CONTROL LABS

BUILDING P

- FIRST FLOOR :OFFICES
-GROUND FLOOR: PRODUCTION PENEM STERILE GLASS VIALS/STERILE DUPLEX

BUILDING C

- PRODUCTION CEFALOSPORINS STERILE GLASS VIALS

BUILDING E

BUILDING A

GEOGRAPHIC AREA

PLANT EQUIPMENT

Sterile Glass Vial Flow Chart

Classified Area (Grade C → B)

- Autoclave: Moist Heat Steam (Sterilization of rubber stoppers, filters, equipment pieces)
- Vented Pass through U.V. box: U.V light at nm wavelenght/Hepa filters (API's Sterbags entrance into Clean Room)

Classified Area (Grade C)

- Glass Vials Washing Machine
- Glass Vials Depirogenation Tunnel
- Glass Vials dedusting machine (Final external surface cleaning)

Classified Area (Grade A/B, Clean Room)

- Filling, Stoppering & Exit of vials Grade A ; L.A.F. (laminar air flow hood)

Classified area (Grade C/A) Vial sealing (Grade C)

- Crimping is performed in Grade A under L.A.F.

Not Classified Area

- Cartoning Machine, Labeling Machine, Shipper Case Machine.

PLANT EQUIPMENT

Sterile Duplex Flow Chart

Classified Area (Grade C)/Preparation Area

NaCl Dispensing & weighing room; Solution preparation & Sterile Filtration

- Double preparation automatic system - 2.000 l tanks equipped with Triblendering powder mixer and tank magnetic Stirring system
- Filter Skid consisting in double 0,22 micron filters in series
- Piping connection to the nozzle filling machine

DUPLEX® Carrier Transfer Modules

- Sterile Carriers are moved into a L.A.F. Unwrap Station
- Carrier pressure decay leak tester (horizontal L.A.F)
- UV Tunnel transfer station - 360° high intensity UV

Classified Area (Grade C → A/ B Cleanroom)

- Autoclave: Moist Heat Steam (equipment pieces sterilization)
- Vented Pass through U.V. box: API's external surface sanitization

Classified Area (Grade A/B Clean Room → C Preparation Area)

- Washing Machine pass-BOX – Equipment and Spare parts Cleaning

PLANT EQUIPMENT

Sterile Duplex Flow Chart

Classified Area (Grade A)

DB2 Automatic Filling Machine (4 modules):

- Carrier entry
- Bag orientation and Tare weight
- API Powder Filling and gross weight
- Liquid Filling

Not Classified Area

Cartoning Machine, Labeling Machine, Integrity test Machine, Visual Inspection.

PLANT EQUIPMENT

Tablet Flow Chart

- Wet & dry granulators
- Miller
- Tableting Machine
- Coating Machine
- Counter Machine
- Tumbler Machine
- Bottling Machine
- Blistering Machine
- Case Packing Machine
- Cartoning Machine