



Safety Guideline

General guidelines for **safety**, **health**, **energy** and **environment**

at GP Grenzach Produktions GmbH – including special guidelines for employees of outside companies
Good Manufacturing Practices (GMP)



Effective as of: April 2019



Accident/
Emergency

- **Who:** calls it
- **Where:** read from tel.: building, floor, room, north/south
- **What:** Nature of the damage
- **How many:** Number of injured persons, nature of the injury
- **Wait: for inquiries**
- Greet/direct paramedics by person at the entrance in reception

Fixed-network **444** (or 112 only from factory network)

Mobile (cell phone)
+ 49 7624 909 444 NEVER 112

Clear way for the responders and direct the responders

Production = North

Administration = South

wait in front of the entrance

keep elevator (if applicable freight elevator) ready or fetch employee who is able to operate it.

Escort responders



Assist the responders by:

Answering questions precisely and carrying out instructions



Fire/Hazardous situation/
Gas alarm

- **Who:** calls it
- **Where:** read from tel.: building, floor, room, north/south
- **What:** Nature of the damage
- **How many:** Number of injured persons, nature of the injury
- **Wait: for inquiries**
- Greet and direct fire department by person at the entrance in reception

Fixed-network **555** (or 112 only from factory network)

Mobile (cell phone)
+ 49 7624 909 2555 NEVER 112

Factory/Test alarm

Continuous tone for 10 - 60 seconds

YES

Clearly audible?

NO

All-clear signal

Continue to work normally

Only inform the fire department

If alarm poorly audible:

Info to GPS

Indicate room no.

Gasalarm

Wailing sound

Outdoors:

proceed to the nearest building, take people with you, close windows/doors, do not leave building

The fire department will let you know when the danger is over and it is permissible to leave the building again.

Evacuation alarm

Intermittent tone sequence

if possible: try to put out fire with fire extinguisher, doors/windows closed - don't take any risks!

Evacuate building, hurry to assembly point, do not use elevators Advise evacuation responder

Inform fire department about: completeness, missing persons, nature/location of the event

Brief intermittent tone sequence of 1 minute

Stay calm

Follow the instructions on the sign posted close to your workplaces.

PROCEDURE IN EVENT OF EVACUATION ALARM

Gas alarm: wailing sound, 1 minute

Seek out a building: close doors and windows

Factory alarm: continuous tone for 1 minute

No danger - Please remain in place!

Evacuation alarm: intermittent tone sequence, 1 minute

Accident / Emergency

Fixed-network: 444

Mobile: +49 7624 909 444

Fire situation / Hazardous situation / Gas alarm

Fixed-network: 555

Mobile: +49 7624 909 2555

Evacuation alarm

The employees at this workplace have to proceed as follows:


1. Exit the building immediately via staircase

2. Use marked escape routes

3. Accompany the evacuation responders to the assembly point.

Do not use elevators!

Assembly point: meadow in front of Building 60/600



If your building is not directly affected by the event, remain at your regular workplace or proceed there.

Emergency calls may be made from any telephone set by dialing the emergency number.

Accident / Emergency

Fixed-network **444**

Mobile tel. **+49 7624 909 444**

Fire / Hazardous situation

Fixed-network **555**

Mobile tel. **+49 7624 909 2555**

For the case of a total power failure, special emergency telephones are installed, on which only these two emergency numbers can be dialed.



Safety Guideline	
Organization	04
HSE ² Principles and management systems	04
Occupational safety and health protection	06
First Aid	11
Fire protection	12
Behavior in hazardous situations	13
Energy	15
Environmental protection	16
Safety, health, energy and environmental protection guidelines for employees of outside companies	
Introduction	19
Access authorization	19
Protective precautions	20
Order execution	21
Permit	21
Working equipment inspection	23
Directory of structures	24
Declaration	24
Good Manufacturing Practices (GMP)	25

Principles for health, safety, environmental protection and energy

As an enterprise that maintains or strives for the management system according to DIN EN ISO 14001, 50001, 45001(if applicable, 18001), GP Grenzach Produktions GmbH adheres to the following principles of environmentally proper behavior.

The contents of the principles for the protection of health, safety and environment as well as energy management for GP Grenzach Produktions GmbH essentially comprises eight points:

- 1. Objective:** Constant improvement of our performances in the HSE² management systems (energy is separate)
- 2. Responsibility:** Protection of employees and environment regardless of the economic interests
- 3. Leadership task:** Exemplary function, improving awareness of responsibility on the part of the employees
- 4. Occupational safety and health protection:** Striving for optimum safety as well as the physical and emotional well-being of our employees
- 5. Environmental protection:** Constant reduction and prevention of environmental pollution
- 6. Energy-related data:** Continuous reduction of our energy consumption by optimal use of resources
- 7. Cooperation:** Formulation of effective standards in cooperation with Bayer Corporate Functions and, if applicable, other enterprises for the protection of people and environment
- 8. Communication:** Conducting open discussions with employees, neighbors, authorities, etc.

The respective current version can be found in the intranet of GP Grenzach at HSE2 or in the Internet under www.gp-grenzach.de

In connection with their options, the employees have the obligation to respect and implement measures for improvement of occupational safety, health protection, environmental protection and energy efficiency.

7 entities provide important assistance:

Tel.: + 49 7624 907–

- **Industrial safety specialists**
– 3102, – 2502, – 3634
- **Works council** – 4009, – 2661, – 2996
- **Safety officer**
- **Industrial safety committee**
- **Energy manager** – 2702
- **Environmental protection officer** – 3102
- **Company physician** Tel. +49 7624 14 – 2582

Industrial safety specialists

The tasks of the industrial safety specialists in connection with occupational safety, accident prevention, industrial safety including ergonomic configuration of the workplace are derived in detail from the Occupational Safety

Act. Within the scope of their powers, three safety specialists are accountable for GP Grenzach Produktions GmbH.

The **Head of the Safety and Environmental Protection Department** is simultaneously the lead safety specialist and coordinates the work of the safety specialists.

The **safety specialist** is responsible for the education and further education of the safety officers, for accident investigations and reports and for selection of the personal protective equipment. They are likewise accountable for questions of machine safety and hazardous substances and also toward outside companies in connection with occupational safety. In the capacity of fire protection officer of GP, the **Commander of the One Serve Site Fire Department** is responsible for the concerns of preventive fire protection.

Works council

Besides other obligations, the duties of the works council also include monitoring of oc-

cupational and operational environmental protection (§ 89 BetrVG [German Employees Representation Act]). In order to do justice to these activities, the works council assists the industrial safety specialists substantially in accident investigation (§193 SGB VII [Social Security Code Book VII]), inspections and in the Occupational Safety Committee.

Energy team

The energy team is composed of the energy management officer and deputies from units of the site that have a relevant influence on the resource-saving and efficient use of utilities on site. The energy team is responsible for maintaining the energy management system as well as achieving improvements in energy-related performance.

Company physician and first responders

Besides general tasks in occupational medicine, the company physician of Roche Pharma AG is also accountable for all questions of health protection in connection with occupational safety and accident prevention. In detail,

the tasks are derived from the Industrial Safety Act. First responders are trained.

Safety officers

In all departments of our enterprise, employees are appointed and trained as safety officers. Basically, the task of the safety officers extends to their immediate work area. They assist the operational supervisors in the accident prevention work by their behavior and their personal influence on their colleagues. It is also their task to make their colleagues aware of erroneous behavior as well as to report deficiencies in apparatus and facilities to their supervisor. Names and telephone numbers of the safety officers can be found on the posted officer list or emergency posters.

Industrial safety committee

The industrial safety committee has the task of advising on matters of occupational safety, accident prevention, fire protection and first aid and of formulating suggestions to Executive Management.

The industrial safety committee includes:

- The Managing Director
- The industrial safety specialists
- Two representatives of the safety officer
- Two representatives of the works council
- One company physician of Roche Pharma AG
- One representative of Production
- One representative of the laboratories (Building 70)
- One representative of Servicing Member of the One Serve Site Fire Department
- The Head of the Human Resources Department
- The chairperson of the committee is the managing director.

Management system officer

The GPS Department includes a waste officer as well as the head of the management systems for environmental protection and occupational safety. Officers for Business Continuity Management, water protection and hazardous materials can also be reached via GPS.

Looking after your health around the clock!



Thomas Zeyner



Isabella Heitz



Cornelia Finke



Aline Dierkes



Bernd Müller

Establishment medical services
Monday through Friday
07.30 a.m. - 04.30 p.m.
Emergency service in the factory
via 444 - Around the clock
Tel.: 07624 / 14 - 2582
E-mail: grenzach.betriebsarztlicher_dienst@roche.com

Establishment medical services

Commuting to work

For the direct route from home to the job site, accident insurance protection is provided, just as at the workplace. This is also the case for carpooling, detours to bring children to day school, business travel, etc.

Basic instruction

Upon being hired, and thereafter at least one time per year in general, every employee will be trained by his supervisor in the special hazards associated with his employment („JSAs“ and operating instructions, „BAs“). If the safety measures to be followed are not clearly understood, or should items of equipment be missing, the supervisor is to be so advised immediately.

Personal protective equipment (PPE)

To the extent necessary, all employees receive work clothes and shoes or safety shoes, protective goggles, hard hats and further protective equipment, such as gloves and breathing masks.

Every employee is obligated to use the PPE made available. see PPE catalog; in case of questions, contact GPS.

Foot protection

During all work involving danger of foot injury, safety shoes must be worn – this obligation applies to the entire factory premises as well as to leased areas, with the exception of Administration in Building 60 south side.

Hard hats

Hard hats must be worn in specially marked areas. This applies, for example, to the entire sewer system of the site and during **construction measures**.

Protective goggles

Protective goggles must be worn in all marked areas and wherever the eyes are in danger, e.g. during handling of acids and corrosive liquids, during welding, grinding, etc.

In special cases, where spattering of liquids under pressure may be expected, **face shields** or **full-protection safety goggles** must be worn.



Respiratory protection

Where necessary, suitable respirators, particle filters, gas filters, breathing helmets, compressed airline units, portable insulating devices must be used.

They must be worn if harmful gases, mists or dusts may be present.

If an oxygen level of at least 17% by volume cannot be guaranteed in the ambient atmosphere of the manufacturing facilities by wearing residual oxygen meters, or if substances and their concentrations are unknown, **the room has to be exited immediately**. Spent filter inserts must be replaced immediately.

Only employees having basic instruction are permitted to perform work using respirators. Depending on device type and nature of the work to be performed, this requires a medical examination of the suitability of respiratory protection beforehand.

Hearing protection

In the **noisy areas** marked with blue mandatory signs, **hearing protection must be worn**, because a noise level of at least 85 dB(A) has been measured here, which is damaging to hearing. In addition, noise protection is recommended.

Hand protection

During work in which the hands are in danger, hand protection must be worn. Depending on the nature of the danger, chemical-resistant gloves or gloves for protection against mechanical hazards are required. Additional hand protection is available in accordance with the skin protection plan.

Eating and drinking

For hygienic reasons, in GMP zones, eating and drinking is **not** permitted **at the workplace** but only in the break rooms in Buildings 60, 600 and 70.

Consumption of alcoholic beverages is pro-

hibited on the entire premises of the establishment. In case of accidents blamed on alcohol consumption, the insurance protection may be voided.

Behavior at the workplace

Operation of machinery and equipment without initial instruction and also outside the employee's own work area is prohibited. It is permissible to operate machinery only with intact safety equipment. Damage and defects must be reported immediately to the supervisor and repaired. Pranks and bantering are accident-prone and therefore must be avoided.

In order to avoid unnecessary searches by the fire department in the event situation, each individual must sign out consistently when leaving the workplace.

It is not permissible to operate alarm and emergency-calling devices improperly.

If this happens inadvertently, it is always required **to wait** for the return call from the alarm center.



Traffic rules on the factory premises

The factory premises are private area. **The rules of the Road Traffic Regulation are applicable: Factory traffic (including forklifts, rail traffic and leading rail escort vehicles) ALWAYS has RIGHT OF WAY! Pedestrians must use the footpaths on the north and west side of the company's premises. They are not permitted to cross over the truck parking area on the east side of Building 60 in order to reach their own building.** The posted traffic signs must be obeyed. The speed limit is set at 20 km/h. On all roads in the factory, the priority rule is „right before left“. In general, factory traffic (forklifts, trucks, etc.) has the right of way. Vehicular traffic on the factory premises has to be reduced to a minimum.

Building 60 south side - an absolute ban on stopping is in effect along the building, since this area must be kept clear at all times for the rescue personnel!

Keeping to the left side on the opposite lane in the outbound direction is permitted, and this also applies to taxicabs. There they are permitted to stop on the hatched surfaces. (for pedestrians on the way to the cafeteria, see p. 24). In particular, reference is made to the current posters concerning traffic changes for pedestrians within the factory premises as well as all other road users. Moreover, craftsmen are permitted to park in the parking places on the north side of Building 60 if they have to visit the vehicle frequently. In addition, it is permissible to remain at the east dock for loading and unloading, but while doing so it is not permissible to obstruct other delivery traffic and accesses to stairways. Parking for non-factory personnel/craftsmen is authorized on blue parking places only with a parking permit of the gate; it is not permissible to use hatched areas for stopping, loading, unloading or parking (traffic areas of the fire department and rescue service).

In all operating areas, including operating

premises, the use of headphones is not permissible (except for operational purposes); break rooms are exempt from this regulation provided alarm signals and also calls for help from colleagues can be reliably heard.

Bicycles/motor cycles/small vehicles

The use of **private bicycles on factory premises is not permitted.** These, just like motor cycles, must be parked on the covered bicycle racks. Traveling on pedestrian paths (< 2 m wide) is prohibited. Furthermore, a general ban on transportation means such as in-line skates, skateboards, kickboards, etc. is in effect on the entire factory area.

Private vehicles (passenger cars)

Private vehicles are permitted to drive on the factory premises only with appropriate authorization in form of a registration with Factory Protection, and they must be equipped with a transponder. For parking, the parking places marked for this pur-

pose are to be used. The travel-direction arrows painted on the driving lanes are to be obeyed.

Rail traffic always has the right of way!



Pedestrians / vehicles **PLEASE ALWAYS WAIT** until the tanker train has passed and do **NOT** „just quickly dart“ between leading vehicle and tanker train, because then the tanker-train driver **MUST** always initiate a hazardous emergency stop. However, it may be that, because of the sometimes very long braking distance, the train does not safely come to a stop in time and runs over pedestrians or a vehicle. In addition, the tanker may then suffer damage!

Driving with special vehicles

Driving with **GP-owned special vehicles** (forklifts, floor conveyors, etc.) is permitted only for GP employees with valid **driver's license, general instruction certificate, specific instruction certificate for equipment and valid driving order in case of issuance of order in the on-site operational factory traffic.** For driving their own special vehicles on the factory premises, workers of outside companies need the operator's license required in the statutory regulations. These are to be presented upon request to the safety specialists of GP and to the site managers.

Utility tunnels

Access to the utility tunnels and roofs is basically not permitted. Exceptions apply for employees who execute tasks expressly there.

It is permissible to enter utility tunnels only after signing in at the main gate (+ 49 7624 909 25 51) with explosion warning and per-

sonal emergency signaling device. Name and approximate place of occupancy must be reported. Upon leaving the utility tunnels, the worker has to sign out once again. Items to be taken along are hard hat, protective goggles and explosion-protected electrical work equipment, such as a flashlight. In general, work is to be done only with appropriately valid work permit.

Server rooms (e.g. Building 60 UG distribution)

Access to the server room, together with personal emergency signaling device, is permitted only after consultation with the IT Department and sign in at the main gate tel. + 49 7624 909 25 51.

Storage

For pallets, drums, steel bottles and other containers, precautions must be taken for fall-proof storage as well as to safeguard against falling over or rolling away. **It is not permissible to move doors, gates, traffic routes and safety equipment.**



Private vehicles need authorization.



Parking place for bicycles



Driving with special vehicles

Repairs

Lock Out, Tag Out, Try Out (LOTOTO) is to be applied in a manner corresponding to the implementation status. The following points are generally applicable:

It is only after release by the establishment that it is permissible to commence opening of pipelines conveying substances and utilities, repairs, entry into vessels or shutdown of safety and monitoring systems (in this regard, see matching work permit). This is the case in particular for safety guards on packaging machines or the like. It is permissible to perform tasks only with flawless and inspected tools and auxiliary equipment, used as intended. It is prohibited to remain in place under a suspended load. Floor hatches, pits, shafts, tunnels and other hazardous depressions have to be safeguarded by means of proper barriers to prevent falls into them.

Before any repairs are begun, apparatus and pipelines must be cleaned as well as possible and separated from the other apparatus. Special care is called for when detaching flanges. In the process, face shields or full-protection goggles must be worn.

Only workshop personnel or specially instructed establishment employees are permitted to install and remove dummy plates.

For use of ladders, stepladders, scaffolds, platforms or electrical equipment see page 22 - For testing of work equipment, see page 23.

Elevators

It is not permissible to overload elevators; no transportation of goods in personnel elevators (exception: transportation of laundry in south elevator and middle personnel elevator)! During transportation of hazardous working substances, a safe and sealed storage box must be used. Loads are to be secured against shifting. It is not permissible to operate alarm and emergency-calling devices in elevators improperly, since this triggers a false alarm to the rescue personnel; **in the event of erroneous operation, it is required to wait for the response from the gate! During an evacuation alarm, it is not permissible to use elevators, because of the danger of a power failure or smoke generation.**

Tasks requiring a permit (AES)

In general, a work permit is required for the following tasks: work permits must be issued in general for all activities. Exceptions from this are routine activities, which are

described in a JSA/operating instruction and are implemented by GP employees. The following AES are available for assessment of the work:

- AES for general activities
- AES for fire-endangered activities
- AES for tasks in the laboratory

Additional documents (require one of the AES listed above):

- AES for vessels / confined spaces
- AES for tasks at heights

It is only permissible to begin tasks for which an AES is required when all qualifications required by the AES are available, the necessary precautions have been taken and the GP certifying employee has issued the final release by signature!

For **tasks in vessels and confined spaces**, the „Guidelines for entering vessels“, DGVV Rule 113-004, must be observed in addition.



**Aufzug im
Gefahrenfall
nicht
benutzen!**

First aid

Office hours of the establishment medical service

The establishment medical service (BÄD) in Building 13 is occupied during the posted opening hours. During this period, incoming emergency calls are accepted directly by the BÄD.

If the receiver is not picked up there after five rings, the call is automatically switched to the alarm center at the main gate (Building 108).

Outside the posted opening times, all calls coming in via the emergency number are switched to the alarm center at the main gate.

If necessary, the paramedics are alerted by Works Protection.



First aid measures by employees until arrival of the paramedics or of the physician

Within the scope of their capabilities, the employees are legally obligated to render first aid. Each department has trained first responders who should be called in. To prevent hypothermia, rescue blankets from the stretcher cabinet are to be used.

In case of eye injuries, the eyes must be thoroughly flushed immediately on the spot (for about 10 minutes) with the eyewash or the already provided eye-flushing solution (use the entire contents of both flushing bottles!).

At the same time, the establishment medical service should be called immediately at the emergency number

Fixed tel. network: 444

Mobile tel.:

+49 7624 909 444

In order to guarantee help as soon as possible, it is imperative that the rescue personnel is briefed. (distinguish between north/south building section!)

In the process, it is permissible to circumvent hygiene, garment-changing and zone regulations in urgent situations.

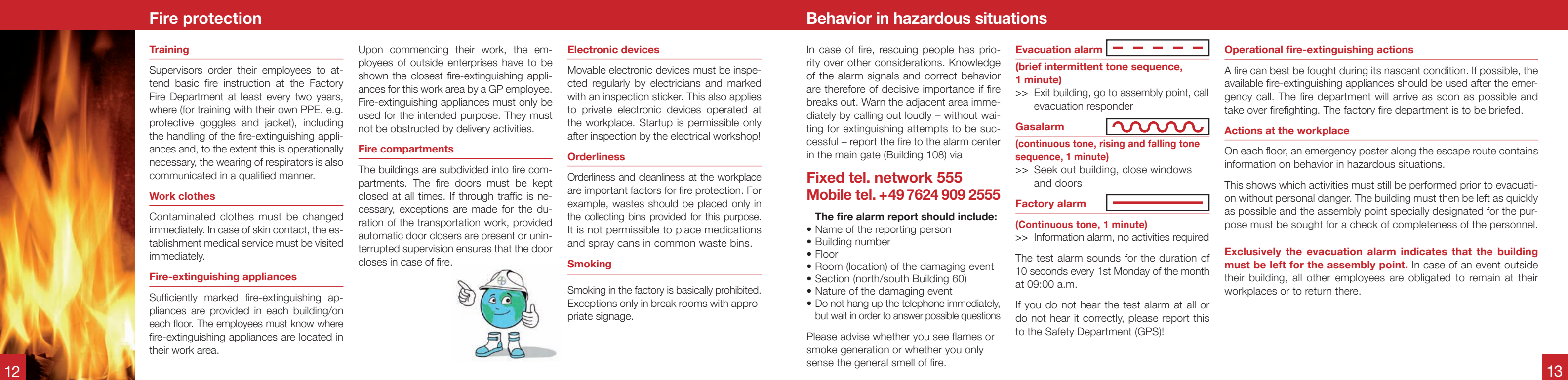
First aid boxes

On each floor of the buildings, medical dressing boxes containing materials for emergencies in which first aid must be rendered are installed at central points.

These facilities are dedicated to care for the personal, and it is permissible to use them only in emergencies.



After use, the first-aid kits must be replaced in the establishment medical service.



Fire protection

Training

Supervisors order their employees to attend basic fire instruction at the Factory Fire Department at least every two years, where (for training with their own PPE, e.g. protective goggles and jacket), including the handling of the fire-extinguishing appliances and, to the extent this is operationally necessary, the wearing of respirators is also communicated in a qualified manner.

Work clothes

Contaminated clothes must be changed immediately. In case of skin contact, the establishment medical service must be visited immediately.

Fire-extinguishing appliances

Sufficiently marked fire-extinguishing appliances are provided in each building/on each floor. The employees must know where fire-extinguishing appliances are located in their work area.

Upon commencing their work, the employees of outside enterprises have to be shown the closest fire-extinguishing appliances for this work area by a GP employee. Fire-extinguishing appliances must only be used for the intended purpose. They must not be obstructed by delivery activities.

Fire compartments

The buildings are subdivided into fire compartments. The fire doors must be kept closed at all times. If through traffic is necessary, exceptions are made for the duration of the transportation work, provided automatic door closers are present or uninterrupted supervision ensures that the door closes in case of fire.



Electronic devices

Movable electronic devices must be inspected regularly by electricians and marked with an inspection sticker. This also applies to private electronic devices operated at the workplace. Startup is permissible only after inspection by the electrical workshop!

Orderliness

Orderliness and cleanliness at the workplace are important factors for fire protection. For example, wastes should be placed only in the collecting bins provided for this purpose. It is not permissible to place medications and spray cans in common waste bins.

Smoking

Smoking in the factory is basically prohibited. Exceptions only in break rooms with appropriate signage.

Behavior in hazardous situations

In case of fire, rescuing people has priority over other considerations. Knowledge of the alarm signals and correct behavior are therefore of decisive importance if fire breaks out. Warn the adjacent area immediately by calling out loudly – without waiting for extinguishing attempts to be successful – report the fire to the alarm center in the main gate (Building 108) via

Fixed tel. network 555
Mobile tel. +49 7624 909 2555

The fire alarm report should include:

- Name of the reporting person
- Building number
- Floor
- Room (location) of the damaging event
- Section (north/south Building 60)
- Nature of the damaging event
- Do not hang up the telephone immediately, but wait in order to answer possible questions

Please advise whether you see flames or smoke generation or whether you only sense the general smell of fire.

Evacuation alarm



(brief intermittent tone sequence, 1 minute)

>> Exit building, go to assembly point, call evacuation responder

Gasalarm



(continuous tone, rising and falling tone sequence, 1 minute)

>> Seek out building, close windows and doors

Factory alarm



(Continuous tone, 1 minute)

>> Information alarm, no activities required

The test alarm sounds for the duration of 10 seconds every 1st Monday of the month at 09:00 a.m.

If you do not hear the test alarm at all or do not hear it correctly, please report this to the Safety Department (GPS)!

Operational fire-extinguishing actions

A fire can best be fought during its nascent condition. If possible, the available fire-extinguishing appliances should be used after the emergency call. The fire department will arrive as soon as possible and take over firefighting. The factory fire department is to be briefed.

Actions at the workplace

On each floor, an emergency poster along the escape route contains information on behavior in hazardous situations.

This shows which activities must still be performed prior to evacuation without personal danger. The building must then be left as quickly as possible and the assembly point specially designated for the purpose must be sought for a check of completeness of the personnel.

Exclusively the evacuation alarm indicates that the building must be left for the assembly point. In case of an event outside their building, all other employees are obligated to remain at their workplaces or to return there.

Behavior in hazardous situations

- Upon leakage of flammable liquids,
- upon gas eruption,
- upon release of large quantities of corrosive liquids,
- upon leakage of water-polluting liquids

or during other damage situations, which cannot be eliminated without danger to the reporting person and other persons using equipment specific to the establishment, a call must be made via

Fixed network tel. 555

Mobile tel.

+49 7624 909 2555

to inform the alarm center in the main gate (Building 108). The necessary actions will be initiated from there.

If necessary, an **evacuation alarm** will be tripped in the affected building. Simultaneously, a **factory alarm** will sound in the other factory areas.

The emergency exits must be kept clear at all times!

Notausgang
freihalten

Make sure you know where the fire extinguisher closest to your workplace is mounted.



Energy

Energy efficiency is not only a current societal and political issue, but it is also important quite specifically for us at the Grenzach site.

Reducing energy consumption means keeping the energy costs as low as possible on the one hand and on the other hand also reducing the direct (caused by us) and indirect greenhouse gas emissions.

Beyond this, working in an environmentally aware manner contributes significantly to the safety of our site.

In order to do justice to this issue, an energy management system meeting the requirements of the ISO 5001 international standard was introduced at the Grenzach site in 2015.

This system is intended to help us configure the use of energy as economically and efficiently as possible.

The energy team is an essential component of the energy management team.

At regular intervals, this team discusses energy-relevant issues at the site and initiates projects intended to contribute to energy economy.

In addition to the energy team, the commitment of all employees towards finding diverse approaches to reduce energy consumption is naturally in particular demand.

After all, even we have hidden energy saving potentials that lie dormant which we would like to use as well as possible in the future!

Walk through GP Grenzach Produktions GmbH with open eyes and also use the VV module of the Learning Factory for meaningful improvement suggestions in the area of energy management.

Likewise, environmentally aware behavior also makes a lasting contribution to improving our energy balance.



Energy-efficient lighting



Every kilowatt counts



Steam energy is precious

Taking wastes with you

Taking wastes with you is prohibited! Any violation will be treated as theft and prosecuted.

Waste disposal

Proper disposal of all wastes generated in the factory is carried out by the Waste Management Department of DSM. The employees of that department can be reached at **tel. 6 27 25** and are available to anyone for any questions regarding waste. The waste officer of GP can be reached at **tel. 3634**.

Until verified disposal, GP is fully responsible for the correct disposal of all generated waste types subject to sorting.

Mixing of wastes is prohibited!

Wastes will be recycled.

An important prerequisite for this is that the wastes will be collected in a manner sorted by type. For example, flat glass is not permitted in the glass dumpster but instead must be disposed of as special construction rubble. For smaller waste quantities, special bins are provided in each department, in which the wastes mainly generated there are collected. For disposal of the wastes, these collecting bins are picked up by the internal waste transportation service, emptied and returned. Moreover, larger dumpsters marked according to waste type are distributed on the factory premises for the most common waste types. The locations of these dumpsters, especially the dumpsters on the north dock of Building 60, are indicated in a plan in the Appendix. Wastes must be placed in these dumpsters by the persons who generated them. Only the waste types for which the dumpsters are intended may be placed therein.

Doubts have to be clarified under tel. 6 27 25 (+49 7624 909 27 25).

Emptying of the full waste dumpsters is organized by the Waste Management Department of DSM. All wastes that cannot be placed in dumpsters must be thoroughly secured, labeled as waste and placed on pallets for disposal. They are disposed of exclusively with a waste transportation certificate (ATS).

Spray cans

It is not permissible to dispose of spray cans together with the commercial waste that resembles household waste. A collecting bin for this purpose is available on the north side (lower level 1).

Prevention of wastewater contamination

All water produced, for example by rain on roofs and impervious surfaces (streets, parking lots), is defined collectively as **surface water**. **Cooling water** from cooling processes and surface water are discharged without treatment into the Rhine, since they are not contaminated. Therefore no contaminants or wastewater is permitted to enter the cooling water. Wastewaters, especially such containing noxious substances, are not permitted to be discharged into the sewer system or into rain gullies, unless the relevant procedural instructions of DSM and GP are obeyed and the departments in question of DSM, such as alarm center and the wastewater treatment system have been informed sufficiently long in advance. Therefore street surfaces must be kept clean, i.e. all solid and liquid contaminants must be completely eliminated immediately.

Solid contaminants are to be collected with shovel and broom, liquids with bin-

ding agents and then the soaked binding agents are to be eliminated with shovel and broom.

Attention! It is prohibited to dispose of chemicals and even residues of cleaning agents and disinfectants via the wastewater (in the original packaging and GHS-labeled or suitable packaging and delivered to Waste Management!).

Release of which chemicals may be discharged into the wastewater is to be discussed in each individual case with GPS and the water protection officer of DSM.

If the danger exists that contaminants may reach the sewer system or the cooling water, the alarm center in the main gate (Building 108) must be alerted! Upon request by DSM, cooling-water samples must be sent to Analytics.

Fixed tel. network 555
Mobile tel
+49 7624 909 2555

Indicate the name, place and nature of the damage. The alarm center then arranges for startup of the cooling-water retention basin and, if necessary, for technical assistance by the factory fire department.

Chemical wastewater

All wastewaters generated during the normal production workflow in Buildings 60 and 70 are directed into the so-called chemical wastewater. The chemical wastewater is cleaned in the wastewater treatment system. In no case is it permissible to dispose of liquid wastes such as all dyes, oils, solvents or similar substances together with the chemical wastewater. For exceptions, see „Attention“ text box.

In case of damage, and prior to discharge of batches (even partly), the wastewater treatment system must be consulted; the DSM-SOP G106 and G105 is applicable. G104 is applicable for permitted discharges (see HSE Manual).



Recycle resources



Production wastewater



Proper disposal

Environmental protection

Solid wastes such as garbage, seals, cable binders, pieces of wood, etc. must be collected with the shovel. It is not permissible to dispose of them in the chemical sewer system.

Production wastewater

It is permissible to discharge production wastewater only if the composition is as intended and meets the requirements of the existing workplace procedures. If deviations exist, the further procedure must be clarified beforehand with the supervisor and the wastewater treatment department. Defective batches must always be disposed of as waste and not be discharged into the wastewater.

Immission protection

By appropriate measures in his area, every employee has to prevent noxious substances from reaching the exhaust air. This starts at the office and workshop by using appropriate working substances and conti-

nues in the laboratory by careful handling of hazardous substances. It is particularly important in the production operations during operation as intended of the installed exhaust-air cleaning systems in accordance with the existing workplace procedures.

The following establishment-specific agreement is entered into between executive management and the works council of GP Grenzach Produktions GmbH.

The guidelines for „Safety, health, energy and environmental protection“ described in the foregoing were established jointly.
Grenzach-Wyhlen, dated March 01, 2019

Dr. Dirk Oebels,
Managing Director

Willy Bass,
Chairman of the Works Council

Finn Petersen,
Head of Safety and
Environmental Protection

Jörg Steiner
Energy Manager

W. Bass
Finn Petersen
Jörg Steiner

Hazardous goods

For shipping of hazardous goods, respect the pertinent SOPs and contact the hazardous goods officer (**safety and environmental protection**), tel. 3634.



Immission protection



Spontaneously flammable substances



Hazardous goods markings

Special guidelines for employees of outside companies

Introduction

The instructions listed in this brochure were issued to ensure compliance with the safety, health, energy and environmental protection requirements, based on our management systems for industrial and environmental protection and for energy (see Principles on page 4). The requirements must be followed on the establishment premises of GP Grenzach Produktions GmbH as well as on the leased areas.

Aside from these instructions that have to be followed in principle, all employees must be informed about the special hazards in their area of service and in case of doubt contact the respective GP advisor or unit manager to obtain information they need about the particular safety precautions.

Upon issuance of each order, a corresponding notice is provided about the area of service and about any regulations that may apply there in addition.

In principle, employees of outside enterprises, while present on the GP establishment premises, are subject to the following rule, both inside and outside the buildings:

The instructions of the GP employees must be followed immediately!

The managing director, owner or other responsible employees of the hired enterprise are obligated to make the employees or subcontractors they use for work on the GP-owned premises aware of the contents of these safety guidelines, including the special notes applicable to the respective work area (e.g. as an attachment), and to ensure that they are followed.

For all subcontractors, the special guidelines described here for „outside firms“ are applicable without restriction.

He confirms awareness of the contents of these safety, health, energy and environmental protection guidelines for employees of outside companies and the basic

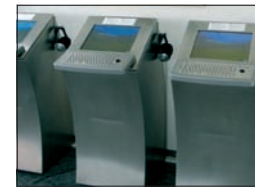
instruction given in this respect to his employees (e.g. in the AES - Tasks requiring a permit).

Moreover, he is obligated to comply with the statutory working time provisions governing maximum working, break and rest times for his employees, so that unsafe handling due to exhaustion is prevented.

Access authorization to the factory premises

Upon request of a GP employee, the factory protection department issues each outside company employee an outside firm ID in form of a „Day factory ID“ or „Permanent factory ID with photograph“ as access authorization to the factory.

The ID is to be worn at all times.



Terminal for training in safety issues



Special vehicles



Fire protection

Special guidelines for employees of outside companies



Before issuing this ID, the factory protection department checks whether the outside company employee possesses adequate knowledge about the safety and environmental protection rules in effect on the factory premises.

The outside company ID will be issued only once a test is successfully passed.

If the test is not passed, the outside company employee cannot obtain any access to the factory premises.

In addition, for **Building 60**, outside company employees with a day factory ID may obtain a „visitor ID“ from the respective unit or department manager. After briefing in the garment-changing and hygiene procedures, this authorizes them to pass through the corresponding airlocks.

Upon completion of the respective order, these IDs must be returned immediately and without being prompted to the corresponding department or to the main gate. See page 8 for explanations about parking authorization.

Protective measures / Precautions

In addition to the work clothes in accordance with the work permit, all outside company employees must, if necessary, wear further protective gear, e.g.:

- **safety shoes** • **protective goggles**
- **hard hat** • **gloves**
- **breathing mask**

This equipment is not provided by GP, and any time spent for procuring it does not count toward the ordered working time at GP. Without the PPE defined in the work permit, the tasks cannot be performed.

For suppliers, tradespersons and outside firm associates (except in administrative areas), wearing of safety shoes is mandatory!

On construction sites, **head protection (hard hat, bump cap, etc.)** must always be worn in addition.

The detailed information on the subjects of

- **Occupational safety and health protection**
- **First aid**
- **Fire protection**
- **Behavior in hazardous situations**

on pages 6 through 13 must be observed without exception!



Order execution

Before commencing work, the employee of the outside enterprise has to report to the accountable person in the establishment in question and to undergo briefing there.

In principle, access to the correspondingly marked areas is permitted only when the outside employee has duly reported to the GP person who hired him. Each outside employee always has to remain in his work area. Operation of machinery and facilities outside his own work area is prohibited.

Working only with work permit

At least one work permit is required for tasks; the precautions and protective measures defined therein must be implemented prior to the beginning of work and the GP certifying employee must have issued final release by signature. Particular qualifications or certificates for welders, electricians or

the like must be shown to the responsible person of GP prior to commencement of work.

The detailed information on page 10 must be observed without exception!

Working in vessels

For **tasks in vessels and confined spaces**, the „Guidelines for entering vessels“ must be observed in addition.

Access to the **utility tunnels** and roofs is basically not permitted. Exceptions apply for those company employees and outside employees who have to execute orders expressly there.

It is permissible to enter utility tunnels only when the person has signed in beforehand at the main gate (tel. 6 27 25).

Name, firm name and the approximate whereabouts are to be noted. Upon leaving the utility tunnels, the employee has to sign out again at the gate.

If the person stays too long or forgets to sign out, a fire department action will be triggered.

Work in the utility tunnel is permitted only in **pairs**. In the utility tunnel, it is **mandatory to wear hard hats and protective goggles**. Furthermore, a flashlight must always be taken along. All devices used must be explosion-protected.



Order execution



Working with scaffolds



Electrical devices



Work equipment

All work is permitted to be done only with **flawless and inspected tools**, auxiliary equipment and PPE.

Important when **working with ladders**:

- Working with ladders is permissible only when the task is of **small scope**, meaning done by one person alone within a brief period.
- **Leaning ladders** are to be designed such that slipping is prevented. A second person must additionally help to secure the ladder against slipping.
- If work is to be performed from a ladder but it is not possible to hold firmly with one hand onto fixed structural parts, or if there is danger of losing balance, the ladder must be additionally secured by fastening to fixed structural parts. In addition, a safety belt with a short sling rope must be used and is likewise to be attached to fixed structural parts with a snap hook.

- For work that can be performed from **stepladders**, the foregoing regulation applies likewise, with the exception of fastening.

In principle, safeguarding by means of belt and safety rope must be undertaken in all work where there is danger of falling down or inward.

If safe performance is not guaranteed during working with ladders, movable or securely fixed scaffolds have to be used in case of doubt.

Important during **working with scaffolds**:

- After assembly, scaffolds must be inspected by a qualified person. The result of this inspection is to be documented on a scaffold release certificate, on which the other features (permissible load, owner, etc.) are listed. The **scaffold release certificate** has to be affixed visibly and durably on the scaffold. A visual inspection must be undertaken and documented daily by the employee who first mounts the scaffold.

Important in GMP areas (p. 25 et seq.):

No overshoes are permitted to be worn on ladders and stairways as well as scaffolds. Before taking action, please inform the GMP personnel concerning any required immediate cleaning and disinfection!

The use of **electrical devices** is permitted only using specially safeguarded power sources (ground fault circuit interrupters, construction site distribution boards with safeguards subjected to appropriate daily inspection). Economical handling of energy, especially the use of energy-efficient devices and systems, must be observed.

Testing of work equipment

The work equipment and devices needed for the tasks must be in flawless condition from the safety viewpoint. Devices subject to testing in the DGUV procedures, the Industrial Safety Regulation or in BG procedures (BG = employers liability insurance associations) are permitted to be used only when the test period has not lapsed and their testing is made outwardly apparent by an attached test sticker.

Efficient and economical handling of utilities and resources

The outside company is obligated to work economically with utilities and resources (e.g. power, steam, compressed air, water). Unnecessary emissions into the environment (e.g. noise, dust, odors, waste, wastewater, vibrations, exhaust gases) are likewise to be avoided. Electrical loads no longer needed (e.g. lighting, machines, heaters) must be turned off. Leaks and running empty are to be prevented. Windows and doors in climate-controlled rooms have to be kept closed, unless occupational safety is jeopardized thereby. These measures are to be thoroughly checked, especially before the end of work. Only energy-efficient work equipment and devices that conform with the current state of the art (e.g. Ecodesign Directive) are to be used.

If work equipment and devices have an energy demand of greater than 100 kWh/day for power, steam or compressed air, intermediate meters must be installed. In addition, the energy management officer must be informed.

Please advise us of leaks, wastefulness or savings potentials, even if they do not fall within the area of responsibility of your activities.

Prevention of wastewater contamination

Surface waters, including rain runoff, cooling wastewater, chemical wastewater, solid wastes

Liquid wastes (e.g. on construction sites) have to be collected separately in separate containers and secured against leaking and overflowing with troughs and rain shelters. The detailed information on pages 16-18 must be observed without exception.

Waste disposal

Wastes will be recycled

If a service provider brings in wastes from materials, it must remove them and dispose of them by itself.

The service provider is permitted to dispose of wastes that originate from GP materials (e.g. construction rubble, glass plate, cables, etc.) only via the Waste Management Department of DSM. For this purpose, the wastes must be sorted as specified in the waste SOP of GP.

If contractually agreed, the service provider itself is permitted to dispose of the waste only if

- the waste contains no hazardous noxious substances and therefore is not hazardous waste, and
- a memorandum about the waste quantities and associated waste code numbers is compiled for the Waste Management Department of DSM and the waste officer of GP concerning the waste balance of GP.

Special guidelines for employees of outside companies

Footpath to the cafeteria

All GP and outside firm employees must proceed within the marked footpaths. For detailed information please refer to the current posters; see also explanations on page 8-9!

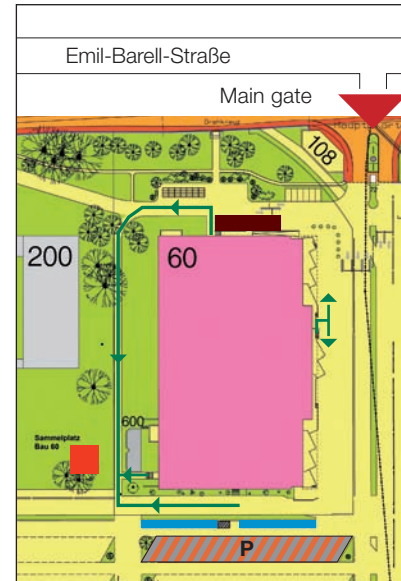
Stopping in front of Building 60 south side

See p. 8 and the „Traffic safety“ brochure of DSM, Roche and GP. Stopping on hatched areas at the entrances and exits is permitted only on the opposite lane (west>east) on the parking side - Stopping is **NOT** permitted in front of Building 60 south. Exception: Deliveries of brine and landscape gardeners.

Logistic area east

Stopping and walking in the truck marshalling area is generally **prohibited!** Exceptions to this are Logistics employees, who are wearing a fluorescent safety vest. The official footpath is located on the west side.

Locations of waste dumpsters as well as parking options



- GP Grenzach Produktions GmbH
- Roche Pharma AG
- Waste dumpsters
Paper, plastic canisters, household refuse, plastic bags, glass, cardboard
- P Parking
- P Visitor parking, taxicabs, tradespersons
- Escape routes
- Assembly point

Good Manufacturing Practices (GMP)

What does GMP mean

The phrase „Good Manufacturing Practice“ (GMP) combines the guidelines for quality assurance of the production processes and the production environment during manufacture of medicinal products and active ingredients. Furthermore, GMP requirements also apply to the manufacture of cosmetics, medical devices and food supplements.

The GMP directive applicable for the EU is the „EU GMP Guide for Human and Veterinary Medicinal Products“. In Germany, this regulatory code is part of the Medicinal Product and Active Ingredient Manufacturing Regulation, which is binding upon all medicinal product manufacturers. GP Grenzach Produktions GmbH holds a manufacturing permit for medicinal products. The above-mentioned GMP guidelines are applicable for all products manufactured at GP.

Please note: GMP does not invalidate any occupational safety measures! (In this respect, see p. 18-23 and p. 21 on ladders and platforms!). Should occupational safety measures be necessary in any GMP area, please inform the persons responsible for that area in advance. Consequently, measures may be taken in order to preserve or restore the GMP status of the area.

What is this about?

The GMP rules are based on the principle that the required quality of a medicinal product does not result from final inspections of the finished product, but instead that it must be achieved and ensured systematically even before the first manufacturing step. Therefore all operational areas and processes that may influence product quality and unequivocal proof of this - especially employees, hygiene, buildings and premises, technical equipment for manufacturing and quality control, raw materials as well as packaging materials and their suppliers, manufacturing

processes and analytics, warehousing and shipping as well as documentation - are impacted by the GMP regulations. The quality assurance system forms the basis and framework for all activities associated with this.

For example, the GMP rules are meant to ensure

- that chemical or microbial contamination cannot occur during the manufacture of medicinal products, whether due to mix-up of ingredients or due to impurities;
- that not only are the accurately specified quantities of active ingredients present in the final product, but also that each process is conducted reproducibly and safely, so that each batch has quality in conformity with the specifications;
- that this quality is assured over the entire (shelf) life of the product.



Employees are dressed in accordance with zone concept.



Machines are cleaned and sterilized.



Concentration on proper performance of the work is important.

Good Manufacturing Practices (GMP)



GMP and related guidelines cover the following subject areas among others:

- Quality assurance system, i.e. the entirety of all measures taken to ensure that medicinal products have the quality required for the intended use.
- Responsibilities and personnel training
- Hygiene, especially microbial contamination by personnel or climate control systems
- Zone concept, i.e. subdivision of premises into various cleanliness classes for various work steps (e.g. separation of production areas from warehouse and break rooms) and control thereof
- Requirements for creating, approving, distributing, archiving and annulling documents
- Quality of the materials - active ingredients and excipients, packaging material, bulk goods, proprietary medicinal products, culture media, cleaning

agents and disinfectants - their consistent and unambiguous marking, appropriate warehousing and quality inspection

- In-process controls during manufacture
- Dealing with complaints and product recalls
- Rules for self-inspection (self-monitoring) and for audits by authorities and clients (monitoring by outside agencies)
- Validation, i.e. furnishing of proof, that methods, processes and systems actually lead to the expected results
- Qualification, i.e. furnishing of proof, that items of equipment work flawlessly, reliably and as intended in connection with defined parameters

How is this achieved?

- Complying with the dress regulations for the various areas
- Complying with the zone concept
- Complying with personal hygiene (e.g. no jewelry, no decorative cosmetics in various areas)
- Checking the health status
- Complying with the hygiene requirements in the various areas (e.g. cleaning and disinfection procedures, prohibiting eating, chewing, drinking and smoking)
- Performing inspections in various areas (e.g. monitoring of the microbiological status, in-process controls during various production steps)
- Training of the persons working at and for GP Grenzach Produktions GmbH

- Active readiness of our employees to sign up for the offered training classes, to attend training classes and to implement what they learn
- Active development of awareness of our employees of the importance of complying with the GMP rules

Why is GMP so important?

Working together, we must all help to ensure that the medicinal products and other products that we manufacture, test and bring to market have flawless and consistent quality. This is the prerequisite for continuing to convince our clients and customers of our quality and reliability, and it is the basis for the successful future development of GP Grenzach Produktions GmbH.



Only trained personnel are permitted to operate the machines.



The focus is on product quality.



The products are carefully inspected.



GP Grenzach Produktions GmbH
Emil-Barell-Straße 7
D-79639 Grenzach-Wyhlen

Tel. +49 7624 907- 0
Fax +49 7624 907- 34 20

gp-grenzach@bayer.com
www.gp-grenzach.de