



SLOVENSKI STANDARD
oSIST prEN 13212:2009

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Road marking materials - Requirements for factory production control

Straßenmarkierungsmaterialien - Anforderungen an die werkseigene Produktionskontrolle

Produits de marquage routier - Exigences pour le contrôle de la production en usine

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EUROPEAN STANDARD
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English Version

Road marking materials - Requirements for factory production control

Produits de marquage routier - Exigences relatives au contrôle de la production en usine

Straßenmarkierungsmaterialien - Anforderungen an die werkseigene Produktionskontrolle

This draft European Standard is submitted to CEN members for enquiry. It has been drawn up by the Technical Committee CEN/TC 226.

If this draft becomes a European Standard, CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

This draft European Standard was established by CEN in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN Management Centre has the same status as the official versions.

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Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

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Foreword

This document (prEN 13212:2008) has been prepared by Technical Committee CEN/TC 226 "Road equipment", the secretariat of which is held by AFNOR.

This document is currently submitted to the CEN Enquiry.

This document will supersede EN 13212:2001.

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prEN 13212:2008 (E)**1 Scope**

This European Standard gives the requirements for factory production control (FPC) for the manufacturer of road marking materials

This European Standard specifies which types of test have to be taken into consideration within the FPC but it leaves the precise methods to be applied to be dependent on the characteristics of the manufacturer's installation and production methods. The precise parameters and methods will be found in the written procedures agreed between the manufacturer and the third party responsible for the initial assessment of the FPC.

2 Normative references

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated into it by amendment or revision. For undated references the latest edition of the publication referred to applies (including amendments).

EN 1423, *Road marking materials – Drop on materials – Glass beads, antiskid aggregates and mixtures of the two*

EN 1424, *Road marking materials – Premix glass beads*

EN 1463-1, *Road marking materials – Retroreflective road studs – Part 1 : Initial performance requirements*

EN 1790, *Road marking materials – Preformed road markings*

EN 1871, *Road marking materials – Physical properties*

EN 12802, *Road marking materials – Laboratory methods for identification*

EN ISO 9001: 2000, *Quality management systems - Requirements*

3 Terms and definitions

For the purpose of this standard the following terms and definitions apply:

3.1 reference sample

sample, labelled and stored for some period of time, to be used in case additional testing or verification is needed.

3.2 batch

amount of product produced as one complete operation not being part of a continuous process.

3.3 factory production control or FPC

permanent internal control of production exercised by the manufacturer.

3.4. factory

single site of production consisting of one or more production lines where raw materials are converted into final products.

4 General requirements for factory production control (FPC)

4.1 General

The manufacturer shall establish, document and maintain an FPC system to ensure that the products placed on the market conform to the declared performance characteristics. The FPC system shall consist of written procedures (works' manual), regular inspections and tests and/or assessments and the use of the results to control raw and other incoming materials or components, equipment, the production process and the product. Records shall remain legible, readily identifiable and retrievable.

The manufacturer shall be responsible for organizing the effective implementation of the FPC system. Tasks and responsibilities shall be documented and this documentation shall be kept up-to-date.

In each factory, the manufacturer may delegate the action to a person who shall have the necessary authority to:

- Identify procedures to demonstrate conformity of the product at appropriate stages;
- Identify and record any instance of non-conformity;
- Identify procedures to correct instances of non-conformity.

The manufacturer shall establish procedures to ensure that the production tolerances allow for the product performances to be in conformity with the declared values, derived from initial type testing.

The procedures shall be chosen in the interests of ensuring that the level of confidence obtained by the production control is effectively the same for all conceivable situations of manufacture.

All these procedures, elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic manner in the form of written policies and procedures.

The manufacturer shall implement these procedures and instructions and record the operations and results. The results shall be used to correct the effects of any deviations and, where necessary, treat any resulting non-conformity and, if required, to revise the FPC system to rectify the cause of non-conformity.

The results of inspections, tests or assessments requiring action shall be recorded, as shall any action taken. The action to be taken when control values or criteria are not met shall be recorded and retained for the period specified in the manufacturer's FPC procedures.

A complaint register shall contain a short chronological view of the received complaints concerning the products covered by this FPC, identifying the source of complaint, its content and its follow-up.

The complaint register shall contain the additional documents relating to the treatment of the complaint.

The FPC system shall at least include the necessary procedures for:

- Records and treatment of non-conformity
- Personnel
- Installations and equipment
- Raw materials
- Manufacturing process
- Conformity control
- Packaging, labelling, handling and storage
- Final testing

An FPC system conforming with the requirements of EN ISO 9001:2000, and made specific to the requirements of the specific product standard and this document, shall be considered to satisfy the above requirements.

prEN 13212:2008 (E)**4.2 System requirements****4.2.1 Personnel**

The responsibility, authority and the relationship between personnel that manages, performs or verifies work affecting product conformity, shall be defined. This applies in particular to personnel that need to initiate actions preventing product non-conformities from occurring, actions in case of non-conformities and to identify and register product conformity problems. Personnel performing work affecting product conformity (e.g. operator, sample taking, lab-assistant, warehouse manager...) shall be competent on the basis of appropriate education, training, skills and experience for which records shall be maintained.

4.2.2 Installations and equipment

All weighing, measuring and testing equipment necessary to achieve, or produce evidence of, conformity shall be calibrated or verified and regularly inspected according to documented procedures, frequencies and criteria. Control of monitoring and measuring devices shall comply with the appropriate clause of EN ISO 9001:2000.

All equipment used in the manufacturing process shall be regularly inspected and maintained to ensure use, wear or failure does not cause inconsistency in the manufacturing process.

Inspections and maintenance shall be carried out and recorded in accordance with the manufacturer's written procedures and the records retained for the period defined in the manufacturer's FPC procedures.

The manufacturer shall have a scheme or a flow sheet of the plant equipment, resuming the whole production process, from the incoming of the raw material to the storage of the products. This document is the basis for the documentation of the manufacturing processes (see 4.2.4).

4.2.3 Raw materials

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The specifications of all incoming raw materials and components shall be documented, as shall the inspection scheme for ensuring their conformity. The verification of conformity of the raw material with the specification shall be in accordance with EN ISO 9001:2000, 7.4.3.

The manufacturer shall prepare and keep up-to-date documented procedures and instructions for:

- The use of the relevant materials from "approved suppliers";
- The conformity control and testing of raw materials: cullets (glass composition), binder, pigment, fillers, solvent, additive, premix glass beads;
- Drop-on antiskid aggregates (also used in mixtures with glass beads) may be either CE-marked products or they shall be tested by the manufacturer as 4.3.2.4) (acting as a user).

4.2.4. Design process

The FPC system shall document the various stages in the design of products; identify the checking procedure and those individuals responsible for all stages of design.

During the design process itself, a record shall be kept of all checks, their results, and any corrective actions taken. This record shall be sufficiently detailed and accurate to demonstrate that all stages of the design phase, and all checks, have been carried out satisfactorily. Compliance with EN ISO 9001:2000, 7.3 shall be deemed to satisfy the requirements of this sub-clause.

The manufacturing process shall be documented. Processes may also be shown by flowcharts indicating related documents and responsibilities (see also 4.2.3). Processes which are covered by this document and undertaken by subcontractors shall be documented by the manufacturer or the subcontractor as if done on the site of the manufacturer.

4.2.5 Production control

The manufacturer shall plan and carry out production under controlled conditions. Compliance with EN ISO 9001:2000, 7.5.1 and 7.5.2 shall be deemed to satisfy the requirements of this sub-clause.

The manufacturer shall have a FPC system in order to ensure that all manufactured products fulfil the relevant requirements of the concerned product standard.

The test methods to be applied and the tolerances for the results of all the tests used shall be specified in the FPC system of the manufacturer.

The minimum frequency of final testing for each product shall be as clause 4.3.2.

The laboratory for internal control shall have the measuring and test equipments necessary to carry out the tests required by this document and the product standard.

The manufacturer may call upon measuring and test equipment from an external laboratory. The mutual obligations of the manufacturer and the external laboratory for the internal control shall be defined in a written agreement.

The appropriate calibrations shall be carried out on defined measuring and testing equipment.

If products have been delivered before all the results of testing are available, a procedure and records shall be maintained for notifying customers in the event of non conforming products

Test results on products shall be kept for a period of 5 years

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4.2.6 Test sample

The test samples shall be representative of the product. If the product standard specifies the rules for sampling, these rules shall be followed or the equivalence of an alternative method shall be demonstrated.

4.2.7 Reference sample

When the final testing is successful a sample shall be labelled and stored as a reference sample for at least one year after production.

The minimum quantities for the reference samples shall be as Table 1:

Table 1 – Minimum quantities for reference samples

Product	Reference sample
Paint	0,5 l
Thermoplastic (preformed or not)	1 kg
Cold plastic	the necessary quantity of each of the components in order to make at least 0,5 l of the final mix
Drop-on materials and premix glass beads	0,25 kg
Antiskid aggregates	1 kg
Mixtures of glass beads and antiskid aggregates	0,25 kg
Preformed road marking (all other types)	0,15 m ²
Road studs	3 studs

prEN 13212:2008 (E)**4.2.8 Packaging, labelling, handling and storage**

Individual products batches shall be identifiable and traceable with regard to their production origin. The manufacturer shall have written procedures ensuring that processes related to affixing traceability codes and/or markings are inspected regularly. Compliance with EN ISO 9001:2000, 7.5.3 shall be deemed to satisfy the requirements of this sub-clause.

The manufacturer shall have procedures providing methods of product handling and shall provide suitable storage areas preventing damage or deterioration.

The identification of stored and delivered products shall provide the necessary information for traceability, including trade name, batch numbers, date of production and date of end of use. In case of delivery in bulk, the system shall provide a suitable method for traceability.

The manufacturer shall follow all requirements for the labelling described in the product standard of each material and, if any, in the ZA annex concerning this product.

4.2.9 Records and treatment of non-conformity

The records shall include everything that is necessary to ensure the traceability and all results of tests executed to control the raw materials, to control the production process and the product. Traceability shall include the recording of to whom products or batches were first sold.

Records shall include at least the following information:

- identification of the product tested,
- date of sampling and testing
- test methods performed,
- test results...

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The manufacturer shall have written procedures (including a recall procedure) which specify how non-conforming products shall be dealt with. Any such events shall be recorded as they occur and these records shall be kept for the period defined in the manufacturer's written procedures. Compliance with EN ISO 9001:2000, 8.3 shall be deemed to satisfy the requirements of this sub-clause.

If the result of any test shows that the product does not meet the declared performance, the necessary corrective action shall be taken. Products or batches not conforming to declared performance shall be isolated and properly identified.

If the non-conformity can be corrected, the necessary verification of conformity shall be repeated once the non-conformity has been corrected.

4.2.10 Corrective action

The manufacturer shall have documented procedures that instigate action to eliminate the cause of non-conformities in order to prevent recurrence. Compliance with EN ISO 9001:2000, 8.5.2 shall be deemed to satisfy the requirements of this sub-clause.