

Quality statement

DSM Food Specialties B.V.

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Delvotest[®] Ampoules

To Whom It May Concern,

We recently discovered a technical issue in our ampoules production line, which may have caused delivering ampoules batches to our customers containing a small number of defective ampoules. The current estimate is that 1-2% of the ampoules in a certain batch could be affected.

The nature of the defect is poor adhesion of the sealing foil to the top of the ampoule, which could result in a lower medium level in these ampoules because of evaporation of water from the agar medium.

We recommend that ampoules with low agar level and/or loose sealing foil should not be used. Customers can take out these ampoules and should contact their DSM representative for compensation.

Based on a risk assessment of this issue, DSM has decided to not initiate a product recall. The nature of the defect means that affected ampoules may reject milk even at antibiotics residue levels below the specified detection limits, but there is no increased risk of a false-negative test result. This means that there is no food safety risk that a batch of milk containing more antibiotics residue than the specified detection limits will have a negative test result. DSM is currently inspecting 100% of the ampoules before shipment in order to prevent sending out any more batches that contain this type of defective ampoules. At the same time, DSM is doing everything possible to solve the technical issue in our production process and prevent this issue from occurring in the future.

Kind regards,

DSM Food Specialties B.V.
Customer QA team

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