Agroscope Fact Sheet | Nr. 193 / 2023

Statement on Bismuth Residues in Milk and Dairy Products Caused by Intramammary Teat Sealants

Authors: Jan-Erik Ingenhoff, John Haldemann, Thomas Berger

Background

The udders of dairy cows are particularly susceptible to infections and disease during the dry period, especially if the teat canal remains open. To avoid bacterial infections of the udder (= mastitis), pathogens must be prevented from entering the udder and/or multiplying. Aside from the use of antibiotic drying agents, teat sealants are an effective means of preventing disease. In the case of intramammary (internal) teat sealants, the viscous product is injected into the lower part of the teat canal after the final milking. The teat sealant acts as a physical barrier and prevents the entry of mastitis pathogens via the teat canal without itself having a bactericidal or bacteriostatic effect. Consequently, these products are often marketed and used as an effective antibiotic-free alternative to conventional drying agents. For this reason, these products are also important in the context of the National Antibiotic Resistance Strategy (StAR) as they help reduce the use of antibiotics during the dry period. Orbeseal®, Noroseal®, Ubroseal® Blue and ShutOut® teat sealants are approved for use in Switzerland.

Intramammary teat sealants contain 65% bismuth subnitrate (CAS number 1304-85-4) in a liquid paraffin base. Bismuth subnitrate increases the viscosity and density of the teat sealant, causing it to plug the treated area of the udder and form a stable barrier.

In the US, black spot defect was reported in Cheddar cheese in the years following the introduction of Orbeseal® in 2003 and the teat sealant containing bismuth was identified as the source. It was hypothesised that product residues became entrained with the milk due to incomplete removal before the first milking. The originally white product reacts with hydrogen sulfide (H_2S) released during cheese aging to form bismuth III sulfide (Bi_2S_3), which gives the characteristic grey/black discolouration of the cheese. Field trials have subsequently shown that both Orbeseal® and pure bismuth subnitrate do indeed cause the reaction in cheese. The distinctive discolouration of the cheese mass was the characteristic reaction in all cases. In another trial series, mixtures of cheese and teat sealant (or bismuth subnitrate) were exposed to H_2S under controlled conditions, resulting in a comparable discolouration in a matter of minutes. Thus the two products responsible for the discolouration are now known.

Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
Confederaziun svizra

Swiss Confederation

Federal Department of Economic Affairs, Education and Research EAER
Agroscope

In recent years, Agroscope has dealt with questions relating to the presence of black spot defect in Swiss hard cheeses caused by teat sealants containing bismuth, which is why it has been highlighting this issue at training and information events. Swissmedic has also responded to recent events by updating the product information for the four teat sealants approved in Switzerland with additional measures to avoid residues in milk and cheese.

Analysis, toxicity and limit values

The samples investigated by Agroscope contained spots of roughly 0.5-3 mm in diameter which were distributed throughout the cheese but more frequent at the edges. After a microbial source had been ruled out by analysis, the cheese samples underwent ICP analysis (inductively coupled plasma). This method of quantifying inorganic elements detected a significantly higher concentration of bismuth in the dark zones compared with the normal-coloured cheese mass.

The European Medicines Agency (EMA) had already published documents on the risk assessment of oral- or intramammary-administered bismuth subnitrate in 1997 and 1999. They state that bismuth subnitrate administered orally is largely eliminated via the faeces. Ingested bismuth is excreted via both the urine and the faeces (including the bile). In humans, absorption into the bloodstream after oral intake is reported to be <0.005%. Thus it is unlikely that intramammary administration would result in absorption into the circulatory system in the animal. Since the risk of bismuth-induced toxicity is described as very low, the EMA concluded that it was not necessary to set a maximum residue level in food after the intramammary use of bismuth as a teat sealant.

In 2016 the Codex Committee for Residues of Veterinary Drugs in Food (WHO/FAO) placed bismuth subnitrate from teat sealants and the resulting bismuth residues in milk on the priority list for risk assessment by the Joint Expert Committee on Food Additives (JECFA). As a result, statutory maximum levels were to be defined if this was deemed necessary. The final assessment has yet to be published.

Bismuth III sulfide, the presumed reaction product formed when teat sealants react with hydrogen sulfide released during cheese aging, was not included in the risk assessments referred to above. Based on current safety data, there is no reason to assume an increased health risk to consumers compared with the base substance.

Summary and measures

Teat sealant residues in milk and cheese can lead to the formation of dark spots in the cheese during aging which are clearly visible to the naked eye. Although the residues containing bismuth pose no direct health risk to consumers, these mainly cosmetic cheese defects can result in a dramatic reduction in the value of affected products and thus represent a serious financial risk to cheese producers, especially producers of hard cheeses.

Probably the most effective preventive measure is the correct training of users. In addition to very strict hygiene practices to avoid introducing bacteria into the udder, the following points must be observed:

Administration:

- Preheat the syringes to room temperature to facilitate application.
- Pinch the upper part (base) of the teat between the fingers when administrating the teat sealant.
- Adjust the amounted injected to the size of the teat.
- Do not massage the udder/teat after application.

After calving:

- Remove any residual product from the teat canal by hand and discard. To remove the teat sealant, pinch each teat at the base and milk out the contents together with teat sealant using a downward movement. DO NOT use milking equipment to remove the teat sealant. Do not allow new-born calves to suckle before the plug has been manually removed.
- Wait eight days after calving before milking, then discard the foremilk from each milking*
- Squeeze each quarter 10 to 12 times before the first milking.
- After the first milkings, check the teat rubber, milking clusters, filter and cleaning machines for residues.
- Regularly check the milking parlour for product deposits.

Coloured teat sealants are also available. The advantage of these is that any product residues present in the milk are immediately visible, enabling prompt action to be taken to reduce contamination, e.g. discarding the milk or using raw milk purification technologies.

*In accordance with the Ordinance on Hygiene in Milk Production (VHyMP) Art. 10 Para. 1g and k

Further links

Lay AM, Kolpin KM, Sommer DA, Rankin SA, 2007. Hot Topic: Black Spot Defect in Cheddar Cheese Linked to Intramammary Teat Sealant. Journal of Dairy Science. 90(11):4938-41. https://doi.org/10.3168/jds.2007-0385.

Codex Alimentarius, 2016. Codex committee in residues of veterinary drugs in food. P1-6. Vol. RVDF/23 CRD/22.

European Agency for the Evaluation of Medicinal Products (EMEA) (1997) Committee for Veterinary Medicinal Products. Bismuth Subnitrate, Bismuth Subcarbonate, Bismuth Subgallate, Bismuth Subsalicylate: Summary Report 1. EMEA/MRL/201/97-FINAL. April 1997.

European Agency for the Evaluation of Medicinal Products (EMEA) (1999). Committee for Veterinary Medicinal Products. Bismuth Subnitrate. Extension to intramammary administration. Summary Report 2. EMEA/MRL/705/99-FINAL. October 1999.

Swissmedic, 2022. HPC – NoroSeal ad us. vet., suspension intramammaire / OrbeSeal ad us. vet., Suspension in Injektoren / ShutOut, intramammäre Suspension für trockenzustellende Kühe / Ubroseal blue ad us. vet., intramammäre Suspension - Massnahmen zur Verhinderung von Rückstanden in Milch und Käse. Healthcare Professional Communication vom 09.12.2022.

Imprint

Publisher	Agroscope Schwarzenburgstrasse 161 3003 Bern www.agroscope.ch
Information	Jan-Erik Ingenhoff
Edited by	Jan-Erik Ingenhoff
Photos	John Haldemann
Copyright	© Agroscope 2023