

EUROPEAN CHEMICALS AGENCY

Public consultation on potential candidates for substitution :

GLUTARALDEHYDE (CAS n° 111-30-8)

Saint Jacques de la Lande, 13/02/2014.

Today, glutaraldehyde has no alternative in specific applications where virucidal and sporicidal activities are necessary, with the exception of oxidants, which are corrosive for many materials and incompatible with some materials used for TP2, TP3 and TP4 applications (metals such as galvanized steel, aluminum, etc..). Especially for veterinary and livestock applications, glutaraldehyde is difficult to replace:

- According to the Notice of the French Agency for Food Safety on the "effectiveness of authorized biocidal products under deemed contagious diseases according to the environment to treat" (Reference No. 2008-SA-0024) 15 / 07/2008 "The foot-and-mouth virus is a" naked "virus, not wrapped. Its resistance in the environment is relatively high. Many inactivation methods have been tested against this virus, which is a major agent of reputed contagious animal diseases. (...) Formaldehyde, glutaraldehyde and peracetic acid are also used. Phenolic compounds and quaternary ammonium compounds are not effective. In the absence of organic material, the oxidizing agents, such as hypochlorite, inactivate the virus. "
- According to the report AMU-2008-010 EFSA the Assessment Methodology Unit of 15/04/2008 "Enable notifications available data on biocidal efficacy under field conditions (Compared to sodium hydroxide and sodium carbonate)" : " Listed biocidal efficacy: Apparently biocides with lipophilic properties (QACs, phenols) are active against group A (enveloped) viruses and not against group B and C (small non-enveloped and other non-enveloped viruses), whereas chlorine and iodine compounds, oxidising agents, some aldehydes and strong acidic agents seem to have an effect against most viruses. However, few standardized studies, which properly reproduce field outbreaks situations, have been found to substantiate the efficacy of these biocides against high pathogenic viral diseases. "
- According to the FAO Corporate Document Repository, "Manual on procedures for disease eradication by stamping out ... (www.fao.org) ; Part 3: Decontamination Procedures, Chapter 3: Weapons: disinfectants and chemicals and for inactivation of exotic viruses and disease agents ": "**Glutaraldehyde**. A very effective disinfectant (Scott and Gorman, 1991) active against all virus families and other microorganisms in concentrations of 1 to 2 percent. It remains effective in moderate concentrations of organic material, is chemically stable, and only mildly corrosive for metals. For large-scale decontamination, however, the cost is likely to be high". "
- TABLE 4. Recommended disinfectants and concentrations for inactivation of viruses. "

Disinfectant group	Form	Strength		Contact time	Applications and virus category
		Usual dilution	Final		
Glutaraldehyde	Conc. solution	as Appropriate	2% (w / v)	10-30 min	Excellent disinfectant effective against virus categories A, B and C.

- According to the United Nations Organization for food and agriculture / World Animal Health organization/ The World Bank, the FAO study for Animal Production and Health No. 169 dated 2011, "Good practices for biosecurity in the pig sector - Issues and options in developing or transition economies countries. "

Disinfectant	Bacteria	Viruses	Fungus	Spores	Mycobacteria	Risks for human health
Alcohol	Bactericide	Virucide	Fungicide	Inhibitor	Inhibitor	Flammable, strong odor
Formaldehyde	Bactericide	Virucide	Fungicide	Sporicide	Myco bactericide	Irritant, explosive, carcinogen, allergen
Glutaraldehyde	Bactericide	Virucide	Fungicide	Sporicide	Myco bactericide	Allergen
Halogens: chlorine, bromine, iodine	Bactericide	Virucide	Fungicide	Sporicide	Myco bactericide in alcohol	Irritant, reaction with other chemical products
Phenolic compounds	Bactericide	Virucide	Fungicide	Inhibitor	Myco bactericide	Toxic, skin absorbed, bio accumulable
Quaternary ammonium compounds	Bactericide	Lipophilic virucide		Inhibitor	Inhibitor	
Peroxides	Bactericide	Virucide	Fungicide	Sporicide	Myco bactericide	Explosive, irritant
Acids	Bactericide	Virucide	Fungicide			Corrosive

The equivalence of disinfectant spectrum efficacy and particularly virucidal activity was possible with formaldehyde but it was substituted for classification reasons... by glutaraldehyde, since a decade. In case of glutaraldehyde use stops for livestock disinfectants formulation, there will be a significant health risk for humans and animals, of survival and spread of infectious disease agents. In France, the decree of 28.02.1957 give the list of approved disinfectants in case of contagious animal diseases: more than 45% of farm disinfectants officially authorized by the French Ministry of Agriculture under this decree contain glutaraldehyde, and more than 50% of livestock disinfectant allowed in cases of FMD. On the website managed by the French Ministry of Ecology (www.simmbad.fr) that identifies biocides on the national market, there are more than 650 products containing glutaraldehyde, mainly for TP2, 3, 4. Glutaraldehyde containing disinfectants are now used by trained professionals, used to wear PPE. Moreover several countries have now established occupational exposure limits for this substance.

Disinfection in veterinary and livestock environment is one of the most difficult to achieve, due to the diversity of pathogens encountered (including bacteria and spore forming ones, yeasts and molds, naked and enveloped viruses, mycobacteria), application conditions (presence of organic matter sometimes in large quantities, low temperature, etc.). There is no quickly and easily accessible substitute to glutaraldehyde for formulators for disinfection in veterinary and livestock areas, without reducing the effectiveness against the emergence and spread of certain viral diseases. The use of oxidant-based disinfectants as a substitute to glutaraldehyde-based ones will cause a very high risk of oxidative degradation on farms cages, fences, feeding equipment, watering and restraint, usually made with galvanized steel. Moreover, glutaraldehyde-based products can be easily dispersed by spraying or fogging at a large scale in the livestock industrial areas, allowing diffusion of the disinfectant in less accessible areas (height, equipment specificities, etc.). The equipment used for aerial application of disinfectant is usually constructed of lightweight metal and is incompatible with the use of oxidant-based-disinfectants, corrosive to metals. In case of glutaraldehyde use stops, the use of oxidant-based disinfectants will increase the degradation of farms equipments and the farmers will probably reduce the frequency of use of these disinfectants (against health safety recommendations), or will use them with lower concentrations than those in the products authorizations, to save their plants, or will have to spend large amount of money to replace their equipment by others less sensitive to very aggressive disinfectants.

A handwritten signature in black ink, appearing to be 'M. Lefeuvre'.

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