Good Chemical Advice – demands and criteria for cleaning agents, disinfectants, udder care products, hoof care products and chemical products for litter beddings

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The general criteria apply to all the stated applications. There may be supplementary criteria for each application. These may be stricter or provide relief from the general criteria.

Throughout these criteria, substances mean all substances added to the products including known additives and contaminants in the substances or raw material.

Unless otherwise specified, classification shall mean the rules contained in Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (CLP-regulation)

General criteria

The concentration limits given in the criteria apply to the ready-to-use solution of the product. It still applies that:

- the product in itself must be possible to handle safely
- the risk for using the wrong dosage is minute
- the product in other aspects fulfils current legislation.

1. Environmental requirements on the substances included in the product

Environmental data for all substances used in a product will be verified against the ECHA database of registered substances and the Prevent[1] database of chemical substances.
Approved products are grades as either recommended (fulfil rigorous criteria) or accepted (fulfil less rigorous criteria).

1.1 Substances classified as environmentally dangerous with long term effects is approved in following maximum concentrations in ready to use solution:

Aquatic Chronic 1; H410	0,005%
Aquatic Chronic 2; H411	0,005%
Aquatic Chronic 3; H412	0,05%
Aquatic Chronic 4; H413	0,05%

Note that the concentration limit for Chronic 1 decreases with the magnitude of an eventual M-factor, i.e. a substance having an M-factor 10 is only allowed with a concentration of 0,0005% of ready to use solution.

1.2 A substance that fulfil the criteria for PBT (persistent, bioaccumulative and toxic) or vPvB (very persistent and very bioaccumulative) according to REACH shall not be included in the product.

[1] Prevent is a Swedish working environment organization.

1.3 A substance classified Aquatic acute 1, H400, “Very toxic to aquatic life” may be included up to a level of 0,05% in ready-to-use solution (graded as recommended) or 0,25% provided it is aerobically and anaerobically degradable (graded as accepted). These concentration limits decrease according to an eventual M-factor.

1.4 Peracetic acid may be contained up to a level of 1,25% in ready-to-use solution (graded as accepted).

1.5 Iodine in its free form may be included in disinfecting udder care products up to a level of 0,25% (graded as accepted). If PVP-iodine is included the assessment is based on the corresponding concentration of free iodine[2].

1.6 Sulfamic acid may be included up to 1,25% in disinfectants except udder care products (graded as accepted).

1.7 For a substance with known degradation products, which are classified as environmentally dangerous the above criteria apply as if the degradation products were included in the same concentration as the mother substance.

1.8 Hydrogen peroxide may be included up to 1,25% in disinfectants except udder care products (graded as accepted).

Exceptions for complexing agents:

Complexing agents often exhibit particularly high toxicity to algae because they block the algae’s access to important nutrients/trace elements by binding them in a complex. The “toxicity” measured is therefore not representative and is of no relevance. The ecotoxicological assessment of complexing agents is therefore based only on the toxicity values from fish and daphnia.

2. Health requirements on products and substances

2.1 Products classified as very toxic or toxic (GHS06), as corrosive (GHS05), as harmful (GHS07) or hazardous (GHS08) cannot be approved.

Exceptions to the above:

1. Products classified as harmful with only "Harmful if swallowed" (Acute tox 4, H302) and "May be fatal if swallowed and enters airways" (Asp tox, H304) may be approved. These properties are not considered relevant in normal handling.
2. Products which as concentrated solution are classified as "Harmful if inhaled" (Acute Tox 4, H332) and/or “Harmful in contact with skin” (Acute tox 4 H312) because of the content of hydrogen peroxide or peracetic acid may be approved if the ready-to-use solution is not classified as Harmful if inhaled or in contact with skin (grades as accepted).

[2] Products may contain PVP iodine. The formal H411 " Toxic to aquatic life with long lasting effects" is not relevant because PVP and iodine should be seen as separate substances. Iodine is classified H400 and PVP is very poorly degradable but has very low toxicity. PVP iodine contains about 10-12% iodine.

3. Products classified as corrosive in ready-to-use solution may be approved, if they do not get in contact with animals, and if the user is informed in the product sheet, label and safety data sheet about protective equipment required.
4. Products classified as corrosive in its concentrated form but classified as “Irritatant to skin” or “Irritating to eyes” in ready-to-use solution may be approved if neither the concentrated solution or ready-to-use solution get in contact with animals, and if the user is informed in the product sheet, label and safety data sheet about protective equipment required.
5. Products classified as corrosive in its concentrated form but neither classified as corrosive or irritant in ready-to-use solution may be approved (grades as accepted).
6. Powdered products intended to be used as a disinfectant/bacterial inhibitor for bedding shall be designed so as to avoid dusting and risk for eye irritation or irritation of respiratory tract by inhalation.

Note that products classified as sensitising (may produce an allergic reaction) cannot be approved. Products which get in contact with animals cannot be approved if the concentrated product is classified as corrosive even if the ready-to-use solution is not classified.

2.2 The product must not contain substances classified as carcinogenic, mutagenic or toxic for reproduction, CMR, (H350, H340, H360). The product must not contain substances classified as CMR category 2 (H341, H351, H361) in concentrations that give rise to classification of the product as CMR category 2 (H341, H351, H361). The product shall not contain substances prioritised in “Overall Category 1 and 2” in the list of suspected endocrine disruptors drawn up by the European Commission[3].

3. Other environmental and health requirements for substances

3.1 Colouring agents are not allowed in the product. In certain cases, however, they may be approved if they have a specific function, are approved for use in food and are easily wiped or rinsed off. A colouring agent is a substance that is added to a product primarily to give the product a certain colour.

3.2 Perfumes are not allowed in the product. Perfumes are defined as substances that are added to a product primarily to give the product a certain fragrance.

3.3 Chlorinating compounds[4], e.g. sodium hypochlorite, are not allowed in approved products.

3.4 The product must not contain intentionally added nanomaterials.

3.5 Quaternary ammonium compounds are not allowed as this may adversely affect the raw material in the further processing.

3.6 For products claiming to have a vasodilating effect or to increase the blood flow (e.g. ointments containing camphor), it is referred to the regulations on medical products for external use (LVFS 1995:19) issued by Sweden's Medical Products Agency. The marketing of such products requires authorisation from

[3] List of substances available from http://ec.europa.eu/environment/chemicals/endocrine/index_en.htm
[4] Reactive chloride compounds are defined in a separate annex

the Medical Products Agency. In order for such products to be approved, the supplier/manufacturer must present a marketing authorisation for the products.

3.7 Disinfecting udder care products and disinfecting hoof care products must be approved by The Danish Veterinary and Food Administration www.foedevarestyrelsen.dk).

4. Other requirements on the product

The products must be provided with an updated safety data sheet (SDS) according to REACH.

4.2 Labelling and information on the packaging of the product should meet the requirements of the authorities in Sweden and the EU. Product information and labelling must be clear and easy to read.

4.3 Packaging design must meet the requirements of the Swedish Chemicals Agency (KIFS 2008: 2, Chapter 2, §§ 2-3), or of the CLP Regulation.

4.4 The product must be registered with the Swedish Poisons Information Centre.

4.5 The product should, if it is imported/manufactured in quantities larger than 100 kg, be registered with the Swedish Products Register.

4.6 The company placing the product on the Swedish market must be affiliated to FTI (Packaging and Newspaper Collection Service) in Sweden.

4.7 All substances included must be pre-registered or registered under REACH.

4.8 According to Industry Guidelines for Hygienic Milk production, disinfection of teats may only be performed after milking.

4.9 A disinfectant product will have to be approved as a biocide according to Biocides regulation[5]. The product must also be packaged and labelled in accordance with this Regulation. Note that Biocides entered into force as recently as September 2013 why some national approval will exist in parallel for a transitional period

5. Function

For cleaning agents it must be confirmed that the product has been used with good results in the European market for 5 years (this can also refer to similar products). As an alternative there must be documentation to show that the product has undergone a performance test in the laboratory.

For disinfectants disinfecting udder care products and disinfecting hoof care products it must be confirmed that the product has been used with good results in the European market for 5 years (this can also refer to similar products). As an alternative it should be confirmed that the product has passed defined requirements in a well-documented test. To test the disinfectant effect standardized suspension tests are available, as DS/EN 1276 and DS/EN 1650 or equivalent. The requirements in suspension tests is

5 Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products.

a 5 log reduction of bacteria and a 4 log reduction for spores, yeasts and molds. See DS/EN 1276 and DS/EN 1650.

6. Other environmental labelling schemes

Products labelled with the Nordic Ecolabel (The Swan), Good Environmental Choice or EU Ecolabel are approved for use in connection with milk production on the farm and industry. It may be, for example cleaning products, personal hygiene products or detergents. Products marked with one of these eco-labels do not need to apply for approval from Good Chemical Advice, they can apply only to be registered on the list without further approval.

Annex
Chlorinating disinfectants

Several disinfectants contain active chlorine with varying chlorine generating capability. All of them are therefore not counted as chlorinating by the criteria in this document.

Substances that in in ready-to-use use solution has a lower chlorine generating power than a tenth of the power of the corresponding working solution of sodium hypochlorite at pH = 7 are not considered as chlorinating. This means that chlorine dioxide and chloramine-T are not considered chlorination.

Chlorinating effect can be measured as follows: Make a solution of 100 mg (1.06 mmol) of phenol in one litre of water. Make a solution from the test substance with a molar concentration ten times higher than this (10.6 mmol). Provide the solution with a buffer so that the reaction can take place at pH close to 7, e.g. by addition of 24 g of potassium dihydrogen phosphate and 5 g of sodium hydroxide. Make sure the temperature of both solutions is about 20°C. Mix them and let them react for 5 minutes. Add 2 g of solid sodium hydrosulphite to stop the reaction. Divide the AOX content after this reaction by the AOX content from the corresponding reaction of phenol and sodium hypochlorite at the same conditions as above. The ratio must not exceed 0.1.

Chlorinating agents in contact with organic substances are capable of producing significant amount of polychlorinated organic substances. These often have high toxicity, are persistent and very bioaccumulative. Substances with a weak chlorine generating power produce only small amounts of mainly mono chlorinated substances. These usually have lower toxicity, are more readily biodegradable and have lower potential to bioaccumulate.