

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

4XLA Post-Milking Germicidal Teat Dip Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

4XLA Base

<u>Active ingredient</u>	<u>% w/v</u>
Sodium Chlorite	0.64

4XLA Activator

<u>Active ingredient</u>	<u>% w/v</u>
Lactic Acid	2.64

Excipients

Tartrazine (E102)	0.30	(colourant)
Sodium Benzoate (E211)	0.04	(preservative)

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Teat Dip Solution (two components to be mixed 1:1 before use).

4 CLINICAL PARTICULARS

4.1 Target Species

Dairy cows

4.2 Indications for use, specifying the target species

A post milking teat dip for prophylactic use in the lactating dairy cow, as an aid in the prevention of mastitis in dairy cows.

4.3 Contraindications

Do not use on cut, damaged or inflamed teats.

Discontinue use in any cow showing signs of irritation or hypersensitivity to the product.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

Prior to milking, wash teats thoroughly with water or a compatible udder wash using proper procedures.

After use of the teat dip, do not turn cows out in freezing weather until teats are completely dry. Drying takes approximately 8 - 20 minutes under these conditions.

If product in dip cup becomes visibly dirty, discard contents and refill with fresh solution.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

Wash hands after use.

Avoid contact with eyes. If contact occurs, flush eyes with large quantities of water. If irritation develops, seek medical advice immediately and show the label to the physician.

In the event of accidental exposure, remove by dilution i.e.:

External: wash with water.

Ingestion: drink water.

Inhalation: remove to fresh air.

4.6 Adverse reactions (frequency and seriousness)

Irritation of the teats occurs infrequently. It largely depends on the hygiene procedures, i.e. whether residues are effectively removed prior to milking. If residues from the last teat dip are allowed to build up, a dry crust may form. Removal of such crust may then leave the teat skin sore and irritated.

See section 4.5 for appropriate precautions for use.

4.7 Use during pregnancy, lactation or lay

4XLA Post-Milking Germicidal Teat Dip is indicated for use in lactating dairy cows.

4.8 Interaction with other medicinal products and other forms of interactions

None known.

4.9 Amounts to be administered and administration route

For topical use as a teat dip.

Mix together equal volumes of the 4XLA Base and 4XLA Activator until the colour is uniform throughout. The gold colour in the mixed product may fade with time and this may be more rapid at higher temperatures. This does not affect the efficacy of the product.

Wash udders and teats and dry before milking. Immediately **after** milking dip all teats at least one half their length in the mixed product. Allow to air dry before cows are turned out to pasture, especially in freezing weather. Do not wipe. On average, approximately 4ml of product will be used per cow per milking. Always use freshly mixed 4XLA. Discard unused teat dip at the end of each milking.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

Not applicable.

4.11 Withdrawal period(s)

Meat and offal: 0 days.

Milk: 0 days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

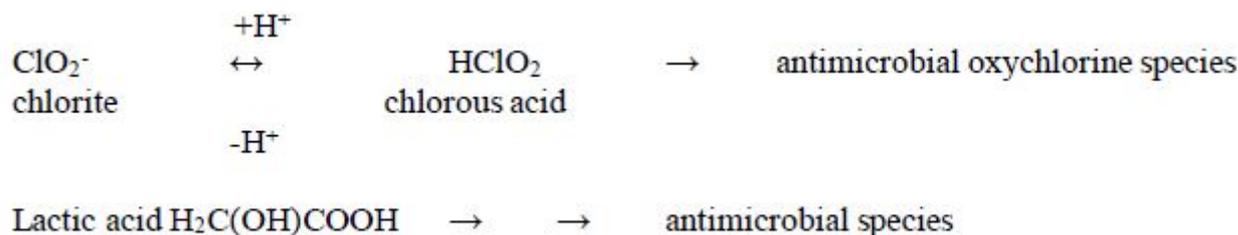
Pharmacotherapeutic group: Products for teats and udder, disinfectants.

ATCvet code: QG52A

5.1 Pharmacodynamic properties

When the chlorite active ingredient in the 4XLA Base is activated by acidification with the lactic acid in the 4XLA Activator, a germicidal system is formed in equilibrium with the chlorite and consisting of short-lived chlorous acid and its related oxychlorine disproportionation products including chlorine dioxide. The excess lactic acid present from the 4XLA Activator also

has the inherent microbicidal characteristics of its chemical family, the alpha hydroxy carboxylic acids.



The chlorous acid/derived species system has a highly potent and broad spectrum of germicidal activity, probably via oxidative attack at susceptible sites on the microbial envelope.

The lactic acid (excess) exerts its antimicrobial effect by absorbing to cell surfaces and promoting leakage of hydrogen ions across the cell membrane, resulting in the acidification of the cell interior and inhibition of nutrient transport.

5.2 Pharmacokinetic particulars

Absorption of the chlorite active ingredient by the skin of the teat is extremely low. No significant chlorite residues are detectable in milk from cows treated with 4XLA.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Base:

Disodium Edetate
Sodium Hydroxide
Purified Water

Activator:

Glycerol
Hydroxyethylcellulose
Tartrazine (E102)
Sodium Laurilsulfate
Sodium Benzoate (E211)
Purified Water

6.2 Major incompatibilities

None known.

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years

Shelf life after first opening the immediate container: 2 years

Once the solutions have been mixed, any remaining mixed, ready-to-use solution should be discarded at the end of milking.

6.4 Special precautions for storage

Store away from food, drink and animal feedstuffs.

Store below 25°C. Protect from direct sunlight.

Store in tightly closed original containers.

Do not freeze. However, freezing will not affect the performance of the product provided that the contents are thawed out and agitated thoroughly before mixing 4XLA Base and 4XLA Activator.

6.5 Nature and composition of immediate packaging

HDPE containers, one each for base and activator, which fills 20, 56.8 and 208 litres, respectively, sealed with HDPE screw on caps.

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Any unused product or waste material should be disposed of in accordance with national requirements.

Unused teat dip should be diluted with plenty of water and flushed down a drain for waste water.

Wash out used containers thoroughly and dispose of safely. Do not re-use empty containers.

Harmful to fish. Do not contaminate ponds, waterways or ditches with the product formulation or used containers.

Teat dip cups and other accessories should be emptied after use and thoroughly washed before re-use.

Washing waters should be flushed down a drain for waste water.

7 MARKETING AUTHORISATION HOLDER

Ecolab Deutschland GmbH

Ecolab-Allee 1

40789 Monheim am Rhein

Germany

8 MARKETING AUTHORISATION NUMBER(S)

VPA10795/002/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 10 February 2006

Date of last renewal: 29 October 2008

10 DATE OF REVISION OF THE TEXT

November 2021