



Ministry of Health

DEPARTMENT OF VETERINARY PUBLIC HEALTH , NUTRITION AND
FOOD SAFETY

DIRECTORATE-GENERAL FOR ANIMAL HEALTH AND VETERINARY MEDICINE
DEPARTMENT IV

THE DIRECTOR

AFTER TAKING INTO CONSIDERATION Decree-Law No. 193 of 6 April 2006
“implementation of the directive 2004/28/CE on the Community code relating to veterinary medicinal
products”;

AFTER TAKING INTO CONSIDERATION Decree-Law No. 165 of 30 March 2001 concerning
the “general rules on the work ordinance for public services”;

AFTER TAKING INTO CONSIDERATION the application by which the Company CHEMICALS
LAIF S.r.l., having its registered office and domicile for tax purposes in Vigonza (PD) – V.le
dell’Artigianato 13 – VAT No. 02580270284 - has required the marketing authorization for the veterinary
medicinal product “API-Bioxal” 886mg/g soluble powder for honey-bees, in the packaging sizes recorded in
the relative section of the this decree and manufactured in the CHEMIFARMA SpA factory, sited in Forlì,
Via Don Eugenio Servadei 16;

AFTER TAKING INTO CONSIDERATION that the Advisory Committee for veterinary medicine,
in the reunion dated 14-15-16 March 2011, has required others informations to the firm;

POSITIVELY EVALUATED the additional documents and relative informations submitted by the
firm about the Quality of the product;

AWAITED that the factory for manufacture is able to perform the manufacturing process;

HAVING TAKEN INTO CONSIDERATION the documentary evidence of the payment of the fee
provided for by the regulations in force;

DECREES

Art.1

The Marketing Authorization of the veterinary medicinal product “API-Bioxal” 886 mg/g soluble
powder for honey-bees is authorized at the conditions stated below:

MARKETING AUTHORISATION HOLDER:

CHEMICALS LAIF s.r.l., having its registered office in Vigonza (PD) – Viale dell’Artigianato 13 – VAT
No. 02580270284.

MANUFACTURER RESPONSIBLE FOR THE BATCH RELEASE:

factory of CHEMIFARMA SpA seated in Forlì, Via Don Eugenio Servadei n° 16

AUTHORIZED PACKAGING SIZE AND MARKETING AUTHORIZATION NUMBERS:

- | | |
|----------------------------------|-------------------------------------|
| - Thermalsolderind bag of 35 g; | Marketing Authorization n°104384019 |
| - Thermalsolderind bag of 175 g; | Marketing Authorization n°104384021 |
| - Thermalsolderind bag of 350 g; | Marketing Authorization n°104384033 |

COMPOSITION: 100 g of product contains:

active substances: oxalic acid dihydrate 88,60 g

excipients colloidal silica hydrate 3,00 g; glucose monohydrate q. b. 100,0 g.

TARGET SPECIES:

Honey bees (*Apis mellifera*)

INDICATIONS:

Bees (*Apis mellifera*)

Treatment of varroosis (*Varroa destructor*, parasite of *Apis mellifera*).

WITHDRAWAL PERIOD:

Honey: Zero days

SHELF-LIFE:

Shelf-life of the veterinary medicine as packaged for sale: 2 years.

Shelf-life after first opening the immediate packaging: 3 months

DISTRIBUTION PATTERN OF DRUG

The sale is under no-repeat veterinary prescription in single copy.

Art. 2

The packaging of the veterinary medicine must be marketed with official printouts as per the texts enclosed in this Decree.

The summary of the product characteristics enclosed to this Decree is also approved.

Art. 3

This Decree will be effective from the day when it is published in the Italian Official Journal and will be notified to the Company in question.

Rome, 08 June 2011

THE DIRECTOR OF DEPARTMENT

(illegible signature)

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MANUFACTURER AND RESPONSIBLE FOR BATCH RELEASE

MARKETING AUTHORISATION HOLDER

CHEMICALS LAIF s.r.l.

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