

PART 3 SAFETY DOCUMENTATION

3.A Introduction and General Requirements

According to Directive 2001/82 as amended, the safety must be demonstrated
Cf [Biblio-3](#) & [Biblio-4](#)

3.B Laboratory Tests

3.B.1 Safety of the administration of one dose

Cf [Report-10](#) – Lab study

3.B.2 Safety of one administration of an overdose

Cf [Report-10](#) – Lab study

3.B.3 Safety of the repeated administration of one dose

Cf [Report-10](#) – Lab study

3.B.4 Examination of reproductive performance

Cf [Report-11](#) – Lab study

3.B.5 Examination of immunological functions

Cf [Report-11](#) – Lab study

3.B.6 Special requirements for live vaccines

Cf [Report-12](#) – Lab study

3.B.7 User safety

Blablabla...

3.B.8 Study of residues

No residues

3.B.9 Interactions

No interactions

3.C Field Studies

Cf [Report-13](#) – Field study
& [Report-14](#) – Field study

3.D Environmental Risk Assessment

Refer to Part IIIE + [Biblio-5](#)

3.E Assessment required for Veterinary Medicinal Products Containing or Consisting of Genetically Modified Organisms

See details in [Part IIIE](#).

Cf [Report-15](#) – GMO study + [Report-16](#) – GMO study

And [Biblio-6](#) & [Biblio-7](#)

Conclusion

The safety is demonstrated