

TITLE: OECD TG 439 skin irritation classification of AGIVIR extract

STUDY PROTOCOL N°

PS 66-20

STUDY DIRECTOR

PAOLO BURATTI

SPONSOR**SERGE FERRARI**
BP 54 - 38352
La Tour-du-Pin Cedex
France**GLP TESTING FACILITY****VitroScreen Srl**
Via Mosè Bianchi,103
20149 Milano (Italia)

TITLE: OECD TG 439 skin irritation classification of AGIVIR extract

INDEX

1. INTRODUCTION AND AIM OF THE STUDY3
2. RESULTS AND REGULATORY CLASSIFICATION3
3. REFERENCES3
4. SIGNATURES4

TITLE: OECD TG 439 skin irritation classification of AGIVIR extract

1. INTRODUCTION AND AIM OF THE STUDY

This Resume was required by the Sponsor and it faithfully reports the results obtained in the GLP Study Report RS 66-20 including the Quality Assurance Statement: it belongs to **Serge Ferrari S. A. S.**

The aim of the study was to assess the skin irritation potential of **AGIVIR** a new composite membrane including a biocide, tested as an extract, eluate in saline solution, in compliance with OECD 439 and using the EpiDerm™ Skin Irritation Test (EPI-200-SIT) adopting the specific procedure for liquids.

2. RESULTS AND REGULATORY CLASSIFICATION

Skin irritation was assessed after 35 minutes exposure followed by 25 minutes exposure at room temperature, product washing and 42 hours of post-exposure incubation.

The viability of the EpiDerm™ tissue was measured by MTT in comparison to tissues treated with negative control substance (% viability).

According to MTT results (100.00%) and prediction model the test item was classified as reported in the following table.

TEST ITEM	UN GHS CLASSIFICATION
AGIVIR extract in saline solution	No Category NON IRRITANT FOR THE SKIN

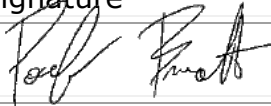


3. REFERENCES

- **OECD TG 439:** *In Vitro* Skin Irritation: Reconstructed Human *Epidermis* Test Method. June 2019.
- MatTek Protocol *In Vitro* EpiDerm™ Skin Irritation Test (**EPI-200-SIT**) (10/02/2019).

TITLE: OECD TG 439 skin irritation classification of AGIVIR extract

4. SIGNATURES

The following persons were responsible for key elements of the study within VitroScreen Laboratories:

Name - Surname - Function	Signature	
Paolo Buratti Study Director		Date: 26/06/2020
Euridice Santirocco Quality Assurance		Date: 26/06/2020
Marisa Meloni Testing Facility Director		Date: 26/06/2020

TITLE: OECD TG 439 skin irritation classification of AGIVIR

STUDY PROTOCOL N°

PS 64-20

STUDY DIRECTOR

PAOLO BURATTI

SPONSOR**SERGE FERRARI**
BP 54 - 38352
La Tour-du-Pin Cedex
France**GLP TESTING FACILITY****VitroScreen Srl**
Via Mosè Bianchi,103
20149 Milano (Italia)

TITLE: OECD TG 439 skin irritation classification of AGIVIR

INDEX

1. INTRODUCTION AND AIM OF THE STUDY3

2. RESULTS AND REGULATORY CLASSIFICATION3

3. REFERENCES3

4. SIGNATURES4

TITLE: OECD TG 439 skin irritation classification of AGIVIR

1. INTRODUCTION AND AIM OF THE STUDY

This Resume was required by the Sponsor and it faithfully reports the results obtained in the GLP Study Report RS 64-20 including the Quality Assurance Statement: it belongs to **Serge Ferrari S. A. S.**

The aim of the study was to assess the skin irritation potential of **AGIVIR** a new composite membrane including a biocide, in compliance with OECD 439 and using the EpiDerm™ Skin Irritation Test (EPI-200-SIT) adopting the specific procedure for solids.

2. RESULTS AND REGULATORY CLASSIFICATION

Skin irritation was assessed after 35 minutes exposure followed by 25 minutes exposure at room temperature, product washing and 42 hours of post-exposure incubation.

The viability of the EpiDerm™ tissue was measured by MTT in comparison to tissues treated with negative control substance (% viability).

According to MTT results (100.00%) and prediction model the test item was classified as reported in the following table.

TEST ITEM	UN GHS CLASSIFICATION
AGIVIR	No Category NON IRRITANT FOR THE SKIN

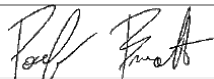
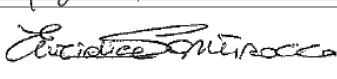
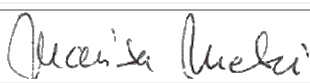
3. REFERENCES

- **OECD TG 439:** *In Vitro* Skin Irritation: Reconstructed Human *Epidermis* Test Method. June 2019.
- MatTek Protocol *In Vitro* EpiDerm™ Skin Irritation Test (**EPI-200-SIT**) (10/02/2019).

TITLE: OECD TG 439 skin irritation classification of AGIVIR

4. SIGNATURES

The following persons were responsible for key elements of the study within VitroScreen Laboratories:

Name - Surname - Function	Signature
Paolo Buratti Study Director	 Date: 26/06/2020
Euridice Santirocco Quality Assurance	 Date: 26/06/2020
Marisa Meloni Testing Facility Director	 Date: 26/06/2020

TITLE: OECD TG 439 skin irritation classification of AGIVIR

STUDY PROTOCOL N°

PS 64-20

STUDY DIRECTOR

PAOLO BURATTI

SPONSOR**SERGE FERRARI**
BP 54 - 38352
La Tour-du-Pin Cedex
France**GLP TESTING FACILITY****VitroScreen Srl**
Via Mosè Bianchi, 103
20149 Milano (Italia)

TITLE: OECD TG 439 skin irritation classification of AGIVIR

INDEX

1. INTRODUCTION AND AIM OF THE STUDY	3
2. RESULTS AND REGULATORY CLASSIFICATION	3
3. REFERENCES	3
4. SIGNATURES	4

TITLE: OECD TG 439 skin irritation classification of AGIVIR

1. INTRODUCTION AND AIM OF THE STUDY

This Resume was required by the Sponsor and it faithfully reports the results obtained in the GLP Study Report RS 64-20 including the Quality Assurance Statement: it belongs to **Serge Ferrari S. A. S.**

The aim of the study was to assess the skin irritation potential of **AGIVIR** a new composite membrane including a biocide, in compliance with OECD 439 and using the EpiDerm™ Skin Irritation Test (EPI-200-SIT) adopting the specific procedure for solids.

2. RESULTS AND REGULATORY CLASSIFICATION

Skin irritation was assessed after 35 minutes exposure followed by 25 minutes exposure at room temperature, product washing and 42 hours of post-exposure incubation.

The viability of the EpiDerm™ tissue was measured by MTT in comparison to tissues treated with negative control substance (% viability).

According to MTT results (100.00%) and prediction model the test item was classified as reported in the following table.

TEST ITEM	UN GHS CLASSIFICATION
AGIVIR	No Category NON IRRITANT FOR THE SKIN

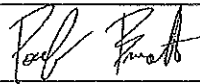
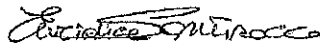
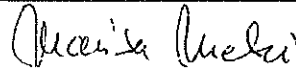
3. REFERENCES

- **OECD TG 439:** *In Vitro* Skin Irritation: Reconstructed Human *Epidermis* Test Method. June 2019.
- MatTek Protocol *In Vitro* EpiDerm™ Skin Irritation Test (**EPI-200-SIT**) (10/02/2019).

TITLE: OECD TG 439 skin irritation classification of AGIVIR

4. SIGNATURES

The following persons were responsible for key elements of the study within VitroScreen Laboratories:

Name - Surname - Function	Signature	Date
Paolo Buratti Study Director		Date: 26/06/2020
Euridice Santirocco Quality Assurance		Date: 26/06/2020
Marisa Meloni Testing Facility Director		Date: 26/06/2020