TEST REPORT/CERTIFICATE

Product name: HP7

Subject: Skin-friendliness

Novatech reference	Version	Date	End date	Laboratory
49200-150309-001	1.0	09-03-2015	-	VITO

Subject of the test report/certificate	
Determination of the extent of skin corrosivity and skin-friendliness of HP7	
Test standard/protocol	CLP regulation EC 1272/2008
Result	Not classified as skin-corrosive

Abstract

HP7 was examined by the Flemish Institute for Technological Research (VITO) according to the CLP EC 1272/2008 standard. This standard describes skin corrosivity, or the extent to which a product causes skin irritation.

The results of this investigation indicate that HP7 is not classified as a skin-corrosive product. The "corrosive" sign must consequently **not** be mentioned on the label/MSDS.

It may therefore be stated that HP7 is a skin-friendly product that with normal use on healthy skin **causes no skin irritation.**

Test laboratory/certifying authority information

VITO (Flemish Institute for Technological Research) is a leading European independent research organisation in the field of cleantech and sustainable development.
VITO provides objective investigations, studies and advice on the basis of which industry and the authorities can set out their future policy. VITO employs a staff of around 750 employees who work on international projects across the whole world.

Annexes	
Reference	
VITO-COR14001-B	VITO test report
VITO press	Testing authority details

Note: The annexes form a full part of this certificate

Date	Signature
23/04/2015	Novatech International NV Vertegenwoordigd door Novatio Invest NV Vast vertegenwoordiger De heer Bert Vissers, Gedelegeerd bestuurder

Confidential

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Executive Summary : non-GLP study

Study number: **COR14001-B** Test substances: **Novatech HP7**

Skin corrosivity testing: Testing of Novatech HP7

Corrositex according OECD guideline 435
Theoretical calculations of CLP category according Regulation (EC) No 1272/2008

TEST ITEM	Test facility code	Tested	
Novatech HP7	**14B011**	**Corrositex**	**CLP calculations**

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CONTENTS

GOAL OF THIS EXECUTIVE SUMMARY

The goal of this executive summary is to summarize the report of study number COR14001-B on test substance Novatech HP7, dated 17 July 2014.

STUDY SPECIFIC INFORMATION

Test item: Novatech HP7	
Experimental dates:	**Start:** 17/02/2014 **End:** 18/02/2014
Test site:	**VITO unit ABS:** Building BIO1, room 0230

SUMMARY

The potential of Novatech HP7 to cause skin corrosion with the Corrositex kit was determined. Novatech HP7 was administrated as obtained by the sponsor.

Novatech HP7 was categorized as Corrositex category 2 and the Corrositex Breakthrough time was found to be more than 60 min.

According to the **Corrositex** skin corrosion scale stated in the INVITTOX protocol no 116 "CORROSITEX™ Continuous Time Monitor Assay", dated February 2001, and the OECD guideline 435 "In Vitro Membrane Barrier Test Method for Skin Corrosion", dated 16 July 2006, **Novatech HP7** is considered to be **non-corrosive for skin**.

Theoretical CLP calculations for skin corrosion and skin irritation were performed on Novatech HP7.

For skin irritation **CLP calculations** resulted in a **no-classification for skin irritation** for **Novatech HP7**.

1. PURPOSE OF THE STUDY

The purpose of this study was to evaluate the corrosive potential Novatech HP7.

Novatech HP7 was tested with the Corrositex kit. This is an *in vitro* testing system that mimics the effect of corrosives on living skin. This test replaces the rabbit test of dermal corrosivity by providing a reliable means of mimicking this test.

Furhtermore, for Novatech HP7 theoretical CLP calculations were performed for skin irritation. Criteria for the classification of substance and mixtures are laid down in the CLP Regulation (EU) No. 1272/2008. Classification of mixtures follows a tiered approach based on weight of evidence. All the available information has to be used for classification and for the development of an intelligent testing strategy. Test item 1-8 are mixtures according to the definition in CLP (CLP regulation 2008).

2. CORROSITEX

2.1. CORROSITEX TEST SYSTEM

The Biobarrier consists of a hydrated collagen matrix and supporting filter membrane. The Biobarrier covers a compartment filled with a Chemical Detection System (CDS= 2 pH dye indicator; one for acids, one for bases).

The time it takes for the Test item to break through the Biobarrier – seen as a color change in the pH sensitive compartment- is a measure for the degree of corrosiveness of the Test item. The recorded Corrositex time is governed by three factors:

- The strength of the acid or base capacity of the Test item
- The rate of diffusion of the Test item
- For very corrosive substances, the rate of destruction of the Biobarrier

The obtained data are used to assign the Test item to the proper U.N. Packing Group classification for U.S. DOT or EPA compliance, or to rank the Test item for corrosivity.

U.N. Packing Group Classification: hazards are classified in nine U.N. classes. For packing purposes dangerous goods of all classes have been classified in four groups according to the degree of danger they present: Packing I: great danger; Packing II: medium danger; Packing III: minor danger and No classification. For each above-mentioned class it is prescribed what type of packaging can be used. These recommendations on the transport of dangerous goods have been developed by the United Nations Committee of Experts on the Transport of Dangerous Goods to ensure the safety of people, property and environment.

Corrosive substances (class 8) are subdivided in four U.N. Packing Group classes:

- Packing Group I: strong corrosive = EU-Risk Phrase R35= GHS[1] 1A
- Packing Group II: corrosive = EU- Risk Phrase R34 =GHS 1B
- Packing Group III: weak corrosive = EU- Risk Phrase R34= GHS 1C
- Packing Group No classification= non-corrosive

These packing groups are in accordance with the 2002 OECD Guideline for Testing of Chemicals, Number 404 "Acute Dermal Irritation/Corrosion".

2.2. CORROSITEX TEST GUIDELINES

The Corrositex test followed SOP TCOR001v04, which is based on the procedures indicated by the international accepted guidelines and recommendations:

- OECD guideline 435: In Vitro Membrane Barrier Test Method for Skin Corrosion (2006).
- The Corrositex is considered scientifically valid by ECVAM (Barratt et al 1998; Fentem et al 1998; ECVAM 2000; INVITTOX n°116) and ICCVAM (ICCVAM 1999; 2003).
- The agencies (e.g. DOT, ECVAM, EU/OECD, FDA, CPSC, IATA, NIEHS, OSHA, EPA, Transport Canada[2]) have accepted this test for skin corrosion testing.

2.3. STANDARD OPERATING PROCEDURES CONCERNING THE STUDY

- SOP TCOR001v04: Determine corrosivity with Corrositex kit (Utilization date: 20/02/2013).
- SOP TTOES083v06: Use of micropipettes (1 or more channels and repetition).
- SOP BTOES075v04: Calibrating thermometers.
- SOP BTOES031v08: Use and maintenance of fridge or freezer.
- SOP TTOES027v04: Use and maintenance of laminar flow.
- SOP's concerning safety aspects: SOP BVEIL009v03; VITO-401-WER-001-N v08; VITO-401-WER-003-N v03, VITO-401-WER-004-N v02; VITO-402-WER-001-N v14.

2.4. ACCEPTANCE CRITERIA OF THE STUDY

The experiment is considered valid if the following criteria are met:

- Criterion 1: the Corrositex time of positive control item falls between 0.5 and 2.0 min.
- Criterion 2: the Corrositex time of negative control item is more than 60 min.
- Criterion 3: when included, the concurrent vehicle/solvent control item is not corrosive.

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[1] GHS: Globally Harmonized System of Classification and Labelling of Chemicals. A joint acitivity of OECD (EHS), the UN Economic and Social Council's Sub Committee of Experts on the Transport of Dangerous Goods (UNSCETDG), the Interorganization Programme for the Sound Management of Chemicals (IOMC) and the International Labour Organization (ILO) (UNECE, 2004).

[2] DOT: Department of Transportation - DOT-E 10904; ECVAM: European Centre for the Validation of Alternative Methods; EU/OECD: organisation for Economic Co-operation and Development; FDA: Food & Drug Administration; CPSC: Consumer Product Safety Commission; IATA: International Air Transportation Association; NIEHS: National Institute of Environmental Health Sciences; OSHA: Occupational Safety and Health Administration; EPA: US Environmental Protection Agency.

2.5. EVALUATION CRITERIA OF THE TEST RESULTS

The Test item is considered to be skin corrosive or non-corrosive in the study if:

	CORROSITEX Time (min)			
Category 1	0 to 3 min	>3 to 60 min	>60 to 240 min	>240 min
Category 2	0 to 3 min	>3 to 30 min	>30 to 60 min	>60min

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Packing group I	Packing group II	Packing group III	No Classification
Strong corrosive	**corrosive**	**weak corrosive**	**non corrosive**

3. CLP CALCULATION

3.1. CHARACTERIZATION AND JUSTIFICATION

Criteria for the classification of substance and mixtures are laid down in the CLP Regulation (EU) No. 1272/2008. Classification of mixtures follows a tiered approach based on weight of evidence. All the available information has to be used for classification and for the development of an intelligent testing strategy. Test item Novatech HP7 is a mixture according to the definition in CLP (CLP regulation 2008).

3.2. CLP CALCULATION DESCRIPTION

By order of preference mixtures are classified based on

- Data on the whole mixture
- Bridging principles
- Calculation method

If valid test data are available for the whole mixture they have precedence. If no such data exist, the so called bridging principles have to be applied if possible. The bridging principles provide the opportunity to classify mixtures with no data from a mixture with data. If the bridging principles are not applicable an assessment on the basis of data for the components of the mixture is applied, i.e. the calculation method.
The danger of substances and mixtures is expressed by a pictogram, a signal word (Danger of Warning) and a hazard statement (H-statement). The classification is indicated by a hazard class, meaning the nature of the hazard (e.g. eye, skin) and the hazard category reflecting the severity of the hazard (a higher category number means a less severe effect).

4. RESULTS CORROSITEX

4.1. CONTROL ITEMS

- *Criterion 1:* the mean Corrositex Breakthrough time of sulfuric acid (95-97%), used as a positive control, was 0.80 min.
- *Criterion 2:* the mean Corrositex Breakthrough time of negative control (propionic acid, 6%, dissolved in milli-Q-water) was more than 60 min.
- *Criterion 3:* Not applicable. The Test item was tested as provided by the sponsor.

On basis of these findings, the data generated with Novatech HP7 is accepted.

4.2. NOVATECH HP7

For this study a kit was used with lot number CT040113 with expiration date: 30/04/2015.

I. Corrositex Biobarrier Preparation

The Biobarriers were checked for their quality. No air bubbles of the Biobarrier Mix on the membrane discs were detected.

II. Corrositex Testing Protocol with 3 steps for 2-methyl-2-(nitroamino)-1-propanol solution:

- **Step 1: Qualify = Compatibility Test**

Novatech HP7 was added to the quality test tube and a change in color in CDS was observed and this study was continued to step 2.

- **Step 2: Categorize = Categorisation Test**

Novatech HP7 was added to the categorization tubes A and B.
For Novatech HP7 in tube A, no change in color or consistency in CDS could be observed, it stayed yellow. In tube B the color changed from colorless to light purple.
The color change was matched to the color chart and Novatech HP7 was assigned to Corrositex Category 2.

- **Step 3: Classify = Classifying Test**

The mean Corrositex Breakthrough time for Novatech HP7 was more than 60 min, no reaction was observed in the Chemical Detection System.

5. RESULTS CLP CALCULATIONS

5.1. DATA ARE AVAILABLE FOR THE COMPLETE MIXTURE

For Test item Novatech HP7 data is available from the *in vitro* CORROSITEX-test. The outcome shows that this Test item does not have to be classified for skin corrosion.

5.2. DATA ARE AVAILABLE FOR ALL OR ONLY SOME COMPONENTS OF THE MIXTURE

Data on the hazardous properties of the components were provided in Safety Data Sheets by the client, see study report COR14001-B.

Hazardous properties concerning sin corrosion and skin irritation of the components of Test item Novatech HP7 is presented the study report COR14001-B.

CLP provides a summation method to calculate the classification of mixtures from their composition. The summation rules for skin corrosion and skin irritation at pH 2-11.5 are relevant for the classification for skin effects of Test item Novatech HP7. These summation rules are presented in Table 1.

Table 1 Generic concentration limits of ingredients of a mixture for skin effects category 1 and 2 (from CLP table 3.2.3):

Sum of ingredients classified as	Concentration triggering classification of a mixture as:	
	Irreversible Eye Effects	Reversible Eye Effects
	Category 1	Category 2
Skin Corr. cat. 1 (i.e.1A, 1B, 1C)	≥ 5 %	≥1 % but < 3 %
(10 x Skin Corr. cat. 1) + Skin Irritant cat. 2		≥ 10 %

If the concentration of a component is below the general cut-off value of 1% for skin corrosion or skin irritation for substances in mixtures, the concentration of that component is not used in the calculation method (CLP regulation 2008).

Classification of the Test item Novatech HP7 based on the classification of the components:
→ Category 1: sum of the concentrations of Skin Corr. cat. 1: not applicable. So Test item Novatech HP7 is not classified for Skin corrosion.
→ Category 2: (10 x Skin Corr. cat. 1) + Skin Irritant cat. 2 = 4.25% + 1.44% + 0.31% = 6%. This concentration is below the generic concentration limit of 10%, so Novatech HP7 is not classified for Skin irritation.

6. CONCLUSIONS

Novatech HP7 is categorized in Corrositex category 2.
According to OECD 435 (2006), with the mean **Corrositex** time more than 60 min, Novatech HP7 can be assigned to Packing Group No classification = **non-corrosive**.

According to CLP Regulation (EU) No. 1272/2008 for skin irritation, which as requested by the sponsor, have not been tested *in vitro* with rhe-models. The **CLP calculation** method results in a **no-classification for skin irritation** for Novatech HP7.

7. ANNEX 1: TABLES OF CORROSITEX RESULTS

SUMMARY TABLE OF RESULTS

Test item	Batch no	Conc. Tested (g/l)	Qualified (Q or NQ)	Category (1 or 2)	MCB time ± SD (min)	U.N. PG	EU Risk Phrase	GHS SC category	Corrosive potential
Novatech HP7	Lab sample 27.01.2014	As supplied by sponsor	Q	2	> 60	No classification	/	/	Non-corr.

MCB: Mean Corrositex Breakthrough; SD: Standard Deviation; UN PG: United Nations Packing Group; EU: European Union; GHS: Globally Harmonized System; SC: Skin Corrosion; Cor: corrosive.

TABLE OF RESULTS IN DETAIL

Test item or control items	Conc. Tested	Qualified (Q or NQ)	Category (1 or 2)	MCB time ± SD (min)	CB time 1 (min)	CB time 2 (min)	CB time 3 (min)	CB time 4 (min)
TI: Novatech HP7	As supplied	Q	2	> 60	> 60	> 60	> 60	> 60
PC: Sulfuric acid	95-97 %	ND	ND	0.80	0.80	ND	ND	ND
NC: Propionic acid	6 %	ND	ND	> 60	> 60	ND	ND	ND

TI: Test item; PC: positive control; NC: negative control; MCB: Mean Corrositex Breakthrough; CB: Corrositex Breakthrough; ND: not determined.
