

TEST REPORT/CERTIFICATE



Product name: HP7

Subject: Eye irritancy

Novatech reference	Version	Date	End date	Laboratory
49200-150310-001	1.0	10-03-2015	-	VITO

Subject of the test report/certificate	
Determination of the extent of eye irritancy of HP7	
Test standard/protocol	CLP regulation EC 1272/2008
Result	Not classified as eye irritating

Abstract
HP7 was examined by the Flemish Institute for Technological Research (VITO) according to the CLP EC 1272/2008 standard. This standard describes eye irritancy, or the extent to which a product causes eye damage. The results of this investigation indicate that HP7 is not classified as an eye irritating product.

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-BCO-14001-A	VITO test report
VITO press	Testing authority details

Note: The annexes form a full part of this certificate

Date	Signature
28/04/2015	Novatech International NV Vertegenwoordigd door Novatio Invest NV Vast vertegenwoordiger De heer Bert Vissers, Gedelegeerd bestuurder

Executive summary: non-GLP study

Study number: BCO 14001-A

Test substance: HP7

CLP calculation for test item HP7

Theoretical calculations of CLP category according Regulation (EC) No 1272/2008

Study director:

Sandra Verstraelen

VITO - ABS

Flemish Institute for Technological Research – Team Applied Bio & Molecular Systems

Industriezone Vlasmeer 7

B-2400 MOL

Tel: 00 32 14 33 52 12

Fax: 00 32 14 58 05 23

e-mail: sandra.verstraelen@vito.be

Sandra Verstraelen



20/04/2015

Sponsor: Novatech

Industrielaan 5B


B-2250 Olen

Tel: +32 (0)14 85 97 37

Personnel:


Sandra Verstraelen, study director

Lieve Geerts, researcher

	Executive summary Non-GLP study CLP calculations	BCO 14001-A Page 2 of 6 Date: 20-4-2015 16:24 print
---	---	---

CONTENTS

GOAL OF THE EXECUTIVE SUMMARY	3
SPECIFIC INFORMATION	3
SUMMARY	3
1. PURPOSE OF THE STUDY	4
2. CLP METHODOLOGY	4
3. RESULTS CLP CALCULATIONS	4
3.1. Classification of mixtures when data are not available for the complete mixture: bridging principles	4
3.2. Classification of mixtures when data are available for all components or only for some components of the mixture	5
4. CONCLUSIONS	6
5. REFERENCES	6

	Executive summary Non-GLP study CLP calculations	BCO 14001-A Page 3 of 6 Date: 20-4-2015 16:24 print
---	---	---

GOAL OF THE EXECUTIVE SUMMARY


The goal of this summary is to summarize the report of study number BCO 14001-A on test substance HP7, dated 9 July 2014.

SPECIFIC INFORMATION

Test item:	HP7
Test site:	VITO unit ABS: Building BIO1, room 0230

SUMMARY

CLP theoretical calculations of eye irritancy potency were made for test item HP7. HP7 is considered to be substantially similar to Novatio Novakleen not classified as category 1 for severe eye damage based on *in vitro* BCOP data (BCO14001) and as a result no prediction could be made on eye irritancy potency (category 2) of Novatio Novakleen according to UN GHS and OECD guideline 437. In addition, HP7 contains a colorant and fragrance that are not classified for skin corrosion or serious eye damage. All together, test item HP7 is not classified as category 1 for severe eye damage, but test item HP7 is classified by the summation method for serious eye irritation (Eye category 2).

	Executive summary Non-GLP study CLP calculations	BCO 14001-A Page 4 of 6 Date: 20-4-2015 16:24 print
---	---	---

1. PURPOSE OF THE STUDY

CLP theoretical calculations of eye irritancy potency were made for test item HP7. Criteria for the classification of substances 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 HP7 in this study is a mixture according to the CLP definition (1).

2. CLP METHODOLOGY

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 or 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).

3. RESULTS CLP CALCULATIONS

3.1. Classification of mixtures when data are not available for the complete mixture: bridging principles

HP7 is considered to be substantially similar to Novatio Novakleen not classified as category 1 for severe eye damage based on *in vitro* BCOP data (BCO14001) and as a result no prediction could be made on eye irritancy potency (category 2) of Novatio Novakleen according to UN GHS (2) and OECD guideline 437 (3).

For similar mixtures the bridging principles can be used. Hazardous properties of components that influence the classification for eye damage of a mixture are not only serious damage to the eyes, but also skin corrosivity. For test item HP7, no data for these endpoints are available. The difference in the composition of test item Novatio Novakleen and HP7 is the presence of small concentrations of a colorant and a fragrance in test item HP7. For colorants and fragrances that are not classified for skin corrosion or serious eye damage, it can be assumed that they will not have an influence on the classification for serious eye damage of

the mixtures. The colorant or fragrance used in test item HP7 are not classified for skin corrosion or serious eye damage. Hence, test item HP7 can be considered to be substantially similar to Novatio Novakleen and share the no classification for serious eye damage (category 1).

3.2. Classification of mixtures when data are available for all components or only for some components of the mixture

In case no test data would be available on the test item, or for those test items where the bridging principles do not apply, the classification can be calculated from the properties of the components.

Data on the hazardous properties of the components were provided in Safety Data Sheets by the client, see study report BCO 14001A; only the classification for eye effects and skin corrosion is taken into consideration here because these are the only relevant hazards for the calculation of the classification for eye effects.

Hazardous properties concerning eye damage, eye irritation, and skin corrosion of the components of test item HP7 are presented in the study report .

CLP provides a summation method to calculate the classification of mixtures from their composition. The summation rules that take into account skin corrosion and eye effects at pH 2-11.5 are relevant for the classification for eye effects of test item HP7. Those summation rules are presented in Table 1.


Table 1: Generic concentration limits of ingredients of a mixture for eye effects and skin corrosion category 1 and 2 (from CLP table 3.3.3)

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

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

Classification of HP7 based on the classification of the components:

- **Category 1:** The sum of the concentrations of Eye effects cat. 1 and Skin corr. Cat 1 = 2.98%.
This concentration is below the generic concentration limit of 3%, so test item HP7 is not classified for serious eye damage.

	Executive summary Non-GLP study CLP calculations	BCO 14001-A Page 6 of 6 Date: 20-4-2015 16:24 print
---	---	---

- **Category 2:** 10 x (Skin Corr. cat. 1A, 1B, 1C + Eye effects cat. 1) + Eye effects cat. 2 = 10 x 2.98% + 4.25% + 1.78% + 1.44% = 37%. The sum is above the generic concentration limit of 10%.

Based on the calculation method, test item HP7 is classified for serious eye irritation:

- Hazard class and category: Eye, category 2
- Signal word: Warning
- Hazard phrase: H319 (causes serious eye irritation)
- Pictogram: exclamation mark (GHS07)

4. CONCLUSIONS

Based on the preference of the basis for CLP classification it can be concluded that:

- Test item HP7 that contain a colorant and fragrance that are not classified for skin corrosion or serious eye damage are considered to be substantially similar to Novatio Novakleen. Based on the bridging principles test item HP7 is not classified for serious eye damage (category 1).
- Test item HP7 is classified by the summation method for serious eye irritation (Eye category 2).

5. REFERENCES

1. CLP Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures. Official Journal of the European Union L353 p. 1 dd 31.12.2008
2. UN (2011). United Nations Globally Harmonized System of Classification and Labelling of Chemicals (GHS), ST/SG/AC.10/30 Rev 4, New York and Geneva: United Nations. Available: [http://www.unece.org/trans/danger/publi/ghs/ghs_rev04/04files_e.html].
3. OECD Test Guideline 437: The Bovine Corneal Opacity and Permeability (BCOP) Test Method for Identifying Ocular Corrosives and Severe Irritants, Addendum to the OECD Guidelines for the Testing of Chemicals, published by OECD, (adopted in 2009 and updated in 2013).

Guidance on the application of the CLP criteria. Version 4.0. via <http://echa.europa.eu/support/guidance>
