

# **Hydrolysed Proteins**

## **DOCUMENT M-CA, Section 2**

### **PHYSICAL AND CHEMICAL PROPERTIES OF THE ACTIVE SUBSTANCE**

---

**Version history<sup>1</sup>**

| <b>Date</b> | <b>Data points containing amendments or additions and brief description</b> | <b>Document identifier and version number</b> |
|-------------|---|---|
|             |   |   |
|             |   |   |
|             |   |   |

<sup>1</sup> It is suggested that applicants adopt a similar approach to showing revisions and version history as outlined in SANCO/10180/2013 Chapter 4 How to revise an Assessment Report

---

---

## Table of Contents

|                |  |          |
|----------------|--|----------|
| <b>CA 2</b>    | <b>PHYSICAL AND CHEMICAL PROPERTIES OF THE ACTIVE SUBSTANCE .....</b>                                | <b>4</b> |
| <b>CA 2.1</b>  | <b>Melting point, freezing point, boiling point.....</b>   | <b>4</b> |
| <b>CA 2.2</b>  | <b>Vapour pressure, volatility .....</b>   | <b>4</b> |
| <b>CA 2.3</b>  | <b>Appearance (Physical state, colour) .....</b>   | <b>4</b> |
| <b>CA 2.4</b>  | <b>Spectra (UV/VIS, IR, NMR, MS), molar extinction at relevant wavelengths, optical purity .....</b> | <b>5</b> |
| <b>CA 2.5</b>  | <b>Solubility in water .....</b>   | <b>5</b> |
| <b>CA 2.6</b>  | <b>Solubility in organic solvents .....</b>  | <b>5</b> |
| <b>CA 2.7</b>  | <b>Partition co-efficient n-octanol/water .....</b>  | <b>5</b> |
| <b>CA 2.8</b>  | <b>Dissociation in water .....</b>   | <b>6</b> |
| <b>CA 2.9</b>  | <b>Flammability and self-heating.....</b>  | <b>6</b> |
| <b>CA 2.10</b> | <b>Flash point.....</b>  | <b>6</b> |
| <b>CA 2.11</b> | <b>Explosive properties.....</b>   | <b>7</b> |
| <b>CA 2.12</b> | <b>Surface tension .....</b>   | <b>7</b> |
| <b>CA 2.13</b> | <b>Oxidising properties .....</b>  | <b>8</b> |
| <b>CA 2.14</b> | <b>Other studies .....</b>   | <b>8</b> |

## CA 2 PHYSICAL AND CHEMICAL PROPERTIES OF THE ACTIVE SUBSTANCE

It should be noted that grey script reflects studies already submitted and evaluated by Greece in 2017 in the context of the zonal registration of the product SVMA14-004. These studies were considered acceptable.

Please note that according to the composition of the Hydrolysed proteins and the product SVMA14-004 (Please refer to Document J), the studies conducted with the product SVMA14-004 are relevant to cover data required for the active substance as manufactured.

Black script reflects new studies not yet provided nor evaluated in Europe

| Test or Study & Data Point                                 | Guideline and method        | Test material purity and specification                            | Findings  | GLP Y/N                    | Reference   |
|--|-----------------------------|---|---|----------------------------|---|
| <b>CA 2.1 Melting point, freezing point, boiling point</b> | ASTM D56/2002<br>CIPAC MT/1 | Batch No. 201801005000  | The boiling point is 102.1°C<br>The freezing point is < -10°C.  | N<br>(derogation proposed) | Montse Sala Vila, 2018                                    |
| <b>CA 2.2 Vapour pressure, volatility</b>                  | -                           | -   | Not applicable due to the nature of the active substance Hydrolysed Proteins since it cannot be purified. Please refer to Document J. | -                          |   |
| <b>CA 2.3 Appearance (Physical state, colour)</b>          | Visual observations         | Batch n° 141209LAB, contains 30 % w/v of pure hydrolysed proteins | It is a homogeneous brown opaque liquid   | Y                          | Demangel B., 2015<br>Defitraces, Report No. 15-919069-002 |

| Test or Study & Data Point  | Guideline and method | Test material purity and specification | Findings  | GLP Y/N                    | Reference              |
|---|----------------------|--|---|----------------------------|------------------------|
| <b>CA 2.4 Spectra (UV/VIS, IR, NMR, MS), molar extinction at relevant wavelengths, optical purity</b> | FT-IR                | Batch No. 201801005000                 | Please refer to spectra of the report.  | N<br>(derogation proposed) | Montse Sala Vila, 2018 |
| <b>CA 2.5 Solubility in water</b>   | -                    | -                                      | Due to the nature of the active substance Hydrolysed Proteins, the active substance is completely soluble in water. Please refer to Document J. | -                          | -                      |
| <b>CA 2.6 Solubility in organic solvents</b>  | OECD                 | Batch No. 201801005000                 | Miscible in dichloromethane and methanol. Immiscible in acetone, ethyl acetate, toluene and heptane   | N<br>(derogation proposed) | Montse Sala Vila, 2018 |
| <b>CA 2.7 Partition co-efficient n-octanol/water</b>  | -                    | -                                      | Not applicable due to the nature of the active substance Hydrolysed Proteins since it cannot be purified. Please refer to Document J.           |                            |                        |

| Test or Study & Data Point  | Guideline and method               | Test material purity and specification                            | Findings   | GLP Y/N | Reference  |
|---|------------------------------------|---|--|---------|--|
| <b>CA 2.8 Dissociation in water</b> <ul style="list-style-type: none"> <li>dissociation constant(s) (pKa values)</li> <li>identity of dissociated species</li> <li>dissociation constant(s) (pKa values) of the active principle</li> </ul> | -                                  | -   | Not relevant due to the nature of the active substance Hydrolysed Proteins. Please refer to Document J.          | -       | -  |
| <b>CA 2.9 Flammability and self-heating</b>   | EC A15 method                      | Batch n° 141209LAB, contains 30 % w/v of pure hydrolysed proteins | Only a preliminary test was performed: No auto-ignition temperature was observed up to 599 °C (corrected value). | Y       | Demangel B., 2015 Defitraces, Report No. 15-919069-001 |
| <b>CA 2.10 Flash point</b>  | EC A9 method and ISO Standard 3679 | Batch n° 141209LAB, contains 30 % w/v of pure hydrolysed proteins | No flash point was observed up to 120.0 °C (corrected value).  | Y       | Demangel B., 2015 Defitraces, Report No. 15-919069-001 |

| Test or Study & Data Point          | Guideline and method                      | Test material purity and specification                            | Findings   | GLP Y/N | Reference  |
|-------------------------------------|---|---|--|---------|--|
| <b>CA 2.11 Explosive properties</b> | Exothermic reactions by DSC and statement | Batch n° 141209LAB, contains 30 % w/v of pure hydrolysed proteins | <p>According to their composition and structural formula, proteins from animal proteins hydrolysate (30.0% w/v) are not expected to be explosive. Moreover, it is an aqueous solution (Please refer to Document J). Water is an inert component.</p> <p>Furthermore, the Differential Scanning Calorimetry (DSC) graphs show no exothermic effect; this confirms that it is not expected to present a significant hazard for explosivity, and testing is considered as unnecessary. Explosive properties test should not be required.</p> <p>The active substance Hydrolysed Proteins shall not be classified as explosive.</p> <p>Therefore, Hydrolysed Proteins meet the criteria for the approval of low-risk active substance because not considered as explosive.</p> | Y       | Demangel B., 2015 Defitraces, Report No. 15-919069-001 |
| <b>CA 2.12 Surface tension</b>      | EC A5 method and OECD No. 115             | Batch n° 141209LAB, contains 30 % w/v of pure hydrolysed proteins | <p>The mean surface tension at 19.9 °C was 39.9 mN/m <math>\pm</math> 0.4 mN/m.</p> <p>The active substance Hydrolysed Proteins was considered as surface-active in the experimental conditions used.</p>  | Y       | Demangel B., 2015 Defitraces, Report No. 15-919069-001 |

| Test or Study & Data Point          | Guideline and method | Test material purity and specification                            | Findings   | GLP Y/N | Reference  |
|-------------------------------------|----------------------|---|--|---------|--|
| <b>CA 2.13 Oxidising properties</b> | Statement            | Batch n° 141209LAB, contains 30 % w/v of pure hydrolysed proteins | <p>According to their composition and structural formula, proteins from animal proteins hydrolysate (30.0% w/v) are not expected to have oxidising properties. Moreover, it is an aqueous solution (Please refer Document J). Water is an inert component.</p> <p>Accordingly, the active substance Hydrolysed Proteins is not expected to present a significant hazard for oxidising properties, and testing is considered as unnecessary.</p> <p>Oxidising properties test should not be required.</p> | Y       | Demangel B., 2015 Defitraces, Report No. 15-919069-001 |
| <b>CA 2.14 Other studies</b>        | -                    | -   | No supplementary study deemed necessary.   | -       | -  |