

### Simvastatin Formulation

| Version<br>6.0 | Revision Date: 23.03.2020 | SDS Nu<br>24353-0 |                             | Date of last issue: 13.09.2019<br>Date of first issue: 21.10.2014 |
|----------------|---------------------------|-------------------|-----------------------------|-------------------------------------------------------------------|
| SECTION        | N 1. PRODUCT AND C        | OMPANY II         | DENTIFICA                   | TION                                                              |
| Product name   |                           | : Sim             | vastatin For                | mulation                                                          |
| Man            | ufacturer or supplier     | s details         |                             |                                                                   |
| Com            | npany                     | : Org             | anon & Co.                  |                                                                   |
| Add            | ress                      |                   | a Treze de N<br>npinas, São | laio, 1161<br>Paulo, Brazil B-2220                                |
| Tele           | phone                     | : 551             | -430-6000                   |                                                                   |
| Eme            | ergency telephone         | : 215             | -631-6999                   |                                                                   |
| E-m            | ail address               | : EHS             | SSTEWARD                    | @organon.com                                                      |
|                | ommended use of the       |                   | and restrict                |                                                                   |

#### SECTION 2. HAZARDS IDENTIFICATION

#### GHS Classification in accordance with ABNT NBR 14725 Standard

|   | Skin irritation                                       | : | Category 3                                   |
|---|-------------------------------------------------------|---|----------------------------------------------|
|   | Skin sensitization                                    | : | Category 1                                   |
| I | Specific target organ toxicity -<br>repeated exposure | : | Category 2 (Liver, muscle, optic nerve, Eye) |
|   | Short-term (acute) aquatic hazard                     | : | Category 3                                   |
|   | Long-term (chronic) aquatic hazard                    | : | Category 3                                   |

#### GHS label elements in accordance with ABNT NBR 14725 Standard

| Hazard pictograms |                                                                                                                                                                                                                                                                                                             |       |
|-------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------|
| Signal Word       | : Warning                                                                                                                                                                                                                                                                                                   |       |
| Hazard Statements | <ul> <li>H316 Causes mild skin irritation.</li> <li>H317 May cause an allergic skin reaction.</li> <li>H373 May cause damage to organs (Liver, muscle, optic needs)</li> <li>Hyperbolic through prolonged or repeated exposure.</li> <li>H412 Harmful to aquatic life with long lasting effects.</li> </ul> | erve, |



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| Preca   | autionary Statements      | P280 Wear p<br>Response:<br>P314 Get me<br>P333 + P313<br>vice/ attentior | elease to the environment.<br>rotective gloves.<br>dical advice/ attention if you feel unwell.<br>If skin irritation or rash occurs: Get medical ad- |

#### Other hazards which do not result in classification

Dust contact with the eyes can lead to mechanical irritation. May form explosive dust-air mixture during processing, handling or other means.

#### SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

| Components |
|------------|
|------------|

| Chemical name           | CAS-No.    | Classification                                                                                                                                                                                                                                                                                       | Concentration (% w/w) |
|-------------------------|------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Simvastatin             | 79902-63-9 | Skin irritation,<br>Category 2<br>Skin sensitization,<br>Category 1<br>Specific target organ<br>toxicity - repeated<br>exposure (Liver, mus-<br>cle, optic nerve, Eye),<br>Category 1<br>Short-term (acute)<br>aquatic hazard,<br>Category 2<br>Long-term (chronic)<br>aquatic hazard,<br>Category 2 | >= 5 -< 10            |
| Starch                  | 9005-25-8  |                                                                                                                                                                                                                                                                                                      | >= 5 -< 10            |
| Cellulose               | 9004-34-6  |                                                                                                                                                                                                                                                                                                      | >= 1 -< 5             |
| Citric acid monohydrate | 5949-29-1  | Eye irritation,<br>Category 2A                                                                                                                                                                                                                                                                       | >= 1 -< 5             |
| Titanium dioxide        | 13463-67-7 | Carcinogenicity (Inha-<br>lation), Category 2                                                                                                                                                                                                                                                        | >= 0,1 -< 1           |

#### **SECTION 4. FIRST AID MEASURES**

General advice

: In the case of accident or if you feel unwell, seek medical advice immediately.

When symptoms persist or in all cases of doubt seek medical advice.



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|-------------------------|------------------------------------------------------|-----|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|--|--|--|
|                         |                                                      |     |                                                                                                                                                                                                                                             |                                                                                                                                                                   |  |  |  |  |
| lf inha                 | aled                                                 | •   | : If inhaled, remove to fresh air.<br>Get medical attention.                                                                                                                                                                                |                                                                                                                                                                   |  |  |  |  |
| In case of skin contact |                                                      | :   | In case of contac<br>Remove contami<br>Get medical atter<br>Wash clothing be                                                                                                                                                                | t, immediately flush skin with plenty of water.<br>nated clothing and shoes.<br>ntion.                                                                            |  |  |  |  |
| In ca                   | se of eye contact                                    | :   | If in eyes, rinse w                                                                                                                                                                                                                         |                                                                                                                                                                   |  |  |  |  |
| lf swa                  | If swallowed                                         |     | If swallowed, DO Get medical atter                                                                                                                                                                                                          | NOT induce vomiting.<br>ntion if symptoms occur.<br>oughly with water.                                                                                            |  |  |  |  |
|                         | important symptoms<br>effects, both acute and<br>red | :   | <ul> <li>Causes mild skin irritation.</li> <li>May cause an allergic skin reaction.</li> <li>May cause damage to organs through prolonged or rep<br/>exposure.</li> <li>Dust contact with the eyes can lead to mechanical irrita</li> </ul> |                                                                                                                                                                   |  |  |  |  |
| Prote                   | Protection of first-aiders Notes to physician        |     | First Aid respond<br>and use the record                                                                                                                                                                                                     | ers should pay attention to self-protection,<br>mmended personal protective equipment<br>al for exposure exists (see section 8).                                  |  |  |  |  |
| Notes                   |                                                      |     |                                                                                                                                                                                                                                             | ically and supportively.                                                                                                                                          |  |  |  |  |
| SECTION                 | 5. FIRE-FIGHTING ME                                  | ASL | JRES                                                                                                                                                                                                                                        |                                                                                                                                                                   |  |  |  |  |
| Suita                   | ble extinguishing media                              | :   | Water spray<br>Alcohol-resistant<br>Carbon dioxide (<br>Dry chemical                                                                                                                                                                        |                                                                                                                                                                   |  |  |  |  |
|                         | Unsuitable extinguishing media                       |     | None known.                                                                                                                                                                                                                                 |                                                                                                                                                                   |  |  |  |  |
| Spec<br>fightir         | ific hazards during fire<br>ng                       | :   | concentrations, a potential dust exp                                                                                                                                                                                                        | dust; fine dust dispersed in air in sufficient<br>nd in the presence of an ignition source is a<br>plosion hazard.<br>bustion products may be a hazard to health. |  |  |  |  |
| Haza<br>ucts            | rdous combustion prod-                               | :   | Carbon oxides                                                                                                                                                                                                                               |                                                                                                                                                                   |  |  |  |  |
| Spec<br>ods             | Specific extinguishing meth-<br>ods                  |     |                                                                                                                                                                                                                                             | g measures that are appropriate to local cir-<br>the surrounding environment.                                                                                     |  |  |  |  |

| Use water spr | ay to cool unopened containers. |
|---------------|---------------------------------|

| Remove undamaged containers from fire area if it is safe to do |
|----------------------------------------------------------------|
| S0.                                                            |
| Evacuate area.                                                 |

# Special protective equipment:In the event of fire, wear self-contained breathing apparatus.for fire-fightersUse personal protective equipment.

#### SECTION 6. ACCIDENTAL RELEASE MEASURES

| Personal precautions, protec-<br>tive equipment and emer-<br>gency procedures | : | Use personal protective equipment.<br>Follow safe handling advice and personal protective<br>equipment recommendations. |
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| Environmental precautions                                                     | : | Discharge into the environment must be avoided.                                                                         |



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| Prevent further leakage or spillage if safe to do so.<br>Retain and dispose of contaminated wash water.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                        |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|
| <ul> <li>Methods and materials for containment and cleaning up</li> <li>Sweep up or vacuum up spillage and collect in suitable container for disposal.<br/>Avoid dispersal of dust in the air (i.e., clearing dust surfawith compressed air).<br/>Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they released into the atmosphere in sufficient concentration.<br/>Local or national regulations may apply to releases and disposal of this material, as well as those materials and employed in the cleanup of releases. You will need to determine which regulations are applicable.<br/>Sections 13 and 15 of this SDS provide information regacertain local or national requirements.</li> </ul> | aces<br>/ are<br>items |

#### SECTION 7. HANDLING AND STORAGE

| Technical measures :                                   | Static electricity may accumulate and ignite suspended dust causing an explosion.<br>Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Local/Total ventilation :<br>Advice on safe handling : | Use only with adequate ventilation.<br>Do not get on skin or clothing.<br>Do not breathe dust.<br>Do not swallow.<br>Avoid contact with eyes.<br>Handle in accordance with good industrial hygiene and safety<br>practice, based on the results of the workplace exposure<br>assessment<br>Minimize dust generation and accumulation.<br>Keep container closed when not in use.<br>Keep away from heat and sources of ignition.<br>Take precautionary measures against static discharges.<br>Take care to prevent spills, waste and minimize release to the<br>environment. |
| Hygiene measures :                                     | If exposure to chemical is likely during typical use, provide eye<br>flushing systems and safety showers close to the working<br>place.<br>When using do not eat, drink or smoke.<br>Wash contaminated clothing before re-use.<br>The effective operation of a facility should include review of<br>engineering controls, proper personal protective equipment,<br>appropriate degowning and decontamination procedures,<br>industrial hygiene monitoring, medical surveillance and the<br>use of administrative controls.                                                  |
| Conditions for safe storage :                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| Materials to avoid :                                   | Do not store with the following product types:<br>Strong oxidizing agents<br>Organic peroxides                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |



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Explosives Gases

#### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Ingredients with workplace control parameters

| Components       | CAS-No.                   | Value type<br>(Form of<br>exposure) | Control parame-<br>ters / Permissible<br>concentration | Basis    |  |
|------------------|---------------------------|-------------------------------------|--------------------------------------------------------|----------|--|
| Simvastatin      | 79902-63-9                | TWA                                 | 25 µg/m3 (OEB 3)                                       | Internal |  |
|                  | Further information: DSEN |                                     |                                                        |          |  |
|                  |                           | Wipe limit                          | 250 µg/100 cm <sup>2</sup>                             | Internal |  |
| Starch           | 9005-25-8                 | TWA                                 | 10 mg/m³                                               | ACGIH    |  |
| Cellulose        | 9004-34-6                 | TWA                                 | 10 mg/m³                                               | ACGIH    |  |
| Titanium dioxide | 13463-67-7                | TWA                                 | 10 mg/m <sup>3</sup><br>(Titanium dioxide)             | ACGIH    |  |

| Engineering measures :                                                                     | All engineering controls should be implemented by facility<br>design and operated in accordance with GMP principles to<br>protect products, workers, and the environment.<br>Containment technologies suitable for controlling compounds<br>are required to control at source and to prevent migration of<br>the compound to uncontrolled areas (e.g., open-face<br>containment devices).<br>Minimize open handling. |
|--------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Personal protective equipment                                                              |                                                                                                                                                                                                                                                                                                                                                                                                                      |
| Respiratory protection       :         Filter type       :         Hand protection       : | If adequate local exhaust ventilation is not available or<br>exposure assessment demonstrates exposures outside the<br>recommended guidelines, use respiratory protection.<br>Particulates type                                                                                                                                                                                                                      |
| Material :                                                                                 | Chemical-resistant gloves                                                                                                                                                                                                                                                                                                                                                                                            |
| Remarks :<br>Eye protection :                                                              | Consider double gloving.<br>Wear safety glasses with side shields or goggles.<br>If the work environment or activity involves dusty conditions,<br>mists or aerosols, wear the appropriate goggles.<br>Wear a faceshield or other full face protection if there is a<br>potential for direct contact to the face with dusts, mists, or<br>aerosols.                                                                  |
| Skin and body protection :                                                                 | Work uniform or laboratory coat.<br>Additional body garments should be used based upon the<br>task being performed (e.g., sleevelets, apron, gauntlets,<br>disposable suits) to avoid exposed skin surfaces.<br>Use appropriate degowning techniques to remove potentially<br>contaminated clothing.                                                                                                                 |

#### SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance

: powder



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|-------------|-----------------------------------------------------|------------------------------|---|------------------------------------|-------------------------------------------------------------------|
|             | Color                                               |                              | : | No data available                  | 9                                                                 |
|             | Odor                                                |                              | : | odorless                           |                                                                   |
|             | Odor Threshold                                      |                              | : | No data available                  | )                                                                 |
|             | рН                                                  |                              | : | No data available                  | <b>)</b>                                                          |
|             | Melting                                             | point/freezing point         | : | No data available                  | 9                                                                 |
|             | Initial b<br>range                                  | oiling point and boiling     | : | No data available                  |                                                                   |
|             | Flash p                                             | oint                         | : | Not applicable                     |                                                                   |
|             | Evapor                                              | ation rate                   | : | Not applicable                     |                                                                   |
|             | Flamma                                              | ability (solid, gas)         | : | May form explosi handling or other | ve dust-air mixture during processing, means.                     |
|             | Flamma                                              | ability (liquids)            | : | No data available                  |                                                                   |
|             | Upper explosion limit / Upper<br>flammability limit |                              | : | No data available                  |                                                                   |
|             | Lower explosion limit / Lower flammability limit    |                              | : | No data available                  |                                                                   |
|             | Vapor p                                             | pressure                     | : | Not applicable                     |                                                                   |
|             | Relative                                            | e vapor density              | : | Not applicable                     |                                                                   |
|             | Relative                                            | e density                    | : | No data available                  |                                                                   |
|             | Density                                             |                              | : | No data available                  |                                                                   |
|             | Solubili<br>Wat                                     | ty(ies)<br>er solubility     | : | No data available                  | 9                                                                 |
|             | Partition octanol                                   | n coefficient: n-            | : | Not applicable                     |                                                                   |
|             |                                                     | hition temperature           | : | No data available                  | 9                                                                 |
|             | Decom                                               | position temperature         | : | No data available                  |                                                                   |
|             | Viscosi <sup>.</sup><br>Visc                        | ty<br>osity, kinematic       | : | Not applicable                     |                                                                   |
|             | Explosi                                             | ve properties                | : | Not explosive                      |                                                                   |
|             | Oxidizir                                            | ng properties                | : | The substance of                   | r mixture is not classified as oxidizing.                         |
|             | Particle                                            | size                         | : | No data available                  |                                                                   |



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#### SECTION 10. STABILITY AND REACTIVITY

| Reactivity<br>Chemical stability<br>Possibility of hazardous reac-<br>tions | <ul> <li>Not classified as a reactivity hazard.</li> <li>Stable under normal conditions.</li> <li>May form explosive dust-air mixture during processing,<br/>handling or other means.<br/>Can react with strong oxidizing agents.</li> </ul> |  |
|-----------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|
| Conditions to avoid                                                         | : Heat, flames and sparks.<br>Avoid dust formation.                                                                                                                                                                                          |  |
| Incompatible materials                                                      | : Oxidizing agents                                                                                                                                                                                                                           |  |
| Hazardous decomposition<br>products                                         | : No hazardous decomposition products are known.                                                                                                                                                                                             |  |

#### SECTION 11. TOXICOLOGICAL INFORMATION

| : | Inhalation   |
|---|--------------|
|   | Skin contact |
|   | Ingestion    |
|   | Eye contact  |
|   | :            |

#### Acute toxicity

Not classified based on available information.

#### Components:

| Simvastatin:              |   |                                                                                                                                      |
|---------------------------|---|--------------------------------------------------------------------------------------------------------------------------------------|
| Acute oral toxicity       | : | LD50 (Rat): 5.000 mg/kg                                                                                                              |
|                           |   | LD50 (Mouse): 3.800 mg/kg                                                                                                            |
| Starch:                   |   |                                                                                                                                      |
| Acute oral toxicity       | : | LD50 (Rat): > 5.000 mg/kg                                                                                                            |
| Acute dermal toxicity     | : | LD50 (Rabbit): > 2.000 mg/kg                                                                                                         |
| Cellulose:                |   |                                                                                                                                      |
| Acute oral toxicity       | : | LD50 (Rat): > 5.000 mg/kg                                                                                                            |
| Acute inhalation toxicity | : | LC50 (Rat): > 5,8 mg/l<br>Exposure time: 4 h<br>Test atmosphere: dust/mist                                                           |
| Acute dermal toxicity     | : | LD50 (Rabbit): > 2.000 mg/kg                                                                                                         |
| Citric acid monohydrate:  |   |                                                                                                                                      |
| Acute oral toxicity       | : | LD50 (Mouse): 5.400 mg/kg                                                                                                            |
| Acute dermal toxicity     | : | LD50 (Rat): > 2.000 mg/kg<br>Method: OECD Test Guideline 402<br>Assessment: The substance or mixture has no acute dermal<br>toxicity |



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| Titan          | ium dioxide:                 |        |                                                                                                                                                           |                                                                   |  |
| Acute          | e oral toxicity              | :      | LD50 (Rat): > 5.000 mg/kg                                                                                                                                 |                                                                   |  |
| Acute          | Acute inhalation toxicity    |        | LC50 (Rat): > 6,82 mg/l<br>Exposure time: 4 h<br>Test atmosphere: dust/mist<br>Assessment: The substance or mixture has no acute inhala-<br>tion toxicity |                                                                   |  |
| Skin           | corrosion/irritation         |        |                                                                                                                                                           |                                                                   |  |
| Caus           | es mild skin irritation.     |        |                                                                                                                                                           |                                                                   |  |
| Com            | ponents:                     |        |                                                                                                                                                           |                                                                   |  |
| Simv           | astatin:                     |        |                                                                                                                                                           |                                                                   |  |
| Spec<br>Rema   |                              | :      | Rabbit<br>Moderate skin irri                                                                                                                              | tation                                                            |  |
| Citric         | c acid monohydrate:          |        |                                                                                                                                                           |                                                                   |  |
| Spec<br>Resu   | ies                          | :      | Rabbit<br>No skin irritation                                                                                                                              |                                                                   |  |
| Titan          | ium dioxide:                 |        |                                                                                                                                                           |                                                                   |  |
| Spec<br>Resu   | ies                          | :      | Rabbit<br>No skin irritation                                                                                                                              |                                                                   |  |
| Serio          | ous eye damage/eye irı       | ritati | ion                                                                                                                                                       |                                                                   |  |
|                | lassified based on availa    |        |                                                                                                                                                           |                                                                   |  |
|                | ponents:                     |        |                                                                                                                                                           |                                                                   |  |
|                | astatin:                     |        |                                                                                                                                                           |                                                                   |  |
| Spec<br>Rema   | ies<br>arks                  | :      | Rabbit<br>slight irritation                                                                                                                               |                                                                   |  |
| Starc          | :h:                          |        |                                                                                                                                                           |                                                                   |  |
| Spec<br>Resu   | ies<br>It                    | :      | Rabbit<br>No eye irritation                                                                                                                               |                                                                   |  |
| Citric         | acid monohydrate:            |        |                                                                                                                                                           |                                                                   |  |
| Spec<br>Resu   |                              | :      | Rabbit<br>Irritation to eyes,                                                                                                                             | reversing within 21 days                                          |  |
| Titan          | ium dioxide:                 |        |                                                                                                                                                           |                                                                   |  |
| Spec<br>Resu   | ies                          | :      | Rabbit<br>No eye irritation                                                                                                                               |                                                                   |  |
|                |                              |        |                                                                                                                                                           |                                                                   |  |



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| Resp         | iratory or skin sensit                        | izatio | n                                                                                                                    |                                                                                                              |
| Skin         | sensitization                                 |        |                                                                                                                      |                                                                                                              |
| May          | cause an allergic skin i                      | eactic | n.                                                                                                                   |                                                                                                              |
| Resp         | iratory sensitization                         |        |                                                                                                                      |                                                                                                              |
|              | lassified based on ava                        | ilable | information.                                                                                                         |                                                                                                              |
|              | ponents:                                      |        |                                                                                                                      |                                                                                                              |
| Simv         | astatin:                                      |        |                                                                                                                      |                                                                                                              |
|              | ssment                                        | :      | Probability or ev                                                                                                    | idence of skin sensitization in humans                                                                       |
| Resu         |                                               | :      | positive                                                                                                             |                                                                                                              |
| Starc        | :h:                                           |        |                                                                                                                      |                                                                                                              |
| Test         |                                               | :      | Maximization Te                                                                                                      | est                                                                                                          |
|              | es of exposure                                | :      | Skin contact                                                                                                         |                                                                                                              |
| Spec<br>Resu |                                               |        | Guinea pig<br>negative                                                                                               |                                                                                                              |
|              |                                               |        | - 3                                                                                                                  |                                                                                                              |
|              | ium dioxide:                                  |        |                                                                                                                      |                                                                                                              |
| Test         | Type<br>es of exposure                        | :      | Local lymph noc<br>Skin contact                                                                                      | le assay (LLNA)                                                                                              |
| Spec         |                                               | :      | Mouse                                                                                                                |                                                                                                              |
| Resu         |                                               | ÷      | negative                                                                                                             |                                                                                                              |
|              | n cell mutagenicity<br>lassified based on ava | ilable | information.                                                                                                         |                                                                                                              |
|              | ponents:                                      |        |                                                                                                                      |                                                                                                              |
| Simv         | astatin:                                      |        | Test Type: Bact                                                                                                      | erial reverse mutation assay (AMES)                                                                          |
| Simv         |                                               | :      | Test Type: Bact<br>Result: negative                                                                                  | erial reverse mutation assay (AMES)                                                                          |
| Simv         | astatin:                                      | :      | Result: negative                                                                                                     | ine elution assay                                                                                            |
| Simv         | astatin:                                      | :      | Result: negative<br>Test Type: Alkal<br>Result: negative                                                             | ine elution assay<br>mosomal aberration                                                                      |
| Simv         | astatin:                                      | :      | Result: negative<br>Test Type: Alkal<br>Result: negative<br>Test Type: Chro<br>Result: negative                      | ine elution assay<br>mosomal aberration<br>ro mammalian cell gene mutation test                              |
| Simv         | astatin:                                      | :      | Result: negative<br>Test Type: Alkal<br>Result: negative<br>Test Type: Chro<br>Result: negative<br>Test Type: In vit | ine elution assay<br>mosomal aberration<br>ro mammalian cell gene mutation test<br>onucleus test<br>te: Oral |

Starch:



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| Geno           | Genotoxicity in vitro        |      | Test Type: Bacter<br>Result: negative                                                                                                                  | ial reverse mutation assay (AMES)                                              |
| <br>Cellu      | llose:                       |      |                                                                                                                                                        |                                                                                |
|                | otoxicity in vitro           | :    | Test Type: Bacter<br>Result: negative                                                                                                                  | ial reverse mutation assay (AMES)                                              |
|                |                              |      | Test Type: In vitro<br>Result: negative                                                                                                                | o mammalian cell gene mutation test                                            |
| Genc           | otoxicity in vivo            | :    | Test Type: Mammalian erythrocyte micronucleus test (in viv<br>cytogenetic assay)<br>Species: Mouse<br>Application Route: Ingestion<br>Result: negative |                                                                                |
| II<br>Citri    | c acid monohydrate:          |      |                                                                                                                                                        |                                                                                |
|                | ptoxicity in vitro           | :    | Test Type: Bacter<br>Result: negative                                                                                                                  | ial reverse mutation assay (AMES)                                              |
|                |                              |      | Test Type: in vitro<br>Result: positive                                                                                                                | micronucleus test                                                              |
|                |                              |      | Test Type: Bacter<br>Result: negative                                                                                                                  | ial reverse mutation assay (AMES)                                              |
| Genc           | otoxicity in vivo            | :    |                                                                                                                                                        | enicity (in vivo mammalian bone-marrow<br>chromosomal analysis)<br>: Ingestion |
| ••<br>Titan    | nium dioxide:                |      |                                                                                                                                                        |                                                                                |
|                | otoxicity in vitro           | :    | Test Type: Bacter<br>Result: negative                                                                                                                  | ial reverse mutation assay (AMES)                                              |
| Geno           | otoxicity in vivo            | :    | Test Type: In vivo<br>Species: Mouse<br>Result: negative                                                                                               | micronucleus test                                                              |
|                | inogenicity                  |      |                                                                                                                                                        |                                                                                |
|                | classified based on availa   | able | information.                                                                                                                                           |                                                                                |
|                | ponents:                     |      |                                                                                                                                                        |                                                                                |
|                | vastatin:                    |      |                                                                                                                                                        |                                                                                |
| Spec<br>Appli  | ies<br>cation Route          | :    | Mouse<br>Oral                                                                                                                                          |                                                                                |
| Expo           | sure time                    | :    | < 92 weeks                                                                                                                                             |                                                                                |
|                | et Organs                    | :    | Harderian gland                                                                                                                                        |                                                                                |
| Rema           | or Type<br>arks              | :    | Liver, Lungs<br>The significance of                                                                                                                    | of these findings for humans is not certain.                                   |
|                |                              |      |                                                                                                                                                        |                                                                                |



# **Simvastatin Formulation**

| Version<br>6.0   | Revision Date: 23.03.2020                     |      | 98 Number:<br>353-00015                                                                                                                                                               | Date of last issue: 13.09.2019<br>Date of first issue: 21.10.2014                                                                                                                        |  |
|------------------|-----------------------------------------------|------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|
| Expos            | ation Route<br>sure time<br>r Type            | :    | Rat<br>Oral<br>2 Years<br>Liver, Thyroid<br>The significance o                                                                                                                        | of these findings for humans is not certain.                                                                                                                                             |  |
|                  | es<br>ation Route<br>sure time                | :    | Rat<br>Ingestion<br>72 weeks<br>negative                                                                                                                                              |                                                                                                                                                                                          |  |
| Specie<br>Applic | ation Route<br>sure time<br>od<br>t           |      | Rat<br>inhalation (dust/m<br>2 Years<br>OECD Test Guide<br>positive<br>The mechanism c<br>mans.                                                                                       |                                                                                                                                                                                          |  |
| ment             | II                                            |      | Limited evidence of carcinogenicity in inhalation studies with animals.                                                                                                               |                                                                                                                                                                                          |  |
|                  | oductive toxicity<br>assified based on availa | able | information.                                                                                                                                                                          |                                                                                                                                                                                          |  |
| Comp             | oonents:                                      |      |                                                                                                                                                                                       |                                                                                                                                                                                          |  |
|                  | <b>astatin:</b><br>s on fertility             | :    | Test Type: Fertilit<br>Species: Rat, mal<br>Application Route<br>Fertility: LOAEL: 2                                                                                                  | e                                                                                                                                                                                        |  |
| Effect           | s on fetal development                        | :    | Species: Rat<br>Application Route<br>Embryo-fetal toxic<br>Result: No teratog<br>Test Type: Embry<br>Species: Rabbit<br>Application Route<br>Embryo-fetal toxic<br>Result: No teratog | city.: NOAEL: 25 mg/kg body weight<br>genic effects., No adverse effects.<br>ro-fetal development<br>: Oral<br>city.: NOAEL: 10 mg/kg body weight<br>genic effects., No adverse effects. |  |
|                  |                                               |      | Species: Rat                                                                                                                                                                          | ro-fetal development                                                                                                                                                                     |  |

Application Route: Oral

Embryo-fetal toxicity.: LOAEL: 60 mg/kg body weight Result: Teratogenic potential.



| ersion<br>.0                                                                                                                                | Revision Date:<br>23.03.2020                                                                                                                                                                                                                                          |                  | DS Number: Date of last issue: 13.09.2019<br>4353-00015 Date of first issue: 21.10.2014                                                                                                                                                                                                                                                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                                                                                                                             |                                                                                                                                                                                                                                                                       |                  | Remarks: Based on data from similar materials                                                                                                                                                                                                                                                                                                                                                                       |
| Cellul                                                                                                                                      | 050.                                                                                                                                                                                                                                                                  |                  |                                                                                                                                                                                                                                                                                                                                                                                                                     |
|                                                                                                                                             | s on fertility                                                                                                                                                                                                                                                        | :                | Test Type: One-generation reproduction toxicity study<br>Species: Rat<br>Application Route: Ingestion<br>Result: negative                                                                                                                                                                                                                                                                                           |
| Effects                                                                                                                                     | s on fetal development                                                                                                                                                                                                                                                | :                | Test Type: Fertility/early embryonic development<br>Species: Rat<br>Application Route: Ingestion<br>Result: negative                                                                                                                                                                                                                                                                                                |
| Citric                                                                                                                                      | acid monohydrate:                                                                                                                                                                                                                                                     |                  |                                                                                                                                                                                                                                                                                                                                                                                                                     |
|                                                                                                                                             | s on fetal development                                                                                                                                                                                                                                                | :                | Test Type: Embryo-fetal development<br>Species: Rat<br>Application Route: Ingestion<br>Result: negative                                                                                                                                                                                                                                                                                                             |
| STOT                                                                                                                                        | -single exposure                                                                                                                                                                                                                                                      |                  |                                                                                                                                                                                                                                                                                                                                                                                                                     |
|                                                                                                                                             | position bound on availa                                                                                                                                                                                                                                              | blo              | information                                                                                                                                                                                                                                                                                                                                                                                                         |
| NOL CI                                                                                                                                      | assified based on availa                                                                                                                                                                                                                                              | Die              |                                                                                                                                                                                                                                                                                                                                                                                                                     |
|                                                                                                                                             | -repeated exposure                                                                                                                                                                                                                                                    | DIE              | e mornauon.                                                                                                                                                                                                                                                                                                                                                                                                         |
| STOT                                                                                                                                        | -repeated exposure<br>ause damage to organs                                                                                                                                                                                                                           |                  |                                                                                                                                                                                                                                                                                                                                                                                                                     |
| STOT<br>May c<br>expos                                                                                                                      | -repeated exposure<br>ause damage to organs                                                                                                                                                                                                                           |                  |                                                                                                                                                                                                                                                                                                                                                                                                                     |
| STOT<br>May c<br>expos<br><u>Comp</u>                                                                                                       | -repeated exposure<br>ause damage to organs<br>ure.                                                                                                                                                                                                                   |                  |                                                                                                                                                                                                                                                                                                                                                                                                                     |
| STOT<br>May c<br>expos<br><u>Comp</u><br>Simva                                                                                              | -repeated exposure<br>ause damage to organs<br>ure.<br>ponents:                                                                                                                                                                                                       |                  | iver, muscle, optic nerve, Eye) through prolonged or repeat<br>Liver, muscle, optic nerve, Eye                                                                                                                                                                                                                                                                                                                      |
| STOT<br>May c<br>expos<br>Comp<br>Simva<br>Target<br>Asses                                                                                  | -repeated exposure<br>ause damage to organs<br>ure.<br>ponents:<br>astatin:<br>t Organs                                                                                                                                                                               |                  | iver, muscle, optic nerve, Eye) through prolonged or repeat<br>Liver, muscle, optic nerve, Eye<br>Causes damage to organs through prolonged or repeated                                                                                                                                                                                                                                                             |
| STOT<br>May c<br>expos<br>Comp<br>Simva<br>Targe<br>Asses<br>Repea                                                                          | -repeated exposure<br>ause damage to organs<br>ure.<br>ponents:<br>astatin:<br>t Organs<br>sment                                                                                                                                                                      |                  | iver, muscle, optic nerve, Eye) through prolonged or repeat<br>Liver, muscle, optic nerve, Eye<br>Causes damage to organs through prolonged or repeated                                                                                                                                                                                                                                                             |
| STOT<br>May c<br>expos<br>Comp<br>Simva<br>Targe<br>Asses<br>Repea<br><u>Comp</u>                                                           | -repeated exposure<br>ause damage to organs<br>ure.<br>conents:<br>astatin:<br>t Organs<br>sment<br>ated dose toxicity<br>conents:                                                                                                                                    |                  | iver, muscle, optic nerve, Eye) through prolonged or repeat<br>Liver, muscle, optic nerve, Eye<br>Causes damage to organs through prolonged or repeated                                                                                                                                                                                                                                                             |
| STOT<br>May c<br>expos<br>Comp<br>Simva<br>Targe<br>Asses<br>Repea<br><u>Comp</u>                                                           | -repeated exposure<br>ause damage to organs<br>ure.<br>conents:<br>astatin:<br>t Organs<br>sment<br>ated dose toxicity<br>conents:<br>astatin:                                                                                                                        |                  | iver, muscle, optic nerve, Eye) through prolonged or repeat<br>Liver, muscle, optic nerve, Eye<br>Causes damage to organs through prolonged or repeated                                                                                                                                                                                                                                                             |
| STOT<br>May c<br>expos<br>Comp<br>Simva<br>Asses<br>Repea<br>Comp<br>Simva<br>Specia<br>NOAE                                                | -repeated exposure<br>ause damage to organs<br>ure.<br>oonents:<br>astatin:<br>t Organs<br>sment<br>ated dose toxicity<br>oonents:<br>astatin:<br>es                                                                                                                  |                  | iver, muscle, optic nerve, Eye) through prolonged or repeat<br>Liver, muscle, optic nerve, Eye<br>Causes damage to organs through prolonged or repeated<br>exposure.                                                                                                                                                                                                                                                |
| STOT<br>May c<br>expos<br>Comp<br>Simva<br>Targe<br>Asses<br>Repea<br>Comp<br>Simva<br>Specie<br>NOAE<br>LOAE                               | -repeated exposure<br>ause damage to organs<br>ure.<br>conents:<br>astatin:<br>t Organs<br>sment<br>ated dose toxicity<br>conents:<br>astatin:<br>es<br>statin:<br>es                                                                                                 |                  | iver, muscle, optic nerve, Eye) through prolonged or repeat<br>Liver, muscle, optic nerve, Eye<br>Causes damage to organs through prolonged or repeated<br>exposure.<br>Rat<br>5 mg/kg<br>30 mg/kg                                                                                                                                                                                                                  |
| STOT<br>May c<br>expos<br>Comp<br>Simva<br>Targe<br>Asses<br>Repea<br>Comp<br>Simva<br>Specie<br>NOAE<br>LOAE<br>Applic                     | -repeated exposure<br>ause damage to organs<br>ure.<br>conents:<br>astatin:<br>t Organs<br>sment<br>ated dose toxicity<br>conents:<br>astatin:<br>es<br>tL<br>L<br>ation Route                                                                                        | :<br>:<br>:<br>: | iver, muscle, optic nerve, Eye) through prolonged or repeat<br>Liver, muscle, optic nerve, Eye<br>Causes damage to organs through prolonged or repeated<br>exposure.<br>Rat<br>5 mg/kg<br>30 mg/kg<br>Oral                                                                                                                                                                                                          |
| STOT<br>May c<br>expos<br>Comp<br>Simva<br>Targe<br>Asses<br>Repea<br>Comp<br>Simva<br>Specie<br>NOAE<br>LOAE<br>Applic<br>Expos            | -repeated exposure<br>ause damage to organs<br>ure.<br>conents:<br>astatin:<br>t Organs<br>sment<br>ated dose toxicity<br>conents:<br>astatin:<br>es<br>statin:<br>es                                                                                                 | :<br>:<br>:<br>: | iver, muscle, optic nerve, Eye) through prolonged or repeat<br>Liver, muscle, optic nerve, Eye<br>Causes damage to organs through prolonged or repeated<br>exposure.<br>Rat<br>5 mg/kg<br>30 mg/kg                                                                                                                                                                                                                  |
| STOT<br>May c<br>expos<br>Comp<br>Simva<br>Targe<br>Asses<br>Repea<br>Comp<br>Simva<br>Specie<br>NOAE<br>LOAE<br>Applic<br>Expos<br>Targe   | -repeated exposure<br>ause damage to organs<br>ure.<br>conents:<br>astatin:<br>t Organs<br>sment<br>ated dose toxicity<br>conents:<br>astatin:<br>es<br>L<br>L<br>ation Route<br>cure time<br>t Organs                                                                | :<br>:<br>:<br>: | iver, muscle, optic nerve, Eye) through prolonged or repeat<br>Liver, muscle, optic nerve, Eye<br>Causes damage to organs through prolonged or repeated<br>exposure.<br>Rat<br>5 mg/kg<br>30 mg/kg<br>Oral<br>14 - 104 Weeks                                                                                                                                                                                        |
| STOT<br>May c<br>expos<br>Comp<br>Simva<br>Target<br>Asses<br>Repea<br>Simva<br>Specia<br>NOAE<br>LOAE<br>Applic<br>Expos<br>Target         | -repeated exposure<br>ause damage to organs<br>ure.<br>conents:<br>astatin:<br>t Organs<br>sment<br>ated dose toxicity<br>conents:<br>astatin:<br>es<br>iL<br>L<br>ation Route<br>oure time<br>t Organs<br>es<br>L                                                    |                  | iver, muscle, optic nerve, Eye) through prolonged or repeat<br>Liver, muscle, optic nerve, Eye<br>Causes damage to organs through prolonged or repeater<br>exposure.<br>Rat<br>5 mg/kg<br>30 mg/kg<br>Oral<br>14 - 104 Weeks<br>Liver, Testis, Musculo-skeletal system, Eye<br>Dog<br>10 mg/kg                                                                                                                      |
| STOT<br>May c<br>expos<br>Comp<br>Simva<br>Targe<br>Asses<br>Repea<br>Comp<br>Simva<br>Specia<br>NOAE<br>LOAE<br>Applic<br>Expos<br>Targe   | -repeated exposure<br>ause damage to organs<br>ure.<br>conents:<br>astatin:<br>t Organs<br>sment<br>ated dose toxicity<br>conents:<br>astatin:<br>es<br>iL<br>L<br>ation Route<br>oure time<br>t Organs<br>es<br>L<br>ation Route                                     |                  | <ul> <li>iver, muscle, optic nerve, Eye) through prolonged or repeate<br/>Causes damage to organs through prolonged or repeate<br/>exposure.</li> <li>Rat<br/>5 mg/kg<br/>30 mg/kg<br/>Oral<br/>14 - 104 Weeks<br/>Liver, Testis, Musculo-skeletal system, Eye</li> <li>Dog<br/>10 mg/kg<br/>Oral</li> </ul>                                                                                                        |
| STOT<br>May c<br>expos<br>Comp<br>Simva<br>Targei<br>Asses<br>Repea<br>Comp<br>Simva<br>Specie<br>NOAE<br>LOAE<br>Applic<br>Expos<br>Targei | -repeated exposure<br>ause damage to organs<br>ure.<br>conents:<br>astatin:<br>t Organs<br>sment<br>ated dose toxicity<br>conents:<br>astatin:<br>es<br>iL<br>L<br>ation Route<br>oure time<br>t Organs<br>es<br>L                                                    |                  | iver, muscle, optic nerve, Eye) through prolonged or repeat<br>Liver, muscle, optic nerve, Eye<br>Causes damage to organs through prolonged or repeated<br>exposure.<br>Rat<br>5 mg/kg<br>30 mg/kg<br>Oral<br>14 - 104 Weeks<br>Liver, Testis, Musculo-skeletal system, Eye<br>Dog<br>10 mg/kg                                                                                                                      |
| STOT<br>May c<br>expos<br>Comp<br>Simva<br>Targei<br>Asses<br>Repea<br>Comp<br>Simva<br>Specie<br>NOAE<br>LOAE<br>Applic<br>Expos<br>Targei | -repeated exposure<br>ause damage to organs<br>ure.<br>conents:<br>astatin:<br>t Organs<br>sment<br>ated dose toxicity<br>conents:<br>astatin:<br>es<br>statin:<br>es<br>L<br>ation Route<br>oure time<br>t Organs<br>es<br>L<br>ation Route<br>oure time<br>t Organs |                  | <ul> <li>iver, muscle, optic nerve, Eye) through prolonged or repeated</li> <li>Liver, muscle, optic nerve, Eye</li> <li>Causes damage to organs through prolonged or repeated exposure.</li> <li>Rat</li> <li>5 mg/kg</li> <li>30 mg/kg</li> <li>Oral</li> <li>14 - 104 Weeks</li> <li>Liver, Testis, Musculo-skeletal system, Eye</li> <li>Dog</li> <li>10 mg/kg</li> <li>Oral</li> <li>14 - 104 Weeks</li> </ul> |



| Version<br>6.0                    | Revision Date:<br>23.03.2020                                   | SDS Number:<br>24353-00015                                                | Date of last issue: 13.09.2019<br>Date of first issue: 21.10.2014                                                                               |  |
|-----------------------------------|----------------------------------------------------------------|---------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------|--|
|                                   | L<br>cation Route<br>t Organs                                  | : 50 mg/kg<br>: Oral<br>: Liver, Kidney                                   |                                                                                                                                                 |  |
|                                   | es<br>EL<br>cation Route<br>sure time                          | : Rat<br>: >= 2.000 mg/k<br>: Skin contact<br>: 28 Days<br>: OECD Test Gu | -                                                                                                                                               |  |
|                                   | es                                                             | : Rat<br>: >= 9.000 mg/k<br>: Ingestion<br>: 90 Days                      | g                                                                                                                                               |  |
| Specie<br>NOAE<br>LOAE<br>Applic  | EL                                                             | : Rat<br>: 4.000 mg/kg<br>: 8.000 mg/kg<br>: Ingestion<br>: 10 Days       |                                                                                                                                                 |  |
| Specie<br>NOAE<br>Applic<br>Expos | EL<br>cation Route<br>sure time                                | : Rat<br>: 24.000 mg/kg<br>: Ingestion<br>: 28 Days                       |                                                                                                                                                 |  |
| Specie<br>NOAE<br>Applic<br>Expos | es<br>EL<br>cation Route<br>sure time                          | : Rat<br>: 10 mg/m <sup>3</sup><br>: inhalation (dus<br>: 2 y             | t/mist/fume)                                                                                                                                    |  |
| Not cl                            | ation toxicity<br>assified based on ava<br>rience with human e |                                                                           |                                                                                                                                                 |  |
| -                                 | oonents:                                                       |                                                                           |                                                                                                                                                 |  |
|                                   | astatin:<br>contact<br>tion                                    | : Target Organs<br>Symptoms: up<br>dominal pain, o                        | produce an allergic reaction.<br>: Liver<br>per respiratory tract infection, Headache, Ab-<br>constipation, Nausea<br>: Musculo-skeletal system |  |



| ersion<br>.0     | Revision Date: 23.03.2020                   | SDS Number:<br>24353-00015 |                                                                             | Date of last issue: 13.09.2019<br>Date of first issue: 21.10.2014           |  |  |
|------------------|---------------------------------------------|----------------------------|-----------------------------------------------------------------------------|-----------------------------------------------------------------------------|--|--|
| ECTION           | CTION 12. ECOLOGICAL INFORMATION            |                            |                                                                             |                                                                             |  |  |
| Ecoto            | oxicity                                     |                            |                                                                             |                                                                             |  |  |
| Comp             | oonents:                                    |                            |                                                                             |                                                                             |  |  |
| Simva            | astatin:                                    |                            |                                                                             |                                                                             |  |  |
| Toxici           | ty to fish                                  | :                          | LC50 (Pimephales<br>Exposure time: 96<br>Method: OECD Te                    |                                                                             |  |  |
|                  | ty to daphnia and other<br>ic invertebrates | :                          | EC50 (Daphnia m<br>Exposure time: 48<br>Method: OECD Te                     |                                                                             |  |  |
| Toxici<br>plants | ty to algae/aquatic                         | :                          | EC50 (Pseudokiro<br>mg/l<br>Exposure time: 96                               | chneriella subcapitata (green algae)): > 25<br>6 h                          |  |  |
|                  |                                             |                            | NOEC (Pseudokir<br>mg/l<br>Exposure time: 96                                | chneriella subcapitata (green algae)): 25<br>Sh                             |  |  |
| Toxici           | ty to microorganisms                        | :                          | EC50: > 30 mg/l<br>Exposure time: 3<br>Test Type: Respir<br>Method: OECD Te | ation inhibition                                                            |  |  |
|                  |                                             |                            | NOEC: 21 mg/l<br>Exposure time: 3<br>Test Type: Respir<br>Method: OECD Te   | ation inhibition                                                            |  |  |
| Cellul           | ose:                                        |                            |                                                                             |                                                                             |  |  |
| Toxici           | ty to fish                                  | :                          | Exposure time: 48                                                           | pes (Japanese medaka)): > 100 mg/l<br>s h<br>on data from similar materials |  |  |
| Citric           | acid monohydrate:                           |                            |                                                                             |                                                                             |  |  |
|                  | ty to fish                                  | :                          | LC50 (Pimephales<br>Exposure time: 96                                       | s promelas (fathead minnow)): > 100 mg/l<br>5 h                             |  |  |
|                  | ty to daphnia and other<br>ic invertebrates | :                          | EC50 (Daphnia m<br>Exposure time: 24                                        | agna (Water flea)): 1.535 mg/l<br>⊦h                                        |  |  |
| Titani           | um dioxide:                                 |                            |                                                                             |                                                                             |  |  |
|                  | ty to fish                                  | :                          | LC50 (Oncorhync<br>Exposure time: 96<br>Method: OECD Te                     |                                                                             |  |  |
|                  | ty to daphnia and other<br>ic invertebrates | :                          | EC50 (Daphnia m<br>Exposure time: 48                                        | agna (Water flea)): > 100 mg/l<br>s h                                       |  |  |



# Simvastatin Formulation

| Version<br>6.0      | Revision Date:<br>23.03.2020                      |      | DS Number:<br>353-00015                                                    | Date of last issue: 13.09.2019<br>Date of first issue: 21.10.2014 |
|---------------------|---------------------------------------------------|------|----------------------------------------------------------------------------|-------------------------------------------------------------------|
| Toxicity<br>plants  | ∕ to algae/aquatic                                | :    | EC50 (Skeletone<br>Exposure time: 7                                        | ma costatum (marine diatom)): > 10.000 mg/l<br>2 h                |
| Toxicity            | / to microorganisms                               | :    | EC50: > 1.000 m<br>Exposure time: 3<br>Method: OECD T                      |                                                                   |
| Persist             | tence and degradabi                               | lity |                                                                            |                                                                   |
| Compo               | onents:                                           |      |                                                                            |                                                                   |
| Simva               | statin:                                           |      |                                                                            |                                                                   |
| Biodeg              | radability                                        | :    | Result: rapidly de                                                         | gradable                                                          |
| Stability           | y in water                                        | :    | Hydrolysis: 50 %                                                           | (3,2 d)                                                           |
| Celluic             | ose:                                              |      |                                                                            |                                                                   |
| Biodeg              | radability                                        | :    | Result: Readily b                                                          | iodegradable.                                                     |
| Citric a            | acid monohydrate:                                 |      |                                                                            |                                                                   |
| Biodeg              | radability                                        | :    | Result: Readily b<br>Biodegradation:<br>Exposure time: 2<br>Method: OECD T | 97 %                                                              |
| Bioaco              | umulative potential                               |      |                                                                            |                                                                   |
| Compo               | onents:                                           |      |                                                                            |                                                                   |
| Simva               | statin:                                           |      |                                                                            |                                                                   |
| Partitio<br>octanol | n coefficient: n-<br>I/water                      | :    | log Pow: > 4,07                                                            |                                                                   |
|                     | acid monohydrate:<br>n coefficient: n-<br>l/water | :    | log Pow: -1,72                                                             |                                                                   |
|                     | a available                                       |      |                                                                            |                                                                   |
|                     | <b>adverse effects</b><br>a available             |      |                                                                            |                                                                   |

#### SECTION 13. DISPOSAL CONSIDERATIONS

#### **Disposal methods**

| Waste from residues    | : | Dispose of in accordance with local regulations.          |
|------------------------|---|-----------------------------------------------------------|
| Contaminated packaging | : | Empty containers should be taken to an approved waste     |
|                        |   | handling site for recycling or disposal.                  |
|                        |   | If not otherwise specified: Dispose of as unused product. |



### **Simvastatin Formulation**

| Version<br>5.0                                                                                                 | Revision Date:<br>23.03.2020                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | SDS Number:<br>24353-00015                                                                                  | Date of last issue: 13.09.2019<br>Date of first issue: 21.10.2014                        |
|----------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------|
| SECTION                                                                                                        | 14. TRANSPORT IN                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | FORMATION                                                                                                   |                                                                                          |
| Interi                                                                                                         | national Regulations                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | 6                                                                                                           |                                                                                          |
| UNR <sup>-</sup><br>Not re                                                                                     | <b>TDG</b><br>egulated as a danger                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | ous good                                                                                                    |                                                                                          |
|                                                                                                                | -DGR<br>egulated as a danger                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | ous good                                                                                                    |                                                                                          |
|                                                                                                                | <b>-Code</b><br>egulated as a danger                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | ous good                                                                                                    |                                                                                          |
|                                                                                                                | sport in bulk accord                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | -                                                                                                           | ARPOL 73/78 and the IBC Code                                                             |
| Dom                                                                                                            | estic regulation                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                                                             |                                                                                          |
|                                                                                                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                                                             |                                                                                          |
| ANT                                                                                                            | r<br>egulated as a danger                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | ous good                                                                                                    |                                                                                          |
| ANT<br>Not re                                                                                                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                                                             |                                                                                          |
| ANTT<br>Not re<br>SECTION<br>Safet<br>mixtu                                                                    | egulated as a danger<br>15. REGULATORY I<br>y, health and enviro<br>ure                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | INFORMATION                                                                                                 | /legislation specific for the substance or                                               |
| ANTT<br>Not re<br>SECTION<br>Safet<br>mixtu<br>Natio                                                           | egulated as a danger<br><b>15. REGULATORY I</b><br><b>ty, health and enviro</b><br><b>ure</b><br>nal List of Carcinoger                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | INFORMATION                                                                                                 |                                                                                          |
| ANTT<br>Not re<br>SECTION<br>Safet<br>mixtu<br>Natio                                                           | egulated as a danger<br>15. REGULATORY I<br>y, health and enviro<br>ure                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | INFORMATION                                                                                                 |                                                                                          |
| ANTT<br>Not re<br>SECTION<br>Safet<br>mixtu<br>Natio<br>Grou<br>Titani                                         | agulated as a dangero<br><b>15. REGULATORY I</b><br><b>ty, health and enviro</b><br><b>ure</b><br>nal List of Carcinoger<br>p 2B: Possibly carcino<br>ium dioxide<br>I. List of chemicals co                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | INFORMATION                                                                                                 | s - (LINACH)<br>13463-67-7                                                               |
| ANT<br>Not re<br>SECTION<br>Safet<br>mixtu<br>Natio<br>Group<br>Titani<br>Brazil<br>Police                     | agulated as a dangero<br><b>15. REGULATORY I</b><br><b>ty, health and enviro</b><br><b>ure</b><br>nal List of Carcinoger<br>p 2B: Possibly carcino<br>ium dioxide<br>I. List of chemicals co                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | INFORMATION<br>Inmental regulations<br>nic Agents for Humans<br>ogenic to humans                            | s - (LINACH)<br>13463-67-7                                                               |
| ANTT<br>Not re<br>SECTION<br>Safet<br>mixtu<br>Natio<br>Group<br>Titani<br>Brazii<br>Police                    | egulated as a dangero<br><b>15. REGULATORY I</b><br><b>ay, health and enviro</b><br><b>are</b><br>nal List of Carcinoger<br>p 2B: Possibly carcino<br>ium dioxide<br>I. List of chemicals co<br>e<br><b>national Regulations</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | INFORMATION                                                                                                 | s - (LINACH)<br>13463-67-7                                                               |
| ANTT<br>Not re<br>SECTION<br>Safet<br>mixtu<br>Natio<br>Group<br>Titani<br>Brazii<br>Police                    | agulated as a dangero<br><b>15. REGULATORY I</b><br><b>17. REGULATORY I</b><br><b>17</b> | INFORMATION                                                                                                 | s - (LINACH)<br>13463-67-7<br>al : Not applicable<br>in the following inventories:       |
| ANTT<br>Not re<br>SECTION<br>Safet<br>mixtu<br>Natio<br>Grouy<br>Titani<br>Brazil<br>Police<br>Intern<br>The i | agulated as a dangero<br><b>15. REGULATORY I</b><br><b>17. REGULATORY I</b><br><b>17</b> | INFORMATION<br>Inmental regulations<br>nic Agents for Humans<br>ogenic to humans<br>Introlled by the Federa | s - (LINACH)<br>13463-67-7<br>al : Not applicable<br>in the following inventories:<br>ed |

#### Further information

| Sources of key data used to | : | Internal technical data, data from raw material SDSs, OECD |
|-----------------------------|---|------------------------------------------------------------|
| compile the Material Safety |   | eChem Portal search results and European Chemicals Agen-   |
| Data Sheet                  |   | cy, http://echa.europa.eu/                                 |

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.



### Simvastatin Formulation

| Version<br>6.0                                                                                                                                                                                                                                                        | Revision Date:<br>23.03.2020                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | SDS Number:<br>24353-00015                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Date of last issue: 13.09.2019<br>Date of first issue: 21.10.2014                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Full to<br>ACGI                                                                                                                                                                                                                                                       | ext of other abbreviat<br>H                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | reshold Limit Values (TLV)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| ACGI                                                                                                                                                                                                                                                                  | H / TWA                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | : 8-hour, time-wei                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | ghted average                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| Land<br>Carcin<br>Stand<br>x% re<br>ENCS<br>x% gr<br>tem; 0<br>- Inte<br>Equip<br>centra<br>cal Si<br>Mariti<br>ganis<br>centra<br>Letha<br>n.o.s.<br>Conce<br>Loadi<br>Zeala<br>ment;<br>lative<br>es; ((<br>1907/<br>Autho<br>ture; Si<br>tion o<br>tions;<br>- Ver | of Brazil; ASTM - Ame<br>nogen, Mutagen or Re<br>lardisation; DSL - Dome<br>esponse; ELx - Loadin<br>S - Existing and New C<br>rowth rate response; El<br>GLP - Good Laboratory<br>ment of Ships carrying<br>ation; ICAO - Internatio<br>ubstances in China; IM<br>me Organization; ISHL<br>ation for Standardizatio<br>ation to 50 % of a test<br>I Dose); MARPOL - Ir<br>- Not Otherwise Speci<br>entration; NO(A)EL - N<br>ng Rate; NOM - Officia<br>nd Inventory of Chemic<br>OPPTS - Office of Che<br>and Toxic substance; I<br>Q)SAR - (Quantitative<br>2006 of the European F<br>prisation and Restriction<br>SDS - Safety Data She<br>f Dangerous Goods; TS<br>UNRTDG - United Nat | rican Society for the<br>eproductive Toxicant;<br>estic Substances List<br>g rate associated with<br>chemical Substances<br>RG - Emergency Resp<br>Practice; IARC - Inter<br>t Association; IBC -<br>g Dangerous Chemica<br>nal Civil Aviation Orga<br>IDG - International M<br>- Industrial Safety ar<br>on; KECI - Korea Exis<br>population; LD50 - Le<br>thernational Convention<br>fied; Nch - Chilean No<br>o Observed (Adverse<br>al Mexican Norm; NTF<br>cals; OECD - Organiz<br>emical Safety and Poll<br>PICCS - Philippines Ir<br>o) Structure Activity<br>Parliament and of the G<br>on of Chemicals; SAD<br>et; TCSI - Taiwan Che<br>SCA - Toxic Substance<br>ions Recommendation | ces; ANTT - National Agency for Transport by<br>Testing of Materials; bw - Body weight; CMR -<br>DIN - Standard of the German Institute for<br>(Canada); ECx - Concentration associated with<br>h x% response; EmS - Emergency Schedule;<br>(Japan); ErCx - Concentration associated with<br>bonse Guide; GHS - Globally Harmonized Sys-<br>national Agency for Research on Cancer; IATA<br>International Code for the Construction and<br>ils in Bulk; IC50 - Half maximal inhibitory con-<br>anization; IECSC - Inventory of Existing Chemi-<br>aritime Dangerous Goods; IMO - International<br>of Health Law (Japan); ISO - International Or-<br>sting Chemicals Inventory; LC50 - Lethal Con-<br>thal Dose to 50% of a test population (Median<br>on for the Prevention of Pollution from Ships;<br>prm; NO(A)EC - No Observed (Adverse) Effect<br>P - National Toxicology Program; NZIoC - New<br>ation for Economic Co-operation and Develop-<br>ution Prevention; PBT - Persistent, Bioaccumu-<br>wentory of Chemicals and Chemical Substanc-<br>Relationship; REACH - Regulation (EC) No<br>Council concerning the Registration, Evaluation,<br>T - Self-Accelerating Decomposition Tempera-<br>emical Substance Inventory; TDG - Transporta-<br>es control Act (United States); UN - United Na-<br>hs on the Transport of Dangerous Goods; vPvB<br>HMIS - Workplace Hazardous Materials Infor- |

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

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