

## ANNEXURE 7

### Comparison of health and environmental test methods proposed by GHS and SA Requirements and Practice

The GHS does not prescribe mandatory test methods for health and environmental hazards. Test methodologies that determine hazardous properties, which are conducted according to internationally recognised scientific principles, are considered acceptable. The analysis in this section focuses on the test method/methodology *per se*. When applying the test method, there may be variances in the specific criteria being tested for. The gaps in criteria are extensively dealt with in the section on Classification Criteria, Section 2.3 and Annexure 5.

| GHS  | Current Requirement/Practice   | Compliance or Gap  |
|--|--|--|
| <p><b>1. Acute Toxicity</b></p> <p>LD<sub>50</sub> (oral, dermal) or LC<sub>50</sub> (inhalation)</p> <p>Oral and inhalation – rat</p> <p>Dermal toxicity – rat or rabbit</p>  | <p><b>1. Acute Toxicity</b></p> <p>SABS 0228 – LD<sub>50</sub> (oral, dermal) or LC<sub>50</sub> (inhalation)</p> <p>SABS 0265 – LD<sub>50</sub> (oral, dermal) or LC<sub>50</sub> (inhalation)</p> <p>SABS 0304 – LD<sub>50</sub> (oral, dermal) or LC<sub>50</sub> (inhalation)</p>  | <p>SABS 0228, SABS 0265, and SABS 0304 – Methods compliant, but criteria differ with those of the GHS; SABS 0304 does not include inhalation toxicity.</p>   |
| <p><b>2. Skin Corrosion/irritation</b></p> <p><i>2a. Skin corrosion</i> – Produces destruction of the skin tissue in at least 1 of 3 tested animals after exposure up to 4-hour duration and an observation period of 14 days.</p> <p><b>2b. Skin irritation – Erythema / eschar or for oedema in tested animals; or</b></p> | <p><b>2. Skin Corrosion/Irritation</b></p> <p>SABS 0228 - Based on experience and the length of time of contact necessary to produce full thickness destruction of the intact skin tissue. Substances that do not cause full thickness destruction of the intact skin are still considered corrosive substances owing to their potential to corrode metal surfaces.</p> <p>SABS 0265 – When applied to healthy intact skin causes full thickness destruction of the skin tissue within 4 hours. A pH value of <math>\leq 2</math> and <math>\geq 11.5</math> can be used as a guideline for possible corrosive properties</p> <p>SABS 0228: - No test method prescribed</p> <p>SABS 0265 – When applied to healthy intact skin for</p> | <p>SABS 0228 – Method compliant, but some of the criteria differ with those of the GHS</p> <p>SABS 00265 – Methods compliant, but some of the criteria differ with those of the GHS</p> <p>SABS 0228 - Not Compliant</p> |

| GHS   | Current Requirement/Practice   | Compliance or Gap   |
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| <b>Inflammation that persists to the end of the observation period.</b>   | up to 4 hours causes significant inflammation that is still present 24 hours or more after the exposure period.  | SABS 00265 – Method compliant, but some of the criteria differ with those of the GHS                              |
| <b>3. Serious Eye Damage/Eye Irritation</b><br>i) The cornea, iris or conjunctiva of test animal not expected to reverse or have fully reversed within an observation; and/or<br>ii) a positive response of corneal opacity and/or iritis after installation of the test material.<br>iii) pH | <b>3. Serious Eye Damage/Eye Irritation</b><br>SABS 0228 - No test method prescribed<br>SABS 0265 – Use rabbit eye irritation testing accordance with OECD 405, or any other internationally recognised test method  | SABS 0228 - Not Compliant<br>SABS 00265 – Method compliant, but some of the criteria differ with those of the GHS |
| <b>4. Respiratory or Skin Sensitization</b><br>i) Evidence in humans that the substance can induce specific respiratory hypersensitivity; and/or<br>ii) Positive results from an appropriate animal test.   | <b>4. Respiratory or Skin Sensitization</b><br>SABS 0228: - No test method prescribed<br>SABS 0265:1999 – Respiratory sensitization is based on practical observations of humans; or, positive response in test animals. Skin sensitization is based on adjuvant-type test method in accordance with OECD 406, or any other internationally recognised test -method                                      | SABS 0228 - Not Compliant<br>SABS 0265 – Compliant  |
| <b>5. Germ Cell Mutagenicity</b><br>Chemicals known to induce heritable mutations or to be regarded as if they induce heritable mutations in the germ cells of humans.<br>Positive results from human epidemiological studies.<br>Positive results from in vivo test in mammals               | <b>5. Germ Cell Mutagenicity</b><br>SABS 0228 - No test method prescribed<br>SABS 0265 – Primarily based on appropriate animal tests, or other relevant information, e.g. epidemiological data. Assays that show Mutagenic effects; cellular interactions relevant to mutagenicity in germ cells of mammals <i>in vivo</i> , i.e. <i>bone marrow micronucleus test, metaphase analysis of peripheral</i> | SABS 0228 - Not Compliant<br>SABS 0265 – Method compliant, but some of the criteria differ with those of the GHS  |

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| and results from test showing mutagenic effects in germ cells of humans without demonstration of transmission to progeny.   | <i>lymphocytes, and the mouse coat colour spot test; Mutagenic effects in somatic cells of mammals in vivo, e.g. sister chromatic exchanges; unscheduled DNA synthesis; covalent binding; and DNA damage</i> |  |
| <b>6. Carcinogenicity</b><br><br>OECD Test and Assessment Methodology (OECD Monograph Series No.17, 1998)   | <b>6. Carcinogenicity</b><br><br>SABS 0228 - No test method prescribed<br><br>SABS 0265 – Primarily based on appropriate animal tests, or other relevant information, e.g. epidemiological data.             | SABS 0228 - Not Compliant<br><br>SABS 0265:1999 – Compliant  |
| <b>7. Reproductive Toxicity</b><br><br>Known or presumed human reproductive or developmental toxicant.  | <b>7. Reproductive Toxicity</b><br><br>SABS 0228 - No test method prescribed<br><br>SABS 0265 – Impaired fertility and developmental toxicity to humans  | SABS 0228 - Not Compliant<br><br>SABS 0265 – Method compliant, but some of the criteria differ with those of the GHS |
| <b>8. Specific Target Organ Systemic Toxicity – Single Exposure</b><br><br>Toxicity in humans or, on the basis of evidence from studies in experimental animals   | <b>8. Specific Target Organ Systemic Toxicity – Single Exposure</b><br><br>SABS 0228 - No test method prescribed<br><br>SABS 0265 – No test method prescribed  | SABS 0228 - Not Compliant<br><br>SABS 0265 – Not Compliant   |
| <b>9. Specific Target Organ Systemic Toxicity – Repeated Exposure</b><br><br>Toxicity in humans or, on the basis of evidence from studies in experimental animals | <b>9. Specific Target Organ Systemic Toxicity – Repeated Exposure</b><br><br>SABS 0228 - No test method prescribed<br><br>SABS 0265 – No test method prescribed  | SABS 0228 - Not Compliant<br><br>SABS 0265 – Not Compliant   |

| GHS  | Current Requirement/Practice   | Compliance or Gap   |
|--|--|---|
| <p><b>10. Hazardous to the aquatic environment</b></p> <p>Basic Elements: OECD Test Guidelines</p> <p>Acute Aquatic Toxicity: OECD Test Guideline 201, 202, 203 or equivalent</p> <p>Bioaccumulation Potential: OECD Test Guideline 107 or 117</p> <p>Rapid Durability: OECD Test Guideline 301</p> <p>Chronic Aquatic Toxicity: OECD Test Guideline 201, 210 or 211</p> | <p><b>10. Dangerous to the aquatic environment</b></p> <p>SABS 0228 - No test method prescribed</p> <p>SABS 0265 – Acute toxicity based on environmental effects: LC<sub>50</sub> (fish), EC<sub>50</sub> (daphnia), IC<sub>50</sub> (algae). Readily degradable determined by 28 day biodegradation study</p> | <p>SABS 0228 - Not Compliant</p> <p>SABS 0265 - Method partially compliant, but some of the criteria differ with those of the GHS Bioaccumulation Potential and Chronic Aquatic Toxicity not specified:</p> |
|  | <p><b>11. Dangerous to the non- aquatic environment</b></p> <p>SABS 0228 - No test method prescribed</p> <p>SABS 0265 – Toxic to flora, toxic to fauna, toxic to soil organisms, toxic to bees, may cause long term adverse effects in the environment; dangerous for the ozone layer.</p>                     | <p>SABS 0228 – No test method required</p> <p>SABS 0265 – This category 'Dangerous to the non- aquatic environment' is not specified in GHS</p>   |