ZDHC

ZDHC MRSL Conformance Guidance

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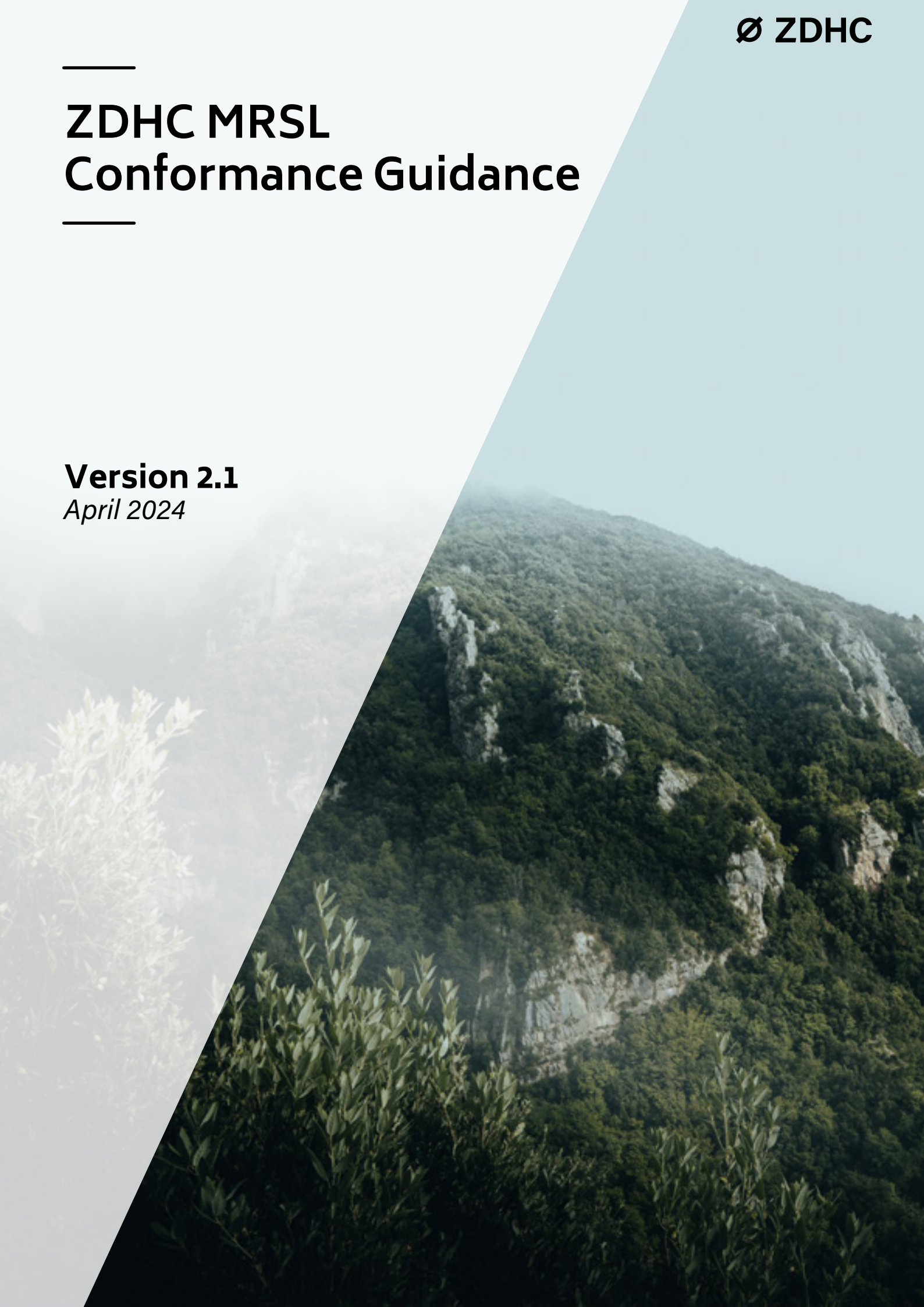

NOTES

ZDHC refers to the UN GHS (Globally Harmonized System of Classification and Labelling of Chemicals) as the internationally recognised standard for hazardous material classification and labelling. All the other national and/or regional existing schemes, derived from the implementation of the UN GHS, have to be considered included in the list of the accepted ZDHC standards for this purpose. To simplify the ZDHC MRSL Conformance Guidance comprehension, ZDHC uses the UN GHS throughout the document as its reference for hazard statements and pictograms in Safety Data Sheets (SDS) and labels in order to avoid local variables.

DISCLAIMERS

The ZDHC Foundation (hereinafter "ZDHC") MRSL Conformance Guidance is not intended to replace brand-specific requirements for chemical management but to be supportive or complimentary to such requirements.

The information in this ZDHC MRSL Conformance Guidance is provided for information only and does not guarantee the following:

- Compliance with, or take the place of, legal or regulatory requirements. Examples might include: stricter legal, local or regional regulatory requirements on the use, storage and transport of chemical products; or other requirements relating to the handling and disposal of chemical products, which shall supersede any requirements as set forth in this document.
- Compliance with, or conformance to, any national or international environmental or workplace safety requirements, including, but not limited to, relevant regulations and/or standards. Nor do the ZDHC MRSL Conformance Guidance replace above-mentioned regulations and/or standards.

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- For any results obtained or not obtained from the use of the ZDHC MRSL Conformance Guidance.

For the avoidance of doubt this Disclaimer applies to all related documents produced by the ZDHC Group.

Contents

Abbreviations

- AAS – Atomic Absorption Spectroscopy
- ANSI – American National Standards Institute
- CHA – Chemical Hazard Assessment
- CMS – Chemical Management System
- EC – European Commission
- EHS – Environment Health and Safety
- EMS – Environmental Management System
- GC/MS – Gas Chromatography/Mass Spectrometry
- GHS – Globally Harmonised System of Classification and Labelling of Chemicals
- GRI – Global Reporting Initiative
- HIRA – Hazard Identification and Risk Assessment
- ICP – Inductively Coupled Plasma
- IEC – International Electrotechnical Commission
- ISO – International Organization for Standardization
- JIS – Japanese Industrial Standards
- LC/MS – Liquid Chromatography/Mass Spectrometry
- MRSL – Manufacturing Restricted Substances List
- OES – Optical Emission Spectrometry
- OHSMS – Occupational Health and Safety Management System
- PPE – Personal Protective Equipment
- QMS – Quality Management System
- REACH – Registration, Evaluation, Authorisation and Restriction of Chemicals
- RSL – Restricted Substances List
- SDS – Safety Data Sheet
- SOP - Standard Operating Procedures

Purpose of ZDHC Conformance Guidance

ZDHC Conformance Guidance explains the process and requirements of organisations that want to become a ZDHC Approved MRSL Certifier. It also explains the criteria for conformance of a chemical formulation to the ZDHC Manufacturing Restricted Substances List (MRSL) and how it is transitioned in the ZDHC Gateway.

CHAPTER 1

Introduction

1.1 About ZDHC MRSL

The ZDHC Manufacturing Restricted Substances List (ZDHC MRSL) is a list of chemical substances banned from intentional use in textile, leather and footwear manufacturing (except metallic trims). Using chemical formulations that meet the requirements of (conform to) ZDHC MRSL allows suppliers to assure both their customers, and themselves, that banned chemical substances are not intentionally used during production and manufacturing processes. See ZDHC MRSL at **mrsl.roadmaptozero.com**.

The ZDHC Roadmap to Zero Programme has defined its scope of activities for zero discharge of hazardous chemicals based on the substances in ZDHC MRSL.

For inclusion of a substance in the ZDHC MRSL, the ZDHC MRSL Council evaluates substances on a case-by-case approach primarily for the following hazard endpoints:

- Carcinogenic, mutagenic, reprotoxic
- Persistent, bioaccumulative, toxic to aquatic life (PBT and vPvB) or equivalent concern like:
    - Endocrine disrupting properties*
    - Persistent, mobile, and toxic (PMT & vPvM)*
    - Respiratory sensitising properties

In addition, new hazard classes with "similar concern" properties to the ones above would also be considered when chemical authorities such as the UN (GHS), the EU (CLP), or other applicable jurisdictions have finalised their respective legislations and established unambiguous criteria for the new hazard classes. Verifiable self-classifications would be valid as well.

Entities and members of the ZDHC MRSL Council can propose the inclusion of new substances to the ZDHC MRSL through the ZDHC Submission Platform. The ZDHC SCM Competence Centre will also engage with stakeholders for feedback and suggestions for the ZDHC MRSL update. Nevertheless, written information is required on the hazards mentioned above from the proposing entities to allow an assessment of whether there is a health risk for consumers, workers, or an environmental risk. Additional information must be provided on:

- Exposure
- Widespread use
- Aggregated tonnage
- Consumer use
- Possible scalable safer alternative(s) with proof of these not being regrettable substitutions.

ZDHC MRSL goes beyond traditional approaches of chemical restrictions that only apply to finished products – Restricted Substances List (RSL) – by restricting the chemicals at or before the point of use during production. This preventative approach helps protect consumers while minimising the possible impact of banned hazardous substances on production workers, local communities, and the environment.

1.2 About ZDHC MRSL Conformance

There are three levels of ZDHC MRSL Conformance. ZDHC MRSL Conformance Levels 1-3 give a confidence rating that this requirement would be met consistently as we go from Level 1 to 3. More details are available at higher levels of ZDHC MRSL Conformance, which demonstrate a continuous production of chemical formulations according to responsible manufacturing practices and consistent conformance to the applicable ZDHC MRSL Guidelines.

* *After UN-GHS and EU-CLP or other applicable jurisdictions have finalised their respective legislation and defined criteria for PMT and ED Class 1. Verifiable self-classification would be valid as well.*

Requirements for ZDHC MRSL Conformance Levels:

- Level 1 – Document review of SDS for information relevant to ZDHC MRSL and testing of the formulation which includes screening and analytical testing or only analytical testing.
- Level 2 – On-site assessment of management systems plus evidence that Level 1 principles of analytical evaluation for ZDHC MRSL conformance are fulfilled.
- Level 3 – Chemical hazard assessment capability plus evidence that Level 1 and Level 2 principles for ZDHC MRSL conformance are fulfilled.

ZDHC Foundation will review methods and business practices of all those that apply for approval to certify for ZDHC MRSL conformance. Those that meet the requirements outlined in Section 3 and 4 of this document will be accepted as ZDHC Approved MRSL Certifiers.

ZDHC MRSL conformance process includes an approach to assist chemical formulators on their journey to demonstrating conformance through ZDHC Approved MRSL Certifier. They can upload their ZDHC MRSL conformant chemical formulations in the ZDHC Gateway – Chemical Module to have transparency and visibility to all stakeholders.

1.3 About ZDHC Gateway

ZDHC Gateway harnesses the power of transparency and collaboration to eliminate harmful substances from the global supply chains of the textile, apparel and footwear (including leather and rubber) industries. It is the world's largest database dedicated to enabling safer choices of chemical products for the textile, apparel and footwear industries and the go-to platform to find and source ZDHC MRSL conformant chemical products.

Through ZDHC Gateway's Chemical and Wastewater Modules, the implementation and monitoring of a supplier's input and output chemical management is facilitated.

Registration of the formulator and its products in the ZDHC Gateway – Chemical Module is the initial step in the process of gaining visibility for the chemical formulations in use throughout the industry.

CHAPTER 2

Introduction to Stakeholders

This conformance guidance will help all ZDHC stakeholders, such as ZDHC Approved MRSL certifiers, chemical formulators, brands, and suppliers to understand the steps involved and the recommended way of working towards ZDHC MRSL conformance.

2.1 ZDHC Approved MRSL Certifiers

A ZDHC Approved MRSL Certifier includes certification bodies and certification standards which are defined as:

1- Certification Bodies

A third-party certification body, or a laboratory approved in accordance with the applicable ZDHC MRSL and ZDHC MRSL Conformance Guidance and which issues and/or confirms the validity of the certificates indicating the ZDHC MRSL Conformance Levels entered on the ZDHC Gateway.

2- Certification Standards

A third-party umbrella standard/organisation for one or more certification bodies or laboratories that assess chemical formulations against the standard's own requirements and for conformance to the ZDHC MRSL.

ZDHC Approved MRSL Certifiers who have passed the due diligence process of ZDHC become ZDHC MRSL Conformance Indicators and are in effect approved as able to provide certificates as an indication of conformance to the ZDHC MRSL.

The role of ZDHC Approved MRSL Certifiers is not only to develop and maintain their individual certification system to review chemical formulations for hazard assessment, restricted substances and other criteria. It is also to provide full information on their certification system and process to the ZDHC Foundation to determine their

acceptability for approval as a ZDHC Approved MRSL Certifier at the relevant ZDHC MRSL Conformance Levels specified above.

The ZDHC Approved MRSL Certifier is expected to have a system for investigating information or complaints from stakeholders about formulations that have been certified by them. They should meet the requirements as specified in section 3 and 4 of this document and may make their methods and related validation data (if pertinent) available to chemical formulators, brands, material formulators, and product finishers on request. Evaluation of requirements relevant to ZDHC MRSL Conformance Levels should be transparent in their methodology. ZDHC reserves the right to suspend or terminate the contract, limit the certified products and investigate the complaints as needed. The acceptance requirements for ZDHC Approved MRSL Certifiers are based on ISO/IEC 17065 and ISO/ISE 17021-1.

2.2 Chemical Formulators

ZDHC MRSL Conformance Guidance provides clarity and transparency to assist chemical formulators to work on their goals, policies, and strategies to produce sustainable chemistry. Chemical formulators should always aim to achieve the highest ZDHC MRSL Conformance Level for their formulations.

2.3 Brands and Suppliers

ZDHC MRSL Conformance Guidance provides clarity and transparency for brands and suppliers (manufacturing facilities) to set goals, policies and strategies to drive sustainable chemical management practices through the use of ZDHC MRSL conformant chemical formulations.

Sustainable chemical management practices are explained further in the **ZDHC CMS Framework**.

Supply chain implementation is explained further in the **ZDHC Chemical Management System Technical Industry Guide (ZDHC CMS TIG)**.

Brands and suppliers use ZDHC InCheck solutions, such as ZDHC Performance InCheck report, for monitoring a supplier's chemical inventory for ZDHC MRSL conformance.

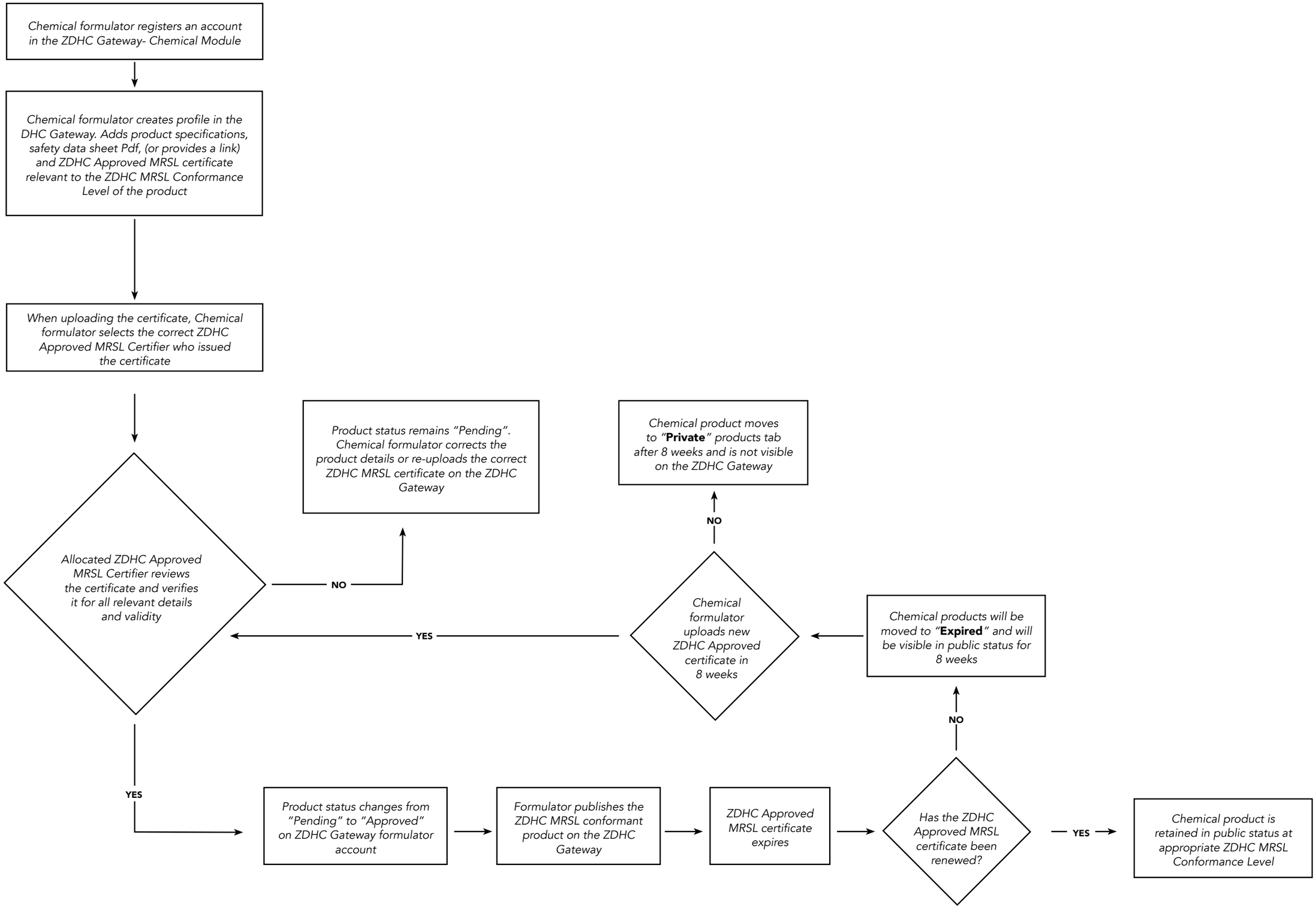
CHAPTER 3

ZDHC MRSL Conformance Process and Levels

Chemical formulators need to follow a standardised process to ensure their chemical formulations are certified for ZDHC MRSL conformance and that the information is shared on the ZDHC Gateway to meet the expectations of brands and suppliers (manufacturing facilities). Formulators must be registered on the ZDHC Gateway and must engage with **ZDHC Approved MRSL Certifiers** to initiate the process. There are three steps:

- Formulator registers to the **ZDHC Gateway** or gets invited by supplier or **ZDHC Approved MRSL Certifier**.
- Instruct ZDHC Approved MRSL Certifier to certify chemical formulation(s) according to ZDHC MRSL Conformance Guidance.
- Start pathway for ZDHC MRSL conformance for chemical formulations.

The pathway of the ZDHC MRSL conformance process for chemical formulations is illustrated in Figure 1.


Chemical formulator registers an account in the ZDHC Gateway- Chemical Module
Chemical formulator creates profile in the DHC Gateway. Adds product specifications, safety data sheet Pdf, (or provides a link) and ZDHC Approved MRSL certificate relevant to the ZDHC MRSL Conformance Level of the product
When uploading the certificate, Chemical formulator selects the correct ZDHC Approved MRSL Certifier who issued the certificate
Allocated ZDHC Approved MRSL Certifier reviews the certificate and verifies it for all relevant details and validity
NO
Product status remains "Pending". Chemical formulator corrects the product details or re-uploads the correct ZDHC MRSL certificate on the ZDHC Gateway
YES
Product status changes from "Pending" to "Approved" on ZDHC Gateway formulator account
Formulator publishes the ZDHC MRSL conformant product on the ZDHC Gateway
ZDHC Approved MRSL certificate expires
Has the ZDHC Approved MRSL certificate been renewed?
NO
Chemical products will be moved to "Expired" and will be visible in public status for 8 weeks
Chemical formulator uploads new ZDHC Approved certificate in 8 weeks
YES
NO
Chemical product moves to "Private" products tab after 8 weeks and is not visible on the ZDHC Gateway
YES
Chemical product is retained in public status at appropriate ZDHC MRSL Conformance Level

ZDHC MRSL Conformance Levels consist of Level 1, Level 2, and Level 3 as described in Figure 2.

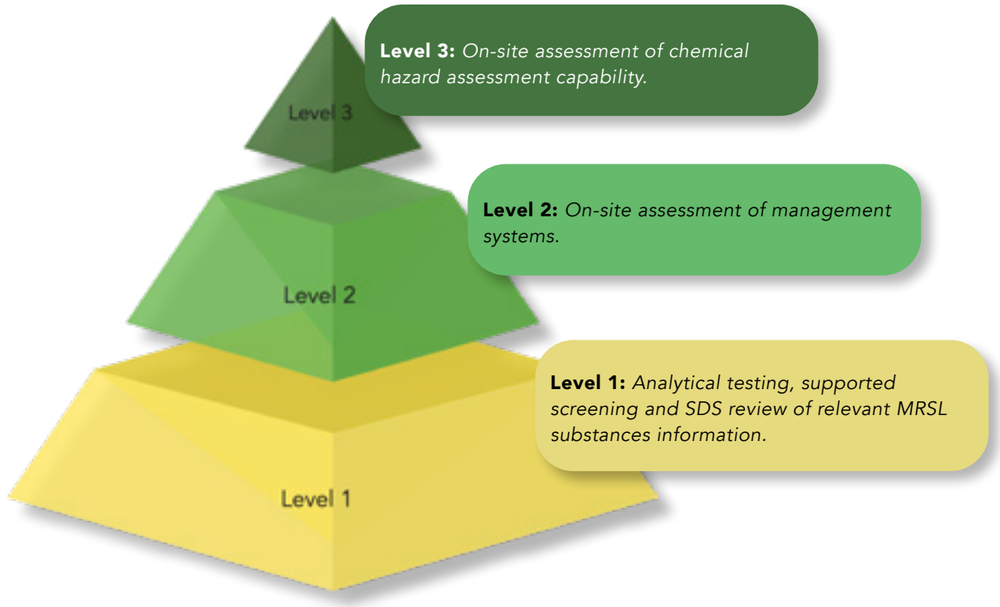


Figure 2. ZDHC MRSL Conformance Levels

3.1 Level 1

ZDHC MRSL Conformance Level 1 is based on analytical testing of the chemical formulation for MRSL risks. An analytical test report from a ZDHC Approved Laboratory accredited for ISO 17025 with proper scope is required as evidence of ZDHC MRSL conformance for impurities. A screening analysis by gas chromatography/mass spectrometry (GC/MS), liquid chromatography/mass spectrometry (LC/MS), or inductively coupled plasma (ICP), or any other advanced detection equipment, can also be done to help determine addition of ZDHC MRSL substances.

The ZDHC MRSL Level 1 Conformance is accomplished by having a certification for the chemical formulation from a ZDHC Approved Certifier based on:

1) Review of a valid safety data sheet (SDS) for information on ZDHC MRSL substances (such as section 3 of GHS SDS) to determine ZDHC MRSL risks for analytical testing of the formulation (and to check potential presence of substances in the ZDHC MRSL Archived List). The SDS should be prepared according to American National Standards Institute (ANSI) Z400.1/Z129.1-2010, International Organization for Standardization (ISO) 11014(1), European Commission (EC) 1272/2008 Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), Globally Harmonised System (GHS), or Japanese Industrial Standards (JIS) Z 7253:2012. The review of SDS will support and integrate into the professional judgement of the ZDHC Approved MRSL Certifier for analytical testing.

2) Analytical testing for ZDHC MRSL substances by the certifier using professional judgement, Appendix A (**Smart Testing Grid**) and methods recommended in **ZDHC MRSL V3.1** to select the test parameters. ZDHC Approved Certifier selects the appropriate testing and declares chemical formulation meets the requirement of the ZDHC MRSL based on the testing performed and review of information in SDS. A certifier shall not declare conformance of a formulation to ZDHC MRSL based on testing conducted on parameters selected by the chemical formulator.

3) A screening analysis from the ZDHC Approved MRSL Certifier such as GC/MS, LC/MS, ICP, or any other advanced detection equipment, to identify ZDHC MRSL failures caused by the intentional addition of ZDHC MRSL substances or inactive substances in the chemical formulation. Laboratories are encouraged to conduct screening analysis to support their professional judgement to determine analytical tests for ZDHC MRSL risks in the chemical product.

4) The length of validity for the certification depends on the ZDHC MRSL Approved Certifier. However, in case of revision in the ZDHC MRSL version during the validity period of the certification, the formulation should be re-certified to the latest ZDHC MRSL version by the ZDHC MRSL Approved Certifier within the transition period. The certifier must demonstrate a process of being notified by the formulator of any change in composition or production process of the certified formulation during the validity period. In such a case, a chemical formulator must provide an updated SDS and the certifier can decide whether re-evaluation is required.

Certification may be renewed by a ZDHC Approved MRSL Certifier at the end of the validity period by following the required criteria in the ZDHC MRSL Conformance Guidance document.

It is the responsibility of the ZDHC Approved MRSL Certifier to certify the formulation for ZDHC MRSL conformance based on the above requirements.

3.2 Level 2

ZDHC MRSL Conformance Level 2 requires:

- Evidence that Level 1 principles of analytical evaluation for ZDHC MRSL conformance are fulfilled, including making available on the ZDHC Gateway a GHS or equivalent SDS or a link to the company website to access the specific SDS.
- In the case of formulations eligible for a Level 2 conformance directly, compliance with the principles of analytical testing is achieved through the on-site assessment of the chemical management system by the ZDHC Approved MRSL Certifier. This assessment will include the evaluation of the formulator's testing regime and/or the ZDHC Approved MRSL Certifier's own testing plan and the ability to provide sufficient and reliable information on the formulations' conformance to ZDHC MRSL.
- On-site visit to the chemical formulation facility to evaluate the management systems including environmental management system (EMS), occupational health and safety management system (OHSMS), raw material management system, quality management system (QMS), chemical management system (CMS) and appropriate wastewater and solid waste management systems by the ZDHC Approved MRSL Certifier. If the same product is manufactured in multiple locations, it is preferable that all the production facilities be audited or, in any case, evaluated for ZDHC MRSL Conformance Level 2 requirements.
- Demonstration of executive-level commitment to protect the environment, worker health and safety, preferably by any of the below:
  - Evidence that manufacturing is conducted according to ISO (or equivalent) standards for QMS and EMS.
  - Policy related statement on the website or in the annual report to highlight all commitments.

  - A commitment to apply a common global standard to products, such as conformance to ZDHC MRSL.
  - Commitment to industry initiatives, such as Responsible Care©, by direct membership or through membership of a trade association aligned to such initiatives.
  - Commitment to implementing a robust process that ensures any batch of a ZDHC Gateway formulation unexpectedly found to be ZDHC MRSL non-conformant is not released for sale as a standard product. If it has already entered the supply chain the affected material must be clearly identified and communicated to customers so that they can ensure that it is not used for production which requires the use of ZDHC MRSL conformant formulations.
  - External assessments such as Dow Jones Sustainability Index, B Corp, and Global Reporting Initiative (GRI).

3.2.1 Implementation of an EMS

This is a set of processes and practices that enable a facility to reduce its environmental impacts and increase operational efficiency. For example:

- ISO 14001 certification, European Union Eco-Management and Audit Scheme, or equivalent EMS.
- Evidence of regular self-inspections followed by root cause analysis and corrective action implementation when required.
- Log of corrective actions and incident reports.
- A written policy and procedure to be shared and available at all times to involved personnel.
- Details of the person(s) responsible are documented and displayed where necessary.
- Aspect impact assessment to evaluate all operational activities and their impact on the environment.
- Monitoring and logging use of energy, water, waste and discharges, with logs accessible at all times.

- Clear targets to reduce the impact on the environment and use of energy, water, waste, and discharge and to prepare corresponding reports.
- Periodical training of all relevant personnel on the topics of impact assessment, monitoring, and improvement in the use of energy, water, wastewater, and discharge.

3.2.2 Implementation of an OHSMS:

All health and safety working conditions are met by considering hazards and their context.

- Personal Protective Equipment (PPE) is provided to workers free of cost to protect their health and to perform required action safely.
- The company provides occupational medical assistance when necessary, e.g. by keeping a medical facility at the worksite.
- A hazard identification and risk assessment (HIRA) is performed regularly.
- Employees receive regular health check-ups related to chemical handling.
- Periodical safety training is provided for selected personnel for fire prevention and evacuation drills.
- Method and list of trained personnel for safety training is documented and displayed at the worksite, with roles clearly explained and defined for the trained personnel.
- Procedure to document and follow up any health, safety or hazard incident, or other emergency response process.

3.2.3 Raw material supplier management:

- Suppliers of raw materials (components, basic products, active ingredients and other materials required for the manufacturing of the final chemical formulation) are evaluated to ensure adequate transparency.
- Communication of clear product specifications and ZDHC MRSL (latest version) conformance, and conformance to other substances of concern (such as EU REACH, Cal Prop 65 etc.), plus relevant listing of the country or region-specific inventories, as applicable.

- Evidence of checking for ZDHC MRSL conformance during purchasing or receipt of raw materials, or toll-manufactured or outsourced chemical products.
- Verification process to ensure raw material supplier quality specifications are consistently achieved.
- Assessment of raw material vendors for their quality and chemical management systems.

3.2.4 Quality Management Systems (such as ISO 9001 or equivalent) which should include:

Setting and maintaining raw material, in-process and finished product specifications for quality parameters.

- A process to restrict the release of finished products until specifications are confirmed.
- A process to address non-conformances to quality specifications which includes root cause analysis and corrective actions.
- Processes which outline standard operating procedures (SOP) including actions to be taken in the case of deviations.
- Documented in-process controls and evidence of implementation and consistent performance.
- Training of personnel to ensure they are sufficiently skilled and qualified to check and grant quality requirements of formulations. Relevant activities must be recorded, documented and kept ready during the audit. Required documents must include but are not limited to:
  - Certificates of education and competence
  - Participation in training courses
  - Demonstrated experience
  - Involvement in relevant regulatory or voluntary activities

3.2.5 Chemical Management System (CMS):

Should be implemented to properly track, store and manage input inventory and finished products, to ensure correct product stewardship. This may include but is not limited to:

- Monitoring ZDHC MRSL and/or other restricted substances as applicable in finished formulations through internal or external systems of testing for restricted substances.
- Responsible person or team for chemicals management/product stewardship.
- Up-to-date chemical inventory of raw materials, work-in-progress and finished products.
- Availability of an updated SDS for all formulations.
- Critical hazard information of on-site chemicals is available to workers in the local language.
- Process for evaluating and communicating chemical hazards, including training for all employees.
- SOP for chemical handling, PPE or engineering controls as required.
- Safe storage conditions for all on-site chemicals.
- Process flow diagrams, bill of materials for each chemical batch, and conditions of manufacturing (time, temperature, pressure etc).
- Capability and resources to demonstrate expertise in providing users of the formulations with sufficient technical and suitable application knowledge and information to assist them in fulfilling their customer's requirements. This can be achieved via technical data sheets, on-site visits, e-mail, or verbal communication.
- Recording, reporting and continuous improvement concerning chemical-related accidents and incidents.

3.2.6 Wastewater, waste and air emissions management:

This should include but is not limited to:

- Wastewater treatment and discharge meets legally permitted limits.
- A schematic flowchart of the wastewater treatment process.

- A copy of the discharge permit or licence to operate, including a list of the regulated parameters, their limits, and associated test data.
- Log details of the quantity of wastewater discharged (direct or indirect) against either a daily limit or maximum limit allowed.
- Demonstrating, with proper evidence, that the waste storage and disposal system, including the sludge generated, is in place and meets local regulation.
- A copy of the necessary permits for waste disposal should be present.
- All air emissions must meet legally permitted limits and a copy of necessary permits for air emissions should be documented.

3.3 Level 3

ZDHC MRSL Conformance Level 3 requires evidence that the principles of analytical testing for ZDHC MRSL Conformance Level 1 and the principles of management systems for Level 2 are being achieved. The required compliance with the principles of analytical testing is achieved through the on-site assessment of the chemical management system by the ZDHC Approved MRSL Certifier. This assessment will include the evaluation of the formulator's testing regime and/or the ZDHC Approved MRSL Certifier's own testing plan and the ability to provide sufficient and reliable information on the formulations' conformance to ZDHC MRSL.

Additionally, a review of the chemical hazard assessment (CHA) capability of the formulator will form an attribute of this ZDHC MRSL conformance level.

CHA capability includes the ability to assess and interpret diverse toxicological and other health and environmental information for classification and labelling of a formulation in accordance with GHS as required. This expertise can be in-house or subcontracted to a consultant. This may include but is not limited to:

- The formulator should be able to provide complete and correct data as well as a standard methodology for hazard profiling of a formulation, including assessment for ZDHC MRSL and other relevant authoritative lists such as ECHA, CLP, REACH, IARC, Toxic Substances Control Act (TSCA) etc.

- Streamlining with positive lists such as Safer Chemical Ingredients List of United States Environment Protection Agency (US EPA).
- Active tracking of the applicable legislation on chemical restrictions for all relevant sales jurisdictions and communication of appropriate information to downstream users.
- Expertise in authoring SDS, including the capability to translate into country-specific SDS formats (preferably IT-supported).
- Expertise in Transport of Dangerous Goods classification to provide appropriate transport information in Section 14 of a GHS conformant SDS.
- Reformulation capability to identify safer (less hazardous) alternatives to substances of concern and to successfully reformulate. This includes:
    - Demonstrate chemical and application expertise to evaluate the performance of the reformulated product(s) and evidence of implementation.
    - Demonstrable capability to evaluate the replacement of substances of concern with safer alternatives according to current best practices such as;
        - OECD (2021), Guidance on Key Considerations for the Identification and Selection of Safer Chemical Alternative.
        - OECD Series on Risk Management, No. 60, Environment, Health and Safety, Environment Directorate, OECD (CB) National Research Council 2014 – A Framework to Guide Selection of Chemical Alternatives. Washington, DC: The National Academies Press.
        - Interstate Chemicals Clearinghouse (IC2), 2017: Alternatives Assessment Guide Version 1.1
    - Keep a database of full product composition for all formulations.
    - Demonstrate change management capability in case of new regulations and new hazard classification of substances.
    - Have data on the possible safer alternatives, their application, and the corresponding performance results.

3.4 "Expired" Formulations

Formulations whose validity for ZDHC MRSL Conformance Level 1, 2 or 3 have expired will be placed in "Expired" category on the ZDHC Gateway. "Expired" formulations are not considered as a ZDHC MRSL Conformance Level. However, it helps to maintain the transparency process in ZDHC Gateway through the Performance InCheck Report.

Such chemical products will be placed under "Expired' for eight weeks on the ZDHC Gateway. After eight weeks, the chemical product is set back to 'private' in the 'products' tab in the formulator's account on the ZDHC Gateway. The formulator will be able to publish the product and make it visible under the product tab in their profile in ZDHC Gateway only if they recertify the product with a ZDHC Approved MRSL Certifier at the appropriate ZDHC MRSL Conformance Level.

CHAPTER 4

General Requirements to Become a ZDHC Approved MRSL Certifier

4.1 Responsibility

4.1.1 Legal Structure

The ZDHC Approved MRSL Certifier shall be a legal entity, or a defined part of a legal entity, such that the legal entity can be held legally responsible for all its certification activities.

4.1.2 Certification Agreement

The ZDHC Approved MRSL Certifier shall provide its certification service based on an agreement signed by the applicants.

4.1.3 Responsibility for Certification Decisions

The ZDHC Approved MRSL Certifier shall have final responsibility for granting, maintaining, extending, suspending, and withdrawing certification.

4.2 Impartiality, Objectivity and Non-Discriminatory Conditions

4.2.1 Impartiality

All certification activities shall be undertaken impartially. The ZDHC Approved MRSL Certifier shall not allow commercial, financial, or other pressure to compromise impartiality.

To manage impartiality, the ZDHC Approved MRSL Certifier shall identify, analyse, and document any risks to impartiality and work to minimise these risks. This shall include those risks that arise from its activities, relationships, and the relationships of its personnel.

The certification activity shall be undertaken by the certifier without any conflict of interest with any other services being provided to the certified company.

4.2.2 Non-Discriminatory Conditions

The ZDHC Approved MRSL Certifier shall make its services accessible to all applicants whose activities fall within the scope of its operation. Access to the certification process shall not be conditional upon the size of the client or membership of any association or group, nor the number of certifications already issued. There shall not be an undue financial burden (for example, with regard to the fee structure) or other burdensome conditions imposed on the applicant.

4.3 Access to Information

4.3.1 Transparency

ZDHC Approved MRSL Certifiers should provide:

- Public access to, or disclosure of, certification requirements.

- Information on procedures for application including the rules and procedures for granting maintaining, extending, or reducing the scope of, suspending, withdrawing or for rejecting certification.
- The fee structure for its services.
- A description of the rights and duties of applicants, including requirements, restrictions and limitations.
- Information on procedures for handling general complaints and appeals.

4.3.2 Use of Certificates

The ZDHC Approved MRSL certifier shall exercise control over ownership, use and display of certificates and any other mechanisms for indicating a product is certified. The ZDHC Approved MRSL Certifier will have a procedure to manage and prevent incorrect references to the certification scheme, or misleading use of certificates, marks or any other mechanism for indicating a chemical product by that body.

4.4 Confidentiality

The ZDHC Approved MRSL Certifier shall make adequate arrangements, through legally-enforceable commitments, to safeguard the confidentiality of the information obtained during the performance of all certification activities.

4.5 Resources

4.5.1 Personnel

The ZDHC Approved MRSL Certifier shall employ sufficient and competent personnel to perform certification activities. The ZDHC Approved MRSL Certifier shall ensure that the personnel have competent knowledge relevant to the application processes of the products in the downstream fields. The ZDHC Approved MRSL Certifier shall identify training needs and provide training as necessary on certification scheme requirements.

The ZDHC Approved MRSL Certifier shall require personnel involved in the certification process to declare any prior or present association on their own part or the part of their employer, with the applicant seeking certification to which they are assigned to perform certification procedures. The ZDHC Approved MRSL Certifier shall use this information to identify risks to impartiality raised by the activities of such personnel.

4.5.2 Resource of Evaluation

When the ZDHC Approved MRSL Certifier performs evaluation activities, the resource used should have sufficient expertise to evaluate the ZDHC MRSL conformance requirements. If the ZDHC Approved MRSL Certifier outsources any evaluation activities (such as testing, inspection, and auditing), the ZDHC Approved MRSL Certifier shall ensure it only outsources to bodies that meet the applicable requirements.

A legally binding contract should be signed by responsible persons from both sides. The ZDHC Approved MRSL Certifier shall take full responsibility for all outsourced activities. The complete process should never be outsourced.

4.5.3 Adequate Facilities and Equipment

The ZDHC Approved MRSL Certifier shall ensure that its testing facility and equipment (internal or external) meet its certification system requirements.

4.6 Quality Management System

4.6.1 General

The ZDHC Approved MRSL Certifier shall establish and maintain a QMS to impart confidence in its ability to perform certification.

4.6.2 Management System Manual

The ZDHC Approved MRSL Certifier shall establish, document and maintain all applicable procedures in a manual or documents, to ensure uniform and consistent application, such as ISO 9001 standard.

The manual shall contain:

- The policy and objectives.
- An organisation chart with a clear indication of authority and responsibilities.
- Procedures applied by the ZDHC Approved MRSL Certifier while performing certification, including granting, maintaining, renewing, extending, suspending, and withdrawing certification.
- Procedures for the recruitment, selection, training, and assignment of the ZDHC Approved MRSL Certifier's personnel.
- Policy and procedures for appeals against certification decisions and other complaints.
- Policy and procedures for reviewing quality.

All personnel involved in certification activities shall have access to the manual and relevant documentation

4.6.3 Document Control

The ZDHC Approved MRSL Certifier shall establish and maintain procedures to control its documents that relate to its certification functions.

The ZDHC Approved MRSL Certifier shall:

- Approve documents for adequacy before issue.
- Ensure all relevant documents are up to date.
- Control the distribution of all documents to ensure the appropriate documentation is provided to relevant personnel.

4.6.4 Operational Control

The ZDHC Approved MRSL Certifier shall establish and maintain operational control procedures to ensure the quality management system is implemented throughout all its activities.

4.6.5 Record Control

The ZDHC Approved MRSL Certifier shall establish and maintain a system of record keeping. Records include evidence that the certification procedures have been fulfilled effectively, these including application forms, evaluation reports, and documents relating to granting, renewing, extending, suspending and withdrawing certification.

The system shall ensure the integrity of the process and the confidentiality of the information. Records shall also be kept for a minimum of five years, or according to local legislation.

4.6.6 Internal Audit

The ZDHC Approved MRSL Certifier shall seek and achieve continuous quality improvement. It shall perform internal audits according to the type, scope and volume of certification performed. The interval between two internal audits must be determined in a way to ensure the objective of quality management is fulfilled.

4.6.7 Management Review

The ZDHC Approved MRSL Certifier shall ensure that the top management of the ZDHC Approved MRSL Certifier reviews the performance of the QMS periodically to ensure its continuing suitability, adequacy and effectiveness.

The management review shall give input relating to the internal audit results, feedback from clients and interested parties, follow-up actions from previous reviews, changes that could affect the QMS, and appeals and complaints. The management review shall be able to advise on the improvement of the effectiveness of the QMS, its processes and resource needs.

4.6.8 Subcontracting or Outsourcing

When a ZDHC Approved MRSL Certifier decides to subcontract (outsource) work relating to certification (such as a site visit), to an external body, a legally binding agreement (contract) covering the arrangements, including confidentiality and conflict of interest, shall be drawn up. The ZDHC Approved MRSL Certifier should take full responsibility of subcontractors meeting ZDHC requirements on the process they are performing related to ZDHC MRSL conformance.

4.7 Analysis Requirement

The analysis requirements given below are for reference only. Labs can develop their own approach for screening methodology.

1- Screening Method

Any Level 1 certification based solely on laboratory testing requires a semi-quantitative screening method. This screening may be followed by a focused, quantitative analysis. GC/MS using acetone dissolution is suitable for most chemical formulations which contain semi-volatile organic compounds. For chemicals with low volatility, high-performance LC/MS is required.

For ZDHC MRSL parameters that are based on elemental metals, ICP, atomic absorption spectroscopy (AAS) or equivalent methods may be used.

2- GC/MS Screening

All samples are analysed by two complimentary GC/MS methods, headspace analysis and acetone extraction. For headspace analysis, an aliquot of the sample is heated at 120°C for 25 minutes in a sealed vial, and the resulting vapour is injected into the GC. A second aliquot of the sample is extracted in acetone by ultrasonication for 10 minutes at 40°C, filtered, and injected into the instrument.

3- MS Calibration

The instrument must be calibrated daily according to the formulator's specifications over a specified mass range using an appropriate calibration standard such as FC-43 or DFTPP.

4- Semi-quantitative Standards

- Headspace samples – benzene
- Acetone – dodecane, 50-ppm

5- Search Library

Peaks detected during analysis are identified using standard MS libraries such as NIST and Wiley MS reference libraries. The comparison of the spectra is made with a Euclidean distance algorithm, using both forward and reverse search parameters. The maximum value for a forward or reverse score is 999 for a perfect match. As a general guide, 900 or greater is an excellent match, 800–900 is a good match, 700– 800 is a fair match, and less than 600 is a poor match. For each peak, a list of compounds with the highest-scored matches will be generated. Generally, the higher-ranked match provides better chemical identification, but the match should always be verified by a knowledgeable analyst. Recommended MS library constraints for the library matching are:

- Parameter setting search type – similarity
- Simple background subtraction – yes
- Minimum abundance 10
- Minimum m/z 29
- Maximum m/z 600
- Minimum MW 30
- Maximum MW 1000
- Minimum score 700
- Maximum matches/peak 6

ICP-optical emission spectrometry, ICP-MS, or AAS

Appropriate screening for heavy metals can be accomplished by ICP-optical emission spectrometry (ICP-OES), ICP-MS and AAS, either alone or in combination. Acidification

of the sample by acid digestion or dilution of the chemical formulation sample into acid will be required before analysis.

Each qualitative result with a match of 700 or greater and an estimated concentration with a factor of five of the ZDHC MRSL limit must be confirmed using the methods listed in ZDHC MRSL V3.1 (for example, if the limit is 1,000, any result over 200 must be confirmed).

Laboratories will be required to submit information and references to their screening procedure for ZDHC review before acceptance.

4.8 Certification Decision

The ZDHC Approved MRSL Certifier retains the authority to make decisions regarding all aspects of certification.

4.9 Documentation

The ZDHC Approved MRSL Certifier shall provide its applicants with formal certification documentation which clearly indicates the certification status.

The certification document shall include:

- Scope of certification.
- Date, name and address of the applicant, and the name and address of the ZDHC Approved MRSL Certifier.
- Signature of the responsible person from the ZDHC Approved MRSL Certifier.

The ZDHC Approved MRSL Certifier shall always maintain up-to-date information on certified products which contain (at minimum) the identification of the product, the version of the ZDHC MRSL the product was assessed against, and the identity of the applicant. These should be provided in a way that allows for data exchange with the ZDHC Gateway-Chemical Module. The identity of certified products shall be made available to related interested parties such as clients of the applicants and ZDHC Signatories.

4.10 Appeals and Complaints

The ZDHC Approved MRSL Certifier shall have policies and procedures for the resolution of complaints and appeals received from chemical formulators or other parties (stakeholders) about the handling of certification or any other related matters. In particular, the ZDHC Approved MRSL Certifier shall:

- Take appropriate subsequent action to resolve complaints and appeals.
- Document the action taken and its effect.

CHAPTER 5

Application and Review Procedure for ZDHC Approved MRSL Certifier

5.1 Application Submission and Contract

ZDHC Foundation or its designee will review and accept new third-party ZDHC Approved MRSL Certifiers. To do this, the ZDHC Approved MRSL Certifier should submit an application through the Solution Provider Platform and, if accepted, the application will be reviewed as described below.

5.2 Assessment

The ZDHC Approved MRSL Certifier applicant undergoes an assessment through the Solution Provider Platform and uploads relevant documents as required for each ZDHC MRSL Conformance Level that is applied for. ZDHC Foundation or its designee will review the assessment inputs and supporting documentation addressing the requirements shown above in Section 3 and 4. Where required, the applicant may be requested to send additional documentation to ZDHC Foundation. ZDHC Foundation reserves the right to conduct a remote or in-person review of the ZDHC Approved MRSL Certifier.

5.3 Assessment Document Checklist (Indicative Only)

Type of documentation expected to be reviewed for the acceptance process:

- Statement of qualifications and expertise.
- Organisation chart.
- CVs of key personnel.
- Certification process or protocol.
- Accreditations, certifications, and licences.
- Laboratory certifications (if applicable).
- Quality assurance practices, for example, internal audit process and corrective action process.
- Examples of laboratory test reports, including calibrations and other quality control results.
- Example of certification template.
- Complaints record.
- Additional documents as requested on Solution Provider Platform.

5.4 Decision of Approval and Contract

After the assessment and document review, ZDHC Foundation or its designee may discuss any findings with the certifier applicant. Following the correction of any needed actions, ZDHC Foundation or its designee will make a final decision on acceptance and approval of the certifier applicant. Upon approval, the certifier shall sign a contract and abide by the terms and conditions of the contract. Approval will be valid until the next revision of the ZDHC MRSL and ZDHC MRSL Conformance Guidance documents. If ZDHC Foundation declines to grant acceptance, the ZDHC Approved MRSL Certifier applicant may appeal the decision to the ZDHC Foundation.

CHAPTER 6

General Requirements for Chemical Formulator

6.1 Requirements for ZDHC MRSL Conformance Level

Please refer to all the requirements for ZDHC MRSL Conformance Levels given in section 3.

6.2 Certification of Chemical Products through ZDHC Approved MRSL Certifiers

All chemical formulators certify their chemical formulations for the appropriate ZDHC MRSL Conformance Level through ZDHC Approved MRSL Certifiers. Formulators can find the **ZDHC Approved MRSL Certifiers** on the official ZDHC website (**roadmaptozero.com**). Formulators are free to choose a ZDHC Approved MRSL Certifier based on their preference.

6.3 ZDHC Gateway Procedures after Certification

ZDHC Gateway is the go-to platform and the largest database of verified ZDHC MRSL conformant chemical products published by formulators and accessed by suppliers to make informed purchasing decisions for ZDHC MRSL conformance in their input chemical inventory.

After the chemical formulator has certified a chemical formulation with one of our ZDHC Approved MRSL Certifiers, the formulators can create an organisation account on the ZDHC Gateway and upload the product with the required product information (Certification of ZDHC MRSL Conformance with respective Level and a valid SDS a link to the SDS or to the company's customer support platform through which an SDS may be obtained.) and make it visible to suppliers and brands after ZDHC Approved MRSL Certifier verifies the formulator's chemical products for the appropriate ZDHC MRSL Conformance Level on ZDHC Gateway. Formulators can find more information on how to get started on our **ZDHC Knowledge Base.**

CHAPTER 7

ZDHC Gateway Process

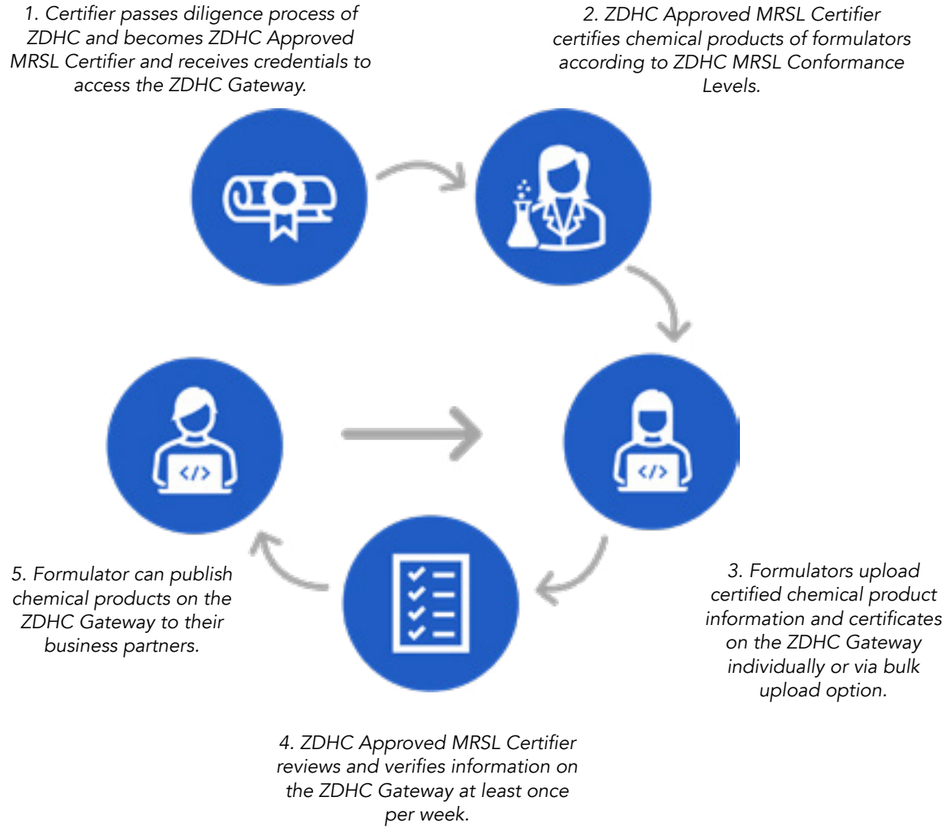


Figure 3: ZDHC Gateway process for product registration

CHAPTER 8

Change Log for ZDHC MRSL Conformance Levels

Version Number	Version 2.1
Time of Publication	April 2024
CHANGES MADE	
Topic	**Description**
Criteria for inclusion of substances in the ZDHC MRSL	Explanation of the hazard criteria and process of submission of new substance and approval by the ZDHC MRSL Council.
Figure 1. Pathway to ZDHC MRSL Conformance for chemical formulations	Information added in the flow chart that a link to the SDS for access or SDS upload can be done by the formulator.
Section 3.2: Level 2 criteria	▪ Point added for eligibility of the formulation for direct Conformance to Level 2 through on-site assessment of the chemical management system by the ZDHC Approved MRSL Certifier, with an explanation on the assessment of analytical testing regime. ▪ Change in the requirement of executive level commitment in terms of robust process to ensure ZDHC MRSL non-conformant product is not released to sale as a standard product.
Section 3.2.5 Chemical Management System (CMS)	Requirement on the capability to produce Technical Data Sheet modified and expanded.
Section 3.3: Level 3 criteria	Point added for eligibility of the formulation for direct conformance to Level 3 through on-site assessment of the chemical management system by the ZDHC Approved MRSL Certifier, with an explanation on the assessment of analytical testing regime
Section 6.3: ZDHC Gateway Procedures after certification	Sentence on the provision of a link to access the SDS through company website added.
Section 7: Gateway process	Step 3 in the flowchart modified as “formulators upload certified chemical product information and certificates on the ZDHC Gateway individually or via bulk upload option.

Version Number	Version 2.0
Time of Publication	1st November 2022
CHANGES MADE	
Topic	**Description**
Hazard end points for ZDHC MRSL substances	Description of hazard endpoints for substances to be included in the scope of ZDHC MRSL are listed and reference given to the ZDHC MRSL Submission Platform.
Level 1 criteria	Additional requirements to support professional judgement for certification of a formulation: ▪ Review of SDS for information relevant to the ZDHC MRSL and Archived List. ▪ Screening methodology included to determine addition of ZDHC MRSL substances in a formulation.
Validity of ZDHC MRSL certification	The length of validity for the certification depends on the ZDHC Approved MRSL Certifier. However, in case of a revision in the ZDHC MRSL version during the validity period of the certification, the formulation should be re-certified to the latest ZDHC MRSL version by the ZDHC MRSL Approved Certifier within the transition period.
Level 2 criteria	Evidence that Level 1 principles of analytical evaluation are fulfilled. On-site evaluation of chemical formulation facility for management systems.
Level 3 criteria	Evidence that principles of analytical testing for Level 1 and principles of management systems for Level 2 are achieved. Additionally, an on-site review of Chemical Hazard Assessment capability of the formulator.
"Expired" formulations	Formulations whose validity for ZDHC MRSL Conformance Levels have expired will be placed in "Expired" category on the ZDHC Gateway for eight weeks. The option of uploading formulations in 'Registered' category on the ZDHC Gateway is discontinued.
Pathway to ZDHC MRSL Conformance	New pathway illustrated in Figure 1 of the document.
MRSL Conformance Levels	New MRSL Conformance Levels illustrated in Figure 2.
Appendix A	Smart Testing Grid includes the substances included in ZDHC MRSL V3.1
Appendix B	This Appendix on 'Types of documentation expected to be reviewed for acceptance process' deleted and included in Section 5.3 (Assessment document checklist).

Glossary

ZDHC Glossary contains explanation on all the common terms that we are using across our guidelines.

Appendix A

This Appendix gives a **'Smart Testing Grid'** based on potential MRSL risks for different use categories of formulations. By this way not every chemical formulation needs to be tested for each ZDHC MRSL parameter. Laboratories should use the Smart testing grid as guidance for certifying for ZDHC MRSL Level 1 conformance, using screening techniques and SDS information additionally for professional judgment.

ZDHC Approved Laboratories must consistently produce acceptable quality data. There may be differences in analytical methods to some extent. However, the methods should meet the same quality requirements to allow for comparability while allowing for advancements in analytical techniques.

Refer this document for recommended test per formulation type ("smart testing") **here**