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OECD Guidance For Characterising Hydrocarbon Solvents For Assessment Purposes

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**OECD Environment, Health and Safety Publications
Series on Testing and Assessment**

No. 230

**OECD GUIDANCE FOR CHARACTERISING HYDROCARBON SOLVENTS FOR
ASSESSMENT PURPOSES**

IOMC

INTER-ORGANIZATION PROGRAMME FOR THE SOUND MANAGEMENT OF CHEMICALS

A cooperative agreement among **FAO, ILO, UNDP, UNEP, UNIDO, UNITAR, WHO, World Bank and OECD**

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Paris 2015

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FOREWORD

Substance identification is an essential part of the implementation of any chemical legislation. Unambiguous characterisation of a substance is a prerequisite to various regulatory processes and relies on information on composition and analytical information. While characterising well-defined substances (including mono-constituent and multi-constituent substances) can in general be regarded as straightforward, the characterisation of UVCB substances (Substances of Unknown or Variable composition, Complex reaction products or Biological materials) is often more challenging due to their complex origin and unknown and/or variable composition. A common understanding and approach to characterising UVCBs would enable regulatory authorities to increase cooperation in the field of hazard assessment and help industry deal with regulatory requirements from multiple jurisdictions.

The purpose of this document is to present a harmonized method for characterising, for assessment purposes, one specific subcategory of UVCBs: hydrocarbon solvent substances. UVCB hydrocarbon solvent substances are a combination of linear, branched, and cyclic alkanes, and aromatic hydrocarbons with carbon numbers predominantly in the range of C5-C20. They are commonly derived from petroleum feedstock and are used as solvents, although there may be other non-solvent uses of these materials as well. Although some hydrocarbon solvents such as cyclohexane are well defined substances, many hydrocarbon solvents are UVCBs as the number of discrete chemical constituents is relatively high and the definitive composition may be unknown and variable. The method presented in this document gives guidance on how hydrocarbon solvent substances can be characterised in a way that their composition is accurately and consistently reflected. This ensures that substances with the same chemical composition, manufactured in different countries, can be characterised with the same description for hazard assessment purposes.

The concepts expressed herein are not, by default, expected to be applicable to other UVCB substance types which have their own specific substance characterisation issues.

This document has been prepared by the OECD correspondence group on characterisation of UVCB substances of the Task Force on Hazard Assessment. It is being published under the responsibility of the Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology.

1. HISTORY

This document is the second in the series of OECD guidance documents dedicated to the characterization of UVCB substances. A first guidance document in this series concentrated on oleochemical substances¹ and was published in March 2014.

The content of this paper has been developed by the OECD correspondence group on characterisation of UVCB substances. It is a combination of ideas based on experience and current guidance, such as that produced by the European Chemicals Agency (ECHA)², the Hydrocarbon Solvents Producers Association (HSPA)³, and the US Environmental Protection Agency (EPA) High Production Volume (HPV) Challenge Program⁴.

2. INTRODUCTION

The purpose of this paper is to present a harmonised method for characterising hydrocarbon solvent substances in a way that their composition is accurately and consistently described for hazard assessment purposes. This method ensures that substances with the same chemical composition can be characterised with the same description, whilst ensuring comparability of their toxicological and ecotoxicological properties. This facilitates a number of processes in terms of efficiency, consistency and accuracy, for example:

- Sharing of data
- Collaboration on hazard assessment between multiple producers or countries
- Chemical name searching
- Harmonisation of classification and labelling of substances

This guidance could be used for characterising substances assessed within several international collaborative frameworks e.g. the OECD Cooperative Chemicals Assessment Programme (CoCAP), the international program of chemical safety (IPCS) and the development of a global harmonised list of classification and labelling.

Countries/regions may also decide to utilise this guidance in their own hazard assessment activities.

It is also important to note that this guidance focuses solely on hydrocarbon solvent substances. The concepts expressed herein are not, by default, expected to be applicable to other UVCB substance types which have their own specific substance characterisation issues.

¹OECD guidance for characterizing oleochemical substances for assessment purposes March 2014 (<http://www.oecd.org/chemicalsafety/testing/seriesontestingandassessmentpublicationsbynumber.htm>)

² ECHA Guidance for identification and naming of substances under REACH version 1.2 March 2012

³ HSPA Substance identification and naming convention for hydrocarbon solvents under REACH

⁴ EPA High Production Volume (HPV) Challenge Program (<http://www.epa.gov/hpv/index.htm>)

3. BACKGROUND ON HYDROCARBON SOLVENT SUBSTANCES

UVCB hydrocarbon solvent substances are commonly derived from petroleum feedstock and typically contain hydrocarbons from one or more of the following classes:

- saturated linear hydrocarbons (n-alkanes)
- saturated branched hydrocarbons (branched alkanes)
- saturated cyclic hydrocarbons (cycloalkanes)
- aromatic hydrocarbons

The major process for transforming petroleum feed stocks into hydrocarbon solvent substances is a combination of various process steps that may include distillation of the feedstock, hydrodesulphurization, mild or heavy hydrogenation, and finally a distillation and a stripping of light components. The corresponding manufacturing process is designed as such that the amount of olefins and heteroatoms is kept to its absolute minimum. In case olefins or heteroatoms are present in significant amounts the guidance has to be adapted accordingly.

It is known that aromatics are expected to have a substantially higher boiling point than the alkanes with the same carbon number. For aromatics the boiling point does not only goes up with the increasing carbon number, but also with increasing ring number (2-ring C14 aromatic: 292°C; 3-ring C14 aromatic: 343°C). Therefore aliphatic hydrocarbons with carbon numbers up to C20 contain generally aromatics with a significant lower carbon number and mostly containing not more than 2 rings. In case multi-ring aromatic molecules are present, they would have to be analysed and mentioned in the characterisation of the substance if the amount is above the limit for classification and labelling.

The difference between the types of hydrocarbon solvents is mainly due to their different hydrocarbon classes and their carbon number range. The carbon number distribution depends on the targeted distillation range of the final product. Due to the variability in the composition of the starting materials, many hydrocarbon solvents fall under the definition of a UVCB substance. The hydrocarbon solvent carbon numbers are typically narrow cuts of hydrocarbon lengths over C5 and below C20.

Source and process descriptors vs. composition based descriptors

The Chemical Abstract Services (CAS) descriptions and numbers have been used historically to identify chemical substances. CAS descriptions exist for a number of hydrocarbon substances derived from petroleum refining and chemical conversion. Because a major historical use of the CAS descriptors used to describe petroleum feed stocks and products has been to identify “existing substances” for regulatory purposes, these CAS entries are based on a combination of source and/or process descriptors and/or the composition. Therefore, these descriptions are overly broad to describe hydrocarbon solvent substances because hydrocarbon solvents typically have narrower carbon number ranges and different processing.

The source descriptor describes the origin of the petroleum feedstock used to manufacture a particular hydrocarbon solvent substance. In general every petroleum feedstock source provides a typical carbon number distribution in the final hydrocarbon solvent substance. In addition, the process descriptor describes the process steps used to manufacture a particular hydrocarbon solvent substance from a petroleum feedstock. The process steps influence the composition of the final hydrocarbon solvent substance. For that reason often the source and process descriptors have been used instead of composition based descriptors, e.g. *Naphtha (petroleum) hydrotreated heavy* as opposed to *Hydrocarbons, C9-C11*,

n-alkanes, branched alkanes, cycloalkanes, and < 2% aromatics. However, although sufficient to describe an “existing substance”, the source and process descriptors may not provide sufficient information on the variability in composition of the final products to facilitate an in-depth risk assessment and is therefore less relevant than composition based descriptors. Moreover composition based descriptors are not strictly tied to a single source or production process and can therefore be used independent of the origin (including use of mixed sources) and the production process used.

4. OECD CHARACTERISATION, FOR HAZARD ASSESSMENT PURPOSES, OF HYDROCARBON SOLVENT SUBSTANCES

i. Qualitative descriptors

The group of hydrocarbon solvent substances comprises substances whose individual constituents have a common structural feature: they consist of only hydrogen and carbon. Their constituents differ from each other with respect to one or more of the following characteristics:

- Number of carbon atoms in chain/cycle (carbon number)
- The description of the hydrocarbon structures present as the Paraffins, Isoalkanes (branched alkanes), Naphthenes, Aromatics (PINA)) structure: n-alkanes (or n-paraffins / saturated linear alkanes), branched alkanes (or isoparaffins), cycloalkanes (or naphthenes) and aromatics.
- Components with specific toxicology or hazard classification

The constituents can be sufficiently and systematically characterised by using the following four descriptors:

- Chemical character descriptor
- Carbon number descriptor
- Hydrocarbon structure descriptor
- Specific component descriptor

Chemical character descriptor

The chemical character descriptor identifies the chemical character of the substance as “Hydrocarbons”.

Carbon number descriptor

The carbon number descriptor describes the number of carbon atoms in the carbon chain length(s), including the carbons in cycloalkanes:

- In general, the carbon number descriptor refers to the overall carbon number range of the substance irrespective of the hydrocarbon structure, e.g. “C12–C14” corresponds to “C12, C13, C14” including both even and odd numbered alkyl-chains;

It should be indicated if the carbon number descriptor refers only to even or odd numbered alkyl chains e.g. C12-C14 (even numbered)

A hydrocarbon solvent characterised with a narrow carbon number distribution is not equal to a hydrocarbon solvent characterised with a broader one e.g. “C12–C14” is not equal to “C12–C18”. Accordingly, a hydrocarbon solvent characterised with carbon number descriptor “C12–C18” is not equal to a hydrocarbon solvent with carbon number descriptor “C12–C14”.

Hydrocarbon structure descriptor

The description of the hydrocarbon structures present or the PINA structure: n-alkanes (or n-paraffins / saturated linear alkanes), branched alkanes (or isoparaffins), cycloalkanes (or naphthenes) and aromatics.

The hydrocarbon structure descriptors are included after the carbon number descriptor and are separated by a comma, e.g. “C12–C14, branched alkanes, < 2% aromatics” or “C12–C14, n-alkanes, branched alkanes, < 2% aromatics”.

Specific component descriptor

Components with specific toxicology or classification (e.g. n-hexane and naphthalene) will be mentioned using the classification cut off as an indication level.

UVCBs vs. Well Defined Substances

The system outlined above can be used to describe substances with variation in the carbon numbers. This guidance is not applicable if the variation in carbon number is sufficiently controlled and the substance can be defined as a well-defined substance⁵.

In conclusion, the information on the chemical character descriptor, carbon number descriptor, hydrocarbon structure descriptor and specific component descriptor are the basis for characterising a hydrocarbon solvent UVCB substance. In addition, information on the source and the process may be important to support the characterisation of the substance.

ii. Quantitative descriptors

Quantitative criteria or cut-off values for carbon numbers that should be considered for the characterisation of a hydrocarbon solvent UVCB substance are defined below:

- The hydrocarbon solvent substances that are covered by this guidance are UVCBs due to their variation in the carbon number distribution and the different combinations of hydrocarbon classes. However, if one chemical structure is present at a minimum concentration of 80%⁶, the substance is considered a well-defined hydrocarbon solvent substance and not as a UVCB hydrocarbon solvent substance.
- For a composition based characterisation, all carbon numbers and hydrocarbon classes, whose concentration is $\geq 10\%$ (based on the maximum concentration value of the concentration range),

⁵ This typically means a substance composed of molecules with particular atoms arranged in a definite, known structure which accounts for >80% of the substance composition.

⁶ The 80% concentration limit is a value used historically that has been used in both Europe and US.

should be part of the characterisation. The sum of the maximum concentration values of each carbon number mentioned in the name must be at least 80% (w/w) of the substance composition.

- In case of group of constituents with same carbon number, each present with a concentration $\geq 10\%$ (based on the maximum concentration value of the concentration range), that altogether do not compose $\geq 80\%$ (w/w) of the substance, all carbon numbers, regardless of their concentration, should be considered for the characterisation. However, if justifiable, manufacturer intent can be used to determine whether carbon numbers with a concentration $< 10\%$ (based on the maximum concentration value of the concentration range) should be included as part of carbon number descriptor or not. If over 20% (w/w) of the carbon number, or over 20% (w/w) of the hydrocarbon classes, are unknown, the substance may need to be considered as something other than a hydrocarbon solvent (i.e. another type of UVCB substance that is not covered by this guidance).

Quantitative criteria or cut-off values for the maximum concentration value of aromatics to be included in the name are defined below:

- If the maximum concentration value of aromatics is below 2%⁷, this is specified in the hydrocarbon structure descriptor.
- If the maximum concentration value of aromatics is between 2 - 25% in lower boiling hydrocarbon solvents or 2 - 30% in higher boiling hydrocarbon solvents⁸, this is specified in the hydrocarbon structure descriptor.
- If the maximum concentration value of a component with specific toxicological properties is above a classification cut off, this is specified in the specific component descriptor (i.e. toxic substance x > cut-off x%)⁹.

Rules for establishing the typical, minimum and maximum concentration values

The typical, minimum and maximum concentration value for a given constituent or group of constituents should be considered in the substance characterisation. This information can be established by analysing a number of separate batches (typically five) over a period of time. The average value of this multiple batch analysis can be used to set the typical value.

The hydrocarbon solvent substances are UVCBs and, therefore, their composition may vary both qualitatively and quantitatively. Variations in feedstock and process conditions determine the final product composition.

⁷ Origin of 2% concentration limit: OECD High Production Volume (HPV) Chemicals Programme

⁸ Percentage differences are due to the fact that for higher boiling solvents (C14 – C20) composition constitutes of a slightly higher percentage of mass of aromatic hydrocarbons (up to 30%) than the lower boiling ones (C9-C14) (up to 25%).

⁹ Based on current knowledge of industry the relevant chemicals with specific toxicological properties that could be present in hydrocarbon solvents are, n-hexane and naphthalene. It is recognized that classification cut-off values may vary depending on the territory. This needs to be taken into account when exchanging assessment results between territories.

Step-wise process to establishing carbon number descriptor:

1. Analyse substance
2. Group constituents based on carbon number
3. For each group establish the maximum concentration (% w/w)
4. Establish the name based on the rules

Example:

C8 = 1% w/w max

C9 = 10% w/w max

C10 = 40% w/w max

C11 = 42% w/w max

C12 = 6% w/w max

C13 = 1% w/w max

Carbon number descriptor = C9–C11

Step-wise process to establishing hydrocarbon structure descriptor:

1. Analyse substance
2. Group constituents based on hydrocarbon classes (n-alkanes, branched alkanes, cycloalkanes).
3. For each hydrocarbon class from above establish the maximum concentration (% w/w)
4. Establish the name based on the preceding rules

Example:

n-alkanes = 25% w/w max

branched alkanes = 25% w/w max

cycloalkanes = 49.6% w/w max

aromatics = 0.4% w/w max

Hydrocarbon structure descriptor = n-alkanes, branched alkanes, cycloalkanes

Illustrative example

The chemical character descriptor is usually the most important part of the name and as such it should be mentioned first followed by the carbon number descriptor and hydrocarbon structure descriptor e.g. “*Hydrocarbons, C9-C11, n-alkanes, branched alkanes, cycloalkanes, < 2% aromatics*”

Chemical character descriptor: "Hydrocarbons"; describes the chemical character of the substance.

Carbon number descriptor: “C9-C11”; describes all the carbon numbers present at concentrations $\geq 10\%$ and $< 80\%$ in the substance.

Hydrocarbon structure descriptor: “n-alkanes, branched alkanes, cycloalkanes, < 2% aromatics” describes the hydrocarbon classes present at concentrations $\geq 10\%$ and $< 80\%$, and indicates the aromatic content $< 2\%$.

5. IDENTIFIERS

Identifiers are necessary to establish the overall substance characterisation in a comprehensive way. Further information on identifiers for hydrocarbon solvent substances is described in Appendix 1.

6. EXAMPLES

Three examples of existing hydrocarbon solvent substances are provided in appendix 2. They have been chosen to illustrate how the characterisation, described in this paper, has been applied by Hydrocarbon Solvents Producers Association (HSPA). They highlight how substances with broad generic names can be characterised more precisely.

APPENDIX 1 - IDENTIFIERS

i. Information on chemical composition

Information on chemical composition means typical concentration and concentration ranges (minimum and maximum values) for all known constituents. This information can be established by analysing a number of separate batches (typically five) over a period of time, the substance specifications, and data of variation of physico-chemical properties of the substance. The average value of this multiple batch analysis can be used to set the mean value and the minimum and maximum values could be set by appropriate statistical methods. Concentration variations from the typical value may occur. In any case the variation should not result in a different hazard profile. Consideration should be given to ensure the concentration ranges are reasonable, i.e. not overly broad, and reflect the reality.

ii. Source and process description

For hydrocarbon solvent substances, where the composition is relatively well-defined, toxicological properties can be linked more directly to the chemical structure of the individual constituents rather than to the nature of the source/starting material. However, information on source and process description is important for the following reasons:

- 1) To understand and verify the composition profile, in particular the concentration ranges established for individual constituents.
- 2) Different sources (e.g. petroleum versus renewable sources) will have different profiles including minor constituents that may not be reported in the final substance composition but nevertheless may affect the toxicological properties of the substance.

Information on source and process description typically includes, as appropriate:

- Carbon number distribution with upper and lower concentration ranges and name of source (e.g. petroleum) if known and available.
- Process type e.g. desulfurization
- Description of the manufacturing process including each individual process step (block diagrams can be a useful way to illustrate this)
- Relevant non-confidential operating parameters (e.g. targeted distillation range at a particular manufacturing step) that influence or determine the composition of the manufactured substance

iii. Analytical information

The analytical information and spectral data provided should be sufficient to be able to verify the composition of the substance. A combination of the following spectral and chromatographic analysis is usually sufficient:

- Ultra violet (UV) spectroscopy;
- Infra-red (IR) spectroscopy;
- Nuclear Magnetic Resonance (NMR) and/or Mass spectroscopy (MS)
- Gas or High Performance Liquid Chromatography (GC or HPLC)

iv. Impact on CAS identifiers and other identifiers such as EC entries

Over the years, manufacturers of UVCBs have obtained CAS Registry Numbers and Chemical Abstracts (CA) Index Names (with associated supplemental definitions where appropriate) for some of their UVCB substances and reported the chemicals with these identities under different regulatory programmes around the world.

If CAS identification is used in conjunction with the characterisation convention presented in this paper then it is important that the use of a CAS Registry Number and corresponding CAS name (and CAS definition) is consistent with the substance in question i.e. it does not contradict the substance characterisation provided by applying the convention described in this paper.

Use of this characterisation convention does not exclude the substances from any legal responsibilities arising from matching listings in national inventories.

APPENDIX 2 – EXAMPLES

The examples below have been provided by the Hydrocarbon Solvents Producers Association (HSPA) who is a sector group of the European Chemical Industry Council (CEFIC). The examples demonstrate how existing substances, which have existing names and CAS numbers, can be named based on the conventions in this paper. The examples given should not be regarded as product specifications.

Example No.	1	2	3
Carbon number distribution (%)			
C5			<10
C6			~45 (35 - 55)
C7			~45 (35 - 55)
C8	1 (0 - 1)	1 (0 - 1)	<10
C9	10	10 (8 - 12)	
C10	40 (38 - 42)	40 (37 - 43)	
C11	42 (40 - 44)	42 (40 - 44)	
C12	6 (4 - 8)	6 (4-11) variation affects the naming	
C13	1 (0 - 2)	1 (0 - 2)	
Hydrocarbon class distribution (%)			
n-alkanes	~25	~22	35 (20 - 50)
branched alkanes	~25	~26	45 (30 - 60)
cycloalkanes	~49.6	~33	20 (15 - 30)
aromatics	~0.4	~19	< 0.1
Benzene	< 0.0001	< 0.01	< 0.01
Phys-chem properties			
Distillation range e.g. ENISO 3405, ASTM D86	160 - 190°C EN ISO 3405	151 - 200°C EN ISO 3405	70 - 100°C EN ISO 3405
Flash point e.g. APcc or PMcc	44°C EN ISO 2719	38.5°C IP 170	< -35°C DIN 51755

Example No.	1	2	3
Specific component descriptor			
e.g Naphthalene, n-hexane			> 5% n-hexane ¹⁰
Name based on conventions in this paper	Hydrocarbons, C9-C11, n-alkanes, branched alkanes , cycloalkanes , < 2% aromatics	Hydrocarbons, C9-C12, n-alkanes, branched alkanes , cycloalkanes , aromatics (2 - 25%)	Hydrocarbons, C6-C7, n-alkanes, branched alkanes , cycloalkanes , > 5% n-hexane
Associated CAS No. (based on source and process)	64742-48-9	64742-82-1	64742-49-0 64742-89-8
Associated CAS Name (based on source and process)	<u>Naphtha (petroleum), hydrotreated heavy</u> : A complex combination of hydrocarbons obtained by treating a petroleum fraction with hydrogen in the presence of a catalyst. It consists of hydrocarbons having carbon numbers predominantly in the 6 - 13 range and boiling in the range of approximately 65°C to 230°C (149°F to 446°F).	<u>Naphtha (petroleum), hydrodesulfurized heavy</u> A complex combination of hydrocarbons obtained from a catalytic hydrodesulfurization process. It consists of hydrocarbons having carbon numbers predominantly in the 7 - 12 range and boiling in the range of approximately 90°C to 230°C (194°F to 446°F).	<u>Naphtha (petroleum), hydrotreated light</u> A complex combination of hydrocarbons obtained by treating a petroleum fraction with hydrogen in the presence of a catalyst. It consists of hydrocarbons having carbon numbers predominantly in the range of C4 through C11 and boiling in the range of approximately minus 20°C to 190°C (-4°F to 374°F). Solvent naphtha (petroleum), light aliphatic A complex combination of hydrocarbons obtained from the distillation of crude oil or natural gasoline. It consists predominantly of saturated hydrocarbons having carbon numbers predominantly in the range of C5 through C10 and boiling in the range of approximately 35°C to 160°C (95°F to 320°F).

¹⁰ Cut-off value according to European Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP Regulation)