

What is a Registered Substance Factsheet?

May 2018

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Version	Changes	Date
1.0	First version	May 2018

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Reference: ECHA-18-H-14-EN ISBN: 978-92-9020-593-7 Cat. Number: ED-01-18-565-EN-N DOI: 10.2823/42973 Publ.date: May 2018 Language: EN

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1. The factsheet

The REACH registered substance factsheet is a dissemination tool introduced by the European Chemical Agency (ECHA) to publish information from Agency's registered substance database.

ECHA is committed to making sure that the public has the widest-possible access to its documents. In accordance with ECHA's legal obligations to make (non-confidential) information on chemicals publicly available, the REACH registered substance factsheet contains public information on registered substances from ECHA's databases. It contains the unique set of non-confidential information from all registration dossiers for each registered substance.

The REACH registered substance factsheet is the set of public information from ECHA's databases for a single joint or individual registrations. It is accessible from ECHA's registered substances webpage, from the substance Infocard and Brief Profile, and from the eChemPortal.

As an Agency, ECHA aims to enhance the safe use of chemicals for humans and the environment, while at the same time promoting innovation and competitiveness in the chemical sector. With the REACH registered substance factsheet and related dissemination tools such as the Infocard and the Brief Profile, the Agency wishes to make people more aware of the risks to which they may be exposed, thus encouraging an overall safer use of chemicals.

The REACH registered substance factsheet's main user functionalities are:

- Presents substance information in a user friendly and printable format;
- Compiles non-confidential information available on a substance extracted from all dossiers of a single or individual registrations under REACH regulation;
 - The information presented in the factsheet is:
 - Substance identification
 - All the unique compositions provided by the registrants
 - $_{\odot}$ $\,$ Identities of registrants / suppliers and year of last update
 - Non-confidential registration numbers
 - o Contact persons responsible for the safety data sheet
 - o Classification and labelling and PBT assessment
 - Manufacture, use and exposure
 - Physical and Chemical properties
 - Environmental fate and pathways
 - Ecotoxicological information
 - Toxicological information
 - Analytical methods
 - o Guidance on safe use
 - Indication whether an assessment report has been provided
 - Details on reference substances
 - Indication of the category(ies) to which a substance can belong

Please note: the REACH registered substance factsheet comes in two shades of blue according to the registration type: a) light blue, for full and intermediate registrations; and b) darker blue for NONS registrations.

hloroacetic acid				D2, #
number: 201-178-4 CAS num	duer. 79 11 8			
() General information	General information	Registration data Administrative data	Contract Pressons responsible for the SUS	
Classeficient on & Laber Eng & PET assessment	Identification			
Manufacture, use & exposure		Display Name	Chloroacetic acid	
~		EC Number	201-178-4	
hysical & Chemical properties		ED Name:	Chloroacetic acid	
4		CAS Number:	79-11-8	
Environmental fate & pathways	-Ac	Molecular formula:	C2H3ClO2	
() Economicological information	CI	IUPAC Name:	2-chlaroscetic acid	
A Texicological information	Type of substance	mono-coratilise	1 mbrianna	
Andynaulandunda	Origin:	organic		
(1)				
Dublance on safe use	Other names			
- 19 ⁴	Trade names:	MCA		
Assessment reports		Manachiaro Acs	Sic Acid	
*		Monochiloroapet		
Reference substances		Monochicrosost Polyanionic Call	ic acid (Solid) (MCA)	
		Polyacione can	Contrast of Conference	
	Total tonnage band			
	Total range:	10 000 - 100 000	lonnes per annum	
	REACH			
	Registered as:	FULL		
		The second se		
	Submitted:	Joint Submissio		

a) Full and intermediate registrations

of the information on department in the ETMA Local S

-3)PEPTIDE			
umber 427-530-9 CAS number -			
General information Mentification Compart on Survivoution Static lay & PET exercision	Registration deta Administrative dete	Context Persons responsible for the SDL	
anofarroy, me & equipara	Display Name:		
*	CC Number:	427-530-9	
visioal & Chemical properties	EC Name:		
9	CAS Number		
truerrisertal fate & participary	IUPAC Name:		
Total tonnage band			
Total range	Tonnage Data (Confidential	
Icoleo ogicel information NONS			
Anti-structured as:	NONS		
Submitted	Individual Subr	lission	
Ouldence on safe use Publication dates			
First published	16-Dec-2013		
Last modified:	21-Apr-2017		
Reference substances Chemical safety assessment			
Performed for this substance:	NO		
Compositions			open all close a
+ Composition 1			
Registrants /Suppliers	of the substance		

b) NONS registrations

1.1. Dissemination

Dissemination is the publication of regulatory and substance centric data from ECHA's databases.

Detailed information on dissemination process in relation to publishing data from registration dossiers under REACH can be found in the manual on "**Dissemination and confidentiality under the REACH Regulation**" following the link <u>https://echa.europa.eu/manuals</u>.

1.2. Generating the factsheets

The registered substance factsheet has been created by ECHA in consultation with various stakeholders, from industry associations to NGOs, and from national authorities to European institutions. The registered substance factsheet is produced based on data in ECHA's databases and maintained by the Agency, and therefore as a dissemination tool it falls under ECHA's responsibility. However, the data contained therein is the responsibility of industry.

Due to the quantity of information and the number of chemicals subject to dissemination, the factsheet is automatically generated based on the information available. The Agency tries to aggregate the information on chemicals in the best possible way, however, the information is not manually verified and therefore, ECHA cannot check whether all the information provided by industry is free of errors.

1.3. Dealing with factsheet errors

If you have questions or concerns regarding the dissemination process or any other comments or suggestions please contact ECHA via <u>https://echa.europa.eu/contact</u>.

If you are a journalist, please contact the ECHA Press Office (press (at) echa.europa.eu).

2. Factsheet sections

The registered substance factsheet provides sections with the most complete data extracted from all dossiers of a single joint or individual registrations. Each section displays the content of the corresponding IUCLID section and includes subsections equivalent to the IUCLID section tree.

IUCLID is a software provided for free by ECHA to record, store, maintain and exchange data on intrinsic and hazard properties of chemicals substances submitted to the Agency under REACH regulation.

Please note: there can be multiple set of results provided per subsection.

E.g. Ecotoxicological information > Aquatic toxicity > Short-term toxicity to fish.

The factsheet header contains ECHA's preferred substance name that has been notified to ECHA, or of which ECHA is aware.

Formaldehyde			
C number: 200-001-8 CAS num	aber: 50-00-0		
Central information Classification & Labelling & PBT assessment Manufacture, use & exposure Physical & Chernical properties Control optical faite & pathway Environmental faite & pathway Environmental faite & pathway Control optical information	Control colocial Summary Contry Control colocial Summary Control colocial Summary	Short-term toxicity to fish Currently viewing: \$-01 Summary Administrative data Link to relevant study record(s) Description of key information Administrative data Link to relevant study record(s) Description of key information Administrative data Link to relevant study record(s) Description of key information Acute toxic to fish: LC59 (96h) = 6.18 mg/L Key value for chemical safety assessment	V
Analytical methods Guidance on safe use Guidance on safe use Assessment reports Assessment reports Reference substances		Additional information The acute data on formaldehyde toxicity to fish are similar and do not vary to a great extent. The most sensitive species is the str (Morone saxatilis) for wich a LC50 (96 h) = 6.18 mg/L is reported (Reardon, 1990). A lower LC50-value of 1.98 mg/L was obtaine same study. However, due to additional hypoosmotic stress this value is considered not relevant.	
hat the information in the dossier i ne Agency or any other authority. T	a correct or that the dossier is complian he content is subject to change without p n of this information may be subject to	ich have been assigned a registration number. The assignment of a registration number does however not guarantee t with Regulation (EC) No 1907/2006 (the REACH Regulation). This information has not been reviewed or verified by role notice.	HA ALS AGENC

Factsheet navigation menu

2.1. General Information

Compiles the most general information on the substance extracted from all dossiers of a single joint or individual registrations under REACH regulation.

E.g. substance identifiers, compositions, registration and administrative data, and contact

information for the safety data sheet (SDS).

2.1.1. Identification

The 'Identification' subsection identifies each substance by name and other identifiers of the same substance. The information of the substance is extracted from all dossiers of a single joint or individual registrations under REACH regulation. The substance identifiers displayed in the factsheet are the substance name, EC number, EC name, CAS number, molecular formula and structural formula image, and IUPAC name, where provided and not claimed confidential.

2.1.1.1. Display name

The display name if provided by the registrant is linked to the relevant Reference substance, which contains the full non-confidential details of the (Reference) substance. For more information on Reference substances see <u>section 2.8</u>.

2.1.1.2. EC number

The European Community (EC) number is the official numerical identifier for substances within the European Union (EU) used by ECHA and are found in the EC Inventory. The EC Inventory is a combination of three independent and legally approved European lists of substances from the previous EU chemicals regulatory frameworks (EINECS, ELINCS and the NLP-list). If the substance was not covered by the EC Inventory, a list number is attributed by ECHA for REACH registration and CLP notification purposes.

2.1.1.3. EC name

The European Community (EC) name is the official nomenclature identifier that has been assigned to substances for regulatory purposes within the European Union by the European Commission.

2.1.1.4. CAS number

The CAS registry number is the substance numerical identifier assigned by the Chemical Abstract Service, a division of the American Chemical Society, to substances registered in the CAS registry database. The CAS number is a widely used chemical identifier.

2.1.1.5. Molecular formula

The molecular formula identifies each type of element by its chemical symbol and identifies the number of atoms of each element found in one discrete molecule of the substance. If the substance ID is not claimed confidential, the molecular formula will be displayed.

2.1.1.6. Molecular structure

The molecular structure provided by the registrants is displayed if not claimed confidential.

General information	Identification Compositions Re	gistration data Administrative data	Contact Persons responsible for the SDS
Classification & Labelling & PBT assessment	Identification	_	
Manufacture, use & exposure	CH3	Display Name:	
2000		CAS Number:	1122460-01-8
hysical & Chemical properties	, i h	CH ₃ Molecular formula:	C14H25NO3

Molecular structure

2.1.1.7. IUPAC name

The IUPAC name is provided by registrants if not confidential and should be based on the international standard chemical nomenclature set by the International Union of Pure and Applied Chemistry (IUPAC).

The IUPAC nomenclature is a systematic way of naming chemical substances, both organic and inorganic. In IUPAC nomenclature, prefixes, suffixes and infixes are used to describe the type and position of functional groups in the substance.

2.1.1.8. Type of substance

Substances under REACH are defined by its chemical composition and origin. The REACH registered substance factsheet publishes the type of substance chosen by the joint submission lead registrant.

- 1. **Composition**: registrants can identify their substance as being a mono-constituent substance, multi-constituent substance, UVCB, polymer or specify another type.
- 2. **Origin**: registrants can identify the origin of their substance (e.g. element, inorganic, organic, organometallic, petroleum product or other).

2.1.1.9. Other names

1. **Trade names:** This list of names is generated from all non-confidential names registered by any registrant in a joint submission under REACH Regulation.

2.1.1.10. Total tonnage band

This is the substance total tonnage placed on the European Economic Area (EEA) market, calculated based on the last reported non-confidential data from all full registration dossiers in the joint submission. For individual submissions a total tonnage is calculated if the submission is of a full registration dossier and the tonnage band is not requested confidential. The exact volume in which a substance is manufactured / imported by a specific registrant is always confidential.

2.1.1.11. REACH

2.1.1.11.1. Registration types

REACH allows to register a substance in different registration types:

- 1. **Full**: registration of a substance that is imported or manufactured per registrant in quantities over 1 ton per year.
- 2. **Intermediate:** registration of a substance that is manufactured for and consumed in or used for chemical processing in order to be transformed into another substance.
- 3. **NONS**: registrations that come from the previous Directive 67/548/EEC before REACH entered into force. On June 1st 2008 NONS was replaced by REACH and notification responsibilities under the NONS directive were repealed. Substances that were notified under NONS and have a recognised notification number were transferred into REACH and are regarded as already having been registered (at the relevant tonnage band).

REACH requires registrants of the same substance to share data and submit information jointly to ECHA:

- 1. **Joint submission:** When a substance is manufactured or imported by more than one company, these companies are required to submit certain information jointly. Joint submission applies to any substance to be registered, including on-site or transported isolated intermediates.
 - a. Lead registrant: a registrant submitting the joint registration dossier to ECHA on behalf of the other registrant(s) in the joint submission. This can include information such as the boundary composition of the substance, classification and labelling of the substance, uses, study summaries, endpoints on physico-chemical, environmental, toxicological and ecotoxicological data, and testing proposals.
 - b. Member registrant: all the registrants that join the joint submission created by the lead registrant and who shall submit the member dossiers to ECHA. This should include information about the identity of the company and the substance, the identified volumes of manufacture / import and can include additional information on their own uses of the substance and the exposure information (for substances between 1 to 5 tonnes).
- 2. **Individual submission**: all registrants that have submitted their registrations individually i.e. not as a members of a joint submission.

2.1.1.11.2. Indication arising from joint submissions

- 1. No indication implies that the data is provided by the lead registrant.
- 2. 'Opt-out' in brackets after a study indicates that the same data is provided by both the lead registrant and a joint submission member, and that the member has opted out for whatever reason.
- 3. The 'JS Member' followed by 'opt-out' in brackets after a study indicates that the data comes only from joint submission member(s), who have opted out from any data provided by the joint submission lead and have instead provided their own data.
- 'JS member' in brackets indicates that the data comes only from joint submission member(s) who have provided their own data, for example in the section Guidance on safe use.

thanol			as a second s
number: 200-578-6 CAS num	ber: 64-17-5		
Classification & Labelling & Classification & Labelling & PBT assessment Manufacture, use & exposure Physical & Chemical properties Servironmental fate & pathways	Toxicological Summary Toxicokinetics, metabolism and distribution Acute Toxicity Irritation / corrosion Sensitisation Repeated dose toxicity Genetic toxicity Carcinogenicity Toxicity to reproduction Specific investigations Neurotoxicity Immunotoxicity Immunotoxicity Indocrine disrupter mammalian screening - in vivo (level 3)	Administrative data Justification for class Administrative of 010 Sup 005 Sup 005 Sup 007 Sup 010 Sup 011 Sup 013 Sup 013 Sup 013 Sup 013 Sup 013 Sup	porting Experimental result porting Experimental result porting Experimental result porting Experimental result porting Experimental result porting Experimental result (Op-out) porting Experimental result (JS Member) (Opt-out)
Ecotoxicological information	 Specific investigations: other studies Exposure related observations in 	Key value for chemical	•
	humans		aiauon route
Toxicological information	 Toxic effects on livestock and pets 	Endpoint conclusion	
	- Additional toxicological data	Endpoint conclusion:	adverse effect observed
Analytical methods		Dose descriptor:	NOAEC
			19 000 mg/m³
		Study duration:	subchronic

Indications from joint submission: Data provided by the lead registrant and 'Opt-outs'

Ethanol		8 🚔
EC number: 200-578-6 CAS numb	ber; 64-17-5	
General information	Guidance on Safe Use	
Classification & Labelling & PBT assessment Classification & Labelling & PBT assessment Manufacture, use & exposure Physical & Chemical properties SS Environmental fate & pathways Ecotoxicological information Calculation of the state of the stat	Currently viewing: 0021 Guidance on safe use (JS Member) Administrative data 0021 Guidance on safe use (JS Member) Big Guidance on safe use (JS Member) 0041 Guidance on safe use (JS Member) 0051 Guidance on safe use (JS Member) 0051 Guidance on safe use (JS Member) 0051 Guidance on safe use (JS Member) 0051 Guidance on safe use (JS Member) 0051 Guidance on safe use (JS Member) 0051 Guidance on safe use (JS Member) 0051 Guidance on safe use (JS Member) 0051 Guidance on safe use (JS Member) 0051 Guidance on safe use (JS Member) 0051 Guidance on safe use (JS Member) 0051 Guidance on safe use (JS Member) 0051 Guidance on safe use (JS Member) 0051 Guidance on safe use (JS Member) 0051 Guidance on safe use (JS Member) 0151 Guidance on safe use (JS Member) 015 Guidance on safe use (JS Member) 0151 Guidance on safe use (JS Member) 015 Guidance on safe use (JS Member) 0151 Guidance on safe use (JS Member) 021 Guidance on safe use (JS Member) 021 Guidance on safe use (JS Member) 021 Guidance on safe use (JS Member) 021 Guidance on safe use (JS Member) 021 Guidance on safe use (JS Member) 021 Guidance on safe use (JS Member) 021 Guidance on safe use (JS Member) 0221 Guidance on safe use (JS Member) 021 Guida	
	and the second	na akin kalif

Indications from joint submission: Information provided only by JS members

2.1.1.12. Publication dates

- 1. **First published**: it refers to the first publication date of the REACH registered substance factsheet on the ECHA website.
- 2. **Last modified**: it refers to the last modification date of the REACH registered substance factsheet on the ECHA website.

2.1.1.13. Chemical safety assessment:

The Chemical safety assessment (CSA) ensures that the risks related to exposure to a substance, during its manufacture and use, are controlled when specific operational conditions (exposure scenario) and risk management measures are applied.

If a CSA was performed then an indication of this will be published in the REACH registered substance factsheet. Additional information on the parts contained in the chemical safety report (CSR) and the tool used to generate the CSA/CSR is published in the 'Assessment reports' section, unless claimed confidential. However, the chemical safety report itself is not published.

2.1.2. Compositions

The composition describes the identity of the substance at a compositional level. A composition may contain the identities of each constituent and the main impurities and additives, if relevant for hazard classification and labelling, and not claimed confidential.

2.1.2.1. Type of composition

The 'Type of composition' field allows registrants to indicate more precisely the nature of the composition they have provided:

- 1. **Legal entity composition**: it reflects the composition of the registered substance as manufactured or imported by the registrant.
- 2. **Boundary composition of the substance**: it refers to the technical reporting in the IUCLID technical dossier of all the compositions of the substance covered by the registration.
- 3. **Composition of the substance generated upon use**: it is a composition / form of the registered substance generated in the supply chain by processes other than manufacture such as purification or generation or nanoform from bulk form by mechanical process.
- 4. **Other**: a composition of any other type as provided by a registrant.

All non-confidential registered compositions submitted in REACH dossiers are published.

Please note: All non-confidential registered compositions from the above types 2-4 will only appear in dossiers submitted after 21st June 2016.

2.1.2.2. State and Form

The information on the physical state and form of the registered substance should be provided, in particular when the substance can exist in different states and forms, and then these may have an impact on the properties and classification of the substance. Where the substance covers different physical states or forms, a separate composition will be created for each of them. The information on state and form will be published.

2.1.2.3. Degree of purity

The degree of purity corresponds to the overall concentration range of the main constituents in the composition. The degree of purity needs to be provided and it will be published if the registrant indicates that at least one impurity or additive is essential to the classification and labelling of the substance (i.e. dangerous). However, the degree of purity will not be published if the registrant claimed it confidential.

2.1.2.4. Constituents

A constituent is any single species present in a substance that can be characterised by its unique chemical identity. A main constituent, not being an additive or impurity, is a constituent that makes up a significant part of that substance.

For legal entity compositions, the identity of each constituent will be published unless there is a confidentiality claim on the IUPAC name of the registered substance. However, for boundary compositions, compositions of the substance generated upon use and other composition types, the identity of each constituent will be published unless there is a constituent in the composition that is claimed confidential.

2.1.2.5. Impurities

Impurities are unintended constituents present in a substance as manufactured. It may, for example, originate from the starting materials or be the result of secondary or incomplete reactions during the production process.

Impurities that are relevant for the substance classification need to be indicated and will be published unless claimed confidential by the registrant.

2.1.2.6. Additives

Additives are the constituents which have been intentionally added during the manufacturing process to stabilise the substance.

Additives that are relevant for the substance classification need to be indicated and will be published unless claimed confidential by the registrant.

2.1.3. Registration data

2.1.3.1. Registrants / Suppliers of the substance

This section provides information on registrants or / and suppliers of a substance registered under REACH. Company names and locations are published as submitted in REACH registration dossiers.

1. Active: a registrant has indicated to ECHA that the registered substance is being manufactured and / or imported actively within the EU market.

In the case of a merge between two companies having a registration for the same substance, registration containing the higher tonnage band will be maintained as active, whereas the other registration as annulled. The annulled registration is still legally valid and considered as an active registration but is no longer updated.

2. **Inactive**: a registrant has indicated to ECHA that they have ceased manufacture and / or import of their registered substance.

Please note: when the registration status is revoked, the registration will still be published as active for a period of 90 days due to ongoing appeals, however when the appeal outcome is known, the registration will appear determined by the appeal decision. A registration can be revoked for different reasons (e.g. not paying a fee to ECHA or not performing a requested analysis or for breaching the 'one substance, one registration' principle).

Under the 'Registrants / Suppliers of the substance' section, ECHA compiles in tables information on the registrants by current status (e.g. active or not), adds a black dot feature

(•) next to the name of those registrants that have updated their dossier at least once since registration, and displays a IUCLID symbol $\stackrel{\blacktriangleleft}{\stackrel{\bullet}{}}$ under the year of the latest dossier update.

rmaldehyde	R 🚔
	General information
	Identification Compositions Registration data Administrative data Contact Persons responsible for the SDS
	- Registrants / Suppliers - INACTIVE
	Latest dossier received
	Registrant / Supplier details 2008 2009 2010 2011 2012 2013 2014 2015 2016 2017 2018
	Caldic Chemie Produktie B.V. Westerlaan 1 3016 CK Rotterdam Netherlands
	FARCOLL Fabbrica Resine Collanti via Lorenzo Perosi 40 15057 TORTONA (AL) PIEMONTE Italy
	EOCHIM PLC East Industrial Zone, Himkombinatska Str. 6403 Dimitrovgrad askovo Bulgaria
	The Acta Group EU, Ltd (22) Brook House Suite 2B 64-72 Spring Gardens M2 2BQ Manchester United Kingdom
	Administrative data open all close all + Registration numbers - ACTIVE
	+ Registration numbers - INACTIVE
	+ Registration numbers - RETIRED
	Contact Persons responsible for the SDS open all close all
	+ Contact info
nat the information in the dossier ne Agency or any other authority. T	ces comes from registration dossiers which have been assigned a registration number. The assignment of a registration number does however not guarantee is correct or that the dossier is compliant with Regulation (EC) No 1907/2006 (the REACH Regulation). This information has not been reviewed or verified by The content is subject to change without prior notice. In of this information may be subject to copyright protection. Use of the information without obtaining the permission from the owner(s) of the respective of the owner.

Features in Registrant / Suppliers section

2.1.4. Administrative data

2.1.4.1. Registration number

The REACH registration number is assigned by ECHA to the registrant once the registration of a substance under the REACH Regulation is complete. The REACH registration number for each registrant is considered to be information contained in the SDS and will therefore be published in full unless claimed confidential. The registration number is published partially when the legal entity name is claimed confidential.

- Registration numbers - ACTIVE	
. 01-2120002101-88-0000	
a bar D. A. Marine S. M. M. M. S. S. S. S.	an general second and a second an grade.
Registration number pu	blished completely
dministrative data	open all close a
Registration numbers - ACTIVE	
01-2119430456-42-XXXX	
01-2119430456-42-XXXX	and and the second second second second
01-2119430456-42-XXXX Registration number p	ublished partially
an gan an again an	ublished partially
Registration number p	

Registration number claimed confidential

Please note: the REACH registration number can be communicated down the supply chain to avoid duplicate registration. However, substances without a registration number will not be allowed to be sold on the EU market.

- 1. Active: a registrant has indicated that the registered substance is being manufactured and / or imported within the EU market.
- 2. **Inactive**: a registrant has indicated they have ceased manufacture or import of their registered substance and / or a registration has been revoked.
- 3. **Retired**: Two registrants each with a registration for the same substance, have merged. As a result the registration for the lower tonnage is marked annulled, however, legally valid but no longer to be updated.

2.1.5. Contact persons responsible for the SDS

This section provides the contact details of the legal person (i.e. company name and address) identified as responsible for the safety data sheet. The information on this contact person is provided by a registrant and it is disseminated unless claimed confidential.

2.2. Classification and labelling and PBT assessment

Classification and labelling of hazardous chemicals is based on the Globally Harmonised System (GHS), agreed in the United Nations. All the information in this section will be published, except for the substance name if the IUPAC name of the registered substance, or one of the constituents in a related composition, has been claimed confidential. All the different classifications and labellings provided by registrants are published in the subsection GHS.

The same dissemination practice as for GHS applies also to information on Dangerous Substances Directive / Dangerous Products Directive (DSD – DPD). The Classification, Labelling and Packaging (CLP) Regulation has amended these directives, and is the only legislation in force in the EU for classification and labelling of substances and mixtures since 2015. All the old classifications and labellings provided by registrants under the previous Directive are published in the subsection DSD-DPD.

PBT substances are persistent, bioaccumulative and toxic, while vPvB substances are

characterised by a particular very high persistence in combination with a very high tendency to bioaccumulate, but not necessarily experimentally proven toxicity. A PBT/vPvB assessment is required for all substances for which a chemical safety assessment (CSA) must be conducted. The information on the PBT/vPvB assessment is considered to be information contained in the safety data sheet and is therefore published, unless claimed confidential. There might be exceptions in the publication of the reference substance attached to this endpoint study record. All summaries and studies provided by registrants are published in the subsection PBT.

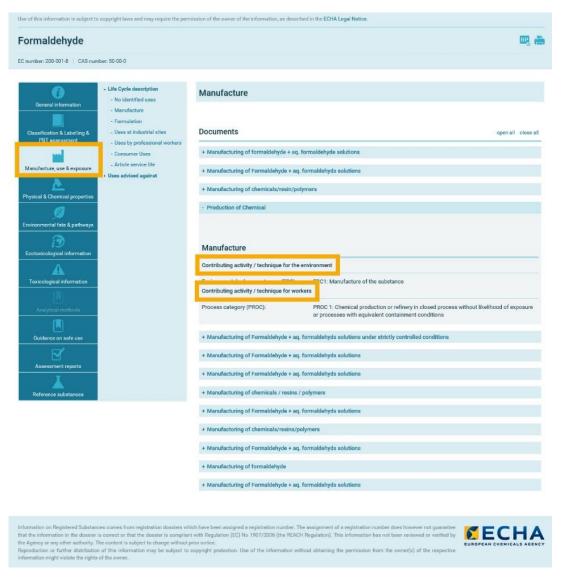
2.3. Manufacture, use and exposure

The 'Manufacture, use and exposure' section is split into two subsections to capture the lifecycle stage of a substance and the uses advised against. The lifecycle stages are published in a structured way that they provide an indication of the type of organisations concerned by the use (e.g. formulators, industrial sites, small scale professional activities, consumers) and whether the substance is in an article during the use. Furthermore, each use of the substance has to be assigned to one of the lifecycle stages and is published as a separate record. Moreover, registrants are required to carry out an exposure assessment in the context of the Chemical Safety Assessment (CSA) and advise against the use for precautionary reasons.

Each use record contains fields for the related exposure scenario indicated as a tab connected to the relevant use. The exposure scenarios are the set of conditions, including operational conditions and risk management measures, that describe how the substance is manufactured or used during its lifecycle and how the manufacturer or importer controls, or recommends downstream users to control, exposures of humans and the environment.

The information on generic exposure potential is also incorporated into the lifecycle description. Information on uses and certain elements related to exposure scenarios are considered information contained in the SDS and it is only published where they have been submitted, unless claimed confidential. This information is present only from submissions where IUCLID 6 was used.

The exposure scenarios are published under contributing activity / technique repeatable blocks and are split into environment and workers / consumers uses. The exposure scenarios include the use descriptor of the relevant type, e.g. Process category (PROC), Environmental Release Category (ERC), Chemical Product category (PC), Article category (AC) and Sector of use (SU).



Exposure scenarios labelling

2.4. Physical & Chemical properties, Environmental fate & pathways, Ecotoxicological and Toxicological information

Article 12(1) and Annex VI of REACH require to collect and include in the registration dossier all physico-chemical and environmental fate properties, as well as toxicity and ecotoxicity data of the substance. Data requirements depend on the tonnage level.

The information contained in each of these sections, i.e. Physical & Chemical properties, Environmental fate & pathways, Ecotoxicological and Toxicological information, is structured as in IUCLID dossiers and includes subsections equivalent to the IUCLID section tree.

Please note: there can be multiple set of results provided per subsection.

The endpoint study records provide information about a study carried out within the subject area defined by the title of the section (e.g. Short-term toxicity to fish). The endpoint study records within an endpoint are displayed in the following order:

- 1. Ordered by Adequacy of a study
 - a. Key study
 - b. Supporting study
 - c. Weight of evidence
 - d. Disregarded due to major methodological deficiencies
 - e. Other information
- 2. Ordered by Type of information
 - a. Experimental study
 - b. Experimental study planned
 - c. Experimental study planned (based on read-across)
 - d. (Q)SAR
 - e. Calculation (if not (Q)SAR)
 - f. Read across based on grouping of substances (category approach)
 - g. Read across from supporting substance (structural analogue or surrogate)
 - h. Not specified
 - i. Other

Fields referring to results will always be published as well as the test material and identity of transformation products with certain exceptions.

Fields referring to robust study summary data will be published if the endpoint study record is not claimed confidential. Robust study summary contains the objectives, methods, results and conclusions of a full study report. ECHA does not hold full study reports.

The endpoint summaries indicate the study results that are considered most relevant to perform a chemical safety assessment for a given endpoint. Information provided in the joint submission lead dossier, if available, is displayed before any information coming from joint submission member dossier(s). Information on endpoint summaries has been published from new and updated summaries from dossiers that were submitted after 20 June 2016. This information enables registrants to highlight key results in the profile of their substance. Furthermore, certain information on the key values for chemical assessment will always be published, even if the endpoint summary is claimed confidential. Additional information from endpoint summaries will be published if not claimed confidential. After the REACH registration deadline of 31 May 2018, any dossier which has not been updated will be reprocessed in order to publish this additional data.

2.5. Analytical methods

This information is requested in accordance with Annexes IX and X of REACH which make possible to detect a hazardous substance when discharged into the environment as well as to determine the direct exposure of humans.

2.6. Guidance on safe use

This section is published in its entirety and should be consistent with the information provided in the SDS.

Furthermore, the Guidance of safe use of the substance can be provided by the Lead registrant on behalf of all members, or separately on a voluntary basis by each member individually.

2.7. Assessment reports

If a chemical safety assessment (CSA) was performed then an indication of this will be published, including additional information on the parts contained in the chemical safety report (CSR) and the tool used to generate the CSA/CSR, unless claimed confidential. However, the chemical safety report itself will not be published.

2.8. Reference substances

The 'Reference substances' section contains the full non-confidential details of every substance relevant to the factsheet. This includes the registered substance itself, constituents, additives, impurities and test materials. Each is stored as a separate 'Reference substance' document, which records all the key information on the molecule such as chemical identifiers and structural information. In the factsheet this information is published if not claimed confidential. Note that if a reference substance is not listed in the EC inventory then the phrase 'No inventory information available' is displayed.

2.9. Categories

The 'Categories' section indicates the category(ies) in which the substance has been placed. A substance can belong to more than one category.

A category is an entity that allows a chemical category to be described within IUCLID 6. The category dataset will be included in registration dossier of the substance to be registered.

	ber: 8002-74-2 sons obtained from petroleum fractions by	olvent crystallization (solvent deoiling) or by the sweating process. It consists predominantly of straight chain hydrocarbons having carbon nu	mbers
eral information	Categories		
cation & Labelling &	Currently viewing: CATEGOR CATEGOR CATEGOR	2	
ture, use & exposure	Category name: Justifications and discus	CONCAWE Paraffin and Hydrocarbon Waxes	
<u>&</u>	Category definition:	see category justification document, sections 1.1, 1.2 & 1.3.	
& Chemical properties	Category order description:	see category justification document, section 1.4.	
ental fate & pathways	Category rationale:	see category justification document, section 2.	
logical information			
ance on safe use			
essment reports			
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Categories

The 'Justification and discussions' subsection specifies the category definition, an order description and the rationale used for defining the chemical category.

- 1. **Category definition:** describe the molecular structure a substance must have to be included in the category, including criteria such as carbon chain length, functionality, chemical or metabolite equivalence considerations, etc., and list the specific substances covered.
- 2. **Category order description:** describe the order of the substance grouped in the category including a brief explanation, if the properties of the category members follow a certain pattern.
- 3. **Category rationale:** describe the rationale behind the category, including the category justification.

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