



IEA Bioenergy
Technology Collaboration Programme

Registration of DTL products and derivatives

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Preface

One of the objectives of IEA Task 34 is to facilitate commercial deployment of Direct Thermochemical Liquefaction (DTL) technologies. A very important and sometimes underestimated step in commercialization of new chemicals and substances is mandatory registration of the new products as well as related costs. Within Task34 an activity was defined to provide some further information and guidance on the registration of DTL products and derivatives.

Summary

The liquid products from Direct Thermochemical Liquefaction process may require registration as a chemical substance to allow introduction on the market. Different registration systems are in place around the world but have in common that they all aim to better protect human health and the environment.

Important part of any registration is the proper description of a substance including chemical, physical and toxicological data. The Global Harmonized System (GHS) was developed by experts from the United Nations (UN) as a universal system to replace different national systems to eliminate mutual misunderstandings and confusion in interpretation of hazard classifications, labels, or SDS's and thus create more unity.

Different substance registrations systems exist like the American TSCA and the European REACH. The latter one is described in some more detail in the report. REACH - Registration, Evaluation, Authorisation and restriction of Chemicals- is an obligatory registration for any chemical substance produced or imported in Europe at quantities above 1 t/a. In the registration a distinction is made in the annual produced or imported tonnage of that substance: tonnage bands are: 1-10 t/a, 10-100 t/a, 100-1000 t/a and >1000 t/a. Fees for registration will increase with increasing tonnage band, but more important also additional substance data should be provided which can become very costly. For the lowest tonnage band, total costs can be in the order of 50 - 150 k€, whereas for the highest tonnage band it can increase to over a million euro.

To support the development of new products a special registration was introduced in REACH called PPORD (Product and Process Orientated Research and Development). It is a simplified registration allowing to perform product testing at any scale and the dossier is confidential. A limitation is that the products from testing cannot be sold, and in principle they need to be recollected and destroyed after the evaluation phase.

The REACH database has been searched for registrations of DTL products. Only a few could be found, being fast pyrolysis bio-oil and fractions thereof.

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List of abbreviations

BTG	Biomass technology Group BV
CSA	Chemical Safety Assessment
CSR	Chemical Safety Report
DEFRA	Department for Environment Food & Rural Affairs
DTL	Direct Thermochemical Liquefaction
DU	Downstream User
ECHA	European Chemicals Agency
EPA	Environmental Protection Agency
FPBO	Fast Pyrolysis Bio-oil
GHS	Globally Harmonized System
GLP	Regulation for Classification, Labelling and Packaging
HPO	Hydrotreated Pyrolysis Oil
HSE	Health and Safety Executive
HTL	Hydrothermal liquefaction
HTU	Hydrothermal upgrading
IUCLID	International Uniform Chemical Information Database
LOA	letter of excess
LPL	Liquid Pyrolytic Lignin
MCL	Mandatory Classification and Labelling
MSW	Municipal Solid Waste
OSHA	Occupational Safety and Health Administration
PPORD	Process Orientated Research and Development
PS	Pyrolytic Sugar
RDF	Refuse Derived Fuel
REACH	Registration, Evaluation, Authorization and restriction of Chemicals
REACH-it	IT application/system to safely submit, process/manage data & dossiers to ECHA
SDS	Safety Data Sheet
SPL	Solid Pyrolytic Lignin
SR&D	scientific research and development
SVHC	substances of very high concern
TSCA	Toxic Substances Control Act
UVBC	Unknown or Variable Composition, Complex Reaction Products and Biological Materials

Introduction

IEA-Task 34 aims to support the commercial deployment of Direct Thermochemical Liquefaction (DTL) processes. One specific aspect concerns the proper labeling and registration of new products to enable market introduction, and obviously also applicable to DTL products.

The United Nations took the initiative to standardize the classification and labelling of chemicals resulting in GHS (Globally Harmonized System of Classification and Labelling of Chemicals) and the use of standard Safety Data Sheets (SDS) and similar symbols. The GHS data is required for the registration process.

Registration of new products is not globally harmonized and differ per country, but have in common that their aim is to improve the registration of chemical substances and to better protect human health and the environment. In Table Table 1 an overview is given of systems existing in the IEA-Task34 participating countries and a few others (1).

Table 1: Registration systems in different countries

Country	System
Canada	(N)DSL - (Non) Domestic Substances List
Finland	REACH - Registration, Evaluation, Authorisation & restriction of Chemicals
The Netherlands	
Germany	
Denmark	
United Kingdom	REACH-UK
USA	TSCA - Toxic Substances Control Act
India	CMSR - Indian Chemical Registration
New Zealand	NZIoC - New Zealand Inventory of Chemicals
Australia	AICIS - Australian Industrial Chemicals Introduction Scheme
China	IECSC - Inventory of Existing Chemical Substance in China China-REACH
Korea	K-REACH - The Act on the Registration and Evaluation of Chemicals
Japan	ENCS - Existing and New Chemical Substances Inventory

Generally, each country/region has its own registration process and registration is obligatory for each product to be produced or imported in a country. Differences do exist in the level of detail required and may depend on the production volume.

In the US the Toxic Substance Control Act (TSCA) was already adopted as a law in 1979 and gives the EPA (Environmental Protection Agency) the authorities to regulate the import, manufacturing, use,

introduction (of new) & distribution of chemicals in the US. The EPA assesses chemicals and new chemicals before entering the market by investigating existing data and or by demanding additional or new tests on environmental and health effect from producer/importer. In case of new chemical (imported or produced), a pre-manufacturing notification is submitted to the EPA. New chemical notifications are then extensively reviewed and depending on the outcome of the various tests (outcome on human health and the environment), the use might be approved, limited, or even banned, noteworthy here is that the TSCA doesn't categorise chemicals in degree of toxicity. When approved the new chemical is added to the list of chemicals which is called the TSCA inventory. Some chemicals are excluded from the TSCA, because they fall under different regulations/acts, such as for instance pesticides and pharmaceuticals (2).

The development of the REACH system started at later stage and included the experiences gained with the development and implementation of TSCA. Some examples of the difference between REACH and TSCA is that the TSCA only uses one list and doesn't distinguish between good or bad (degree of toxicity), a chemical is on or off the list. The ECHA is responsible for carrying out REACH. The ECHA is continue examining and evaluating/assessing new and existing chemicals and substances. The listing of chemicals and substances is more complex and categories having sub-lists. The ECHA applies for instance a Restricted Substances List (substances to be phased out), Authorisation List of substances of very high concern (SVHC) (extra monitored substance) and a Candidate List of SVHC's (substances to be further evaluated). Furthermore, often chemicals to be registered under REACH require more toxicological and eco-toxicological data compared to TSCA and are not simply grandfathered. In generally it can be said that the TSCA is less strict than REACH (3) (4) .

A special case is the United Kingdom where after Brexit a EU-Reach registration is not applicable anymore. The UK initiated the UK-REACH for the regulation on the production and trade of chemical substances. The UK-REACH started as a mirroring of the EU-REACH and it was introduced by the withdrawal act of 2018, applying for England, Scotland & Wales while Northern Ireland enforces the EU-REACH. The principle of the UK-REACH is similar to the EU-REACH regulation, but a separate registration is needed. For example, the EU-Reach registration of fast pyrolysis oil is no longer valid for the UK and export of FPBO to UK is not possible anymore unless a UK-Reach registration is filed by an UK entity or agent (5).

In all cases a proper SDS will be required and preferably should follow GHS. The preparation of the SDS according to GHS will be described in more detail in the next chapter. As an example of the registration process, the EU-REACH system will be briefly described. Finally, current known registration of DTL products will be given.

Globally Harmonized System (GHS) & Safety Data Sheets (SDS)

A Safety Data Sheet should be available for every chemical substance and preferably it has been using the criteria given by GHS. A proper SDS is also of importance for registration of chemicals, and both GHS and SDS are briefly explained below.

GHS

GHS refers to the **Globally Harmonized System** of classification and labelling of chemicals. GHS is a set of criteria for classifying the hazardous properties of substances and mixtures and it aims to adopt these criteria globally to ensure that the correct info on e.g. toxicity is available to protect human health and the environment during handling & transport. The GHS was developed by experts from the United Nations (UN) as a universal system to replace different national systems to eliminate mutual misunderstandings and confusion in interpretation of hazard classifications, labels, or SDS's and thus create more unity. The first GHS version was launched in 2003 and the GHS further evolved and developed in recent years, the latest revised GHS edition was published in 2021 as version 9. The 2 most important elements in the GHS are the rules for classifying the hazards of chemical products and the way these are communicated in e.g., a SDS. In GHS, 9 hazard pictograms are adopted together with multiple hazard statements and precautions. The new hazard pictograms consisting of a diamond outlined in red with a black symbol on a white background replace the old orange black signs (see Table 2) and new labelling phrases (H & P) are introduced (6) (7) (8).

Table 2: Old (left) and new (right) pictograms

	E	Explosive		GHS 01 Explosive
	F+	Extremely flammable		GHS 02 Flammable
	F	Highly flammable		GHS 02 Flammable
	O	Oxidizing		GHS 03 Oxidizing
No symbol				GHS 04 pressurized gases
	C	Corrosive		GHS 05 Corrosive
	T+	Very toxic		GHS 06 Toxic
	T	Toxic		GHS 06 Toxic
	Xi	Irritant		GHS 07 Irritant
	Xn	Harmful		GHS 08 Harmful
	N	Harmful to the environment		GHS 09 Harmful to the environment

EU-GHS & CLP

In 2008 the GHS developed by the UN was adopted in EU law as the regulation for Classification, Labeling and Packaging of substances and mixtures also abbreviated as CLP. The EU-GHS/CLP was subsequently entered into force in 2009 and fully implemented in 2015 (transition period 2009-2015) (1). CLP is legally binding in the whole EU and directly applicable to all industries. The most important objective of CLP is to determine the classification of a substance or mixture and whether it is hazardous including the corresponding signals and phrases. Furthermore, CLP describes the standards (correct labelling etc.) for packaging and shipment of chemical substances and mixtures to ensure safe transport. Subsequently, CLP also often serves as the basis of risk management of chemical substances and mixtures in legislation (9) (10) (11).

EU-GHS is also an important part of REACH and they are well aligned. REACH was adopted to better protect human health and the environment, and chemical substances produced or imported in certain quantities should have a REACH registration. When registration of a new chemical substance is required various physical & toxicological etc. tests must be performed to determine/assign the appropriate classes, symbols, and H & P phrases according to the GHS. The H-phrases briefly describe the hazard properties/statements and the P-phrases the measures to be taken in case of prevention/contact/disposal etc. Additionally, this same info also needs to be used in the preparation of an SDS (9) (12). The REACH registration process is explained in more detail in the next chapter.

SDS - Safety Data Sheet

According to the REACH regulation, chemicals/substances need to have a SDS (Safety Data Sheet), previously also called a MSDS (Material Safety Data Sheet). This SDS must be prepared by the party who is producing or importing that particular chemical/substance. The SDS can be seen as a universal information package for the receiving party on among others safety, storage, etc. A SDS should be drafted according REACH regulations No. 1907/2006 and CLP Regulations No. 1272/2008, with a revised version No. 2015/830 (due to changing GHS/CLP symbols etc.). As earlier mentioned, comprehensive chemical, physical, toxicological & eco-toxicological analysis needs to be performed when building REACH dossier. From these studies the hazards are then classified and translated to hazard pictograms, multiple hazard statements and precautions (H & P symbols) which should then be used in the corresponding SDS. In case changes are made to the dossier or information is added, e.g. due to a change in annual production or changing regulations by ECHA, obviously an update of the corresponding SDS should be prepared. For the follow substances a SDS is required (13) (14):

1. a substance or a mixture meets the criteria for classification as hazardous according to CLP; or
2. a substance is persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB), according to the criteria given in Annex XIII of REACH, or;
3. a substance is included in the candidate list for eventual authorisation according to Article 59 (1) of REACH for any other reasons.

For some substances mixture no SDS's is required such as certain foodstuffs, animal feeds, medicines, wastes, non-isolated intermediates etc. A SDS is made up of 16 different sections with different sub-sections which were internationally agreed, as shown in Table 3, an extended overview of this can be found in reference (14).

Table 3. SDS layout by sections

Section	Description
1	Identification of the substance/mixture and of the company/undertaking
2	Hazards identification
3	Composition/information on ingredients
4	First aid measures
5	Firefighting measures
6	Accidental release measures
7	Handling and storage
8	Exposure controls/personal protection
9	Physical and chemical properties
10	Stability and Reactivity
11	Toxicological information
12	Ecological information
13	Disposal considerations
14	Transport Information
15	Regulatory information
16	Other information

In Appendix A examples are given of a SDS for FPBO as well as HTL Biocrude. However, each supplier is responsible for its own SDS.

REACH registration

As previously mentioned, each country/region has its own registration system. As an example of such registration process the European REACH is discussed in some more detail.

REACH is the European Union regulation on the production and trade of chemical substances in the EU, it stands for **R**egistration, **E**valuation, **A**uthorisation and **R**estriction of **C**hemicals. REACH was adopted (on 1 June 2007) to better protect human health and the environment. All chemical substances produced or imported in quantities above 1 t/y are obligated to have a REACH registration with some exceptions (e.g. radioactive substances, waste materials and pesticides). In principle, there is no distinction in what industry or application the chemical substance is used. In other words, chemical substances used in f.i. cleaning products, care products or food stuff need to be registered just like chemical substances used in the industrial (chemical/manufacturing) processes. Companies who produce, import, distribute or use chemical substances must deal with REACH. To comply with REACH, companies producing or importing chemical substances must present the risks associated with those substances. In general, this means that comprehensive chemical, physical and toxicological analysis needs to be performed (degree also depending on the annual production) and how the product can be safely used and thus what risk mitigation should be taken. This data is then reviewed by the ECHA and should also be used in the SDS. The ECHA (European Chemicals Agency) executes and manages REACH and can subsequently accept the dossier, ask for additional input or restrict or even forbid the use (together with EU members) of a substance in certain applications if the risks cannot be sufficiently controlled (15) (16) (17).

Registration process

The registration process starts with the submission of a so-called inquiry dossier to ECHA with the aim to determine whether already a registration or inquiry exists for the same chemical. It would allow for data sharing, limit the need for e.g. animal testing and minimize the costs of registration. In case the substance is already registered access to the existing data and registration should be obtained via a “*Letter of Access*” from the Lead registrant. When multiple inquiries exist for a specific substance but not yet registered then the approach is to build a consortium to prepare the substance dossier together (“*Joint submission*”). One of the members of such consortium will act as the Lead Registrant. In case the substance was not yet registered, and no other inquiries exist an own registration dossier should be prepared (“*single submission*”).

Dossier building

All chemical substances produced or imported in the EU in quantities above 1 t/y are thus obligated to have an EU-REACH registration. A substance dossier should be prepared in the online ECHA tool called IUCLID (International Uniform Chemical Information Database), and a simplified IUCLID version does exist for SMEs. A dossier consists of several chapters & sections requiring data on e.g. chemical & physical properties, environmental and toxicological data, information on safe use, etc, see Table 1. Each chapter has several subsections (16) (18).

Table 1: IUCLID chapters

IUCLID Chapter	Content
1	General Information
2	Classification & Labelling and PBT assessment
3	Manufacture, use and exposure
4	Physical and chemical properties
5	Environmental fate & pathways
6	Ecotoxicological information
7	Toxicological information
8	Analytical methods

9	Residue in food and feeding stuffs
10	Effectiveness against target organisms
11	Guidance on safe use
12	Literature search
13	Assessment reports
14	Information requirements

The exact data required for a substance dossier depends on the type of registration and tonnage band. Four different tonnage bands exist: 1-10 t/a, 10-100 t/a, 100-1,000 t/a and > 1,000 t/a. The latter one requiring the most detailed information. Often in REACH dossier building of a new substance starts with the lowest band and in time this is expanded to a higher band. Data obtained in a lower band registration can be used in the following higher band, but as mentioned additional info is required. In case the substance is used as raw material for further processing (on-site or elsewhere) registration as isolated intermediate can be considered, which requires limited data on the substance. A special registration category is the so-called PPORD suitable for product research and development (see next §).

A complication concerning the registration of DTL products are their definition. Pyrolysis oil and HTL biocrude contain many different components and exact composition will even depend on the original biomass feedstock. In REACH these products qualify as UVCB's: substances of Unknown or Variable Composition, Complex Reaction Products and Biological Materials. UVCB's have a complex composition which often complicates the execution of standard testing and often therefore require extra/other tests.

PPORD

PPORD stands for Product and Process Orientated Research and Development and is a special kind of registration under REACH which allows the import & production of substances in quantity larger than 1 t annually for scientific research and development (SR&D). An advantage of PPORD is that it only demands a relatively concise dossier/registration (cheap) compared to a full REACH dossier/registration. PPORD gives many exemptions from authorization and restrictions and there is no limit on the amount of product manufactured or imported. A large disadvantage though is that products or final products cannot be used/sold to the general public. A product is made and can subsequently be tested by an end-user, but after the evaluation phase the product needs to be recollected and destroyed. Also, PPORD registration is limited to a specified time and customers need to be registered as well. PPORD is confidential which might be a clear advantage in the RTD period (19) (20).

CSA & CSR

When a chemical/substance is produced or imported in quantities of ≥ 10 t/y, a chemical safety assessment (CSA) has to be performed. A producer has to do this both for both the manufacturing process and different uses, an importer only has to do this for the uses. A CSA consist of different steps, first a hazard assessment must be performed to determine human health hazards, environmental hazards and so called PBT and vPvB assessment (persistent, bio-accumulative and toxic substances and very persistent and very bio-accumulative substances). In case the hazard assessment concludes that the chemical/substance is indeed a hazardous substance with additional classification, an exposure assessment and risk characterisation have to be performed. In the exposure assessment the effect of the chemical/substance during the manufacturing or use by employees/end-user is assessed. Together with this also an exposure scenario(s) need(s) to be prepared in which each exposure (contact) step with employees/end-users and/or the environment during manufacturing and use is described. The risk characterisation actually combines the info obtained in the hazard assessment and the exposure assessment to indicate the risk on humans and the environment. All the info gathered in the CSA is subsequently reported in a document, called the chemical safety report

(CSR) which should be submitted to the ECHA (21) (22).

Costs of REACH registration

REACH registration of chemicals and substances is a costly process and can be roughly subdivided in three categories:

- Fees for registration
- Costs for data generation (e.g. outsourcing chemical, physical, toxicological analysis)
- Time (own time and/or consultancy services)

In case of a single submission all the costs must be carried by the (sole) registrant. From a cost point of view a joint submission is attractive as some of the costs can be shared, making the total costs for individual registrants lower. For an existing registered substance access to a registration can be bought via a “letter of access”. This LoA is not for free, and will compensate the original registrant(s) for the cost made for preparing the dossier.

Registration fees

The fees for REACH registration are a relatively small part of the total costs and depend on the annual production capacity and the company size. An indication of the ECHA fees is given in Table 4 (23).

Table 4. Cost ECHA registration

Production band	Company size & cost (€)			
	Normal	Medium	Small	Micro
>1000 t/y	24,901	16,185	8,715	1,245
100-1000 t/y	9,237	6,004	3,233	462
10-100 t/y	3,454	2,245	1,209	173
1-10 t/y or intermediate	1,285	835	450	64

Cost for data generation

In particular, performing and/or outsourcing all the required chemical/physical and toxicological analysis can be very expensive. Furthermore, the data requirement will increase with increasing tonnage band and therefore also the costs. In a research paper by M. Fleischer, an estimation was made on the laboratory costs per annual production band and given in Table 5 (line 1). The information gathered in this paper was obtained by a survey sent to 28 independent laboratories located in different countries. Similar to this, an estimation was made of the cost of “the required information” by an UK consultancy company also given in the same table (line 2). Both estimations are in the same order of magnitude (23) (24) (25).

Table 5. Cost estimation of REACH information gathering

Reference		k€/annual production band			
		1-10 t/y	10-100 t/y	100-1000 t/y	>1000 t/y
1	Average prices given in survey Fleischer (25)	56	280	800	1,583
2	Cost of required info by consultant (24)	< 10-80	50-200	150-900	750-2,000

Own time & Consultancy services

Preparing a registration dossier is time consuming and needs specific expertise. Large companies typically have in-house experts, but SMEs often need to contract consultants to guide and support the registration process (Substance inquiry, dossier building and IUCLID submission). Based on experience at BTG, the fees for external consultancy service can also be in the range of 40-50 k€ per registration in addition to the own time spent.

Letter of Access

A Letter of Access (LoA) is a way to access the required information for registration of a substance in case there is already an existing registration for a specific substance. By buying a LoA from the lead registrant or consortium, part of the costs made in the dossier building and registration are paid. A LoA provides access to the required information, but not the ownership of the data. The new registrant still must complete its own registration at ECHA. The costs of LoA depend on the specific substance and can vary substantially, e.g. it depends on number of producers/importers, and actual costs made for analysis. A LoA or registration cannot be traded or transferred to another party (26) (27).

Downstream user

In a substance registration dossier, the use of the substance is also described. If an application is not covered by the registration, then either the lead registrant can be asked to add the application, or a Downstream User Report should be prepared. A downstream user or DU is the party that uses chemicals/substances that are produced or imported in the EU and apply them in their process. A DU can be an end-user, but also a company that just trades the chemical/substances or blends it in certain formulations (e.g., paints, resins, etc.). A DU receives the chemical/substance from a certain producer/supplier which includes the SDS of the substance. In the SDS, the use of the substance is described including exposure scenarios (≥ 10 t/y) from production to disposal (provided as annex to SDS). The DU is obliged to ensure that his application is covered or mentioned in the SDS including the correct risk management measures. In case the existing SDS is not or not completely covering (exposure scenarios) the new application, the supplier should assess the new application and additional data concerning safe use should be provided. Additionally missing data could be obtained from e.g., a SDS of another supplier if relevant or by preparing a Downstream User Chemical Safety Report (DU CSR) (28) (29).

Existing registrations of DTL products & derivatives

REACH registration is also obligatory to products derived from Direct Thermochemical Liquefaction processes or imported into Europe at quantities exceeding 1 t/a. The ECHA database has been searched for existing registration of DTL (derived) products. Additionally, some substances were identified which might be relevant for ‘substance inquires’.

Fast Pyrolysis Bio-Oil (FPBO)

Fast Pyrolysis Bio-oil has been registered in REACH. The activities started in 2012 with a pre-registration of the oil which included oil from fast and slow pyrolysis. Due to differences in properties and toxicity it was decided to split in two separate registrations. Finnish company Fortum took the lead in the registration of fast pyrolysis oil derived from lignocellulosic biomass. Other co-registrants were a.o. Green Fuel Nordic, Billerud and UOP.

Table 6: Substance Identity Profile for FPBO in the EU-REACH registration

SIP - Substance Identity Profile		
Substance name:	Fast Pyrolysis Bio-Oil (FPBO)	
Cas number:	1207435-39-9	
Definition:	Liquid condensate recovered by thermal treatment of biomass, like wood, at short hot vapour residence time (typically less than about 10 seconds) typically at between 450-600 °C at near atmospheric pressure or below, in the absence of oxygen,	
Properties	value	unit
pH	2-3.5	-
Water	<40	wt%
Ash content	<0.5	wt%
Solids content	<0.5	wt%
Viscosity (40 °C)	<200	mm ² /s
Density(kg/dm ³)	1.1-1.3	kg/L
Polar components		
Formaldehyde	<0.5	wt%
Methanol	< 3	wt%
Non-polar components		
PAH 13 ^a	< 35	ppm
Benzo(a)pyrene	< 0.01	wt%
Dibenzo(a,h) anthracene	<0.01	wt%
Sum of Carc, 1B classified substances ^b	< 0.1	wt%
Sum of Carc, 2 classified substances	<1.0	wt%
^a Sum PAH13: Anthracene, Benz[a]anthracene, Benzo[a]pyrene, Benzo[a] fluoranthene, Benzo[k]fluoranthene, Benzoperylene, Chrysene, Dibenz[a,h], Anthracene, Fluorene, Fluoranthene, Indenopyrene, Phenantrene, Pyrene. ^b Carc. 1B classified substances (Annex VI of CLP regulation 1272/2008), e.g. Benz[a]anthracene, Benzo[a]pyrene, Benzo[k] fluoranthene, Chrysene, Dibenzo[a,h]anthracene. ^c Carc. 2 classified substances (Annex VI of CLP regulation 1272/2008): e.g. Formaldehyde, Acetaldehyde, Furfural		

FPBO is a complex product and first proper definition of the product is needed for registration. For the purpose of the REACH registration FPBO is described in the so-called SIP - Substance Identity Profile, see Table 6. On one hand the definition should be specific enough to characterize the product,

on the other hand it aims to be broad enough to cover FPBOs of different origin to avoid that each FPBO would require its own registration. The current definition covers FPBO from different fast pyrolysis technologies as well as different biomass feedstocks. It excludes pyrolysis oil from slow and intermediate pyrolysis as well as oil produced from plastics or biomass/plastic mixtures (e.g. RDF, MSW, etc). Whether FPBO from catalytic pyrolysis complies with the SIP is unclear as it may affect e.g. the concentration on non-polar components. The measurement of the polar and non-polar components in FPBO appeared to be complicated and it requires specific attention (30), (31).

FPBO is classified as a so-called UVCB (Unknown or Variable composition, Complex reaction products or biological materials). In the EU, FPBO is REACH registered for a production band of >10,000 to 100,000 t/y. Application of the FPBO is described as a fuel. The registration is a joint submission and the lead registrant for the REACH registration of FPBO is Finnish company Savon Voima Joensuu Oy. The registration itself can be found at the ECHA- site (32). The registration dossier was largely built on the data generated in the European BioTox project (BIOTOX NNE5/744/2001) (33).

In Fig. 1 the companies who are currently listed as FPBO supplier are listed. Empyro and Pyrocell were not a member of the original consortium but entered this dossier via a Letter of Access.

Registrants / suppliers of the substance

[open all](#) [close all](#)

- Registrants / Suppliers - Active		
Registrant / Supplier	Registered	Updated
Empyro B.V. Boldershoekweg 51 7554 RT Hengelo Overijssel Netherlands	2018	2018
GFN Lieksa Oy Talttatie 10 81700 Lieksa Finland	2021	2022
Pyrocell AB Redovisning Box 3071 169 30 Solna Sweden	2022	
Savon Voima Joensuu Oy PL 1024 Kapteeninväylä 5 70900 Toivala Finland	2013	2014; 2016; 2021
UOP S.r.l._OR005 Viale Milanofiori Strada 1 - Palazzo E1 20090 Assago Italy	2017	2022

Fig. 1: Companies currently listed in the FPBO REACH dossier

HTL Biocrude

No existing registration dossier of HTL biocrude was found yet in the ECHA database (34). It is possible that a PPORD was submitted for this product but these dossiers are confidential. One registration was found concerning oil products from hydrothermal treatment of waste plastics but considered less relevant in the context of this report.

FPBO fractionation products

In FPBO, the original functionalities of the biomass material are retained in shorter molecules. The fractionation of FPBO to obtain the pyrolytic sugar & pyrolytic lignin has been developed and individual fractions can be used as raw material for e.g. biobased products (35). To enable commercialization and product development PPORDS as well as standard registrations have been submitted by BTG for the lignin as well as the sugar fraction.

The PPORD and registration dossiers for both products were developed together with strong support from a dedicated consultant. Part of the required analysis was done in-house, but significant part was outsourced to a (certified) lab. The costs of a single dossier (registration, consultancy service, external analysis) were around 125 k€ excluding internal costs. In both cases the registration is just for a capacity of 10 t/a.

Liquid Pyrolytic Lignin (LPL)

LPL (CAS nr 2411004-28-7) is a product from FPBO fractionation. Fractioning is done by water addition leading to a water phase enriched in sugar derivatives (pyrolytic sugar) and an organic phase with the lignin-derived fragments (LPL). The substance can be isolated in amounts up to 30 wt. % of the original oil. LPL is an UVCB and initially PPORD registered followed by a full registration (EC list number: 951-939-6/858-660-8). REACH number PL: 01-2120886738-31-0000, REACH dossier (1-10 t/y) submitted in June 2021. Lead registrant: BTG Biomass Technology Group BV.

Pyrolytic lignin

EC number: - | CAS number: -

Substance identity

Identification Type of substance Substance identifiers Compositions

Identification

Display Name: Pyrolytic lignin from fast pyrolysis bio-oil
CAS Number: 2411004-28-7
IUPAC Name: Pyrolytic lignin from fast pyrolysis bio-oil

Type of Substance

Composition: UVCB
Origin: organic

Substance Identifiers [open all](#) [close all](#)

EC number

- 858-660-8

Compositions

Boundary Composition(s) [open all](#) [close all](#)

- Pyrolytic lignin from fast pyrolysis bio-oil

Fig. 2: Reach registration of pyrolytic lignin

Solid Pyrolytic Lignin (SPL)

SPL (CAS nr 2411004-20-9) is produced from Liquid Pyrolytic lignin (LPL) by thermal aftertreatment. LPL is an UVCB and REACH registered (see above); the produced SPL is a polymer according to REACH criteria, and therefore does not require an own registration.

Pyrolytic Sugar (PS)

PS (CAS 2414605-13-1) is the other product obtained from the fractionation of FPBO and is enriched in sugar derivatives. PS is an UVCB and initially PPORD registered followed by a full registration (EC list number: 951-905-0/858-661-3). REACH number PS: 01-2120886739-29-0000, REACH dossier (1-10 t/y) was submitted in June 2022. Lead registrant: BTG Biomass Technology Group BV

Pyrolytic sugar BP

EC number: - | CAS number: -

General information

- Classification & Labelling & PBT assessment
- Manufacture, use & exposure
- Physical & Chemical properties
- Environmental fate & pathways
- Ecotoxicological information
- Toxicological information
- Analytical methods
- Guidance on safe use
- Assessment reports
- Reference substances

Administrative information

Substance registration details Registrants/suppliers of the substance Registration numbers

Contact Persons responsible for the SDS

Substance registration details

Total tonnage band

Total range: ≥ 1 to < 10 tonnes

REACH

Registered as: FULL

Submitted: Joint Submission

Publication dates

First published: 12-Jul-2021

Last modified: 27-Jun-2022

Chemical safety assessment

Performed for this substance: NO

Registrants / suppliers of the substance open all close all

- Registrants / Suppliers - Active

Registrant / Supplier	Registered	Updated
BTG Biomass Technology Group BV Josink Esweg 34 7545 PN Enschede Netherlands	2021	2022

Fig. 3: REACH registration of Pyrolytic sugar

Products with potential relevance for substance inquiries

New products from DTL processes may require their own registration, but the first step is always to evaluate whether existing registration will already cover the new product.

Liquid smoke

Liquid smoke is prepared by the pyrolysis of certain wood (hardwood) species. Liquid smoke is used as a flavouring agent in the preparation of foodstuff e.g. meat or in BBQ sauces. Liquid smoke flavouring is not obligated to have a REACH registration because it falls under foodstuff/food additives. Nevertheless, it falls under the supervision of the EFSA and smoke flavouring is a topic of discussion due to its composition and being weakly genotoxic. There was no CAS or EC number found for liquid smoke, although it is registered in the (US) Food and Drug Administration (FDA) under no: 977102-14-9.

Wood creosote

Wood creosote is produced by the dry distillation of wood and was in the past used in medicine and more recently used in the preservation of wood and wood products to protect them against the elements and wood decaying insects and fungi. Wood creosote is CAS registered (8021-39-4) and it has an EC list number (232-419-1) and has a ECHA infocard (no full REACH registration). This wood creosote dossier might be relevant/useful for the registration of light components derived from pyrolytic lignin.

Wood vinegar/Pyroligneous acid

Wood vinegar or pyroligneous acids is produced by the slow pyrolysis of ligno-cellulosic biomass. In slow pyrolysis the biomass is converted to char, pyrolysis vapours and non-condensable gases. From the vapours the wood vinegar is produced after condensation. Wood vinegar contains a large part of water and is acid due to the a.o. present acetic acid. Wood vinegar is f.i. used as a fertiliser and or pesticide. Wood vinegar is CAS registered (8030-97-5) and it has a EC list number (232-450-0) and a ECHA infocard (no full REACH registration).

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Annexes

- A. Example SDS Fast Pyrolysis Bio-Oil
- B. Example SDS HTL Biocrude

Disclaimer

These examples of Safety Data Sheets are provided for illustration only.

No representation, warranty or guarantee is made as to its accuracy, reliability, or completeness. No warranty of merchantability, fitness for any particular purpose or any other warranty, express or implied, is made concerning the information herein provided. It is the supplier's and user's responsibility to satisfy themselves as to the suitability and completeness of such information for the particular use. We do not accept liability for any loss or damage that may occur from the use of this information.

Annex A - Example SDS Fast pyrolysis Bio-Oil

Safety Data Sheet

Biomass derived bio-oil by fast pyrolysis

1. Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Common name: Pyrolysis oil
Trade name: Fast pyrolysis bio-oil
Definition: Liquid condensate recovered by thermal treatment of lignocellulosic biomass, at short vapor residence time (typically less than about 10 seconds), typically at between 450-600°C, at near atmospheric pressure or below, in the absence of oxygen.
Common synonyms: Wood derived bio-oil, pyrolysis oil, wood fuel oil, wood distillate.
Origin: Fast pyrolysis of lignocellulosic biomass
Reach Registration No.: Pyrolysis oil has been registered under CAS No. 1207435-39-9.
CAS No: 1207435-39-9
EINECS No: 692-061-0

1.2. Relevant identified uses of the substance or mixture and uses against relevant identified uses

Relevant identified uses: Industrial uses [SU3]; Fuels [PC13], Laboratory chemicals [PC21]
Uses advised against: Not applicable.

1.3. Details of the supplier of the Safety Data Sheet

Company: BTG Biomass Technology Group BV
Address: Josink Esweg 34
7545 PN Enschede
The Netherlands
Phone number: +31 53 4861186
Email address: office@btgworld.com

1.4. Emergency telephone number

Poison Information Centre (in The Netherlands); open 24 hours daily
+31 (0)30 2748888

2. Hazards identification

2.1. Classification of the substance or mixture

2.1.1. Classification according to (EC) No 1272/2008 [CLP]

Aspiration hazard, Category 1
H304: May be fatal if swallowed and enter airways.
Skin irritation, Category 2
H315: Causes Skin Irritation.
Skin sensitization, Category 1
H317: May cause an allergic skin reaction.
Eye irritation, Category 2
H319: Causes serious eye irritation.
Hazardous to the aquatic environment, long-term hazard, Category 3
H412: Harmful to aquatic life with long lasting effects.

2.2. Label elements

Labeling according to Regulation (EC) No 1272/2008 [CLP]

Hazard pictograms



Signal word: **Warning**

Hazard statements:

H304: May be fatal if swallowed and enter airways.
 H315: Causes Skin Irritation.
 H317: May cause an allergic skin reaction.
 H319: Causes serious eye irritation.
 H412: Harmful to aquatic life with long lasting effects.

Precautionary statements prevention:

P280 Wear protective gloves/ eye protection.

Precautionary statements response:

P302 + P352 IF ON SKIN: Wash with plenty of soap and water.
 P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
 P333 + P313 If skin irritation or rash occurs: Get medical advice/attention.
 P337 + P313 If eye irritation persists: Get medical advice/attention.
 P362 Take off contaminated clothing and wash before reuse.

Precautionary statements disposal:

P501 Dispose of contents/container at a disposal facility in accordance with local regulations.

2.3. Other hazards

Strong characteristic odour

3. Composition/ information on ingredients

CAS No.	EC No	Index No.	REAC H No.	Wt.%	Name	Classification according to Regulation (EC) No 1278/2008 (CLP)
1207435-39-9	692-061-0	N.A.*	N.A.*	100	Fast pyrolysis bio-oil	Aspiration hazard, Category 1 H304 Skin irritation, Category 2 H315 Skin sensitization, Category 1 H317 Eye irritation, Category 2 H319 Hazardous to the aquatic environment, long-term hazard, Category 3 H412
50-00-0	200-001-8	605-001-00-5		<0,01	Formaldehyde	

*Not available

4. First aid measures

General

If breathing is irregular or has stopped, give artificial respiration. In all cases of doubt or if symptoms persist, seek medical attention and show this sheet to the doctor.

Inhalation:

If irritation is happening, move to fresh air until symptoms disappear.

Contact with skin:

Remove all contaminated clothing immediately and wash affected skin area with soap and water.

Contact with eyes:

Immediately flush eyes with plenty of water for at least 15 minutes, occasionally lifting the upper and lower lids. Any contact lens must be removed. Get medical attention even if the injury appears mild.

Ingestion:

First immediately rinse your mouth several times with water. Should the product be swallowed, take 2 – 3 glasses of water for dilution. Do not induce vomiting. Stay calm and seek medical advice.

Self protection of the first aider:

Wear protective gloves and eye protection

Antidote:

No specific antidote exists. The product is acidic (pH 2.5) and is partly soluble in water. Treat symptomatically.

5. Fire fighting measures

5.1. Extinguishing media

Water, foam, carbon dioxide, dry powder.

Use water spray to cool product containers and tanks near the fire.

5.2. Special hazards arising from the substance or mixture

- A fire will often produce a thick black smoke. Exposure to decomposition products may be hazardous to health.
- Do not breathe in smoke.
- In the event of a fire, the following may be formed: carbon monoxide (CO), carbon dioxide (CO₂), high concentration of unburned vapours.

5.3. Advice for firefighters

Do not inhale smoke from the fire. Wear self-contained breathing apparatus and full protective clothing.

6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

- Wear rubber gloves and suitable eye and face protection. If there is inadequate ventilation, a suitable organic vapours filter mask or NIOSH approved respirator must be worn.
- Cover contaminated area with absorbent (saw dust, peat, sand etc.).
- Take up absorbent and place in closed container.
- Transport to approved landfill or incinerator.

6.2. Environmental precautions

Prevent any material from entering drains or waterways.

6.3. Methods and material for containment and cleaning up

Contain and control the leaks or spills such as sand, earth, saw dust, peat in drums for waste disposal. Clean preferably with a detergent.

6.4. Reference to other sections

No data available.

7. Handling and storage

7.1. Precautions for safe handling

Always wash hands after handling. Remove and wash contaminated clothing before re-using.

Recommended equipment and procedures:

- For personal protection, see section 8.
- Observe precautions stated on label and also industrial safety regulations.
- Avoid inhaling vapors.
- Avoid skin and eye contact with this mixture.

Prohibited equipment and procedures:

No smoking, eating or drinking in areas where the wood oil is used.

7.2. Conditions for safe storage including any incompatibilities

- Keep containers tightly closed and store at temperatures below 55 degrees C in a well ventilated area.
- The product contains compounds that may either consume oxygen creating an underpressure in the container; or may emit vapours to create an overpressure in the container.
- Recommended storage materials are stainless steel, plastics (PETE, PP, HDPE), glass.

7.3. Specific end use(s)

No data available.

8. Exposure controls/personal protection

8.1. Control parameters

Occupational exposure limits are not available.

Control banding approach:

Based on H-statements it is possible to assess the risk for exposure. (<http://www.hse.gov.uk/pubns/guidance/coshh-technical-basis.pdf>)

According to the above-mentioned document wood oil has a medium volatility and has a maximum vapour exposure limit in the range of 50-500 ppm.

Type	Hazard group	Conc. Range [ppm]	H statements	Volatility
Wood oil	A	>50-500	H315	Medium

For storage of amounts in the range of milliliters is general ventilation good enough. Local exhaust ventilation from well-positioned capturing and receiving hoods to effective partial enclosing hoods are required for storage of amounts in the range of liters to cubic meters inside a building.

Occupational exposure limit values (Workplace Exposure Limits)

Chemical name	STEL (15 min)	TWA (8 hr)	Country
Formaldehyde	0.5 mg/m ³	0.15 mg/m ³	The Netherlands
Formaldehyde	0.74 mg/m ³	0.37 mg/m ³	Germany
Formaldehyde	2.0 ppm	0.75 ppm	USA

8.2. Exposure controls

Personal protection measures, such as personal protective equipment:

- Use personal protective equipment that is clean and has been properly maintained.
- Store personal protective equipment in a clean place, away from the work area.
- Never eat, drink or smoke during use.
- Remove and wash contaminated clothing before re-using.
- Ensure that there is adequate ventilation, especially in confined areas.

Eye / face protection:

- Avoid contact with eyes.
- Use eye protectors designed to protect against liquid splashes.
- Before handling, wear safety goggles with protective sides accordance with standard EN166.
- Prescription glasses are not considered as protection.
- Individuals wearing contact lenses should wear prescription glasses during work where they may be exposed.
- Provide eyewash stations in facilities where the product is handled constantly.

Hand protection:

- Use suitable protective gloves that are resistant to chemical agents in accordance with standard EN374.

Body protection:

- Avoid skin contact.
- In the event of substantial spatter, wear liquid-tight protective clothing against chemical risks (type 6) in accordance with EN13034 or (type 3) in accordance with EN14605 to prevent skin contact.
- Work clothing worn by personnel shall be laundered regularly.
- After contact with the product, all parts of the body that have been soiled must be washed.

Respiratory protection:

- Avoid breathing vapours.
- If the ventilation is insufficient, wear appropriate breathing apparatus such as mask with anti-gas and vapour filter(s) (Combined filters) in accordance with standard EN14387: A1 (Brown).

9. Physical and chemical properties

9.1. Information on basic physical and chemical properties

State: Liquid
Appearance: Dark brown
Odor: Strong characteristic, smoky

Boiling point:	< 100 °C (start of char formation, polymerization)
Pour point:	-20 °C
Flash point:	>35 °C, Unable to sustain combustion
Evaporation rate:	not available
Vapour pressure:	not available
Density:	1100 - 1300 kg/m ³
Viscosity 20°C:	40 - 225 cSt
Viscosity 50°C:	6 - 60 cSt
Water insoluble:	Soluble in water at concentration < 30% water.
Soluble:	Soluble in alcohols, ketones, organic acids. Insoluble in hydrocarbons
Corrosion rate:	Negligible for: SS316L, SS304L, Copper (99.9% electrolytic), polyethylene HDPE, polypropylene PP, SAE carbon steel (2.9 mm/year) and aluminum (4.8 mm/year) not suitable
pH:	2.5 – 3.5
Explosive properties:	No heat and shock explosive.
Auto ignition temperature:	> 500°C
Decomposition temperature:	> 150°C

9.2. Other information

No data available.

10. Stability and Reactivity

10.1. Reactivity

Avoid high temperatures. Above 100°C polymerization takes place under formation of harmful vapours.

10.2. Chemical stability

This substance is stable under the recommended handling and storage conditions in section 7.

10.3. Possibility of hazardous reactions

Heating above 100 °C: polymerization may occur with release of harmful fumes.

10.4. Conditions to avoid

Avoid heating above 100°C.

10.5. Incompatible materials

The substance may corrode metals (e.g. aluminum and carbon steel). However the substance is not classified as corrosive. SS304 & SS316 are suitable materials. Gaskets materials such as EPDM, Viton and NBR are swelling. The gaskets should be replaced after removal of flanges. Kalrez, PTFE and polyamides are suitable gasket materials.

10.6. Hazardous decomposition products

The thermal decomposition at temperatures higher than 150°C may release/form: carbon monoxide (CO), carbon dioxide (CO₂) and harmful fumes.

11. Toxicological information

11.1. Information on toxicological effects

Causes skin irritation.	4 hour exposure – mean scores over 24, 48 and 72 hours were 2.3 for erythema and 0.7 for oedema.
Causes eye irritation.	Not done because of ethical reasons.
May cause an allergic skin reaction.	EC ₃ value 3.19% skin sensitization test.

Not toxic by oral route and by 7 days oral gavage.
Not mutagenic via In Vivo MAS test.

12. Ecological information

12.1. Toxicity

EC50 (acute toxicity to Daphnia Magna):
Algal growth test:
Others:

> 100 mg/l. Not toxic.
> 100 mg/l. No significant inhibition of algal growth.
Large quantities may decrease the pH value.

12.2. Persistence and degradability

Biodegradation:

Modified Sturm test. The product biodegrades rapidly at percentages between 32 and 50%. Low biodegradation under anaerobic conditions.

12.3. Bioaccumulative potential

The product is not likely to bio accumulate, because most of the components are highly soluble in water and/ or biodegrade rapidly.

12.4. Mobility in soil

No data available.

12.5. Results of PBT and vPvB assessment

No data available.

12.6. Other adverse effects

No data available.

13. Disposal considerations

Proper waste management of the mixture and/or its container must be determined in accordance with Directive 2008/98/EC.

13.1. Waste treatment methods

Do not pour into drains or waterways.

Waste:

- Waste management is carried out without endangering human health, without harming the environment and, in particular without risk to water, air, soil, plants or animals.
- Recycle or dispose of waste in compliance with current legislation, preferably via a certified collector or company.
- Do not contaminate the ground or water with waste, do not dispose of waste into the environment.

Soiled packaging:

- Empty container completely. Keep label(s) on container.
- Give to a certified disposal contractor.

14. Transport information

Transport product in compliance with provisions of the ADR for road, RID for rail, IMDG for sea and ICAO/IATA for air transport (ADR 2009 - IMDG 2008, ICAO/IATA 2009).

Wood derived oil is **not** classified as dangerous goods.

Transport in bulk according to annex II of MARPOL73/78 and the IBC code

a	b	c	d	e	f	g	h	i	j	k	l	m	n	o
Wood oil		Z	S	3	2G	Cont.	Vent.		O	No	No		No	Use stainless steel tanks or tanks with PP liners.

15. Regulatory information

15.1. Safety, health and environmental regulations/legislations specific for the substance or mixture

No data available.

15.2. Chemical safety assessment

No data available.

16. Other information

- Since the user's working conditions are not known by us, the information supplied on this safety data sheet is based on our current level of knowledge and on national and community regulations.
- The mixture must not be used for other uses than those specified in section 1 without having first obtained written handling instructions.
- It is at all times the responsibility of the user to take all necessary measures to comply with legal requirements and local regulations.
- The information in this safety data sheet must be regarded as a description of the safety requirements relating to the mixture and not as a guarantee of the properties thereof.

Annex B - Example SDS HTL Biocrude

Due to missing public availability of commercial HTL biocrude SDS, an example from academia is given here. This example has not been updated to changes in REACH rules that were implemented in the meantime and therefore represents an outdated example.'

Safety Data Sheet according to WHS Regulations

Printing date 25.09.2019

Version number 1

Revision: 25.09.2019

1 Identification

- **Product identifier**
- **Trade name:** **Paul II chemical mixture**
- **Relevant identified uses of the substance or mixture and uses advised against**
No further relevant information available.
- **Application of the substance / the mixture**
Test material
Sample
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
Karlsruher Institut für Technologie (KIT)
Institut für Katalysatorforschung und Technologie (IKFT)
Hermann-von-Helmholtz-Platz 1
D-76344 Eggenstein-Leopoldshafen
Tel.: +49 721 608-22401
Fax: +49 721 608-22244
office@ikft.kit.edu
- **Informing department:**
Klaus Raffelt
E-Mail klaus.raffelt@kit.edu
Tel. +49 721 60826507
- **Emergency telephone number:**
Phone +49 721 608-22401
(Office hours 9:00 - 16:30)

2 Hazard(s) Identification

- **Classification of the substance or mixture**



health hazard

Repr. 1A H360 May damage fertility or the unborn child.
STOT RE 2 H373 May cause damage to the central nervous system and the hearing organs through prolonged or repeated exposure. Route of exposure: Inhalation.



corrosion

Skin Corr. 1B H314 Causes severe skin burns and eye damage.
Eye Dam. 1 H318 Causes serious eye damage.



Acute Tox. 4 H302 Harmful if swallowed.

- **Label elements**
- **GHS label elements**
The product is classified and labelled according to the Globally Harmonised System (GHS).

(Contd. on page 2)

Safety Data Sheet

according to WHS Regulations

Printing date 25.09.2019

Version number 1

Revision: 25.09.2019

Trade name: Paul II chemical mixture

(Contd. from page 1)

Hazard pictograms


GHS05 GHS07 GHS08

Signal word Danger

Hazard-determining components of labelling:

p-cresol
toluene
ethylbenzene
1-butylpyrrolidin-2-one

Hazard statements

H302 Harmful if swallowed.
H314 Causes severe skin burns and eye damage.
H360 May damage fertility or the unborn child.
H373 May cause damage to the central nervous system and the hearing organs through prolonged or repeated exposure. Route of exposure: Inhalation.

Precautionary statements

P102 Keep out of reach of children.
P201 Obtain special instructions before use.
P240 Ground/bond container and receiving equipment.
P260 Do not breathe mist/vapours/spray.
P280 Wear protective gloves/protective clothing/eye protection/face protection.
P301+P312 IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.
P301+P330+P331 IF SWALLOWED: rinse mouth. Do NOT induce vomiting.
P302+P352 IF ON SKIN: Wash with plenty of water.
P304+P340 IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P405 Store locked up.
P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

Other hazards
Results of PBT and vPvB assessment

- **PBT:** Not applicable.
- **vPvB:** Not applicable.

3 Composition and Information on Ingredients

Chemical characterisation: Mixtures

• **Description:** Mixture of the substances listed below including additives not requiring identification.

Dangerous components:

100-41-4	ethylbenzene ⚠ Flam. Liq. 2, H225; ⚠ STOT RE 2, H373; Asp. Tox. 1, H304; ⚠ Acute Tox. 4, H332; Skin Irrit. 2, H315; Eye Irrit. 2A, H319	10 - 25%
3470-98-2	1-butylpyrrolidin-2-one ⚠ Acute Tox. 4, H302; Skin Irrit. 2, H315; Eye Irrit. 2A, H319	10 - 25%
106-44-5	p-cresol ⚠ Acute Tox. 3, H301; Acute Tox. 3, H311; ⚠ Skin Corr. 1B, H314	≥ 5 - ≤ 10%
108-88-3	toluene ⚠ Flam. Liq. 2, H225; ⚠ Repr. 1A, H360; STOT RE 2, H373; Asp. Tox. 1, H304; ⚠ Skin Irrit. 2, H315; STOT SE 3, H336	≥ 3 - < 10%

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629-78-7	Heptadecane ⚠ Asp. Tox. 1, H304	2.5 - 10%
123-07-9	p-Ethylphenol ⚠ Eye Dam. 1, H318	≥ 3 - ≤ 10%
108-68-9	3,5-xylenol ⚠ Acute Tox. 3, H301; Acute Tox. 3, H311; ⚠ Skin Corr. 1B, H314	≥ 2.5 - < 5%
520-69-4	1H-Pyrrole, 3-ethyl-2,4,5-trimethyl- ⚠ Acute Tox. 3, H301	2.5 - 10%
43152-94-9	1-Ethyl-6-methyl-3-piperidinone ⚠ Acute Tox. 3, H301	< 2.5%

· **Additional information** For the wording of the listed hazard phrases refer to section 16.

4 First Aid Measures

- **Description of first aid measures**
- **General information**
Personal protection for the First Aider.
Instantly remove any clothing contaminated by the product.
- **After inhalation**
Supply fresh air and call for doctor for safety reasons.
In case of unconsciousness bring patient into stable side position for transport.
In case of unsteady breathing or breathing arrest induce artificial respiration.
- **After skin contact**
Instantly wash with water and soap and rinse thoroughly.
Call a doctor immediately.
Wash contaminated clothing before re-use.
Discard contaminated shoes.
- **After eye contact**
Rinse opened eye for several minutes under running water.
Call a doctor immediately.
- **After swallowing**
Do not induce vomiting; instantly call for medical help.
Give small quantities of water to drink.
Rinse mouth and immediately consult physician.
- **Information for doctor**
- **Most important symptoms and effects, both acute and delayed**
No further relevant information available.
- **Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

5 Fire Fighting Measures

- **Extinguishing media**
- **Suitable extinguishing agents**
Extinguishing powder, foam or water jet. Fight larger fires with water jet or alcohol-resistant foam.
- **For safety reasons unsuitable extinguishing agents** Water with a full water jet.
- **Special hazards arising from the substance or mixture**
Inhalation of combustion gases may cause serious health hazards.
During incomplete combustion carbon monoxide can be formed.
Can form explosive gas-air mixtures.
Vapours are heavier than air and may travel long distances along ground, ignite and flash back to source.
- **Advice for firefighters**
- **Protective equipment:** Wear self-contained breathing apparatus.

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- **Additional information**

Use water to keep fire exposed containers cool.
Dispose of contaminated fire fighting water in accordance with official regulations.

6 Accidental Release Measures

- **Personal precautions, protective equipment and emergency procedures**

Avoid contact with the product.
Wear protective equipment. Keep unprotected persons away.
Keep away from sources of ignition - No smoking.

- **Environmental precautions:**

Do not allow to enter drainage system, surface or ground water.
Prevent from spreading (e.g. by damming-in or oil barriers).
Inform respective authorities in case product reaches water or sewage system.

- **Methods and material for containment and cleaning up:**

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders).
Dispose of contaminated material as waste according to section 13.
Ensure adequate ventilation.
Clean contaminated objects and floorings considering environmental regulations.

- **Reference to other sections**

See Section 7 for information on safe handling
See Section 8 for information on personal protection equipment.
See Section 13 for information on disposal.

7 Handling and Storage

- **Handling**

- **Precautions for safe handling**

Ensure good ventilation/exhaustion at the workplace.
Prevent formation of aerosols.

- **Information about protection against explosions and fires:**

Keep ignition sources away - Do not smoke.
Fumes can combine with air to form an explosive mixture.

- **Conditions for safe storage, including any incompatibilities**

- **Storage**

- **Requirements to be met by storerooms and containers:**

Keep container tightly closed and store upright to prevent any spill of product.

- **Information about storage in one common storage facility:**

Store away from foodstuffs.
Store away from oxidising agents.

- **Further information about storage conditions:** Keep container tightly sealed.

- **Specific end use(s)** No further relevant information available.

8 Exposure controls and personal protection

- **Additional information about design of technical systems:**

At open handling local exhaust equipment shall be used.

- **Control parameters**

- **Components with limit values that require monitoring at the workplace:**

WEL: workplace exposure limit
OEL: Occupational Exposure Limit

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100-41-4 ethylbenzene

WES	Short-term value: 543 mg/m ³ , 125 ppm Long-term value: 434 mg/m ³ , 100 ppm
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108-88-3 toluene

WES	Short-term value: 574 mg/m ³ , 150 ppm Long-term value: 191 mg/m ³ , 50 ppm Sk
-----	--

· DNELs**108-88-3 toluene**

Oral	DNEL (consumer, long-term, systemic)	8.13 mg/kg bw/day (human)
Dermal	DNEL (worker, long-term, systemic)	384 mg/kg bw/day (human)
Inhalative	DNEL (consumer, long-term, systemic)	226 mg/kg bw/day (human)
	DNEL (worker, short-term, systemic)	384 mg/m ³ (human)
	DNEL (worker, long-term, systemic)	192 mg/m ³ (human)
	DNEL (consumer, short-term, systemic)	226 mg/m ³ (human)
	DNEL (consumer, long-term, systemic)	56.5 mg/m ³ (human)
	DNEL (worker, short-term, local)	384 mg/m ³ (human)
	DNEL (worker, long-term, local)	192 mg/m ³ (human)
	DNEL (consumer, short-term, local)	226 mg/m ³ (human)
	DNEL (consumer, long-term, local)	56.5 mg/m ³ (human)

· PNECs**108-88-3 toluene**

PNEC aqua (freshwater)	0.68 mg/L (.)
PNEC aqua (marine water)	0.68 mg/L (.)
PNEC STP	13.61 mg/L (.)
PNEC soil	2.89 mg/kg soil dw (.)
PNEC sediment (freshwater)	16.39 mg/kg sedim. dw (.)
PNEC sediment (marine water)	16.39 mg/kg sedim. dw (.)
PNEC aqua (intermittent releases)	0.68 mg/L (.)

· **Additional information:** The lists that were valid during the compilation were used as basis.

· Exposure controls**· Personal protective equipment****· General protective and hygienic measures**

Keep away from foodstuffs, beverages and food.

Take off all contaminated clothing immediately.

Wash hands during breaks and at the end of the work.

Store protective clothing separately.

Avoid contact with the eyes and skin.

· Breathing equipment:

In case of brief exposure or low pollution use breathing filter apparatus. In case of intensive or longer exposure use breathing apparatus that is independent of circulating air.

· Protection of hands:

Protective gloves.

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

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Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

- **Material of gloves**

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

Fluorocarbon rubber (Viton)

- **Penetration time of glove material**

In case of a layer thickness of 0.7 mm the penetration time is longer than 480 minutes.

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

- **Eye protection:**



Tightly sealed safety glasses.

- **Body protection:**

Protective work clothing.

Wash contaminated clothing after use.

Boots

9 Physical and Chemical Properties

- **Information on basic physical and chemical properties**

- **General Information**

- **Appearance:**

Form:	Fluid
Colour:	Colourless
· Odour:	Aromatic
· Odour threshold:	Not determined.

- **pH-value at 20 °C:** 8

- **Change in condition**

Melting point/freezing point:	Not determined
Initial boiling point and boiling range:	110.6 °C

- **Flash point:** > 701 °C

- **Inflammability (solid, gaseous)** Not applicable.

- **Ignition temperature:** 210 °C

- **Decomposition temperature:** Not determined.

- **Self-inflammability:** Product is not selfigniting.

- **Explosive properties:** Product is not explosive.

- **Critical values for explosion:**

Lower:	1 Vol %
Upper:	7.8 Vol %

- **Vapour pressure at 20 °C:** 23 hPa

· Density at 20 °C	0.9 - 1 g/cm ³
· Relative density	Not determined.
· Vapour density	Not determined.
· Evaporation rate	Not determined.

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- | | |
|--|--|
| · Solubility in / Miscibility with Water: | Not miscible or difficult to mix |
| · Partition coefficient: n-octanol/water: | Not determined. |
| · Viscosity: | |
| dynamic: | Not determined. |
| kinematic at 40 °C: | > 300 mm ² /s |
| · Other information | No further relevant information available. |

10 Stability and Reactivity

- **Reactivity** No further relevant information available.
- **Chemical stability**
- **Thermal decomposition / conditions to be avoided:**
No decomposition if used according to specifications.
- **Possibility of hazardous reactions** No dangerous reactions known
- **Conditions to avoid** No further relevant information available.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:**
None in case of intended use and storage in compliance with instructions.

11 Toxicological Information

- **Information on toxicological effects**
- **Acute toxicity**

- **LD/LC50 values that are relevant for classification:**

100-41-4 ethylbenzene

Oral	LD50	3,500 mg/kg (rat)
Dermal	LD50	17,800 mg/kg (rabbit)

106-44-5 p-cresol

Oral	LD50	207 mg/kg (rat)
Dermal	LD50	301 mg/kg (rabbit)
Inhalative	LC50	> 0.71 mg/l/1h (rat)

108-88-3 toluene

Oral	LD50	5,580 mg/kg (rat) (EU B.1)
Dermal	LD50	12,267 mg/kg (rabbit)
Inhalative	LC50	28.1 mg/l/4h (rat) (OECD 403)

108-68-9 3,5-xylenol

Oral	LD50	608 mg/kg (rat)
------	------	-----------------

- **Primary irritant effect:**
- **Skin corrosion/irritation** Caustic effect on skin and mucous membranes.
- **Serious eye damage/irritation** Strong caustic effect.
- **Additional toxicological information:**
The product shows the following dangers according to the calculation method of the General EC Classification Guidelines for Preparations as issued in the latest version:
Toxic
Corrosive
Swallowing will lead to a strong caustic effect on mouth and throat and to the danger of perforation of esophagus and stomach.

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· Repeated dose toxicity
108-88-3 toluene

Oral	NOAEL (90d)	625 mg/kg bw/day (mouse) (EU B.26)
Inhalative	NOAEC (90d)	1,131 mg/m ³ (rat) (OECD 453)

· CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)

Repr. 1A

12 Ecological Information

· Toxicity
· Aquatic toxicity:
100-41-4 ethylbenzene

EC50 (static)	1.8 mg/l/48h (Daphnia magna)
LC50	5.1 mg/l/96h (Menidia menidia)

106-44-5 p-cresol

EC50 (static)	7.8 mg/l/48h (Desmodesmus subspicatus) (DIN 38412-9)
	7.7 mg/l/48h (Daphnia magna) (DIN 38412-11)
LC50 (static)	4.4 mg/l/96h (Salmo trutta)
	7.4 mg/l/96h (Oncorhynchus mykiss)

108-88-3 toluene

EC50 (static)	84 mg/l/24h (Bacteria)
EC50 (static)	3.78 mg/l/48h (Ceriodaphnia dubia) (US EPA 600/4-91-003)
LC50 (dynamic)	5.5 mg/l/96h (Oncorhynchus mykiss)

· Terrestrial toxicity:
108-88-3 toluene

NOEC (28 d)	≥ 150 mg/kg soil dw (Eisenia fetida)
-------------	--------------------------------------

· Persistence and degradability No further relevant information available.

· Other information: There are no data available about the preparation.

· Behaviour in environmental systems:
· Bioaccumulative potential No further relevant information available.

· Mobility in soil No further relevant information available.

· Ecotoxicological effects:
· Behaviour in sewage processing plants:
108-88-3 toluene

EC50 (static)	134 mg/l/3h (Chlamydomonas angulosa)
---------------	--------------------------------------

· Additional ecological information:
· General notes:

Water hazard class 2 (German Regulation) (Self-assessment): hazardous for water.

Do not allow product to reach ground water, water bodies or sewage system.

Must not reach sewage water or drainage ditch undiluted or unneutralised.

Danger to drinking water if even small quantities leak into soil.

· Results of PBT and vPvB assessment
· PBT: Not applicable.

· vPvB: Not applicable.

· Other adverse effects No further relevant information available.

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13 Disposal considerations

- **Waste treatment methods**
- **Recommendation**
Must not be disposed of together with household garbage. Do not allow product to reach sewage system.
The waste code numbers mentioned are recommendations based on the probable use of the product.
- **Uncleaned packagings:**
- **Recommendation:**
Dispose of packaging according to regulations on the disposal of packagings.
Non contaminated packagings can be used for recycling.
Packagings that cannot be cleaned are to be disposed of in the same manner as the product.

14 Transport information

- | | |
|--|--|
| <ul style="list-style-type: none"> · UN-Number · ADG, IMDG, IATA | UN1760 |
| <ul style="list-style-type: none"> · UN proper shipping name · ADG · IMDG, IATA | 1760 CORROSIVE LIQUID, N.O.S. (CRESOLS, XYLENOLS)
CORROSIVE LIQUID, N.O.S. (CRESOLS, XYLENOLS) |
| <ul style="list-style-type: none"> · Transport hazard class(es) · ADG | <div style="text-align: center;">  </div> |
| <ul style="list-style-type: none"> · Class · Label | 8 (C9) Corrosive substances.
8 |
| <ul style="list-style-type: none"> · IMDG, IATA | <div style="text-align: center;">  </div> |
| <ul style="list-style-type: none"> · Class · Label | 8 Corrosive substances.
8 |
| <ul style="list-style-type: none"> · Packing group · ADG, IMDG, IATA | II |
| <ul style="list-style-type: none"> · Environmental hazards: | Not applicable. |
| <ul style="list-style-type: none"> · Special precautions for user · Kemler Number: · EMS Number: · Stowage Category · Stowage Code | Warning: Corrosive substances.
80
F-A,S-B
B
SW2 Clear of living quarters. |
| <ul style="list-style-type: none"> · Transport in bulk according to Annex II of Marpol and the IBC Code | Not applicable. |

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· Transport/Additional information:**· ADG****· Limited quantities (LQ)**

1L

· Excepted quantities (EQ)

Code: E2

Maximum net quantity per inner packaging: 30 ml

Maximum net quantity per outer packaging: 500 ml

· Transport category

2

· Tunnel restriction code

E

· IMDG**· Limited quantities (LQ)**

1L

· Excepted quantities (EQ)

Code: E2

Maximum net quantity per inner packaging: 30 ml

Maximum net quantity per outer packaging: 500 ml

· UN "Model Regulation":

UN 1760 CORROSIVE LIQUID, N.O.S. (CRESOLS, XYLENOLS), 8, II

15 Regulatory information**· Safety, health and environmental regulations/legislation specific for the substance or mixture****· Australian Inventory of Chemical Substances**

100-41-4 ethylbenzene

106-44-5 p-cresol

108-88-3 toluene

629-78-7 Heptadecane

123-07-9 p-Ethylphenol

108-68-9 3,5-xyleneol

· Standard for the Uniform Scheduling of Medicines and Poisons

108-88-3 toluene

S6

· Australia: Priority Existing Chemicals

None of the ingredients is listed.

· Directive 2012/18/EU**· Named dangerous substances - ANNEX I** None of the ingredients is listed.**· National regulations****· Information about limitation of use:**

Employment restrictions concerning young persons must be observed.

Employment restrictions concerning women of child-bearing age must be observed.

· Water hazard class: Water hazard class 2 (Self-assessment): hazardous for water.**· Substances of very high concern (SVHC) according to REACH, Article 57**

None of the ingredients is contained.

· Chemical safety assessment: A Chemical Safety Assessment has not been carried out.**16 Other information**

These data are based on our present knowledge. However, they shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

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· **Department issuing data specification sheet:**

This Material Safety Data Sheet has been drawn up in cooperation with:

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· **Abbreviations and acronyms:**

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

DNEL: Derived No-Effect Level (REACH)

PNEC: Predicted No-Effect Concentration (REACH)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

SVHC: Substances of Very High Concern

vPvB: very Persistent and very Bioaccumulative

Flam. Liq. 2: Flammable liquids – Category 2

Acute Tox. 3: Acute toxicity – Category 3

Acute Tox. 4: Acute toxicity – Category 4

Skin Corr. 1B: Skin corrosion/irritation – Category 1B

Skin Irrit. 2: Skin corrosion/irritation – Category 2

Eye Dam. 1: Serious eye damage/eye irritation – Category 1

Eye Irrit. 2A: Serious eye damage/eye irritation – Category 2A

Repr. 1A: Reproductive toxicity – Category 1A

STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

STOT RE 2: Specific target organ toxicity (repeated exposure) – Category 2

Asp. Tox. 1: Aspiration hazard – Category 1

· **Sources**

The basis for the preparation of this safety data sheet are the information provided by the distributor.



IEA Bioenergy
Technology Collaboration Programme