

23-04-2018 4/14  
AN: 80/2018  
Priority:

**Substances Information Exchange Forum Agreement (SIEF Agreement)  
according to REACH Regulation (EC) No 1907/2006<sup>1</sup>**

**SIEF Agreement**

This SIEF Agreement (hereinafter the "Agreement") is entered into by and between:

BASF SE, Carl-Bosch-Strasse 38, D-67056 Ludwigshafen/Rhein, Germany, as Lead Company for the registration of 3-Methylbutan-1-ol, CAS Number 123-51-3, EC Number: 204-633-5 under REACH Regulation (hereinafter referred to as "**Lead Registrant**" or "**BASF**")

And the SIEF Participant signatory of the present Agreement (hereinafter referred to as "**Non-Lead Member**")

Hereinafter referred to as "the Parties"

**Preamble**

Whereas the Parties to this Agreement have pre-registered 3-Methylbutan-1-ol, CAS Number 123-51-3, EC Number: 204-633-5, and have agreed on the identity and the sameness of the

<sup>1</sup> Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), OJ L 336 of 29.5.2007

*Handwritten signature*

Substance (see SIP in Annex 2 of this Agreement), and thus are Participants of the same Substance Information Exchange Forum ("SIEF") as potential registrants for that Substance under the meaning of Article 29 of the European Community Regulation EC 1907/2006 ("REACH");

Whereas the REACH Regulation imposes on manufacturers and importers as well as on only representatives the obligation to register the Substance within the prescribed deadlines;

Whereas the REACH Regulation requires, subject to certain exceptions, multiple registrants of the same substance to share certain data and jointly submit through a Lead Registrant part of the information required for the registration relating to the Substance to the European Chemicals Agency ("Agency");

Whereas the Lead Registrant defined in the Article 1 of this Agreement will have prepared the Joint Registration Dossier to be submitted to the Agency;

Whereas the Lead Registrant is aware that he has co-operation and data sharing obligations with other SIEF participants.

Whereas the Non-Lead Member has the intention to register the Substance and he is willing to appoint the Lead Registrant as lead registrant in order to have him to submit the Joint Registration Dossier.

Whereas the Agency represented in its REACH guidance that it is advisable for the SIEF participants to agree in writing certain SIEF operational rules concerning data sharing, rights on the developed information and sharing of costs.

Therefore, with a view to fulfilling their regulatory obligations under the REACH Regulation in respect to the Substance, the Parties hereto have decided to pursue the following objectives (hereinafter the "Purpose"):

1. to agree on the operating rules governing the exchanges of information between the SIEF potential registrants (Title I);

2. to agree on the rules regarding the rights to participate in the joint submission of data, to use the (robust) study summaries and to refer to the relevant full study reports in the Joint Registration Dossier developed by the Lead Registrant (Title II);

under the terms and conditions set forth in this Agreement.

THE PARTIES HAVE AGREED UPON THE FOLLOWING:

#### **Article I. Definitions**

Terms written in capital letters are defined in the Preamble above, in this Article 1 or in other parts of this Agreement. To the extent not otherwise defined in this Agreement, any definition specified in REACH, in particular in Article 3, shall apply to this Agreement:

**Affiliate:** Any legal entity controlling, controlled by, or under common control with, either directly or indirectly, a Party or in case of an only representative, the affiliate of the non-EU manufacturer or in case of a third representative, the affiliate of the legal entity represented. For these purposes, "control" shall refer to: (i) the possession, directly or indirectly, of the power to direct the management or policies of a person, whether through the ownership of voting rights, by contract or otherwise; or (ii) the ownership, directly or indirectly, of 50 % or more of the voting rights or other ownership interest of a person.

**Data Owner:** Any entity holding rights to use Information on the Substance, either as SIEF participant or as non SIEF participant.

**Information:** studies, other scientific, statistical, or technical data, including but not limited to composition, characteristics, properties and processes and applications, and any information in any form made available by a Party or generated by the Parties jointly, pursuant to or in the course of this Agreement.

**Joint Registration Dossier:** The data that the Parties are required to submit jointly to the Agency in order to register the Substance, pursuant to Article 11 (1), paragraph 2 and 4 REACH. The information according to Article 10 (b) will not comprise the Chemical Safety Report according to Annex I of the REACH Regulation and the Chemical Safety Report shall not be part of the Joint Registration Dossier.

**Parties:** being the signing parties to this Agreement, having the quality of either:

**-Lead Registrant:** a SIEF participant who is subject to the registration requirements under REACH, which the Non-Lead Member agree hereto to appoint acting as Lead Registrant as defined under Article 11 (1) REACH.

**-Non-Lead Member:** a SIEF participant being neither the Lead Registrant nor a data holder (article 28 (7) REACH) and that agrees to rely on the Joint Registration Dossier prepared and/or made available by the Lead Registrant, on his own behalf, for its Affiliates, and/or on behalf of the represented potential registrants in case he is a third party representative.

**Substance:** 3-Methylbutan-1-ol, CAS Number 123-51-3, EC Number: 204-633-5

## Title I: SIEF OPERATING RULES

### Article II. Confidentiality

#### 1. The Parties shall:

- a) treat all Information as confidential and not disclose it to third parties, unless regulatory disclosure requirements apply. Each Party shall advise immediately the other Parties in writing of any disclosure or misuse by any Party or a third party of Information, as well as of any request by competent authorities relating to the disclosure of that Information.

Disclosure of Information as required for legal and/or regulatory purposes including the REACH Regulation, shall only take place by the Parties in a form (for example short summaries where possible) reflecting the minimum information required to be disclosed. This restriction does not apply to the Party who has provided the Information.

- b) use the Information only for the Purpose or otherwise as permitted under or in accordance with this Agreement.

- c) disclose the Information to their employees, Affiliates, external experts and/or consultants and if the Non-Lead Member is an only representative or a third party representative, the non-EU manufacturer(s) or the legal entity(ies) represented by any of them, only on a need to know basis and only to the extent absolutely necessary for the Purpose or otherwise as permitted under or in accordance with this Agreement. Each Party shall have in place policies and procedures to ensure the confidentiality of Information, and require that its external experts and/or consultants also have such policies and procedures in place to ensure their compliance with these confidentiality obligations.

2. The obligations specified in Article II.1 above shall not apply to Information for which the receiving Party can reasonably demonstrate that such Information:

- a) was known to the receiving Party on a non-confidential basis prior to its disclosure pursuant to this Agreement;
- b) is publicly known at the time of disclosure or thereafter becomes publicly known without breach of the terms of this Agreement on the part of the receiving Party;
- c) becomes known to the receiving Party through disclosure by sources other than the disclosing Party, having a right to disclose such Information,
- d) was independently developed by the receiving Party without access to the disclosing Party's Information, as evidenced by documentary records,

Specific items of Information shall not fall within any exception merely because they are combined with more general Information falling within any exception. Likewise, any combination of specific items of Information shall not fall within any exception merely because the specific items fall within any exception, but only if the combination itself, and its principles of operation, fall within any exception.

### **Article III. Competition Law compliance**

1. The Parties acknowledge that any activities carried out under this Agreement have to be carried out in full compliance with EU competition law, in particular but not limited to Articles 101 and 102 TFEU Treaty as well as any applicable national laws. The Parties explicitly agree to observe Cefic REACH Competition Law compliance guidance attached as Annex 1 to this Agreement.

2. Should it become apparent at any time that this Agreement, any provision of this Agreement, or any activity or decision of the Parties, can have a potentially restrictive effect on open and fair competition, in breach of any statutory provision, each Party to this Agreement shall take immediate steps to remedy that situation.

### **Article IV. Legal personality**

This Agreement or the cooperation contemplated herein shall not constitute or be deemed to constitute a legal entity or partnership between the Parties.

## **TITLE II: DATA SHARING AND JOINT SUBMISSION OF THE DOSSIER**

### **1. OBLIGATIONS OF THE LEAD REGISTRANT**

#### **Article V. Participation in the joint submission of data by multiple registrants**

1. According to Article 11 (1) REACH, the Parties hereto agree to have the Joint Registration Dossier for the Substance submitted by the Lead Registrant on behalf of the Non-Lead Member having fulfilled its obligations under Article VIII to this Agreement, sufficiently before end of the applicable registration deadline to enable the Non-Lead Member to register in time. Upon demand of the Agency, within the requested deadline and to the extent necessary, the Lead Registrant agrees to complete the Joint Registration Dossier.

1a. In case the Joint Registration Dossier includes data owned by Data Owners, the respective parts of the Joint Registration Dossier can only be submitted on behalf of the Non-Lead Member if either

- a) the Lead Registrant is entitled to pass on usage rights to the respective data; or
  - b) the Non-Lead Member has acquired usage rights directly from the owning third party.
- The Lead Registrant shall provide information for which data the Non-Lead Member needs to acquire usage rights sufficiently before end of the applicable registration deadline to enable the Non-Lead Member to obtain acquire the respective usage rights. The Lead Registrant is entitled to request confirmation from the Non-Lead Member that he will acquire usage rights directly from the owning third party.

2. Notwithstanding anything to the contrary under this Agreement, the Parties remain individually responsible to comply with REACH, in particular, but not limited to, in relation to the individual submission of the information required under Article 11(1) REACH.

3. The participation in the Joint Registration Dossier may deviate per requesting Non-Lead Member according to its tonnage band.

4. If the Non-Lead Member requests the submission of the Joint Registration Dossier on behalf of an Affiliate, the Non-Lead Member shall notify the Lead Registrant with its name, address, UUID and other relevant data documenting such status of Affiliate within 4 months before the registration due date. Upon receipt of such information, the Lead Registrant shall submit the Joint Registration Dossier also on behalf of such Affiliate.

5. If the Non-Lead Member is a third party representative and requests the submission of the Joint Registration Dossier on behalf of a legal entity represented by him in the SIEF, the Non-Lead Member shall notify the Lead Registrant under confidentiality obligations with the name, address, UUID and other relevant data of the represented legal entity within 4 months before the registration due date. Upon receipt of such information, the Lead Registrant shall submit the Joint Registration Dossier also on behalf of such legal entity.

6. The Lead Registrant shall open a joint submission object in REACH-IT.

7. The Lead Registrant shall pay the fee (in accordance to Article 11 (4) REACH) as invoiced by the Agency for the submission of the Joint Registration Dossier without undue delay.



8. The Lead Registrant shall make available the data referred to in Article 11 (1) paragraph 2 and 4 REACH (the information according to Article 10 (b) will not comprise the Chemical Safety Report according to Annex I of the REACH Regulation and the Chemical Safety Report shall not be part of the Joint Registration Dossier) that have been submitted in the joint submission, to the Non-Lead Member, and/or Non-Lead Member's Affiliate notified under Article V.4 of this Agreement, provided the Non-Lead Member has fulfilled its obligations under Article VIII of this Agreement.

#### **Article VI. Grant of right to use the (robust) studies summaries in the Joint Registration Dossier and to refer to the full study reports.**

1. Subject to the payment of the Joint Registration Compensation as specified under Article VIII of this Agreement, the Lead Registrant grants the Non-Lead Member the non-exclusive, non-transferable and non-terminable right:

(a) to use the (robust) studies summaries and other Information used in the Joint Registration Dossier within the applicable tonnage band;

(b) to refer to the full study reports on which basis the (robust) studies summaries have been developed; and

(c) to grant the rights referred to under (a) and (b) hereabove to the Non-Lead Member's Affiliates notified under Article V.4, with the right to sub-license such rights only to their only representatives.

2. Notwithstanding the foregoing, if the Non-Lead Member is a third party representative, he is granted only with the rights specified under (a) and (b) hereabove, and only for the purpose to pass them to the legal entities represented by him in the SIEF and notified to the Lead Registrant under Article V.5.

3. The rights granted under this Article can be exercised only for the purpose of compliance with REACH. The Parties shall abstain from any other use, whether commercial or non-commercial. For the avoidance of doubt, any further use of the studies shall be subject to an additional written agreement.

#### **Article VII. Information on the submission of the Joint Registration Dossier**

1. Provided the Non-Lead Member has fulfilled its obligations under Article VIII, the Lead Registrant shall inform immediately the Non-Lead Member of the creation of the joint submission object in REACH-IT and shall provide the valid security token number and the name of the joint submission. The Non-Lead Member shall only make use of the security token if he has acquired usage rights for those data the Lead Registrant indicated according to Article V.1a (b).

2. The Lead Registrant shall inform immediately the Non-Lead Member of the submission of the Joint Registration Dossier to the Agency and provide documentation of the same.

3. The Lead Registrant shall further communicate the confirmation that the joint registration has been successful and shall inform the Non-Lead Member of the reception of the relevant registration number that has been obtained from the Agency without undue delay.



## 2. OBLIGATIONS OF THE NON-LEAD MEMBER

### **Article VIII. Financial compensation for the Joint Registration Dossier**

1. Before execution by BASF of its obligations pursuant to Title II.1 of this Agreement, the Non-Lead Member shall compensate in a fair, transparent and non-discriminatory way BASF with a "Joint Registration Compensation" for the development and submission of the Joint Registration Dossier and the rights granted under Article VI.

2. The following costs shall be shared between the Parties:

a) Costs related to the preparation and submission of the Joint Registration Dossier by the Lead Registrant.

b) Administrative costs reasonably incurred by the Lead Registrant including but not limited to, secretarial services, management of confidential data and costs of external experts.

c) Costs for rights to use existing studies of BASF and existing studies jointly developed by BASF and third parties according to Annexes VI to XI of REACH if the Lead Registrant is authorized by the joint owners to transfer to Non-Lead Member the rights specified under Article VI. paragraph 1.

d) Costs for rights to use studies from Data Owners, if the Lead Registrant is authorized by Data Owners to transfer to Non-Lead Member the rights specified under Article VI. paragraph 1.

3. Costs referred to above shall be allocated equally, in a transparent, fair and non-discriminatory way, to all SIEF participants with the intent to become members of the joint submission. However, where a Non-Lead Member registers the Substance in a tonnage band lower than the one covered by the Joint Registration Dossier, compensation for the right to use studies is limited to the studies required for this tonnage band.

4. In order to calculate the Joint Registration Compensation for each member, BASF will give notice to all SIEF participants to express their intent to become members of the Joint Registration within 17 (seventeen) days. After that deadline, Joint Registration Compensation will be fixed. Registrants joining later will not trigger recalculation or reimbursement of costs.

5. Based on the above, the Lead Registrant will send an invoice to the Non-Lead Members for their cost share after their request for joint submission. The Non-Lead Members will only receive the valid security token number after payment of the invoice. Payment is due within 14 (fourteen) days after receipt of an invoice issued by BASF.

6. In case new studies have to be purchased or performed after conclusion of this Agreement, the resulting cost will be equally divided between all SIEF participants who are required to incorporate the results of these new studies into their registration dossier. Registrants joining later will not trigger recalculation or reimbursement of costs.

7. If the SIEF comprises various Affiliates of the Non-Lead Member, only one of these Affiliates within the SIEF shall be subject to the obligation to compensate the Joint Registration Dossier. Such single Joint Registration Compensation will be calculated on base of the highest tonnage band of all these Affiliates. Accordingly, the Affiliates of the compensating Non-Lead member, or the Affiliates of the non-EU established companies represented by an Only Representatives being a Non-Lead Member, shall also have the right

to refer to the Joint Registration Dossier under the same conditions without additional payment. In that case, the Non-Lead Member that has paid the compensation is responsible for compliance of its Affiliates or their Only Representative with the rights and obligations pursuant to this Agreement, including the confidentiality obligations under Title I, Article II of this Agreement.

8. If an only representative represents more than one non-EU entity within the SIEF, such only representative shall compensate the Lead Registrant on account of each non-EU entity it represents by the payment of a separate Joint Registration Compensation per Non-EU entity and its Affiliates, considering point 6 above.

9. If a third party representative represents more than one entity within the SIEF, such third party representative shall compensate the Lead Registrant on account of each entity it represents by the payment of a separate Joint Registration Compensation per entity and its Affiliates, considering point 6 above.

10. If a Non-Lead Member is joining after the calendar year of BASF's initial offer, an adjustment of the Joint Registration compensation will be made for additional each calendar year including the year of joining. Such adjustment will be based on the inflation rate in Germany as published by the Statistische Bundesamt for each respective preceding year.

11. All payments due hereunder shall be net payments, i.e. free of any bank or transfer charges or similar charges and without deduction of any taxes, levies or other dues payable. If payer is required to withhold any tax or to make any other deduction from any such payments, then the said payments shall be increased to the extent necessary to ensure that, after making of the required deduction or withholding, payee receives and retains (free from any liability in respect of any such deduction or withholding) a net sum equal to the sum which it would have received and so retained had no such deduction or withholding been made or required to be made (gross-up amount). If upon application of the beneficiary any withholding tax can be reduced, or refunded, or an exemption from withholding tax is granted, payer shall file on behalf of payee for such reduction, refund or exemption. Payee shall render any assistance to payer to obtain such withholding tax reduction, refund or exemption. Payer shall be entitled to any refund of withholding taxes.

12. Indirect taxes, including but not limited to Value Added Tax (VAT), Goods and Service Tax (GST), service tax, business tax, as applicable pursuant to the relevant tax law, shall be borne by payer. However, payer is entitled to withhold any payment of indirect taxes unless payee has provided payer with a sufficient invoice for purposes of indirect taxation.

### **3. OWNERSHIP OF INFORMATION**

#### **Article IX. Ownership of Information**

1. This Agreement does not grant any ownership rights or change existing ownership rights to any of the Information provided under this Agreement to the Non-Lead Member, on whatever form and whenever, by the Lead Registrant, including without limitation, the Joint Registration Dossier.

2. Such Information shall consist in any and all data and/or studies:

a) Individually developed by BASF;



b) Acquired from Data Owner(s) for which BASF, as the case may be, have been granted valid rights.

3. Neither this Agreement nor any disclosure of Information shall vest any present or future rights in any patents, trade secrets or property rights and no license is granted.

### **TITLE III: FINAL PROVISIONS**

#### **Article X. Limitation of liability in the SIEF**

1. The Parties shall undertake their Purpose related activities specified hereunder in good faith and according to all applicable laws and regulations, and they shall use all reasonable endeavours to ensure the best possible results based on the evidence, methods and techniques known at the time.

2. Each Party having submitted a study which has been used in the Joint Registration Dossier represents to the others (i) that it is the rightful owner of the study(ies) and free to grant rights therein, (ii) that, to the knowledge of this Party, these studies do not infringe on the rights, in particular, but without limitation, intellectual property rights, of any third party and (iii) that this Party has not received a claim or notice of any alleged infringement.

3. It is the individual responsibility of each Party to critically assess the Information that is generated or that is made available. Each Party assumes the full responsibility for its own use of the Information so developed or received. No warranty for acceptance by the Agency of the Joint Registration Dossier or any data it contains is given.

4. None of the Parties, including the Lead Registrant, shall be held liable for any direct, indirect or consequential loss or damage incurred by any Party in connection with the activities contemplated in this Agreement, unless caused by gross negligence or wilful misconduct. In particular, BASF shall not be held responsible and liable for delays in the completion and submission of the Joint Registration Dossier, unless caused by gross negligence or wilful misconduct.

#### **Article XI. Term and termination**

1. This Agreement shall be in force until 1 June 2018.

2. This Article and the provisions relating to the protection of confidentiality (Article II), ownership of Information (Article IX), dispute resolution and applicable law (Article XIV) and limitation of the liability (Article X) shall survive the termination of this Agreement. With regard to the studies, the obligations specified in Article II of this Agreement shall survive for a period of twelve (12) years following the initial submission to the Agency. With regard to all other Information, the obligations specified in Article II shall survive for a period of 5 years after termination of the SIEF.

3. The Lead Registrant has the right to terminate its functions as lead registrant under the conditions that it has been validly replaced in its functions within the SIEF and the Non-Lead Members have been notified about such replacement.

4. The Non-Lead Member has the right to terminate the present Agreement subject a prior written notice to the Lead Registrant at the latest four months before the relevant registration deadline. No reimbursement shall be due.

#### **Article XII. Legal entity change**

The consent of the other Party shall not be required in case a Party assigns, transfers or delegates its rights and obligations under this Agreement to any of its Affiliates or to a legal successor in ownership by sale, division, merger or consolidation of all or substantially the whole of the business relevant to the Substance referred to in this Agreement, subject to acceptance by the assignee of the terms of this Agreement, to be notified to the other Party without undue delay.

#### **Article XIII. Administration and reporting of costs**

1. All financial settlements, billings, and reports rendered under this Agreement shall reflect properly the facts which may be relied upon as being complete and accurate in any further recording and reporting made by a Party for any purpose.

2. In accordance with generally accepted accounting procedures, documentation will be maintained and preserved including but not limited to written and electronic records, records on expenses, books of account, correspondence, memoranda and receipts.

#### **Article XIV. Dispute resolution and applicable law**

1. The Parties shall first attempt to settle amicably any dispute arising out of this Agreement. Any dispute shall be resolved by arbitration, ousting jurisdiction by ordinary courts, by a panel of three arbitrators. Each party to the dispute will nominate one arbitrator. These two arbitrators will then designate a third arbitrator who will also act as chairman. The arbitration decision shall be binding on the parties. The arbitration rules of the CEPANI shall be applicable. The place of any hearing shall be Brussels and the language of the arbitration shall be English.

Each Party may at any time request from any competent judicial authority any interim or conservatory measure.

2. This Agreement shall be governed by the laws of Belgium.

3. If at any time any provision of this Agreement is or becomes invalid or illegal in any respect, this shall have no effect on the validity of the remaining contractual provisions. The invalid provisions are to be replaced, backdated to the time of their becoming ineffective, by provisions which come closest to achieving their objective.

The Parties are validly bound by this Agreement when the BASF and the Non-Lead Member has given its consent to this Agreement by signing it.



For and on behalf of

BASF SE

Signature: J. V. Fast

Name: Dr. Beate Fast

Title: Regulatory Affairs &  
Product Safety (Petrochemicals)

Date: 16.04.2018

For and on behalf of

Axxence Slovakia s.r.o.

Signature: [Signature]

Name: Martin Minárik

Title: Ing.

Date: 10.04.2018

[Signature]

Dr. Peter Schwab

Senior Vice President

17.04.2018

**ANNEXES:**

**Annex 1**

**Cefic guidance on competition compliance**



**Cefic REACH  
guidance DO & DON'T**

**Annex 2**

**SIP (Substance Information Profile)**

Version	Company	SUBSTANCE IDENTIFICATION PROFILE (SIP)		
v.1	BASF SE			
[date]				
No.	1.1. Chemical Name	1.2. EC Number	1.3. CAS Number	1.4. Composition Type
	3-Methylbutan-1-ol	204-633-5	123-51-3	Mono-Constituent Substance
This Substance Identification Profile (SIP) is developed to represent the identification parameters of the Substance described in line with the Substance identification requirements of REACH Annex VI and relevant Guidances for the purpose to identify the				
Reference	SI Parameter	Value / Not necessary / Not for SIP	Remark / Justification	
2.1.A	Name or other identifiers of the substance			
2.1.1.a	IUPAC Name	3-methylbutan-1-ol		
2.1.1.b	Other International chemical name			
2.1.2.a	Chemical Name	3-methylbutan-1-ol		
2.1.2.b	Abbreviation			
2.1.2.c	Other names	Isamylalcohol		
2.1.3.a	EC Number	204-633-5		
2.1.3.b	EC Name	3-methylbutan-1-ol		
2.1.3.c	EC Description	Not available		
2.1.4.a	CAS Number	123-51-3		
2.1.4.b	CAS Name			
2.1.4.c	CAS Description			
2.1.5.a	IUBMB Number			
2.1.5.b	INCI Number			
2.1.5.c	Other Catalogue identifiers			
2.1.B	Substances (with core identifiers) also falling under this substance (with justification)			
2.1.6.a	Chemical Name		None	
2.1.6.b	EC Number			
2.1.6.c	CAS Number			
2.2	Information related to molecular and structural formula of the substance			
2.2.1.a	Molecular Formula	C5H12O		
2.2.1.b	Structural Formula	(CH3)2CHCH2CH2OH		
2.2.1.c	Smiles notation	CC(C)CCO		
2.2.2.a	Optical activity	not applicable		
2.2.2.b	Typical ratio of (stereo) isomers			
2.2.3.a	Molecular Weight	88.15		
2.2.3.b	Molecular Weight range	-		
2.3	Chemical Composition of the substance			
2.3.1	Main Constituent			
2.3.1.a	Name - Main Constituent	3-methylbutan-1-ol		
2.3.1.b	CAS Number - Main Constituent	123-51-3		
2.3.1.c	EC Number - Main Constituent			
2.3.1.d	Concentration range - Main Constituent	80%		
	- Lower value			
2.3.1.e	Concentration range - Main Constituent	100%		
	- Upper value			
2.3.1.f	Typical concentration - Main Constituent (= Degree of purity)	>98%		
2.3.2	Impurity / Impurities (above 1% or lower if contributing to the hazard, classification or PTB profile)			
2.3.2.a	Agreed strategy for Impurity profile on SIP	No impurities classified as carcinogenic, mutagenic, reprotoxic or as sensitising to skin or respiratory system >=0.1%. No PBT substances >0.1%		
2.3.2.1.a	Name - Impurity (1)			
2.3.2.1.b	CAS Number - Impurity (1)			
2.3.2.1.c	EC Number - Impurity (1)			
2.3.2.1.d	Molecular Formula - Impurity (1)			
2.3.2.1.e	Concentration range - Impurity (1)			
2.3.2.1.f	Concentration range - Impurity (1)			
2.3.2.1.g	Typical concentration - Impurity (1)			
2.3.2.1.h	Hazard - Impurity (1)			
2.3.3	Additive(s) (above 1% or lower if contributing to the hazard)			
2.3.3.a	Agreed strategy for Additives profile on SIP			
2.4	Substance sameness checking procedure			
2.4.1	Agreed Spectral data to be used			
2.4.2	Agreed Analytical Methods to be used			
2.4.3.a	Agreed Verification Method for sameness checking procedure (Consortium)			
2.4.3.b	Agreed conditions for the Verification Method (Consortium)			
2.4.3.c	Agreed Verification Method for sameness checking procedure (SIEF)			
2.4.3.d	Agreed conditions for the Verification Method (SIEF)			
2.4.4.a	Agreed role of the SIP in the SIEF			
2.4.4.b	Agreed person to be suggested as SIEF Formation Facilitator (if applicable)			
2.5	Approval of the SIP			
2.5.1	Agreed approval method for the sameness checking procedure using this SIP (Consortium)			
2.5.2	Agreed approval method for the sameness checking procedure using this SIP (SIEF)			
<p>By signing or otherwise approving this Substance Information Profile (SIP), the Company declares that he agrees with the content and purpose of this Substance Identification Profile.</p> <p>He agrees that his substance does to the best of his knowledge completely fall under the substance identity being represented by the SIP sections 2.1 up to 2.3 sufficient for the purpose of meeting the SIEF requirements and opting for the joint submission Registration dossier to be created by the lead registrant in line with the REACH requirements.</p> <p>He agrees to fulfil the requirements of the Verification Method described and agreed in the SIP Section 2.4 and takes the appropriate follow-up actions if the substance appears not to fall under the SIP agreed. He agrees that the final result of the Agreed Verification Method for sameness checking procedure is binding.</p> <p>He agrees that he will inform the Consortium via the Secretariat or the SIEF via the Lead registrant if he has (new) information that might change the content of this SIP or if his Substance is changed in such a way that it might or does no longer fall under the SIP or might potentially have an impact on the content of the Registration dossier</p> <p>He understands and agrees to be fully responsible for the proper linkage of the substance to the REACH Registration dossier and informing of his supply chain on the safe use of his substance and fulfilling his REACH requirements accordingly.</p>				

REACH SIEF Agreement 3-Methylbutan-1-ol, CAS 123-51-3, 22. March 2013

*He. He.*

### 3-Methylbutan-1-ol, CAS No 123-51-3

BASF does not grant a LoA:

List of study records for which the Lead Registrant is not entitled to pass on usage rights for REACH registration purposes.

#### 7.1.1 Basics toxicokinetics (Annex VIII)

Reference Type	Author	Year	Title	Testing laboratory	Report No	Owner Company	Report date
Study report	Oxo Process Panel - ACC	2004	Respiratory Bioavailability of a Series of Acetate Esters and Alcohols in Rats.	Pacific Northwest, National laboratory, Operated by Battelle for the U. S. Department of Energy	43863	Oxo Process Panel, American Chemistry Council	2004-10-31

#### 7.5.1: Repeated dosis toxicity oral (Annex IX) and

#### 7.8.1: Toxicity to reproduction (Annex IX)

Reference Type	Author	Year	Title	Testing laboratory	Report No	Owner Company	Report date
Study report  (D90-wat-rat)	BG-Chemie	1990	Study on the oral toxicity of 3-methylbutanol-1 in rats Administration via the drinking water over 3 months.	BASF AG	33S0056/88020	BG-Chemie	1990-10-02

#### 7.6.2: Genetic toxicity in vivo (Annex VIII)

Reference Type	Author	Year	Title	Testing laboratory	Report No	Owner Company	Report date
Study report  (MNT)	BG-Chemie	1999	3-Methylbutanol-1 (BG-Nr. 95) - Micronucleus test in mice after oral administration.	Institut of Toxicology, Merck Darmstadt	T14125 - BG-Nr. 95	BG-Chemie	1999-08-27

#### 7.8.2: Developmental toxicity /teratogenicity (Annex IX)

Reference Type	Author	Year	Title	Testing laboratory	Report No	Owner Company	Report date
Study report  (TERA-ihl-rat)	BG-Chemie	1990	Prenatal toxicity of 3-methylbutanol-1 in Wistar rats after inhalation	BASF AG	37R0056/88041	BG-Chemie	1990-04-09
Range-finder  (TERA-ihl-rat-PRE)	BG-Chemie	1990	Range-finding study for prenatal inhalation toxicity of 3 methylbutanol-1	BASF AG	94R0056/88015	BG-Chemie	1988-09-01

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7.8.2: Developmental toxicity /teratogenicity (Annex X)

Reference Type	Author	Year	Title	Testing laboratory	Report No	Owner Company	Report date
Study report  (TERA-ihl-rbt)	BG-Chemie	1990	Prenatal toxicity of 3-methylbutanol-1 in rabbits after inhalation	BASF AG	90R0056/88042	BG-Chemie	1990-04-18
Range-finder  (TERA-ihl-rbt-PRE)	BG-Chemie	1990	Range-finding Versuch zur praenatalen Inhalationstoxizitaet von 3-Methylbutanol-1 (MEB) 9 an Kaninchen.	BASF AG	94R0056/88016	BG-Chemie	

*hs. mn.*